

JAG

Joint Advisory Group
on GI Endoscopy



BSG Quality and Safety Indicators for Endoscopy

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ABOUT THIS DOCUMENT

These indicators were originally developed by the BSG Endoscopy Committee in conjunction with the National Bowel Cancer Screening Programme, AUGIS and ACP. They have been revised and will be ratified by the Joint Advisory Group on Gastrointestinal Endoscopy (the JAG). The revised indicators are at a draft stage and comments on the revisions are very welcome. Feedback should be directed to roger.barton@nhct.nhs.uk or roland.valori@endoscopy.nhs.uk.

The guidance will be reviewed on an annual basis and released in April each year.

The guidance underpins the Endoscopy Global Rating Scale (see below). It is expected that guidance issued in April will be applicable at the next GRS census (October each year). Quality and safety have been separated to highlight the difference between the benefits (quality) and harm (safety) of endoscopic procedures. The indicators have been separated further into two broad categories:

- Relatively fixed items: structure, process and staffing
- More dynamic indicators: auditable outcomes and quality standards (see below)

Originally there was concern regarding use of numbers when there was no clear evidence base to support them. For example, numbers of procedures demonstrating continued competence, or outcomes for clinical problems where case mix is variable, such as gastrointestinal bleeding. To overcome this problem it has been proposed that the quality and safety indicators should fall into two categories: auditable outcomes and quality standards.

An **auditable outcome** refers to an outcome, which is important to monitor and review, for which it is not possible to assign a standard. Examples of this might be use of reversal agents for over sedation, minimum number of procedures required to maintain competence, or outcome of endoscopic therapy for variceal bleeding.

A **quality standard** is an auditable outcome for which there is an evidence base that can recommend a minimum standard, for example completion rates for colonoscopy or bleeding rates for sphincterotomy. As the evidence base improves it is expected that it will be possible to convert auditable outcomes into quality standards.

The format for standards for bowel cancer screening follows a slightly different format.

Relationship of quality and safety indicators to the Global Rating Scale (GRS)

The quality and safety indicators underpin the respective items of the GRS (www.grs.nhs.uk). They identify the minimum items that should be monitored and the GRS assesses the extent to which the audit cycle has been applied to them. The intention is for the layering of the GRS to remain fixed, while the quality and safety indicators that underpin it remain flexible as evidence and practice evolve.

Role of IT in monitoring quality and safety

In time it is expected that the main providers of endoscopy reporting systems will be asked to run queries of their systems to provide a standard report of all the auditable outcomes and quality standards in this document. The idea is that an endoscopy unit with such an IT reporting system will be able to print a standard report automatically for unit governance meetings. Such standard reports do not preclude units running their own customised queries for individualised reports.

GENERAL QUALITY AND SAFETY INDICATORS

These markers apply to all endoscopic procedures performed within the department.

	Quality	Safety
Structure	<ul style="list-style-type: none"> ▪ Adequate numbers of video endoscopes to provide an uninterrupted service ▪ An appropriate range of ancillary equipment for all procedures performed in the department ▪ IT endoscopy reporting system ▪ Supportive radiology and pathology service ▪ Image capture 	<ul style="list-style-type: none"> ▪ Correctly functioning diathermy equipment ▪ Haemostasis equipment to control unexpected bleeding, eg loops, clips ▪ Properly equipped recovery area of appropriate size ▪ Appropriate equipment for oxygen monitoring, BP and ECG monitoring ▪ Resuscitation equipment in procedure and recovery areas compliant with Trust (or organisation) policy
Process	<ul style="list-style-type: none"> ▪ Agreed antibiotic policy ▪ Agreed anticoagulant policy ▪ Agreed diabetic policy ▪ Agreed sedation policy ▪ All policies published in paper and electronic form in the department ▪ Compliance with Trust (or organisation) consent policy 	<ul style="list-style-type: none"> ▪ Monitoring and review of unpredicted adverse events and near misses ▪ Adherence to BSG and DH guidelines on decontamination and traceability ▪ Agreed radiology protection policy ▪ Adherence to local resuscitation policy
	<ul style="list-style-type: none"> ▪ All policies based on UK National Guidelines where they exist ▪ An endoscopy user group that meets regularly 	
Staffing	<ul style="list-style-type: none"> ▪ Staffing levels and skill mix appropriate to the volume and type of procedures ▪ Staff are assessed according to the Knowledge and Skills Framework (KSF) ▪ Only staff assessed to be competent for that task are allowed to practice without supervision ▪ Adequate managerial and clerical support staff to ensure that the unit operates with maximum efficiency ▪ Identified medical and nurse leads ▪ All trainees must be supervised ▪ Trainees allowed to practice independently after formal evaluation of competence 	
Auditable outcomes	<ul style="list-style-type: none"> ▪ Number of procedures performed by each operator 	<ul style="list-style-type: none"> ▪ Unplanned admissions and operations within 8 days of procedure ▪ 30 day mortality ▪ Use of flumazenil ▪ Use of naloxone ▪ Need for ventilation ▪ Perforation ▪ Bleeding ▪ Sustained drop in O2 saturation <90%

DIAGNOSTIC UPPER GI ENDOSCOPY

	Quality	Safety
Auditable outcomes	<ul style="list-style-type: none"> ▪ Success of intubation ▪ Completeness of procedure 	
Quality standards	<ul style="list-style-type: none"> ▪ Repeat endoscopy for gastric ulcers within 12 weeks. (100%). Gastric ulcer defined by break in gastric mucosa >5mm in diameter and beyond submucosa. If repeat endoscopy not indicated (because of age+/- co-morbidity) this should be recorded in the patient file. 	

COLONOSCOPY/FLEXIBLE SIGMOIDOSCOPY

	Quality	Safety
Auditable outcomes	<ul style="list-style-type: none"> ▪ Sedation and analgesic doses ▪ Comfort levels ▪ Tattooing of suspected malignant polyps ▪ Tattooing of tumours if small, or if position not clear 	
Quality standards	<ul style="list-style-type: none"> ▪ 90% unadjusted completion rate for colonoscopy ▪ Adenoma detection rate >10% for colonoscopy and flexible sigmoidoscopy ▪ Polyp recovery >90% ▪ Good quality bowel prep > 90% ▪ Diagnostic colo-rectal biopsies for persistent diarrhoea (100%) 	<ul style="list-style-type: none"> ▪ Colonoscopy perforation rates <1:1000 ▪ Post polypectomy bleeding requiring transfusion <1:100 (for >1cm polyps) ▪ Post polypectomy perforation rate <1:500 ▪ Flexible sigmoidoscopy perforation rate <1:5000

Note 1

There has been much debate about the use of polyp detection as a quality standard with differing, strongly-held views. Concerns have been raised about the influence of age and case mix and the difficulty with current IT systems in capturing adenoma, as opposed, to polyp detection rates. The standard of >10% adenoma detection rate has been left in but it is appreciated that current IT systems might make it difficult to monitor this standard. Local audit processes are encouraged to take this into account when reviewing performance. However, there is a consistent view that if IT systems were able to capture the important quality endpoint (significant adenoma as defined in the ACP/BSG guidelines), and if standards could take into account case mix and age, then we should eventually have a standard for detection of significant adenoma.

THUS: the service is given due warning that in 2-3 years (2009-10) there will be a standard of significant adenoma detection, adjusted for case mix, that will supercede previous polyp detection rate standards. This will give the service sufficient time to set in place IT systems that can capture this information automatically.

Note 2

The JAG committee has decided to amend the completion rate standard to 90% and not have further adjustments with time. The rationale is that with the supporting document 'Guidance on supporting colonoscopists that do not achieve national standards' there are recommended processes to support colonoscopists who do not achieve this standard. A colonoscopist who falls short of 90% completion does not necessarily need to stop colonoscopy. Please see the guidance for more detail.

Note 3

It has been recommended that tattooing of tumours should no longer be a quality indicator and it has been changed to an auditable outcome. Concern had been raised about inappropriate tattooing and members of the ACP have been asked to draw up guidance on tattooing that will be disseminated through the training centres and other routes.

THERAPEUTIC UPPER GI ENDOSCOPY (NON GI BLEEDING)

	Quality	Safety
Structure	<ul style="list-style-type: none"> ▪ Adequate provision of equipment for the dilatation of upper GI strictures (TTS & OTW balloons, bougies) ▪ Units offering palliation of oesophageal cancer should have access to multimodal therapy (laser, SEMS, APC, brachytherapy) 	<ul style="list-style-type: none"> ▪ Access to radiographic screening must be available to assist dilatation whenever there is difficulty passing a guidewire/balloon catheter through a stricture for the purpose of dilatation
Process	<ul style="list-style-type: none"> ▪ Agreed guidelines on dilatation of oesophageal stricture ▪ The decision to deploy an oesophageal stent should be taken by the upper GI cancer multidisciplinary team, or after discussion with a named consultant of that team. ▪ Patients with suspected achalasia should undergo contrast radiography (and normally manometry) to confirm the diagnosis before treatment 	<ul style="list-style-type: none"> ▪ Agreed guidelines on monitoring of patients following all dilatation and stent placing procedures
Staffing	<ul style="list-style-type: none"> ▪ Oesophageal dilatation and SEMS insertion should be undertaken by (or under direct supervision of) experienced endoscopists who perform sufficient numbers to maintain their skills 	<ul style="list-style-type: none"> ▪ Access to appropriate surgical opinion and management should be readily available to endoscopy units performing oesophageal dilatation in case perforation should occur
Auditable outcomes	<ul style="list-style-type: none"> ▪ Satisfactory positioning of SEMS at the end of the procedure ▪ Re-intervention (dilatation, laser/APC, re-stenting) rate in SEMS ▪ Dysphagia assessed using a standard scoring system in > 90% to provide an objective measure of the efficacy of therapeutic intervention 	<ul style="list-style-type: none"> ▪ 30-day mortality for SEMS
Quality standards		<ul style="list-style-type: none"> ▪ Perforation rates following dilatation of: <ul style="list-style-type: none"> ○ Benign stricture <1:100 ○ Malignant stricture <1:20 ○ Achalasia <1:20 ○ Gastric outlet obstruction <1:20

THERAPEUTIC UPPER GI ENDOSCOPY (GI BLEEDING)

	Quality	Safety
Structure	<ul style="list-style-type: none"> ▪ Availability of equipment to treat ulcer-related bleeding (adrenaline 1/10000 injection, thermal haemostatic device [heater probe, bipolar coagulation], endoscopic clips) ▪ Availability of equipment to treat variceal bleeding (banding ligation device, sclerosant [eg ethanolamine] or tissue adhesive [eg cyanoacrylate glue] injection, balloon tamponade) ▪ Availability of equipment to treat mucosal bleeding (laser or APC) ▪ Facilities to provide emergency endoscopy out of hours 	<ul style="list-style-type: none"> ▪ Availability of facilities to perform endoscopy with anaesthetist and GA support
Process	<ul style="list-style-type: none"> ▪ Documented agreed guidelines on preferred management approaches to ulcer-related and variceal bleeding ▪ Contemporaneous written report in notes of all in-patients including recommendations on further management 	<ul style="list-style-type: none"> ▪ Documented agreed guidelines on the monitoring and resuscitation of patients before and after all emergency procedures for GI bleeding ▪ Locally agreed policies on the involvement of anaesthetists in patients with GI bleeding
Staffing	<ul style="list-style-type: none"> ▪ Endoscopy for GI bleeding should only be undertaken by (or under direct supervision of) experienced endoscopists who perform sufficient numbers to maintain their skills 	<ul style="list-style-type: none"> ▪ Access to a surgical opinion should be readily available to endoscopy units performing emergency endoscopy for upper GI bleeding ▪ For each case, a minimum of 3 endoscopy assistants with appropriate competences
Auditable outcomes	<ul style="list-style-type: none"> ▪ Rates of primary haemostasis (exact definition to be determined locally – eg failure defined by transfusion, +/- need for repeat endoscopy, +/- surgery) 	
Auditable outcomes (affected by factors other than the procedure and thus beyond the remit of GRS)	<ul style="list-style-type: none"> ▪ Operation rates ▪ Timeliness indicators (ie time from admission to first endoscopy) ▪ Blood transfusion requirements ▪ Appropriate use of medication – PPIs for ulcers, pressins for varices ▪ Length of stay 	<ul style="list-style-type: none"> ▪ 30-day mortality in relation to the Rockall or equivalent risk assessment scoring system ▪ Pneumonia ▪ Spontaneous bacterial peritonitis in patients with variceal bleeding

ERCP

	Quality	Safety
Structure	<ul style="list-style-type: none"> An Endoscopy Unit caseload of at least 150 procedures per year Sufficient accessories to perform all standard therapeutic manoeuvres at the time of the procedure 	<ul style="list-style-type: none"> Haemostasis equipment to control unexpected bleeding Availability of emergency lithotriptor
Process	<ul style="list-style-type: none"> Pre-ERCP assessment of all patients by appropriately trained staff Indications for ERCP and place of ERCP in the management pathway to be agreed locally Evidence of consultant involvement in every decision to perform (c/f request) ERCP Contemporaneous report in notes of all patients 	<ul style="list-style-type: none"> Formal record of adverse incidents e.g. significant complications and mortality Compliance with local radiological protection guidelines Prophylactic antibiotics given according to local guidelines
Staffing	<ul style="list-style-type: none"> An agreed minimum workload (procedure type/volume) per endoscopist A minimum of 2 ERCP-trained endoscopists within a centre or local network, to enable continuous service provision 	<ul style="list-style-type: none"> For each case, a minimum of 3 endoscopy assistants with appropriate competences
Auditable outcomes	<ul style="list-style-type: none"> Number of procedures performed by each operator Success in cannulating desired duct and in performance of intended therapeutic procedure 	<ul style="list-style-type: none"> Frequency of post-procedure clinical pancreatitis Please refer back to “General quality and safety indicators”
Quality Standards	<ul style="list-style-type: none"> >90% of ERCPs intended as therapeutic Completion of the intended therapeutic procedure (eg decompression of dilated and/or obstructed biliary system) at initial ERCP in at least 80% of cases Following failed initial ERCP, decompression of obstructed biliary systems within 5 working days in a stable patient, or within 24hr in an unstable patient (e.g. severe cholangitis) 	<ul style="list-style-type: none"> Sphincterotomy bleeding requiring transfusion < 2% Perforation rate <2% Clinically symptomatic pancreatitis <5% Procedure related mortality <1% Continued appropriate antibiotic treatment when obstruction unrelieved by ERCP in 100% of cases

EUS

	Quality	Safety
Structure	<ul style="list-style-type: none"> ▪ Image storage facilities – video and paper print or digital imaging/PACS 	
Process	<ul style="list-style-type: none"> ▪ Integration of findings into appropriate multidisciplinary team meetings ▪ Agreed protocols for: <ul style="list-style-type: none"> ○ indications ○ antibiotic use ○ FNA / biopsy ▪ Other interventional EUS: <ul style="list-style-type: none"> ○ oesophageal dilatation for staging EUS 	
Staffing	<ul style="list-style-type: none"> ▪ Experienced cytopathologist or cytology technician essential 	<ul style="list-style-type: none"> ▪ Staff familiar with use of FNA/core biopsy needles and slide/smear preparation
Auditable outcomes	<ul style="list-style-type: none"> ▪ Minimum agreed procedure volume/centre/endoscopist: <ul style="list-style-type: none"> ○ oesophagogastric cancer ○ staging ○ pancreaticobiliary imaging ○ EUS fine needle aspiration 	
Quality Standards	<ul style="list-style-type: none"> ▪ Completion rates for diagnostic imaging should approach >90% ▪ Completion rates for FNA/biopsy should approach: <ul style="list-style-type: none"> ○ >90% mediastinal /other lymph nodes ○ >75% pancreatic /other masses ▪ Diagnostically adequate FNA specimens should approach: <ul style="list-style-type: none"> ○ >75% (pancreas); ○ >90% other lesions ▪ Staging accuracy for cancers consistent with major published figures 	<ul style="list-style-type: none"> ▪ Complication rates <1%. This includes oesophageal perforation, acute pancreatitis post FNA, infection, bleeding.

PEG

	Quality	Safety
Structure	<ul style="list-style-type: none"> Appropriate equipment for placing a PEG 	
Process	<ul style="list-style-type: none"> Agreed guidelines on indications for PEG Multidisciplinary team involvement in all decisions Agreed policy on consent for individuals unable to give consent Post procedure guidelines for managing the PEG 	<ul style="list-style-type: none"> Agreed guidelines on antibiotic prophylaxis
Staffing	<ul style="list-style-type: none"> Two operators with the appropriate competences to complete the procedure, at least one of which is a competent upper GI endoscopist Involvement of dietetic team (or equivalent) following placement 	
Auditable outcomes	<ul style="list-style-type: none"> Satisfactory placement of PEG (satisfactory determined at the end of the procedure) 	<ul style="list-style-type: none"> Infection requiring antibiotics Peritonitis Bleeding

QA STANDARDS SPECIFIC TO COLONOSCOPY IN THE NATIONAL BOWEL CANCER SCREENING PROGRAMME

(Investigation after positive guaiac FOBt: Age 60 – 69)

Objective	Measure	Standard
1. Investigate individuals with positive FOB test results	<ul style="list-style-type: none"> Acceptance rate of colonoscopy after positive FOBt 	<ul style="list-style-type: none"> > 85% undergo colonoscopy
2. Entire colon examined	<ul style="list-style-type: none"> Completion rate with photographic evidence of ileocaecal valve/appendix orifice 	<ul style="list-style-type: none"> 90% unadjusted completion
3. Identification of adenoma/cancer present in the population	<ul style="list-style-type: none"> Adenoma detection rate 	<ul style="list-style-type: none"> 6 per 1000 people screened 35 per 100 colonoscopies
	<ul style="list-style-type: none"> Cancer detection rate 	<ul style="list-style-type: none"> 2 per 1000 screened 11 per 100 colonoscopies
4. Availability of polyps for pathological examination	<ul style="list-style-type: none"> Polyp recovery 	<ul style="list-style-type: none"> >90% polyps excised
5. Planning of surgery •	<ul style="list-style-type: none"> Identification of tumour position in correct segment of colon 	<ul style="list-style-type: none"> >95% cancers
	<ul style="list-style-type: none"> Tattooing of suspected malignant polyps 	<ul style="list-style-type: none"> 100%
6. Minimising harms to the population	<ul style="list-style-type: none"> Minimum number of screening colonoscopies undertaken per year by each screening colonoscopist 	<ul style="list-style-type: none"> >150 (with full audit data of all standards listed)
	<ul style="list-style-type: none"> Perforation rate 	<ul style="list-style-type: none"> <1:1000 colonoscopies
	<ul style="list-style-type: none"> Post polypectomy bleeding requiring transfusion 	<ul style="list-style-type: none"> <1:100 colonoscopies
	<ul style="list-style-type: none"> Post polypectomy perforation rate 	<ul style="list-style-type: none"> <1:500 colonoscopies
	<ul style="list-style-type: none"> Rate of serious colonoscopic complications requiring unplanned admission 	<ul style="list-style-type: none"> <3 per 1000 colonoscopies

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