

## **Quality Assurance Guidelines for Colonoscopy**

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# **QUALITY ASSURANCE GUIDELINES FOR COLONOSCOPY**

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# 1. INTRODUCTION

## 1.1 Purpose of the guidance

The purpose of this guidance is to define key areas of quality assurance (QA) in the delivery of colonoscopy and to embed them in routine practice. The document seeks to provide the rationale for the described quality standards (both qualitative and quantitative) and to set in place a framework for the collection of quality assurance data and for monitoring performance against the standards.

The guidance has been produced under the auspices of the NHS Bowel Cancer Screening Programme's endoscopy quality assurance group.\*

## 1.2 Background

The principal aim of the Bowel Cancer Screening Programme (BCSP) is to reduce deaths from bowel cancer. Randomised control trials of population screening using biennial Faecal Occult Blood testing (FOBT)<sup>1</sup> have demonstrated a 16% reduction in mortality from colorectal cancer, with successful replication of the trials in the UK pilot programme.<sup>2</sup> It is anticipated that the BCSP will cover the whole of England by the middle of 2010. Once the programme is fully rolled out it will be one of the largest of its kind in the world, inviting men and women aged 60 to 74 to be routinely screened every two years.

The delivery of the BCSP is rooted in the provision of a high quality, effective and patient centred service. Quality assurance (QA) is the mechanism for maintaining minimum standards while striving for excellence. It ensures equity of provision and access to consistent reproducible standards for screening subjects throughout the programme and aims to minimise the risks and maximise the benefits of screening. All activity in the NHS BCSP is quality assured to national standards and the performance of the programme against these standards is monitored locally by SHA QA teams and nationally through national professional quality assurance groups.

## 1.3 Quality assuring colonoscopy in the BCSP

Colonoscopy is fundamental to the management of lower gastrointestinal (GI) disease; it has diagnostic, therapeutic and preventative roles. Colonoscopy needs to strike a balance between benefit and harm. The procedure is invasive, with the potential for causing serious and significant adverse events. In England colonoscopy performance has been found to be variable, as identified by a national audit<sup>3</sup> which demonstrated poor completion rates and higher than expected perforation rates.

In order to optimise the benefit to risk ratio of screening, colonoscopy services in the BCSP must be delivered to national standards and underpinned by a robust QA framework. The aim is to provide high quality colonoscopy that is safe, effective, comfortable and adheres to best practice.

The current national quality standards for colonoscopy are based on varying levels of evidence, ranging from expert consensus to evidence from randomised controlled trials. The ongoing collec-

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\*The editors gratefully acknowledge the contributions of Professor Peter Cotton and Dr Tom Lee to the drafting of these Guidelines.

tion and scrutiny of colonoscopy performance data provides an unparalleled opportunity to define and quantify procedure related risk in diagnostic and therapeutic colonoscopy within a screening programme. This will permit refinement of the national quality standards for colonoscopy.

### 1.4 BCSP accredited colonoscopists

Colonoscopy as part of a screening investigation requires public and professional acceptance to ensure the ongoing success of the screening programme. Quality assurance in colonoscopy is supported through the JAG (Joint Advisory Group on Gastrointestinal Endoscopy) accreditation of endoscopy units and through rigorous accreditation for colonoscopists working in the BCSP. Aspirant screening colonoscopists undertake a summative assessment of knowledge and skills to test their competencies. A failure by an accredited BCSP colonoscopist to reach national standards, or provide the required data returns, may result in a series of possible sanctions.<sup>4</sup>

### 1.5 BCSS reports

Work is currently being undertaken to develop a set of reports derived from the screening IT system (BCSS) to allow the QA standards to be monitored.

### 1.6 National statistical returns

National statistical returns are being developed for the BCSP. The proposed cohort return will report on individuals who have a screening episode which began in the report year. Part 1 of the return reports on patients undergoing endoscopy; Part 2 covers other investigations such as imaging and Part 3 will allow adverse events following colonoscopy to be monitored.

## 2. QUALITY INDICATORS, STANDARDS AND AUDITABLE OUTCOMES

### 2.1 Rationale

National objectives, measures and standards<sup>5</sup> for colonoscopy in the BCSP were developed at the outset of the programme based on data from the pilot. Experience has shown that these are insufficiently detailed and specific for effective quality assurance purposes and this document provides revised and more detailed standards that draw on the BCSS dataset. These have been developed by the endoscopy committee of the British Society of Gastroenterology (BSG) in conjunction with the BCSP, the Association of Upper Gastrointestinal Surgeons (AUGIS) and the Association of Coloproctology of Great Britain and Ireland (ACPGBI) and have been ratified by JAG.

In some areas of colonoscopy, no clear evidence currently exists to support the setting of national standards. Nevertheless, there are key performance indicators which are based on a consensus of expert opinion and which will be monitored in the BCSP. To support the measurement of quality indicators, the terms **auditable outcome** (an important indicator for which no clear evidence base exists) and **quality standard** (an auditable outcome for which there is an evidence base that can support a minimum standard) have been adopted.

The quality standards provided in this document are summarised in Appendix 1. This sets out

- the **objective** to be achieved in each area of activity
- the **measure** used to evaluate whether that objective is being achieved
- the **minimum standard** expected of each screening centre (or, for certain standards, each colonoscopist). It is recognised that there are many reasons why performance might fall below the minimum standard, and shortfalls will not attract a penalty. However, they will be taken to indicate that closer monitoring or support may be needed
- the **target** towards which all centres should be working (and which some may already have achieved).

The quality standards presented in this document apply to the prevalent screening round only. Quality standards for incident screening rounds will be developed once such data become available. In the interim, incident round quality measures will be reported as auditable outcomes.

It is anticipated that the collection and monitoring of data from the BCSP will help to identify areas for quality improvement and will provide a robust evidence base for revising and consolidating future quality standards and key performance indicators. Much of this intelligence and analysis will emerge from the BCSP evaluation group.

## 2.2 Minimum number of screening colonoscopies

To support the maintenance of colonoscopists' clinical competence, a minimum number of screening colonoscopies should be undertaken each year.

Quality measure	Minimum number of screening colonoscopies undertaken annually by each screening colonoscopist
Objective	Harm minimisation to screening population
Standard	>150 BCSP colonoscopies per annum
Accountability	Colonoscopist
Comments	Equates to 1 BCSP list per week Supports other key performance indicators Minimum number of procedures permits meaningful comparative statistical analysis

## 2.3 Bowel preparation

Effective bowel preparation is key to detailed interrogation of the bowel. There are many published data to support a variety of regimens with variable tolerability. Good bowel preparation supports improved polyp detection and caecal intubation. Poor bowel preparation is associated with failure to reach the caecum and hinders the detection of lesions.<sup>6</sup>

Adequate hydration is vital to protect against adverse effects of bowel preparation; however a regimen acceptable to patients and meeting the cleanliness standard is best locally agreed and administered. In practice there are many different regimens (diet and catharsis, gut lavage and phosphate preparations), but no ideal exists. The BCSP does not endorse any single bowel cleansing regimen.

Endoscopy units and specialist screening practitioners (SSPs) need to work in collaboration to achieve effective bowel preparation while ensuring patient acceptability and tolerability. In cases of multiple sensitivities to conventional bowel preparations and their excipients, SSPs or (in complex cases) Screening Directors should work with the patient to find a suitable alternative, consulting specialists in other areas if necessary.

Quality measure	Bowel cleanliness at colonoscopy
Objective	Maximise pathology detection, minimise the need for additional procedures
Standard	≥90% bowel preparation described as excellent or adequate
Accountability	Screening centre
Comments	Validated scoring systems exist such as the Ottawa <sup>7</sup> and Aronchick <sup>8</sup> scales. Such a scale may be introduced to ensure that SSPs collect data in a validated format. However the current BCSS categorises bowel preparation as follows: excellent, adequate, complete despite poor preparation, or failed due to poor preparation. Until this is revised, we recommend the following pragmatic criteria for each category <b>Excellent:</b> no or minimal solid stool and only clear fluid requiring suction <b>Adequate:</b> collections of semi-solid debris that are cleared with washing/suction <b>Complete despite poor prep:</b> solid or semi-solid debris that cannot be cleared effectively but which still permits intubation to caecum <b>Failed due to poor prep:</b> solid debris that cannot be cleared effectively and prevents intubation to caecum. Reasons for poor preparation should be documented in the patient's care plan
Evidence	<i>Gastrointest Endosc</i> , 2004, 59(4): 482–486 <sup>7</sup> <i>Am J Gastroenterol [A]</i> , 1999, 94: 2667 <sup>8</sup> <i>Gastrointest Endosc</i> , 2001, 54: 829–832 <sup>9</sup> BCSS Dataset

## 2.4 Response rate (acceptance rate) for colonoscopy (index and surveillance)

The BCSP standard for patients with positive FOB test results is that 85% or more will undergo colonoscopy. Health and social deprivation rates within screening communities and local health economies will influence the response rate for colonoscopy. Care should be taken to ensure that all communities and sections of society have equal access to colonoscopy and that specific needs are catered for.

It is essential that the decision to perform or withhold screening colonoscopy in patients with significant comorbidity is made on sound clinical grounds. This judgement must be arrived at on the basis of risks and benefits, and the reasons must be clearly documented.

Patients who need colonoscopy but for whom the procedure would not be suitable (or has been incomplete) may instead be offered an alternative whole colon imaging examination. Where patients are unlikely to be fit enough for an imaging examination or any subsequent intervention they should not automatically be referred. Instead they should have the options explained to them (and, if appropriate, to their carer) before being advised on whether to continue with the screening procedure.

Quality measure	Response rate (acceptance rate) for colonoscopy after positive FOBt
Objective	Investigate individuals with positive FOBt results
Standard	≥ 85% of individuals with positive FOBt results undergo colonoscopy
Accountability	Screening centre
Comments	Data should be collected on conversion rate from positive FOBt to SSP clinic, and the conversion rate from SSP clinic to colonoscopy
Evidence	1st and 2nd round evaluation of BCS pilot <sup>2</sup>

## 2.5 Surveillance colonoscopy attendance rate

The effectiveness of screening programmes is compromised by low uptake, making the monitoring and optimising of colonoscopy attendance rates a key priority.

Quality measure	Surveillance attendance
Objective	Optimise attendance for surveillance procedures
Standard	≥ 85% of individuals scheduled for surveillance colonoscopy undergo that procedure within 3 months of scheduled date
Accountability	Screening centre
Comments	Reasons for non-attendance should be recorded. Clock starts following last complete colonoscopy in previous episode
Evidence	<i>Adenoma Surveillance</i> (NHS BCSP Guidance Note No 1, 2009) <sup>10</sup>

## 2.6 Consent

Consent must be in line with DH and GMC guidance on informed consent<sup>11,12</sup> and in accordance with BSG guidance on consent for colonoscopy.<sup>13</sup> The BCSP has also published guidance on consent to cancer screening.<sup>14</sup>

The colonoscopist must identify any comorbidity, use of anticoagulants or antiplatelet drugs,<sup>15</sup> or allergies. Consent for colonoscopy must include a clear and realistic explanation of the procedure, possible attendant discomfort, the risks and benefits and a clear relevant discussion of potential adverse events. Patients need to be aware of the possibility of late adverse events and how to seek help. For further advice and guidance see [www.bsg.org.uk](http://www.bsg.org.uk) and [www.grs.nhs.uk](http://www.grs.nhs.uk).

The right of the patient to withdraw consent at any stage of the colonoscopy process should be understood by all members of the team.

## 2.7 Safe sedation and comfort

It is essential that colonoscopy in the BCSP is performed to a high standard and is both safe and comfortable. This requires appropriate sedation. While no direct evidence exists on which to base targets, as a minimum standard all sedation used should be recorded to permit later audit.

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Quality measure	Colonoscopic comfort
Objective	Harm minimisation to screening population, optimisation of the patient experience
Standard	Auditable outcome
Accountability	Colonoscopist
Comments	<p>Recorded for all lower GI procedures.</p> <p>The programme intention is to introduce validated patient comfort scores once they are available. Until that time, endoscopy units should use the current system on BCSS. To add objectivity to this scale, the following Modified Gloucester comfort score descriptors should be used:</p> <p><b>No:</b> No discomfort – resting comfortably throughout</p> <p><b>Minimal:</b> one or two episodes of mild discomfort, well tolerated</p> <p><b>Mild:</b> More than two episodes of discomfort, adequately tolerated</p> <p><b>Moderate:</b> Significant discomfort, experienced several times during the procedure</p> <p><b>Severe:</b> Extreme discomfort, experienced frequently during the procedure</p> <p>Sedation should be delivered in line with BSG guidance. All screening and non-screening units should be conducting rolling audits of sedation practice, patient comfort scores and the use of reversal agents in line with GRS requirements</p>
Evidence	<i>BSG Guidelines on Safety and Sedation during Endoscopic Procedures, September 2003</i> <sup>17</sup>

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Quality measure	Medication use for comfort during lower GI endoscopy
Objective	Harm minimisation to screening population, optimisation of the patient experience
Standard	Auditable outcome
Accountability	Colonoscopist
Comments	<p>Proportion of all patients undergoing lower GI endoscopy who have the following</p> <ul style="list-style-type: none"> <li>• Nil of below</li> <li>• Entonox but no intravenous medication</li> <li>• Intravenous sedative/opioid medication*</li> <li>• Intravenous propofol</li> </ul> <p>*for patients in this category, median doses (and range) of drugs should be recorded, subcategorised into patients under 70, and those of 70 years and over</p>
Evidence	<i>BSG Guidelines on Safety and Sedation during Endoscopic Procedures, September 2003</i> <sup>17</sup> Gray A and Bell GD/NCEPOD/NPSA guidance on safe sedation in elderly <sup>16</sup>

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Quality measure	Use of reversal agents
Objective	Harm minimisation to screening population, optimisation of the patient experience
Standard	Auditable outcome
Accountability	Colonoscopist
Comments	Proportion of patients who receive intravenous sedative/opioid medication who are then given flumazenil/naloxone reversal agents (respectively)
Evidence	<i>BSG Guidelines on Safety and Sedation During Endoscopic Procedures</i> , September 2003 <sup>17</sup> Gray A and Bell GD/ NCEPOD/ NPSA guidance on safe sedation in elderly <sup>16</sup>

## 2.8 Caecal intubation rate (CIR)

Complete examination of the colon is a fundamental objective of colonoscopy and a key performance indicator. A proportion of colonic neoplasms will be located proximal to the ileo-caecal valve (ICV). For the avoidance of doubt an unadjusted (intention to scope) figure of 90% or more has been set as the programme standard. This is consistent with the performance standards adopted by the US Multi-Society Task Force on Colorectal Cancer<sup>18</sup> and Cancer Care Ontario Colonoscopy standards<sup>19</sup> of a 95% completion rate, but adjusted for poor bowel preparation and structural lesions. Early indications from the BCSP suggest that it is achievable for all accredited practitioners. The CIR is a marker of full colonoscopy and when supported by the other performance measures it contributes to a high quality patient centred outcome.

Photographic evidence of either the ICV or the appendix orifice must be available to support completion colonoscopy.

Quality measure	Caecal intubation rate (CIR)
Objective	To ensure that the entire colon is visualised; marker of quality of colonoscopy
Standard	90% unadjusted CIR with photographic evidence
Accountability	Colonoscopist
Comments	Limited to colonoscopies Caecal intubation defined as passage of the scope beyond the ileo-caecal valve (ICV) into the caecal pole or terminal ileum (passage of scope to anastomosis with small intestine also accepted) Photographic evidence of appendix orifice and/or ICV and/or terminal ileum and/or anastomosis is required to document complete intubation
Evidence	<i>Gastroenterology</i> , 2008,134: 150–159 <sup>18</sup> <i>Can J Gastroenterol</i> , 2007, 21(Suppl D): 5–24 <sup>19</sup> <i>GI Endosc</i> , 2006, 63(Suppl 4): S16–S28 <sup>20</sup> BCSS Dataset

## 2.9 Neoplasia detection rates

### 2.9.1 Cancer detection in FOB positive patients

The principal aim of the NHS Bowel Cancer Screening Programme is to reduce deaths from bowel cancer by detecting cancer earlier, at an asymptomatic stage rather than on symptomatic presentation. Standards for cancer detection in the BCSP, based on pilot data, have been set at least 2 per 1000 people screened by FOB, and at least 11% of screening colonoscopies. Cancer detection rate is probably less accurate than adenoma detection rate as a measure of colonoscopist quality; as the UK screening pilots underlined, cancer detection rates vary regionally (between England and Scotland) and by gender.

Quality measure	Cancer detection rate
Objective	Identification of pathology in patients undergoing screening colonoscopy
Standard	≥2 per 1000 screened ≥11 per 100 colonoscopies
Accountability	Screening centre
Comments	Limited to index colonoscopies The UK screening pilots demonstrated differences in cancer detection between England and Scotland and between genders

### 2.9.2 Adenoma detection rate (ADR)

The putative purpose of adenoma removal is to prevent the progression of benign lesions to bowel cancers. Data from the national polyp study<sup>21</sup> suggested that colonoscopy and polypectomy prevented 76–90% of incident cancers; however a proportion of incident cancers will be related to missed lesions. There are reported differences between endoscopists' rates of small and large adenoma detection. Tandem studies<sup>22</sup> demonstrated a miss rate for advanced adenomas (>1 cm) of up to 6% and as high as 27% in adenomas less than 5 mm in size. In studies that compare CT colonography and optical colonoscopy<sup>23</sup> using segmental un-blinding, a discrepancy of 12% was identified between the two techniques in detecting lesions of greater than 1 cm. Withdrawal time clearly influences and informs ADR.<sup>24,25</sup>

ADR is a robust and key metric of quality of colonoscopy. Standards for detection in the BCSP based on pilot data have been set at an ADR of 35% (compared with a 25% polyp ADR in men and 15% in women in US screening studies).

Quality measure	Adenoma detection rate (ADR)
Objective	Identification of pathology, prevention of cancer; marker of quality of colonoscopy
Standard	Histologically confirmed adenomas detected in $\geq 35\%$ of screening colonoscopies
Accountability	Colonoscopist
Comments	Limited to index screening colonoscopies Surveillance procedures and repeat endoscopic procedures are excluded ADR is a more important quality standard than withdrawal time ADR standards may need reviewing for incident rounds of screening
Evidence	<i>BMJ</i> , 2004, 329: 133–135 <sup>2</sup> BCSS Dataset

## 2.10 Withdrawal time in negative colonoscopies

In the setting of a negative colonoscopy (ie no pathology detected) withdrawal time should take a minimum of 6 minutes. Two large studies have supported withdrawal times of 6 minutes or longer.<sup>24,25</sup> The two studies demonstrated significant variability in adenoma detection amongst experienced colonoscopists. A linear relationship between withdrawal time and adenoma detection was observed. A study by Barclay et al<sup>24</sup> found that the percentage of patients with adenomas detected was 9.4–32.7% and withdrawal times in negative colonoscopies ranged from 3.1–16.8 minutes. This translated into a three-fold difference in ADR amongst the colonoscopists. Colonoscopists were stratified into two groups according to withdrawal time (less than 6 minutes and greater than 6 minutes). Colonoscopists with withdrawal times of greater than 6 minutes had higher detection of any neoplasia (28.3% vs. 11.8%); more importantly, detection of advanced neoplasia was significant (6.4% vs. 2.6%,  $P 0.005$ ). This study demonstrates a clear correlation between withdrawal time and the detection of both small and large adenomas. It strongly supports the concept of withdrawal time as a surrogate marker of quality of colonoscopy. The studies support the position that longer withdrawal times translate into greater lesion detection.

As a result of Barclay et al's 2006 paper,<sup>24</sup> the practice in which it was performed set a quality standard with a target withdrawal time of 8 minutes in screening colonoscopy. A total of 2325 screening colonoscopies were evaluated, and the percentage of patients with one or more adenomas increased, as did the number of adenomas per patient screen and the number of advanced adenomas per patient screened.<sup>26</sup>

Quality measure	Colonoscopy withdrawal time
Objective	Maximise pathology detection; marker of colonoscopy quality
Standard	$\geq 6$ minutes inspection time on withdrawal from caecal pole to anus in $\geq 90\%$ of negative procedures
Accountability	Colonoscopist
Comments	Assessed as $\geq 6$ mins for colonoscopy where no polyps/cancer detected Although less relevant than adenoma detection rate (ADR), withdrawal time requires close scrutiny if ADR fails to reach the standard
Evidence	<i>N Engl J Med</i> , 2006, 355(24): 2533–2541 <sup>24</sup> <i>Aliment Pharmacol Ther</i> , 2006, 24(6): 965–71 <sup>25</sup> <i>Gastroenterol Hepatol</i> , 2008, 6(1): 1091 <sup>26</sup>

## 2.11 Polyp recovery

The standard requires retrieval of 90% of all excised polyps. In the first round evaluation of the UK colorectal screening pilot 552 screening detected cancers were identified, of which 92 (16.6%) were polyp cancers. In a three year analysis of the BCSP 49 054 polyps were identified, of which 1.9% were malignant; however stratified by size (0–9 mm, 10–19 mm, 20–29 mm) 0.3%, 4.4% and 8% respectively were malignant (data courtesy of the BCSS and Tom Lee). These data underpin and emphasise the importance of polyp retrieval.

Quality measure	Polyp retrieval rate
Objective	Availability of polyps for histological evaluation
Standard	Retrieval of 90% polypectomy specimens for histological analysis
Accountability	Colonoscopist
Comments	Includes polypectomy at both colonoscopy and flexible sigmoidoscopy Denominator = number of polyps recorded during lower GI endoscopies Numerator = number of polyps with histological tissue retrieved for analysis
Evidence	<i>BMJ</i> , 2004, 329(7458): 133–135 <sup>2</sup>

### 2.11.1 Polypectomy and endoscopic mucosal resection (EMR)

The purpose of the BCSP is to reduce death from colorectal cancer. Essential to this is the removal of early cancers and precursor lesions. It is essential that safe and effective therapy be deployed in this key area. (See *Colonoscopic Polypectomy and Endoscopic Mucosal Resection: A Practical Guide*.<sup>27</sup>) The first priority of all BCSP accredited colonoscopists is patient safety. It is essential that all screeners understand their personal, practical and therapeutic limitations. A successful accreditation does not confer enhanced therapeutic skills on the colonoscopist. A colonoscopy competency/credentialling system is in development to address these issues. The QA group recognises that considerable therapeutic expertise exists within the wider endoscopy community; however these endoscopists may not wish to provide conventional BCS screening, but provide an enhanced therapeutic endoscopic service (tertiary referral). In order to provide such a service individuals will be required to undertake the bowel cancer screening colonoscopy assessment and submit annual QA data to the assessor's panel. The mechanism to meet this need is currently in development.

All endoscopists carrying out therapeutic procedures on BCS patients are required to be accredited bowel cancer screeners. While competencies and training in EMR are being defined it is important that screeners make a judgement of whether to attempt resection of large lesions based on a balance of the nature and position of the lesion, their competence level, and patient factors and preference. The judgement will be affected by the attitude of the colonoscopist, but should always be based on the patient's best interests.

### 2.11.2 Tattooing of suspected malignant polyps

Tattooing is an important technique for lesion location at surgery, identification of colonic lesions (suspected malignancy) or resection sites at future colonoscopy (repeat therapeutic colonoscopy or incomplete/suspected incomplete removal of lesions). Tattooing of sites or lesions that may require later surgical or endoscopic localisation is recommended. It is advisable to tattoo the area with an indelible compound. India ink is a common indelible marker; however it requires dilution

and sterilisation. SPOT, a pure based carbon marker, is a pre-packaged, sterile injectable product. Concerns have been raised about the safety of indelible markers; however the published studies show a low complication rate for both products.<sup>28,29</sup>

The literature suggests marked variability in technique exists. It is advised that local agreement between screening centres and their colorectal MDT will aid in refining policy on tattooing.

## 3. HARM REDUCTION AND ADVERSE EVENTS

### 3.1 Adverse events in colonoscopy

Colonoscopic adverse events are unusual, but may be potentially life threatening. The majority of adverse events are associated with the application of therapy (electrocautery). It is difficult to draw firm conclusions on the incidence of adverse events from the literature. Most published series come from single centres with extensive experience in colonoscopy, without separation of symptomatic and screening patients. Results may therefore not reflect standard practice. One problem with reporting adverse events is that authors often use different definitions. Although the definition of perforation is relatively clear, the same does not apply for bleeding, as some bleeding is almost inevitable after polypectomy. The American Society for Gastrointestinal Endoscopy (ASGE) recently sponsored a workshop to devise a lexicon for adverse events, and approved the report.<sup>30</sup> This lexicon forms the basis of that to be used in the BCSP.

In the BCSP, colonoscopists are accredited through a validated, summative assessment process; however the assessment is not consistently able to assess the application of therapeutic techniques in accredited screening colonoscopists. Prospective data collection on all screening derived colonoscopies will provide new insights into adverse event rates in screening and therapeutic colonoscopy. Knowledge, skills, attitudes and early recognition of adverse events followed by the appropriate management will minimise harm and will improve outcomes for patients.

#### 3.1.1 Adverse event definition

An 'adverse event' is defined as one that prevents completion of the planned procedure (excluding technical failure or poor preparation), and/or results in

- admission to hospital or prolongation of existing hospital stay
- another interventional procedure (endoscopic, radiological or surgical) or
- subsequent medical consultation.<sup>30</sup>

Adverse events may occur prior to the procedure (for example as a result of bowel preparation), during the procedure and recovery period, or afterwards. Post-procedural events may present within minutes, or many days or even years after the procedure (for example a stricture at the site of previous endoscopic mucosal resection). The timescale post-procedure should be recorded.

### 3.1.2 Attribution of adverse events

It is not always clear whether an adverse event relates to the procedure. After root cause analysis by the appropriate QA team, attribution of events should be recorded as definite, probable, possible or unlikely.

### 3.1.3 Capturing adverse events

Consideration should be given to a proactive and robust mechanism for detecting and recording adverse events, especially those which occur after patients leave the unit.

More trivial events, called 'incidents' (such as minor bleeding that is adequately controlled during the procedure, or intravenous cannula site phlebitis), should also be documented so that quality improvement processes can be applied and to assess if they predict subsequent adverse events.<sup>30</sup>

The standards described in this document provide an indication of complication rates and do not capture all adverse events (for example complications from flexible sigmoidoscopy are not assessed in these standards). However *all* adverse events should still be recorded on the BCSS and the reporting processes outlined in Appendices 2 to 4 followed.

## 3.2 Colonic perforation

Perforation is defined as evidence of air, luminal contents or instrumentation outside the GI tract. It may result from direct mechanical trauma to the bowel wall during insertion, over-insufflation of the colon (barotrauma) or from therapeutic procedures (hot biopsy, polypectomy, dilatation). Results from a study in the 1970s<sup>31</sup> (25 000 colonoscopies and 1000 polypectomies), revealed a perforation rate of 0.2% for diagnostic colonoscopy and 0.32% for polypectomy. A study published in 2008 of 97 091 people undergoing colonoscopy aged 50 to 75 years revealed a perforation rate of 0.6%.<sup>32</sup> In a series of 1172 patients with 1555 polypectomies<sup>33</sup> there was one perforation. These low adverse event rates must be viewed against a population based study of Medicare patients<sup>34</sup> aged 65 years or older (39 286 colonoscopies) where the overall perforation risk was 1:500; however the incidence of perforation in the screening group was 1:1000. Risk factors identified for perforation were increasing age and diverticulosis.

In the BSG colonoscopy audit<sup>3</sup> the perforation rate was 1:769. It is clear that widely varying perforation rates have been reported. In the Medicare<sup>34</sup> series the perforation rate (1:1000) in their screening patients does not translate to the BCSP screening population in England, due to the high polyp burden of FOBt positive patients (>35% require polypectomy). Anecdotal experience suggests that the risk of perforation with hot biopsy is high. Perforation is more likely to occur in larger right-sided sessile polyps.<sup>35</sup> Submucosal injection to raise polyps is potentially protective by limiting thermal injury from electrocautery: most colonic perforation is associated with polypectomy as a result of thermal injury from electrocautery, therefore a clear understanding of technique and equipment is essential. This core knowledge is tested as part of the summative assessment process for accreditation of BCSP colonoscopists.

The current standards for perforation will remain under review and amended as performance data accumulates. The risks associated with EMR will become clearer, but for now all therapeutic perforations will be counted.

### 3.2.1 Perforation rate

Quality measure	Perforation rate
Objective	Harm minimisation to screening population
Standard	< 1:1000 colonoscopies
Accountability	Colonoscopist
Comments	Includes all colonoscopy, whether diagnostic or therapeutic See Appendix 3 for stratification and reporting of perforation Perforation rate needs to be interpreted carefully, as some colonoscopists will appropriately perform advanced therapeutic procedures (which may carry higher perforation rates)
Evidence	<i>JAMA</i> , 1976, 235(9): 928–930 <sup>31</sup> <i>Gastroenterology</i> , 2008, 135(6): 1899–1906 <sup>32</sup> <i>Dis Colon Rectum</i> , 1986, 29(12): 825–830 <sup>33</sup> <i>J Natl Cancer Inst</i> , 2006, 95(3): 230–236 <sup>34</sup> <i>Dis Colon Rectum</i> , 1993, 36(12): 1126–1131 <sup>35</sup>

### 3.2.2 Post polypectomy perforation rate

Quality measure	Post polypectomy perforation rate
Objective	Harm minimisation to screening population
Standard	<1:500 colonoscopies where polypectomy is performed
Accountability	Colonoscopist
Comments	Includes all polypectomies at colonoscopy See Appendix 3 for stratification and reporting of perforation Perforation rate needs to be interpreted carefully, as some colonoscopists will appropriately perform advanced therapeutic procedures (which may carry higher perforation rates)
Evidence	<i>JAMA</i> , 1976, 235(9): 928–930 <sup>31</sup> <i>Gastroenterology</i> , 2008, 135(6): 1899–1906 <sup>32</sup> <i>Dis Colon Rectum</i> , 1986, 29(12): 825–830 <sup>33</sup> <i>J Natl Cancer Inst</i> , 2006, 95(3): 230–236 <sup>34</sup> <i>Dis Colon Rectum</i> , 1993, 36(12): 1126–1131 <sup>35</sup>

## 3.3 Post polypectomy bleeding (PPB)

Bleeding is the most frequent adverse event following polypectomy. Blended or pure cut diathermy is said to be associated with more immediate bleeding,<sup>36</sup> whereas pure coagulation electrocautery is associated with more delayed bleeding. The evidence for this is poor but supported by expert consensus. PPB due to the removal of small polyps is the most frequent cause of bleeding and is usually related to complications of electrocautery. An expert consensus is developing supporting the position that small polyps that are not pedunculated should be cold snared, thus preventing the development of late bleeding, a complication of electrocautery. Bleeding associated with cold snaring is usually immediate and of no clinical significance. Immediate bleeding allows the endoscopists the opportunity for endoscopic management.

A variety of studies have reported bleeding rates 0.3–6.1% of polypectomies.<sup>35,37</sup> The risk of bleeding increases with the size of polyp and location, with some series reporting up to 10% bleeding rates for polyps larger than 2 cm located in the right colon. There is evidence that removable snares (endoloops) placed on pedunculated polyp stalks reduce early bleeding. Adrenaline injection into the polyp base may decrease immediate bleeding. It is not clear if clipping and apposing mucosal defects following polypectomy reduces bleeding; however the practice is intuitively appealing.

All BCSP colonoscopists should be comfortable with a range of therapeutic interventions aimed at controlling PPB. They should be familiar with the techniques, maintain staff competencies and support ongoing training to ensure seamless application of these therapies. Around 90% of PPB should be amenable to conservative management without the need for surgical intervention.

For more information on polypectomy techniques see *Colonoscopic Polypectomy and Endoscopic Mucosal Resection: A Practical Guide*.<sup>27</sup>

Quality measure	Post polypectomy bleeding (PPB)
Objective	Harm minimisation to screening population
Standard (individual performance standard)	< 1:100 colonoscopies where polypectomy is performed
Accountability	Colonoscopist
Comments	Includes EMR, endoscopic submucosal dissection and all other polypectomies at colonoscopy Definition of bleeding, terminology, severity categorisation and information to record are described in Appendix 2 Subcategorisation of bleeding severity will permit more robust analysis and revision of standards Data will be measured up to 30 days post colonoscopy
Evidence	Riley, <i>Colonoscopic Polypectomy and Endoscopic Mucosal Resection: A Practical Guide</i> <sup>27</sup> <i>J Natl Cancer Inst</i> , 2006, 95(3): 230–236 <sup>34</sup> <i>Dis Colon Rectum</i> , 1993, 36(12): 1126–1131 <sup>35</sup> <i>Gastrointest Endosc</i> , 2000, 51(6): 676–681 <sup>36</sup>

### 3.4 Other adverse events

Adverse events may occur anywhere in the patient journey. The causes are multiple and varied: they include pain, post polypectomy syndrome, vasovagal events and arrhythmia. All of these may result in unplanned admissions. These events require clear standard documentation, collection of outcomes and discussion at screening centre governance meetings.

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Quality measure	Rate of other adverse events
Objective	Harm minimisation to screening population
Standard	Auditable outcome
Accountability	Individual colonoscopist and screening centre
Comments	Report should be stratified according to severity (100%) Definitions, terminology, severity categorisation and information to record are described in Appendix 4 Adverse events secondary to bleeding and perforation will be viewed as separate to other adverse events Endoscopists' attitudes vary in managing risk. This will impact on individual thresholds for admission and observation of patients. Safe practice is encouraged but the outcomes will inform a wider review of practice; subcategorisation of AE severity will permit more robust analysis and revision of standards

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## 4. INTERVAL CANCERS

The English national bowel cancer screening programme has three phases – FOBt, screening colonoscopy and surveillance. Thus there are three types of interval cancer:

- a) **FOBt interval cancer** – a cancer diagnosed in the two year interval between a negative FOBt and the next proposed FOBt. If the patient is 70 (later to be 75 or over) an interval cancer will be defined as a cancer diagnosed within two years of their last screening episode.
- b) **Colonoscopy interval cancers (non-surveillance)** – a cancer diagnosed in the two year interval between a negative screening colonoscopy (ie where colonoscopic surveillance is not required) and the next proposed episode of a standard FOBt (if aged under 70; later to be under 75).
- c) **Surveillance interval cancer** – a cancer diagnosed in any surveillance interval whether one year (high risk) or three years (intermediate risk).

Note: cancers detected *at* a surveillance colonoscopy are not considered interval cancers.

Cancers detected following a negative screening colonoscopy may represent missed lesions and qualitative concerns; however some cancers may be a facet of aggressive tumour biology. No standard has been set for the BCSP but the goal is to minimise the number of interval cancers. Once monitoring processes have been established, it is anticipated that monitoring of interval cancers will become an important component of quality assurance in the BCSP. The NHS BCSP is working with the National Cancer Intelligence Network to develop protocols for routine monitoring of interval cancers.

The national polyp study<sup>21</sup> suggested that polypectomy might prevent as many as 90% of interval cancers; however not all studies have demonstrated this level of effect. In the chemopreventative study by Robertson et al<sup>38</sup> in which patients had had at least one polyp removed, he found three times the interval cancer rate of the national polyp study. In a study by Farrar et al<sup>39</sup> of 830 patients who had undergone colonoscopy, 45 (5.4%) developed interval cancers. Of these 45 patients, 15 had previous negative colonoscopies, 28 had adenomas and 14 had advanced adenomas. Thirty

per cent of these cancers exhibited microsatellite instability (MSI), a factor known to promote rapid growth, compared with only 10% MSI in a control group of non-interval cancers. Most of the interval cancers were smaller and three times more likely than non-interval cancers to occur on the right side of the bowel. This suggests that a proportion of interval cancers occur due to aggressive tumour biology but missed lesions and incomplete polyp removal are important contributing factors.

A recent study by Imperiale et al<sup>40</sup> investigated the risk of a positive finding (cancer or advanced adenoma) on colonoscopy five years after a negative screening colonoscopy in an average risk population of approximately 57 years of age. It found 1.3% had adenomas, while no cancers were detected in 1256 patients. This needs to be viewed against a number of studies that have demonstrated that screening colonoscopy provides less protection against right sided colon cancers than left sided.<sup>41-43</sup> In Baxter's case-control study<sup>43</sup> the odds ratio for preventing death from left sided lesions was 0.33 and 0.99 for right sided lesions, thus demonstrating no effect for right sided cancers. Completion, quality of the bowel cleansing and the experience of the colonoscopist could not be evaluated in this study. It is therefore important to be aware of this issue and limit it through adherence to quality standards and effective endotherapy. These will provide some protection against this unwanted outcome.

## 5. FAILURE TO MEET AGREED QUALITY STANDARDS

A process for dealing with suboptimal performance and mechanisms for resolving this is being developed by the endoscopy QA group and will be published separately.

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# APPENDIX 1: REVISED PREVALENT ROUND QUALITY STANDARDS FOR COLONOSCOPY WITHIN THE NHS BOWEL CANCER SCREENING PROGRAMME

<b>Objective</b> to be achieved in each area of activity listed	<b>Measure</b> used to evaluate whether the objective is being achieved	<b>Minimum Standard</b> the minimum expected of each screening centre/ colonoscopist (Falling short of the minimum standard will not attract a penalty but will be taken to indicate the need for closer monitoring and support. See Section 2.1)	<b>Target</b> the standard towards which all centres/ colonoscopists should be working
Investigate individuals with positive FOBt results	Response rate (acceptance rate) for colonoscopy after positive FOBt	≥ 85 per 100 individuals undergo colonoscopy	≥ 88 per 100 individuals undergo diagnostic examination
Optimise attendance for surveillance procedures	Surveillance colonoscopy performed when due	≥ 85 per 100 individuals undergo surveillance colonoscopy within 3 months of scheduled date	≥ 85 per 100 individuals undergo surveillance colonoscopy within two months of scheduled date
Entire colon examined	Caecal intubation rate on intention to treat basis with photographic evidence of completion	≥ 90 per 100	≥ 97 per 100 (per colonoscopist)
	Proportion of bowel preparation described as excellent or adequate	≥ 90 per 100 bowel preparations	≥ 95 per 100 bowel preparations (per centre)
	≥ 6 minutes inspection time upon colonoscope withdrawal from caecal pole to anus for negative procedures	≥ 90 per 100 negative procedures	≥ 99 per 100 negative procedures (per colonoscopist)
Identification of adenoma/cancer present in the screening population	Adenoma detection rate (ADR) (Age 60–69 prevalent round)	≥ 6 per 1000 individuals screened ≥ 35% of screening colonoscopies	≥ 7 per 1000 people screened ≥ 40 per 100 screening colonoscopies
	Cancer detection rate (Age 60–69 prevalent round)	≥ 2 per 1000 individuals screened ≥ 11 per 100 screening colonoscopies	Auditable outcome

Continued on next page

<b>Objective</b> to be achieved in each area of activity listed	<b>Measure</b> used to evaluate whether the objective is being achieved	<b>Minimum Standard</b> the minimum expected of each screening centre/ colonoscopist (Falling short of the minimum standard will not attract a penalty but will be taken to indicate the need for closer monitoring and support. See Section 2.1)	<b>Target</b> the standard towards which all centres/ colonoscopists should be working
Availability of polyps for pathology evaluation	Polyp retrieval rate	> 90 per 100 polyps excised	> 95 per 100 polyps excised (per colonoscopist)
Minimising harm to screening population	(i) Minimum number of BCSP colonoscopies per annum undertaken by an accredited BCSP colonoscopist	≥ 150 colonoscopies	Not applicable
	(ii) Perforation rate	< 1 per 1000 colonoscopies	Auditable outcome
	(iii) Post polypectomy perforation rate	< 1 per 500 colonoscopies where polypectomy is performed	Auditable outcome
	(iv) Post polypectomy bleeding rate (intermediate severity or higher)	< 1 per 100 colonoscopies where polypectomy is performed	Auditable outcome
	(v) Rate of other adverse events	100% recorded	Auditable outcome
	(vi) Colonoscopy comfort	100% recorded	Auditable outcome
	(vii) Sedation use and doses	100% recorded	Auditable outcome
	(viii) Use of reversal agents	100% recorded	Auditable outcome

## APPENDIX 2: REPORTING OF BLEEDING

Criteria	Severity	Action
Rectal bleeding within 30 days of procedure resulting in any of the following		
<ul style="list-style-type: none"> <li>• Procedure aborted</li> <li>• Unplanned post-procedure medical consultation</li> <li>• Unplanned hospital admission, or prolongation of hospital stay, for <math>\leq 3</math> nights</li> </ul>	Minor	<ul style="list-style-type: none"> <li>• Record on BCSS as adverse event</li> <li>• Record timing post-procedure</li> <li>• Record site in colorectum</li> <li>• Record cause of bleeding, equipment used, diathermy settings, additional factors etc.</li> <li>• Record haemoglobin drop</li> <li>• Record number of units transfused</li> <li>• Record interventional procedure(s) and surgery</li> <li>• Record length of stay</li> </ul>
<ul style="list-style-type: none"> <li>• Hb drop of <math>\geq 2</math> g/dL</li> <li>• Transfusion</li> <li>• Unplanned admission or prolongation for 4–10 nights</li> <li>• ITU admission for 1 night</li> <li>• Interventional procedure (endoscopic or radiological)</li> </ul>	Intermediate	As above, plus <ul style="list-style-type: none"> <li>• Report to QARC</li> <li>• Root cause analysis</li> </ul>
<ul style="list-style-type: none"> <li>• Surgery</li> <li>• Unplanned admission or prolongation for <math>&gt;10</math> nights</li> <li>• ITU admission <math>&gt; 1</math> night</li> </ul>	Major	
<ul style="list-style-type: none"> <li>• Death</li> </ul>	Fatal	As above, plus <ul style="list-style-type: none"> <li>• Record cause and time of death</li> </ul>

Adapted from Cotton et al.<sup>30</sup>

## APPENDIX 3: REPORTING OF PERFORATION

Criteria	Severity	Action
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.		
<ul style="list-style-type: none"> <li>Managed conservatively (no endoscopy/surgery)</li> <li>Endoscopic management</li> <li>Surgery</li> </ul>	Major	<ul style="list-style-type: none"> <li>Record on BCSS as adverse event</li> <li>Report to QARC</li> <li>Root cause analysis</li> <li>Record timing post-procedure</li> <li>Record site in colorectum</li> <li>Record cause of perforation, whether diagnostic or at site of therapy/ instrumentation, equipment used, diathermy settings, additional factors etc.</li> <li>Record interventional procedure(s) and surgery</li> <li>Record length of stay</li> </ul>
<ul style="list-style-type: none"> <li>Death</li> </ul>	Fatal	As above, plus <ul style="list-style-type: none"> <li>Record cause and time of death</li> </ul>

Adapted from Cotton et al<sup>30</sup>

## APPENDIX 4: REPORTING OF OTHER ADVERSE EVENTS

Criteria	Severity	Action
<p>Various other unplanned events may occur as a result of a BCS colonoscopy. These should be recorded, with appropriate details provided.</p> <p>Categorisation of severity of adverse event (AE) is given below. Note that bleeding and perforation have their own categorisation (see separate tables).</p> <p>Every event should be recorded, even if it is deemed unlikely to have been caused by the procedure (see 'Attribution of event').</p> <p>Excludes admissions for social reasons.</p>		<ul style="list-style-type: none"> <li>Record on BCSS as adverse event</li> <li>Record whether pre-, during or post-procedure; record timing if post-procedure</li> <li>Record details of event</li> <li>Record any procedures required</li> <li>Record length of stay</li> </ul>
<ul style="list-style-type: none"> <li>Procedure aborted (or not started) due to AE</li> <li>Unplanned post-procedure medical consultation</li> <li>Unplanned hospital admission, or prolonged hospital stay, for <math>\leq 3</math> nights</li> <li>Use of reversal agent</li> <li>Hypoxia (<math>O_2</math> saturations <math>&lt; 85\%</math>)</li> <li>Hypotension (<math>&lt; 90/50</math> mmHg)</li> </ul>	Minor	<p><b>Attribution of events</b></p> <p>It is not always clear whether an adverse event relates to the procedure. After root cause analysis, attribution of AEs should be recorded by the appropriate QA team as follows</p> <ul style="list-style-type: none"> <li>Definite</li> <li>Probable</li> <li>Possible</li> <li>Unlikely</li> </ul>
<ul style="list-style-type: none"> <li>Unplanned admission or prolongation for 4–10 nights</li> <li>ITU admission for 1 night</li> <li>Interventional procedure (endoscopic or radiological)</li> <li>Interventional treatment for skin or other tissue injuries</li> <li>Unplanned ventilatory support during conscious sedation</li> </ul>	Intermediate	<p>As above, plus</p> <ul style="list-style-type: none"> <li>Report to QARC</li> <li>Root cause analysis</li> </ul>
<ul style="list-style-type: none"> <li>Surgery for adverse event/sequelae</li> <li>Permanent disability</li> <li>Unplanned admission or prolongation for <math>&gt; 10</math> nights</li> <li>ITU admission <math>&gt; 1</math> night</li> </ul>	Major	
<ul style="list-style-type: none"> <li>Death</li> </ul>	Fatal	<p>As above, plus</p> <ul style="list-style-type: none"> <li>Record cause and time of death</li> </ul>

Adapted from Cotton et al.<sup>30</sup>

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