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UK key performance indicators and quality assurance standards for colonoscopy

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ABSTRACT

Colonoscopy should be delivered by endoscopists performing high quality procedures. The British Society of Gastroenterology, the UK Joint Advisory Group on GI Endoscopy, and the Association of Coloproctology of Great Britain and Ireland have developed quality assurance measures and key performance indicators for the delivery of colonoscopy within the UK. This document sets minimal standards for delivery of procedures along with aspirational targets that all endoscopists should aim for.

INTRODUCTION

Colonoscopy is the 'gold standard' investigation for assessment of the large bowel, allowing diagnosis, biopsy, and therapy to be undertaken. Colonoscopy detects and prevents colorectal cancer,¹ and is important in the diagnosis and treatment of non-neoplastic conditions. Colonoscopy can lead to rare but serious complications^{2–5} and poor quality colonoscopy is associated with increased rates of interval cancers.⁶ The quality of UK colonoscopy has improved over recent years,^{7 8} but unacceptable variation in practice still exists.^{8 9} Additionally the demand for colonoscopy is increasing.^{10–13}

In 2013, the Joint Advisory Group on GI Endoscopy (JAG), the British Society of Gastroenterology (BSG), and the Association of Coloproctology of Great Britain and Ireland (ACPGBI) commissioned a working group to review existing and define new quality assurance (QA) measures and key performance indicators (KPI) for colonoscopy. The three governing bodies nominated members of the working group who authored the paper. Working group members took responsibility for groups of standards and undertook a review of existing literature, existing standards, and evidence for those standards. Where evidence was available it was used to frame the standards. Where no clear evidence existed then existing standards and the expert opinion of the working group were used to arrive at agreed standards. The standards were reviewed and amended by the governing groups of the JAG, BSG and ACPGBI and then further edited by the authors. The document concentrates on the agreed standards and considers why a particular standard was agreed.

This document establishes clear minimal standards for KPI and QA measures. Where practice falls below these levels then interventions are required to raise

the performance of those colonoscopists. Where the authors believed that higher standards would be ideal an aspirational target was set. The authors believe that this is the level that all colonoscopists should be aiming for to provide high quality practice.

CAECAI INTUBATION RATE

Minimal unadjusted caecal intubation 90%. Colonoscopists should aspire to achieve 95% unadjusted caecal intubation. Photographic documentation of caecal intubation should be obtained with images taken of clear caecal landmarks or of terminal ileum.

It is important to examine the whole colon, but practice is variable.^{7 14 15} The consequences of an incomplete examination are missed diagnosis and failure to prevent interval cancers.^{16 17} In a British Society of Gastroenterology (BSG) audit of all colonoscopies performed within the UK over a 2 week period,⁸ the unadjusted caecal intubation rate (CIR) was 92.3% rising to 95.8% following adjustment for impassable strictures and poor bowel preparation. A further UK study⁹ demonstrated an unadjusted CIR at 92.5% (95% CI 91.2% to 92.6%). The English Bowel Cancer Screening Programme (BCSP) published the results of the first 3 years of screening¹⁸ with an unadjusted CIR of 95.2% (range 76.2–100%). Given the CIR is in excess of 90% for large series, this unadjusted rate should be the minimal standard. The BCSP demonstrates that a higher CIR can be achieved in a large programme and a standard of 95% unadjusted CIR should be aspired to.

ADENOMA DETECTION RATE

Minimal adenoma detection rate should be 15%. Aspirational adenoma detection rate should be 20%. Where polyp detection rate can be shown to be accurate it may be used as a marker of ADR.

Thorough examination of the colonic mucosa is crucial to maximise the effectiveness of colonoscopy as a diagnostic test. The adenoma detection rate (ADR) is the proportion of colonoscopies where one or more adenomas are detected. The ADR is the marker most commonly used for this purpose. Lower ADRs are associated with higher rates of interval cancers.^{6 19} Colonoscopists with an ADR <20% had a hazard ratio for interval cancer that was 10 times higher than colonoscopists with an ADR >20%. A recent UK study

| Quality indicator | Minimal standard | Aspirational target | Comment |
|---|--|--|---|
| Caecal intubation rate (CIR) (unadjusted) | 90% | 95% | Photographic proof of ileocaecal valve, terminal ileum, anastomosis or appendix orifice required in all cases |
| Adenoma detection rate (ADR) in general all patient population (not screening) | 15% | 20% | ADR is the quality standard. Given the difficulty in reporting ADR then polyp detection rate or polypectomy rate may be used where it has been demonstrated to reflect accurately ADR for that unit/clinician |
| Bowel preparation of sufficient diagnostic quality to not warrant repeat or alternative test | 90% | 95% | |
| Rectal retroversion rate | 90% | | |
| Colonoscopy withdrawal time (for negative procedures) | Mean of ≥ 6 min | Mean of ≥ 10 min | |
| Sedation level for age <70 Median total dose: ≤ 50 mg pethidine (≤ 100 μ g fentanyl) ≤ 5 mg midazolam (or equivalent drugs) | Auditable outcome | | |
| Sedation level for age ≥ 70 Median total dose: ≤ 25 mg pethidine (≤ 50 μ g fentanyl) ≤ 2 mg midazolam (or equivalent drugs) | Auditable outcome | | |
| Number of colonoscopies undertaken by endoscopist (or directly supervising trainee in room) per year | 100 | | If numbers <150 then other key performance indicators, eg, CIR and ADR, should be scrutinised more closely and, if concerns, action taken |
| Polyp retrieval rate | $\geq 90\%$ | | |
| Tattooing of all lesions ≥ 20 mm and/or suspicious of cancer outside of rectum and caecum | Tattoo placed in 100% of cases | | Tattoo according to trust policy |
| Diagnostic biopsies for unexplained diarrhoea | Rectal biopsies taken in 100% of cases | Right and left colonic biopsies taken in 100% of cases | Aspiration should be that a minimum of two right and two left colon biopsies should be taken, but as minimum standard rectal biopsies should always be taken (unless there is a contraindication) |
| Post-colonoscopy colorectal cancer | Auditable outcome | | All post-colonoscopy colorectal cancers diagnosed within 3 years of a colonoscopy should be reported as adverse events and each unit should have a policy for capturing post-colonoscopy colorectal cancer data |
| Comfort level | Auditable outcome | | Units should audit this and <10% of patients should have moderate or severe discomfort |
| Overall colonoscopic perforation rate | <1 in 1000 | <1 in 3000 | |
| Diagnostic colonoscopic perforation rate | <1 in 2000 | <1 in 4000 | |
| Colonoscopic perforation rate where polypectomy performed | <1 in 500 | <1 in 1500 | |
| Colonoscopic perforation rate where dilatation performed | <3% (<1 in 33) | <1% (<1 in 100) | |
| Diagnostic flexible sigmoidoscopy (FS) perforation rate | <1 in 5000 | <1 in 10 000 | |
| Colorectal stenting perforation rate | <10% | <5% | |
| Post-polypectomy bleeding rate (intermediate severity or higher) | <1 in 200 | <1 in 1000 | |
| Unplanned admission rate | Auditable outcome; review every case | | |
| Use of reversal agents | Auditable outcome; review every case | | |

Auditable outcome—endoscopy units should audit these measures.

Additional recommendations

Management of polyps—all units should have a policy for management of polyps including a policy for dealing with large and large sessile polyps.

Tattoo policy—all units should have a policy for tattooing of polyps and cancers and should audit whether this is being followed.

Rectal examination should be performed at colonoscopy or before endoscopy. All units should audit practice.

Terminal ileal intubation—all units should audit practice and agree local policy.

demonstrated wide variation in ADR with a global ADR (excluding screening colonoscopy) of 15.9%.⁹

ADR will vary according to the nature of the population colonoscoped and the indication for the procedure. However, even allowing for variation in population ADR, the current 10% UK minimum is too low. The 20% ADR reported by Kaminski *et al*⁶ is aspirational, but was for a screening age population. Therefore for the UK all age population a standard of 15% has been set with an aspirational target of 20%.

Measuring ADR currently requires interrogation of pathology databases to obtain polyp histology. The polyp detection rate (PDR) is often much more simple to obtain. ADR is the key performance measure but where it can be demonstrated that a ratio between an endoscopist's PDR and ADR has been developed and validated, then PDR may be an acceptable surrogate marker^{20–22} with the minimum value set to ensure an ADR of 15% (20% aspiration) is achieved. It is recommended that review of the validity of PDR to represent ADR is audited on an ongoing basis.

BOWEL PREPARATION

Bowel preparation of at least adequate quality to be achieved in 90% of patients.

Aspirational: bowel preparation of at least adequate quality to be achieved in 95% of patients.

Aspirational: easy to use, validated national bowel preparation scale should be developed.

High quality colonoscopy cannot occur without good quality bowel preparation, which maximises CIRs and the detection of neoplasia. This is highlighted by the 2013 ESGE position statement²³ issued to guide European countries setting up bowel cancer screening services. Evidence in the UK shows that 22% of failed colonoscopies were due to poor bowel preparation.⁸

There is a lack of evidence for one superior bowel cleansing agent,²³ therefore units should select their preferred agent based on local experience and BSG guidance.²⁴

At least five validated bowel preparation evaluation scales exist,^{25–29} however, all involve relatively complex scoring systems and are not in common usage in the UK. The BCSP uses a four point scale: excellent, adequate, complete despite poor preparation, or failed due to poor preparation.³⁰ Despite the subjectivity of this scale we recommend this or a similar scale is recorded for all colonoscopies.

The minimum proposed CIR is 90%, and audit suggesting that excellent or adequate bowel preparation can be achieved by the BCSP in 94.2% of patients¹⁸ means that we recommend bowel preparation be excellent or adequate in at least 90% of patients, and in line with an aspirational CIR of 95%, would have an aspirational standard of 95%.

We also have an aspiration to see validation of the BCSP scale or a similar easy-to-use tool to become the UK standard bowel preparation scale.

RECTAL EXAMINATION AND RECTAL RETROFLEXION

Rectal examination or omission should be recorded in 100% of cases.

Rectal retroflexion should be performed in 90% of cases.

Digital rectal examination

Digital rectal examination (DRE) has been recommended as a standard part of endoscopic examination of the lower gastrointestinal tract with the aim of preparing the anal canal for the insertion of the scope and to examine the anal canal and lower rectum for pathology.³¹ A comparison of DRE and rectal retroflexion showed that DRE was sensitive for detection of abnormalities in the lower rectum and upper anal canal that were subsequently demonstrated on retroflexion of the endoscope.³²

Rectal retroflexion

A number of studies have demonstrated increased detection of pathology by using retroflexion after standard views of the rectum have been obtained. An increase in yield of 8% was demonstrated in one study,³³ with others demonstrating a yield of around 2–2.5%.^{34–37} Manoeuvre success rates between 94%³⁶ and 100%³⁸ have been reported. Retroversion may rarely cause rectal injury^{39–40} with the estimated risk 0.01%.⁴¹ We recommend that digital rectal examination and retroflexion are attempted in all cases.

COLONOSCOPY WITHDRAWAL TIME

Minimum mean withdrawal time of 6 min for negative procedures.

Aspirational: mean withdrawal time of 10 min for negative procedures.

Withdrawal times should be routinely recorded and audited.

Colonoscopy withdrawal times (CWTs) of >6 min for negative procedures have frequently been linked to higher ADR,⁴² with the suggestion that longer times are beneficial,^{43–44} and an increased ADR for trainees when the CWT was over 10 min.⁴⁵ An increased withdrawal time may also be associated with improved technique such as position change, better aspiration of fluid pools, and more attention to deep folds and difficult corners.⁴⁶ Other studies, however, have not shown a link between CWT and polyp detection using the cut-off of 6 min⁴⁷ or 7 min.⁴⁸

Mean withdrawal times for negative procedures should be more than 6 min with an aspirational goal of achieving 10 min. This KPI should be linked to the ADR or PDR such that a low CWT with a low ADR strongly suggests inadequate technique (in the absence of other explanations such as population group) that requires managed changes in performance.

SEDATION

Sedation level for age <70: median total dose ≤50 mg pethidine (≤100 µg fentanyl), ≤5 mg midazolam or equivalent drugs.

Sedation level for age ≥70: median total dose ≤25 mg pethidine (≤50 µg fentanyl), ≤2 mg midazolam or equivalent drugs.

In the UK, the majority of colonoscopies are performed under conscious sedation. These standards are based upon the current BSG sedation guidelines.⁴⁹ The recent BSG audit reported >90% of sedation practice was in line with these guidelines. More than 10% of procedures were performed without sedation, with nitrous oxide used as the sole sedative agent in 4.2% of procedures. Reversal agents were required in only 0.1% of procedures. Similar sedation practice was reported in a large regional study,⁵⁰ with 85.6% of procedures performed under conscious sedation. These data suggest that conscious sedation can be performed safely and it appears to be satisfactory in the majority of cases, accepting the limitations of current methods of measuring comfort. Current sedation standards should be maintained.

NUMBER OF COLONOSCOPIES PERFORMED PER ANNUM

Minimum number colonoscopies to achieve competence: 200.

Minimum numbers per annum to maintain competence: 100.

Achieving competency

Accepting that CIR is usually self-reported, the literature reports a number of studies that evaluate how many procedures are required to consistently reach a CIR of 90%. Current UK standards require at least 200 procedures to achieve competency, strengthened with a publication⁵¹ showing competency (based on a CIR of 90%) is reached by 41% of trainees after 200 procedures. Similar figures of between 175 and 400 have been quoted, with the average trainee requiring 275 procedures.^{52–54} Although a numbers-based approach is easy to document, a broader evaluation is recommended by most learned societies.

Maintaining competency

A few studies point to a figure of at least 100 procedures per annum in order to maintain competency (ie, a CIR of ≥90%).^{55–56} Other studies have suggested a higher procedural volume of 200–300 may be necessary to maintain competent

and safe practice with figures below that being associated with lower CIR⁵⁶ and higher complication rates.⁵ Other markers of competence such as ADR do not appear to correlate well with procedural numbers.⁵⁷

POLYP RETRIEVAL

Polyps should be retrieved for histological assessment in 90% of cases.

Following successful polyp removal it is important to retrieve it for histological assessment. This is important to establish the histological nature of the polyp to determine surveillance intervals and to establish the presence of advanced features such as high-grade dysplasia, villous components or cancer. Polyps whose diameter is <1 cm are less likely to contain these features; however, retrieval is still important to determine whether there are adenomatous features that determine the need for surveillance. Polyp retrieval is also considered a reflection of the technical skill of the colonoscopist. No evidence correlating polyp retrieval rates with other markers of quality exists. We recommended polyp retrieval rates should be $\geq 90\%$ in the UK.

TATTOOING OF SUSPECTED MALIGNANT LESIONS IN THE COLON

Tattooing of all lesions ≥ 20 mm and/or suspicious of cancer outside of the rectum and caecum should take place in 100% of cases following local trust guidance.

Tattooing aids the accurate marking of suspected malignant lesions and resection sites, to guide future surgical resection and/or endoscopic surveillance. This technique⁵⁸ has been shown to guide surgical resections safely and accurately.⁵⁹

As polyps increase in size the risk that they harbour cancer increases. All polyps >2 cm in diameter should be marked by tattoo. Lesions <2 cm in diameter should be assessed by careful inspection and marked if they have high risk features as described in the guidelines of the BCSE.⁶⁰

There should be a clear local policy agreed by the colorectal multidisciplinary team meeting (MDT) defining the number of tattoos and their site relative to the lesion so that there is no ambiguity at the time of surgery or repeat endoscopy. The report should clearly describe the position of tattoos and highlight any potential for confusion if there is more than one set of tattoos in the colon.

DIAGNOSTIC BIOPSIES FOR UNEXPLAINED DIARRHOEA

100% of patients with unexplained diarrhoea to have rectal biopsies.

As an aspiration 100% of patients with unexplained diarrhoea undergoing colonoscopy to have right and left sided colonic biopsies.

A macroscopically normal examination does not exclude all causes of unexplained diarrhoea,⁶¹ with the most common diagnosis being microscopic colitis. Microscopic colitis can be patchy and biopsies from both the right and transverse colon are required for diagnosis,^{62–65} a practice reinforced by the American Society for Gastrointestinal Endoscopy (ASGE) guidelines.⁶⁶ We recommend that, unless there is a contraindication, the minimum standard remains that 100% of patients with unexplained diarrhoea should have rectal biopsies performed. As an aspiration, 100% of patients undergoing colonoscopy to investigate unexplained diarrhoea should have right and left sided colonic biopsies.

POST-COLONOSCOPY COLORECTAL CANCER RATE

All units should develop a system for capturing data on and reviewing each case of post-colonoscopy colorectal cancer (PCCRC) as a clinical incident subject to root cause analysis. Units should aspire to a target of <5% PCCRC at 3 years.

There is wide variation in the PCCRC rate from 0% at mean of 5 years⁶⁷ to 9%.⁶⁸ Some of this may derive from study design—especially data origin, exclusion criteria and population studied, and from method of calculation used. A recent study⁶⁹ in England between 2001 and 2008 looking at National Cancer Data Repository information and central procedural data shows an 8.5% overall PCCRC rate for colonoscopies performed between those dates, although the rate fell over time from 10.6% to 6.8%.

Colonoscopists with high adenoma detection and polypectomy rates provide increased protection for proximal cancers compared with those with lower polypectomy rates.⁶⁸ Specialty and volume of examinations performed have an influence on interval cancer rates.^{17 70} A landmark paper in the *New England Journal of Medicine*⁶ demonstrated that mucosal visualisation and adenoma detection influence the rate of future cancers.

Polypectomy technique also influences PCCRC, with incomplete polypectomy⁷¹ contributing to later interval cancers. Pooled North American post-polypectomy studies⁷² demonstrated missed cancer contributing 52% to the interval cancer rate, with 19% possibly due to incomplete polyp resection. A further study⁷³ found 27% of interval cancers developed in the same segment as a previous polypectomy, indicating incomplete treatment may have been a contributory factor. Particular emphasis should be placed upon detection of easily missed lesions such as flat, depressed and serrated lesions, particularly in the proximal colon.^{74 75}

COMFORT

Units should audit comfort and <10% of patients should have moderate or severe discomfort.

Patient experience of colonoscopy is important and patients should have as comfortable a procedure as possible. A national audit⁸ demonstrated that 10% of patients experienced moderate or severe discomfort. Although measuring comfort is difficult, a number of scoring systems exist and all units should consistently record patient comfort. Validated measures of patient comfort should be developed.

ADVERSE EVENTS

Colonoscopy is an invasive procedure, which carries a risk of bleeding, perforation and even death. Although the risk is small with diagnostic colonoscopy, it increases markedly when therapeutic procedures such as polypectomy are performed. It is important that endoscopy units develop QA approaches to investigate adverse events and consider the frequency with which these events might be expected (tables 1–3, box 1).

Perforation

The overall colonoscopic perforation rate is influenced by the proportion of diagnostic to therapeutic procedures performed. In four recent large series overall perforation rates ranged from 0.03% to 0.085%.^{2–5} A recent review of studies calculated an overall perforation rate of 0.07%.⁷⁶ The BSG audit⁸ demonstrated an overall perforation rate of 0.04%. For diagnostic colonoscopy perforation rates of 0–0.2% are reported.^{77–79} The two main risk factors for

Table 1 Stratification of bleeding severity

| Criteria | Severity |
|--|--------------|
| Rectal bleeding within 30 days of procedure resulting in any of the following Procedure aborted Unplanned post-procedure medical consultation Unplanned hospital admission, or prolongation of hospital stay, for ≤ 3 nights | Minor |
| Haemoglobin drop of ≥ 2 g Transfusion Unplanned admission or prolongation for 4–10 nights ITU admission for 1 night Interventional procedure (endoscopic or radiological) | Intermediate |
| Surgery Unplanned admission or prolongation for >10 nights ITU admission >1 night | Major |
| Death | Fatal |

Taken from Rutter+Chilton,⁸⁸ in turn adapted from Cotton *et al.*⁸⁹
ITU, intensive therapy unit.

post-polypectomy perforation are the size and proximal (caecal) location of polyps.⁷⁹ Two small series reported polypectomy perforation rates of 0.65% and 0.27%, whereas two slightly larger retrospective series reported rates of 0.11% and 0.06%.^{80–83} The recent review of studies calculated the perforation rate in therapeutic colonoscopy to be 0.1%,⁷⁶ in keeping with the BCSP perforation rate in polypectomy procedures of 0.09%.⁷⁹

Bleeding

The risk of post-procedure bleeding is very small with diagnostic colonoscopy, but increases markedly when polypectomy is performed. The two main risk factors are the size and proximal (caecal) location of polyps.^{79 81} Other reported risk factors include co-morbid cardiovascular or chronic renal disease,⁸⁴ age,^{84–86} anticoagulant use^{84 85} and endoscopist experience.⁸⁵ Studies assessing the effect of polyp morphology are inconclusive.^{79 86 87} Bleeding rates of 0.3–6.1% for polypectomies are reported.^{77 85} The recent UK audit reported a bleeding rate of 0.26%.⁸ A recent large series reported a colonoscopy bleeding rate of 0.164%.⁵ BCSP data illustrate the importance of stratifying bleeding severity: in one study the overall bleeding rate (including many clinically insignificant bleeds) was calculated as 0.59%; limiting the analysis to intermediate or major severity bleeds (haemoglobin drop of 2 g, transfusion, ITU admission, unplanned hospital admission for four or more nights, interventional radiology or endoscopy, or surgery), the rate was 0.13%;¹⁸ and limiting only to bleeding requiring transfusion, the rate was 0.04%.⁷⁹ We recommend that standardised severity stratification systems are used.⁸⁸

Table 2 Stratification of perforation severity

| Criteria | Severity |
|---|----------|
| Any perforation within 30 days of procedure should be recorded. Perforation is defined as evidence of air, luminal contents or instrumentation outside the gastrointestinal tract Managed conservatively (no endoscopy/surgery) Endoscopic management Surgery | Major |
| Death | Fatal |

Taken from Rutter+Chilton,⁸⁸ in turn adapted from Cotton *et al.*⁸⁹

Table 3 Stratification of other adverse event severity

| Criteria | Severity |
|---|--------------|
| Various other unplanned events may occur as a result of a colonoscopy. These should be recorded, with appropriate details provided Categorisation of severity of adverse event (AE) is given below. Note that bleeding and perforation have their own categorisation (see separate tables) Every event should be recorded, even if it is deemed unlikely to have been caused by the procedure (see 'Attribution of event') Excludes admissions for social reasons | |
| Procedure aborted (or not started) due to AE Unplanned post-procedure medical consultation Unplanned hospital admission, or prolonged hospital stay, for ≤ 3 nights Use of reversal agent Hypoxia (O ₂ saturations $<85\%$) Hypotension ($<90/50$ mm Hg) | Minor |
| Unplanned admission or prolongation for 4–10 nights ITU admission for 1 night Interventional procedure (endoscopic or radiological) Interventional treatment for skin or other tissue injuries Unplanned ventilatory support during conscious sedation | Intermediate |
| Surgery for adverse event/sequelae Permanent disability Unplanned admission or prolongation for >10 nights ITU admission >1 night | Major |
| Death | Fatal |

Taken from Rutter+Chilton,⁸⁸ in turn adapted from Cotton *et al.*⁸⁹
ITU, intensive therapy unit.

Box 1 Attribution of event

It is not always clear whether an adverse event relates to the procedure. After root cause analysis, attribution of adverse events should be recorded as follows

- ▶ Definite
- ▶ Probable
- ▶ Possible
- ▶ Unlikely

CONCLUSION

The agreed QA measures and KPI should be implemented across the UK. Individual endoscopy units are responsible for measuring and acting upon the standards. The JAG will monitor adherence to these standards. Where performance falls below the standards then units should explore and understand underperformance and measures to improve performance should be instituted.

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