



## Complete Summary

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### GUIDELINE TITLE

Colorectal cancer screening.

### BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Colorectal cancer screening. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Jun. 53 p. [68 references]

## COMPLETE SUMMARY CONTENT

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## SCOPE

### DISEASE/CONDITION(S)

Colorectal cancer

### GUIDELINE CATEGORY

Evaluation  
Prevention  
Risk Assessment  
Screening

### CLINICAL SPECIALTY

Family Practice  
Gastroenterology  
Internal Medicine  
Preventive Medicine

### INTENDED USERS

Advanced Practice Nurses  
Allied Health Personnel  
Health Care Providers  
Health Plans  
Hospitals  
Nurses  
Physician Assistants  
Physicians

#### GUIDELINE OBJECTIVE(S)

- To increase the percent of people aged 50 to <80 who are up-to-date with colorectal screening
- To increase patient participation in screening for colorectal cancer
- To increase the percent of positive colorectal cancer screening tests that have follow-up tests
- To reduce wasteful, unproductive processes for colorectal cancer screening

#### TARGET POPULATION

Patients meeting all of the following criteria for routine screening for colorectal cancer:

- 50 to <80 years old
- No personal history of polyps and/or colorectal cancer
- No family history of colorectal cancer in one first order relative diagnosed before age 65, two first order relatives diagnosed at any age, or a single first order relative diagnosed after age 65
- No family history of adenomatous polyps in a first order relative diagnosed before age 60

#### INTERVENTIONS AND PRACTICES CONSIDERED

1. Prescreening education and counseling
2. Risk assessment and determination of need for increased risk surveillance
3. Colonoscopy
4. Barium enema
5. Flexible sigmoidoscopy
6. Fecal occult blood test (FOBT)
7. Double contrast barium enema (DCBE)
8. Digital rectal examination (DRE)
9. Biopsy
10. Computed tomographic (CT) colonography

#### MAJOR OUTCOMES CONSIDERED

- Incidence of and mortality rates from colorectal cancer
- Cost-effectiveness of screening measures
- Adverse effects of screening measures
- Sensitivity and specificity of screening tests for colorectal cancer

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

### NUMBER OF SOURCE DOCUMENTS

No additional description of literature search strategies is available.

### METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality.

#### Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results

from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

#### Study Quality Designations:

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

#### Classes of Research Reports:

##### A. Primary Reports of New Data Collection:

###### Class A:

- Randomized, controlled trial

###### Class B:

- Cohort study

###### Class C:

- Nonrandomized 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

#### METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

#### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

#### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

#### COST ANALYSIS

The guideline developers reviewed published cost analyses.

#### METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing  
Internal Peer Review

#### DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Institute Partners: System-Wide Review

The guideline draft, discussion, and measurement specification documents undergo thorough review. Written comments are solicited from clinical, measurement, and management experts from within the member medical groups during an eight-week period of "Critical Review."

Each of the Institute's participating medical groups determines its own process for distributing the guideline and obtaining feedback. Clinicians are asked to suggest modifications based on their understanding of the clinical literature coupled with their clinical expertise. Representatives from all departments involved in implementation and measurement review the guideline to determine its operational impact. Measurement specifications for selected measures are developed by the Institute for Clinical Systems Improvement (ICSI) in collaboration with participating medical groups following general implementation of the guideline. The specifications suggest approaches to operationalizing the measure.

#### Guideline Work Group: Second Draft

Following the completion of the "Critical Review" period, the guideline work group meets 1 to 2 times to review the input received. The original guideline is revised as necessary, and a written response is prepared to address each of the suggestions received from medical groups. Two members of the Preventive Services Steering Committee carefully review the Critical Review input, the work group responses, and the revised draft of the guideline. They report to the entire committee their assessment of two questions: (1) Have the concerns of the medical groups been adequately addressed? (2) Are the medical groups willing and able to implement the guideline? The committee then either approves the guideline for pilot testing as submitted or negotiates changes with the work group representative present at the meeting.

#### Pilot Test

Medical groups introduce the guideline at pilot sites, providing training to the clinical staff and incorporating it into the organization's scheduling, computer, and other practice systems. Evaluation and assessment occur throughout the pilot test phase, which usually lasts for three months. Comments and suggestions are solicited in the same manner as used during the "Critical Review" phase.

The guideline work group meets to review the pilot sites' experiences and makes the necessary revisions to the guideline, and the Preventive Services Steering Committee reviews the revised guideline and approves it for implementation.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

The recommendations for colorectal cancer (CRC) screening are presented in the form of 2 algorithms with a total of 34 components and accompanied by detailed annotations. Algorithms are provided for: [Screening](#) and [Flexible Sigmoidoscopy/Total Colon Evaluation \(TCE\)](#). Clinical highlights and selected annotations (numbered to correspond with the algorithms) follow.

Class of evidence (A-D, M, R, X) and conclusion grade (I-III, Not Assignable) definitions are repeated at the end of the "Major Recommendations" field.

#### Clinical Highlights

1. Screening criteria for this guideline includes:
  - Adults between the ages of 50 and <80 years old\*
  - No personal history of polyps and/or colorectal cancer
  - No family history of colorectal cancer involving:
    - one first order relative\*\* diagnosed before age 65

or

  - two first order relatives\*\* diagnosed at any age
  - No family history of adenomatous polyps in first order relative\*\* diagnosed before age 60.

\*The best data available support screening between ages 50 and 80; however, otherwise healthy individuals over the age of 80 may be candidates for screening if their presumed life expectancy is 8 or more years.

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

Any person not meeting the above criteria is not appropriate for colorectal cancer screening within the context of this guideline.

(Annotation #3)

2. Colorectal cancer screening is recommended for all patients 50 to <80 years of age using one of the following methods based on joint decision making by patient and provider:
  - Flexible sigmoidoscopy every 5 years
  - Annual fecal occult blood test (FOBT)
  - Combination of flexible sigmoidoscopy every 5 years and annual FOBT
  - Total colon evaluation as defined in the guideline

(Annotation #6)

### Screening Algorithm Annotations

#### 1. Prescreening Education and Counseling

This guideline represents its work group's contribution to colon 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 colon cancer screening, thereby increasing the rate of early detection of this disease.

#### 2. Prevention Opportunity

A prevention opportunity may be any visit to a provider which provides the opportunity for conducting the screening process, a preventive services visit, and outreach to patients who historically do not come in for visits.

#### 3. Meets Screening Criteria?

All four of the screening criteria must be met to advance individuals in the guideline for colorectal cancer screening:

- Between the ages of 50 and <80 years old\*
  - No personal history of polyps and/or colorectal cancer (See the Discussion and References #3 "Meets Criteria for Routine Screening for Colorectal Cancer?" in the original guideline document)
  - No family history of colorectal cancer involving:
    - one first order relative\*\* diagnosed before age 65
- or
- two first order relatives\*\* diagnosed at any age
  - a single first order relative diagnosed after age 65 may put patients at a very slightly increased risk
  - No family history of adenomatous polyps in first order relative\*\* diagnosed before age 60.

\*The best data available support screening between ages 50 and 80; however, otherwise healthy individuals over the age of 80 may be candidates for screening if their presumed life expectancy is 8 or more years.

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

#### 4. Increased Risk for Development of Colorectal Cancer?

Patients with the following history are considered to be at increased risk:

- Prior polyp (adenoma with villous component, or any adenomatous polyp >10 mm)
  - Prior colorectal cancer
  - Family history of colorectal cancer involving:
    - one first order relative\* diagnosed before age 65
- or
- two first order relatives\* diagnosed at any age
  - a single first order relative diagnosed after age 65 may put patients at a very slightly increased risk.

Certain patients are considered to be at high risk for development of colorectal cancer. Relevant conditions include familial polyposis coli and variants, long-standing chronic ulcerative colitis, and non-polyposis hereditary colorectal cancer. Surveillance of patients with these disorders lies outside the scope of this screening guideline.

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

Evidence supporting this recommendation is of classes: B, C, D, R

#### 5. Increased Risk Surveillance

Patients at increased risk of developing colorectal cancer as indicated in Annotation #4 "Increased Risk for Development of Colorectal Cancer?" require colonoscopic surveillance at a 3- to 5-year interval, and are outside the scope of this guideline.

Whenever colonoscopy is utilized, it should begin at age 50 or five years before the index carcinoma, whichever comes first. Follow-up intervals should be dictated by the results of colonoscopy but should occur at least every five years.

Patients with only one first order relative with a history of colorectal cancer could be followed using combined barium enema and flexible sigmoidoscopy at five year intervals.

#### 6. Patient and Provider Choose Screening Test Pathway

Screening intervals apply to patients between 50 and <80 years old without clinical factors that place them at increased risk for colorectal cancer. Clinical groups may decide internally as to which screening pathway will be offered routinely at their site. Alternatively, individual clinicians may advise each patient as to which pathway might be most suitable and, with the patient's preference in mind, choose one of the pathways recommended in subsequent annotations. Practitioners should keep in mind that 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 post-procedure recovery and providing a driver for transport home after the procedure.

Evidence supporting this recommendation is of classes: A, B, C, D, M

#### 7. FOBT Annually

#### 8. Patient Submits 3 FOBT Test Slides

A minimum of 3 FOBT cards should be submitted by a patient annually. Standard protocols for obtaining the specimens should be followed as specified by the manufacturer and/or individual testing lab (usually based on 2 samples from 3 different stool specimens). Slide rehydration as an option when testing specimen is not recommended.

Annual or biannual routine FOBT done for large, average risk, randomly selected populations reduce mortality rates for colorectal cancer [Conclusion Grade I: See Conclusion Grading Worksheet - Appendix A in the original guideline document – Annotation #7 & 8 (FOBT)]

FOBTs, even when combined with flexible sigmoidoscopy, fail to detect colorectal cancer in at least 24% of those with cancer. [Conclusion Grade II: See Conclusion Grading Worksheet - Appendix B in the original guideline document – Annotation #7 & 8 (FOBT & Flexible Sigmoidoscopy)]

Evidence supporting this recommendation is of classes: A, C, D, R, X

## 9. Any Positive Tests?

A positive result on any one of the submitted test cards constitutes a "positive" result but requires additional testing with total colon examination to determine if colon cancer or adenomatous polyps are present. (This would include a positive result done from glove used for routine digital rectal exam.)

Evidence supporting this recommendation is of classes: A, C, D, R, X

## 10. Combination of 60 cm Flexible Sigmoidoscopy Every 5 Years and FOBT Annually

Refer to Annotations #7, 8, and 9 for information on FOBT. Refer to Annotation #11 for information on flexible sigmoidoscopy. When this pathway is chosen, the FOBT should be completed before the flexible sigmoidoscopy.

## 11. 60 cm Flexible Sigmoidoscopy Every 5 Years

Direct examination of the colon is recommended using a 60 cm flexible sigmoidoscope, preferably with the capacity for performing a biopsy. A digital rectal examination (DRE) may be performed just prior to insertion of the scope.

Suggested minimal preparation may include two phosphosodyl enemas (e.g., Fleet's) on the morning of the procedure and nothing by mouth (NPO) for four to six hours prior to the procedure. Special attention may need to be directed to the diabetic patient who is NPO or the anticoagulated patient.

Mortality from colorectal cancer can be decreased by flexible sigmoidoscopy examination every 5 years. Additionally, a distal villous or tubulovillous adenoma increases the likelihood of an advanced neoplasm [Conclusion Grade III: See Conclusion Grading Worksheet - Appendix C in the original guideline document – Annotation #11 (Flexible Sigmoidoscopy)]

Evidence supporting this recommendation is of classes: C, R

## 13. Total Colon Evaluation (TCE)

### Colonoscopy

Colonoscopy, which can visualize the entire colon, is analogous in performance to flexible sigmoidoscopy which has been shown to reduce colorectal cancer mortality.

National consensus guidelines suggest an interval of 5 to 10 years between colonoscopy examinations for an average risk population.

Colonoscopy has been shown to reduce the incidence of colorectal cancer in a population of patients with adenomatous polyps. There is, however, no evidence of reduction of colorectal cancer mortality in an average risk population by randomized trial, nonrandomized trial, or case-control studies

through the use of colonoscopy, as no studies have been published directly addressing the question. Cost-effectiveness estimates suggest a possible benefit. [Conclusion Grade IV: See Conclusion Grading Worksheet - Appendix D in the original guideline document – Annotation #12 (Colonoscopy)]

#### Barium Enema

Barium enema may be performed with either double contrast technique (DCBE) or a fluoroscopic barium enema study conducted by a radiologist with advanced specialized training in gastrointestinal procedures. There are no studies evaluating whether screening by barium enema alone reduces mortality from colorectal cancer in people at average risk for the disease. This option is based on evidence that screening double contrast barium enemas can image the entire colon and detect cancers and large polyps almost as well as colonoscopy or flexible sigmoidoscopy. [Conclusion Grade III: See Conclusion Grading Worksheet - Appendix E in the original guideline document – Annotation #13 (DCBE)]

The fluoroscopic barium enema is performed at Mayo Clinic. At that site, approximately 3,500 colon contrast studies are performed annually. The fluoroscopic barium enema is performed in conjunction with a proctoscopy or flexible sigmoidoscopy.

Evidence supporting this recommendation is of class: C

#### Computed Tomographic (CT) Colonography

When double read CT colonography is employed the sensitivity of CT colonography vs. air contrast barium enema is 81% vs. 45% respectively for polyps >1 cm. This difference is statistically significant.

Flexible sigmoidoscopy is also recommended in certain colorectal cancer screening algorithms. In a study of 703 asymptomatic persons at higher-than-average risk undergoing CT colonography and conventional colonoscopy, flexible sigmoidoscopy would have detected less than 30% of all large polyps (only 24% were located in the rectum and sigmoid colon).

For a primary screening exam for neoplasm detection, CT colonography is clearly superior to FOBT, flexible sigmoidoscopy, and air contrast barium enema. Evidence continues to build showing CT colonography as a viable alternative to colonoscopy.

Criticisms for including CT colonography in the screening algorithm include the need to still perform optical colonoscopy in positive cases, the detection of extracolonic findings that will need subsequent work-up and reimbursement issues. One criticism of the technique is that should an abnormality be detected at CT colonography then an additional conventional colonoscopy will need to be performed. In a recent study, using a threshold of 8mm as size criteria for sending patients to colonoscopy, only 13.5% of patients would

have needed subsequent colonoscopy. Therefore, it is likely only a small number of cases will need additional colonoscopy.

Another criticism of CT colonography is that extracolonic findings will be detected which will require additional work-up and increase the overall cost of the exam. In a study of 681 patients at Mayo Clinic, ten percent of patients had extracolonic findings of high clinical importance, 27% of medium importance, and 50% of low importance. Subsequent medical or surgical interventions resulted in 9 of 681 patients (1.3%). The costs of subsequent radiologic follow-up studies were \$23,380.59, which translated to an average added cost per CT colonography examination of \$34.33.

Insurance companies and Medicare may not cover the examination, possibly incurring out-of-pocket expenses for the patient. Preliminary data from Mayo Clinic indicate that some insurance companies are beginning to cover the examination including screening indications. Currently Medicare is not covering the procedure but is considering a type I code for reimbursement. Currently only provisional Current Procedure Terminology (CPT) codes are available for CT colonography (effective July 2004).

Evidence supporting this recommendation is of classes: C, D

### [Flexible Sigmoidoscopy/Total Colon Evaluation \(TCE\) Algorithm Annotations](#)

#### 16. Exam Adequate?

##### Flexible Sigmoidoscopy

The decision with respect to the adequacy of a flexible sigmoidoscopy exam is at the discretion of the provider. Reasons for which an exam would be inadequate include:

- inadequate bowel prep
- limited distance of scope insertion due to patient discomfort
- other technical difficulties
- uncertainty as to the significance of findings
- unsuccessful biopsy

##### Barium Enema

The decision with respect to the adequacy of a barium enema is at the discretion of the provider. Reasons for which an exam would be inadequate include:

- inadequate bowel prep
- inadequate evaluation of recto-sigmoid
- other technical difficulties
- uncertainty as to the significance of findings

The provider may reschedule the examination with an altered bowel preparation and suggest a proctoscopy, flexible sigmoidoscopy, or colonoscopy depending on the nature of the findings and/or limitations of the study.

Colonoscopy

See Annotation #24, "Colonoscopy Exam Adequate?"

#### 17. Schedule Reexam

A reexamination could be performed immediately after adequate prepping or at the discretion of the provider, dependent on individual patient factors.

#### 18. Positive Findings?

A positive finding on screening includes an invasive cancer, polyp, bleeding source, or mucosal abnormality. From the standpoint of colorectal cancer screening, diverticula, hyperplastic polyps, and single tubular adenomas less than 10 mm are not precursors to cancer. As a frame of reference, a standard biopsy forceps fully opens to a diameter of 7 mm.

Evidence supporting this recommendation is of classes: B, C

#### 21. Adenomatous Polyp?

Attempt biopsy of every polyp under 5 mm in diameter. Polyps larger than 10 mm should be referred for complete excision at colonoscopy (no biopsy needed). Intermediate-sized polyps (>5 mm and <10 mm) may be referred for colonoscopic removal. If the polyp was biopsied at flexible sigmoidoscopy and is hyperplastic on histology, no further exam is needed at this screening. Nonadenomatous polyps (juvenile, hyperplastic, lipomatous, inflammatory) have no precancerous potential and do not require referral for colonoscopy.

Completion of a biopsy may be dependent upon the operator's comfort or skill level. If a biopsy is indicated but not performed, the patient should be referred.

#### 24. Colonoscopy Exam Adequate?

The decision with respect to the adequacy of a colonoscopy is at the discretion of the provider. Reasons for which an exam would be inadequate include:

- inadequate bowel prep
- limited distance of scope insertion due to patient discomfort
- other technical difficulties
- uncertainty as to the significance of findings
- unsuccessful biopsy

#### 25. Prep Inadequate?

#### 26. Radiologic Exam

The colonoscopy exam may be inadequate for a number of reasons. The preparation of the colon may be inadequate for an accurate exam. If this is the case, the patient should be repped with an alternate or more vigorous preparation method and the colonoscopy repeated.

If the colonoscopy is inadequate due to a partially obstructing lesion that precludes a more proximal advance of the colonoscope, the more proximal colon should be evaluated by radiologic means. In those locations where computed tomography colonography is available, this has been shown to provide more accurate examination of the proximal colon than air contrast barium enema, provided this segment is adequately cleaned out. If CT colonography is not available, use of a contrast enema to evaluate the more proximal colon is advised.

Evidence supporting this recommendation is of classes: C, D

### 31. Confirmed Diagnosis of Colorectal Cancer?

Positive pathology from the biopsy specimen report confirms the diagnosis of colorectal cancer.

### 32. Adenomatous Polyp?

When the biopsy report is normal mucosa/hyperplastic polyp, return to screening activities and intervals as per the [Screening Algorithm](#). Patient education and communication should occur at this time.

Adenomatous polyps should be removed as part of the colonoscopy procedure. Confirmation of the presence of adenomatous polyps places the patient in an increased risk group. Such patients should be followed according to the increased risk surveillance protocol. (See Annotation #5, "Increased Risk Surveillance.")

### 33. Refer to Increased Risk Surveillance (Annotation #5)

Due to the precancerous nature of certain adenomatous polyps, patients with such polyps should be monitored more closely than patients in the [Screening Algorithm](#), and are outside the scope of this guideline.

### 34. Care Management: Out of Guideline

Management of confirmed colorectal cancer is beyond the scope of this guideline and should be undertaken via appropriate specialty referral and care management.

## Definitions:

### Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and

consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

#### Study Quality Designations:

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Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

#### Classes of Research Reports:

##### A. Primary Reports of New Data Collection:

###### Class A:

- Randomized, controlled trial

###### Class B:

- Cohort study

Class C:

- Nonrandomized 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

## CLINICAL ALGORITHM(S)

Two detailed and annotated clinical algorithms are provided for:

- [Screening](#)
- [Flexible Sigmoidoscopy/Total Colon Evaluation \(TCE\)](#)

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guideline contains an annotated bibliography and discussion of the evidence supporting each recommendation. The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

In addition, key conclusions contained in the Work Group's algorithm are supported by a grading worksheet that summarizes the important studies

pertaining to the conclusion. The type and quality of the evidence supporting these key recommendations is graded for each study.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

Decreased mortality from colorectal cancer due to earlier detection

### POTENTIAL HARMS

- Colonoscopy. Colonoscopy involves a higher risk of perforation than flexible sigmoidoscopy. If conscious sedation is used, there is a risk of complications related to medication as well as a requirement for a period of post-procedure recovery and providing a driver for transport home after the procedure.
- False positive screening tests. The specificity of a positive fecal occult blood test is low. Numerous case studies report a very high rate (60% to 80%) of false positives.
- False negative screening tests. Fecal occult blood tests (FOBT), even when combined with flexible sigmoidoscopy, fail to detect colorectal cancer in at least 24% of those with cancer.

## CONTRAINDICATIONS

### CONTRAINDICATIONS

Anticoagulation is a relative contraindication to conventional colonoscopy.

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This medical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.
- 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 made on the judgment of the clinician, taking into account other significant factors discussed in the discussion section of the original guideline document, 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. One study shows that one time combined screening fails to detect 24% of advanced colonic neoplasia. The guideline work group does not see sufficient evidence to reach absolute consensus as to which screening test is preferable, but does advocate screening by one or both tests. In recommending choice, the work group is basically in accord with the recommendations of the United States Preventive Services Task Force and the National Institutes of Health (NIH).

- There are no studies evaluating whether screening by barium enema alone reduces mortality from colorectal cancer in people at average risk for the disease. This option is based on evidence that screening double contrast barium enemas (DCBEs) can image the entire colon and detect cancers and large polyps almost as well as colonoscopy or flexible sigmoidoscopy.
- There is no evidence of reduction of colorectal cancer mortality in an average risk population by randomized trial, nonrandomized trial, or case-control studies through the use of colonoscopy. Colonoscopy, which can visualize the entire colon, is analogous in performance to flexible sigmoidoscopy, which has been shown to reduce colorectal cancer mortality.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

### RELATED NQMC MEASURES

- [Colorectal cancer screening: percentage of people aged 51 to less than 80 who are seen in the last month and who are up-to-date with respect to screening for colorectal cancer.](#)

- [Colorectal cancer screening: percentage of patients aged 50 to less than 80 with counseling on colorectal cancer screening, whether or not the screening test was done.](#)

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Staying Healthy

### IOM DOMAIN

Effectiveness

Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Colorectal cancer screening. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Jun. 53 p. [68 references]

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

1995 May (revised 2004 Jun)

### GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

### GUIDELINE DEVELOPER COMMENT

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## GUIDELINE COMMITTEE

Preventive Services Steering Committee

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## GUIDELINE STATUS

This is the current release of the guideline.

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#### GUIDELINE AVAILABILITY

Electronic copies: Available from the [Institute for Clinical Systems Improvement \(ICSI\) Web site](#).

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#### AVAILABILITY OF COMPANION DOCUMENTS

None available

#### PATIENT RESOURCES

None available

#### NGC STATUS

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