UK Key Performance Indicators & Quality Assurance Standards for Colonoscopy

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Introduction

Colonoscopy is the ‘gold standard’ investigation for assessment of the large bowel allowing diagnosis, biopsying, and therapy to be undertaken. Colonoscopy detects and prevents colorectal cancer[1], and is important tin 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, the British Society of Gastroenterology and the Association of Coloproctology commissioned a group to review existing and define new quality measures and key performance indicators for colonoscopy. For each standard a review of existing literature and evidence was undertaken. Where evidence exists it has been used to frame the standards. Where no clear evidence exists then existing standards and expert opinion have been used to arrive at agreed standards.

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 has been set. The authors believe that this is the level that all colonoscopists should be aiming for to provide the highest quality of practice.

Summary of Quality standards

Quality indicator	Minimal standard	Aspirational target	Comment
Caecal intubation rate (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 patients population (not screening).	15%	20%	Adenoma detection rate 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 accurately reflect 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 mins	Mean of ≥10 minutes	
Sedation level for age < 70 Median total dose ≤ 50mg Pethidine (≤100mcg Fentanyl) ≤ 5mg Midazolam (Or equivalent drugs)	Auditable outcome		

Sedation level for age ≥ 70 Median total dose ≤ 25 mg Pethidine (≤ 50 mcg Fentanyl) ≤ 2 mg Midazolam (Or equivalent drugs)	Auditable outcome		
Number of colonoscopies undertaken by endoscopist (or directly supervising trainee in room) per year	100	150	If numbers less than 150 then other KPI e.g. CIR and ADR should be scrutinised more closely and if concerns identified then action should be taken
Polyp retrieval rate	≥ 90%		
Tattooing of all lesions ≥ 20mm and / or suspicious of cancer outside of rectum and caecum	100%		Tattoo according to trust policy
Diagnostic biopsies for unexplained diarrhoea	Rectal biopsies taken in 100% of cases	Minimum of 2 right and 2 left colon biopsies	
Post Colonoscopy Colorectal Cancer	Auditable Outcome		All Post Colonoscopy Colorectal Cancers (PCCRC) should be reported as adverse events and each unit should have a policy for capturing PCCRC data.
Comfort level	Auditable Outcome		Units should audit this and units should aim to have less than 10 % of patients with moderate or severe discomfort.
Overall colonoscopic perforation rate	<1 in 1000	<1 in 3000	
Diagnostic colonoscopic perforation	<1 in 2000	<1 in 4000	

rate			
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 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		

Additional Recommendations:

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

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

3. Rectal examination should be performed at colonoscopy or prior to endoscopy.

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

Caecal Intubation Rate

Minimal caecal intubation 90%.

Colonoscopists should aspire to achieve 95% 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 was 92.3% rising to 95.8% following adjustment for impassable strictures and poor bowel preparation. A further UK study[9] demonstrated an unadjusted CIR at 92.5% (95% CI 91.2 – 92.6%). The English Bowel Cancer Screening Programme (BCSP) published the results of the first 3 years of screening[18] with an unadjusted CR of 95.2% (range 76.2 – 100%). Given the caecal intubation rate in excess of 90% for large series this should be the minimal standard. The BCSP demonstrates that a higher caecal intubation rate can be achieved in a large programme and a standard of 95% 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 maybe 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 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 less than 20% had a hazard ratio (HR) for interval cancer that was ten times higher than colonoscopists with an ADR of greater than 20%. A recent UK study demonstrated wide variation in ADR with a global ADR (excluding screening colonoscopy) of 15.9%[9].

The data indicates that 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. Based upon the available UK population study for a population of all ages 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 caecal intubation rates and the detection of neoplasia. This is highlighted by the 2013 ESGE position statement[23] 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 caecal intubation rate is 90% and audit suggesting that excellent or adequate bowel preparation can be achieved by the BCSP in 94.2% of patients[18] means that we recommend bowel preparation be excellent or adequate in at least 90% of patients, and in line with an aspirational caecal intubation rate 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 GI 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 increased 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 the risk 0.01% [41]. We recommend that digital rectal examination and retroflexion are attempted in all cases.

Withdrawal time

Minimum mean withdrawal time of 6 minutes.

Aspirational: mean withdrawal time of 10 minutes.

Withdrawal times should be routinely recorded and audited.

Colonoscopy withdrawal times (CWT) of more than 6 minutes 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 minutes[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 WT and polyp detection using the cut off of 6 minutes[47] or 7 minutes[48].

Mean withdrawal times should be more than 6 minutes with an aspirational goal of achieving 10 minutes. This KPI should be linked to the ADR or PDR such that a low WT 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 ≤ 50mg Pethidine (≤100mcg Fentanyl) ≤ 5mg Midazolam or equivalent drugs.

Sedation level for age ≥ 70: Median total dose ≤ 25 mg Pethidine (≤ 50 mcg Fentanyl) ≤ 2 mg Midazolam or equivalent drugs.

In the UK, the majority of colonoscopies are performed under conscious sedation. The current BSG sedation guidelines[49] match the KPI values suggested here. 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 by 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, 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 publication[51] 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 (that is, a CIR of ≥90%)[55, 56]. Other studies have suggested a higher procedural volume of 200-300 maybe necessary to maintain competent and safe practise with figures below that being associated with lower CIR[56] 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% 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 less than 1cm 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 (PRR) should be ≥ 90% in the UK.

Tattooing of suspected malignant lesions in the colon

Tattooing of all lesions ≥ 20mm and / or suspicious of cancer outside of 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 technique[58] has been shown to safely and accurately guide surgical resections[59].

As polyps increase in size the risk that they harbour cancer increases. All polyps greater than 2 cm in diameter should be marked by tattoo. Lesions less than 2cm in diameter should be assessed by careful inspection and marked if they have high risk features as described in the guidelines of the BCSP[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% 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 commonest 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 ASGE guidelines[66]. We recommend that the minimum standard remains that 100% of patients with unexplained diarrhoea 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 (PCCRC)

All units should develop a system for capturing data on and reviewing each case of 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 years[67] 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 study[69] in England between 2001 and 2008 looking at National Cancer Data Repository information and central procedural data show 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 than 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 influences the rate of future cancers.

Polypectomy technique also influences PCCRC, with incomplete polypectomy[71] contributing to later interval cancers. Pooled North American post polypectomy studies [72] demonstrated missed cancer contributing 52% to the interval cancer rate, with 19% possibly due to incomplete polyp resection. A further study[73] found 27% of their interval cancers developed in the same segment as a previous polypectomy, indicating incomplete treatment may have been a contributory factor. Detection of subtle, flat, depressed and serrated lesions is highly variable amongst endoscopists particularly in the proximal colon[74, 75].

Comfort

Units should audit comfort and less than 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 audit[8] 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.

Perforation

The overall colonoscopic perforation rate is influenced by the proportion of diagnostic to therapeutic procedures performed. In 4 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 audit[8] demonstrated overall perforation rate of 0.04%. For diagnostic colonoscopy perforation rates of 0% to 0.2% are reported [77-79]. The two main risk factors for 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 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 to 6.1% for polypectomies are reported[77, 85]. The recent UK audit reported a bleeding rate of 0.26%[8]. A recent large series reports a colonoscopy bleeding rate of 0.164%[5]. BCSP data illustrates 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 2g, transfusion, ITU admission, unplanned hospital admission for 4 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].

Appendix 1 – Classification of adverse events

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
Hb drop of ≥2g 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].

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 GI 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 nor started) due to AE Unplanned post-procedure medical consultation Unplanned hospital admission, or prolonged hospital stay, for ≤3 nights Use of reversal agent Hypoxia (O2 saturations <85%) Hypotension (<90/50)	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]

Table 4 – attribution of event

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

- Definite
- Probable
- Possible
- Unlikely

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