



INSTITUTE FOR CLINICAL
SYSTEMS IMPROVEMENT

Health Care Guideline: Colorectal Cancer Screening

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- health plans, health systems, health care organizations, hospitals and integrated health care delivery systems;
- health care teaching institutions;
- health care information technology departments;
- medical specialty and professional societies;
- researchers;
- federal, state and local government health care policy makers and specialists; and
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Screening Algorithm

All algorithm boxes with an "A" and those that refer to other algorithm boxes link to annotation content.

Text in blue throughout the document also provides links.

Box 1: Criteria for average-risk screening
The patient meets the following criteria:

- 50 years or older, (if African American or American Indian, 45 years or older)
- No personal history of polyps and/or colorectal cancer
- No personal history of inflammatory bowel disease
- No family history of colorectal cancer in:
 - One first-degree relative diagnosed before age 60, or
 - Two first-degree relatives diagnosed at any age
- No family history of adenomatous polyps in:
 - One first-degree relative diagnosed before age 60

Box 2: Considerations for informed decision-making

- Performance characteristics and risks of screening test options
- Patient factors such as comorbidities and preference
- Cost of options to patient
- Availability of quality endoscopy and/or radiology
- Frequency of testing intervals and likelihood of compliance

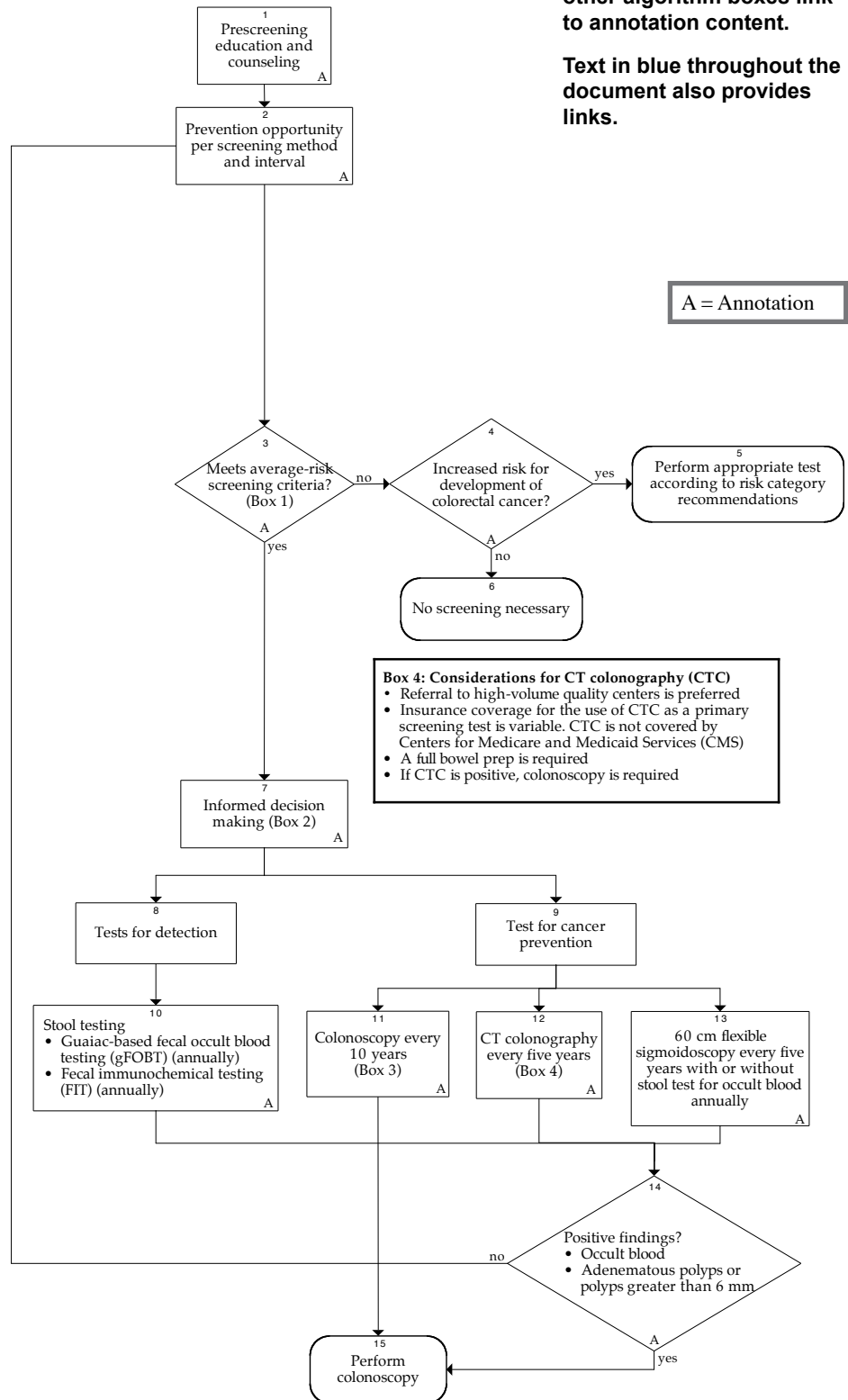
Box 3: Quality indicators for colonoscopy

- Cecal intubation rate of > 95%
- Mean withdraw times in patients without polypectomy or biopsy over 6 minutes
- Adenoma detection rates similar to community means
- Communication of time interval to next screening to patient and referring provider based on histologic findings

Box 4: Considerations for CT colonography (CTC)

- Referral to high-volume quality centers is preferred
- Insurance coverage for the use of CTC as a primary screening test is variable. CTC is not covered by Centers for Medicare and Medicaid Services (CMS)
- A full bowel prep is required
- If CTC is positive, colonoscopy is required

A = Annotation



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Foreword

The ICSI Colorectal Cancer Screening work group is a subgroup of the ICSI Preventive Services work group.

Scope and Target Population

This guideline addresses appropriate screening methodology for patients at average risk and increased risk for development of colorectal cancer.

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Clinical Highlights and Recommendations

Routine screening for individuals at average risk for colorectal cancer

- The patient meets the following criteria:
 - 50 years or older, or if African American or American Indian, 45 years or older
 - No personal history of polyps and/or colorectal cancer
 - No personal history of inflammatory bowel disease
 - No family history of colorectal cancer in:
 - one first-degree relative diagnosed before age 60, or
 - two first-degree relatives diagnosed at any age
 - No family history of adenomatous polyps in:
 - one first-degree relative diagnosed before age 60

(Annotation #3; Aim #1)

- Colorectal cancer screening is recommended for all patients 50 years of age and older – age 45 and older for African Americans or American Indians – using one of the following methods, based on joint decision-making by patient and provider:
 - Stool testing
 - Guaiac-based fecal occult blood testing (gFOBT) annually
 - Fecal immunochemical testing (FIT) annually
 - 60 cm flexible sigmoidoscopy every five years with or without stool test for occult blood annually
 - CT colonography every five years
 - Colonoscopy every 10 years

(Annotations #7, 10, 11, 12, 13; Aim #2)

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Priority Aims

1. Increase the rate of patients who are up-to-date with colorectal cancer screening. (*Annotation #3*)
2. Increase the rate of patients who have had appropriate screening for colorectal cancer using a screening test method discussed and agreed upon by both the patient and his/her physician. (*Annotation #7*)

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Key Implementation Recommendations

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

1. Establish processes for both identifying age-appropriate individuals who have not undergone appropriate screening and contacting these patients to encourage them to do so (examples may include chart reminders, computer-generated reminder letters, etc.).

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Related ICSI Scientific Documents

Guidelines

- [Preventive Services for Adults](#)

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Disclosure of Potential Conflict of Interest

ICSI has adopted a policy of transparency, disclosing potential conflict and competing interests of all individuals who participate in the development, revision and approval of ICSI documents (guidelines, order sets and protocols). This applies to all work groups (guidelines, order sets and protocols) and committees.

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No work group members have potential conflicts of interest to disclose.

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Introduction to ICSI Document Development

This document was developed and/or revised by a multidisciplinary work group utilizing a defined process for literature search and review, document development and revision, as well as obtaining and responding to ICSI members.

For a description of ICSI's development and revision process, please see the Development and Revision Process for Guidelines, Order Sets and Protocols at <http://www.icsi.org>.

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Evidence Grading System

A. Primary Reports of New Data Collection:

- Class A: Randomized, controlled trial
- Class B: Cohort study
- Class C: Non-randomized trial with concurrent or historical controls
Case-control study
Study of sensitivity and specificity of a diagnostic test
Population-based descriptive study
- Class D: Cross-sectional study
Case series
Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

- Class M: Meta-analysis
Systematic review
Decision analysis
Cost-effectiveness analysis
- Class R: Consensus statement
Consensus report
Narrative review
- Class X: Medical opinion

Citations are listed in the guideline utilizing the format of (*Author, YYYY [report class]*). A full explanation of ICSI's Evidence Grading System can be found at <http://www.icsi.org>.

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Algorithm Annotations

Screening Algorithm Annotations

1. Prescreening Education and Counseling

This guideline represents the work group's contribution to colorectal cancer screening and must be seen within the larger context of all preventive health activities. The work group acknowledges the important role played by education and outreach efforts in helping to increase the number of risk-appropriate individuals who present themselves for colorectal cancer screening, thereby increasing the rate of early detection of this disease.

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2. Prevention Opportunity per Screening Method and Interval

Nearly every patient contact for any reason should be used as a possible prevention opportunity. Relying upon routine "checkup" appointments for the delivery of these services will clearly miss many patients, especially those who may need them the most. A prevention opportunity may be any visit to a provider that provides the opportunity for conducting the screening process, a preventive services visit and outreach to patients who historically do not come in for visits. It is important to consider ways to remind patients of their need for these services at other times than during office visits.

Colorectal cancer screening is ranked as a Level I service in the ICSI Preventive Services for Adults guideline. A Level I service is a preventive service that providers and care systems must deliver (based on the best evidence).

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3. Meets Average-Risk Screening Criteria?

Since the term screening implies testing of asymptomatic individuals at average risk within the population, patients who are symptomatic or who have a history of gastrointestinal symptoms or disease may be excluded from this screening activity. Providers must make an individual decision on a case-by-case basis.

The best data available support screening starting at age 50. No older age limit has been clearly established, although 80 has been suggested. The decision to stop screening would clearly be influenced by comorbidities, patient preferences and expected life span (at least 8 to 10 years to warrant continued screening).

The patient meets the following criteria:

- 50 years or older, or if African American or American Indian, 45 years or older (*Agrawal, 2005 [R]; Perdue, 2008 [C]*)
- No personal history of polyps and/or colorectal cancer
- No personal history of inflammatory bowel disease (*Winawer, 2003 [R]*)
- No family history of colorectal cancer in:
 - one first-degree relative diagnosed before age 60 or
 - two first-degree relatives diagnosed at any age (*Fuchs, 1994 [B]*)
- No family history of adenomatous polyps in:
 - one first-degree relative diagnosed before age 60

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4. Increased Risk for Development of Colorectal Cancer?

Risk Category	Recommendation
One first-degree relative with either colorectal cancer or adenomatous polyps diagnosed before age 60 years	Colonoscopy every five years beginning at age 40 or 10 years before the age of the youngest case in the immediate family
Two or more first-degree relatives diagnosed at any age with colorectal cancer or adenomatous polyps	Colonoscopy every five years beginning at age 40 or 10 years before the age of the youngest case in the immediate family
First-degree relative with either colorectal cancer or adenomatous polyps at greater than or equal to 60 years, or two second-degree relatives with colorectal cancer	The work group recognizes this imposes an increased risk; however, due to lack of evidence supporting the screening recommendations, the work group does not support a recommendation in this category
Inflammatory bowel disease, chronic ulcerative colitis and crohn's disease	Colonoscopy every one to two years starting eight years after the onset of pancolitis or 12 to 15 years after the onset of left-sided colitis
Genetic diagnosis of FAP (familial adenomatous polyposis) or suspected FAP without genetic testing evidence	Annual flexible sigmoidoscopy beginning at age 10 to 12 years, along with genetic counseling
Genetic or clinical diagnosis of hereditary nonpolyposis colorectal cancer	Colonoscopy every one to two years beginning at age 20 to 25 years or 10 years before the age of the youngest case in the immediate family

* First-order relatives include only parents, siblings and children.

(Levin, 2008 [R]; Winawer, 2003 [R])

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7. Informed Decision-Making

Screening intervals apply to patients who are African American or American Indian age 45 or older and all others age 50 and older. These patients do not have clinical factors that place them at increased risk for colorectal cancer. The American College of Gastroenterology and the U.S. Multi-Society Task Force divide the colorectal cancer screening recommendations into "cancer prevention" and "cancer detection" tests. Cancer prevention tests (colonoscopy, flexible sigmoidoscopy or CT colonography) have the ability to detect colon cancer as well as precancerous polyps. The cancer detection tests (stool studies for presence of blood) have low sensitivity for polyps and lower sensitivity for cancer compared with the cancer prevention tests. Clinical groups may decide internally as to which screening pathway will be offered routinely at their site.

When a provider suggests a specific screening pathway for colorectal cancer screening, the patient should be involved in the decision. The patient should be shown the choices and should receive information and/or advice on what the test can and cannot prove. The patient should also be informed as to what the follow-up on a positive test might involve.

Evidence from randomized controlled studies alone is insufficient to determine which screening test (flexible sigmoidoscopy or fecal occult blood test) produces greater benefit (or if both are more beneficial than either alone). However, the value of either in detecting colorectal cancer or adenomatous polyps has been proven. At this time, the choice of using one (or both) of these tests should be based on the judgment of the clinician including informed patient choice. In particular, attention is directed to the high rate of false-positive fecal occult blood tests and the failure of flexible sigmoidoscopy alone to screen the entire colon. As yet unproven is which screening test leads to the most efficient and effective use of colonoscopy.

Fecal occult blood tests, even when combined with flexible sigmoidoscopy, fail to detect colorectal cancer in at least 24% of those with cancer (*Lieberman, 2001 [C]*).

The time interval for the development of malignant changes in adenomatous polyps is estimated at 5 to 25 years. Therefore, the work group has reached a conservative decision to recommend repeating the flexible sigmoidoscopy screening at five-year intervals. Some authors suggest that 10-year intervals would be adequate (*Selby, 1992 [C]*).

If the provider and patient desire an examination of the whole colon, this can be accomplished by either colonoscopy or CT colonography. The interval between examinations with colonoscopy is 10 years. The interval between examinations with CT colonography is five years. Neither of these strategies, however, is supported by direct evidence that they reduce mortality from colorectal cancer.

The recent American Cancer Society recommendations conclude that there is now sufficient data to include CT colonography as an acceptable option for colorectal cancer screening, and the recommended screening interval is every five years (*Lieberman, 2008 [R]*; *U.S. Preventive Services Task Force, 2008 [R]*).

Colonoscopy involves a higher risk of perforation than flexible sigmoidoscopy. If conscious sedation is used, there is risk of complications related to medication, as well as a requirement for a period of postprocedure recovery and providing a driver for transport home after the procedure (*Imperiale, 2000 [C]*; *Lieberman, 2000 [C]*).

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Tests for Cancer Detection

10. Stool Testing

Guaiac-Based Fecal Occult Blood Testing (gFOBT) Annually

There are currently two commercially available methods for testing stool for occult blood: the guaiac-based tests (gFOBT) and immunochemical-based tests (FIT). Guaiac-based tests detect hemoglobin through the pseudoperoxidase activity of heme. Therefore, these tests are not specific for lower intestinal bleeding or even for human blood. The immunochemical-based tests react to human globin and therefore do not require the same dietary restrictions recommended for the guaiac-based fecal occult blood testing. Stool tests for occult blood are designed to detect cancers that may bleed periodically. The goal is to detect these cancers at an early stage that is amenable to therapy and thereby decrease mortality from colorectal cancer. Stool tests are not particularly effective in detecting precancerous polyps, particularly those under 1 cm to 2 cm in size.

There have been prospective randomized controlled trials demonstrating that guaiac-based tests reduce mortality from colorectal cancer by 15% to 33% (*Hardcastle, 1996 [A]*; *Kronborg, 1996 [A]*; *Mandel, 1993 [A]*). The Minnesota Colon Cancer Control Study (*Mandel, 2000 [A]*) also noted a 20% decline in the incidence of colorectal cancer after 18 years of follow-up, presumably because of the detection and removal of polyps in those undergoing colonoscopy for evaluation of a positive stool guaiac test.

There is considerable variability reported in the literature on the sensitivity and specificity of available guaiac-based stool tests. The reported sensitivity for detecting colorectal cancer with a single guaiac-based stool test ranges from 12.9% to 79.4% (*Allison, 1996 [C]*; *Imperiale, 2004 [C]*). Tests with high sensitivity (such as Hemoccult SENSE) are preferred over lower sensitivity tests (such as Hemoccult II) to detect as many occult colorectal cancers as possible. Rehydration of guaiac-based fecal occult blood testing is not recommended because of the increase in false-positives and the impact hydration has on the ability to accurately read the test. Testing stool obtained on rectal exam is not an acceptable form of colorectal cancer screening as this has the potential to miss over 90% of colorectal cancers (*Collins, 2005 [C]*).

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Algorithm Annotations

Patients using a high-sensitivity guaiac-based fecal occult blood test are generally instructed to avoid non-steroidal anti-inflammatory medications and more than one aspirin per day for seven days prior to testing. To avoid false-positive results from dietary factors, the manufacturer of Hemoccult SENSE also recommends patients avoid red meat (beef, lamb and liver) for three days prior to testing and on the day of testing. In addition, vitamin C in excess of 250 mg per day should not be consumed for three days prior to testing or on the day of testing. Vitamin C can interfere with the pseudoperoxidase reaction, resulting in a false-negative test. Patients are instructed to collect two samples from three separate bowel movements for testing.

Advantages of guaiac-based fecal occult blood test are that it is readily available in most clinical settings and there is minimal risk to the patient when performing the test. Providers and patients need to be aware that studies demonstrating a reduction in colorectal cancer mortality with guaiac-based fecal occult blood testing followed a program of annual testing over an extended period of time with colonoscopic evaluation of all positive results. Patients choosing to do guaiac-based fecal occult blood test for colorectal cancer screening should do this annually and be willing to have a colonoscopy if any guaiac-based fecal occult blood testing is positive. Repeat stool testing after a positive guaiac-based fecal occult blood testing is not appropriate nor is follow-up with a test other than colonoscopy.

Fecal Immunochemical Testing (FIT) Annually

Immunochemical stool tests to detect occult blood in stool use one or more monoclonal antibodies to human globin. These tests were developed to try to improve the specificity of stool testing for occult blood and to eliminate the need for dietary restrictions recommended for guaiac-based tests. Because human hemoglobin is digested in the stomach and small intestine, fecal immunochemical testing is more selective for colonic bleeding than are the guaiac-based tests. There have not been any randomized controlled trials of the effects of fecal immunochemical testing on mortality from colorectal cancer. Levi 2007 in a study of 1,000 ambulatory patients undergoing colonoscopy reported a sensitivity of 94.1% and specificity of 87.5% of a quantitative fecal immunochemical testing for colorectal cancer. A study of almost 6,000 patients undergoing flexible sigmoidoscopy comparing fecal immunochemical testing with a high-sensitivity guaiac-based fecal occult blood testing (Hemoccult SENSE) found a sensitivity of 81.8% for fecal immunochemical testing and 64.3% for guaiac-based fecal occult blood testing for colorectal cancer. However, the sensitivity of guaiac-based fecal occult blood testing for advanced adenomas was 41.3%, as compared to a lower sensitivity of 29.5% for fecal immunochemical testing in the same study (*Allison, 2007 [C]*). Studies comparing fecal immunochemical testing to high-sensitivity guaiac-based fecal occult blood testing (*Allison, 2007 [C]*; *Gopalswamy, 1994 [C]*; *Greenberg, 2000 [C]*; *Levi, 2007 [D]*; *Smith, 2006 [C]*; *Wong, 2003 [C]*) have not found a significant difference in sensitivity or specificity between the two test methods.

The fecal immunochemical testing does not require dietary modification for patients and as with the guaiac-based test, is readily available in most clinical settings. These tests do not involve significant risk to the patient. However, just as with the guaiac-based tests, adherence to annual testing is necessary and patients with a positive test need to undergo colonoscopy.

This test employs immunochemical methods to test for blood in the stool. As it detects human globulin, this test is more specific and has low false-positive rates compared to the guaiac-based fecal occult blood test. For the same reason, the fecal immunochemical test does not yield false-negative results in the presence of high-dose vitamin C supplementation and is more specific for lower gastrointestinal bleeding (*Allison, 2007 [C]*).

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Tests for Cancer Prevention

11. Colonoscopy Every 10 Years

The majority of colorectal cancers are thought to develop from adenomatous polyps that evolve to cancers – the adenoma carcinoma sequence. Colonoscopy has the potential to prevent colon cancer by detecting and removing adenomatous polyps. Colonoscopy can be done as a primary screening test or to complete the evaluation of other positive colon cancer screening tests such as fecal occult blood tests or CT colonography. Colonoscopy is the only recommended test for screening in high-risk individuals or for surveillance in those with a history of colon cancer, adenomatous polyps or inflammatory bowel disease.

Evidence of the benefits of colonoscopy have been extrapolated from research on fecal occult blood testing and sigmoidoscopy (*Mandel, 2000 [A]; Selby, 1992 [C]*). The efficacy of colonoscopy in reducing colorectal cancer incidence after polypectomy was evaluated in The National Polyp Study, which reported a 76% to 90% reduction in the incidence of colorectal cancer in patients who underwent colonoscopy and polypectomy, compared with three reference cohorts (*Winawer, 1993a [M]*).

However, not all studies have shown that colonoscopy results in such a dramatic decrease in the incidence of colorectal cancer. Several factors have been identified that may account for decreased effectiveness of colonoscopy. These include poor bowel preparation, variations in tumor biology and the technical ability of the colonoscopist. Colonoscopies performed by proceduralists with poor technique may miss significant pathology. The effectiveness of colonoscopy to decrease the incidence of colorectal cancer depends on the quality of the examination.

Quality indicators for colonoscopy have been established by the American Society for Gastrointestinal Endoscopy and the U.S. Multi-Society Task Force on colorectal cancer screening (*Rex, 2006 [R]; Rex, 2002 [R]*).

Quality indicators that are measurable include cecal intubation rates, colonoscope withdrawal times and adenoma detection rates. Intubation of the cecum involves advancing the colonoscope beyond the ileocecal valve to allow the colonoscopist to see the medial wall of the cecum, between the ileocecal valve and the appendiceal orifice. The American Society for Gastrointestinal Endoscopy and U.S. Multi-Society Task Force guidelines recommend that a photograph of the appendiceal orifice and a photograph of the cecum from a position distal to the ileocecal valve be documented. Colonoscopists should be able to intubate the cecum in $\geq 95\%$ of cases that are performed on healthy adults undergoing a screening examination. The time taken to remove the colonoscope after the cecum has been intubated, excluding time for biopsies or polypectomy, is referred to as withdrawal time. The colonic mucosa should be carefully examined for polyps as the scope is withdrawn.

The American Society for Gastrointestinal Endoscopy recommends an average of at least six minutes to withdraw the scope in patients without previous surgery, with the caveat that application of this standard to an individual case is not appropriate as some colons can be examined adequately in less than six minutes. Adenoma detection rates vary among colonoscopists. Measurement of adenoma detection rates has been identified as a priority in the quality improvement process for colonoscopy (*Rex, 2006 [R]*). The American Society for Gastrointestinal Endoscopy and U.S. Multi-Society Task Force guidelines state that in healthy asymptomatic patients greater than or equal to 50 years of age undergoing screening colonoscopy, a colonoscopist should detect adenomas in greater than or equal to 25% of men and greater than or equal to 15% of women. Providers referring patients for colonoscopy should be familiar with the quality of the colonoscopist they recommend.

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12. CT Colonography Every Five Years

CT colonography (virtual colonoscopy) uses computed tomography and software algorithms to produce a radiologic view of the colon for cancer and polyp screening. It is less invasive than endoscopic screening, though still requires a full bowel preparation and insufflation of the colon with carbon dioxide for quality image acquisition. Intraluminal findings suggesting polyps or tumors are investigated by colonoscopy.

The colorectal cancer screening guideline developed in concert by the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology (*Levin, 2008 [R]*) includes CT colonography among its menu of tests for average-risk colorectal cancer screening. However, the U.S. Preventive Services Task Force does not currently endorse CT colonography, citing inadequate data on benefits and harms (*U.S. Preventive Services Task Force, 2008 [R]*).

Data is evolving on the performance characteristics of CT colonography. In 2003 Pickhardt et al. documented the most impressive performance of CT colonography among an asymptomatic population at an academic center (*Pickhardt, 2003 [C]*). Their study of over 1,200 average-risk asymptomatic adults demonstrated a 94% sensitivity for polyps measuring at least 1 cm. This was in contrast to Cotton and colleagues' community-based study that reported a sensitivity of only 55% for these large, high-malignant-potential polyps (*Cotton, 2004 [C]*).

Two meta-analyses of published CT colonography data from 2005 suggested a per-patient sensitivity for large polyps (greater than 10 mm) of 85%-93% and a specificity of 97%. The cumulative sensitivity for invasive colorectal cancer was 96% (*Halligan, 2005 [M]*; *Mulhall, 2005 [M]*).

In 2008 the American College of Radiology Imaging Network (ACRIN) Study 6664 evaluated the performance of CT colonography among 2600 asymptomatic patients at 15 academic centers (*Johnson, 2008 [C]*). While this highly experienced cohort of radiologists demonstrated 90% sensitivity and 86% specificity for large polyps (> 10 mm) and cancer, the per-patient positive predictive value was only 23%; therefore, 77% of individuals thought to have a large polyp by CT did not have polyps at colonoscopy. Performance characteristics for smaller polyps was lower, with a 78% sensitivity and 88% specificity for polyps greater than or equal to 6 mm.

A major difference between these studies was the experience of the radiologists; whereas those in the Pickhardt et al. and ACRIN trials came from academic groups where they were required to demonstrate proficiency in reading CT colonographs, those in the Cotton et al. trial were community-based radiologists who had limited formal CT colonography training or experience. Although the performance characteristics of CT colonography are clearly dependent on radiologist experience, rigorous certification programs and quality measures are currently lacking and being developed.

Lack of payer coverage is another challenge limiting the use of CT colonography. In 2009 the Centers for Medicaid and Medicare Services made the decision not to reimburse for screening CT colonography on the grounds that data was inadequate to conclude it to be an appropriate screening test. Private insurance coverage for CT colonography is also very sparse throughout most of the United States. Other challenges include the following:

- Limited availability of the test
- Inadequate data on the implications of ignoring polyps less than 5 mm in size as is done by most centers
- Concerns that the technology has difficulty identifying flat and depressed polyps, which are thought to have a higher malignant potential than polypoid polyps and whose prevalence may exceed 5% of the screening population (*Soetikno, 2008 [D]*)
- CT colonography may not be cost effective compared to other strategies, especially when extra-colonic findings are considered (*Vijan, 2007 [M]*)

- Concerns over the radiation risk accumulated through recurrent abdominal and pelvic scans (*Smith-Bindman, 2009 [D]*)

However, CT colonography may be the best total colonic imaging examination in the following clinical situations: after incomplete screening or diagnostic colonoscopy, for anticoagulated patients who cannot safely discontinue anticoagulation therapy, and for patients who refuse endoscopy. In such scenarios, referral to an experienced center may be appropriate if patient cost is not a barrier.

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13. 60 cm Flexible Sigmoidoscopy Every Five Years with or without Stool Test for Occult Blood Annually

Case-controlled trials of flexible sigmoidoscopy have demonstrated a 60% to 80% reduction in colorectal cancer mortality (*Newcomb, 1992 [C]*; *Selby, 1992 [C]*). There are ongoing prospective randomized controlled trials of screening flexible sigmoidoscopy, but the final results are not yet available (*Gondal, 2003 [A]*; *Segnan, 2002 [A]*; *UK Flexible Sigmoidoscopy Screening Trial Investigators, 2002 [A]*; *Weissfeld, 2005 [A]*). Flexible sigmoidoscopy can detect colorectal cancer and adenomatous polyps to the level of insertion of the scope. It is recommended that the scope be inserted to the splenic flexure or beyond 40 cm for the exam to be considered adequate (*Levin, 2008 [R]*).

Patients who have adenomas of any size found at the time of sigmoidoscopy should undergo full colonoscopy because left-sided adenomatous polyps are associated with an increased risk of more proximal polyps or cancers (*Imperiale, 2000 [C]*; *Lieberman, 2001 [C]*). Recent recommendations by the American Cancer Society state that endoscopists performing flexible sigmoidoscopy should be skilled in obtaining biopsies of polyps, or if biopsies are not obtained, all patients with polyps greater than 5 mm should be further evaluated with full colonoscopy (*Levin, 2008 [R]*). The consensus of this work group was that all patients with polyps not completely removed at the time of sigmoidoscopy should undergo colonoscopy.

The accuracy of flexible sigmoidoscopy, as well as colonoscopy, is dependent on the training and skill of the endoscopist, as well as the quality of the bowel preparation. It is recommended that providers exceed the minimum number of training exams delineated in the American Society for Gastrointestinal Endoscopy guidelines before conducting flexible sigmoidoscopies without supervision (*Levin, 2008 [R]*; *Levin, 2005 [R]*). Studies comparing flexible sigmoidoscopy to colonoscopy have found that the shorter exam is 60% to 70% sensitive for colorectal cancer and advanced adenomas, as compared to the complete exam. Providers and patients should be aware that some patient populations have a higher prevalence of right-sided lesions. Significant lesions are more common in the proximal or right colon after the age of 65 (*Levin, 1999 [D]*). Women are more likely to have proximal or right-sided adenomas or colorectal cancer than are men (*Schoenfeld, 2005 [B]*). Ethnicity may also affect the distribution of lesions in the colon. African Americans may have more proximal lesions as compared to Whites (*Nelson, 1997 [C]*). Whites may have more proximal lesions when compared with Hispanics and Asians (*Francois, 2006 [D]*; *Theuer, 2001 [C]*). Those groups at higher risk of proximal lesions may benefit from visualization of the entire colon with colonoscopy or CT colonography rather than flexible sigmoidoscopy.

Flexible sigmoidoscopy can be performed alone as a screening test every five years or combined with annual stool occult blood testing, either guaiac-based fecal occult blood testing or fecal immunochemical testing. If the combination of the two tests is chosen by the patient and his/her provider, it is preferable to do the stool occult blood testing first. If a positive stool test is detected, the patient should go directly to colonoscopy, thereby avoiding an unnecessary sigmoidoscopy.

Patients should be aware of the limitations of flexible sigmoidoscopy. Only the left side of the colon will be seen with flexible sigmoidoscopy. In most clinical practices, flexible sigmoidoscopy is performed as an office procedure without sedation. This can be associated with some discomfort during and after the exam

(Zubarik, 2002 [B]). However, some patients may prefer an exam without sedation so that they can drive or return to work after the procedure. Flexible sigmoidoscopy does require the use of a bowel prep. The risk of colonic perforation with sigmoidoscopy without biopsy or polypectomy is less than 1 in 20,000 (Levin, 2002 [B]; UK Flexible Sigmoidoscopy Screening Trial Investigators, 2002 [A]). Lesions can be missed on sigmoidoscopy, and advanced neoplasia has been found within three years of an exam in published studies (Schoen, 2003 [R]). Patients should understand that finding polyps on a flexible sigmoidoscopy will result in the need for colonoscopy.

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14. Positive Findings?

A positive guaiac-based fecal occult blood test or fecal immunochemical test require further evaluation with colonoscopy. Use of another screening modality such as repeating a stool test, flexible sigmoidoscopy or CT colonography is not appropriate.

A positive finding on flexible sigmoidoscopy would be an adenomatous polyp of any size and would warrant further evaluation with colonoscopy (Imperiale, 2000 [C]; Lieberman, 2001 [C]). From the standpoint of colorectal cancer screening, diverticula and small left-sided hyperplastic polyps are not precursors to cancer and do not need further evaluation. Large hyperplastic polyps proximal to the splenic flexure may be precursors to cancer, and additional follow-up may be warranted (Ferrández, 2004 [D]; Huang, 2004 [R]). There are currently no published or society-endorsed guidelines regarding follow-up of concerning hyperplastic polyps. Characteristics of hyperplastic polyps that should raise concern are multiple hyperplastic polyps proximal to the sigmoid colon, large size (greater than 10 mm – as a frame of reference, most biopsy forceps open to a width of 7 mm), a family history of hyperplastic polyposis syndrome or a family history of colorectal cancer. Follow-up of these patients at this time is individualized but should be at least as aggressive as follow-up for patients with adenomatous polyps (Snover, 2005 [R]).

The American Cancer Society guidelines recommend colonoscopy for any patient with a polyp of 6 mm or greater size (Levin, 2008 [R]). Clinicians should be aware that radiologists do not usually report polyps less than or equal to 5 mm by CT colonography, although there is no multidisciplinary consensus regarding the reporting and management of these small polyps. Clinicians should also be aware that CT colonography provides technically limited images of the entire abdomen and pelvis; therefore, a positive finding outside of the colon (extracolonic) may require additional evaluation even though the colon test is negative.

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Brief Description of Evidence Grading

Individual research reports are assigned a letter indicating the class of report based on design type: A, B, C, D, M, R, X.

A full explanation of these designators is found in the Foreword of the guideline.

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This section provides resources, strategies and measurement specifications for use in closing the gap between current clinical practice and the recommendations set forth in the guideline.

The subdivisions of this section are:

- Priority Aims and Suggested Measures
 - Measurement Specifications
- Key Implementation Recommendations
- Knowledge Resources
- Resources Available

Priority Aims and Suggested Measures

1. Increase the rate of patients who are up-to-date with colorectal cancer screening.

Possible measures for accomplishing this aim:

- a. Percentage of patients age 50 and older who are up-to-date with colorectal cancer screening.
- b. Percentage of African American or American Indian patients age 45 and older who are up-to-date with colorectal cancer screening.

2. Increase the rate of patients who have had appropriate screening for colorectal cancer using a screening test method discussed and agreed upon by both the patient and his/her physician.

Possible measure for accomplishing this aim:

- a. Percentage of adult patients with documentation that one of the following screening methods was performed:
 - Fecal occult blood test yearly
 1. Annual guaiac-based fecal occult blood test with high test sensitivity for cancer, or
 2. Annual fecal immunochemical test with high test sensitivity for cancer
 - Flexible sigmoidoscopy every five years
 - Computed tomographic colonography every five years
 - Colonoscopy every 10 years

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Measurement Specifications

Possible Success Measure #1a

Percentage of patients who meet criteria for colorectal cancer screening who are up-to-date with screening.

Population Definition

Patients age 50 and older.

Data of Interest

Denominator: Number of patients who meet criteria for colorectal cancer screening who were up-to-date with screening at the time of their last visit.

Numerator: Patients in the denominator, having one or more of the following screenings:

- Fecal occult blood test yearly
 1. Annual guaiac-based fecal occult blood test with high test sensitivity for cancer, or
 2. Annual fecal immunochemical test with high test sensitivity for cancer
- Flexible sigmoidoscopy every five years
- Computed tomographic colonography every five years
- Colonoscopy every 10 years

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Priority Aims and Suggested Measures

Possible Success Measure #1b

Percentage of African American or American Indian patients age 45 and older who are up-to-date with colorectal cancer screening.

Population Definition

African American or American Indian patients age 45 and older.

Data of Interest

Denominator: # of African American or American Indian patients age 45 and older who were up-to-date with colorectal cancer screening at the time of their last visit

Numerator: Patients in the denominator, having one or more of the following screenings:

- Fecal occult blood test yearly
 1. Annual guaiac-based fecal occult blood test with high test sensitivity for cancer, or
 2. Annual fecal immunochemical test with high test sensitivity for cancer
- Flexible sigmoidoscopy every five years
- Computed tomographic colonography every five years
- Colonoscopy every 10 years

Method/Source of Data Collection

A random sample of at least 10 patient medical records per month. The status of the individuals is most likely collected with chart abstract data. However, an individual's status may be collected with administrative data and augmented with chart abstraction.

A lack of data on an individual is interpreted as not up-to-date and is not counted in the numerator but is included in the denominator.

Notes

The goal of this measure is to determine up-to-date status of those seen. It will not measure those not seen by a medical group.

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Key Implementation Recommendations

The following system change was identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

1. Establish processes for both identifying age-appropriate individuals who have not undergone appropriate screening and contacting these patients to encourage them to do so (examples may include chart reminders, computer-generated reminder letters, etc.).

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Knowledge Resources

Criteria for Selecting Resources

The following resources were selected by the Colorectal Cancer Screening guideline work group as additional resources for providers and/or patients. The following criteria were considered in selecting these resources.

- The site contains information specific to the topic of the guideline.
- The content is supported by evidence-based research.
- The content includes the source/author and contact information.
- The content clearly states revision dates or the date the information was published.
- The content is clear about potential biases, noting conflict of interest and/or disclaimers as appropriate.

Resources Available to ICSI Members Only

ICSI has a wide variety of knowledge resources that are *only* available to ICSI members (these are indicated with an asterisk in far left-hand column of the Resources Available table). In addition to the resources listed in the table, ICSI members have access to a broad range of materials including tool kits on CQI processes and Rapid Cycling that can be helpful. To obtain copies of these or other Knowledge Resources, go to http://www.icsi.org/improvement_resources. To access these materials on the Web site, you must be logged in as an ICSI member.

The resources in the table on the next page that are not reserved for ICSI members are available to the public free-of-charge.

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Resources Available

*	Author/Organization	Title/Description	Audience	Web sites/Order Information
	American Cancer Society	American Cancer Society: Provides the public with accurate, up-to-date information on cancer.	Health Care Professionals; Patients and Families	http://www.americancancersociety.org
	Centers for Disease Control	Centers for Disease Control: CDC promotes colorectal cancer (cancer of the colon and rectum) prevention by building partnerships, encouraging screening, supporting education and training, and conducting surveillance and research.	Health Care Professionals; Patients and Families	http://www.cdc.gov
	Founding members include the Minnesota Medical Association and seven non-profit Minnesota health plans: Blue Cross and Blue Shield of Minnesota/Blue Plus, First Plan of Minnesota, HealthPartners, Medica, Metropolitan Health Plan, PreferredOne and UCare.	MN Community Measurement: MN Community Measurement is Minnesota's source for information on health care quality.	Health Care Professionals; Patients and Families	http://www.mncm.org
	Mayo Clinic	Mayo Clinic: Mayo Clinic is the first and largest integrated, not-for-profit group practice in the world.	Health Care Professionals; Patients and Families	http://www.mayoclinic.org/colon-cancer/
	The National Comprehensive Cancer Network	The NCCN, a not-for-profit alliance of 21 of the world's leading cancer centers, is dedicated to improving the quality and effectiveness of care. Provided to patients with cancer.	Health Care Professionals; Patients and Families	http://www.nccn.org
	National Guideline Clearinghouse	NGC: Public resource for evidence-based clinical practice guidelines.	Health Care Professionals; Patients and Families	http://www.guideline.gov

* Available to ICSI members only.

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Resources Available

*	Author/Organization	Title/Description	Audience	Web sites/Order Information
	National Institute of Health	The National Cancer Institute: Coordinates the National Cancer Program, which conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients.	Health Care Professionals	http://www.cancer.gov
*	Park Nicollet Health Systems	Park Nicollet Health Systems: This is a pamphlet containing information around colorectal cancer screening and why it is important for patients to be appropriately screened.	Patients and Families	http://www.icsi.org
	U.S. Preventive Services Task Force	USPSTF: Independent panel of experts in primary care and prevention that systematically reviews the evidence of effectiveness and develops recommendations for clinical preventive services.	Health Care Professionals; Patients and Families	http://www.ahrq.gov

* Available to ICSI members only.

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