Guidelines for Use of CT Colonography (CTC) as part of the National Colorectal Screening Programme in Ireland

Dr. Martina Morrin and Professor Helen Fenlon Faculty of Radiologists, Royal College of Surgeons In Ireland

Preface

These guidelines are designed to assist radiologists and radiology departments in providing best practice radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the Faculty of Radiologists in Ireland cautions against the use of these guidelines in litigation in which the clinical decisions of a radiologist are called into question. Therefore, it should be recognized that adherence to these guidelines alone will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the radiologist and radiology departments follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care.

A practitioner or department who employs an approach substantially different from these guidelines is advised to document information sufficient to explain the approach taken.

The authors are members of the Endoscopy & Radiology QA Subgroup of the National Colorectal Cancer Screening Programme for the National Cancer Screening Service (NCSS). They were nominated to this subgroup by the Faculty of Radiologists of the Royal College of Surgeons In Ireland. This document has been based on the ACR Practice Guidelines for Performance of CT Colonography in Adults¹ and Guidelines for the Use of Imaging in the NHS Bowel Cancer Screening Programme ² and has been reviewed and approved by the Board of the Faculty of Radiologists of the Royal College of Surgeons In Ireland.

The guidelines set out below relate specifically to screening CT colonography in the context of the National Colorectal Cancer Screening Programme and may not be relevant or applicable to diagnostic services outside of that programme.

I. BACKGROUND

Computed tomography colonography (CT colonography) is a minimally invasive structural examination of the colon and rectum designed to evaluate the colon for colorectal polyps and neoplasms ³⁻¹⁴. The goal of this examination is to establish the presence or absence of colorectal neoplasia by producing a diagnostic quality study at the lowest feasible radiation dose.

In the context of the NCSS colorectal screening programme, CT colonography will be available as the completion test following an incomplete or unsuccessful colonoscopy in patients who have had a positive Faecal Immunochemical Test and in whom a repeat colonoscopy is unlikely to be successful and also in patients who are medically unfit for colonoscopy.

CT colonography is a relatively new technique currently not embedded as routine in the majority of Irish hospitals. Local practice varies considerably from centre to centre with regard to study technique and interpretation. It is widely accepted that the accuracy of CT colonography is heavily dependent on good technique and reader training and expertise. Accepting these factors, clear

guidelines as to how the test should be performed and how studies should be read are an absolute requirement for a quality programme.

The model chosen for provision of a national CT colonography service as part of the NCSS colorectal cancer screening programme should be constructed to maximise patient safety, minimise patient inconvenience and ensure accurate and timely interpretation of studies. The screening model recommended by the Expert Advisory Group involved establishing dedicated, resourced screening centres with onsite access to CT colonography. It is our understanding that this model is no longer considered affordable and a process of procuring CT colonography studies from existing radiology departments, possibly at locations other than the currently selected screening endoscopy centres, is now envisaged by the NCSS. Given the challenges of such a model without a well established symptomatic CT colonography service throughout the country, a phased-in approach should be adopted with a systematic rollout of the CT colonography programme to insure that patients have easy access to a high quality CT colonography service within their region. The exact number of centres required will depend on patient volumes but the emphasis should be on locoregional access to a high quality service for all patients. A single centre model should be avoided as this centre would quickly become overwhelmed by potentially large numbers of studies (number could exceed 1000 CT colonography examinations per year in the initial phases) and such a model would result in significant inconvenience for patients. The initial phase should be initiated at CT colonography units where there is already established expertise in CT colonography, each of which in turn could support other centres. All CT colonography units should work closely together to optimise scanning protocols, procedures and quality control.

To allow a seamless, controlled mechanism for referral and follow-up of patients for CT colonography in a timely fashion, a centralised booking and patient follow-up system is essential. In addition, results of all CT colonography cases performed as part of this programme should be entered into a suitable, well maintained and monitored centralised database.

II. INDICATIONS AND CONTRAINDICATIONS

A. Indications (See QA document)

The indications for a CT colonography examination in the context of NCSS colorectal screening programme include:

In the context of the NCSS colorectal screening programme, CT colonography should be available to patients with a positive FIT under the following circumstances

- 1. as the completion test following an incomplete or unsuccessful colonoscopy
- 2. in patients for whom a repeat colonoscopy is unlikely to be successful
- 3. for patients who are medically unfit for colonoscopy

B. Contraindications

The relative contraindications or conditions that require caution in performing a CT colonography examination include, but are not limited to:

- a. Acute abdominal symptoms
- b. Acute diarrhea or symptoms of acute colitis
- c. Recent acute diverticulitis
- d. Recent colorectal surgery

- e. Symptomatic colon-containing abdominal wall hernia
- f. Recent submucosal endoscopic biopsy or complicated polypectomy/mucosectomy.
- g. Known or suspected colonic perforation.
- h. Symptomatic or high-grade small bowel obstruction.

III. PERSONNEL – Responsibilities, Training and Workload

Radiologist

The radiologist responsibilities include reviewing indications for the examination; specifying the appropriate imaging protocol, the methods of image reconstruction, and the use and dosage of contrast and pharmacologic agents; interpreting all resulting images and generating an official report; and assuring the quality of the images and the interpretation.

Radiologists' Training and CME Requirements

Each radiologist involved in reading CT colonography studies for the programme should have substantial knowledge of radiation biology, the physics of CT scanning, the principles of CT image acquisition and postprocessing, including the use of diagnostic workstations, and the design of CT protocols, including rate and timing of contrast administration. The radiologist must also have substantial experience in CT interpretation, including CT of extracolonic structures that will be included on the CT colonography examination.

Each Consultant Radiologist is required:

- to be on the Irish Register of Medical Specialists
- to have FFR(RCSI) or equivalent, have cross-sectional fellowship training or equivalent

• to have completed at least one accredited CTC training course including evaluation of 50 CT colonography cases with full colonoscopic correlation or mentored-double reading (with an established expert) of 100 cases, with formal tuition and instruction using primary 2D and/or primary 3D search employing commonly used problem-solving techniques. Ideally this collection of training cases will be chosen to demonstrate the gamut of appearances of colonic polyps and CT colonography interpretation pitfalls. The cases should include examinations performed for a variety of indications and acquisition techniques (e.g., with and without fluid tagging and/ or intravenous contrast). Radiologists should also be trained in techniques of patient preparation, bowel insufflation, and CT colonography image acquisition.

• following appropriate formal CT colonography training, the radiologist should undergo a further period of mentored supervision and double-reading by an experienced CT colonography trained physician of no less than 50 additional cases.

• to maintain annual CME credits as per Faculty of Radiologists guidelines

• to read a minimum of 100 CT colonography cases per year once actively involved in reading screening CT Colonography studies for the NCSS

• to take part in regular national audit to include confidential annual peer review of ten randomly selected cases with feedback regarding the quality of the examinations and accuracy of the original

interpretation; annual review of ten cases selected from the national CT colonography database; review of interval cancers after an appropriate screening interval has elapsed

• to participate in local colorectal MDT activities in their hospital

A variety of other techniques may also be helpful for improving interpretive skills at CT colonography, including:

- o Self-directed individual study of formal texts, atlases, review articles, and teaching files
- Testing with feedback
- Computer-aided detection algorithms, which can be used as a second-reader
- CME sponsored reviews on line, DVDs, or at review courses where case interpretation precedes disclosure of the correct answers
- In the event that a diploma in CT colonography interpretation is developed by ESGAR (European Society of Gastrointestinal and Abdominal Radiology) or the ESR (European Society of Radiology) then reporting radiologists should comply with its requirements

Single-radiologist practices are to be avoided. At least two Consultant Radiologists who are adequately trained in CT colonography will be required per reading centre with a portion of their sessions ring-fenced per week for CT colonography reading as part of the colorectal cancer screening programme. This is essential to allow for adequate access to second opinion, to facilitate internal audit, review of interval cancers etc. The total number of sessions required per centre will depend on the total numbers of centres, volumes per centre etc.

Specific and protected consultant radiology sessions should be assigned to the provision of this service. It is recommended that CT colonography examinations should be batch read during sessions allocated for this activity.

Radiology Workload

The following is proposed as a benchmark for time requirements for Consultant Radiologists engaging in CT colonography performed as part of the screening programme:

The Faculty estimates that typical radiologist staffing requirements are as follows -

For each volume of 200 cases the hospital will require:

a. Consultant Radiologist Staffing

Adequate protected Consultant Radiologists sessions will be required, the number of which will depend on the volume of referrals. This is to cover -

- a. Reading, interpretation and supervision where required
- b. Weekly MDT attendance and / or preparation and attendance
- c. Related activities: providing second opinion, reviewing protocols; training ancillary staff; informal liaison with gastroenterologists; radiation protection, local QA, liaison with data manager and interaction with other / outside centres

As a guideline - In a typical session designated for CT colonography, it is estimated that a consultant radiologist could:

• Supervise, interpret and report approximately five CT colonography examinations, provide second opinion for complex cases and liaise with gastroenterologists in relation to abnormalities detected

or

• Prepare / attend colorectal multidisciplinary team meetings

or

• Prepare / attend audit meetings

or

• Attend to issues related to quality assurance, radiation protection, protocol review and ancillary staff training

Each CT colonography centre should perform at least 100 screening CT colonography studies per year

At least 2 radiologists required per centre (see above). Single person practices to be avoided.

b. Radiography Staffing

There should be a pool of at least three radiographers experienced in CT colonography on site, so that there is always a trained radiographer to perform the CT colonography.

Each radiographer should be familiar with the technical requirements of performing CT colonography, including rectal tube insertion, proper client positioning, colonic insufflation of room air and CO2 with manual and automated techniques, and tube removal.

Radiographers should be able to identify if the study is adequate and if additional scans in other positions or buscopan are required and should be able to evaluate the CT colonography images for free air/gas.

Estimated Radiography Time requirements

 \circ Scanning clients (4-6 clients = 3 hours) 1 session per week

c. Nursing Staffing

- o should be available to assist with administration of tagging agent prior to the procedure
- should assist with clients who have queries and those who experience difficulties or discomfort prior to, during or post-procedure

Time requirements

• Attending clients (4-6 clients = 3 hours) 1 session per week

d. Adminstrative Staff

Local Co-ordinator

Each centre will require a co-ordinator with time ring-fenced for the NCSS colorectal cancer screening programme activities. Based on 200 referrals per year, this person will be responsible for

- receiving and logging requests from the various referral centres (2 hours per week)
- booking cases (1 hours per week)
- dispatching bowel preparation and an information pack to each client (including brochure with details of the procedure, questionnaire to identify any contraindications to the procedure or preparation)
- dealing with client queries and triaging questions to relevant professionals (2 hours per week)
- insuring, in conjunction with data manager, that relevant information is entered into a standardized database (preferably web-based to facilitate inter-communication between all centres (including endoscopy and CTC centres) (1 hour per week)
- o follow up to ensure all cases are reported (30 minutes per week)
- facilitating direct reporting of significant findings to referral endoscopy centre and insuring that any follow-up imaging and/or procedures are organised
- o interfacing with centralized administrative staff at the NCSS (30 minutes per week)
- preparing for ongoing quality assurance (2 hours per week)
- o minimum of 11 hours per week

e. Secretarial Staffing

Each centre will require appropriate radiology secretarial staff support with time allocated to the work of the NCSS colorectal cancer screening programme who will be responsible for

- typing up and sending out reports to endoscopy source units and GPs (4 hours per week)
- assisting the local coordinator

f. Data Manager

Each centre will require a data manager with time ring-fenced for the NCSS colorectal cancer

- to liaise with local coordinator and central NCSS staff regarding data management
- o to maintain database
- o to coordinate audit and QA programme
- o to document follow-up
- 1-2 hours / week for 200 referrals per year

IV. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for CT colonography should provide sufficient information as to the cause of unsuccessful colonoscopy, the region of failure and the quality of bowel preparation to allow for proper performance and interpretation of CT colonography. This is particularly important in the case of same day completion CT colonography. Specific details of why colonoscopy was deemed inappropriate or ill-advised in the case of the medically unfit or frail, elderly patients should be made clear on the request form.

All relevant accompanying clinical information should be provided by a physician or ANP familiar with the patient's medical conditions.

A. COLON PREPARATION

Preparation of the colon for CT colonography should consist of a combination of dietary restriction, hydration, osmotic laxatives such as saline cathartics, and contact laxatives. The intent is to achieve a colon that is free of faecal material and excess fluid or as close to this ideal as possible¹⁵⁻¹⁷

Routine use of oral contrast for labeling colonic stool and fluid ("tagging") to be advocated in conjunction with the above. The goal of tagging is to passively incorporate contrast into any residual fluid and stool in order to raise their inherent CT densities, which helps to discriminate these residua from the soft tissue density of polyps or advanced cancers. Non-cathartic or reduced-cathartic approaches to CT colonography bowel preparation (also known as "prepless" or "minimal prep" CT colonography) aim to reduce patient discomfort associated with pre-examination bowel purgation. While pilot data for these approaches are encouraging, they remain under investigation and have not yet been validated in large clinical trials ¹⁸⁻²¹.

B. EXAMINATION TECHNIQUE

1. The medical history should be reviewed.

2. The patient should evacuate their rectum prior to insertion of the rectal tube.

3. The rectal tube tip should be inserted by a physician or a trained assistant (radiographer, nurse, or physician assistant). If a rectal retention balloon is used, inflation should be discontinued if the patient complains of pain. Pain in this situation may indicate an increased risk of perforation.

4. While the literature suggests that use of buscopan, glucagon or other spasmolytics may decrease insufflation-related discomfort and improve distension, evidence for this remains relatively weak. The use of antispasmotics is not considered mandatory for every examination but is desirable in certain cases.^{22,23.}

5. A sufficient volume of carbon dioxide or room air should be administered, either manually or with an automatic insufflator to provide full colon distention [30]. Use of CO_2 is regarded by many as preferable to room air.

6. The adequacy of colon distention should be checked with a scout image to ensure a complete and full column of gas throughout the colon before each CT acquisition.

7. Complete anatomic imaging of the colon and rectum should be obtained in at least 2 patient positions (usually supine and prone)^{24, 25.} Additional insufflation will usually be necessary before additional acquisitions. Most users advocate continuous insufflation with CO_2 when utilizing the automatic insufflator (i.e. the gas flow should not be discontinued when moving the patient from the supine to the prone position or vice versa).

8. CT colonography studies should be performed using a low-dose, nonenhanced CT technique on a multidetector CT scanner ^{5, 26-28}. CT Colonography studies should be performed such that there is appropriate adaptation of CTDIvol to patient size, using either technique charts or automatic

exposure control. The recommended radiation output for routine screening CT colonography, quantified using CTDIvol, should be less than or equal to one-half the diagnostic reference level for routine abdominal pelvic CT (2008 ACR CT Accreditation Program or equivalent) or onequarter of this value per position (i.e., CTDI vol of 6.25 mGy per position or a total of 12.5 mGy for dual position CTC). Much lower doses for CT colonography examinations can be achieved similar to ranges of the annual background radiation. Generally, for scans performed at a tube potential of 120 kVp, this requires an effective mAs value between 50 and 80 (where effective mAs is equal to the tube current-time product (mAs) divided by the spiral pitch value). Because these factors may not be appropriate for every CT scanner model, the scan protocol parameters should be adjusted as necessary to obtain the required image quality at or below the suggested CTDIvol values (6.25 mGy per scan position or 12.5 mGy total for the supine and prone position scans).

9. Additional imaging after repositioning and reinsufflation may be needed to adequately distend a colonic segment. Additional imaging (e.g., in left or right decubitus position) is appropriate when imaging in 2 positions fails to adequately display the colonic lumen and acquisition of additional data is likely to result in a diagnostic study.

10. For morbidly obese patients, radiation dose should be appropriately increased to maintain diagnostic image quality²⁹. Phantom dose estimates are less accurate in estimating internal organ radiation dose in very obese patients. It should be realized that in these patients, phantom dose estimates do not reflect exposure to the internal organs³⁰.

11. Although not routinely used, intravenous contrast may occasionally be required for CT colonography. When intravenous contrast is injected, CT acquisition parameters should be adjusted to match routine imaging techniques for standard non-colonography CT contrast-enhanced imaging of the abdomen and pelvis.

12. The quality controls specific to the technique of the CTC study are:

a. Complete anatomic coverage of the colon and rectum.

b. Adequate colon distention and adequate overall image quality. The entire luminal surface of each segment of the colon should be visualized in at least one position. Suboptimally visualized colonic segments should be reimaged. The use of decubitus views or reinsufflation may be helpful in cases of suboptimal distention or excessive fluid.

C. QUALITY CONTROL

The following quality controls should be applied to all CT colonography examinations:

1. Colon cleansing and distention should be adequate for detecting polyps 1 cm or larger.

2. Efforts should be made to ensure a diagnostic quality examination before the patient leaves the facility. Focused additional imaging of the patient should be performed as necessary.

3. The following is suggested for a quality control program:

a. Radiologic, endoscopic, and pathologic findings should be correlated whenever available.b. Detection rates for colorectal cancer and polyps of 1 cm or greater should be determined and

periodically monitored. There should be an assessment of false positive rates for all reported polyps.

c. Each centre should engage in comparisons of facility data to national data to determine how local detection and complication rates compare with national rates, and whether performance is adequate or requires further review. The central and local co-ordinators should liaise in this regard.

D. DATA INTERPRETATION

The purpose of CT colonography is to accurately evaluate the colon for the presence or absence of clinically significant neoplastic lesions. Abnormalities may range from discrete mucosal elevations (which may be malignant or at risk to become malignant) to infiltrating tumours. Lesion morphology (sessile, pedunculated, flat) and segmental location should be reported. There are different definitions of what constitutes "flat" and the use of the term should make specific reference to the definition being used. Prior to commencing, the Programme should reach consensus regarding the size threshold for reporting of polyps as well as appropriate interval for surveillance of patients who have as positive finding. In addition, a clear consensus is essential regarding interval that should elapse before another screening colon study.

1. Detection and characterization of colorectal findings

CT data should be interpreted on a computer workstation that allows an integrated approach of 2D and 3D image display techniques (axial imaging, multiplanar reformatted imaging, and 3D endoluminal viewing). Workstations should be able to display both axial supine and prone data together, and should allow the interpreting physician to change the window width and level settings interactively and in real time. The primary search for colorectal polyps and cancers can be performed using either a primary 2D or a primary 3D endoluminal search technique. Whether 2D or 3D is used to primarily detect a lesion, the corresponding views are important for further characterization.

2. Measurement of colorectal findings

Polyps should be measured using either optimized multiplanar reconstruction (i.e., axial, sagittal or coronal view which best elongates lesion) and/or 3D images. Measurement of the size of the lesion should be based on the largest diameter of the polyp head (excluding stalk if present) or at the base of a sessile lesion 31,32 .

3. Extracolonic findings

Extracolonic structures should be evaluated at the time of reading the CT colonography examination. Significant abnormalities should be included in the report. Detecting extracolonic abnormalities may be difficult on CT colonography, particularly with aggressive dose reduction. This should be indicated in the patient information leaflet. On the other hand, attempts should be made not to over investigate insignificant, likely benign findings.

The incidence and nature of reported significant extracolonic findings that require additional tests should be recorded. A policy for where follow-up of extracolonic findings should take place will need to be agreed.

V. DOCUMENTATION AND COMMUNICATION OF RESULTS

Current international recommendations vary from centre to centre but, conservatively, all polyps ≥ 6 mm should be identified and reported.

In patients with only diminutive polyps (\leq 5 mm), the risk of high grade dysplasia or cancer is extremely low ^{8,12,33.} The potential limited benefit of polypectomy in these patients needs to be balanced with the broader risks, including the costs and complications of polypectomy. Given the low risk of advanced neoplasia and the low specificity of CT colonography for such small polyps, a large number of patients could be referred to endoscopy inappropriately ^{34,35,36}. The ACR currently does not believe that reporting of these diminutive lesions is necessary³⁷. The Programme will require multidisciplinary consensus in this regard.

Patients with significant colonic findings should be offered follow-up endoscopy within that centre.

Extracolonic abnormalities of potential medical significance should also be reported. Good patient care mandates that CT colonography interpretation include full evaluation of the numerous extracolonic structures and that findings of potential clinical significance be reported and communicated in a clear and timely fashion. However, most extracolonic findings are not clinically significant in screening/asymptomatic cohorts. In screening cohorts, the prevalence of clinically significant extracolonic findings is low ³⁸⁻⁴³. Caution should be used in the interpretation and reporting of findings likely to be of low clinical significance in order to avoid unnecessary subsequent/serial diagnostic examinations and associated patient anxiety ³⁷.

Clarity and consistency of reporting the colonic and extracolonic findings are critical for effective implementation of CT colonography. One option is the use of CT colonography Reporting and Data System (C-RADS) which is a consensus statement of a standardized reporting structure for CT colonography findings published in 2005, modeled after the Breast Imaging Reporting and Data System (BI-RADS®) reporting of mammography³⁷. This reporting structure describes how to report lesion size, morphology, and location with a summary category score per patient. Polyp size measurement, another important factor for patient care management, is also defined. Patient management criteria based on such a system should be agreed and standardized across all centres.

VI. EQUIPMENT SPECIFICATIONS

Examinations should be performed with MDCT equipment. Equipment should provide diagnostic image quality and networking capability. Equipment should be capable of producing kilovoltage of 120 kVp or greater and \leq 100 mAs.

VII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, radiographers, and all supervising physicians have a responsibility to minimize radiation dose to individual patients, to staff, and to society as a whole, while maintaining the necessary diagnostic image quality. This concept is known as "as low as reasonably achievable (ALARA)."

Facilities, in consultation with the medical physicist, should have in place and should adhere to policies and procedures, in accordance with ALARA, to vary examination protocols to take into account patient body habitus, such as height and/or weight, body mass index or lateral width. The

dose reduction devices that are available on imaging equipment should be active; if not, manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Periodically, radiation exposures should be measured and patient radiation doses estimated by a medical physicist in accordance with the appropriate ACR Technical Standard or equivalent.

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