

*Institute for Clinical and Economic Review
Scoping Committee and Evidence Review Group for CT Colonography(CTC)*

Conference Call Agenda

*Tuesday, July 31, 2007
12:00-1:00PM EDT*

*888-687-4838
passcode 64105550*

12:00-12:05	Introductions
12:05-12:15	ICER Background and Appraisal Process
12:15-12:50	Discussion of Key Questions
12:50-1:00	Closure and Next Steps

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Key Questions for Meeting One:

1. What are the primary clinical, delivery, coverage, and reimbursement questions whose answers will frame decisions around the use of CTC? For instance, should the assessment focus on CTC as:
 - a. An add-on option to colonoscopy for population-based screening?
 - b. A replacement for colonoscopy as routine first-line screening for all patients?
 - c. An integrated service with colonoscopy in the same clinical unit for same-session f/u of positive scans?
2. Should the assessment include consideration of adherence to screening recommendations, i.e. should we model any potential for CTC to increase screening on a population basis?
3. Are there particular patient sub-groups we should evaluate separately in the assessment?
4. What are the key patient outcomes and utilities we should consider?
 - a. Adverse effects of false positive CTC scans?
 - b. Side effects from and anxiety regarding sedation for colonoscopy?
 - c. Other?
5. What are the most important issues about the existing published data that the systematic review and assessment should take into consideration?
6. How should the importance of the size of the polyp (1-5mm , 6-9mm, >1cm) and the intervals for screening be reflected in the assessment?
7. How should the assessment consider the issues surrounding technical variability of CTC:
 - a. 2D vs 3D
 - b. Collimation
 - c. Imaging software that digitally removes all opaque fluid and stool from the image
8. Should non-adenomatous polyps be excluded or included as false positive results?
9. Should the economic model assume that patients with polyps identified via CTC receive future surveillance with CTC or with colonoscopy?
10. Should we include consideration of perforation rates associated with CTC?
11. Are there any key considerations to the costs that should or should not be included for CTC and colonoscopy, such as:
 - a. Anesthesia costs for colonoscopy
 - b. Further evaluation and management of incidental findings on CTC

OVERVIEW

CT Colonography

Introduction

CT colonography is a technique in which CT data are used to generate two and three-dimensional displays of the colon and rectum. First introduced in 1994, CTC continues to evolve rapidly, and now includes the use of software to enhance and clarify the images. Using a workstation and a dynamic display of images, a radiologist conducts virtual examinations of the bowel; the technique has thus often been known as “virtual colonoscopy.”

CTC has been suggested as an alternative or as complementary to conventional colonoscopy in population-based screening for colorectal cancer. While CTC requires a full bowel cleansing preparation and gas insufflation of the intestine similar to that necessary for conventional colonoscopy, no sedation is required and the exam is less time consuming (approximately 5-15 minutes; interpretation of the images can take 15-40 minutes). If a lesion or polyp is found on CTC a traditional colonoscopy is still needed at some future time in order to perform a biopsy or removal of the lesion.

At present, about 40% of eligible patients undergo recommended screening for colorectal cancer. Therefore some commentators have suggested that the speed and relative ease of virtual colonoscopy compared to conventional colonoscopy might enhance patient compliance with screening recommendations. Questions remain, however, about several important issues:

- 1) The sensitivity and specificity of CTC compared to conventional colonoscopy
- 2) Variation in performance across different providers and imaging modalities
- 3) Likely impact of CTC on population screening rates
- 4) Linkages between CTC and colonoscopy for removal of identified polyps
- 5) Management of incidental findings in lung, liver, and kidney
- 6) Cost and cost-effectiveness of CTC

Professional Organizations and Agency Recommendations:

- American College of Radiology (2002): Regarding CT colonography: “Early data suggest that these targeted examinations may be clinically valid. Large, prospective, multicenter trials are currently under way or in the planning phase to evaluate whether these screening exams reduce the rate of mortality.” In 2005 the ACR published indications for the use of CTC and included “as a screening examination in individuals who are at average or elevated risk for CTC or who have a first-degree relative with a history of CTC.”
- American Gastroenterological Association (2003): Virtual colonoscopy is not yet ready for widespread screening outside the research setting pending improvements in the technology, clinical studies of performance in average-risk patients and a better understanding of associated costs.

- America College of Gastroenterology (2002): The ACG has concluded that virtual colonoscopy based on CT or MRI is still in development, has not been established as a reliable screening test, and therefore is not endorsed for colorectal cancer screening.
- American Cancer Society (2003): The ACS Colorectal Cancer Advisory Group concluded that “CT colonography is a compelling, emerging technology that shows considerable promise, but it has not yet been studied in a typical screening population; therefore, whether or not it has comparable or superior performance compared with conventional tests is unknown.”

Recent Technology Assessments

- BCBSA TEC (2004): Failed criteria. The current evidence does not allow conclusions as to the comparative efficacy of CTC and colonoscopy.
- NICE (2005): Current evidence on the safety and efficacy of CTC appears adequate to support the use of this procedure.
- MSAC (2006): Evidence indicates that CTC is less effective and should not be proposed as a substitute for colonoscopy
- ICSI (2006): Due to the high number of extracolonic findings that require additional evaluation, additional studies are needed to determine if CTC can be an alternative to colonoscopy.

Coverage Policies

- Medicare Local Coverage Decisions cover CTC only for preoperative cancer staging or for failure of diagnostic colonoscopy. CTC is not reimbursable when used for screening.
- All private health plans evaluated for this overview cover CTC only for specific situations in which conventional colonoscopy is contra-indicated or has failed. Screening CTC is not covered by Aetna, Tufts, Regence, CIGNA, Harvard Pilgrim, Wellpoint.

Research in Progress

The American College of Radiology Imaging Network (ACRIN) is coordinating a large multicenter study to compare the effectiveness of CTC to conventional colonoscopy. The ACRIN trial is projected to enroll more than 2,300 patients at 15 sites nationwide during a 1-year accrual period. Study participants must be at least 50 years old, scheduled for a screening colonoscopy, and not had a colonoscopy in the past 5 years. Each study participant will have a CT colonography followed by a colonoscopy on the same day. Preliminary results are expected to be presented in the Fall of 2007.

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Scoping meeting participants:

John Ayanian, Department of Health Care Policy, Harvard Medical School

Marc Berger, Eli Lilly, Inc.

Robin Cisneros, Kaiser Permanente

Bill Corwin, Harvard Pilgrim Health Care

Wendy Everett, New England Healthcare Institute

Bob Fletcher, Department of Ambulatory Care and Prevention, Harvard Medical School

Peter Juhn, Johnson and Johnson

Katie Keysor, American College of Radiology

Ron Kikinis, Department of Radiology, Brigham and Women's Hospital

Amy Knudsen, Massachusetts General Hospital

TR Levin, Kaiser Permanente

Bob McDonough, Aetna

Peter Neumann, Center for the Evaluation of Value and Risk in Health, Tufts University

Steven Pearson, ICER

Lisa Prosser, Department of Ambulatory Care and Prevention, Harvard Medical School

Jim Sabin, Department of Ambulatory Care and Prevention, Harvard Medical School

Roberta Scherer, Cochrane Collaborating Center, Johns Hopkins

Paul Schroy, Department of Gastroenterology, Boston University School of Medicine

Uri Shreter, GE

Bill Taylor, Department of Ambulatory Care and Prevention, Harvard Medical School

Sean Tunis, Center for Medical Technology Policy

Sunny Virmani, Philips

Jed Weissberg, Kaiser Permanente

Fiona Wilmot, Blue Shield of California

Mike Zalis, Department of Radiology, Massachusetts General Hospital