ICSI Institute for Clinical Systems Improvement

Health Care Guideline

Colorectal Cancer Screening

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Health Care Guideline:
Colorectal Cancer Screening

Fourteenth Edition
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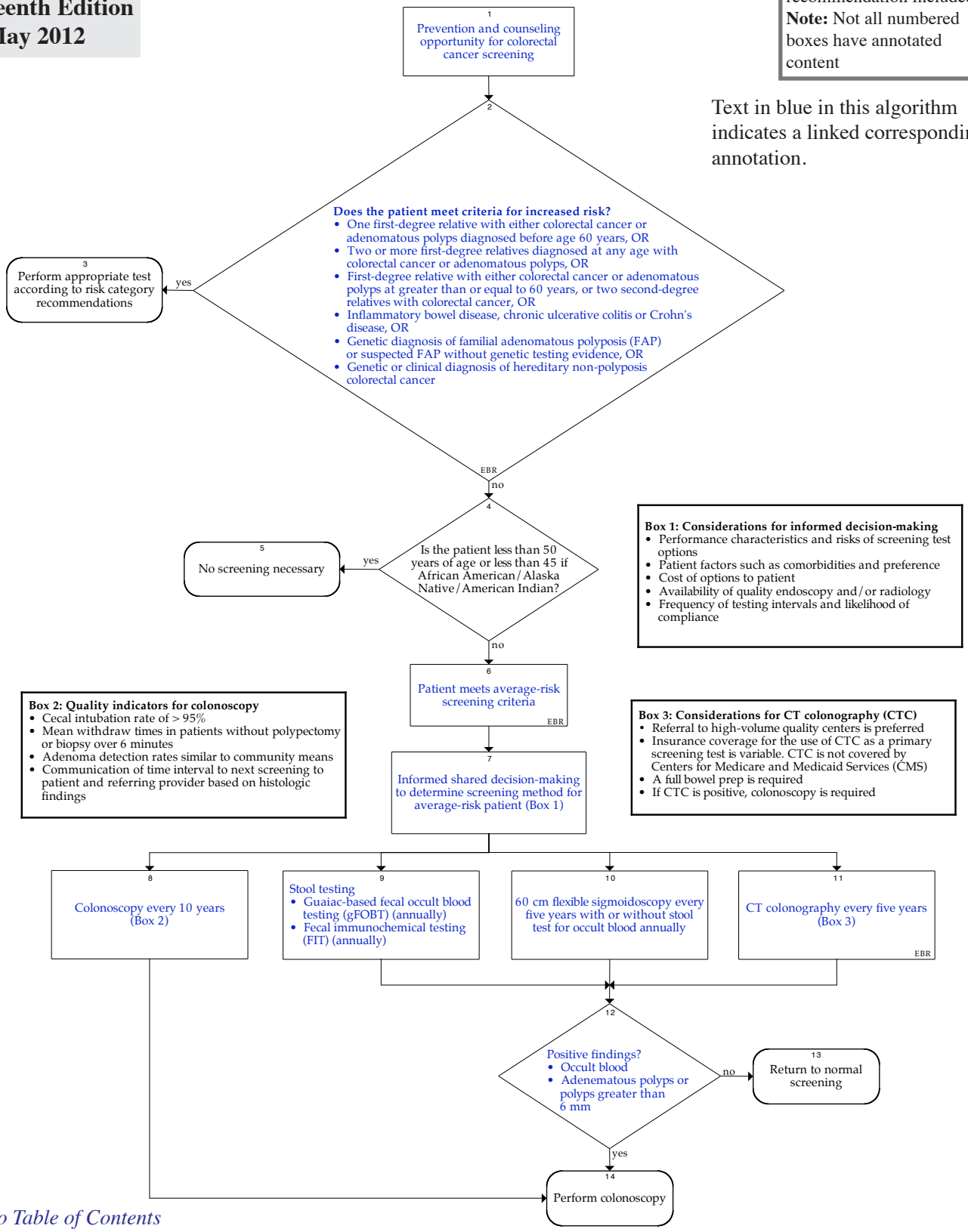
Screening Algorithm

EBR = Evidence-based recommendation included
Note: Not all numbered boxes have annotated content

Text in blue in this algorithm indicates a linked corresponding annotation.



Box 1: 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 2: 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 3: 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

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Evidence Grading

Literature Search

A consistent and defined process is used for literature search and review for the development and revision of ICSI guidelines. The literature search was divided into two stages to identify systematic reviews, (stage I) and randomized controlled trials, meta-analysis and other literature (stage II). Literature search terms used for this revision are below and include literature from January 2010 through November 2011.

The Cochrane and Pub Med databases were searched. The search was limited to screening tests only and did not include diagnostic testing. The search terms included fecal immunochemical test, colonoscopy, fecal occult blood test, flexible sigmoidoscopy and CT colonography.

GRADE Methodology

Following a review of several evidence rating and recommendation writing systems, ICSI has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

GRADE has advantages over other systems including the current system used by ICSI. Advantages include:

- developed by a widely representative group of international guideline developers;
- explicit and comprehensive criteria for downgrading and upgrading quality of evidence ratings;
- clear separation between quality of evidence and strength of recommendations that includes a transparent process of moving from evidence evaluation to recommendations;
- clear, pragmatic interpretations of strong versus weak recommendations for clinicians, patients and policy-makers;
- explicit acknowledgement of values and preferences; and
- explicit evaluation of the importance of outcomes of alternative management strategies.

In the GRADE process, evidence is gathered related to a specific question. Systematic reviews are utilized first. Further literature is incorporated with randomized control trials or observational studies. The evidence addresses the same population, intervention, comparisons and outcomes. The overall body of evidence for each topic is then given a quality rating.

Once the quality of the evidence has been determined, recommendations are formulated to reflect their strength. The strength of a recommendation is either strong or weak. Only outcomes that are critical are considered the primary factors influencing a recommendation and are used to determine the overall strength of this recommendation. Each recommendation answers a focused health care question.

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Category	Quality Definitions	Strong Recommendation	Weak Recommendation
High Quality Evidence	Further research is very unlikely to change our confidence in the estimate of effect.	The work group is confident that the desirable effects of adhering to this recommendation outweigh the undesirable effects. This is a strong recommendation for or against. This applies to most patients.	The work group recognizes that the evidence, though of high quality, shows a balance between estimates of harms and benefits. The best action will depend on local circumstances, patient values or preferences.
Moderate Quality Evidence	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.	The work group is confident that the benefits outweigh the risks, but recognizes that the evidence has limitations. Further evidence may impact this recommendation. This is a recommendation that likely applies to most patients.	The work group recognizes that there is a balance between harms and benefit, based on moderate quality evidence, or that there is uncertainty about the estimates of the harms and benefits of the proposed intervention that may be affected by new evidence. Alternative approaches will likely be better for some patients under some circumstances.
Low Quality Evidence	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change. The estimate or any estimate of effect is very uncertain.	The work group feels that the evidence consistently indicates the benefit of this action outweighs the harms. This recommendation might change when higher quality evidence becomes available.	The work group recognizes that there is significant uncertainty about the best estimates of benefits and harms.

Supporting Literature

In addition to evidence that is graded and used to formulate recommendations, additional pieces of literature are used to direct the reader to other topics of interest. This literature is not given an evidence grade and is instead used as a reference for its associated topic. These citations are noted by *(author, year)* and are found in the references section of this document.

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Recommendations Table

The following table is a list of evidence-based recommendations for the Colorectal Cancer Screening guideline.

Note: Other recommendation language may appear throughout the document as a result of work group consensus but is not included in this evidence-based recommendations table.

Topic	Quality of Evidence	Recommendation(s)	Strength of Recommendation	Annotation Number	Relevant References
Average risk screening	High	Colorectal cancer screening is recommended for all patients 50 years of age and older – age 45 and older for African Americans or American Indians/Alaska Natives – using one of the following methods, based on joint decision-making by patient and clinician: • Guaiac-based fecal occult blood testing (gFOBT) annually, OR • Fecal immunochemical testing (FIT) annually, OR • 60 cm flexible sigmoidoscopy every five years with or without stool test for occult blood annually, OR • Colonoscopy every 10 years	Strong	6	*(Perdue, 2008; U.S. Preventive Services Task Force, 2008; Agrawal, 2005; Winawer, 2003; Fuch, 1994)*
CT colonography	Low	CT colonography may be an option for colorectal cancer screening in the following clinical situations: after incomplete screening or diagnostic colonoscopy, for anticoagulated patients who cannot safely discontinue anticoagulation therapy.	Weak	11	*(Smith-Bindman 2009; Johnson, 2008; Levin, 2008; Soetikno, 2008; Cotton, 2004; Pickhardt, 2003)*
Increased risk screening	High	Colonoscopy should be offered at age 40 or 10 years before the age of the youngest case in the immediate family for the following individuals: • Patients with one first-degree relative with either colorectal cancer or adenomatous polyps diagnosed before age 60 years • Patients with two or more first-degree relatives diagnosed at any age with colorectal cancer or adenomatous polyps. Colonoscopy should be offered 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. Colonoscopy should be offered 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 of genetic or clinical diagnosis of hereditary non-polyposis colorectal cancer.	Strong	2	*(Levin, 2008; U.S. Preventive Services Task Force, 2008; Winawer, 2003)*

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Foreword

Introduction

Colorectal cancer is the third most commonly diagnosed cancer in males and the second in females, with over 1.2 million new cases and 608,700 deaths estimated to have occurred in 2008 *(Jemal, 2011)*. Rates are substantially higher in males than in females.

In the United States, both the incidence and mortality have been slowly but steadily decreasing. Annually, approximately 143,460 new cases of large bowel cancer are diagnosed, of which 103,170 are colon and the remainder rectal cancers *(Siegel, 2012)*. Annually, approximately 51,690 Americans die of colorectal cancer, accounting for approximately nine percent of all cancer deaths.

Most cases of colorectal cancer occur in average-risk individuals (those without a family or predisposing medical history), and increasing age, male sex and black race are associated with increased incidence *(Jackson-Thompson, 2006)*. People at higher risk of developing colorectal cancer should begin screening at a younger age and may need to be tested more frequently. The decision to be screened after age 75 should be made on an individual basis *(U.S. Preventive Services Task Force, 2008)*.

Colorectal screening recommendations are modified for members of hereditary colon cancer syndromes, on the basis of personal or family history of colorectal cancer or adenomas and in patients with inflammatory bowel disease. African Americans have the highest rates of colorectal cancer among all ethnic groups in the United States. Colorectal cancer mortality is about 20% higher in African Americans than it is in Caucasians *(Jemal, 2008)*. Additional risk factors include smoking, obesity, coronary artery disease, diabetes mellitus, acromegaly, renal transplantation and cholecystectomy; however, they do not alter screening recommendations.

Health care clinicians may suggest one or more tests for colorectal cancer screening, including a fecal immunochemical test (FIT), fecal occult blood test (FOBT), flexible sigmoidoscopy, colonoscopy or virtual colonoscopy. Because colorectal cancer screening tests have potential harms, limited accessibility or imperfect acceptability to patients, and no tests could be identified as superior in cost-effectiveness analysis *(Pignone, 2002)*, it is recommended that the choice among recommended methods for colorectal cancer screening be individualized to patients or practice settings *(U.S. Preventive Services Task Force, 2002)*.

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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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Aims

1. Increase the rate of patients who are up-to-date with colorectal cancer screening. *(Annotation #6)*
2. Increase the rate of patients who have had a shared decision-making conversation about colorectal cancer screening tests. *(Annotation #7)*

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Clinical Highlights

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/Alaska Native, 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 #6; 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/Alaska Natives – using one of the following methods, based on joint decision-making by patient and clinician:
  - 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

(Annotation #6; Aim #2)

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Implementation Recommendation Highlights

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

- 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).

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Related ICSI Scientific Documents

Guidelines

- Preventive Services for Adults

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Definition

Clinician – All health care professionals whose practice is based on interaction with and/or treatment of a patient.

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Algorithm Annotations

Screening Algorithm Annotations

1. Prevention and Counseling Opportunity for Colorectal Cancer Screening

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.

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 clinician 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 clinicians and care systems must deliver (based on the best evidence).

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2. Does the Patient Meet Criteria for Increased Risk?

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 familial adenomatous polyposis (FAP) 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; U.S. Preventive Services Task Force, 2008; Winawer, 2003)

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6. Patient Meets Average-Risk Screening Criteria

Recommendation:

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

(High quality evidence, Strong recommendation)

Stool tests for colon cancer screening include fecal immunochemical test (FIT) and fecal occult blood test (FOBT). The main feature of these tests is that no sedation or bowel preparation is needed. These tests are safe, and there is no direct risk to the colon. These tests are fairly inexpensive, and sampling can be done at home annually. The limitations of these tests are that many polyps and some cancers may be missed. Polyps cannot be removed and therefore, if abnormal, colonoscopy will be needed. Both tests can produce false-positive results. Fecal occult blood test (FOBT) has pre-test dietary limitations, which is not true for tecal immunochemical test (FIT). These tests may be the only screening method in some population subgroups due to personal and cultural values.

The recommendation for 60 cm flexible sigmoidoscopy every five years places a relatively high value on direct visualization of the colon as a method of colon cancer detection, as well as the limited bowel preparation and lack of sedation required for the exam. This recommendation places a relatively low value on the partial view of the colon and the potential to miss polyps on the right side of the colon. The effectiveness of this recommendation assumes 100% adherence to the screening interval.

The recommendation for colonoscopy every 10 years places a relatively high value on the direct visualization of the colon as a method of colon cancer detection. This requires bowel preparation and sedation for the exam. There is potential to miss small polyps in the colon. The effectiveness of colonoscopy also depends on the quality of the bowel prep. This is the only screening test that provides visualization of the entire colon along with the ability to remove polyps and take biopsies.

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. Clinicians 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/Alaska Native 45 years or older *(Perdue, 2008; Agrawal, 2005)*
- No personal history of polyps and/or colorectal cancer
- No personal history of inflammatory bowel disease *(Winawer, 2003)*

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- 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)*
- No family history of adenomatous polyps in:
  - one first-degree relative diagnosed before age 60

(U.S. Preventive Services Task Force, 2008)

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7. Informed Shared Decision-Making to Determine Screening Method for Average-Risk Patient

Screening intervals apply to patients who are African American or American Indian/Alaska Natives 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 clinician 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.

Shared decision-making can be accomplished between patients and clinicians either on a one-on-one encounter basis or by adopting a team-based approach. Care teams utilize available resources within the health care facility or community, thus allowing appropriate use of clinicians' time in achieving this objective.

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)*.

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)*.

If the clinician 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.

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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; U.S. Preventive Services Task Force, 2008)*.

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; Lieberman, 2000)*.

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8. Colonoscopy Every 10 Years

The main complications of colonoscopy are perforation, bleeding and postpolypectomy syndrome. Perforation risk from colonoscopy is 3.8 per 10,000 in the United States. Polypectomy is the most common cause of bleeding during or after the colonoscopy. This occurs in approximately 1.5 to 3% of patients who undergoing polypectomy *(Rosen, 1993)*.

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; Selby, 1992)*. 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)*. There is a protective effect of colonoscopy to reduce colon cancer deaths through polyp detection and removal. Mortality from colorectal cancer was 53% lower among patients who had undergone colonoscopy and had adenomas removed *(Zauber, 2012)*.

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 decreasd 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; Rex, 2002)*.

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 ≥ 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

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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)*. 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. Clinicians referring patients for colonoscopy should be familiar with the quality of the colonoscopist they recommend.

(U.S. Preventive Services Task Force, 2008)

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9. Stool Testing

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. Continued stool testing is not recommended after a negative finding on a colonoscopy or CT colonography. While stool collection and gFOBT or FIT have sometimes been performed as part of a digital test in the office research has demonstrated that the sensitivity of in-office sampling is so low that its use should be discouraged *(Levin, 2008; Collins, 2005)*.

Guaiac-Based Fecal Occult Blood Testing (gFOBT) Annually

There have been prospective randomized controlled trials demonstrating that guaiac-based tests reduce mortality from colorectal cancer by 15 to 33% *(Hardcastle, 1996; Kronborg, 1996; Mandel, 1993)*. The Minnesota Colon Cancer Control Study *(Mandel, 2000)* 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% *(Imperiale, 2004; Allison, 1996)*. Tests with high sensitivity (such as Hemoccult SENSA) 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)*.

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 SENSA 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. Clinicians and patients need to be aware

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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.

(U.S. Preventive Services Task Force, 2008)

Fecal Immunochemical Testing (FIT) Annually

If available, FIT is preferred over guaiac-based fecal occult blood testing. 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 SENSA) 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)*. Studies comparing fecal immunochemical testing to high-sensitivity guaiac-based fecal occult blood testing *(Allison, 2007; Levi, 2007; Smith, 2006; Wong, 2003; Greenberg, 2000; Gopalswamy, 1994)* 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, is more specific for lower gasterointestional bleeding, and is therefore preferred over gFOBT as a screening test (*Allison, 2007)*.

(U.S. Preventive Services Task Force, 2008)

The interim report of a study comparing colonoscopy versus fecal immunochemical testing in colorectal cancer screening *(Quintero, 2012)* describes subjects in the FIT group more likely to participate in screening than those in the colonoscopy group. Baseline screening examination reveals the number of subjects in whom colorectal cancer was detected was similar in the two study groups. However, more adenomas were identified in the colonoscopy group. The comparative effectiveness of FIT and colonoscopy for preventing death from colorectal cancer will be assessed at the completion of this 10-year trial.

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10. 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; Selby, 1992)*. There are ongoing prospective randomized controlled trials of screening flexible sigmoidoscopy, but the final results are not yet available *(Weissfeld, 2005; Gondal, 2003; Segnan, 2002; UK Flexible Sigmoidoscopy Screening Trial Investigators, 2002)*. 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)*.

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 *(Lieberman, 2001; Imperiale, 2000)*. 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)*. 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 clinicians exceed the minimum number of training exams delineated in the American Society for Gastrointestinal Endoscopy guidelines before conducting flexible sigmoidoscopies without supervision *(Levin, 2008; Levin, 2005)*. 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. Clinicians 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)*. Women are more likely to have proximal or right-sided adenomas or colorectal cancer than are men *(Schoenfeld, 2005)*. Ethnicity may also affect the distribution of lesions in the colon. African Americans may have more proximal lesions as compared to Whites *(Nelson, 1997)*. Whites may have more proximal lesions when compared with Hispanics and Asians *(Francois, 2006; Theuer, 2001)*. 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 *(U.S. Preventive Services Task Force, 2008)*. If the combination of the two tests is chosen by the patient and his/her clinician, 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)*. 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; UK Flexible Sigmoidoscopy Screening Trial Investigators, 2002)*. Lesions can be missed on sigmoidoscopy, and advanced neoplasia has been found within three years of an exam in published studies *(Schoen, 2003)*. Patients should understand that finding polyps on a flexible sigmoidoscopy will result in the need for colonoscopy.

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11. CT Colonography Every Five Years

Recommendation:

- CT colonography may be an option for colorectal cancer screening in the following clinical situations: after incomplete screening or diagnostic colonoscopy, for anticoagulated patients who cannot safely discontinue anticoagulation therapy *(Low Quality Evidence, Weak Recommendation)*.

CT colonography is a colorectal screening option approved by the American Cancer Society for average-risk individuals *(Levin, 2008)*. 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)*. The recommended screening interval is five years. The bowel preparation for CT colonography and colonoscopy are the same. It is less invasive than colonoscopy – a tube is placed in rectum rather than insertion of colonoscope into the entire colon *(American College of Radiology, 2009)*. CT colonography is essentially a pre-colonoscopy screening test. If an individual has a negative CT colonography, he or she does not need to go on to colonoscopy. Consequently, these individuals avoid the small risk inherent in colonoscopy. If the individual has an abnormal CT colonography, he or she does need to go on to colonoscopy. The CT colonography finding may be disproved by colonoscopy. If the polyp or mass identified by CT colonography is confirmed by colonoscopy, it can be treated or biopsied.

CT colonography does not require sedation. Therefore, after the exam is completed, individuals can return to work and they can drive. It is less expensive than colonoscopy but less likely to be covered by a health insurance. The small amount of radiation received by an individual during CT colonography is now similar to the background radiation that an individual receives from his or her natural environment over one year. As a screening test, it needs to be performed twice as often as colonoscopy. CT colonography always demonstrates the entire colon (sometimes colonoscopy does not). For polyps 10 mm or larger, CT colonography has performed as well as colonoscopy in multicenter research trials *(Lieberman, 2009; Johnson, 2008)*.

CT colonography also demonstrates the other abdominal organs. However, in the interest of decreased radiation exposure, these other organs are demonstrated sub-optimally. The detection of obvious abnormalities such as large abdominal aortic aneurysms benefit the patient. However, the radiologist may report an indeterminate finding in another abdominal organ that requires further evaluation. Although this evaluation may lead to benefit, it may also lead to harm from cost, additional radiation exposure and procedural risks of follow-up examinations *(Berlund, 2009; Gluecker, 2003)*.

CT colonography (virtual colonoscopy) uses computed tomography and software algorithms to produce a radiologic view of the colon for cancer and polyp screening.

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)*. 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)*.

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; Mulhall, 2005)*.

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)*. 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)*
- CT colonography may not be cost effective compared to other strategies, especially when extra-colonic findings are considered *(Vijan, 2007)*
- Concerns over the radiation risk accumulated through recurrent abdominal and pelvic scans *(Smith-Bindman, 2009)*

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. In such scenarios, referral to an experienced center may be appropriate if patient cost is not a barrier.

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12. Positive Findings?

A positive guaiac-based fecal occult blood test or fecal immunochemical test requires 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 *(Lieberman, 2001; Imperiale, 2000)*. 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; Huang, 2004)*. 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)*.

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The American Cancer Society guidelines recommend colonoscopy for any patient with a polyp of 6 mm or greater size *(Levin, 2008)*. 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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The Aims and Measures section is intended to provide guideline users with a menu of measures for multiple purposes, which may include the following:

- Population health improvement measures
- Quality improvement measures for delivery systems
- Measures from regulatory organizations such as The Joint Commission
- Measures that are currently required for public reporting
- Measures that are part of Center for Medicare Services Physician Quality Reporting initiative
- Other measures from local and national organizations aimed at measuring population health and improvement of care delivery

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

The subdivisions of this section are:

- Aims and Measures
- Implementation Recommendations
- Implementation Tools and Resources

Aims and Measures

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

   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 and American Indian/Alaska Native patients age 45 and older who are up-to-date with colorectal cancer screening.

2. Increase the rate of patients who have had a shared decision-making conversation about colorectal cancer screening tests.

   Measure for accomplishing this aim:

   a. Percentage of patients who have had a shared decision-making conversation about colorectal cancer screening tests:

      - 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

Measurement #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

$$\frac{\text{\# of patients with up-to-date colorectal cancer screening}}{\text{\# of patients age 50 and older}}$$

Numerator and Denominator Definitions

Denominator: Number of patients age 50 and older.

Numerator: Number of patients with 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

Identify the number of patients who fit denominator criteria and determine if any of the tests under numerator were performed.

Notes

This is an outcome measure, and improvement is noted as an increase in the rate. The goal of this measure is to determine up-to-date status of those patients seen in your medical practice.

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Measurement #1b

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

Population Definition

African American and American Indian/Alaska Native patients age 45 and older.

Data of Interest

$$\frac{\text{\# of patients with up-to-date colorectal cancer screening}}{\text{\# of African American and American Indian/Alaska Native patients age 45 and older}}$$

Numerator and Denominator Definitions

Denominator: Number of African American and American Indian/Alaska Native patients age 45 and older.

Numerator: Number of patients with 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

Identify the number of patients who fit denominator criteria and determine if any of the tests under numerator were performed.

Notes

This is an outcome measure, and improvement is noted as an increase in the rate. The goal of this measure is to determine up-to-date status of those patients seen in your medical practice.

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Measurement #2a

Percentage of patients who have had a shared decision-making conversation about colorectal cancer screening tests.

Population Definition

African American and American Indian/Alaska Native patients age 45 years and older. All other patients age 50 years and older.

Data of Interest

$$\frac{\text{\# of patients who have had a shared decision-making conversation about colorectal cancer screening tests}}{\text{\# of patients as defined under Population Definition}}$$

Numerator and Denominator Definitions

Numerator: Number of patients who have had a shared decision-making conversation about colorectal cancer screening tests:

- FOBT 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

Denominator: Number of patients as defined under Population Definition.

Method/Source of Data Collection

Identify the number of patients who fit denominator criteria and determine if any of the tests under numerator were performed.

Notes

This is a process measure, and improvement is noted as an increase in the rate. The goal of this measure is to determine if shared decision-making is done for colorectal cancer screening procedures before patients have colorectal cancer screening done.

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Implementation Recommendations

Prior to implementation, it is important to consider current organizational infrastructure that address the following:

- System and process design
- Training and education
- Culture and the need to shift values, beliefs and behaviors of the organization.

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

- 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).

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Implementation Tools and Resources

Criteria for Selecting Resources

The following tools and resources specific to the topic of the protocol were selected by the work group. Each item was reviewed thoroughly by at least one work group member. It is expected that users of these tools will establish the proper copyright prior to their use. The types of criteria the work group used are:

- The content supports the clinical and the implementation recommendations.
- Where possible, the content is supported by evidence-based research.
- The author, source and revision dates for the content is included where possible.
- The content is clear about potential biases and when appropriate conflicts of interests and/or disclaimers are noted where appropriate.

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Implementation Tools and Resources Table

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

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Implementation Tools and Resources Table

Author/Organization	Title/Description	Audience	Web sites/Order Information
National Cancer Institute	**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
UpToDate	UpToDate® is a clinical decision support system that helps clinicians throughout the world provide the best patient care. We use current evidence to answer clinical questions quickly and easily at the point of care. This saves clinicians time, improves outcomes and lowers health care costs.	Health Care Professionals	http://www.uptodate.com
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

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The subdivisions of this section are:

- References
- Appendices

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Links are provided for those new references added to this edition (author name is highlighted in blue).

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Appendix A – ICSI Shared Decision-Making Model

The technical aspects of Shared Decision-Making are widely discussed and understood.

- **Decisional conflict** occurs when a patient is presented with options where no single option satisfies all the patient's objectives, where there is an inherent difficulty in making a decision, or where external influencers act to make the choice more difficult.
- **Decision support** clarifies the decision that needs to be made, clarifies the patient's values and preferences, provides facts and probabilities, guides the deliberation and communication and monitors the progress.
- **Decision aids** are evidence-based tools that outline the benefits, harms, probabilities and scientific uncertainties of specific health care options available to the patient.

However, before decision support and decision aids can be most advantageously utilized, a Collaborative Conversation™ should be undertaken between the provider and the patient to provide a supportive framework for Shared Decision-Making.

Collaborative Conversation™

A collaborative approach toward decision-making is a fundamental tenet of Shared Decision-Making (SDM). The Collaborative Conversation™ is an inter-professional approach that nurtures relationships, enhances patients' knowledge, skills and confidence as vital participants in their health, and encourages them to manage their health care.

Within a Collaborative Conversation™ , the perspective is that both the patient and the provider play key roles in the decision-making process. The patient knows which course of action is most consistent with his/her values and preferences, and the provider contributes knowledge of medical evidence and best practices. Use of Collaborative Conversation™ elements and tools is even more necessary to support patient, care provider and team relationships when patients and families are dealing with high stakes or highly charged issues, such as diagnosis of a life-limiting illness.

The overall framework for the Collaborative Conversation™ approach is to create an environment in which the patient, family and care team work collaboratively to reach and carry out a decision that is consistent with the patient's values and preferences. A rote script or a completed form or checklist does not constitute this approach. Rather it is a set of skills employed appropriately for the specific situation. These skills need to be used artfully to address all aspects involved in making a decision: cognitive, affective, social and spiritual.

Key communication skills help build the Collaborative Conversation™ approach. These skills include many elements, but in this appendix only the questioning skills will be described. (For complete instruction, see O'Connor, Jacobsen "Decisional Conflict: Supporting People Experiencing Uncertainty about Options Affecting Their Health" [2007], and Bunn H, O'Connor AM, Jacobsen MJ "Analyzing decision support and related communication" [1998, 2003].)

1. **Listening skills:**

   Encourage patient to talk by providing prompts to continue such as "*go on, and then?, uh huh,*" or by repeating the last thing a person said, "*It's confusing*."

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Paraphrase content of messages shared by patient to promote exploration, clarify content and to communicate that the person's unique perspective has been heard. The provider should use his/her own words rather than just parroting what he/she heard.

Reflection of feelings usually can be done effectively once trust has been established. Until the provider feels that trust has been established, short reflections at the same level of intensity expressed by the patient without omitting any of the message's meaning are appropriate. Reflection in this manner communicates that the provider understands the patient's feelings and may work as a catalyst for further problem solving. For example, the provider identifies what the person is feeling and responds back in his/her own words like this: "*So, you're unsure which choice is the best for you*."

Summarize the person's key comments and reflect them back to the patient. The provider should condense several key comments made by the patient and provide a summary of the situation. This assists the patient in gaining a broader understanding of the situations rather than getting mired down in the details. The most effective times to do this are midway through and at the end of the conversation. An example of this is, "*You and your family have read the information together, discussed the pros and cons, but are having a hard time making a decision because of the risks*."

Perception checks ensure that the provider accurately understands a patient or family member, and may be used as a summary or reflection. They are used to verify that the provider is interpreting the message correctly. The provider can say "*So you are saying that you're not ready to make a decision at this time. Am I understanding you correctly?*"

2. **Questioning Skills**

Open and closed questions are both used, with the emphasis on open questions. Open questions ask for clarification or elaboration and cannot have a yes or no answer. An example would be "*What else would influence you to choose this?*" Closed questions are appropriate if specific information is required such as "*Does your daughter support your decision?*"

Other skills such as summarizing, paraphrasing and reflection of feeling can be used in the questioning process so that the patient doesn't feel pressured by questions.

Verbal tracking, referring back to a topic the patient mentioned earlier, is an important foundational skill (Ivey & Bradford-Ivey). An example of this is the provider saying, "*You mentioned earlier…*"

3. **Information-Giving Skills**

Providing information and **providing feedback** are two methods of information giving. The distinction between providing information and giving advice is important. Information giving allows a provider to supplement the patient's knowledge and helps to keep the conversation patient centered. Giving advice, on the other hand, takes the attention away from the patient's unique goals and values, and places it on those of the provider.

Providing information can be sharing facts or responding to questions. An example is "*If we look at the evidence, the risk is…*" Providing feedback gives the patient the provider's view of the patient's reaction. For instance, the provider can say, "*You seem to understand the facts and value your daughter's advice*."

Additional Communication Components

Other elements that can impact the effectiveness of a Collaborative Conversation™ include:

- Eye contact
- Body language consistent with message
- Respect

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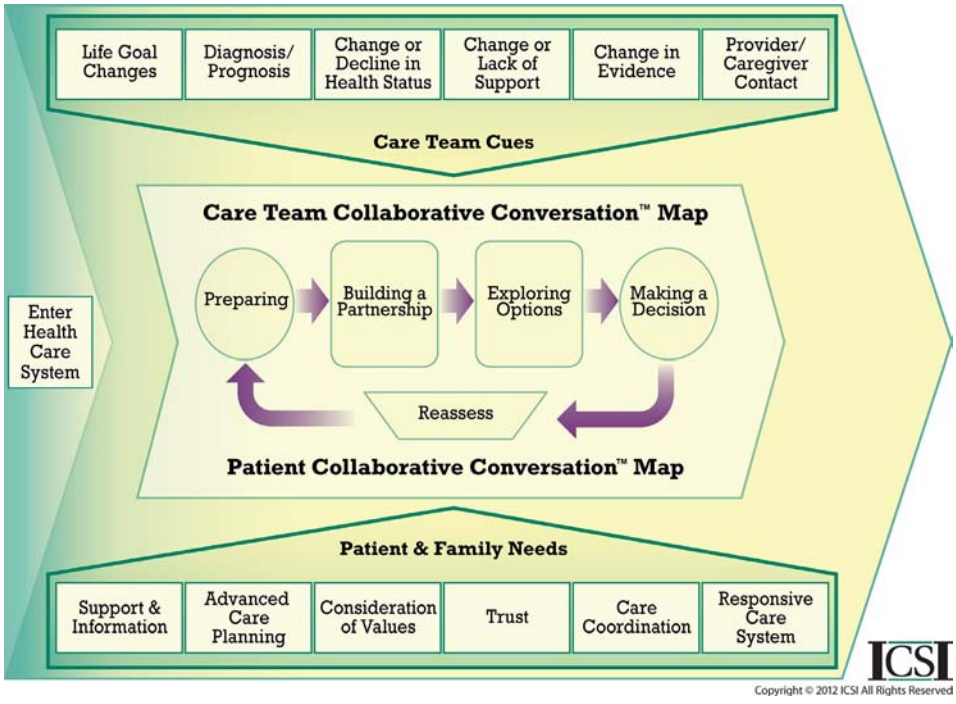
- Empathy
- Partnerships

Self-examination by the provider involved in the Collaborative Conversation™ can be instructive. Some questions to ask oneself include:

- Do I have a clear understanding of the likely outcomes?
- Do I fully understand the patient's values?
- Have I framed the options in comprehensible ways?
- Have I helped the decision-makers recognize that preferences may change over time?
- Am I willing and able to assist the patient in reaching a decision based on his/her values, even when his/her values and ultimate decision may differ from my values and decisions in similar circumstances?

When to Initiate a Collaborative Conversation™

A Collaborative Conversation™ can support decisions that vary widely in complexity. It can range from a straightforward discussion concerning routine immunizations to the morass of navigating care for a life-limiting illness. Table 1 represents one health care event. This event can be simple like a 12 year-old coming to the clinic for routine immunizations, or something much more complex like an individual receiving a diagnosis of congestive heart failure. In either case, the event is the catalyst that starts the process represented in this table. There are cues for providers and patient needs that exert influence on this process. They are described below. The heart of the process is the Collaborative Conversation™. The time the patient spends within this health care event will vary according to the decision complexity and the patient's readiness to make a decision.



Regardless of the decision complexity there are cues applicable to all situations that indicate an opportune time for a Collaborative Conversation™. These cues can occur singularly or in conjunction with other cues.

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Cues for the Care Team to Initiate a Collaborative Conversation™

- **Life goal changes:** Patient's priorities change related to things the patient values such as activities, relationships, possessions, goals and hopes, or things that contribute to the patient's emotional and spiritual well-being.
- **Diagnosis/prognosis changes:** Additional diagnoses, improved or worsening prognosis.
- **Change or decline in health status:** Improving or worsening symptoms, change in performance status or psychological distress.
- **Change or lack of support:** Increase or decrease in caregiver support, change in caregiver, or caregiver status, change in financial standing, difference between patient and family wishes.
- **Change in medical evidence or interpretation of medical evidence:** Providers can clarify the change and help the patient understand its impact.
- **Provider/caregiver contact:** Each contact between the provider/caregiver and the patient presents an opportunity to reaffirm with the patient that his/her care plan and the care the patient is receiving are consistent with his/her values.

Patients and families have a role to play as decision-making partners, as well. The needs and influencers brought to the process by patients and families impact the decision-making process. These are described below.

Patient and Family Needs within a Collaborative Conversation™

- **Request for support and information:** Decisional conflict is indicated by, among other things, the patient verbalizing uncertainty or concern about undesired outcomes, expressing concern about choice consistency with personal values and/or exhibiting behavior such as wavering, delay, preoccupation, distress or tension. Generational and cultural influencers may act to inhibit the patient from actively participating in care discussions, often patients need to be given "permission" to participate as partners in making decisions about his/her care.

  Support resources may include health care professionals, family, friends, support groups, clergy and social workers. When the patient expresses a need for information regarding options and his/her potential outcomes, the patient should understand the key facts about options, risks and benefits, and have realistic expectations. The method and pace with which this information is provided to the patient should be appropriate for the patient's capacity at that moment.

- **Advance Care Planning:** With the diagnosis of a life-limiting illness, conversations around advance care planning open up. This is an opportune time to expand the scope of the conversation to other types of decisions that will need to be made as a consequence of the diagnosis.
- **Consideration of Values:** The personal importance a patient assigns potential outcomes must be respected. If the patient is unclear how to prioritize the preferences, value clarification can be achieved through a Collaborative Conversation™ and by the use of decision aids that detail the benefits and harms of potential outcomes in terms the patient can understand.
- **Trust:** The patient must feel confident that his/her preferences will be communicated and respected by all caregivers.
- **Care Coordination:** Should the patient require care coordination, this is an opportune time to discuss the other types of care-related decisions that need to be made. These decisions will most likely need to be revisited often. Furthermore, the care delivery system must be able to provide coordinated care throughout the continuum of care.

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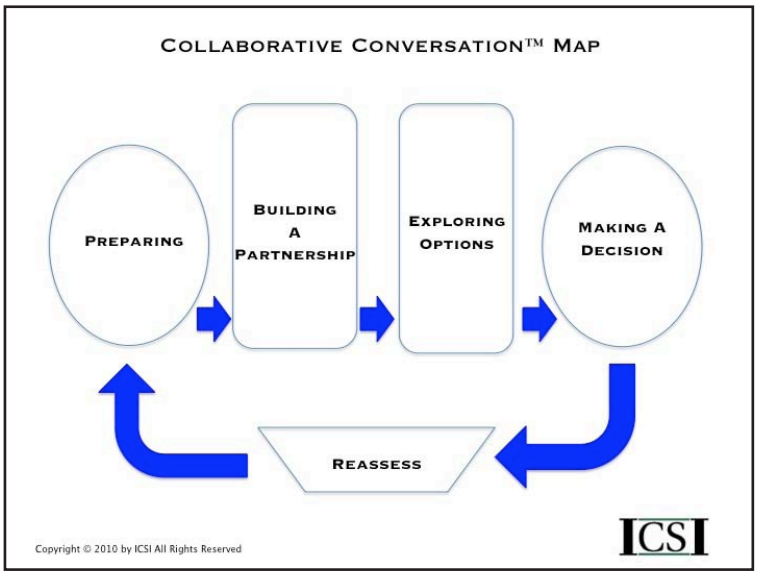
- **Responsive Care System:** The care system needs to support the components of patient- and family-centered care so the patient's values and preferences are incorporated into the care he/she receives throughout the care continuum.

The Collaborative Conversation™ Map is the heart of this process. The Collaborative Conversation™ Map can be used as a stand-alone tool that is equally applicable to providers and patients as shown in Table 2. Providers use the map as a clinical workflow. It helps get the Shared Decision-Making process initiated and provides navigation for the process. Care teams can used the Collaborative Conversation™ to document team best practices and to formalize a common lexicon. Organizations can build fields from the Collaborative Conversation™ Map in electronic medical records to encourage process normalization. Patients use the map to prepare for decision-making, to help guide them through the process and to share critical information with their loved ones.



Evaluating the Decision Quality

Adapted from O'Connor, Jacobsen "Decisional Conflict: Supporting People Experiencing Uncertainty about Options Affecting Their Health" [2007].

When the patient and family understand the key facts about the condition and his/her options, a good decision can be made. Additionally, the patient should have realistic expectations about the probable benefits and harms. A good indicator of the decision quality is whether or not the patient follows through with his/her chosen option. There may be implications of the decision on patient's emotional state such as regret or blame, and there may be utilization consequences.

Decision quality can be determined by the extent to which the patient's chosen option best matches his/her values and preferences as revealed through the Collaborative Conversation™ process.

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Appendix B – Comparing Screening Tests

TESTS	FEATURES	LIMITATIONS
Colonoscopy	• Procedure takes about 30 minutes • Can usually view entire colon • Full bowel preparation needed • Sedation of some kind usually needed • Can biopsy and remove polyps • Can diagnose other diseases of the colon • Done every 10 years	• Can miss small polyps • More expensive on a one-time basis than other forms of testing • Requires sedation so a driver is needed and the patient may miss a day of work • Risk of bleeding, 1.5 to 3% if polyps are removed • Risk of perforation 0.3%
Flexible Sigmoidoscopy	• Procedure takes about 20 minutes • Usually doesn't require full bowel preparation • Sedation usually not used • Done every five years	• Views only about a third of the colon • Can miss small polyps • Can't remove all polyps • Typically no sedation so may be uncomfortable • Risk of serious complications (bleeding, infection, or bowel tear) is 0.34% • Colonoscopy will be needed if abnormal
CT Colonography (CTC)	• Procedure takes about 10 minutes • Always visualizes the entire colon • Full bowel preparation needed • No sedation needed • Less expensive than colonoscopy • Can diagnose diseases in other abdominal organs • Alternative for patients who cannot discontinue anticoagulation therapy • Done every five years	• Can miss polyps under 10 mm • Cannot remove polyps during testing • Colonoscopy will be needed if abnormal • Not available in many communities • Not covered by Medicare and some other payers
Fecal Occult Blood Test (FOBT)	• Done at home • No direct risk to the colon • No bowel preparation • No sedation needed • Should be done annually	• May miss many polyps and some cancers • May produce false-positive test results • May have pretest dietary limitations • Cannot remove polyps • Colonoscopy will be needed if abnormal
Fecal Immunochemical Test (FIT)	• Done at home • No direct risk to the colon • No bowel preparation • No sedation needed • No pretest dietary limitations • Should be done annually	• May miss many polyps and some cancers • May produce false-positive test results • Cannot remove polyps • Colonoscopy will be needed if abnormal

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Appendix C – Shared Decision-Making Brochure

Making a Decision about Colon Cancer Screening

The American Cancer Society recommends that both men and women, beginning at age 50, should have regular testing for colon cancer. Colon cancer screening should begin at age 45 for African-Americans, Native Americans, and Alaska Natives.

This guide will help you think about whether getting screened for colon cancer is right for you, as well as describe the screening options available. This guide is not for you if you have a personal history of colon cancer, inflammatory bowel disease or are already experiencing symptoms such as:

-bleeding from your bowels
-change in your bowel movements
-abdominal pain

If you are experiencing these symptoms, please talk to your doctor.

What is Colon Cancer?

The **colon** is also called the *large intestine* or *large bowel*.

The **rectum** is the passageway that connects the colon to the anus. Cancer that develops in the colon or the rectum is called **colorectal cancer** or simply **colon cancer**.

The American Cancer Society's estimates on the incidence of colorectal cancer cases in the United States in 2012 are as follows:

- 103,170 new cases of colon cancer
- 40,290 new cases of rectal cancer
- The lifetime risk for developing colorectal cancer is about 1 in 20 (5.1%).

How Does Screening Help?

Screening tests can find colon cancer early, when there is a good chance of being cured. Colon cancer screening tests look for colon cancer before you have symptoms.

Some screening tests can find polyps, which are small growths in the colon that can later turn into cancer. During screening, these polyps can be removed before they turn into cancer.

Possible Risks in Being Tested

All abnormal tests require a follow-up colonoscopy. The risks of serious complications from a colonoscopy are less than 5 for every 1,000 people tested.

For every 1,000 people who have a colonoscopy, three people will have serious bleeding and one person will have a tear in the colon.

The Bottom Line

Screening for colon cancer can identify it when it's early. With early treatment, colon cancer is 90% curable. Colon cancer is preventable, treatable and beatable!

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Test Type	Features	Limitations	Frequency
Colonoscopy uses a long, flexible, lighted tube to look inside the entire colon for cancer or polyps (pre-cancer).	• Takes about 30 minutes • Can usually view the entire colon • Can see and remove polyps • Can diagnose other diseases	• Full bowel preparation needed • Small risk of bleeding, bowel tears or infection • Sedation needed so will need a driver to get home and may miss a day of work	Every 10 years
Flexible sigmoidoscopy, like colonoscopy, uses a flexible tube to examine the rectum and lower third of the colon for cancer or polyps. An abnormal test is followed up with a colonoscopy.	• Takes about 20 minutes • Can see and remove polyps • Does not require a full bowel prep • Sedation not needed (no driver needed to get home)	• Minimal bowel preparation needed • Minimal risk of bleeding, bowel tears or infection • Only views one third of the colon	Every 5 years
Stool tests detect blood in the stool. You receive a test kit from your doctor and use a brush or a stick to obtain a small amount of stool, which your provider checks for blood. An abnormal test is followed up with a colonoscopy.	• Done at home • No bowel preparation needed • No direct risk to the colon • Very inexpensive	• Misses some cancers and many polyps • Requires a stool collection at home • Cannot remove polyps	Every year
CT colonoscopy uses x-rays and computers to produce images of the entire colon. The images are displayed on a computer screen. An abnormal test is followed up with a colonoscopy.	• Takes about 10 minutes • Always view the entire colon • Can see polyps • Sedation not needed (no driver needed to get home) • Can diagnose other diseases	• Full bowel preparation needed • Minimal risk of bowel tear • Cannot remove polyps	Every 5 years

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ICSI has long had a policy of transparency in declaring potential conflicting and competing interests of all individuals who participate in the development, revision and approval of ICSI guidelines and protocols.

In 2010, the ICSI Conflict of Interest Review Committee was established by the Board of Directors to review all disclosures and make recommendations to the board when steps should be taken to mitigate potential conflicts of interest, including recommendations regarding removal of work group members. This committee has adopted the Institute of Medicine Conflict of Interest standards as outlined in the report, Clinical Practice Protocols We Can Trust (2011).

Where there are work group members with identified potential conflicts, these are disclosed and discussed at the initial work group meeting. These members are expected to recuse themselves from related discussions or authorship of related recommendations, as directed by the Conflict of Interest committee or requested by the work group.

The complete ICSI Policy regarding Conflicts of Interest is available at http://bit.ly/ICSICOI.

Funding Source

The Institute for Clinical Systems Improvement provided the funding for this guideline revision. ICSI is a not for profit, quality improvement organization based in Bloomington, Minnesota. ICSI's work is funded by the annual dues of the member medical groups and five sponsoring health plans in Minnesota and Wisconsin. Individuals on the work group are not paid by ICSI, but are supported by their medical group for this work.

ICSI facilitates and coordinates the guideline development and revision process. ICSI, member medical groups and sponsoring health plans review and provide feedback, but do not have editorial control over the work group. All recommendations are based on the work group's independent evaluation of the evidence.

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The ICSI Patient Advisory Council meets regularly to respond to any scientific document review requests put forth by ICSI facilitators and work groups. Patient advisors who serve on the council consistently share their experiences and perspectives in either a comprehensive or partial review of a document, and engaging in discussion and answering questions. In alignment with the Institute of Medicine's triple aims, ICSI and its member groups are committed to improving the patient experience when developing health care recommendations.

All ICSI documents are available for review during the revision process by member medical groups and sponsors. In addition, all members commit to reviewing specific documents each year. This comprehensive review provides information to the work group for such issues as content update, improving clarity of recommendations, implementation suggestions and more. The specific reviewer comments and the work group responses are available to ICSI members at http://bit.ly/Colorectal0512.

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ICSI Patient Advisory Council

The work group would like to acknowledge the work done by the ICSI Patient Advisory Council in reviewing the Colorectal Cancer Screening guideline and thank them for their suggestion to improve the shared decision-making resources.

Invited Reviewers

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ICSI Document Development and Revision Process

Overview

Since 1993, the Institute for Clinical Systems Improvement (ICSI) has developed more than 60 evidence-based health care documents that support best practices for the prevention, diagnosis, treatment or management of a given symptom, disease or condition for patients.

Audience and Intended Use

The information contained in this ICSI Health Care Guideline is intended primarily for health professionals and other expert audiences.

This ICSI Health Care Guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients and families are urged to consult a health care professional regarding their own situation and any specific medical questions they may have. In addition, they should seek assistance from a health care professional in interpreting this ICSI Health Care Guideline and applying it in their individual case.

This ICSI Health Care Guideline is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition.

Document Development and Revision Process

The development process is based on a number of long-proven approaches and is continually being revised based on changing community standards. The ICSI staff, in consultation with the work group and a medical librarian, conduct a literature search to identify systematic reviews, randomized clinical trials, meta-analysis, other guidelines, regulatory statements and other pertinent literature. This literature is evaluated based on the GRADE methodology by work group members. When needed, an outside methodologist is consulted.

The work group uses this information to develop or revise clinical flows and algorithms, write recommendations, and identify gaps in the literature. The work group gives consideration to the importance of many issues as they develop the guideline. These considerations include the systems of care in our community and how resources vary, the balance between benefits and harms of interventions, patient and community values, the autonomy of clinicians and patients and more. All decisions made by the work group are done using a consensus process.

ICSI's medical group members and sponsors review each guideline as part of the revision process. They provide comment on the scientific content, recommendations, implementation strategies and barriers to implementation. This feedback is used by and responded to by the work group as part of their revision work. Final review and approval of the guideline is done by ICSI's Committee on Evidence-Based Practice. This committee is made up of practicing clinicians and nurses, drawn from ICSI member medical groups.

Implementation Recommendations and Measures

These are provided to assist medical groups and others to implement the recommendations in the guidelines. Where possible, implementation strategies are included that have been formally evaluated and tested. Measures are included that may be used for quality improvement as well as for outcome reporting. When available, regulatory or publicly reported measures are included.

Document Revision Cycle

Scientific documents are revised every 12-24 months as indicated by changes in clinical practice and literature. Each ICSI staff monitors major peer-reviewed journals every month for the guidelines for which they are responsible. Work group members are also asked to provide any pertinent literature through check-ins with the work group midcycle and annually to determine if there have been changes in the evidence significant enough to warrant document revision earlier than scheduled. This process complements the exhaustive literature search that is done on the subject prior to development of the first version of a guideline.

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