

Supporting Information 2.2
Device-Assisted Enteroscopy (DAE) part

ESGE QIC Smal Bowel Working Group
Delphi voting process

Working Group chair: Cristiano Spada, Italy

ESGE QIC Small-Bowel WG Device-Assisted Enteroscopy (DAE) - Delphi Voting process: Round 1

Domain	Performance Measure	Statement ID: Final	Statement ID: Round 1	PICO/QM ID	Statement - Final version	Population	Intervention	Comperator	Outcome	Group	Consensus [%]	Consensus reached in:
Pre-procedures	Key PM	19	19	1	DAE examinations should be performed for recognised indications as published in technical guidelines.	Patients undergoing device-assisted enteroscopy (DAE)	Indications for device-assisted enteroscopy (DAE)	n/a	Adherence to the recommended indications	Frequency of DAE and detection rate per indication	100	R2
Pre-procedures	Minor PM	18	18	2	All (100%) of patients undergoing device assisted enteroscopy should receive adequate pre-procedure preparation including fasting for anterograde double balloon enteroscopy and approved bowel preparation for retrograde double balloon enteroscopy.	Patients undergoing device-assisted enteroscopy (DAE)	Bowel preparation	No preparation	Increased visualization/↑Dx Yield	Bowel preparation	100	R3
Pre-procedures	Minor PM	18.1	18.2	2	All (100%) of patients referred for anterograde DAE should be fasting for solids for at least 6 hours prior to the procedure.	Patients undergoing device-assisted enteroscopy (DAE)	Bowel preparation	No preparation	Increased visualization/↑Dx Yield	Bowel preparation	88.9	R3
Pre-procedures	Minor PM	18.2	18.3	2	All (100%) of patients referred for anterograde DAE are allowed to take in water until 2 hours prior to the procedure.	Patients undergoing device-assisted enteroscopy (DAE)	Bowel preparation	No preparation	Increased visualization/↑Dx Yield	Bowel preparation	88.9	R3
Pre-procedures	Minor PM	18.3	18.4	2	All (100%) of patients referred for retrograde DAE should follow the same regimen of preparation as recommended by ESGE guidelines for colonoscopy.	Patients undergoing device-assisted enteroscopy (DAE)	Bowel preparation	No preparation	Increased visualization/↑Dx Yield	Bowel preparation	88.9	R3
Completeness of procedure	Key PM	24.1	21	6	Depth of insertion should be marked with <i>tattoo</i> in cases where pan-enteroscopy is intended.	Patients undergoing device-assisted enteroscopy (DAE)	Depth of insertion marked by tattoo	No tattoo	Improved diagnostic yield "Reduced Miss Rate"		100	R2
Completeness of procedure	Minor PM	24	21	6	In all cases, small-bowel depth of insertion should be estimated and recorded.	Patients undergoing device-assisted enteroscopy (DAE)	Estimation of depth of insertion	None	to be defined: number of loops, length in meters	Estimation of maximal depth of insertion	90.9	R2
Identification of pathology	Key PM	21	19.2	5	Cases for DAE should be carefully selected to maintain diagnostic yield. Intervention rates should be audited based on intent to treat and planned interventions and outcomes should be achieved in at least 80% of cases.	Patients undergoing device-assisted enteroscopy (DAE) for bleeding without previous examination	Identification and treatment of significant lesions	none	Percentage of identification and treatment of significant lesions	Frequency of DAE and detection rate per indication	88.9	R3
Identification of pathology	Key PM	22	20.1	7	Current literature is insufficient to set a minimal diagnostic yield for Device Assisted Enteroscopy by Indication or per Endoscopist. Device Assisted Enteroscopy use and diagnostic yield should be audited regularly	Patients undergoing DAE /Endoscopists performing DAE (see notes)	Positivity / rate of significant findings	No proven standard available a) Comparison with Capsule / radiological findings (pre or post- DAE) b) minimum published diagnostic yield	Improved diagnostic yield. Reduced "Miss Rate"	Diagnostic yield: DAE vs capsule	100	R2

ESGE QIC Small-Bowel WG Device-Assisted Enteroscopy (DAE) - Delphi Voting process: Round 1

Domain	Performance Measure	Statement ID: Final	Statement ID: Round 1	PICO/QM ID	Statement - Final version	Population	Intervention	Comperator	Outcome	Group	Consensus [%]	Consensus reached in:
Identification of pathology	Key PM	23	20.2	8	Overall pathology detection rates for capsule endoscopy and device assisted enteroscopy vary according to indication. Indications for both capsule endoscopy and device assisted enteroscopy procedures should be regularly audited and adhere to guidelines, reasons for variations should be examined.	Patients undergoing DAE/ Endoscopists performing DAE (see notes)	positivity / pathology detections rates by indication	No proven standard available a) Comparison with Capsule / Radiological findings (pre / post DAE) b) minimum published diagnostic yield per indication	Improved diagnostic yield by indication "Reduced Miss Rate" by indication	Diagnostic yield: DAE vs capsule	100	R3
Identification of pathology	Minor PM	24.3	21	6	It is recommended to use photodocumentation as a record of findings in all cases.	Patients undergoing device-assisted enteroscopy (DAE)	Photodocumentation/standardised report	No photodocumentation	Improved diagnostic yield "Reduced Miss Rate"		90.9	R2
Management of pathology	Key PM	24.2	21	6	It is recommended practice to mark a lesion which is intended for further intervention.	Patients undergoing device-assisted enteroscopy (DAE)	Marking of lesion	No marking of lesion	Improved diagnostic yield "Reduced Miss Rate"		100	R2
Management of pathology	MPM	21	19.2	5	Cases for DAE should be carefully selected to maintain diagnostic yield. Intervention rates should be audited based on intent to treat and planned interventions and outcomes should be achieved in at least 80% of cases.	Patients undergoing device-assisted enteroscopy (DAE) for bleeding without previous examination	Identification and treatment of significant lesions	none	Percentage of identification and treatment of significant lesions	Frequency of DAE and detection rate per indication	88.9	R3
Complications	Key PM	26	24.1.1	16	The rate of severe adverse events (overall, including perforation, bleeding, pancreatitis) resulting from diagnostic DAE should not exceed 1% in an unselected population.	Patients undergoing device-assisted enteroscopy (DAE)	device-assisted enteroscopy (DAE)	none	All complications	Complications	100	R3
Complications	Key PM	26.1	24.1.2	16	Rate of severe adverse events (overall, including perforation, bleeding, pancreatitis) resulting from therapeutic DAE should not exceed 5% in an unselected population.	Patients undergoing device-assisted enteroscopy (DAE)	device-assisted enteroscopy (DAE)	none	All complications	Complications	100	R3
Complications	Key PM	26.2	24.1.3	16	The overall rate of pancreatitis in DAE should not exceed 0.3%.	Patients undergoing device-assisted enteroscopy (DAE)	device-assisted enteroscopy (DAE)	none	Pancreatitis rate	Complications	88.9	R3
Complications	Key PM	27	24.2	18	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.	Patients undergoing device-assisted enteroscopy (DAE)	Adverse event rates audit by operator and indication	No audit	Bleeding, Perforation, Pancreatitis, adverse event rates	Complications	100	R2
Patient experience	Key PM	28	25	21	Patient comfort should be audited for all DAE procedures.	Patients undergoing device-assisted enteroscopy (DAE)	Air insufflation	CO ²	Percentage of patients having discomfort after device-assisted enteroscopy (DAE)	Air sufflation	90.9	R2
Patient experience	Key PM	29	28	24	Inadequate comfort levels should be audited against route of insertion, sedation, insufflation method and endoscopist experience.	Endoscopists performing device-assisted enteroscopy (DAE)	device-assisted enteroscopy (DAE)	Antegrade device-assisted enteroscopy (DAE) : minimum number per year	Patient tolerance	Patient tolerance by experience	90.9	R2

ESGE QIC Small-Bowel WG Device-Assisted Enteroscopy (DAE) - Delphi Voting process: Round 1

Statement ID: Final	Statement ID: Round 1	Statement Round 2	PICO/QM ID	Quality Measure	Population	Intervention	Comparator	Outcome	Topic area (Evaluative Text)	Editorial Comment	Group	Round 3. Results [%]
18	18	All (100%) of patients undergoing device assisted enteroscopy should receive adequate pre-procedure preparation including fasting for antegrade double balloon enteroscopy and approved bowel preparation for retrograde double balloon enteroscopy.	2	Pre-procedure bowel preparation (including diet, fasting and restrictions of certain medications e.g. iron and NSAIDs)	Patients undergoing device-assisted enteroscopy (DAE)	Bowel preparation	No preparation	Increased visualization/↑D x Yield	Device-assisted enteroscopy (DAE) – Bowel preparation		Bowel preparation	100
18.1	18.2	All (100%) of patients referred for antegrade DAE should be fasting for solids for at least 6 hours prior to the procedure.	2	Pre-procedure bowel preparation (including diet, fasting and restrictions of certain medications e.g. iron and NSAIDs)	Patients undergoing device-assisted enteroscopy (DAE)	Bowel preparation	No preparation	Increased visualization/↑D x Yield	Device-assisted enteroscopy (DAE) – Bowel preparation		Bowel preparation	88.9
18.2	18.3	All (100%) of patients referred for antegrade DAE are allowed to take in water until 2 hours prior to the procedure.	2	Pre-procedure bowel preparation (including diet, fasting and restrictions of certain medications e.g. iron and NSAIDs)	Patients undergoing device-assisted enteroscopy (DAE)	Bowel preparation	No preparation	Increased visualization/↑D x Yield	Device-assisted enteroscopy (DAE) – Bowel preparation		Bowel preparation	88.9
18.3	18.4	All (100%) of patients referred for retrograde DAE should follow the same regimen of preparation as recommended by ESGE guidelines for colonoscopy.	2	Pre-procedure bowel preparation (including diet, fasting and restrictions of certain medications e.g. iron and NSAIDs)	Patients undergoing device-assisted enteroscopy (DAE)	Bowel preparation	No preparation	Increased visualization/↑D x Yield	Device-assisted enteroscopy (DAE) – Bowel preparation		Bowel preparation	88.9
21	19.2	Cases for DAE should be carefully selected to maintain diagnostic yield. Intervention rates should be audited based on intent to treat and planned interventions and outcomes should be achieved in at least 80% of cases.	5	Efficiency of examination/indications	Patients undergoing device-assisted enteroscopy (DAE) for bleeding without previous examination	Identification and treatment of significant lesions	none	Percentage of identification and treatment of significant lesions	Frequency of device-assisted enteroscopy (DAE) and diagnostic yield per indication for patients without previous examination Frequency of device-assisted enteroscopy (DAE) and diagnostic yield for patients performing device-assisted enteroscopy (DAE) as second examinations	Note: Define a satisfying rate of diagnosis? BDC: this item seems out of place in the category of "Completeness"; fits more with "Identification of pathology"; would recommend consideration of documentation of visualization characteristics-adequacy, prep, lesions/issues limiting examination, etc	Frequency of DAE and detection rate per indication	88.9
23	20.2	Overall pathology detection rates for capsule endoscopy and device assisted enteroscopy vary according to indication. Indications for both capsule endoscopy and device assisted enteroscopy procedures should be regularly audited and adhere to guidelines, reasons for variations should be examined.	8	Pathology detection rates by indication	Patients undergoing DAE/ Endoscopists performing DAE (see notes)	positivity / pathology detection rates by indication	No proven standard available a) Comparison with Capsule / Radiological findings (pre / post DAE) b) minimum published diagnostic yield per indication	Improved diagnostic yield by indication "Reduced Miss Rate" by indication	Frequency of device-assisted enteroscopy (DAE) and diagnostic yield per indication for patients without previous examination Frequency of device-assisted enteroscopy (DAE) and diagnostic yield for patients performing device-assisted enteroscopy (DAE) as second examinations	Note: Reported rates of detection (yield) vary according to indication. Could extrapolate from available DAE / CE data. Although would need to be controlled for prior CE / MRE etc.	Diagnostic yield: DAE vs capsule	100
25	22	Combined training in capsule endoscopy and device assisted enteroscopy may enhance lesion recognition and detection and is favoured in those intending to perform DAE.	10	Detection rates and training	Endoscopists	Mandatory formal training course/training period Formal assessment	No formal training	improved quality of DAE and therefore lesion detection	device-assisted enteroscopy (DAE) – Detection rate and training		DAE – Detection rate and training	88.9

ESGE QIC Small-Bowel WG Device-Assisted Enteroscopy (DAE) - Delphi Voting process: Round 1

Statement ID: Final	Statement ID: Round 1	Statement Round 2	PICO/QM ID	Quality Measure	Population	Intervention	Comperator	Outcome	Topic area (Evaluative Text)	Editorial Comment	Group	Round 3. Results [%]
25.1	22.1	Training should only be provided by experienced gastroenterologists in units with a sufficient volume of work (50-100/annum) to ensure appropriate case mix. Trainee proficiency should be assessed by a direct observation of procedures prior to being signed off by their supervisor.	10	Detection rates and training	Endoscopists	High case volume centre	Other centre (low case volume)	improved quality of DAE and therefore lesion detection	device-assisted enteroscopy (DAE) – Detection rate and training		DAE – Detection rate and training	100
26	24.1.1	Rate of severe adverse events (overall, including perforation, bleeding, pancreatitis) resulting from diagnostic DAE should not exceed 1% in an unselected population.	16	Rate of complications per indications	Patients undergoing device-assisted enteroscopy (DAE)	device-assisted enteroscopy (DAE)	none	All complications	Device-assisted enteroscopy (DAE) – rate of complications	Note: Is device-assisted enteroscopy (DAE) – rate of complications	Complications	100
26.1	24.1.2	Rate of severe adverse events (overall, including perforation, bleeding, pancreatitis) resulting from therapeutic DAE should not exceed 5% in an unselected population.	16	Rate of complications per indications	Patients undergoing device-assisted enteroscopy (DAE)	device-assisted enteroscopy (DAE)	none	All complications	Device-assisted enteroscopy (DAE) – rate of complications		Complications	100
26.2	24.1.3	The overall rate of pancreatitis in DAE should not exceed 0.3%.	16	Rate of complications per indications	Patients undergoing device-assisted enteroscopy (DAE)	device-assisted enteroscopy (DAE)	none	Pancreatitis rate	Device-assisted enteroscopy (DAE) – rate of complications		Complications	88.9
31	30.1	Research is needed to determine whether the performance of a minimum number of DAE per year improves correlation with non invasive tests, diagnostic yield and compliance with intended intervention.	26	Pan-enteroscopy/numbers	Endoscopists performing pan-enteroscopy (anterograde and retrograde) device-assisted enteroscopy (DAE)	Anterograde and retrograde device-assisted enteroscopy (DAE)	device-assisted enteroscopy (DAE) : minimum number per year	Completion of small bowel examination	Device-assisted enteroscopy (DAE) – Completion rate by experience	Note: Does the performance of a minimum number of complete small bowel (anterograde and retrograde) device-assisted enteroscopy (DAE) per year improve completion rate?	Completion rate by experience	100

ESGE QIC Small-Bowel WG Device-Assisted Enteroscopy (DAE) - Delphi Voting process: Round 1

Statement ID: Final	Statement ID: Round 1	Statement Round 2	PICO/QM ID	Quality Measure	Population	Intervention	Comparator	Outcome	Topic area (Evaluative Text)	Editorial Comment	Group	Round 2 Results [%]
18	18	All (100%) of patients undergoing device assisted enteroscopy should receive adequate preprocedure preparation.	2	Pre-procedure bowel preparation (including diet, fasting and restrictions of certain medications e.g. iron and NSAIDs)	Patients undergoing device-assisted enteroscopy (DAE)	Bowel preparation	No preparation	Increased visualization/ \uparrow D x Yield	Device-assisted enteroscopy (DAE) – Bowel preparation		Bowel preparation	81.8
18.1	18.2	All (100%) of patients referred for oral DAE should be fasting for solids for at least 6 hours prior to the procedure.	2	Pre-procedure bowel preparation (including diet, fasting and restrictions of certain medications e.g. iron and NSAIDs)	Patients undergoing device-assisted enteroscopy (DAE)	Bowel preparation	No preparation	Increased visualization/ \uparrow D x Yield	Device-assisted enteroscopy (DAE) – Bowel preparation		Bowel preparation	100
18.2	18.3	All (100%) of patients referred for oral DAE are allowed to take in water until 2 hours prior to the procedure.	2	Pre-procedure bowel preparation (including diet, fasting and restrictions of certain medications e.g. iron and NSAIDs)	Patients undergoing device-assisted enteroscopy (DAE)	Bowel preparation	No preparation	Increased visualization/ \uparrow D x Yield	Device-assisted enteroscopy (DAE) – Bowel preparation		Bowel preparation	100
18.3	18.4	All (100%) of patients referred for anal DAE should follow the same regimen of preparation as recommended by ESGE guidelines for colonoscopy.	2	Pre-procedure bowel preparation (including diet, fasting and restrictions of certain medications e.g. iron and NSAIDs)	Patients undergoing device-assisted enteroscopy (DAE)	Bowel preparation	No preparation	Increased visualization/ \uparrow D x Yield	Device-assisted enteroscopy (DAE) – Bowel preparation		Bowel preparation	90.9
19	19	DAE examinations should be performed for recognised indications as published in technical guidelines.	1	Percentage of patients undergoing device-assisted enteroscopy (DAE) as per indications listed in ESGE guidelines	Patients undergoing device-assisted enteroscopy (DAE)	Indications for device-assisted enteroscopy (DAE)	n/a	Adherence to the recommended indications	Frequency of device-assisted enteroscopy (DAE) and diagnostic yield per indication for patients without previous examination Frequency of device-assisted enteroscopy (DAE) and diagnostic yield for patients performing device-assisted enteroscopy (DAE) as second examinations		Frequency of DAE and detection rate per indication	100
20	19.1	Device-assisted enteroscopy (DAE) should be guided by the findings of less invasive investigations. The rate of referral for device assisted enteroscopy after earlier non-invasive tests should be audited, in all (100% of) cases.	3	Rate of referral to enteroscopy after non-invasive tests	Patients referred for device-assisted enteroscopy (DAE)	Pre-procedure investigations (i.e. CE and/or SB cross-sectional imaging) CE: small bowel capsule endoscopy; SB cross sectional imaging: small bowel cross sectional	n/a	Adherence to recommended guidance/ lesion detection	Frequency of device-assisted enteroscopy (DAE) and diagnostic yield per indication for patients without previous examination Frequency of device-assisted enteroscopy (DAE) and diagnostic yield for patients performing device-assisted enteroscopy (DAE) as second examinations	Note: Unless otherwise indicated, the performance of device-assisted enteroscopy (DAE) should be guided by the findings of less invasive investigations (i.e. CE and/or SB cross-sectional imaging) which may also suggest the most favourable route of insertion (i.e. antegrade or retrograde)	Frequency of DAE and detection rate per indication	100

ESGE QIC Small-Bowel WG Device-Assisted Enteroscopy (DAE) - Delphi Voting process: Round 1

Statement ID: Final	Statement ID: Round 1	Statement Round 2	PICO/QM ID	Quality Measure	Population	Intervention	Comperator	Outcome	Topic area (Evaluative Text)	Editorial Comment	Group	Round 2 Results [%]
21	19.2	Cases for DAE should be carefully selected to maintain diagnostic yield. Intervention rates should be audited based on intent to treat and achieve at least 80% compliance.	5	Efficiency of examination/indications	Patients undergoing device-assisted enteroscopy (DAE) for bleeding without previous examination	Identification and treatment of significant lesions	none	Percentage of identification and treatment of significant lesions	Frequency of device-assisted enteroscopy (DAE) and diagnostic yield per indication for patients without previous examination Frequency of device-assisted enteroscopy (DAE) and diagnostic yield for patients performing device-assisted enteroscopy (DAE) as second examinations	Note: Define a satisfying rate of diagnosis? BDC: this item seems out of place in the category of "Completeness"; fits more with "Identification of pathology"; would recommend consideration of documentation of visualization characteristics-adequacy, prep, lesions/issues limiting examination, etc	Frequency of DAE and detection rate per indication	81.8
22	20.1	Current literature is insufficient to set a minimal diagnostic yield for Device Assisted Enteroscopy by Indication or per Endoscopist. Device Assisted Enteroscopy use and diagnostic yield should be audited regularly	7	Overall pathology detection rate	Patients undergoing DAE /Endoscopists performing DAE (see notes)	Positivity / rate of significant findings	No proven standard available a) Comparison with Capsule / radiological findings (pre or post- DAE) b) minimum published diagnostic yield	Improved diagnostic yield. Reduced "Miss Rate"	Frequency of device-assisted enteroscopy (DAE) and diagnostic yield per indication for patients without previous examination Frequency of device-assisted enteroscopy (DAE) and diagnostic yield for patients performing device-assisted enteroscopy (DAE) as second examinations	Note: How to reduce the "miss Rate in DAE" What is the appropriate gold standard to measure DAE performance against? What is the impact of a negative DAE on patient outcome? As with ADR in colonoscopy, should this be personalised ie by endoscopist or refer to detection rates within the population undergoing DAE. One suggests outcome is operator dependant the other reflects the appropriate selection of patients for DAE? BDC: agree with comments; how "significant" findings are defined will differ based on indication; would consider deleting this measure in lieu of pathology detection rates by indication (making DAE more akin to other endoscopic measures); would also consider including "Photodocumentation of findings" in this section as a quality measure	Diagnostic yield: DAE vs capsule	100
23	20.2	Overall pathology detection rates for CE and DAE vary according to indication. Detection rates for both methods should be audited in all cases and adhere to guidelines, and reasons for variations should be examined.	8	Pathology detection rates by indication	Patients undergoing DAE/ Endoscopists performing DAE (see notes)	positivity / pathology detections rates by indication	No proven standard available a) Comparison with Capsule / Radiological findings (pre / post DAE) b) minimum published diagnostic yield per indication	Improved diagnostic yield by indication "Reduced Miss Rate" by indication	Frequency of device-assisted enteroscopy (DAE) and diagnostic yield per indication for patients without previous examination Frequency of device-assisted enteroscopy (DAE) and diagnostic yield for patients performing device-assisted enteroscopy (DAE) as second examinations	Note: Reported rates of detection (yield) vary according to indication. Could extrapolate from available DAE / CE data. Although would need to be controlled for prior CE / MRE etc.	Diagnostic yield: DAE vs capsule	81.8
24	21	In all cases, small-bowel depth of insertion should be estimated and recorded.	6	Estimation of maximal depth of insertion (marked with a tattoo)	Patients undergoing device-assisted enteroscopy (DAE)	Estimation of depth of insertion	None	to be defined: number of loops, length in meters	device-assisted enteroscopy (DAE) – Estimation of maximal depth of insertion (marked with a tattoo)		Estimation of maximal depth of insertion	90.9

ESGE QIC Small-Bowel WG Device-Assisted Enteroscopy (DAE) - Delphi Voting process: Round 1

Statement ID: Final	Statement ID: Round 1	Statement Round 2	PICO/QM ID	Quality Measure	Population	Intervention	Comperator	Outcome	Topic area (Evaluative Text)	Editorial Comment	Group	Round 2 Results [%]
24.1	21	Depth of insertion should be marked with tattoo in cases where pan-enteroscopy is intended.	6	Estimation of maximal depth of insertion (marked with a tattoo)	Patients undergoing device-assisted enteroscopy (DAE)	Depth of insertion marked by tattoo	No tattoo	Improved diagnostic yield "Reduced Miss Rate"	device-assisted enteroscopy (DAE) – Estimation of maximal depth of insertion (marked with a tattoo)			100
24.2	21	It is recommended practice to mark a lesion which is intended for further intervention.	6	Estimation of maximal depth of insertion (marked with a tattoo)	Patients undergoing device-assisted enteroscopy (DAE)	Marking of lesion	No marking of lesion	Improved diagnostic yield "Reduced Miss Rate"	device-assisted enteroscopy (DAE) – Estimation of maximal depth of insertion (marked with a tattoo)			100
24.3	21	It is recommended to use photodocumentation as a record of findings in all cases.	6		Patients undergoing device-assisted enteroscopy (DAE)	Photodocumentation/standardised report	No photodocumentation	Improved diagnostic yield "Reduced Miss Rate"	device-assisted enteroscopy (DAE) – Estimation of maximal depth of insertion (marked with a tattoo)			90.9
25	22	Combined training in capsule endoscopy and device assisted enteroscopy enhances lesion recognition and detection and is favoured	10	Detection rates and training	Endoscopists	Mandatory formal training course/training period Formal assessment	No formal training	improved quality of DAE and therefore lesion detection	device-assisted enteroscopy (DAE) – Detection rate and training		DAE – Detection rate and training	72.7
25.1	22.1	Training should only be provided by experienced gastroenterologists in units with a sufficient volume of work (50-100/annum) to ensure appropriate case mix. Trainee proficiency should be assessed by a direct observation of procedures prior to being signed off by their supervisor.	10	Detection rates and training	Endoscopists	High case volume centre	Other centre (low case volume)	improved quality of DAE and therefore lesion detection	device-assisted enteroscopy (DAE) – Detection rate and training			100
26	24.1.1	Rate of severe adverse events (perforation, bleeding, pancreatitis) resulting from diagnostic DAE should not exceed 1% in an unselected population.	16	Rate of complications per indications	Patients undergoing device-assisted enteroscopy (DAE)	device-assisted enteroscopy (DAE)	none	All complications	Device-assisted enteroscopy (DAE) – rate of complications	Note: Is device-assisted enteroscopy (DAE) safe?	Complications	90.9
26.1	24.1.2	Rate of severe adverse events (perforation, bleeding, pancreatitis) resulting from therapeutic DAE should not exceed 5% in an unselected population.	16	Rate of complications per indications	Patients undergoing device-assisted enteroscopy (DAE)	device-assisted enteroscopy (DAE)	none	All complications	Device-assisted enteroscopy (DAE) – rate of complications			100
26.2	24.1.3	The overall rate of pancreatitis in DAE should not exceed 0.3%.	16	Rate of complications per indications	Patients undergoing device-assisted enteroscopy (DAE)	device-assisted enteroscopy (DAE)	none	Pancreatitis rate	Device-assisted enteroscopy (DAE) – rate of complications			81.8
27	24.2	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.	18	Rate of complications per type of treatment	Patients undergoing device-assisted enteroscopy (DAE)	Adverse event rates audit by operator and indication	No audit	Bleeding, Perforation, Pancreatitis, adverse event rates	Device-assisted enteroscopy (DAE) – rate of complications	Note: Should the management be different after diagnostic and therapeutic device-assisted enteroscopy (DAE) ?	Complications	100
28	25	Patient comfort should be audited for all DAE procedures.	21	Rate of complications per type of treatment	Patients undergoing device-assisted enteroscopy (DAE)	Air insufflation	CO ²	Percentage of patients having discomfort after device-assisted enteroscopy (DAE)	Device-assisted enteroscopy (DAE) – Discomfort and insertion depth with air insufflation	Note: Should CO ² insufflation be used routinely (also for better insertion depth?)	Air sufflation	90.9

ESGE QIC Small-Bowel WG Device-Assisted Enteroscopy (DAE) - Delphi Voting process: Round 1

Statement ID: Final	Statement ID: Round 1	Statement Round 2	PICO/QM ID	Quality Measure	Population	Intervention	Comperator	Outcome	Topic area (Evaluative Text)	Editorial Comment	Group	Round 2 Results [%]
29	28	Inadequate comfort levels should be audited against route of insertion, sedation, insufflation method and endoscopist experience.	24	Patient tolerance/numbers	Endoscopists performing device-assisted enteroscopy (DAE)	device-assisted enteroscopy (DAE)	Antegrade device-assisted enteroscopy (DAE) : minimum number per year	Patient tolerance	Device-assisted enteroscopy (DAE) –Patient tolerance according to experience	Note: Does the performance of a minimum number of device-assisted endoscopy (DAE) per year improve patient tolerance?	Patient tolerance by experience	90.9
30	29	Further research is needed within the field of DAE to guide quality indicators and best practice. All research should be undertaken within standard ethical frameworks.	25	Appropriate diagnosis/numbers	Endoscopists performing more than a minimum number of device-assisted enteroscopy (DAE) procedures per year	device-assisted enteroscopy (DAE)	Radiological/SBC E findings	Endoscopic/histo pathological findings	Device-assisted enteroscopy (DAE) – Appropriate diagnosis/numbers	Note: Does the performance of a minimum number of device-assisted enteroscopy (DAE) per year improve diagnostic yield compared to radiological/CE findings alone?	Appropriate diagnosis	100
31	30.1	Research is needed to determine whether the performance of a minimum number of DAE per year improves completion rate.	26	Pan-enteroscopy/numbers	Endoscopists performing pan-enteroscopy (anterograde and retrograde) device-assisted enteroscopy (DAE)	Anterograde and retrograde device-assisted enteroscopy (DAE)	device-assisted enteroscopy (DAE) : minimum number per year	Completion of small bowel examination	Device-assisted enteroscopy (DAE) – Completion rate by experience	Note: Does the performance of a minimum number of complete small bowel (anterograde and retrograde) device-assisted enteroscopy (DAE) per year improve completion rate?	Completion rate by experience	81.8
32	30.2	Research is needed to determine whether the performance of a minimum number of DAE per year reduces adverse event rates.	27	Complication	Endoscopists performing device-assisted enteroscopy (DAE)	device-assisted enteroscopy (DAE)	device-assisted enteroscopy (DAE) : minimum number per year	Complication rate (perforation, bleeding, surgery or prolonged length of stay)	Device-assisted enteroscopy (DAE) – Completion rate by experience	Note: Does the performance of a minimum number of device-assisted enteroscopy (DAE) per year reduce complications?	Complication rate by experience	90.9

ESGE QIC Small-Bowel WG Device-Assisted Enteroscopy (DAE) - Delphi Voting process: Round 1

Statement ID	Statement Round 1	PICO/QM ID	Quality Measure	Population	Intervention	Comperator	Outcome	Topic area (Evaluative Text)	Editorial Comment	Group	Round 1. Results [%]
18	All (100%) of patients undergoing device assisted enteroscopy should receive adequate preprocedure bowel preparation.	2	Pre-procedure bowel preparation (including diet, fasting and restrictions of certain medications e.g. iron and NSAIDs)	Patients undergoing device-assisted enteroscopy (DAE)	Bowel preparation	No preparation	Increased visualization/↑ Dx Yield	Device-assisted enteroscopy (DAE) – Bowel preparation		Bowel preparation	66.7
18.1	All (100%) patients referred for scheduled DAE should be fasting.	2	Pre-procedure bowel preparation (including diet, fasting and restrictions of certain medications e.g. iron and NSAIDs)	Patients undergoing device-assisted enteroscopy (DAE)	Bowel preparation	No preparation	Increased visualization/↑ Dx Yield	Device-assisted enteroscopy (DAE) – Bowel preparation		Bowel preparation	77.8
18.2	All (100%) of patients referred for oral DAE should be fasting for solids for at least 6 hours prior to the procedure.	2	Pre-procedure bowel preparation (including diet, fasting and restrictions of certain medications e.g. iron and NSAIDs)	Patients undergoing device-assisted enteroscopy (DAE)	Bowel preparation	No preparation	Increased visualization/↑ Dx Yield	Device-assisted enteroscopy (DAE) – Bowel preparation		Bowel preparation	100
18.3	All (100%) of patients referred for oral DAE are allowed to take in water until 2 hours prior to the procedure.	2	Pre-procedure bowel preparation (including diet, fasting and restrictions of certain medications e.g. iron and NSAIDs)	Patients undergoing device-assisted enteroscopy (DAE)	Bowel preparation	No preparation	Increased visualization/↑ Dx Yield	Device-assisted enteroscopy (DAE) – Bowel preparation		Bowel preparation	88.9
18.4	All (100%) of patients referred for anal DAE should follow the same regimen of preparation as recommended by ESGE guidelines for colonoscopy.	2	Pre-procedure bowel preparation (including diet, fasting and restrictions of certain medications e.g. iron and NSAIDs)	Patients undergoing device-assisted enteroscopy (DAE)	Bowel preparation	No preparation	Increased visualization/↑ Dx Yield	Device-assisted enteroscopy (DAE) – Bowel preparation		Bowel preparation	88.9
19	The percentage of device assisted enteroscopy (DAE) examinations procedures performed by indication should be audited in all cases, against known rates obtained from research studies. Examinations performed for indications not included in a published standard list of appropriate indications approved by an internationally recognized endoscopy professional society should be documented and reviewed.	1	Percentage of patients undergoing device-assisted enteroscopy (DAE) as per indications listed in ESGE guidelines	Patients undergoing device-assisted enteroscopy (DAE)	Indications for device-assisted enteroscopy (DAE)		Adherence to the recommended indications	Frequency of device-assisted enteroscopy (DAE) and diagnostic yield per indication for patients without previous examination Frequency of device-assisted enteroscopy (DAE) and diagnostic yield for patients performing device-assisted enteroscopy (DAE) as second examinations		Frequency of DAE and detection rate per indication	77.8

ESGE QIC Small-Bowel WG Device-Assisted Enteroscopy (DAE) - Delphi Voting process: Round 1

Statement ID	Statement Round 1	PICO/QM ID	Quality Measure	Population	Intervention	Comparator	Outcome	Topic area (Evaluative Text)	Editorial Comment	Group	Round 1. Results [%]
19.1	Device-assisted enteroscopy (DAE) should be guided by the findings of less invasive investigations. The rate of referral for device assisted enteroscopy after earlier non-invasive tests should be audited, in all (100% of) cases.	3	Rate of referral to enteroscopy after non-invasive tests	Patients referred for device-assisted enteroscopy (DAE)	Pre-procedure investigations (i.e. SBCE and/or SB cross-sectional imaging) SBCE: small bowel capsule endoscopy; SB cross sectional imaging; small bowel cross sectional imaging		Adherence to recommended guidance/lesion detection	Frequency of device-assisted enteroscopy (DAE) and diagnostic yield per indication for patients without previous examination Frequency of device-assisted enteroscopy (DAE) and diagnostic yield for patients performing device-assisted enteroscopy (DAE) as second examinations	Note: Unless otherwise indicated, the performance of device-assisted enteroscopy (DAE) should be guided by the findings of less invasive investigations (i.e. SBCE and/or SB cross-sectional imaging) which may also suggest the most favourable route of insertion (i.e. anterograde or retrograde)	Frequency of DAE and detection rate per indication	88.9
19.2	The diagnostic yield of DAE by indication should be audited against what is known from research studies.	5	Efficiency of examination/indications	Patients undergoing device-assisted enteroscopy (DAE) for bleeding without previous examination	Identification and treatment of significant lesions	none	Percentage of identification and treatment of significant lesions	Frequency of device-assisted enteroscopy (DAE) and diagnostic yield per indication for patients without previous examination Frequency of device-assisted enteroscopy (DAE) and diagnostic yield for patients performing device-assisted enteroscopy (DAE) as second examinations	Note: Define a satisfying rate of diagnosis? BDC: this item seems out of place in the category of "Completeness"; fits more with "Identification of pathology"; would recommend consideration of documentation of visualization characteristics-adequacy, prep, lesions/issues limiting examination, etc	Frequency of DAE and detection rate per indication	66.7
19.3	Audit items for the diagnostic yield of DAE by indication should include if DAE is used as a first line investigation and after prior non-invasive investigation.	5	Efficiency of examination/indications	Patients undergoing device-assisted enteroscopy (DAE) for bleeding without previous examination	Identification and treatment of significant lesions	none	Percentage of identification and treatment of significant lesions	Frequency of device-assisted enteroscopy (DAE) and diagnostic yield per indication for patients without previous examination Frequency of device-assisted enteroscopy (DAE) and diagnostic yield for patients performing device-assisted enteroscopy (DAE) as second examinations	Note: Define a satisfying rate of diagnosis? BDC: this item seems out of place in the category of "Completeness"; fits more with "Identification of pathology"; would recommend consideration of documentation of visualization characteristics-adequacy, prep, lesions/issues limiting examination, etc	Frequency of DAE and detection rate per indication	66.7

ESGE QIC Small-Bowel WG Device-Assisted Enteroscopy (DAE) - Delphi Voting process: Round 1

Statement ID	Statement Round 1	PICO/QM ID	Quality Measure	Population	Intervention	Comparator	Outcome	Topic area (Evaluative Text)	Editorial Comment	Group	Round 1. Results [%]
20.1	Current literature is insufficient to set a minimal diagnostic yield for Device Assisted Enteroscopy by Indication or per Endoscopist. Device Assisted Enteroscopy use and diagnostic yield should be audited regularly. Device Assisted Enteroscopy should be employed with a clear therapeutic and / or diagnostic intent in the majority of cases and good correlation with original capsule endoscopy and /or cross sectional imaging should be achieved.	7	Overall pathology detection rate	Patients undergoing DAE /Endoscopists performing DAE (see notes)	Positivity / rate of significant findings	No proven standard available a) Comparison with Capsule / radiological findings (pre or post- DBE) b) minimum published diagnostic yield	Improved diagnostic yield. Reduced "Miss Rate"	Frequency of device-assisted enteroscopy (DAE) and diagnostic yield per indication for patients without previous examination Frequency of device-assisted enteroscopy (DAE) and diagnostic yield for patients performing device-assisted enteroscopy (DAE) as second examinations	Note: How to reduce the "miss Rate in DBE" What is the appropriate gold standard to measure DBE performance against? What is the impact of a negative DBE on patient outcome? As with ADR in colonoscopy, should this be personalised ie by endoscopist or refer to detection rates within the population undergoing DBE. One suggests outcome is operator dependant the other reflects the appropriate selection of patients for DBE? BDC: agree with comments; how "significant" findings are defined will differ based on indication; would consider deleting this measure in lieu of pathology detection rates by indication (making DAE more akin to other endoscopic measures); would also consider including "Photodocumentation of findings"	Diagnostic yield: DAE vs capsule	100
20.2	Overall pathology detection rates for CE and DAE vary according to indication. Detection rates for both methods should be audited in all cases against what is known from research studies, and reasons for variations should be examined.	8	Pathology detection rates by indication	Patients undergoing DBE / Endoscopists performing DBE (see notes)	positivity / pathology detections rates by indication	No proven standard available a) Comparison with Capsule / Radiological findings (pre / post DBE) b) minimum published diagnostic yield per indication	Improved diagnostic yield by indication "Reduced Miss Rate" by indication	Frequency of device-assisted enteroscopy (DAE) and diagnostic yield per indication for patients without previous examination Frequency of device-assisted enteroscopy (DAE) and diagnostic yield for patients performing device-assisted enteroscopy (DAE) as second examinations	Note: Reported rates of detection (yield) vary according to indication. Could extrapolate from available DBE / CE data. Although would need to be controlled for prior CE / MRE etc.	Diagnostic yield: DAE vs capsule	88.9
21	In all cases, the extent of insertion should be marked with a tattoo and the depth of insertion estimated and recorded.	6	Estimation of maximal depth of insertion (marked with a tattoo)	Patients undergoing device-assisted enteroscopy (DAE)	Estimation of depth of insertion	None	to be defined: number of loops, length in meters	device-assisted enteroscopy (DAE) – Estimation of maximal depth of insertion (marked with a tattoo)		Estimation of maximal depth of insertion	77.8

ESGE QIC Small-Bowel WG Device-Assisted Enteroscopy (DAE) - Delphi Voting process: Round 1

Statement ID	Statement Round 1	PICO/QM ID	Quality Measure	Population	Intervention	Comperator	Outcome	Topic area (Evaluative Text)	Editorial Comment	Group	Round 1. Results [%]
22	Combined training in capsule endoscopy and device assisted enteroscopy enhances lesion recognition and detection. Training should only be provided by experienced gastroenterologists in units with a sufficient volume of work (75-100/annum as per ERCP) to ensure appropriate case mix and that trainee proficiency is assessed by a direct observation of procedures prior to being signed off by their supervisor.	10	Detection rates and training	Endoscopists	Mandatory formal training course/training period Formal assessment	No formal training	improved quality of DBE and therefore lesion detection	device-assisted enteroscopy (DAE) – Detection rate and training		DAE – Detection rate and training	88.9
23.2	The value of biopsies in altering patient management should be audited. Although no conclusions can be drawn about the impact of biopsy on patents management, the number of cases where biopsy results change patient management should be recorded and audited in order to identify variations in patient management.	11.2	Impact of biopsy on patients management	Patients with device-assisted enteroscopy (DAE) and inflammatory or neoplastic lesions	Biopsy in ulceration, Biopsy in infiltrating tumor, Biopsy in submucosal tumor	No biopsy performed	Percentage of patients with alteration of management triggered by biopsy result	Device-assisted enteroscopy (DAE) – Management of pathology	Note: Is biopsy of different lesions (inflammatory / neoplastic) mandatory to guide management of patients?	Biopsy per indication	44.4
24	DAE is safe. Rate of severe adverse events (perforation, bleeding, pancreatitis) resulting from DAE should not exceed 5 % in an unselected population.	16	Rate of complications per indications	Patients undergoing device-assisted enteroscopy (DAE)	device-assisted enteroscopy (DAE)	none	All complication	Device-assisted enteroscopy (DAE) – rate of complications	Note: Is device-assisted enteroscopy (DAE) safe?	Complications	88.9
24.2	Adverse event rates by operator and indication should be audited for all diagnostic procedures against known rates of adverse events. Reasons for variations from these rates should be examined.	18	Rate of complications per type of treatment		diagnostic	therapeutic	Bleeding, Perforation, Pancreatitis	Device-assisted enteroscopy (DAE) – rate of complications	Note: Should the management be different after diagnostic and therapeutic device-assisted enteroscopy (DAE) ?	Complications	100
24.5	The perforation rate in patients with surgical altered anatomy who undergo DAE should be audited to ensure that is not higher than in those with normal anatomy (≤ 5%).	22	Rate of complications in patients with altered anatomy		device-assisted enteroscopy (DAE) with postsurgical anatomy	Patients without SB surgery	Percentage of perforation	Device-assisted enteroscopy (DAE) – Perforation after SB Surgery	Note: Should the indication for device-assisted enteroscopy (DAE) be stricter after SB surgery? Should the management be different after device-assisted enteroscopy (DAE) in patients with post-surgical anatomy?	Perforation after SB surgery	66.7
25	Patient comfort should be audited for all procedures of small bowel insufflation (CO2 or air). CO2 insufflation reduces abdominal pain and improves intubation depth for oral enteroscopy when compared to air insufflation but not for anal enteroscopy	21	Rate of complications per type of treatment		Air insufflation	CO ²	Percentage of patients having discomfort after device-assisted enteroscopy (DAE)	Device-assisted enteroscopy (DAE) – Discomfort and insertion depth with air insufflation	Note: Should CO ² insufflation be used routinely (also for better insertion depth?)	Air sufflation	55.6

ESGE QIC Small-Bowel WG Device-Assisted Enteroscopy (DAE) - Delphi Voting process: Round 1

Statement ID	Statement Round 1	PICO/QM ID	Quality Measure	Population	Intervention	Comparator	Outcome	Topic area (Evaluative Text)	Editorial Comment	Group	Round 1. Results [%]
28	Patient comfort should be audited for all procedures against route of insertion and endoscopist experience.	24	Patient tolerance/numbers	Endoscopists performing device-assisted enteroscopy (DAE)	device-assisted enteroscopy (DAE)	Antegrade device-assisted enteroscopy (DAE) : minimum number per year	Patient tolerance	Device-assisted enteroscopy (DAE) –Patient tolerance according to experience	Note: Does the performance of a minimum number of device-assisted enteroscopy (DAE) per year improve patient tolerance?	Patient tolerance by experience_inizio giugno	33.3
29	Research is needed to determine whether the performance of a minimum number of DAE per year improves diagnostic yield compared to radiological/SBCE findings alone.	25	Appropriate diagnosis/numbers	Endoscopists performing more than a minimum number of device-assisted enteroscopy (DAE) procedures per year	device-assisted enteroscopy (DAE)	Radiological/SBCE findings	Endoscopic/histopathological findings	Device-assisted enteroscopy (DAE) – Appropriate diagnosis/numbers	Note: Does the performance of a minimum number of device-assisted enteroscopy (DAE) per year improve diagnostic yield compared to radiological/SBCE findings alone?	Appropriate diagnosis	77.8
30.1	Research is needed to determine whether the performance of a minimum number of DAE per year improves completion rate.	26	Pan-enteroscopy/numbers	Endoscopists performing pan-enteroscopy (antegrade and retrograde) device-assisted enteroscopy (DAE)	Antegrade and retrograde device-assisted enteroscopy (DAE)	device-assisted enteroscopy (DAE) : minimum number per year	Completion of small bowel examination	Device-assisted enteroscopy (DAE) – Completion rate by experience	Note: Does the performance of a minimum number of complete small bowel (antegrade and retrograde) device-assisted enteroscopy (DAE) per year improve completion rate?	Completion rate by experience	88.9
30.2	Research is needed to determine whether the performance of a minimum number of DAE per year reduces adverse event rates.	27	Complication	Endoscopists performing device-assisted enteroscopy (DAE)	device-assisted enteroscopy (DAE)	device-assisted enteroscopy (DAE) : minimum number per year	Complication rate (perforation, bleeding, surgery or prolonged length of stay)	Device-assisted enteroscopy (DAE) – Completion rate by experience	Note: Does the performance of a minimum number of device-assisted enteroscopy (DAE) per year reduce complications?	Complication rate by experience	88.9