

CT Colonography Standards

Standards for Gastroenterologists for Performing and Interpreting Diagnostic Computed Tomographic Colonography

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Executive Summary

Prominent among a number of new techniques with which to image the colon, computed tomographic (CT) colonography is extremely attractive because it is noninvasive and also relatively simple for patients to undergo. As the technology evolves, it is important that gastroenterologists not only understand the multiple issues surrounding CT colonography but also that they be able to interpret this examination.¹ The American Gastroenterological Association (AGA) Institute's Governing Board convened the CT Colonography Task Force to develop training standards for gastroenterologists for CT colonography. These standards are intended to outline the basic requirements that board-certified gastroenterologists should meet to be involved in and/or perform CT colonography. All recommendations are based on the literature available at the time this manuscript was developed.

A wide range of sensitivities have been reported for CT colonography; therefore, the current use of CT colonography in clinical practice is controversial. Several studies have evaluated the use of CT colonography after failed colonoscopy; its sensitivity for detecting important lesions is comparable with or better than results with air contrast barium enema (ACBE). CT colonography appears to also be useful for evaluation of the colon proximal to an obstructing lesion. Minimal data are available regarding the use of CT colonography as a screening test in patients with contraindications to colonoscopy or who refuse other screening options. The results of studies using CT colonography as a colorectal cancer (CRC) screening test suggest that this is an area requiring further study. The use of CT colonography for CRC screening is currently controversial and this test has not yet been endorsed as a primary CRC screening tool in asymptomatic, normal-risk adults by any multidisciplinary group involved in CRC screening guideline development.

CT colonography has few contraindications; however, it should not be performed in patients in whom perforation is

a risk and should probably not be performed immediately after failed colonoscopy in patients who had polyps removed or large biopsy specimens taken during colonoscopy because of the risk of perforation from colonic insufflation. Specific clinical circumstances may also exist in which endoscopic examination is preferred to CT colonography (such as patients with known inflammatory bowel disease, high-risk symptoms, and others). Overall, the Task Force finds that CT colonography is appropriate in certain circumstances and has developed the following recommendations to guide gastroenterologists who are interested in performing CT colonography.

CT scanning should be performed by American Registry of Radiologic Technologists-certified radiologic technologists. The extent of training for gastroenterologists to read accurately CT colonography has not been fully defined. However, research shows that response to training is unpredictable, and the "learning curve" for CT colonography interpretation will vary widely among observers. Available literature suggests that review of at least 75 endoscopically confirmed cases is appropriate as a requirement for minimal competence in detecting and characterizing colorectal neoplasia detected by CT colonography. Subsequently, interpretation under the supervised guidance of a qualified physician mentor is required. To maintain clinical expertise in CT colonography after formalized training, physicians should supervise and interpret a minimum number of cases per year, in addition to participating in continuing medical education activities, and update them relating to advances in the field.

Most bowel preparative regimens employ a cathartic agent, the selection of which will depend on patient

Abbreviations used in this paper: ACBE, air contrast barium enema; CRC, colorectal cancer; CT, computed tomography.

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factors as well as physician preferences. Fecal and fluid tagging may permit identification of submerged polyps and reduce false-positive examinations. CT colonography performed without a bowel purge is an area of great promise but cannot currently be recommended because no large clinical studies have verified its performance in a large cohort. Colonic insufflation with automated insufflators results in improved colonic distention compared with manual insufflation.

High-resolution CT is performed in the supine and prone positions following review of an initial CT scout. CT colonography evaluation involves the following 2 steps: first, a primary search for suspicious colonic lesions and, second, lesion characterization. The primary search can be achieved using either a primary 2-dimensional (2D) search or a primary 3-dimensional (3D) search; optimal performance likely involves both search methods. Lesion characterization includes determination of lesion density and lesion mobility.

Reading

All intracolonic findings should be examined, and any segment not adequately evaluated should be documented. All large masses and lesions that compromise luminal caliber should be communicated. The size and location of colorectal lesions should be reported. Extracolonic findings are common, but the majority of these lesions are not clinically significant and do not require follow-up. Characterizing these extracolonic lesions requires expertise in recognizing abnormalities of the lungs, the solid organs, the retroperitoneum, and the extracolonic gastrointestinal tract. A radiologist should review the extracolonic portion of the study.

Reporting

A standardized CT colonography report should encompass elements of preprocedure documentation, patient demographics, indications, technical description, findings, clinical assessment, and recommendations (plan) for follow-up. Reporting by polyp size is controversial. General agreement exists that all polyps ≥ 10 mm should be reported. However, full consensus relating to the reporting or management of subcentimeter polyps discovered at CT colonography has not been reached. The referral of patients to endoscopy for diminutive lesions (when CT colonography specificity is low) could lead to inappropriate referrals to colonoscopy. Moreover, current CT colonography acquisition parameters are tailored to the detection of polyps 6 to 10 mm in diameter. Based on these considerations, it is recommended that all polyps 6 mm or larger should be reported. Controversy exists for small lesions; these should be reported when reader confidence is very high. Extracolonic findings should be reported.

A comprehensive technical and professional quality control program is necessary. Technical quality control

should encompass both the CT scanner and the CT colonography workstation. Professional quality assessment monitors outcomes within a practice for internal quality assessment purposes. Such measures will alert physicians that changes may need to be made in patient educational materials, patient preparation regimens, or interpretation techniques. Retrospective, sporadic review of CT colonography parameters and reports can also ensure that appropriate technique and practice patterns are being followed. Standardized practices followed by all physicians and allied health personnel within a practice can also improve patient safety.

Regulatory Issues

Federal anti-kickback laws and Stark statutes influence who can perform CT colonography as well as the subject of split interpretation (a situation in which one physician interprets intracolonic images and another performs the extracolonic images). Both performing and interpreting CT colonography constitute “designated health services” and are therefore subject to Stark statutory requirements regarding referrals and billing for split interpretation. Compensation arrangements in a situation in which there is dual interpretation are potentially complicated but should not exclude any group from reading CT colonography. A personal services and management agreement (“safe harbor”) is a potentially applicable compensation arrangement between the gastroenterologist and the radiologist in a split interpretation scheme.

Key Executive Summary Recommendations

The key Task Force recommendations related to the basic requirements that board-certified gastroenterologists should meet to be involved in and/or perform CT colonography are summarized below. A complete list of recommendations is included in the full Task Force report.

- CT colonography is effective for evaluation of the colon proximal to an obstructing lesion.
- CT colonography is indicated for adults with failed colonoscopy in whom evaluation of the colon is deemed necessary.
- Minimal data are available regarding the use of CT colonography as a CRC screening test in patients with contraindications to colonoscopy or those who refuse other screening options. CT colonography may be considered in patients unwilling to undergo other primary screening modalities.
- Based on currently available data, CT colonography is not endorsed as a primary screening modality for CRC in asymptomatic adults.
- Training for CT colonography interpretation should

include review and interpretation of at least 75 cases with endoscopic correlation.

- Subsequent to formal training, the gastroenterologist should participate in a mentored CT colonography preceptorship lasting 4 to 6 weeks, occurring within 6 months of the initial training, with the candidate physically present and involved in the interpretation of at least 25–50 additional cases.
- It is expected that those performing CT colonography will undertake ongoing training and self-assessment including attending formal continuing medical education accredited courses in CT colonography.
- Gastroenterologists should work collaboratively with board-certified radiologists to review the extracolonic portion of the CT colonography examination.
- Any polyp ≥ 6 mm in size (ie, widest diameter) should be reported and the patient referred for consideration of endoscopic polypectomy.
- Patients with 3 or more polyps of any size in the setting of high diagnostic confidence should be referred for consideration of endoscopic polypectomy.
- The appropriate clinical management of patients with 1 or 2 lesions no greater than 5 mm in diameter is unknown. In the absence of data, the follow-up interval recommended for these patients should be based on individual characteristics of the patient and the procedure.
- Gastroenterologists considering offering CT colonography should consult with their health care counsel regarding compliance with state and local regulations.

Full Task Force Review and Recommendations

Introduction

ACBE and colonoscopy have been used to image the colon for many years. Recently, a number of new techniques with which to image the colon have been introduced.² Prominent among these is CT colonography (also CTC, CT colography, or “virtual colonoscopy”). CT colonography is a high spatial resolution, low-dose CT examination of the abdomen and pelvis performed following colonic insufflation. CT data sets are reviewed on a computer workstation that generates multidimensional images of the colon. CT colonography is extremely attractive because it is noninvasive and also (relatively) simple for patients to undergo.

As of the spring of 2006, one third of the membership of the American Gastroenterological Association indicated they were either already involved in some way with CT colonography or were interested in learning the technique in the future. Given the interest, and

acknowledging the lack of training standards and guidance for gastroenterologists in this area, the American Gastroenterological Association Executive Committee convened the CT Colonography Task Force to develop minimum training standards for gastroenterologists for CT colonography.

Because of their subspecialized training, gastroenterologists are experts in CRC screening and colorectal disease. Gastroenterologists should be able to translate their knowledge of the endoscopic appearance of colorectal disease to CT colonography, following formalized training in the CT physics, use of intravenous contrast, CT colonography interpretation and image manipulation, and CT colonography performance characteristics. These standards are intended to outline the basic requirements that board-certified gastroenterologists should meet to be involved in and/or perform CT colonography.

Current Status of CT Colonography

Investigation of CT colonography accuracy has been underway since its introduction. CT colonography sensitivity has been studied extensively,^{3–11} with the earliest reports involving small populations at high risk for colorectal pathology and using primarily single-row scanners (see Van Dam et al¹² for review). The per-polyp sensitivity of CT colonography compared with colonoscopy was excellent for larger lesions (some reports stated up to 100%) but was poor for smaller lesions (11%–55% sensitivity). These studies were extremely heterogeneous, varying in terms of patient cohorts, technical methodology, and training of CT colonographers.

Subsequently, further studies demonstrated improved detection sensitivity for polypoid lesions but continued to reveal wide variation in results. In general, the per-polyp sensitivities for lesions based on polyp size were greatest for larger lesions and were in the following ranges: <5 mm (30%–60%), 6–9 mm (45%–85%), and ≥ 10 mm (60%–95%). The specificity of CT colonography varied as well but was generally in the 90%–95% range. Most recently, 2 larger multicenter studies demonstrated that CT colonography was significantly less sensitive than colonoscopy,^{3,4} whereas a third reported that it was as sensitive as colonoscopy for detection of lesions ≥ 10 mm.⁵

A number of variables appear to contribute to the wide range of sensitivities reported for CT colonography. First and perhaps most importantly, as technology has evolved, so has the approach to CT colonography patient preparation and image acquisition. Multidetector CT scanners permit faster scanning with fewer motion artifacts while improving spatial resolution, and automated insufflators improve colonic inflation. Software platforms used to evaluate CT colonography images have also evolved, permitting greater interactivity and improved 3D visualization techniques for surveying the colonic lumen.

Additionally, bowel preparation methods have been variable, and some studies have used oral contrast, whereas others have not. A further critical variable is the cohort of individuals examined. Some studies have examined patients at high risk for colon abnormalities, and others have examined cohorts at low risk. Most studies have examined highly variable cohorts. Finally, the method in which it was ascertained that lesions detected by CT colonography were accurately assessed has varied as well. Colonoscopy has typically been used as the “gold standard”; however, colonoscopy does not detect all lesions, including large polyps.¹³ Thus, its use as a “gold standard” may not be appropriate. One study reported use of a “consensus” view of the colon based on the results of 3 different colon imaging tests as the reference standard,³ an approach likely to be more appropriate than simple use of colonoscopy results.

Additionally, new modifications in software such as novel display techniques, including so called “virtual dissection,”¹⁴ validated computer-aided detection systems, and more are on the horizon.¹⁵ Computer-aided detection systems recognize colorectal neoplasia by means of sophisticated thresholding followed by mathematical rule-based testing on the basis of feature values.^{16,17} Although this technique appears to hold great promise, and will likely be readily integrated into reading schemes,¹⁸ many issues remain to be resolved.

Considerable effort has also been directed at developing CT colonography with minimal preparation.^{19–24} Performance of CT colonography without a cathartic preparation, if proven to be highly sensitive and safe, could revolutionize the entire field.

It is essential that clinicians realize that this area is rapidly evolving and will continue to evolve for the next several years. Several large studies are currently under way that will further impact the practice of colon imaging.

Current Indications for CT Colonography

The current utility of CT colonography is controversial. Some believe that with a sensitivity level generally below that for colonoscopy, implementation should be limited. Others believe that it is ready to be widely implemented. Indications for CT colonography are highlighted below.

Failed Colonoscopy

Incomplete colonoscopic examination occurs in 2%–5% of colonoscopic examinations, usually secondary to patient discomfort or uncooperativeness, anatomic irregularities (eg, tortuosity, strictures, excessive looping), obscuring cancers, or inadequate colon preparation.²⁵ ACBE has traditionally been the test of choice for patients in whom colonoscopy could not be completed. However, ACBE may be difficult to perform immediately

after a failed colonoscopy, and barium coating of the colon wall is sometimes suboptimal after certain colon preparations, usually requiring the patient to undergo an ACBE-specific bowel preparation. Several studies have evaluated the use of CT colonography after failed colonoscopy. In one study, CT colonography and ACBE had comparable results in 10 patients after incomplete colonoscopy.²⁶ In another study, CT colonography was performed within 2 hours after incomplete colonoscopy in 40 patients, all of whom either had lower gastrointestinal symptoms or who were at increased risk of CRC.²⁷ Among the 26 patients who underwent both CT colonography and ACBE, CT colonography was better tolerated ($P < .001$), and CT colonography was judged to adequately reveal 96% of colonic segments compared with 91% for ACBE. Multiple intracolonic abnormalities were described in this at-risk population.

Evaluation of Colon Proximal to an Obstructing Lesion

Current screening guidelines recommend examination of the colon proximal to a CRC lesion because synchronous neoplastic lesions are found in 5%–8% of patients diagnosed with CRC.^{28,29} One study evaluated 29 patients without acute bowel obstruction in which the colonoscope could not be advanced proximal to the obstructing lesion.³⁰ In this trial, findings on CT colonography were compared with findings from preoperative ACBE and/or colonoscopy. CT colonography identified 100% of the occlusive CRC as well as 24 proximal colonic polyps and 2 synchronous proximal adenocarcinomas. In the 4 patients who had preoperative ACBE, ACBE failed to evaluate adequately the proximal colon in any patient, whereas CT colonography adequately examined the proximal colon in all of these patients, one of whom had a synchronous CRC. In another study of 19 patients with distal, occluding CRC,³¹ CT colonography identified all 19 distal lesions as well as 22 lesions proximal to the obstruction, including 2 adenocarcinomas. ACBE was attempted but was unsuccessful in 5 patients, whereas CT colonography adequately demonstrated the proximal colon in all 5 of these patients.

Colonic strictures because of radiation therapy, previous surgery, inflammatory bowel disease, or nonsteroidal anti-inflammatory drugs can also prevent complete colonoscopy. CT colonography has been shown to permit adequate visualization of the proximal colon in these patients.³² To date, no trials have specifically examined the role of CT colonography in a population of patients with colonic strictures because of a single etiology, but, in one prospective study³² of patients with a history of abdominopelvic surgery and/or radiation (41 patients) and controls (20 patients), CT colonography was judged to be successful in all patients. Although clinical outcomes, such as CT colonography sensitivity were not

reported, these data suggest that CT colonography is safe and feasible in this population.

CRC Screening in Patients With Contraindications to Colonoscopy or Who Refuse Other Screening Options

Minimal data are available regarding the use of CT colonography as a screening test in patients with contraindications to colonoscopy (eg, coagulopathy, intolerance to sedation) or who refuse other screening options. However, this is a critical area in which CT colonography may be beneficial. Elderly patients may be another population that could benefit from CT colonography because numerous studies have documented high sensitivity of CT colonography for cancer and the incidence of CRC increases with age. CRC screening of the elderly population with CT colonography is subject to many of the same concerns and criticisms as screening this population with colonoscopy. A recent analysis of screening colonoscopy in the elderly population found that the gain in life expectancy was only 15% of that observed in a younger population.³³ However, a gain in life expectancy is still derived from CRC screening in this population, so the authors recommended that the decision to screen patients of age ≥ 80 years be individualized.

CRC Screening of Asymptomatic, Normal-Risk Adults

Multiple trials have examined the accuracy of CT colonography for the identification of CRC and polyps. Most of the early efforts investigated the role of CT colonography in patients who were at greater than average risk for the development of CRC or who had symptoms referable to the lower gastrointestinal tract.³⁴⁻³⁶ Other studies examining CT colonography accuracy for detecting CRC and colon polyps in screening populations have been published.^{5,6,37-39} Taken as a whole, the body of literature examining CT colonography as a CRC screening test demonstrates significant variability (see Current Status of CT Colonography, above). A recent meta-analysis of 33 studies comparing CT colonography screening to a gold standard (colonoscopy or surgery) concluded that issues such as patient selection, examiner training and experience, scanner collimation and type, and mode of imaging are likely contributors to the heterogeneity observed in these trials.⁴⁰ The heterogeneity of studies in this meta-analysis was felt to preclude conclusions about use of CT colonography as a primary screening modality.

The largest trial of CT colonography as a CRC screening test in average-risk patients was conducted with 1233 patients at a number of military tertiary care hospitals.⁵ Sensitivity of CT colonography for adenomas ≥ 1 cm was 94%, compared with colonoscopy as the gold standard. This trial utilized experienced CT colonography interpreters, fecal and fluid tagging with subsequent digital subtraction of retained stool and fluid in the colon, and relied on a primary 3D interpretation of CT colonogra-

phy images, all techniques that distinguished it from previous, as well as subsequent, studies. Whether or not these factors were critical in the encouraging results observed in this trial remains controversial. Currently, investigators from the military hospital that contributed the majority of the patients for the study cited above are performing a 3000 person study designed to explore further the use of CT colonography as a CRC screening test.³⁹ Preliminary data from this trial have been encouraging, demonstrating diagnostic equivalence of CT colonography with colonoscopy for adenomas ≥ 6 mm in size.³⁹

CT colonography has not yet been endorsed as a primary CRC screening test by any multidisciplinary group involved in CRC screening guideline development.^{29,41,42} Additionally, Medicare does not pay for screening tests in the absence of symptoms. For that reason, the majority of Medicare contractors do not cover CT colonography for CRC screening in asymptomatic patients. It is also not a covered benefit offered by most private insurance companies, although pilot programs have produced promising results.⁴³

Contraindications

CT colonography has few contraindications, however, it should not be performed in patients for whom perforation is a concern. In addition, CT colonography should probably not be performed immediately after failed colonoscopy in patients who had polyps removed or large biopsy specimens taken because of the possible risk of perforation resulting from the required colonic insufflation with CT colonography. Specific clinical circumstances exist in which endoscopic examination is preferred to CT colonography. These include, but are not limited to, situations in which the pretest probability of identifying colonic abnormalities is increased, such as patients with symptoms of organic gastrointestinal disease, patients with familial colon cancer syndromes, or patients with inflammatory bowel disease in whom colonic sampling for dysplasia is recommended.

Task Force Recommendations

- CT colonography is effective for evaluation of the colon proximal to an obstructing lesion.
- CT colonography is indicated for adults with failed colonoscopy in whom evaluation of the colon is deemed necessary.
- Minimal data are available regarding the use of CT colonography as a screening test in patients with contraindications to colonoscopy or who refuse other screening options. CT colonography may be considered in patients unwilling to undergo colonoscopy as a primary screening modality.
- CT colonography should not be performed immedi-

ately after failed colonoscopy in patients who had polyps removed or large biopsy specimens taken during the failed colonoscopy.

- CT colonography is not indicated in patients with high-risk disease symptoms (eg, inflammatory bowel disease, hematochezia) and situations in which the pretest probability of identification of colonic abnormality is increased.
- Based on the data currently available, CT colonography is not endorsed as a primary screening modality for CRC in asymptomatic adults.
- Additional studies comparing CT colonography and other primary screening modalities are required.

Qualifications and Training of Personnel

CT Scanning

CT scanning should be performed by American Registry of Radiologic Technologists-certified radiologic technologists. Prior to CT acquisition, adequate colonic inflation is confirmed using a CT scout. Suboptimal colonic distention can result in falsely negative CT examinations,⁴⁴ so personnel performing CT colonography need to be facile with equipment and techniques to ensure adequate distention. Therefore, a program to ensure technologist expertise in review of CT scout images is required.

Skill and Training to Read CT Colonography

Despite the intensive study and evolution that CT colonography has undergone over the last decade, the extent of training for gastroenterologists to read accurately CT colonography has not been defined. The American College of Radiology practice guidelines⁴⁵ for performing and interpreting diagnostic CT requires licensed medical practitioners who have a thorough understanding of the indications for CT as well as a familiarity with the basic principles and limitations of the technology. Individuals performing CT colonography should have a thorough understanding of CT technology and instrumentation as well as radiation safety. With respect to CT colonography in particular, the American College of Radiology⁴⁶ recommends that the supervising and interpreting physicians should have reviewed at least 50 cases in one or more of the following formats: (1) formal hands-on interactive training on CT colonography interpretation, (2) supervision with a CT colonography-trained physician(s) acting as a double reader, and (3) correlation of CT colonography and endoscopy findings in patients who undergo both procedures. Furthermore, the current Gastroenterology Core Curriculum suggests that trainees “Gain familiarity with the detection of neoplasms of the colon during the performance of CT colonography and other similar techniques.”⁴⁷

A number of studies have examined the variability in the “learning curve” associated with interpretation of CT colonography findings. In one, with 2 blinded teams made up of a radiologist and gastroenterologist,⁴⁸ it was found that increasing experience (after reading 25 cases) led to enhanced specificity and reduced interpretation times. In a study examining reader training at 25, 50, 75, and 96 case intervals, sensitivity improved after reading 50 cases, whereas optimal sensitivity (92% for target lesions) was achieved after interpreting 75 cases.⁴⁹ Another study reported similar findings at the 75-case threshold,⁴⁹ with this study using 2 readers with limited prior experience in reading CT colonography. The performance of nonradiologists (medical students and radiologic technologists) after training using a teaching file of 50 cases followed by blind interpretation of 50 cases with colonoscopic correlation (30 positive, 20 negative) was similar to a separate cohort of radiologists learning CT colonography; interestingly, the performance of nonradiologists improved further following reading of another 100 cases.⁵⁰

Response to training is unpredictable. In one study, 3 radiologists (gastrointestinal radiology consultant, research fellow, and trainee) with no prior experience in CT colonography were tested on 100 cases.⁵¹ Feedback and training were given after the first 50 cases, and performance and reporting times were compared for these and then 50 subsequent data sets. Prior experience of gastrointestinal radiology enhanced the ability to read CT colonography; however, competency could not be assumed after direct training with the database of 50 cases. In another study, inexperienced CT colonography readers (<50 cases read) who completed a CT colonography training module performed better than experienced CT colonography readers with a sensitivity of 70% vs 47%, respectively, in detecting lesions ≥ 10 mm.³ In a study examining performance variability among 6 readers (4 residents, 2 subspecialty gastrointestinal radiologists) without prior CT colonography training in reading (20 cases including 32 polyps), untrained reader sensitivity was low, with marked individual variation; the majority of missed polyps were due to failure of detection (82%–95%).⁵² Based on these observations, the learning curve for CT colonography interpretation will vary widely among observers.

The American College of Cardiology and the American Heart Association recently established criteria for clinical competence in interpreting computed tomography and magnetic resonance imaging studies of the heart, based on physician training and the cognitive skills required for each type of examination.⁵³ Training for each level of clinical competence is based on the cognitive skills required for each scope of practice. Table 1 summarizes the cognitive skills required for physician competence at CT colonography.

Table 1. Cognitive Skills Required for Physician Competence in CT Colonography

Knowledge relating to the colon

- Knowledge of colon, rectal, appendiceal, and ileal anatomy
- Knowledge of colorectal diseases and colon cancer screening recommendations and alternatives

Knowledge relating to CT colonography data acquisition and interpretation of colonic findings

- Knowledge of basic CT physics and CT parameters/acquisition techniques that affect radiation exposure
- Familiarity with colonic insufflation devices
- Knowledge of indications for iodinated intravenous contrast, as well as knowledge of contraindications and treatment of adverse reactions
- Knowledge of spectrum of bowel purgation and cleansing regimens used at CT colonography
- Knowledge of CT colonography interpretation technique
- Knowledge of the varied appearance of colorectal neoplasia at CT colonography
- Knowledge of the performance characteristics of CT colonography for polyps of different sizes and histologies
- Knowledge of the appearance of colonic, rectal, ileal, appendiceal disease at CT
- Knowledge and familiarity with a dedicated CT colonography workstation, including the ability to compare supine and prone images, generate 2D and 3D endoluminal images, and examine CT attenuation

Knowledge relating to the identification and workup of extracolonic disease

- Knowledge of the appearance of extracolonic mass lesions within the abdomen and pelvis at CT
- Understanding of how low-dose, unenhanced CT images affect the ability of CT to display extracolonic structures and findings
- Understanding of appropriate medical workup following the detection of potentially important extracolonic findings

Qualifications for Interpretation of CT Colonography Data Sets

As discussed previously, available literature suggests that review of at least 75 endoscopically confirmed cases is necessary for minimal competence in detecting and characterizing colorectal neoplasia at CT colonography. Because formalized training improves, but does not ensure, adequate performance, CT colonography interpretation under the supervised guidance of a qualified physician mentor is required. Candidates should participate in mentored interpretation during this training period. During this preceptorship, gastroenterologists would be expected to hone the ability to track the colon using CT colonography workstations (a known difficulty for nonradiologists⁵⁰), gain experience in performing quality assessment prior to patient dismissal, become familiar with the application of problem-solving salvage techniques used to improve examination quality, and, of course, refine their ability to detect and characterize colonic lesions. Routine use of a validated computer-aided detection system may also prove helpful^{18,54,55} but cannot be recommended without further data.

Continued Competence in CT Colonography

Ongoing practical experience with the acquisition and interpretation of CT colonography studies is required to maintain clinical competence. Mammography has similar requirements. To maintain clinical expertise in CT colonography after formalized training, physicians should supervise and interpret a minimum number of cases per year, in addition to participating in continuing medical education activities, and update them relating to advances in the field.

Task Force Recommendations

- Gastroenterologists performing and interpreting CT colonography should have a thorough understanding of the indications and the principles and limitations of CT colonography technology.
- Formalized training of gastroenterologists for CT colonography interpretation is mandatory.
- Training for CT colonography interpretation should address cognitive skills required to perform all aspects of the CT colonography examination (Table 1).
- Training should include review and interpretation of at least 75 cases with endoscopic correlation.
- Subsequent to formal training, the gastroenterologist should participate in a mentored CT colonography preceptorship lasting 4 to 6 weeks, occurring within 6 months of the initial training, with the candidate physically present and involved in the interpretation of at least 25–50 additional cases.

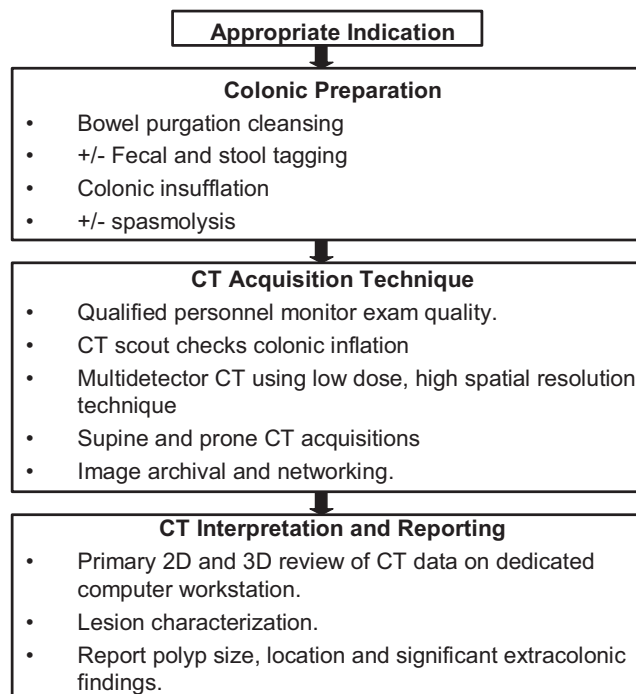


Figure 1. CT colonography care map.

- It is expected that there will be ongoing training and self-assessment including attending formal continuing medical education-accredited courses in CT colonography.
- CT colonography training should focus heavily on detection technique.

Examination and Equipment Specifications

The spectrum of CT colonography practice may vary widely depending on the clinical indication and available equipment, but adherence to recommended standards for all portions of the examination are required to achieve reproducible results (Figure 1).

Colonic Preparation

Most regimens employ a cathartic agent in addition to a colonic stimulant (usually bisacodyl tablets or suppositories). Polyethylene glycol electrolyte solution is a nonabsorbable, osmotically balanced preparation that is safe and results in little fluid shifting during administration and is commonly used prior to CT colonography and colonoscopy. Oral sodium phosphate-based agents are easier to ingest for many patients, because of the smaller volume that must be consumed, but can result in electrolyte shifts when doses exceeding 45 mL daily are employed.⁵⁶ Magnesium citrate is a milder saline cathartic preparation, which performs similarly to polyethylene glycol for CT colonography when combined with fecal tagging agents.⁵⁷ Polyethylene glycol results in increased fluid within the colon compared with oral phosphosoda,⁵⁸ but this generally does not cause diagnostic problems if the patient is scanned in 2 positions to permit redistribution of colonic fluid. The selection of a cathartic agent will depend on patient factors as well as physician preferences; indeed, current preparative regimens for CT colonography are not well tolerated.⁵⁹ Patient factors include underlying conditions that lead to contraindications for electrolyte shifts, fluid shifts, or phosphate ingestion.

Tagging of colonic fluid and stool can be achieved with oral contrast agents prior to CT examination. Fecal and fluid tagging may permit identification of submerged polyps and reduce false-positive examinations because of residual stool.⁶⁰ Use of fecal and fluid tagging is not mandatory if the patient is adequately cleansed with cathartics and scanned in 2 positions, because both fluid and stool generally move with repositioning,¹⁰ and is impractical when CT colonography is performed following incomplete endoscopy.^{27,61} Stool tagging is generally achieved with ingestion of a barium suspension; fluid tagging is performed using an iodinated oral contrast agent. Compliance with fecal and fluid tagging regimens can be challenging for some patients (because of understanding or availability of the tagging agents). CT

colonography performed without bowel purgation cleansing is a promising extension of the CT colonography technique¹⁹⁻²⁴ but cannot currently be recommended because no large clinical studies have documented its performance in an asymptomatic patient population.

Colonic insufflation is performed prior to CT acquisition using air or carbon dioxide, which may reduce postprocedure cramping.⁶² Glucagon, a spasmolytic agent, does not increase colonic distention but may improve patient comfort.⁶³ Colonic insufflation with automated insufflators results in improved colonic distention compared with manual insufflation.⁶⁴ Automatic insufflators may also be safer because of preset ramped flow rates and automatic venting at predetermined intracolonic pressures.⁶⁵

CT Acquisition Technique

Following review of an initial CT scout, high-resolution CT is performed in the supine and prone positions. Scanning the patient in 2 positions is mandatory, to permit redistribution of colonic fluid and air, and improves the detection of colonic polyps compared with a single position.^{10,66}

The ability of CT colonography to detect colorectal polyps is in part dependent on CT acquisition parameters including slice thickness. Slice thickness should be chosen to be at least half of the target polyp size to minimize partial volume averaging with adjacent air. Multislice CT scanners have several advantages over single slice helical scanners for CT colonography. Faster tube rotation times and an increased number of detectors permit faster table speeds so that a patient can be scanned quicker. Faster scanning is important because the patient is holding his/her breath and may be experiencing some discomfort as the colon is maximally inflated. The use of multidetector CT consequently results in better colonic distention and fewer respiratory artifacts, compared with single slice helical CT.⁶⁷ For these reasons, CT colonography should be performed on multidetector scanners with 4 or more detectors. Additionally, most multislice CT scanners are equipped with automatic exposure control, which varies the x-ray tube current over the body region (as the patient travels through the scanner) and projection angle, and results in significant dose savings for average-sized patients.^{68,69} Automatic exposure control may increase the dose for obese patients, as it normalizes noise across the imaged volume, but this dose increase may be important to maintain image quality in the bony pelvis in such patients. Although submillimeter slice thicknesses are now possible with 64-slice CT systems, utilization of such slice thicknesses results in data sets of thousands of images, increases image noise, and will result in increased radiation dose if noise is held constant. Numerous phantom experiments have demonstrated that polyps 6 mm or greater in size can be detected using slice thicknesses of 3 mm or less, with

narrower slice thicknesses potentially increasing lesion conspicuity.⁷⁰⁻⁷² Several large patient studies using 2.5- or 3-mm slice thickness have demonstrated acceptable performance for detecting polyps 6–9 mm in size.^{5,9,73}

Unlike routine abdominal CT, which identifies solid organ abnormalities using differences in x-ray attenuation between soft tissue structures, CT colonography identifies colonic polyps and cancers by exploiting the attenuation difference between these soft tissue lesions and intracolonic air. The resulting attenuation gradient is much greater, permitting CT colonography examinations to be performed at much lower doses. Scanning at lower dose (ie, lower milliamperage settings, higher pitch) increases image noise and complicates visualization of extracolonic structures but does not compromise the detection of colorectal polyps and cancers 5 mm or greater in size.^{71,74-77} The radiation dose for CT colonography examinations using supine and prone acquisitions in published CT colonography protocols averages 8 mSv,⁷⁵ compared with the barium enema, which has an estimated effective dose of 4.0 mSv in males and 8.8 mSv in females.⁷⁸ The tube current used to achieve doses similar to barium enema varies depending on scanner model and other acquisition parameters but should be within this range for average-sized patients for routine CT colonography examinations. The American College of Radiology practice guidelines for CT colonography recommend a kVp of 120 kV and a tube current of <100 mAs for routine CT colonography examinations in adult patients.⁴⁶ The risk of radiation exposure to the public, based on typical CT acquisition parameters and extrapolated to cancer risk estimated for atomic bomb survivors of all ages who had whole body exposures of a mean of 20 mSv, appeared to be low.⁷⁹ Even with these assumptions (because CT colonography involved only older patients with diminished risk for an induced cancer and scanning of the abdomen and pelvis only), it was concluded that “the benefit-risk ratio is large for CT colonography.” When characterization of solid organs is necessary (eg, to evaluate a potentially significant extracolonic finding or to stage an obstructing colon cancer), intravenous contrast with normal dose settings should be employed. Intravenous contrast may also be used to help allow better characterization of polyps (eg, to help distinguish polyp from stool, or in the setting of excess colonic fluid).⁸⁰ In these circumstances, normal dose settings are also appropriate so that the attenuation of colonic lesions can be accurately assessed.

Prior to patient dismissal, CT data sets should be reviewed by a trained technologist or physician to ensure complete imaging of the colorectum and adequate visualization of colonic segments. Repeat scanning after re-inflation, changes in patient position, or intravenous contrast may be required if colonic segments are inadequately visualized because of collapse or excess fluid.^{46,80} CT images should be sent to a dedicated CT workstation

for interpretation as well as archived as part of the medical record for future comparison purposes.

CT Interpretation

CT colonography evaluation can be divided into the following 2 steps: (1) a primary search for suspicious colonic lesions and (2) lesion characterization. The primary search can be achieved using either an initial 2D search strategy, in which enlarged 2D images are evaluated sequentially from rectum to cecum,^{36,81,82} or a primary 3D search, in which the endoluminal surface of the colon is reviewed.⁸³ Performing a primary 3D search in addition to a primary 2D search may increase sensitivity by approximately 10%⁴ but requires additional interpretation time.⁸⁴ Primary 3D search has been cited as a reason for the high sensitivity achieved in some studies,⁵ but smaller studies employing primary 2D search have also achieved similar results.^{9,74} Flat lesions, which appear as cigar-shaped, plaque-like, focal regions of soft tissue attenuation, are best seen using 2D images.⁸⁵ Given the advantage of both primary 2D and 3D search, optimal performance likely involves both search methods. Lesion morphology is assessed by correlation of 2D and 3D images to distinguish polyps from folds. Lesion density is determined by visual interrogation of intralesional attenuation (to differentiate stool from neoplasia or lipoma). Lesion mobility is judged by comparison of lesion position on supine and prone images. When a polyp or cancer is identified, it should be measured on 2D images with lung window settings or using 3D endoluminal views.^{86,87} Adequate CT colonography workstations permit the viewing of enlarged 2D images in multiple planes, 3D endoluminal navigation and interrogation, as well as simultaneous viewing of 2D and 3D images, simultaneous viewing of supine and prone images, and variation of window/level settings and field of view size to examine intralesional attenuation and the extracolonic tissues.⁴⁶

Task Force Recommendations

- The bowel purgative method should be tailored to the patient and local endoscopy practice. Use of stool and fluid tagging agents is preferred but not mandatory.
- Dedicated personnel should be trained in manual and automated insufflation techniques. Automated insufflation is preferred but not mandatory.
- A CT scout should be performed prior to scanning to confirm adequate insufflation. Supine and prone CT acquisitions should be performed. Trained personnel should review 2D images of the colorectum prior to patient dismissal to ensure adequate visualization of all colonic segments.
- CT colonography should be performed using multi-

detector CT (minimum 4 detector) using protocols with high spatial resolution (ie, ≤ 3 -mm slice thickness), low-dose (< 100 mAs) technique. If intravenous contrast is needed, routine dose settings (> 100 mAs) should be used.

- Computer workstations for dedicated CT colonography interpretation should permit comparison of supine and prone data sets, primary 2D and primary 3D visualization of the colonic lumen, correlation of 2D and 3D images, and 2D evaluation in multiple planes using a variety of window settings.
- CT colonography images should be archived for later comparison.
- Primary 2D or primary 3D review of the endoluminal surface of the colorectum is required. Combined primary 2D and primary 3D review is recommended but not required. Polyps and cancers should be measured using 2D images with lung window settings or 3D endoluminal views.
- Physician presence or immediate availability is required near CT scanning in the event of a colonic perforation or in the event of an allergic reaction to intravenous contrast.

Reading and Reporting

Reading

Intracolonic findings. All intracolonic findings should be examined, and any segment not adequately evaluated should be documented. All large masses and lesions that compromise luminal caliber should be communicated. The size and location of colorectal lesions should be reported, with appropriate images annotated or described. Descriptive features of polyps and masses should include morphologic features (sessile, pedunculated, flat), location (rectum, sigmoid, descending, transverse, ascending colon, cecum), and lesion attenuation (soft tissue attenuation and fat).

Extracolonic findings. Extracolonic findings (many of which are incidental findings) are common. In a recent systematic review involving 3488 patients, 40% of the patients had 1 or more abnormality. Extracolonic cancers were detected in 2.7% of patients, and 0.9% had an aortic aneurysm.⁸⁸ Approximately 1%–2% of patients will have highly important findings requiring medical or surgical intervention.^{89,90} The incidence of extracolonic findings far surpasses the incidence of colorectal lesions of 5 mm in size,^{88,91,92} but the large majority of these findings are not clinically significant and require no medical workup (eg, hiatal hernia, cholelithiasis, renal stone).

Typically, the detection and interpretation of extracolonic findings at CT colonography has been performed by radiologists, who have completed formal training programs and passed written and oral subspecialty examina-

tions testing their ability to detect radiographic abnormalities. Radiologists are trained in the use of CT in a variety of practice settings not germane to the practice of CT colonography (eg, trauma, CT angiography, oncologic staging). Additionally, the occasional use of intravenous contrast will necessitate the identification of lesions unseen without intravenous contrast and the characterization of nonspecific abnormalities. These instances require extensive expertise in recognizing abnormalities of the lungs, solid organs, retroperitoneum, and the extracolonic gastrointestinal tract. Therefore, all extracolonic findings should be reported, and a radiologist should be consulted to properly examine the extracolonic portion of the study.

Task Force Recommendations

- CT colonography reading should include the size, morphologic features, and location of polyps and masses and lesion attenuation.
- Overall results and findings of the CT colonography examination should be adequately documented and communicated back to the referring physician and patient.
- Gastroenterologists should work collaboratively with board-certified radiologists to review the extracolonic portion of the CT colonography examination.
- All visualized extracolonic findings should be described, along with recommendations for further workup communicated back to the physician who ordered the test and the gastroenterologist who performed the CT colonography examination.

Reporting

Development of a standardized method of reporting CT colonography will be influenced by local practice, referral patterns, and methods of information dissemination (paper vs electronic). As such, the guidelines here are not intended to represent a standard but rather a framework for covering pertinent aspects of the patient encounter. Not surprisingly, the format of this report parallels that which has been proposed for colonoscopy⁹³ and incorporates elements developed by the American College of Radiology.^{45,46}

Standardized report. The report should encompass elements of preprocedure documentation, patient demographics, indications, technical description, findings, clinical assessment, and recommendations (plan) for follow-up (Table 2). In particular, the preprocedure element should include patient education and a discussion of possible complications (eg, perforation) as well as the risk of missing significant lesions. Review of available alternatives to CT colonography for colonic evaluation is appropriate.

Polyp reporting. One of the most controversial areas in the field has to do with reporting of polyps. In

Table 2. Recommended Elements in CT Colonography Report

-
1. Preprocedure:
 - Preparation type and use of fecal tagging
 - Facility, equipment, and software used
 - IV contrast
 - Slice collimation (≤ 3 mm optimal, maximum is 5 mm) and reconstruction interval (≤ 1.5 mm is optimal, maximum is 2.5 mm)
 - Method of interpretation
 - Primary 2D
 - Primary 3D
 2. Indication(s) for procedure:
 - Recommended documentation in all cases if known
 - Date of last examination and type (eg, colonoscopy, CT colonography)
 - Family history of colorectal cancer in first-degree relative
 - Number of family members
 - Age of index family member(s) who had colorectal cancer
 - Family history of adenoma in first-degree relative
 - Average risk
 - Family history of colorectal cancer (first-degree relative)
 - Family history of adenomatous polyps (first-degree relative)
 - Familial syndrome
 - FAP
 - HNPCC
 3. Technical description:
 - Procedure date and time
 - Insufflation:
 - CO₂ or room air
 - Rectal balloon use
 - Technique (patient or technician controlled)
 - Use of antispasmodic (eg, glucagon)
 - Patient tolerance (good, fair, poor)
 - Position of patient for scanning:
 - Supine and prone
 - Additional views in decubitus
 - Quality of examination:
 - Preparation
 - Colon distention/visualization
 - Segments of colon not adequately distended
 - Segments of colon in which fluid/stool obscures visualization in all positions
 - 4a. Findings: intracolonic
 - Colonic mass (lesion > 3 cm)
 - Anatomic location (use standard terms of rectum, sigmoid colon, descending colon, transverse colon, ascending colon and cecum)
 - Maximum diameter with annotated images referenced in report
 - Morphology
 - Sessile: broad based with a width greater than vertical height
 - Pedunculated: polyp with separate stalk
 - Flat: polyp with vertical height less than 3 mm above surrounding normal colonic mucosa
 - Depth of invasion
 - Circumferential
 - Luminal narrowing (% compromised)
 - Regional lymphadenopathy
 - Distant metastases
 - Colonic polyp(s) (descriptors for each polyp)
 - Anatomic location
 - Maximum diameter (mm) with annotated images referenced in report
 - Morphology
 - Sessile: broad based with a width greater than vertical height
 - Pedunculated: polyp with separate stalk
 - Flat: polyp with vertical height less than 3 mm above surrounding normal colonic mucosa
 - Polyp cluster: multiple polyps (3 or more) in same anatomic region
 - Anatomic location
 - Size range: mm
 - Approximate number in a segment
 - Morphology (sessile/pedunculated/flat)
 - Fat attenuation lesion
 - Anatomic location
 - Size: mm
-

Table 2. (Continued)

Mucosal abnormality
Suspected diagnosis: ulcerative colitis, Crohn's disease, ischemia, infection, and others
Anatomic location/extent
Other findings:
Diverticulosis
Arteriovenous malformations
Hemorrhoids
Other
4b. Findings: extracolonic
E0: limited examination. Compromised by artifact; evaluation of extracolonic soft tissues is severely limited.
E1: normal examination or anatomic variant. No extracolonic abnormalities visible
Anatomic variant: eg, retroaortic left renal vein, replaced hepatic artery arising from the superior mesenteric artery
E2: clinically unimportant finding. No workup indicated.
Liver, kidney: simple cysts
Gallbladder: cholelithiasis without cholecystitis
Vertebra: hemangioma
E3: likely unimportant finding, incompletely characterized. Workup may be indicated depending on local practice and patient preference.
Kidney: minimally complex or homogeneously hyperattenuating cyst
Gallbladder: cholelithiasis without cholecystitis
Vertebra: hemangioma
E4: potentially important finding. Method of communication to referring physician as per accepted practice guidelines (eg, telephone call, written report).
Kidney: solid mass
Lymphadenopathy
Vasculature: aortic aneurysm
Lung: nonuniformly calcified parenchymal nodule ≥ 1 cm
5. Interventions/unplanned events
Events and unplanned interventions during or immediately after CT colonography
Type of event (eg, vasovagal, perforation)
Type of intervention
6. Assessment and follow-up plan
Should be based on history, symptoms, and CT colonography findings
Documentation of communication directly to the patient and referring MD

FAP, familial adenomatous polyposis; HNPCC, hereditary nonpolyposis colorectal cancer.

patients undergoing the examination for screening, polyp size remains one of the most important criterion by which a given lesion could be stratified with respect to the risk of developing into cancer.⁹⁴ The detection and reporting of colorectal polyps is affected by multiple considerations including the screening and surveillance recommendations, the natural history of subcentimeter polyps, the performance (sensitivity and specificity) of CT colonography for polyps of different sizes, the accuracy of polyp measurement at CT colonography, and the selection of CT colonography acquisition parameters and bowel tagging regimens.^{12,29,93,95,96} Even CT colonography studies that have reported satisfactory results for polyps 6–9 mm in size report poor performance for polyps 5 mm or smaller in size.^{9,73}

General agreement exists that all polyps ≥ 10 mm should be reported and the patient referred to endoscopic polypectomy because 10%–25% of these lesions will harbor high-grade dysplasia or cancer.⁹⁷ However, full consensus relating to the reporting or management of subcentimeter polyps discovered at CT colonography has not been reached among all groups.^{12,93,98,99} It is generally agreed that the presence of 3 or more small polyps increases the risk of developing colorectal can-

cer.⁹⁶ In the recent CT colonography reporting and data system consensus proposal, for the purposes of screening, 6 mm was suggested as the minimum size for reporting polyp lesions.⁹³ This viewpoint was endorsed by the European Society of Gastrointestinal and Radiology in a recent consensus statement that recommends polyps 4 mm or smaller should be ignored, and a significant minority among the faculty would ignore 5-mm polyps, even when multiple.¹⁰⁰ The practice guidelines of the American College of Radiology for the performance of CT colonography in adults state that the reporting of polyps ≤ 5 mm is not recommended.⁴⁶ Current American College of Gastroenterology recommendations state that patients with polyps ≥ 6 mm and patients with 3 or more polyps of any size should be offered colonoscopy and polypectomy.⁹⁵ It also recommends that polyps of any size detected with moderate to high confidence should be reported because patients and referring physicians deserve to be aware of the test results.

The referral of patients to endoscopy for diminutive lesions (when CT colonography specificity is low) could lead to a large number of patients being referred to endoscopy⁹⁵ and compromise productivity at subsequent endoscopy. Moreover, current CT colonography acquisi-

tion parameters (principally slice thickness and radiation dose) are tailored to the detection of polyps 6 to 10 mm in diameter, but thinner slices or increased dose might improve performance.^{71,72} Based on these considerations, it is recommended that all polyps 6 mm or larger should be reported but that smaller lesions need not be reported and should only be reported when reader confidence is very high.

Task Force Recommendations

- CT colonography findings should be communicated to the patient as well as the patient's referring physician in a timely manner through direct contact with the patient and a standardized report back to the physician (Table 2).
- Any polyp ≥ 6 mm should be reported and the patient referred for consideration of endoscopic polypectomy.
- Patients with 3 or more polyps of any size in the setting of high diagnostic confidence (The level of diagnostic confidence should be assessed by the examining physician based on patient history, the size of lesion[s], appearance of lesion[s], clinician experience with the procedure, the quality of preparation, the level of distention, and the overall quality of the examination.) should be referred for consideration of endoscopic polypectomy.
- Patients with 1 or 2 lesions each no greater than 5 mm may not need to be reported but can be reported when diagnostic confidence is high. Insufficient data exist to recommend a follow-up interval for repeat study for these patients and whether it should be radiologic CT, colonoscopy, or one of other evolving methods. In the absence of data, the follow-up interval recommended for these patients should be based on individual characteristics of the patient and procedure.
- Further investigation is recommended to understand better the natural history of colon polyps and to facilitate the most appropriate clinical path.

Quality Control and Safety

A comprehensive technical and professional quality control program is necessary. Technical quality control should encompass both the CT scanner and the CT colonography workstation. In addition to routine quality control, facilities performing CT colonography must ensure that all rooms containing x-ray devices are appropriately shielded for radiation in accordance with all federal and state regulations (NRC Regulations; <http://www.nrc.gov/reading-rm/doc-dollections/cfr/part020/full-tex.html>). Annual testing should include uniformity testing of CT number as well as spatial resolution, with

visibility to 5-line pairs/cm bar pattern clearly resolved (http://www.acr.org/accreditation/computed/ct_qc_forms.html). Daily testing should include manufacturer or water phantom testing of CT number and noise, depending on state regulatory requirements. The CT colonography workstation monitor should undergo weekly Society of Motion Picture and Television Engineers (SMPTE) or equivalent video test pattern testing showing lack of aliasing of bar patterns and other artifacts with 95% and 5% squares visible.¹⁰¹

Professional quality assessment monitors outcomes relating to established metrics within a practice. It is anticipated that, over time, national benchmarks for CT colonography performance will be established, which can serve to improve quality and potentially guide reimbursement.^{102,103} A National Radiology Data Registry is under development that could serve as an "overarching" registry in which modality specific data (eg, positron emission tomography scans and CT colonography) could be entered.¹⁰⁴ For internal quality assessment purposes, practices should establish mechanisms to track endoscopic findings in patients referred to colonoscopy so that true-positive rate, false-positive rate, and sensitivity in referred patients can be calculated. The number of "inadequate" examinations, in which full assessment of the colorectum is precluded by excess stool, fluid, or collapse should also be recorded. The adequacy of the preparation, the appropriateness of the follow-up recommendations, and the prompt notification of the patient and the referring physician should also be tracked. Any complications at CT colonography should be recorded, along with any predisposing conditions (such as obstructing lesions, concomitant colonic disease, or type of insufflation).¹⁰⁵ Such measures will alert physicians that changes may need to be made in patient educational materials, patient preparation regimens, or interpretation techniques.

Retrospective, sporadic review of CT colonography parameters and reports can also ensure that appropriate technique and practice patterns are being followed. In particular, retrospective review of technical parameters in average-sized patients should measure compliance with standard acquisition protocols, ensuring low-dose, high spatial resolution technique. Additionally, random CT colonography reports should be reviewed to ensure compliance with guidelines, ensuring that they include information summarizing technique, polyp location, and size and presence of significant extracolonic pathology.

Standardized practices followed by all physicians and allied health personnel within a practice can also improve patient safety. Practices should establish their own policies with respect to the use of intravenous iodinated contrast (eg, indications, rate and amount of administration, contraindications, treatment of adverse reactions).

Task Force Recommendations

- Practices should establish a technical quality control program that monitors spatial resolution, CT number, and noise of CT systems and grey scale of CT colonography computer workstation monitors.
- Professional quality control should include tracking of endoscopic results in patients referred to endoscopy from CT colonography so that true-positive and false-negative rates can be tracked.
- The frequency of “inadequate” examinations and complications should be recorded.
- Random sampling of CT colonography images and reports should be performed to measure compliance with low-dose, high spatial resolution techniques and standardized reporting guidelines.
- Practices should establish their own policies and procedures with respect to the use of iodinated intravenous contrast.

Regulatory Issues

Several regulatory issues affect the gastroenterologist’s decision to perform CT colonography including the following: (1) who can perform the service; (2) split interpretation, in which one physician interprets intracolonic images and another performs the extracolonic images; and (3) risk management issues.

Who Can Perform CT Colonography: Implications of Stark Laws

The first consideration with regard to who is allowed to perform CT colonography centers around the concept of self-referral or “kickback.” Concern that kickback schemes could corrupt the professional judgment of referring physicians and result in overutilization or ordering unnecessary items and services led to the 1972 Federal Anti-kickback Law.¹⁰⁶ Since its creation, the original anti-kickback statute has been revised to allow more than 20 exceptions or “safe harbors” such as for investments in group practices, small health care joint ventures, space rental, and equipment rental. In 1989, Congress passed “Stark I,” prohibiting a physician from referring Medicare patients to an entity for clinical laboratory services if the physician (or their immediate family member) has a financial relationship with that entity. In 1993, “Stark II” expanded the Medicare self-referral ban to prohibit physicians from referring “designated health services” to an entity with which the physician has a financial relationship, unless that financial relationship meets an exception.^{107,108} The definition of “designated health services” is key and includes, among other things, radiology and certain other imaging services, including ultrasound, CT, magnetic resonance imaging, and nuclear medicine. Both performing and interpreting CT

colonography constitute designated health services.¹⁰⁹ Sanctions for violating the Stark statutes are severe, including refunds to the Medicare program, civil monetary penalties, and, under some circumstances, exclusion from the Medicare and Medicaid programs.

Referrals

The Stark statute defines referral very broadly to include the request by a physician for an item or service. Regulations clarify that a physician does not make a referral when he or she personally performs a service. However, a service is not personally performed if it is provided by any other person, including but not limited to the referring physician’s employees, independent contractors, or group practice members. Stark prohibits referrals only if the physician has a financial relationship with the entity to which the referral is made. A financial relationship may consist of an ownership, investment interest, or a compensation arrangement that can be direct or indirect. An indirect financial relationship could arise, for example, if a physician has a contract with, or ownership in, an entity such as an imaging center that has a contract with a hospital to which the physician refers. An indirect ownership interest may pierce through several “holding companies” or layers of ownership established as an intermediary entity through which revenues obtained from referrals, for example, would be distributed to the physicians proportionally to their ownership interests and/or capital investment but not directly based on the volume of referrals.

The Stark regulations clarify that an indirect ownership interest will trigger Stark sanctions only if the entity furnishing the designated health services has actual knowledge of or acts in reckless disregard or deliberate ignorance of the fact that the referring physician (or an immediate family member) has some ownership or investment interest in the entity.¹¹⁰

Split Interpretation and Billing for Services

Billing for CT colonography services when a gastroenterologist furnishes the interpretation of the colonic images and a radiologist furnishes the interpretation of the extracolonic findings appears to be a complicated issue but could be accomplished in several ways. If a gastroenterologist refers the CT colonography to a radiology group or imaging center that bills for the service, and the gastroenterologist is compensated by the group/center for interpreting the colonic images, the gastroenterologist’s compensation would need to meet the Stark Personal Services or Fair Market Value exceptions. If the gastroenterologist is engaged by the group/center through the gastroenterologist’s group practice, the compensation would need to satisfy an indirect compensation arrangement analysis.¹¹¹ Unfortunately, there is no clear definition of “fair market value.” Physicians should not base rates on internally generated analyses,

and fair market values cannot be based on the volume or value of referrals to the physician. Each of the exceptions has additional technical requirements that would need to be satisfied and should be researched further prior to entering into a relationship.

If the gastroenterologist bills for the entire interpretation, but enters into an arrangement with a radiologist to perform a portion, the threshold Stark question is whether the radiologist is furnishing a designated health service. The conservative approach would be for the radiologist to be employed on a part-time basis by the gastroenterology group, or for the gastroenterologist to perform the entire interpretation with a radiologist "overread," so as to strengthen the argument that the radiologist has not in fact furnished a designated health service billed for by the group.

Currently, 2 category III current procedural terminology (CPT) codes (0066T, 0067T) could be used for CT colonography: 1 for screening studies and 1 for diagnostic. Category III codes are temporary codes used to track emerging technologies, services, and procedures.¹¹² Medicare does not set specific reimbursement criteria for these codes; therefore, payment for a category III code is up to the discretion of the specific carriers.¹¹³ The 2 existing codes capture the work associated with the interpretation of all images gathered from the study. No current CPT modifiers could be appropriately used to reflect a split interpretation by 2 different specialists. Therefore, it appears that the service must be billed by one of the 2 interpreting physicians, with the billing physician separately reimbursing the nonbilling physician for his or her interpretation service.

Split interpretation arrangements are potentially problematic because the Centers for Medicare & Medicaid Services-1500 claim form requires certification by the billing physician that "the services shown on this form . . . were personally furnished by (the billing physician) or were furnished incident to (his or her) professional service by (his or her) employee under . . . immediate personal supervision." In situations in which the billing physician interprets only a portion of the CT study, he or she may be falsely certifying that he or she furnished all services; this could be construed as a false claim.

A conservative approach to coding and reimbursement-related concerns would be for the gastroenterologist to perform an interpretation of all images and contract with the radiologist for an overread. The gastroenterologist could argue that he or she has "personally furnished" all of the services claimed. In a presumed split interpretation arrangement, the patient would be referred for the CT colonography by the gastroenterologist, who will bill for the interpretation and contract with the radiologist, on a fixed per-interpretation basis, to perform or overread the extracolonic image interpretation. This arrangement, however, potentially implicates the Federal Anti-kickback

Law because it could be alleged that the radiologist is providing remuneration in the form of discounted services in exchange for this referral or other unrelated referrals. Accurately defining "fair market value," therefore, is critical. Unfortunately, no statute or regulation defines "fair market value" under the Federal Anti-kickback Law. The gastroenterologist can minimize exposure under the kickback law by not setting lower fees for the split interpretation in return for the referral or the promise of other business that the radiologist could bill directly.

The only potentially applicable "safe harbor" for a compensation arrangement between the gastroenterologist and the radiologist in a split interpretation or overread arrangement is the personal services and management agreements safe harbor,¹¹⁴ an agreement in advance between 2 physicians that specifies the schedule and precise length of work to be furnished and the aggregate compensation paid over the term of the agreement. In developing such an agreement, the gastroenterologist and radiologist should consult with legal counsel and ensure that the agreement includes at least (1) a specific time frame, (2) the specifics of reimbursement, (3) the parameters of each physician's responsibility, (4) the basis for splitting the interpretation, (5) which physician is responsible for recommending additional diagnostic tests or consults with other specialists, and (6) which physician is responsible for communicating the interpretation results to the patient and for managing the patient's course of treatment.

Oversight

For diagnostic tests payable under the Medicare Physician Fee Schedule, CT studies without contrast require "general supervision." This stipulates that, although the physician's presence is not required during the performance of the procedure, the training of the nonphysician technician who actually performs the test and the maintenance of the necessary equipment and supplies are the continuing responsibility of the supervising physician. CT studies with contrast require "direct supervision," meaning the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the procedure.¹¹⁵

Risk Management Issues

Split interpretations also raise a risk management issue as to whether the gastroenterologist is clinically competent to read colonic and extracolonic images without assistance from a radiologist and, furthermore, whether the radiologist or the gastroenterologist could be held liable for the errors or omissions of the other in connection with their respective interpretations of the CT colonography source images.

The premise that a split interpretation is medically necessary, and indeed clinically preferable, is based on the twin assumptions that (1), although the radiologist is

presumptively qualified (as a matter of education and experience but also by community standard) to provide an interpretation of all source images, the gastroenterologist is qualified to interpret the colonic images and is arguably the more appropriate professional to conduct that portion of the review based on a combination of that physician's training and clinical knowledge of the particular patient; and (2), although the gastroenterologist may be competent to interpret the colonic images, the gastroenterologist may not be best qualified to interpret the extracolonic images absent specialized training and experience akin to that of a radiologist.

The second major risk management question posed by a split interpretation arrangement is whether the gastroenterologist could be held liable for an incorrect or incomplete interpretation of the radiologist. A further question is whether the physician who signs the report is affirming the other physician's interpretation and is therefore assuming any liability associated with that interpretation.

State laws governing medical malpractice determine whether and how physicians can be held liable for the errors and omissions of another physician and how any such liability will be apportioned. Regardless, a malpractice action alleging negligence based directly or indirectly on an interpretation of a set of images will typically include as defendants all physicians who played any role in interpreting those images. As such, there is little that can be done to reduce the risk of a gastroenterologist being named in a lawsuit that involves a split interpretation. To reduce the risk that the gastroenterologist will ultimately be held liable for the acts or omissions of the radiologist, it is recommended that each physician should sign a separate report: the gastroenterologist of his/her interpretation of the colonic images and the radiologist a report of his/her interpretation of the extracolonic images. The report form could include a statement indicating that the radiologist's interpretation is included therein but is not independently validated by the gastroenterologist. Although this might limit the gastroenterologist's potential liability for the professional negligence of the radiologist, this approach would increase the potential false certification and Stark risks as compared with an approach by which the gastroenterologist issues a single report that incorporates the radiologist's overread findings.

The education provided to the patient should expressly include the fact that both the gastroenterologist and the radiologist will be interpreting the images and the reasons therefore. The education should also identify for the patient which physician will discuss the results of the test with the patient and which physician will be in charge of any treatment decisions based on the interpretations.

A gastroenterologist who agrees to a split interpretation arrangement should prospectively consult with

his or her malpractice carrier to obtain guidance from the carrier concerning limitations of coverage relating to such services and whether such limitations could be different in a split interpretation vs an overread arrangement.

Task Force Recommendations

- Split interpretations of CT colonography are feasible under federal anti-kickback and Stark laws.
- Physicians entering into a split interpretation agreement should seek counsel to develop a written split interpretation agreement.
- Gastroenterologists and radiologists performing split interpretations should dictate and sign separate procedure reports that clearly state the specific services they performed related to CT colonography.
- Gastroenterologists considering offering CT colonography should consult with their health care counsel regarding compliance with state and local regulations.

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