

# **Guidelines for the use of imaging in the NHS Bowel Cancer Screening Programme**

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Second Edition



# GUIDELINES FOR THE USE OF IMAGING IN THE NHS BOWEL CANCER SCREENING PROGRAMME

*Second Edition*

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The authors also gratefully acknowledge the colleagues who contributed to the original CT Colonography Standards document. Their original standards have been modified by the committee named above to provide specific guidance tailored to the requirements of the NHS Bowel Cancer Screening Programme (NHSBCSP).

## EXECUTIVE SUMMARY

This document builds on the recommendations laid out in *Guidelines for the use of imaging in the NHS Bowel Cancer Screening Programme* (NHSBCSP Publication No 5), which was published in July 2010. Its aim is to clarify policy on the use of imaging for patients who are unsuitable candidates for colonoscopy.

The main policy points outlined in the document are as follows:

- Patients should undergo whole colon imaging in the context of the NHSBCSP only when they are unsuitable candidates for colonoscopy or when their colonoscopy is incomplete. Full consultation between the screening consultant or director and lead radiologist should be undertaken in equivocal cases.
- Computed tomographic colongraphy (CTC) is the alternative imaging investigation of choice.
- Barium enema should not be performed as a first-line alternative to colonoscopy.
- Patients should be provided with appropriate verbal and written information. Specialist screening practitioners (SSPs) must therefore be fully informed about the procedure. They must manage the start of the consent process.
- Those performing CTC must be appropriately trained and must adhere to recommended protocols pertaining to patient preparation, computed tomography (CT) image acquisition, and patient aftercare.
- Prescription of laxatives must adhere to National Patient Safety Agency (NPSA) guidelines, and routine use of faecal tagging is now recommended. Use of automated carbon dioxide insufflation devices should also be routine.
- Staff must be trained to recognise complications arising before, during, and after procedures, and all such complications must be properly documented.
- CTC interpretation must be undertaken only by appropriately trained consultant radiologists on the UK General Medical Council's specialist register. They must hold a national board certificate in radiology (FRCR or equivalent). Reporting radiologists must be registered as such with the screening centre's director and the Quality Assurance Reference Centre (QARC).
- All departments offering a CTC service to the NHSBCSP must measure and monitor their activity and achievements in relation to patient safety, outcomes, and experience.
- A team approach is critical to the success of CTC. The skills and competencies of team members should be clearly defined in the screening centre's protocols.

# 1 INTRODUCTION

These guidelines replace *Guidelines for the use of imaging in the NHS Bowel Cancer Screening Programme* (NHSBCSP Publication No 5), which was published in July 2010.

Since these original guidelines were published, the role of CTC (or 'virtual colonoscopy') within the NHSBCSP has continued to develop. It is clear that those requesting, performing, and interpreting CTC must be subject to defined standards of practice, and that quality assurance (QA) programmes covering CTC must be in place, as they are for all other facets of the screening programme.

Therefore, a National Coordinating Group for Quality Assurance of Radiology in the NHSBCSP has been formed. This document has been developed by the Committee (for membership, see the 'Authors' section, page iii) to define standards of practice, and to identify areas in need of regular audit and QA.

The standards outlined in this publication build on those originally defined in the CT Colonography Standards document.<sup>1</sup> For ease of use, standards are provided in coloured boxes in order to distinguish them from explanatory text.

## 2 PATIENT ELIGIBILITY FOR IMAGING

Some NHSBCSP patients who require further investigation are unsuitable candidates for colonoscopy or have had an incomplete colonoscopic examination in the past. These individuals may be offered an alternative examination: whole colon imaging.

In the NHSBCSP, conventional colonoscopy is most commonly contraindicated in:

- Patients with significant cardiovascular or respiratory comorbidity, which might compromise the safety of a colonoscopy examination.
- Individuals who are deemed too frail to undergo standard laxative preparation, but who are able to tolerate CTC using a reduced laxative faecal tagging regimen.
- Individuals with a history of incomplete colonoscopy.

In some cases, there may be additional reasons for preferring whole colon imaging to colonoscopy. The screening consultant/director and lead radiologist (where appropriate) should discuss such patients to establish whether colonoscopy or alternative imaging is most suitable to their case.

In some circumstances, after full discussion with the patient, it may be decided that an individual undergoes no further investigation. Where patients are unlikely to be fit enough for an imaging examination or any subsequent intervention, they should not be automatically referred. Instead they should have their options explained to them (and, if appropriate, to their carer) before a decision is made on whether to continue with the screening procedure.

**2.1** Where alternative imaging is indicated, CTC is the preferred method.

Double-contrast barium enema is reported to have a false negative rate that is fourfold higher than that of CTC, and therefore is not appropriate for screening patients.<sup>2</sup> Where high quality CTC is not available locally, the patient should be referred elsewhere for examination.

**2.2** CTC must always be performed to the standards described in this document, and should take place as close to the patient's home (or other preferred location) as possible.

**2.3** If the examination can be performed to a high standard at the screening centre, but local CTC interpretative experience is lacking, then CTC data should be transferred to a suitably experienced radiologist for double reporting.

### 3 PATIENT INFORMATION AND CONSENT

- 3.1** A national information leaflet is being developed for patient use. In the interim, local leaflets (which must comply with international CTC standards) should be made available.<sup>1</sup>
- 3.2** Where laxatives governed by NPSA guidelines are to be prescribed, patient referral forms must comply with NPSA advice on the suitability of patients for bowel preparation.
- 3.3** A record should be kept, detailing when consent to the procedure (verbal or written) was obtained from the patient. It should include the name and designation of the individual to whom consent was given.
- 3.4** The SSP will initiate the consent process at the initial consultation, although it is expected that the team undertaking the examination will complete the consent procedure. The SSP must discuss with the patient the reasons behind their referral for CTC instead of colonoscopy, and must present the patient with detailed information pertaining to CTC. The process of providing patient information should mirror established pathways for colonoscopy. Patients should be offered an opportunity to ask questions about the planned CTC examination, and its intended benefits and possible risks. They may also be provided with a 'story book' explaining the procedure.
- 3.5** The SSP should be sufficiently informed to resolve routine queries about CTC, and should remain the patient's main point of contact regarding the examination and the screening programme.
- 3.6** Contact details for an experienced CTC team member should be made available, so that patients can resolve additional queries before the day of the examination.

## 4 BOWEL PREPARATION

**4.1** Full laxation (using 'dry' purgatives) without faecal tagging is still commonly used. However, international consensus supports the use of faecal tagging in all patients to increase diagnostic accuracy.<sup>3</sup> Faecal tagging also permits reduced laxative regimens, which may be more appropriate for frail patients. Although faecal tagging may add to the cost and complexity of patient preparation, routine use is recommended. Local protocols should detail methods for the provision of tagging agents to patients.

**4.2** Decisions on bowel preparation should aim to ensure that the dose of laxative is consistent with the vulnerability of the patient and the nature of the target lesion. For example, a reduced laxative dose may suit a frail patient in whom the target lesion is cancer.

**4.3** The possibility of an allergic reaction should be considered when prescribing iodinated oral contrast to outpatients. SSPs must ask the patient about any allergy to iodinated contrast before requesting a CTC, and must inform the CTC team in all cases where a true allergy exists. Local protocols that clearly define the nature of a true allergy (e.g. a documented reaction to iodinated contrast agents) must be in place.

## 5 SCANNER PARAMETERS AND PROTOCOLS

**5.1** Multi-detector CT (MDCT) should be used. Pitch/table feed per rotation should be adjusted to achieve full anatomical coverage within a single breath hold and to minimise movement artefact.

**5.2** The dose should be kept as low as is reasonably practicable (the ALARP principle):

- 120 kVp is generally recommended.
- The current (milliamperes, mA) should be ALARP. The dose should be reduced to the minimum (and tailored to the colon alone) for at least one of the scan acquisitions. Typical current values for a 64-detector row scanner (when intravenous contrast medium is not administered) would be 80 mA for the initial acquisition (frequently, but not necessarily, supine) and 30 mA for the prone scan. However, parameters will vary according to patient body mass index, use of intravenous contrast medium, and CT platform.
- The patient should be imaged in the cranio-caudal direction.

**5.3** Collimation and slice thickness should be  $\leq 3$  mm respectively, with a typical reconstruction interval of 0.5–0.8 ( $\times$  slice width), utilising a softer (e.g. soft tissue) CT reconstruction algorithm.

**5.4** Effective doses should be monitored locally and dose reference levels should be set and recorded.

**5.5** Where it is available, dose modulation should be used. Caution should be exercised with obese patients, however, as dose modulation may inadvertently increase the dose in some cases. CT teams are advised to seek local medical physics advice when devising CTC protocols.

## 6 ON THE SCANNER TABLE

- 6.1** If same-day CTC is to be performed following incomplete colonoscopy, consideration should be given to performing a low-dose CT scan of the abdomen and pelvis to exclude perforation before commencing the procedure (perforation would contraindicate same-day CTC). Such consideration is particularly pertinent if the colonoscopy was difficult or prolonged, or if perforation is suspected.
- 6.2** Dual position scanning is a requirement for CTC. Supine and prone positions should be routine, but in some cases (e.g. individuals with immobility or obesity) lateral decubitus scans should be considered as an alternative.
- 6.3** The SSP should check whether a patient's history includes colonic surgery. If it does, details should be recorded and made known to radiology staff.
- 6.4** Thin rectal catheters should be used, with or without the small inflated balloons that are designed to help reduce anal incontinence of gas.
- Staff performing rectal catheterisation and colonic insufflation should have appropriate levels of anatomical knowledge and technical competence and must be alert to the risks associated with these procedures.
  - Disposable catheters and tubing to insufflation apparatus should be used once only and then discarded.
- 6.5** Hyoscine butyl bromide improves colonic distension during CTC and should be administered unless contraindicated. Glucagon is not recommended as an alternative. Patients should be advised to seek medical attention if they develop painful blurred vision (which may be due to acute glaucoma) following injection.
- 6.6** Colonic distension should be undertaken with carbon dioxide, using an automated insufflator.
- 6.7** An exploratory scout scan should be performed before the full scan acquisition, or sooner if insufflation proves difficult.
- 6.8** All CT images should be reviewed before the end of the examination to determine whether additional scans are needed, for example if distension is suboptimal. This initial review must be undertaken by an experienced practitioner, often a radiographer with appropriate training.

## 7 USE OF INTRAVENOUS CONTRAST MEDIUM

- 7.1** Intravenous contrast medium should not be routinely administered to NHSBCSP patients undergoing CTC unless there is a specific indication for a more detailed review of extracolonic organs.
- 7.2** Reports should state explicitly that no contrast medium has been administered and should note that the ability to exclude potentially significant extracolonic pathology is thereby diminished.

## 8 ADDITIONAL 'ONE STOP' TESTS AFTER CTC

**8.1** Intravenous, contrast-enhanced staging CT should be performed in the majority of cases where evidence of colonic or extracolonic cancer is detected during an examination.

- Staff taking this decision must have the relevant knowledge, skills, and experience to avoid unnecessary additional tests.
- If a cancer is identified on the initial acquisition, whether supine or prone, intravenous contrast medium should be administered for the second acquisition in the opposite patient position. A CT chest scan should be included.
- Consideration must be given to patient renal function prior to the administration of intravenous contrast medium, in accordance with existing local protocols.

**8.2** Same-day endoscopy for cancer may be desirable for some patients, but may be contraindicated, impractical, inappropriate, or inconvenient for others. Where same-day endoscopy is not performed, robust mechanisms should be in place to ensure that the CTC result is made available to local screening practitioners. The result could be shared in the context of a multidisciplinary team (MDT) meeting or via an alternative robust and auditable means of communication.

**8.3** Same-day CTC for incomplete colonoscopy is usually desirable, unless it is inappropriate for the patient or the bowel is inadequately prepared (the latter can be ascertained by endoscopy). Consideration should be given to the oral administration of a small volume of iodinated faecal tagging agent before same-day CTC, to improve colonic visualisation in cases where the endoscopic preparation leaves a significant volume of residual fluid.

## 9 PATIENT EXPERIENCE AND SAFETY

- 9.1** All members of the CTC team must be trained to recognise complications arising before, during, and after procedures.
- 9.2** The CTC team must follow clearly documented and recognised protocols for managing complications such as:
- Cardiovascular symptoms (including angina, hypotension, and bradycardia). These may accompany vasovagal attacks and can result from the use of hyoscine butylbromide.
  - Anaphylaxis.
  - Contrast extravasation or haematoma at the cannula site if intravenous contrast medium has been given.
  - Severe abdominal pain.
  - Colonic perforation.
- 9.3** Resources, including resuscitation and monitoring equipment and appropriately qualified and trained medical and nursing staff, must be available to manage immediate complications.
- 9.4** There must be a local protocol in place for managing diabetic patients (including those taking metformin hydrochloride) if intravenous contrast medium is to be administered.
- 9.5** Radiographers who administer intravenous contrast medium or hyoscine butylbromide must do so in accordance with a locally written Patient Group Directive.
- 9.6** Patients should remain in the CTC department for at least 15 minutes after injection with intravenous contrast medium, and for at least 30 minutes if they are at increased risk of anaphylaxis. If a cannula has been inserted and an adverse event is anticipated, the cannula should remain in place until the patient is ready to leave the department.
- 9.7** Colonic perforation is a recognised complication of CTC and occurs in 1 in 3000 examinations.<sup>4</sup> A radiologist or appropriately trained radiographer should review the two-dimensional scan images to check for perforation before the patient leaves the scanning suite. If a perforation is detected, the reviewer should contact the appropriate surgical team to request a timely clinical assessment. While most perforations caused by CTC are asymptomatic, further management should be at the discretion of the local surgical team.

- 9.8** Patients should have easy access to lavatory and changing facilities
- 9.9** . A comfortable, quiet area should be available for patients to relax and recuperate after a procedure.
- 9.10** Consideration should be given to offering patients light refreshments (such as tea and biscuits) once the initial observation period of 15 minutes following administration of intravenous contrast medium has elapsed. It may be appropriate to restrict refreshments to water, however, until a decision is taken on whether to proceed to same-day endoscopy.
- 9.11** After examination, patients should be provided with information explaining the minor symptoms that commonly follow the procedure and giving advice on what to do in the event of more severe or persistent symptoms (i.e. those lasting more than a few hours).
- 9.12** Following CTC, some patients may need further imaging for the purpose of staging, onward referral, or same-day endoscopy. Staff undertaking this imaging or organising referral (including SSPs) will need additional skills and competencies (including interpretation and communication skills, such as training in breaking bad news). Local policies for handling such patients must be in place and must be followed.
- 9.13** A suitable private area should be available for communicating scan results to patients.

All patients in the NHSBCSP are sent a 30-day questionnaire, in part to assess patient satisfaction. Pathways should be put in place to ensure that relevant patient satisfaction information can be fed back to those providing the CTC service.

## 10 INTERPRETATION METHODS

- 10.1** CTC interpretation requires access to software with 2D displays, multiplanar reformats, and a 3D endoluminal reconstruction. Primary 2D or primary 3D reading methods are both acceptable, provided that access to both 2D and 3D displays is available. Computer-aided detection software is incorporated into several reading platforms and may increase the accuracy of the interpretation.
- 10.2** Readers should be competent in both 2D and 3D reading techniques. The choice of reading method may vary within and between CTC datasets, depending on technical quality and the nature of the target lesion.
- 10.3** CTC interpretation should be undertaken only by consultant radiologists who have been designated to report CTC by the lead radiologist for the screening centre. They must be registered as such with the screening centre's director and the QARC.
- 10.4** Within the NHSBCSP, where there is a particularly high prevalence of early neoplasia, radiologists interpreting CTC should be able to produce audit data of their performance over at least 100 NHS CTC examinations each year. Examinations conducted on symptomatic patients within the NHS, as well as all of those conducted on NHSBCSP-referred individuals, can be counted towards this total for audit purposes. However, all NHSBCSP examinations must be included.

## 11 PATIENT MANAGEMENT AND INTERVAL SURVEILLANCE

- 11.1** Reporting radiologists must have a good knowledge of the NHSBCSP's pathways and its strategies for managing polyps and masses of different sizes and morphologies.
- 11.2** Radiologists should report the probable biological significance of colonic findings, based on their size and morphology.
- 11.3** Radiologists should indicate their degree of confidence (e.g. as a percentage) that a reported abnormality is a true-positive finding. This will help to ensure that the patient is managed appropriately and will quantify the likelihood of a positive finding at endoscopic review.

Surgery without endoscopy/histopathological confirmation is an option if the patient is deemed unfit for endoscopy (because, for example, he or she cannot undergo full laxation) or if colonoscopy has failed but multiple and/or large polyps or masses are seen on the CTC examination. However, the risk–benefit ratio of surgery must be considered carefully in all such cases: surgical intervention should be considered only if a suitably experienced and qualified radiologist (for definitions, see Chapter 14) is confident about his or her findings, if the patient is fit enough for surgery, and if the patient is thought to be at high risk of colorectal cancer. False-positive diagnosis of seemingly significant colonic neoplasia is well described with CTC, and any patient who is a candidate for surgery without endoscopic/histopathological confirmation must be discussed at the MDT meeting before any surgical intervention is commenced.

Patients who are unfit for intervention but whose condition might improve should have their cases reviewed by the SSP and colonoscopist after six months, when further decisions about their management can be taken. Where large polyps ( $\geq 1$  cm) or multiple small polyps (maximum diameter 6–9 mm) are found in such patients, these may be subject to surveillance in accordance with existing NHSBCSP policy.

Where the patient is unfit for surgical intervention and is unlikely to improve over time, the management of a suspected cancer or advanced adenoma should be discussed at the screening MDT meeting.

## 12 PLANNING CTC TEAMS AND LISTS

- 12.1** A radiologist with the necessary CTC expertise should provide leadership and take primary responsibility for the CTC service. This may be the lead radiologist for the NHSBCSP or an appointed deputy.
- 12.2** A team approach is critical to the success of CTC. The local organisation of a team will depend on the skills and competencies of its members. The skills and competencies needed should be clearly defined in the screening centre's protocols.
- 12.3** Governance and risk management strategies should be robust, fully documented, and well understood by all team members. This will help to ensure that responsibilities can be delegated with confidence where necessary.

## 13 MEASURING AND MONITORING CTC ACTIVITY AND OUTCOMES

**13.1** All departments offering a CTC service to the NHSBCSP must measure and monitor their NHSBCSP activity and their achievements in relation to patient safety, patient outcomes, and patient experience.

**13.2** All radiologists must collect their individual audit data for at least 100 examinations each year. All NHSBCSP activity must be included in this dataset. Data from NHS examinations can be used to make up any shortfall where NHSBCSP activity comprises fewer than 100 cases.

**13.3** Patient safety audits should include:

- Clearly displayed protocols for managing complications and adverse reactions.
- Documented monitoring of complications and adverse reactions (e.g. perforation, myocardial infarction, or hospitalisation).
- Demonstrable compliance with the standard acquisition and radiation protection protocols.
- Quality control of CTC equipment, including the workstation and insufflators.

**13.4** Patient outcome measures should include:

- Percentage of the NHSBCSP colonoscopy workload undergoing CTC.
- Description of the reporting methods used for examinations, indicating whether examinations are double reported and, if so, by whom.
- Time interval between CTC examination and receipt of the report by the referrer.
- Assessment of examination quality, including the proportion of inadequate examinations.
- Positive predictive value (PPV) of CTC compared with endoscopy and/or pathology.
- Negative predictive value of CTC (with reference to regional and MDT cancer registries on an annual basis).
- Polyp and cancer detection rate.
- Percentage of examinations with extracolonic finding(s) requiring additional investigation work-up (including the number of examinations and method(s) used, e.g. the imaging modality and PPV for individuals undergoing additional investigation).

**13.5** Patient experience measures should include

- Waiting times.
- In-room examination time.
- Results from the annual Patient Satisfaction Survey.
- Monitoring of complaints.

The Bowel Cancer Screening IT system will be modified to allow these audits.

## 14 TRAINING AND ASSESSMENT

- 14.1** All radiologists interpreting CTC examinations for the NHSBCSP should be consultants on the UK General Medical Council's specialist register. Only practitioners with a national board certificate in radiology (FRCR or equivalent) should report CTC. This applies to both colonic and extracolonic findings.
- 14.2** All interpreting radiologists must have undergone:
- Individual practical training involving at least 50 endoscopically validated CTC cases.
  - Training via lectures or presentations on colonic anatomy, the pitfalls of CTC and its interpretation (including how to accurately estimate polyp diameter), the management of complications, and the pathogenesis/epidemiology of colorectal cancer.
  - Bespoke NHSBCSP workshops to meet these needs are under development. In the interim, relevant training is available in the form of two-day practical CTC workshops, which are currently being offered in several countries. However, training alone cannot guarantee competence.
- 14.3** All radiologists and radiographers who conduct examinations require specific training on examination technique. This must cover options for bowel preparation, how to provide patient information, gaining patient consent, colonic insufflation, CT scan parameters, and radiation safety.
- 14.4** Radiologists who are responsible for interpretation must take part in national NHSBCSP audits when required to do so, and must also participate in colorectal MDT activities in their hospital.
- 14.5** A list of competencies must be drawn up for all CTC team members, consistent with national recommendations. This should be locally agreed, clearly displayed, and regularly reviewed by team members.
- 14.6** Every member of the CTC team, including SSPs and radiology assistants, must undergo training appropriate to their role and responsibilities. Opportunities for role extension should be supported where appropriate.

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