Screening for Colorectal Cancer

Recommendations and Rationale

U.S. Preventive Services Task Force

This statement summarizes the current U.S. Preventive Services Task Force (USPSTF) recommendations on screening for colorectal cancer and the supporting scientific evidence, and it updates the 1996 recommendations contained in the *Guide to Clinical Preventive Services*, second edition.[1] At that time, the USPSTF recommended screening for colorectal cancer with annual fecal occult blood testing (FOBT), periodic sigmoidoscopy, or the combination of FOBT and sigmoidoscopy but concluded that the evidence was insufficient to recommend for or against colonoscopy or barium enema. Explanations of the ratings and of the strength of overall evidence are given in Appendix A and Appendix B, respectively. The complete information on which this statement is based, including evidence tables and references, is available in the article Screening for Colorectal Cancer in Adults at Average Risk: A Summary of the Evidence for the U.S. Preventive Services Task Force[2] (which follows this recommendation) and in the Systematic Evidence Review[3] on this topic. These documents can be obtained through the USPSTF Web site (www. preventive services.ahrq.gov), and through the National Guideline Clearinghouse (www.guideline.gov). The summary of the evidence and the recommendation statement are also available in print through the AHRQ Publications Clearinghouse (call 1-800-358-9295 or e-mail ahrqpubs@ahrq.gov).

Summary of Recommendation

The USPSTF strongly recommends that clinicians screen men and women 50 years of age or older for colorectal cancer. **A recommendation.**

The USPSTF found fair to good evidence that several screening methods are effective in reducing mortality from colorectal cancer. The USPSTF concluded that the benefits from screening substantially outweigh potential harms, but the quality of evidence, magnitude of benefit, and potential harms vary with each method.

The USPSTF found good evidence that periodic fecal occult blood testing (FOBT) reduces mortality from colorectal cancer and fair evidence that sigmoidoscopy alone or in combination with FOBT reduces mortality. The USPSTF did not find direct evidence that screening colonoscopy is effective in reducing colorectal cancer mortality; efficacy of colonoscopy is supported by its integral role in trials of FOBT, extrapolation from sigmoidoscopy studies, limited case-control evidence, and the ability of colonoscopy to inspect the proximal colon. Double-contrast barium enema offers an alternative means of whole-bowel examination, but it is less sensitive than colonoscopy, and there is no direct evidence that it is effective in reducing mortality rates. The USPSTF found insufficient evidence that newer screening technologies (for example, computed tomographic colography) are effective in improving health outcomes.

There are insufficient data to determine which strategy is best in terms of the balance of benefits and potential harms or cost-effectiveness. Studies reviewed by the USPSTF indicate that colorectal cancer screening is likely to be cost-effective (less than $30,000 per additional year of life gained) regardless of the strategy chosen.

It is unclear whether the increased accuracy of colonoscopy compared with alternative screening methods (for example, the identification of lesions that

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FOBT and flexible sigmoidoscopy would not detect) offsets the procedure's additional complications, inconvenience, and costs.

Clinical Considerations

- Potential screening options for colorectal cancer include home FOBT, flexible sigmoidoscopy, the combination of home FOBT and flexible sigmoidoscopy, colonoscopy, and double-contrast barium enema. Each option has advantages and disadvantages that may vary for individual patients and practice settings. The choice of specific screening strategy should be based on patient preferences, medical contraindications, patient adherence, and available resources for testing and follow-up. Clinicians should talk to patients about the benefits and potential harms associated with each option before selecting a screening strategy.
- The optimal interval for screening depends on the test. Annual FOBT offers greater reductions in mortality rates than biennial screening but produces more false-positive results. A 10-year interval has been recommended for colonoscopy on the basis of evidence regarding the natural history of adenomatous polyps. Shorter intervals (5 years) have been recommended for flexible sigmoidoscopy and double-contrast barium enema because of their lower sensitivity, but there is no direct evidence with which to determine the optimal interval for tests other than FOBT. Case-control studies have suggested that sigmoidoscopy every 10 years may be as effective as sigmoidoscopy performed at shorter intervals.
- The USPSTF recommends initiating screening at 50 years of age for men and women at average risk for colorectal cancer, based on the incidence of cancer above this age in the general population. In persons at higher risk (for example, those with a first-degree relative who receives a diagnosis with colorectal cancer before 60 years of age), initiating screening at an earlier age is reasonable.
- Expert guidelines exist for screening very high-risk patients, including those with a history suggestive of familial polyposis or hereditary nonpolyposis colorectal cancer, or those with a personal history of ulcerative colitis.[4] Early screening with colonoscopy may be appropriate, and genetic counseling or testing may be indicated for patients with genetic syndromes.
- The appropriate age at which colorectal cancer screening should be discontinued is not known. Screening studies have generally been restricted to patients younger than 80 years of age, with colorectal cancer mortality rates beginning to decrease within 5 years of initiating screening. Yield of screening should increase in older persons (because of higher incidence of colorectal cancer), but benefits may be limited as a result of competing causes of death. Discontinuing screening is therefore reasonable in patients whose age or comorbid conditions limit life expectancy.
- Proven methods of FOBT screening use guaiac-based test cards prepared at home by patients from three consecutive stool samples and forwarded to the clinician. Whether patients need to restrict their diet and avoid certain medications is not established. Rehydration of the specimens before testing increases the sensitivity of FOBT but substantially increases the number of false-positive test results. Neither digital rectal examination (DRE) nor the testing of a single stool specimen obtained during DRE is recommended as an adequate screening strategy for colorectal cancer.
- The combination of FOBT and sigmoidoscopy may detect more cancers and more large polyps than either test alone, but the additional benefits and potential harms of combining the two tests are uncertain. In general, FOBT should precede sigmoidoscopy because a positive test result is an indication for colonoscopy, obviating the need for sigmoidoscopy.
- Colonoscopy is the most sensitive and specific test for detecting cancer and large polyps but is associated with higher risks than other screening tests for colorectal cancer. These include a small risk for bleeding and risk for perforation, primarily associated with removal of polyps or

biopsies performed during screening. Colonoscopy also usually requires more highly trained personnel, overnight bowel preparation, sedation, and longer recovery time, which may necessitate transportation for the patient. It is not certain whether the potential added benefits of colonoscopy relative to screening alternatives are large enough to justify the added risks and inconvenience for all patients.

- Initial costs of colonoscopy are higher than the costs of other tests. Estimates of cost-effectiveness, however, suggest that, from a societal perspective, compared with no screening, all methods of colorectal cancer screening are likely to be as cost-effective as many other clinical preventive services—less than $30,000 per additional year of life gained.

Scientific Evidence

Epidemiology and Clinical Consequences

Colorectal cancer is the fourth most common cancer in the United States and the second leading cause of cancer death. A person at age 50 has about a 5% lifetime risk of being diagnosed with colorectal cancer and a 2.5% chance of dying from it[4]; the average patient dying of colorectal cancer loses 13 years of life.[5]

More than 80% of colorectal cancers arise from adenomatous polyps. Although fewer than 1% of adenomatous polyps less than 1 cm will eventually develop into cancer, 10% of adenomatous polyps greater than 1 cm become malignant within 10 years, and about 25% become malignant after 20 years.[6] The prevalence of adenomatous polyps increases from 20% to 25% at age 50 to 50% by age 75-80.[7]

Most colorectal cancers occur in persons at average risk, but 20% occur among patients with specific risk factors, such as those with a family history of colorectal cancer in a first-degree relative. A small proportion (6%) is associated with uncommon genetic syndromes such as familial adenomatous polyposis [FAP] or hereditary nonpolyposis colorectal cancer [HNPCC]. Other persons at increased risk include patients with longstanding ulcerative colitis, persons with previously diagnosed large adenomatous polyps or colorectal cancer, and those with a family history of adenomatous polyps diagnosed before age 60.

Accuracy and Reliability of Screening Tests

The USPSTF reviewed evidence of the effectiveness of the following screening tests for colorectal cancer: DRE, FOBT, sigmoidoscopy, colonoscopy, DCBE, and CT colography, singly and in various combinations.

Digital Rectal Examination/Office FOBT

There is little evidence to determine the effectiveness of either DRE or a single office FOBT using a stool sample obtained on DRE. Fewer than 10% of colorectal cancers arise within reach of the examining finger, and some of these lesions will already be symptomatic. The sensitivity of a single office FOBT is likely to be substantially lower than that of screening protocols involving multiple test cards: in 1 study the first test card would have missed 42% of cancers detected by screening.[8] Samples collected by DRE may be affected by other limitations, including inadequate amount of stool or trauma from the exam.

Fecal Occult Blood Testing

Sensitivity of FOBT screening varies with the testing protocol. Sensitivity and specificity of a single test have been estimated at 40% and 96% to 98%, respectively. Hydration of specimen increases sensitivity (60%) but reduces specificity (90%).[9] Of patients who have a positive FOBT using rehydrated slides, only 2% will have cancer; 6% to 8% will have cancer or a large polyp. Using unrehydrated specimens, 5% to 18% of patients with a positive test will have cancer; 20% to 40% will have large polyps or cancer. The probability of cancer increases as the number of positive test windows increase. Tests that incorporate quantitative measures of heme and genetic stool markers have not been evaluated with respect to mortality reduction. Sensitivity and

specificity change when screening is analyzed as a program of periodic screens. Annual screening with hydrated specimens detected 49% of all incident cancers, but 38% of all subjects had at least 1 colonoscopy due to positive results.[10] Programs using unrehydrated specimens and/or biennial testing detect a smaller proportion of cancers (27% to 39%) but require fewer colonoscopies (5% to 28%).[11,12]

Sigmoidoscopy

First-time sigmoidoscopic screening detects approximately 7 cancers and about 60 large or high-risk polyps per 1,000 examinations.[13] Although sigmoidoscopy can only visualize the lower half of the colon,[14] it has been estimated to identify 80% of all patients with significant findings in the colon, because findings on sigmoidoscopy will trigger examination of the entire colon. It is difficult to quantify the "false-positive" rate of endoscopic screening, but screening may lead to the removal of many polyps that are of low malignant potential or that would not have caused clinical disease.

FOBT and Sigmoidoscopy

Combining FOBT and periodic sigmoidoscopy has been advocated to improve the sensitivity of screening. In 3 recent randomized trials, performing flexible sigmoidoscopy in addition to FOBT yielded approximately 7 additional cancers or large polyps per 1,000 patients compared to FOBT alone.[3] Adding FOBT did not improve the yield over sigmoidoscopy alone at the initial screening in these studies, which used flexible sigmoidoscopy, but did in an earlier study that used rigid sigmoidoscopy. Whether additional rounds of FOBT screening will have added benefits over flexible sigmoidoscopy has not been assessed.

Double Contrast Barium Enema

Most studies of DCBE have important limitations for determining accuracy in an asymptomatic screening population. Previous studies have reported high sensitivity (86% to 90%) of DCBE for colorectal cancer and polyps, and high specificity (95%). In the National Polyp Study, however, DCBE detected only 48% of polyps greater than 1 cm.[15] Sensitivity might be higher in a typical screening population where the proportion of large polyps is higher. Specificity of DCBE in this study was 85%.

Colonoscopy

Colonoscopy recently has been advocated for screening, usually at 10-year intervals or as a once-in-a-lifetime examination at age 55-65. The accuracy of colonoscopy is difficult to evaluate because it is usually considered the criterion standard. Estimated sensitivity of a single exam is 90% for large polyps and 75% for small polyps (less than 1 cm).[16] As with sigmoidoscopy, specificity is difficult to define. Many patients will have polyps detected or removed on colonoscopy, but only a minority of those would have developed cancer.

Computed Tomography (CT) Colography

CT colography, or "virtual colonoscopy," is a noninvasive procedure for producing images of the colonic lumen. The examination, which can be performed in 10 to 15 minutes, currently requires a preparation similar to colonoscopy, followed by installation of air through a rectal tube. Although CT colography can be relatively sensitive and specific in research settings (85% to 90%), recent reports have suggested lower accuracy when performed by less experienced examiners. Small and flat polyps are less well visualized on CT colography than are cancers and large polyps. Studies have not yet examined clinical outcomes with CT colography screening.

Effectiveness of Early Detection

Fecal Occult Blood Testing

Three randomized controlled trials (RCTs), all using the Hemoccult® test kit, show reductions in risk of death from colorectal cancer from 15% to 33% from periodic FOBT screening. Two European trials, which randomized patients prior to agreement to participate and used biennial screening and unrehydrated test cards, found 15% to 18%

reductions in mortality.[11,12] In a U.S. study, which randomized volunteers and used rehydrated test cards, colorectal cancer mortality after 18 years of follow-up was 33% lower among persons advised to undergo annual FOBT than among controls who received usual care (9.46 versus 14.09 deaths per 1,000 patients screened); biennial screening reduced mortality by 21%.[10,17] A fourth trial conducted in Sweden has not reported final mortality results, but no significant mortality reduction was reported after 2 rounds of rehydrated testing (RR, 0.88; 95% CI, 0.69 to 1.12).

Sigmoidoscopy

Current evidence of the effectiveness of sigmoidoscopy is limited to several well-designed case-control studies, but 2 ongoing RCTs of screening with flexible sigmoidoscopy are expected to report results within 5 years. A case-control study in a large health plan that had implemented rigid sigmoidoscopy screening suggested that screening reduced the risk of death from cancers within reach of the rigid sigmoidoscope by 59%.[18] A second case-control study in which 75% of the examinations were performed with a flexible instrument found similar protection.[19]

FOBT and Sigmoidoscopy

No RCTs have examined whether combining FOBT and sigmoidoscopy would lower mortality or morbidity more than either test alone. In a nonrandomized, controlled study involving more than 12,000 first-time attendees at a preventive-health clinic screened using rigid sigmoidoscopy, the addition of FOBT detected more cancers on initial screening than sigmoidoscopy alone, but mortality after 9 years was not significantly lower (0.36 per 1,000 patient-years in patients receiving both tests versus 0.63 per 1,000 patient years in controls; P = 0.11).[20] Whether results are generalizable to flexible sigmoidoscopy is uncertain.

Double Contrast Barium Enema

No trial has examined the ability of screening barium enema to reduce the incidence or mortality from colorectal cancer.

Colonoscopy

The effectiveness of colonoscopy to prevent colorectal cancer or mortality has not been tested in a randomized clinical trial. The National Polyp Study, a randomized trial of different intervals of surveillance after polypectomy, estimated that 76% to 90% of cancers could be prevented by regular colonoscopic surveillance exams.[21] These results should be interpreted with caution, however, because they are based on historical controls, and trial participants had more complete polyp removal than may occur in the screening setting. A single case-control study suggests that colonoscopy is associated with lower incidence of colon cancer (odds ratio [OR], 0.47; 95% CI, 0.37 to 0.58) and lower mortality from colorectal cancer (OR, 0.43;95% CI, 0.30 to 0.63).[22] Slightly greater benefits of colonoscopy have been predicted in models that project benefits based on sensitivity of screening and rates of polyp progression.

CT colography

No studies have evaluated the effectiveness of CT colography in reducing morbidity or mortality from colorectal cancer.

When to Start or Stop Screening for Colorectal Cancer

There are few data to determine optimal age for starting or stopping screening. FOBT has been proven effective for persons aged 50-80 and sigmoidoscopy is associated with reduced mortality in persons older than 45. One cost-effectiveness model suggests that beginning screening at age 40 rather than at age 50 would offer less than a 1-day average improvement in life expectancy. Randomized trials suggest that a life expectancy of at least 5 years may be required to realize the benefits of screening.

Potential Harms of Screening

FOBT has few potential harms but false-positive tests can lead to invasive procedures such as colonoscopy. Sigmoidoscopy can, in rare instances, lead to bowel perforation (1 to 2 per 10,000 examinations).[23] In a study of 1,235 screening sigmoidoscopies, adverse effects included pain

(14%), anxiety, bleeding (3%), gas or flatus (25%), but no perforations.[13] One patient died from complications after surgery to remove a severely dysplastic adenoma. A survey of barium enema experience reported that important complications of any type occurred in 1 in 10,000 examinations; perforation occurred in 1 in 25,000 examinations; death in 1 in 55,000 examinations.[24]

Screening colonoscopy poses higher risks than FOBT or sigmoidoscopy, both because it is a more invasive procedure and because generally it is used with conscious sedation, which may lead to complications. The risks of colonsocopy depend on whether it is used simply for screening and diagnosis, or whether it is also used for therapeutic procedures (eg, removal of polyps). In 2 studies of screening colonoscopies in more than 5,000 patients, 0.2% to 0.3% had major complications during or immediately after the procedures, the most common being bleeding requiring hospitalization or emergency care.[25,26]

Risks are higher in therapeutic procedures (eg, when polypectomy is performed) than in diagnostic or screening procedures. Rates of perforation for diagnostic procedures in 16 published studies ranged from 0.03% to 0.61%. There are few data on bleeding complications, but 1 study reported no bleeding events in 250 patients.[3]

The complication rates for therapeutic procedures were higher in some studies: 0.07% to 0.72% for perforations and 0.2% to 2.67% for bleeding. Death was rare (between 1 in 16,000 to 1 in 27,000) and more likely in symptomatic patients with acute problems or those with comorbid conditions. The mortality rate as a result of screening is likely to be on the lower end of this range. Complication rates could increase, however, if widespread adoption of colonoscopy leads to more procedures by less skilled endoscopists. Data are lacking on complications of CT colography.

Patient Preferences and Adherence

Some patients report that they find the FOBT unpleasant or difficult to perform, but 50% to 70% of patients will complete FOBT when advised to by a clinician. A reminder system can increase adherence rates by an average of 14%. Studies conducted in primary care settings have found rates of adherence for sigmoidoscopy to be 25% to 50% for the initial test, but there are no data on adherence to repeat examinations. When given information about screening options and offered the choice of FOBT alone, sigmoidoscopy alone, or both tests together, most patients in an academic internal medicine clinic preferred both tests or FOBT alone; only 8% to 13% preferred sigmoidoscopy alone.[27] However, patient adherence to combined testing is lower than it is for sigmoidoscopy or FOBT alone. Patients' acceptance of barium enema screening has not been evaluated.

Studies examining the relative discomfort of barium enema and colonoscopy have produced inconsistent results. In 1 study of patients in a population with considerable previous screening experience, 38% preferred colonoscopy to other methods. The acceptability and feasibility of CT colography have not been examined.

Cost and Cost-effectiveness

Among 6 high-quality cost-effectiveness analyses examining only direct costs, the average cost-effectiveness ratio values for screening adults older than 50 with each of the major strategies were under $30,000 per life-year saved (Year 2000 dollars).[3] Studies varied as to which strategy was most cost-effective, however.

Recommendations of Others

The American Cancer Society recommends screening people at average risk for colorectal cancer beginning at 50 years of age by (1) FOBT annually, (2) flexible sigmoidoscopy every 5 years, (3) annual FOBT plus flexible sigmoidoscopy every 5 years, (4) double-contrast barium enema every 5 years, or (5) colonoscopy every 10 years.[28] The American Cancer Society does not recommend DRE as a stand-alone screening test for colorectal cancer. Similar recommendations are issued by the American College of Surgeons, the American College of Obstetricians and Gynecologists, and the American

Academy of Family Physicians.[29-31] The American Gastroenterological Association, as part of a consortium of related professional organizations, also issues similar recommendations, which are currently being updated.[4] The American College of Physicians–American Society of Internal Medicine does not have current guidelines on screening.[6] The Canadian Task Force on Preventive Health Care concludes that there is good evidence to recommend annual or biennial FOBT and fair evidence to recommend sigmoidoscopy as part of the periodic health examination in average-risk adults after age 50 years; evidence is insufficient to recommend for or against colonosopy or combined FOBT and sigmoidscopy.[32]

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Appendix A
U.S. Preventive Services Task Force - Recommendations and Ratings

The Task Force grades its recommendations according to one of 5 classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms):

A. The USPSTF strongly recommends that clinicians routinely provide [the service] to eligible patients. *The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.*

B. The USPSTF recommends that clinicians routinely provide [the service] to eligible patients. *The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.*

C. The USPSTF makes no recommendation for or against routine provision of [the service]. *The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.*

D. The USPSTF recommends against routinely providing [the service] to asymptomatic patients. *The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.*

I. The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. *Evidence that [the service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.*

Appendix B
U.S. Preventive Services Task Force - Strength of Overall Evidence

The USPSTF grades the quality of the overall evidence for a service on a 3-point scale (good, fair, poor):

Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

Fair: Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.

Poor: Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

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