Complete Summary

GUIDELINE TITLE

Screening for colorectal cancer: recommendations and rationale.

BIBLIOGRAPHIC SOURCE(S)

U.S. Preventive Services Task Force. Screening for colorectal cancer: recommendations and rationale. Ann Intern Med 2002 Jul 16;137(2):129-31. PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This release updates a previously published guideline: U.S. Preventive Services Task Force. Screening for colorectal cancer. In: Guide to clinical preventive services. 2nd ed. Baltimore (MD): Williams & Wilkins; 1996.

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
Internal Medicine
Obstetrics and Gynecology

INTENDED USERS

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

GUIDELINE OBJECTIVE(S)

- To summarize the current U.S. Preventive Services Task Force (USPSTF) recommendations on screening for colorectal cancer and the supporting evidence
- To update the 1996 recommendations contained in the Guide to Clinical Preventive Services, 2nd edition

TARGET POPULATION

Men and women 50 years of age or older

INTERVENTIONS AND PRACTICES CONSIDERED

1. Home fecal occult blood testing (FOBT)
2. Flexible sigmoidoscopy
3. The combination of home fecal occult blood testing and flexible sigmoidoscopy
4. Colonoscopy
5. Double-contrast barium enema
6. Computed tomography colography

MAJOR OUTCOMES CONSIDERED

- Accuracy and reliability of screening tests in detecting colorectal cancer
- Effect of screening on colorectal cancer incidence and mortality rates
- Adverse effects of screening tests
- Cost-effectiveness of screening strategies

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Search Strategies

To update the evidence on screening for colorectal cancer, the Research Triangle Institute/University of North Carolina Evidence-based Practice Center (EPC) performed three separate literature searches using MEDLINE: one general update from January 1995 to December 2001 and two focused searches for evidence related to barium enema and complications of screening that used search dates from 1966 through December 2001. All searches were limited to "human" subjects.

For the general search, the Evidence-based Practice Center combined the MeSH headings "colorectal neoplasms" or "occult blood" or "sigmoidoscopy" or "colonoscopy" with the term "mass screening."

To identify articles on the use of barium enema, the Evidence-based Practice Center combined the exploded MeSH terms "colorectal neoplasms" and "barium sulfate" and "enema."

For studies about the complications of screening, the Evidence-based Practice Center combined the exploded MeSH terms colonoscopy/ae [Adverse Effects] and sigmoidoscopy/ae [Adverse Effects], intestinal perforation, intraoperative complications, postoperative complications, or gastrointestinal hemorrhage, with a search combining the test names and the keyword "complications."

In addition to these searches, the Evidence-based Practice Center used peer review, hand searching of the bibliographies of included articles and other systematic reviews, as well as articles from the 1996 document (the second edition of the Guide to Clinical Preventive Services.

Eligibility Criteria

The Evidence-based Practice Center developed eligibility criteria to guide decisions about inclusion of articles. In general, they sought to identify and include the highest quality evidence available.

Digital Rectal Examination (DRE): diagnostic accuracy, observational

Fecal Occult Blood Test (FOBT): randomized controlled trials (RCTs)

Sigmoidoscopy: randomized controlled trials, observational studies

Fecal Occult Blood Test plus sigmoidoscopy: controlled trials, observational studies, diagnostic accuracy studies

Barium enema: diagnostic accuracy studies

Colonoscopy: observational studies, diagnostic accuracy studies

Adverse effects (any test): case series, observational studies, randomized controlled trials

Source: Pigone M, Rich M, Teutsch SM, Berg AO, Lohr KN. Screening for colorectal cancer in adults at average risk: summary of the evidence for the U. S. Preventive Services Task Force. Ann Intern Med 2002 Jul;137(2):132-41.

Search Strategy for Cost-Effectiveness Articles

The Evidence-based Practice Center searched the MEDLINE database and the British National Health Service Economic Evaluation Database (NHS EED) between January 1993 and September 2001. They exploded medical subject headings "colorectal neoplasms" and "mass screening." They used different strategies in each database to identify cost-effectiveness analyses. For their MEDLINE search, they added the exploded medical subject heading "costs and cost analysis." In the NHS EED, they limited the search to "economic evaluations."

The Evidence-based Practice Center chose 1993 as a starting point because it was the year in which the first trial establishing strong evidence for the effectiveness of colorectal cancer screening was published. To identify studies not captured by our database searches and studies that are ongoing or unpublished, they manually searched the reference lists of retrieved articles and contacted selected authors and experts in the field.

Article Selection for Cost-Effective Studies

Two investigators reviewed titles and abstracts of publications identified by the literature searches. Using information in the abstracts, the Evidence-based Practice Center excluded studies that were not cost-effectiveness or cost-utility analyses, including other types of economic evaluations that did not quantify the health outcomes achieved for a given cost; studies that reported only cost per patient screened, cost per cancer detected, or costs per death prevented; studies that did not contain original analyses; articles that did not address at least one of our three questions of interest; studies performed from perspectives other than the societal perspective or the perspective of public third-party payers; and studies that used cost or disease incidence estimates from outside the United States. When we encountered multiple publications reporting results from the same cost-effectiveness model, we included the most comprehensive analysis and used other papers for supplemental information.

When the decision about whether to include a study could not be made by reading the title or abstract, we evaluated the full article. Disagreements regarding study inclusion were resolved by consensus of the authors.

Source: Pigone M, Somnath S, Hoerger T, Mandelblatt J. Cost-effectiveness analyses of colorectal cancer screening: a review of the evidence for the U.S. Preventive Services Task Force Ann Intern Med 2002 Jul;137(2):96-104.

NUMBER OF SOURCE DOCUMENTS

Colorectal cancer screening: 19

Barium enema: 13

Complications of screening: 16

Hand searches of bibliographies of included articles and other systematic reviews, as well as articles from the 1996 document: 15

Economic evaluations of colorectal screening: 7

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

The U.S. Preventive Services Task Force (USPSTF) grades the quality of the overall evidence on a 3-point scale (good, fair, or 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 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.

Note: See the companion document titled "Current Methods of the U.S. Preventive Services Task Force: a Review of the Process" (Am J Prev Med 2001 Apr;20[3S]:21-35) for a more detailed description of the methods used to assess the quality and strength of the evidence for the three strata at which the evidence was reviewed.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): A systematic evidence review was prepared by the Research Triangle Institute-University of

North Carolina Evidence-based Practice Center (EPC) for the Agency for Healthcare Research and Quality (AHRQ) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Companion Documents" field).

Scientific Evidence

The final set of eligible articles were used to create evidence tables and a draft report.

Pigone M, Rich M, Teutsch SM, Berg AO, Lohr KN. Screening for colorectal cancer in adults at average risk: summary of the evidence for the U. S. Preventive Services Task Force. Ann Intern Med 2002 Jul;137(2):132-41.

Economic Evidence

All authors reviewed each included article. Reviews focused on the assumptions of each study regarding the epidemiology and natural history of colorectal cancer; estimates of parameters related to the effectiveness of screening, including test accuracy, adherence rates, and complication rates; estimates of the costs of screening, diagnosis, and treatment; the proportion of cancers and cancer deaths prevented by screening; and the effect of varying key variables (sensitivity analyses).

For each study, the Evidence-based Practice Center (EPC) used available data to tabulate outcomes of life-years gained and costs per person for each of the major strategies under consideration: fecal occult blood testing (FOBT) annually; sigmoidoscopy every 5 years; combination of annual fecal occult blood testing and sigmoidoscopy every 5 years; double-contrast barium enema (DCBE) every 5 years; and colonoscopy (every 10 years, at ages 55 and 65, or once-lifetime). The evaluated strategies were arrayed in order of effectiveness. Costs were updated to U.S. dollars in 2000 using the Consumer Price Index (CPI) for medical care.

If one strategy was more costly and less effective than another strategy, it was considered strongly dominated. If a strategy was both less effective and had a higher cost-effectiveness ratio than another strategy, it was considered weakly dominated. Incremental cost-effectiveness ratios were then calculated for all non-dominated strategies, using the formula: (costs strategy 2 - costs strategy 1) / (life-years gained with strategy 2 - life-years gained with strategy 1).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Balance Sheets
Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

When the overall quality of the evidence is judged to be good or fair, the U.S. Preventive Services Task Force (USPSTF) proceeds to consider the magnitude of net benefit to be expected from implementation of the preventive service.

Determining net benefit requires assessing both the magnitude of benefits and the magnitude of harms and weighing the two.

The USPSTF classifies benefits, harms, and net benefits on a 4-point scale: "substantial," "moderate," "small," and "zero/negative."

"Outcomes tables" (similar to 'balance sheets') are the USPSTF's standard resource for estimating the magnitude of benefit. These tables, prepared by the topic teams for use at USPSTF meetings, compare the condition specific outcomes expected for a hypothetical primary care population with and without use of the preventive service. These comparisons may be extended to consider only people of specified age or risk groups or other aspects of implementation. Thus, outcomes tables allow the USPSTF to examine directly how the preventive services affects benefits for various groups.

When evidence on harms is available, the topic teams assess its quality in a manner like that for benefits and include adverse events in the outcomes tables. When few harms data are available, the USPSTF does not assume that harms are small or nonexistent. It recognizes a responsibility to consider which harms are likely and judge their potential frequency and the severity that might ensue from implementing the service. It uses whatever evidence exists to construct a general confidence interval on the 4-point scale (e.g., substantial, moderate, small, and zero/negative).

Value judgments are involved in using the information in an outcomes table to rate either benefits or harms on the USPSTF's 4-point scale. Value judgments are also needed to weigh benefits against harms to arrive a rating of net benefit.

In making its determinations of net benefit, the USPSTF strives to consider what it believes are the general values of most people. It does this with greater confidence for certain outcomes (e.g., death) about which there is little disagreement about undesirability, but it recognizes that the degree of risk people are willing to accept to avert other outcomes (e.g., cataracts) can vary considerably. When the USPSTF perceives that preferences among individuals vary greatly, and that these variations are sufficient to make trade-off of benefits and harms a 'close-call', then it will often assign a C recommendation (see the "Recommendation Rating Scheme" field). This recommendation indicates the decision is likely to be sensitive to individual patient preferences.

The USPSTF uses its assessment of the evidence and magnitude of net benefit to make recommendations. The general principles the USPSTF follows in making recommendations are outlined in Table 5 of the companion document cited below. The USPSTF liaisons on the topic team compose the first drafts of the recommendations and rationale statements, which the full panel then reviews and edits. Recommendations are based on formal voting procedures that include explicit rules for determining the views of the majority.

From: Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow, CD, Teutsch SM, Atkins D. Current methods of the U.S. Preventive Services Task Force: a review of the process. Methods Work Group, Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):21-35.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations according to one of five classifications (A, B, C, D, or I), reflecting the strength of evidence and magnitude of net benefit (benefits minus harms).

A

The U.S. Preventive Services Task Force (USPSTF) strongly recommends that clinicians 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 U.S. Preventive Services Task Force (USPSTF) recommends that clinicians provide [the service] to eligible patients. (The USPSTF found at least fair evidence that [the service] improves health outcomes and concludes that benefits outweigh harms.)

C

The U.S. Preventive Services Task Force (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 it too close to justify a general recommendation.)

D

The U.S. Preventive Services Task Force (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 U.S. Preventive Services Task Force (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.)

COST ANALYSIS

Screening for colorectal cancer appears cost-effective compared with no screening but a single optimal strategy cannot be determined from the currently available data. Additional data regarding adherence with screening over time, complication rates in real-world settings, and colorectal cancer biology are needed. Additional analyses are necessary to determine optimal ages of initiation and cessation.

Note: See the companion document titled "Cost-effectiveness analyses of colorectal cancer screening: a review of the evidence for the U.S. Preventive

Services Task Force" (Ann Intern Med 2002 Jul;137[2]:96-104) for a detailed analysis of the cost-effectiveness of colorectal cancer screening.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Peer Review. Before the U.S. Preventive Services Task Force (USPSTF) makes its final determinations about recommendations on a given preventive service, the Evidence-based Practice Center (EPC) and the Agency for Healthcare Research and Quality (AHRQ) send a draft systematic evidence review to 4 to 6 external experts and to federal agencies and professional and disease-based health organizations with interests in the topic. They ask the experts to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the Task Force in memo form. In this way, the Task Force can consider these external comments and a final version of the systematic review before it votes on its recommendations about the service. Draft recommendations are then circulated for comment from reviewers representing professional societies, voluntary organizations and Federal agencies. These comments are discussed before the whole U.S. Preventive Services Task Force before final recommendations are confirmed.

Recommendations of Others. Recommendations for screening for colorectal cancer from the following groups were discussed: the American Cancer Society, the American College of Surgeons, the American College of Obstetricians and Gynecologists, the American Academy of Family Physicians, the American Gastroenterological Association, the American College of Physicians-American Society of Internal Medicine, and the Canadian Task Force on Preventive Health Care.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and the quality of the overall evidence for a service (good, fair, poor). The definitions of these grades can be found at the end of the "Major Recommendations" field.

- The U.S. Preventive Services Task Force (USPSTF) strongly recommends that clinicians screen men and women 50 years of age or older for colorectal cancer. Grade A recommendation.

  The U.S. Preventive Services Task Force found fair to good evidence that several screening methods are effective in reducing mortality from colorectal cancer. The U.S. Preventive Services Task Force 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 U.S. Preventive Services Task Force found good evidence that periodic fecal occult blood testing reduces mortality from colorectal cancer and fair evidence that sigmoidoscopy alone or in combination with fecal occult blood testing (FOBT) reduces mortality. The U.S. Preventive Services Task Force 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 fecal occult blood testing, 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 U.S. Preventive Services Task Force found insufficient evidence that newer screening technologies (for example, computed tomography 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 U.S. Preventive Services Task Force 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 fecal occult blood testing 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 fecal occult blood testing, flexible sigmoidoscopy, the combination of home fecal occult blood testing 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 fecal occult blood testing 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 fecal occult blood testing. Case-control studies have suggested that sigmoidoscopy every 10 years may be as effective as sigmoidoscopy performed at shorter intervals.
- The U.S. Preventive Services Task Force 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. 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 fecal occult blood testing 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 fecal occult blood testing 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 digital rectal examination is recommended as an adequate screening strategy for colorectal cancer.
- The combination of fecal occult blood testing 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, fecal occult blood testing 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.

Definitions:

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The U.S. Preventive Services Task Force (USPSTF) strongly recommends that clinicians 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.)

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C

The U.S. Preventive Services Task Force (USPSTF) makes no recommendation for or against routine provision of [the service]. (The US Preventive Services Task Force found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms it too close to justify a general recommendation.)

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The U.S. Preventive Services Task Force (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.)

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The U.S. Preventive Services Task Force (USPSTF) grades the quality of the overall evidence for a service on a 3-point scale (good, fair, or poor).

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

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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.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Effectiveness of Early Detection

Fecal Occult Blood Testing (FOBT). 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 fecal occult blood test 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. 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 fecal occult blood test than among controls who received usual care (9.46 versus 14.09 deaths per 1,000 patients screened); biennial screening reduced mortality by 21%. 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 (relative risk [RR], 0.88; 95% confidence interval [CI], 0.69 - 1.12).

Sigmoidoscopy. Current evidence of the effectiveness of sigmoidoscopy is limited to several well-designed case-control studies, but 2 ongoing randomized controlled trials 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%. A second case-control study in which 75% of the examinations were performed with a flexible instrument found similar protection.

Fecal Occult Blood Testing and Sigmoidoscopy. No randomized controlled trials have examined whether combining fecal occult blood testing 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

fecal occult blood testing 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 yeas in controls; p = 0.11). 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. 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 = 0.47; 95% CI, 0.37-0.58) and lower mortality from colorectal cancer (odds ratio = 0.43;95% CI, 0.30-0.63). Slightly greater benefits of colonoscopy have been predicted in models that project benefits based on sensitivity of screening and rates of polyp progression.

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

POTENTIAL HARMS

Potential Harms of Screening

Fecal occult blood test 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). In a study of 1,235 screening sigmoidoscopies, adverse effects included pain (14%), anxiety, bleeding (3%), gas or flatus (25%), but no perforations. 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.

Screening colonoscopy poses higher risks than fecal occult blood test 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 colonoscopy depend on whether it is used simply for screening and diagnosis, or whether it is also used for therapeutic procedures (e.g., removal of polyps). In two 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.

Risks are higher in therapeutic procedures (e.g., 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 one study reported no bleeding events in 250 patients.

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 computed tomography colography.

Patient Preferences and Adherence

Some patients report that they find the fecal occult blood test unpleasant or difficult to perform, but 50% to 70% of patients will complete fecal occult blood test 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 fecal occult blood test alone, sigmoidoscopy alone, or both tests together, most patients in an academic internal medicine clinic preferred both tests or fecal occult blood test alone; only 8% to 13% preferred sigmoidoscopy alone. However, patient adherence to combined testing is lower than it is for sigmoidoscopy or fecal occult blood test 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 one study of patients in a population with considerable previous screening experience, 38% preferred colonoscopy to other methods. The acceptability and feasibility of computed tomography colography have not been examined.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

When to Start or Stop Screening for Colorectal Cancer

There are few data to determine optimal age for starting or stopping screening. Fecal occult blood test (FOBT) has been proven effective for persons aged 50 to 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.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical recommendations. Practice guidelines are relatively weak tools for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Neither the resources nor the composition of the U.S. Preventive Services Task Force equip it to address these numerous implementation challenges, but a number of related efforts seek to increase the impact of future U.S. Preventive Services Task Force reports. The U.S. Preventive Services Task Force convened representatives from the various audiences for the Guide ("Put Prevention Into Practice. A Step-by-Step Guide to Delivering Clinical Preventive Services: A Systems Approach") - clinicians, consumers and policy makers from health plans, national organizations and Congressional staff - about how to modify the content and format of its products to address their needs. With funding from the Robert Wood Johnson Foundation, the U.S. Preventive Services Task Force and Community Guide effort have conducted an audience analysis to further explore implementation needs. The Put Prevention into Practice initiative at the Agency for Healthcare Research and Quality (AHRQ) has developed office tools such as patient booklets, posters, and handheld patient mini-records, and a new implementation guide for state health departments.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the Agency for Healthcare Research and Quality will make all U.S. Preventive Services Task Force (USPSTF) products available through its Web site. The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access U.S. Preventive Services Task Force materials and adapt them for their local needs. Online access to U.S. Preventive Services Task Force products also opens up new possibilities for the appearance of the third edition of the Guide to Clinical Preventive Services. Freed from having to serve as primary repository for all of

U.S. Preventive Services Task Force work, the next Guide may be much slimmer than the almost 1000 pages of the second edition.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals and test results are not always centralized.

IMPLEMENTATION TOOLS

Foreign Language Translations
Patient Resources
Personal Digital Assistant (PDA) Downloads

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

RELATED QUALITY TOOLS

- Pocket Guide to Good Health for Adults
- A Step-by-Step Guide to Delivering Clinical Preventive Services: A Systems Approach
- Colorectal Cancer Screening. What's New from the USPSTF.

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)

U.S. Preventive Services Task Force. Screening for colorectal cancer: recommendations and rationale. Ann Intern Med 2002 Jul 16;137(2):129-31. PubMed

ADAPTATION

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

DATE RELEASED

1996 (revised 2002 Jul)

GUIDELINE DEVELOPER(S)

United States Preventive Services Task Force - Independent Expert Panel

GUIDELINE DEVELOPER COMMENT

The U.S. Preventive Services Task Force (USPSTF) is a Federally-appointed panel of independent experts. Conclusions of the U.S. Preventive Services Task Force do not necessarily reflect policy of the U.S. Department of Health and Human Services (DHHS) or its agencies.

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

U.S. Preventive Services Task Force (USPSTF)

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Task Force Members: Alfred O. Berg, MD, MPH, (Chair); Janet D. Allan, PhD, RN, CS (Vice-chair); Paul S. Frame, MD; Charles J. Homer, MD, MPH; Mark S. Johnson, MD, MPH; Jonathan D. Klein, MD, MPH; Tracy A. Lieu, MD, MPH; Cynthia D. Mulrow, MD, MSc; Tracy C. Orleans, PhD; Jeffrey F. Peipert, MD, MPH; Nola J. Pender, PhD, RN, FAAN; Albert L. Siu, MD, MSPH; Steven M. Teutsch, MD, MPH; Carolyn Westhoff, MD, MSc; Steven H. Woolf, MD, MPH.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The U.S. Preventive Services Task force has an explicit policy concerning conflict of interest. All members and evidence-based practice center (EPC) staff disclose at each meeting if they have an important financial conflict for each topic being discussed. Task Force members and EPC staff with conflicts can participate in

discussions about evidence, but members abstain from voting on recommendations about the topic in question.

From: Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow, CD, Teutsch SM, Atkins D. Current methods of the U.S. Preventive Services Task Force: a review of the process. Methods Work Group, Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):21-35.

GUIDELINE STATUS

This is the current release of the guideline.

This release updates a previously published guideline: U.S. Preventive Services Task Force. Screening for colorectal cancer. In: Guide to clinical preventive services. 2nd ed. Baltimore (MD): Williams & Wilkins; 1996.

GUIDELINE AVAILABILITY

Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site. Also available from the Annals of Internal Medicine Online and the National Library of Medicine's Health Services/Technology Assessment Text (HSTAT) Web site.

Print copies: Available from the Agency for Healthcare Research and Quality Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only). (Outside the United States: 1-410-381-3150; Toll-free TDD service; hearing impaired only: 888-586-6340.)

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

Evidence Reviews:

- Pigone M, Rich M, Teutsch SM, Berg AO, Lohr KN. Screening for colorectal cancer in adults at average risk: summary of the evidence for the U. S. Preventive Services Task Force. Ann Intern Med 2002 Jul;137(2):132-41.

  Electronic copies: Available from the USPSTF Web site and the Annals of Internal Medicine Online.

- Pigone M, Somnath S, Hoerger T, Mandelblatt J. Cost-effectiveness analyses of colorectal cancer screening: a review of the evidence for the U.S. Preventive Services Task Force Ann Intern Med 2002 Jul;137(2):96-104.

  Electronic copies: Available from the USPSTF Web site and the Annals of Internal Medicine Online.

- Pigone M, Rich M, Teutsch SM, Berg AO, Lohr KN. Screening for colorectal cancer in adults. Rockville (MD); Agency for Healthcare Research and Quality;

2002 June. (Systematic evidence review; no. 7). AHRQ publication no. AHRQ02-S003.

Background Articles:

- Woolf SH, Atkins D. The evolving role of prevention in health care: contributions of the U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):13-20.
- Harris RP, Helfand M, Woolf SH, Lohr KN, Mulrow, CD, Teutsch SM, Atkins D. Current methods of the U.S. Preventive Services Task Force: a review of the process. Methods Work Group, Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):21-35.
- Saha S, Hoerger TJ, Pignone MP, Teutsch SM, Helfand M, Mandelblatt. The art and science of incorporating cost effectiveness into evidence-based recommendations for clinical preventive services. Cost Work Group of the Third U.S. Preventive Services Task Force. Am J Prev Med 2001 Apr;20(3S):36-43.

Electronic copies: Available from U.S. Preventive Services Task Force (USPSTF) Web site.

Additional Implementation Tools:

- A step-by-step guide to delivering clinical preventive services: a systems approach. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ), 2001. 189 p. (Pub. No. APPIP01-0001). Electronic copies available from the AHRQ Web site.

  Print copies: Available from the Agency for Healthcare Research and Quality Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

- The Preventive Services Selector, an application for Palm Pilots and other PDA's, is also available from the AHRQ Web site.
- Colorectal cancer screening. What's new from the third USPSTF. Rockville (MD): Agency for Healthcare Research and Quality; 2002 Jun. Electronic copies: Available from USPSTF Web site.

PATIENT RESOURCES

The following is available:

- The Pocket Guide to Good Health for Adults. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2003.

Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site. Copies also available in Spanish from the USPSTF Web site.

Print copies: Available from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to http://www.ahrq.gov/news/pubsix.htm or call 1-800-358-9295 (U.S. only).

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on July 8, 2002. The information was verified by the guideline developer on July 11, 2002.

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