Complete Summary

GUIDELINE TITLE

Colorectal cancer screening and surveillance: clinical guidelines and rationale-update based on new evidence.

BIBLIOGRAPHIC SOURCE(S)

Winawer S, Fletcher R, Rex D, Bond J, Burt R, Ferrucci J, Ganiats T, Levin T, Woolf S, Johnson D, Kirk L, Litin S, Simmang C. Colorectal cancer screening and surveillance: clinical guidelines and rationale-Update based on new evidence. Gastroenterology 2003 Feb;124(2):544-60. [102 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Colorectal cancer

GUIDELINE CATEGORY

Screening

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Internal Medicine
Oncology
Preventive Medicine
Radiology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To incorporate updated evidence into clinical practice recommendations
- To summarize new developments in the field and suggest how they should change practice

TARGET POPULATION

- People in the United States (U.S.) at average risk for colorectal cancer (asymptomatic, age $\geq$ 50 years, no other risk factors)
- People in the U.S. at increased risk for colorectal cancer (history of adenomatous polyps or colorectal cancer; family history of colon cancer, an adenomatous polyp, familial adenomatous polyposis, or hereditary nonpolyposis colorectal cancer)

Note: People with symptoms or signs that suggest the presence of colorectal cancer or polyps fall outside the domain of screening and should be offered an appropriate diagnostic evaluation (see Table 2 in the original guideline document).

INTERVENTIONS AND PRACTICES CONSIDERED

1. Risk stratification based on personal, family, and medical history
2. Patient education regarding screening options
3. Screening tests, including:
    - Fecal occult blood test (FOBT)
    - Sigmoidoscopy
    - Combined FOBT and sigmoidoscopy
    - Colonoscopy
    - Double-contrast barium enema
4. Follow-up of positive screening test including further testing and referral for surgery as appropriate
5. Surveillance of patients at increased risk

MAJOR OUTCOMES CONSIDERED

- Rates of screening for colorectal cancer
- Morbidity and mortality due to colorectal cancer
- Incidence of colorectal cancer
- Sensitivity and specificity of screening procedures
- Cost-effectiveness of screening

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Appropriate members of the guidelines panel, based on their individual interests and expertise, were assigned 1 or more sections of the guidelines previously published by the Gastrointestinal (GI) Consortium. They conducted a literature search on the assigned topic and prepared evidence tables summarizing scientifically strong studies that were relevant to colorectal cancer screening and surveillance.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Evidence tables, with associated citations, were circulated to the Gastrointestinal (GI) Consortium panel for comments. A meeting was held at which the important new evidence was presented and critiqued.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A meeting of the gastrointestinal consortium panel was held at which the supporting evidence was presented and critiqued. Following this, guidelines were drafted based on the meeting consensus, with an accompanying discussion of the rationale, new evidence (since close of evidence gathering for the earlier guidelines in 1996), and recommendations for future research.

These guidelines, like their predecessor, take into consideration the full range of issues that should go into a policy decision. The size of the effect and the strength of the research evidence on which it is based are major considerations. But so also are the complications and inconvenience of screening, patient acceptance, and cost. Individual patients and providers may value some of these elements over others.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Cost-effectiveness analyses have shown that the cost per year of life saved by screening with any of the tests recommended is reasonable by U.S. standards. Although the specific results vary among analyses, in general, the marginal cost-effectiveness of this screening is less than $25,000 per year of life saved. Screening for colorectal cancer was among the highest ranked services in an analysis of the value of preventive services based on the burden of disease prevented and cost effectiveness. Although the up-front costs vary by screening modality, the long-term cost-effectiveness is apparently similar across screening programs, so that decisions about which options to include, in the long run and from the perspective of society, do not need to be heavily affected by costs. Costs increase out of proportion to benefits with shorter intervals between screening examinations. One analysis suggested that screening sigmoidoscopy might be cost-saving over a long period of time.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A draft of the guideline document was edited by the GI Consortium Panel co-chairs and the task force chair and circulated to the members for comments. The final draft was then circulated to appropriate committees of the sponsoring organizations. The final draft was also reviewed and endorsed by the American Cancer Society.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Excerpted by the National Guideline Clearinghouse (NGC)

Note from the guideline developers: These guidelines differ from those published in 1997 in several ways:

- They recommend against rehydrating fecal occult blood tests
- The screening interval for double-contrast barium enema has been shortened to 5 years
- Colonoscopy is the preferred test for the diagnostic investigation of patients with findings on screening and for screening patients with a family history of hereditary nonpolyposis colorectal cancer
- Recommendations for people with a family history of colorectal cancer make greater use of risk stratification
- Guidelines for genetic testing are included

- Guidelines for surveillance are also included
- Follow-up of postpolypectomy patients relies now on colonoscopy, and the first follow-up examination has been lengthened from 3 to 5 years for low-risk patients

General Recommendations

Screening programs should begin by classifying the individual patient´s level of risk based on personal, family, and medical history, which will determine the appropriate approach to screening in that person.

Men and women at average risk should be offered screening for colorectal cancer and adenomatous polyps beginning at age 50 years.

They should be offered options for screening, with information about the advantages and disadvantages associated with each approach, and should be given an opportunity to apply their own preferences in selecting how they should be screened.

If the result of a screening test is abnormal, physicians should recommend a complete structural examination of the colon and rectum by colonoscopy (or flexible sigmoidoscopy and double contrast barium enema if colonoscopy is not available).

Surveillance with colonoscopy should be considered for patients who are at increased risk because they have been treated for colorectal cancer, have an adenomatous polyp diagnosed, or have a disease that predisposes them to colorectal cancer, such as inflammatory bowel disease.

Health care providers who perform the tests should have appropriate proficiency, and the tests should be performed correctly. To achieve these aims, care systems should establish standards and operating procedures.

Screening should be accompanied by efforts to optimize the participation of patients and health care providers--both with screening tests and appropriate diagnostic evaluation of abnormal screening test results--and to remind patients and providers about the need for rescreening at recommended intervals.

Risk Stratification

Clinicians should determine an individual patient´s risk status well before the earliest potential initiation of screening (typically around age 20 years, but earlier if there is a family history of familial adenomatous polyposis) (see figure 1 in the original guideline document). The individual´s risk status determines when screening should be initiated and what tests and frequency are appropriate. Risk stratification can be accomplished by asking several questions aimed at uncovering the risk factors for colorectal cancer:

1. Has the patient had colorectal cancer or an adenomatous polyp?
2. Does the patient have an illness (e.g., inflammatory bowel disease) that predisposes him or her to colorectal cancer?

3. Has a family member had colorectal cancer or an adenomatous polyp? If so, how many, was it a first-degree relative (parent, sibling, or child), and at what age was the cancer or polyp first diagnosed?

A positive response to any of these questions should prompt further efforts to identify and define the specific condition associated with increased risk.

Recommendations for Screening People at Average Risk

Men and women at average risk should be offered screening with one of the following options beginning at age 50 years. The rationale for presenting multiple options is that no single test is of unequivocal superiority and that giving patients a choice allows them to apply personal preferences and may increase the likelihood that screening will occur. The strategies are not equal with regard to evidence of effectiveness, magnitude of effectiveness, risk, or up-front costs. Reviewing the rationale section for each screening test (presented in the original guideline document) will provide clinicians with information that they can use in presenting the relative effectiveness of each test to patients.

Fecal Occult Blood Testing

Offer yearly screening with fecal occult blood test (FOBT) using a guaiac-based test with dietary restriction or an immunochemical test without dietary restriction. Two samples from each of 3 consecutive stools should be examined without rehydration. Patients with a positive test on any specimen should be followed up with colonoscopy.

Sigmoidoscopy

Offer flexible sigmoidoscopy every 5 years.

Combined FOBT and Flexible Sigmoidoscopy

Offer screening with FOBT every year combined with flexible sigmoidoscopy every 5 years. When both tests are performed, the FOBT should be done first.

Colonoscopy

Offer colonoscopy every 10 years.

Double-Contrast Barium Enema

Offer double-contrast barium enema (DCBE) every 5 years.

Recommendations for Screening People at Increased Risk

People With a Family History of Colorectal Cancer or Adenomatous Polyps

People with a first-degree relative (parent, sibling, or child) with colon cancer or adenomatous polyps diagnosed at age <60 years or 2 first-degree relatives

diagnosed with colorectal cancer at any age should be advised to have screening colonoscopy starting at age 40 years or 10 years younger than the earliest diagnosis in their family, whichever comes first, and repeated every 5 years (see Table 3 in the original guideline document).

People with a first-degree relative with colon cancer or adenomatous polyp diagnosed at age ≥60 years or 2 second-degree relatives with colorectal cancer should be advised to be screened as average risk persons, but beginning at age 40 years.

People with 1 second-degree relative (grandparent, aunt, or uncle) or third-degree relative (great-grandparent or cousin) with colorectal cancer should be advised to be screened as average risk persons.

Familial Adenomatous Polyposis

People who have a genetic diagnosis of familial adenomatous polyposis (FAP), or are at risk of having FAP but genetic testing has not been performed or is not feasible, should have annual sigmoidoscopy, beginning at age 10-12 years, to determine if they are expressing the genetic abnormality. Genetic testing should be considered in patients with FAP who have relatives at risk. Genetic counseling should guide genetic testing and considerations of colectomy.

Hereditary Nonpolyposis Colorectal Cancer

People with a genetic or clinical diagnosis of hereditary nonpolyposis colorectal cancer (HNPCC) or who are at increased risk for HNPCC should have colonoscopy every 1-2 years beginning at age 20-25 years, or 10 years earlier than the youngest age of colon cancer diagnosis in the family--whichever comes first. Genetic testing for HNPCC should be offered to first-degree relatives of persons with a known inherited mismatch repair (MMR) gene mutation. It should also be offered when the family mutation is not already known, but 1 of the first 3 of the modified Bethesda Criteria is met (see Table 5 in the original guideline document).

Surveillance of People at Increased Risk

People with a History of Adenomatous Polyps

Patients who have had 1 or more adenomatous polyps removed at colonoscopy should be managed according to the findings on that colonoscopy. Patients who have had numerous adenomas, a malignant adenoma (with invasive cancer), a large sessile adenoma, or an incomplete colonoscopy should have a short interval follow-up colonoscopy based on clinical judgment. Patients who have advanced or multiple adenomas (≥3) should have their first follow-up colonoscopy in 3 years. Patients who have 1 or 2 small (<1 cm) tubular adenomas should have their first follow-up colonoscopy at 5 years. It is not unreasonable, given available evidence, to choose even longer intervals. However, the evidence is still evolving. Future evidence may clarify the intervals more precisely.

The timing of the subsequent colonoscopy should depend on the pathology and number of adenomas detected at follow-up colonoscopy. For example, if the first

follow-up colonoscopy is normal or only 1 or 2 small (<1 cm) tubular adenomas are found, the next colonoscopy can be in 5 years.

People With a History of Colorectal Cancer

Patients with a colon cancer that has been resected with curative intent should have a colonoscopy around the time of initial diagnosis to rule out synchronous neoplasms. If the colon is obstructed preoperatively, colonoscopy can be performed approximately 6 months after surgery. If this or a complete preoperative examination is normal, subsequent colonoscopy should be offered after 3 years, and then, if normal, every 5 years.

People With Inflammatory Bowel Disease

In patients with long-standing, extensive inflammatory bowel disease, surveillance colonoscopy with systematic biopsies should be considered. This applies to both ulcerative colitis and Crohn´s colitis because the cancer risk is similar in both diseases.

CLINICAL ALGORITHM(S)

A clinical algorithm is provided for colorectal cancer screening.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Specific guideline recommendations are accompanied by a discussion of the rationale and new evidence supporting their use.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Increased rates of appropriate and timely colorectal cancer screening based on patient and physician collaboration
- Improved physician and patient understanding of the rationale and evidence supporting colorectal cancer screening options (refer to the rationale section in the original guideline document for the relative effectiveness of each screening test)
- Reduced morbidity and mortality due to colorectal cancer
- Reduced health care costs

POTENTIAL HARMS

- Currently available tests for fecal occult blood fail to detect many polyps and some cancers. Also, most people who test positive will not have colorectal neoplasia (have a false positive test result) and thus will undergo the discomfort, cost, and risk of colonoscopy without benefit.

- Colonoscopy involves greater cost, risk, and inconvenience to the patient than other screening tests, and not all examinations visualize the entire colon.
- Genetic testing can have psychological effects and subject persons with positive tests to the risks of discrimination. Therefore, it should only be performed after genetic counseling of patients and parents of children.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- In applying the recommendations in the guidelines to patients, the individual circumstances of the patient must be considered in addition to the guideline recommendations.
- The recommendations in this guideline are based on the clinical literature or reports accepted for publication and available to the Panel in complete form as of June 1, 2002. Evidence that appears after this date should be taken into account when applying these guidelines. Clinical judgment should be used to tailor recommendations to the individual patient's special circumstances.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

For screening programs to be successful, a cascade of events must be negotiated from beginning to end. Physicians must remember to offer screening, patients must accept this advice, insurers must pay for screening and follow-up testing, and patient care organizations must have systems to track whether screening has taken place and provide reminders if it has not. Therefore, those who care about effective screening programs must be concerned with all of these elements of success.

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)

Winawer S, Fletcher R, Rex D, Bond J, Burt R, Ferrucci J, Ganiats T, Levin T, Woolf S, Johnson D, Kirk L, Litin S, Simmang C. Colorectal cancer screening and

surveillance: clinical guidelines and rationale-Update based on new evidence. Gastroenterology 2003 Feb;124(2):544-60. [102 references] PubMed

ADAPTATION

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

DATE RELEASED

1997 Feb (revised 2003 Feb)

GUIDELINE DEVELOPER(S)

American College of Gastroenterology - Medical Specialty Society
American College of Physicians - Medical Specialty Society
American Gastroenterological Association - Medical Specialty Society
American Society for Gastrointestinal Endoscopy - Medical Specialty Society

GUIDELINE DEVELOPER COMMENT

The original guidelines were prepared by a panel convened by the U.S. Agency for Health Care Policy and Research and published in 1997 under the sponsorship of a consortium of gastroenterology societies. The original GI Consortium Panel was comprised of experts in primary care, gastroenterology, surgery, oncology, epidemiology, behavioral science, clinical economics, and nursing, as well as a patient advocate. The panel responsible for the current guidelines was comprised of representatives from the original panel and of the U.S. Multisociety Task Force on Colorectal Cancer, a combined effort of the American College of Gastroenterology, the American Society of Gastrointestinal Endoscopy, the American Gastroenterological Association, and the American College of Physicians/Society of Internal Medicine. This group was asked to review the original guidelines, prepare appropriate revisions with rationale, highlight new evidence since 1997, and suggest research questions--the answers to which seem critical to progress in colorectal cancer screening and surveillance. Societies with representatives on the panel included the American Academy of Family Practice, American College of Gastroenterology, American College of Physicians-American Society of Internal Medicine, American College of Radiology, American Gastroenterological Association, American Society of Colorectal Surgeons, and American Society for Gastrointestinal Endoscopy.

SOURCE(S) OF FUNDING

This work was supported by the American College of Gastroenterology, American College of Physicians/American Society of Internal Medicine, American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy.

GUIDELINE COMMITTEE

U.S. Multisociety Task Force on Colorectal Cancer

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Members of the U.S. Multisociety Task Force on Colorectal Cancer: Randall Burt, M.D., Huntsman Cancer Institute at the University of Utah, Salt Lake City, Utah; John Bond, M.D., University of Minnesota, Minneapolis, Minnesota; Joseph T. Ferrucci, M.D., Boston University School of Medicine, Boston, Massachusetts; Robert Fletcher, M.D., Harvard Medical School and Harvard Pilgrim Health Care, Boston, Massachusetts (Panel Co-Chair); Theodore Ganiats, M.D., University of California San Diego, La Jolla, California; David A. Johnson, M.D., Eastern Virginia School of Medicine, Norfolk, Virginia; Lynne M. Kirk, M.D., University of Texas Southwestern Medical Center, Dallas, Texas; Theodore R. Levin, M.D., Kaiser Permanente Medical Center, Walnut Creek, Oakland, California; Scott Litin, M.D., Mayo Clinic, Rochester, Minnesota; Douglas K. Rex, M.D., Indiana University School of Medicine, Indianapolis, Indiana (Task Force Chair); Clifford Simmang, University of Texas Southwestern Medical School, Dallas, Texas; Sidney J. Winawer, M.D., Memorial Sloan-Kettering Cancer Center, New York, New York (Panel Co-Chair); and Steven H. Woolf, M.D., MPH, Virginia Commonwealth University, Fairfax, Virginia

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

ENDORSER(S)

American Cancer Society - Disease Specific Society
American College of Gastroenterology - Medical Specialty Society
American Society for Gastrointestinal Endoscopy - Medical Specialty Society
American Society of Colon and Rectal Surgeons - Medical Specialty Society
Crohn's and Colitis Foundation of America - Disease Specific Society
Oncology Nursing Society - Professional Association
Society of American Gastrointestinal Endoscopic Surgeons - Medical Specialty Society

GUIDELINE STATUS

This is the current release of the guideline. It updates a previous version: Winawer SJ, Fletcher RH, Miller L, Godlee F, Stolar MH, Mulrow CD, Woolf SH, Glick SN, Ganiats TG, Bond JH, Rosen L, Zapka JG, Olsen SJ, Giardiello FM, Sisk JE, Van Antwerp R, Brown-Davis C, Marciniak DA, Mayer RJ. Colorectal cancer screening: clinical guidelines and rationale [published errata appear in Gastroenterology 1997 Mar;112(3):1060 and 1998 Mar;114(3):625]. Gastroenterology 1997 Feb;112(2):594-642.

According to the guideline developer, the Clinical Practice Committee meets 3 times a year to review all American Gastroenterological Association guidelines. This review includes new literature searches of electronic databases followed by expert committee review of new evidence that has emerged since the original publication date.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Gastroenterological Association (AGA) Web site.

Print copies: Available from American Gastroenterological Association, 4930 Del Ray Avenue, Bethesda, MD 20814.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on June 30, 1998. It was verified by the guideline developer on December 1, 1998. This summary was updated by ECRI on May 20, 2003. The updated information was verified by the guideline developer on June 24, 2003.

COPYRIGHT STATEMENT

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

© 1998-2004 National Guideline Clearinghouse

Date Modified: 11/8/2004