

AMERICAN GASTROENTEROLOGICAL ASSOCIATION

Colorectal Cancer Screening: Recommendations of the U.S. Preventive Services Task Force

In December 1995, the U.S. Preventive Services Task Force (USPSTF) for the first time urged primary care clinicians to screen for colorectal cancer.¹ The USPSTF is an independent expert panel charged by the U.S. Department of Health and Human Services (HHS) with developing preventive health guidelines based on an objective, in-depth review of available scientific data. During the release of the 1995 edition of their *Guide to Clinical Preventive Services*, Dr. Harold C. Sox, chairman of the USPSTF, emphasized that there is now strong new evidence of efficacy for both fecal occult blood test (FOBT) screening and for screening flexible sigmoidoscopy in the form of prospective controlled trials and high quality case-control studies. He further noted that although the panel's recommendations technically call for FOBT and/or flexible sigmoidoscopy, most clinicians will choose to recommend both screening tests for their average-risk, asymptomatic patients older than 50 years of age. Table 1 contains the summary recommendation of the USPSTF for screening for colorectal cancer.

The Federated Societies of Gastroenterology and Hepatology have lobbied vigorously for the inclusion of colorectal cancer screening in Medicare benefits based on the strength of recent scientific data. It is hoped that this landmark action by the USPSTF will help bring these efforts to fruition. In fact, in response to a question by a reporter from the *AGA News* at the Washington press conference where the guidelines were released, Dr. Philip R. Lee, Assistant Secretary for Health at HHS, not only stressed the importance of these evidence-based recommendations to the health of Americans but also emphasized that new USPSTF recommendations usually do lead to the provision of these benefits for patients receiving Medicare benefits.²

Before final publication, the current guidelines were submitted for review to a number of medical organizations, government agencies, and specialty societies, including both the American Gastroenterological Association and the American Society for Gastrointestinal Endoscopy. The gastrointestinal societies strongly supported the inclusion of this approach to colorectal cancer screening in the new guideline and offered their assistance in informing the medical community and the pub-

lic about the value of these services. At the time of the release in December 1995, the Digestive Health Initiative (DHI) conducted an extensive media campaign informing news publications and radio and television stations across the United States about the recommendations and the importance of colorectal cancer screening in general.

Scientific data supporting colorectal cancer screening are as compelling as data for any of the other major malignancies. Five long-term, controlled, prospective trials involving more than 310,000 participants have evaluated the efficacy of FOBT screening.³ Three of these trials have now reported a significant reduction in mortality rate from the disease as a result of screening (Table 2).^{4,5} In addition, two case-control studies suggest efficacy of FOBT screening.^{6,7} All of the controlled trials have published data indicating that FOBT screening is feasible, that cancers detected in the screened populations are more likely to have a favorable stage, and that survival after diagnosis for screen-detected cancers is better than for non-screen-detected cancers.⁸

The efficacy of flexible sigmoidoscopy screening remains unproven; there has not yet been a completed controlled trial of this modality. The current National Cancer Institute Prostate, Lung, Colon, and Ovary Study, a large multicenter screening trial directed at prostatic, lung, colorectal, and ovarian cancers, includes an investigation of screening flexible sigmoidoscopy. Definitive results from this trial will not be available for another decade. However, two case-control studies, one by Selby et al.⁹ from Kaiser Permanente in northern California and one by Newcomb et al.¹⁰ from the Marshfield Clinic in Wisconsin, indicate a reduction in mortality rate from distal colorectal cancer of 60%–85% as the result of screening sigmoidoscopy. Although the USPSTF concluded that the proper interval for flexible sigmoidoscopy remains uncertain, indirect evidence suggests that those with negative screening results do not need to have the test repeated for 5 years or more.^{9,11}

Based on these impressive data, screening of the asymptomatic, average-risk population for colorectal cancer with annual FOBTs and periodic flexible sigmoidoscopy is now recommended not only by the USPSTF but

Table 1. Summary Recommendation of the USPSTF for Screening for Colorectal Cancer

"Screening for colorectal cancer is recommended for all persons aged 50 and older with annual fecal occult blood testing (FOBT), or sigmoidoscopy (periodicity unspecified) or both. There is insufficient evidence to determine which of these screening methods is preferable or whether the combination of FOBT and sigmoidoscopy produces greater benefit than does either test alone. There is also insufficient evidence to recommend for or against routine screening with digital rectal examination, barium enema, or colonoscopy, although recommendations against such screening in average-risk persons may be made on other grounds. Persons with a family history of hereditary syndromes associated with a high risk of colon cancer should be referred for diagnosis and management."

also by the American Cancer Society, the World Health Organization U.S. Collaborating Center for the Prevention of Colorectal Cancer, and virtually all of the medical and surgical gastrointestinal societies.^{12,13}

Regrettably, although 55,000 Americans die of colorectal cancer annually, implementation and widespread adoption of these recommendations by both the public and the medical community is still being delayed for a number of reasons. One probable reason for this delay is the fact that many managed care groups and other health care payers, including Medicare, do not reimburse for these services. Another possible hindrance may be critics of this approach to screening, who continue to stress theoretical and real limitations of the two main screening tests. Public surveys indicate that only about 50% of those older than 50 years of age have discussed colorectal cancer screening with their primary physicians, and only about 25% have ever had actual screening.¹⁴

Published sensitivity calculations from the Minnesota and Swedish FOBT trials indicate that relatively few cancers are missed using the more sensitive, rehydrated Hemoccult slide test (Smith Kline Diagnostics, San Jose, CA).^{15,16} These findings suggest that screening should be performed with one of the newer guaiac or immunochemical tests that have similar sensitivity for detecting human blood but better specificity (i.e., fewer false-positive results).^{17,18} Now that FOBT screening has been shown to be efficacious, work must continue in the development of tests with improved performance characteristics. Because the greatest cost of screening is for the diagnostic evaluation required by a positive screen, any improvement in test specificity that does not substantially sacrifice sensitivity is likely to be cost-effective. It should also be emphasized that a simple, indirect screening test repeated at prescribed intervals does not have to be completely sensitive to be efficacious as long as it

reliably detects developing cancers before they become incurable.

Flexible sigmoidoscopy accurately diagnoses both cancers and polyps in the part of the large bowel where most of these neoplasms occur. Although some investigators in both the United States and United Kingdom have advocated limiting standard screening to flexible sigmoidoscopy alone, this is probably unacceptable in this country because the examination detects only about one half of all colonic neoplasms in actual practice.¹⁹⁻²¹ The combination of both screening methods provides a means of overcoming some of the limitations of each individual test. Other indirect data that support screening with a combination of FOBTs and sigmoidoscopy include a relative insensitivity of the FOBT for detecting rectal cancers and medium- or small-sized adenomas.

Screening the 70–80 million average-risk people older than 50 years of age in the United States for colorectal cancer admittedly would be very expensive.²² Projections of the total cost of screening, however, often do not consider realistic estimates of compliance or a number of potential cost-saving strategies. For example, a negative colonoscopy following a positive screening test obviates the need for further screening for up to 10 years, resulting in considerable cost savings. The Congressional Budget Office and the Administration's Office of Management and Budget have estimated the actual cost of screening patients receiving Medicare benefits for colorectal cancer for a period of 7 years to be \$750 million and \$1.1 billion, respectively.²³ Health care payers and the public should understand, however, that the cost of missing an early curable colorectal cancer or failing to prevent the disease by resecting premalignant adenomas may be much greater than the cost of screening. Cost-effectiveness analyses performed by both the Congressional Office of Technology Assessment (OTA) and the National Cancer Institute (NCI) indicate that the cost per year of life

Table 2. Results of FOBT Trials

	Mortality reduction (%)	Survival	Stage
Controlled trials			
Minnesota	36	Improved	Improved
New York ^a	43	Improved	Improved
Denmark	19	Improved	Improved
United Kingdom	Pending	Improved	Improved
Sweden	Pending	Improved	Improved
Case-control studies			
Kaiser Permanente	31	NA	NA
Germany	57	NA	NA

NOTE. Data are from Winawer and Bond.³

^aPatients assigned by calendar period.

saved by colorectal cancer screening is about \$25,000, well within the benchmark figure of \$40,000 considered by the government to be cost-effective.^{24,25} The OTA and NCI economists concluded that standard colorectal cancer screening using FOBT plus flexible sigmoidoscopy is a "relatively good investment for U.S. society."²⁶

Another cost-effectiveness analysis recently published in *GASTROENTEROLOGY* by Lieberman indicated that, of five different screening strategies, annual fecal occult blood screening alone was the most cost-effective method.²⁷ Adding flexible sigmoidoscopy every 5 years to annual FOBTs increased cancer prevention 2.2-fold because of its ability to detect precancerous adenomas. In addition, Lieberman's modeling analysis also estimated for the first time the cost of doing no screening. The average cost of caring for cancers that would not be prevented was \$677 per potential screenee for a 10-year period. If failing to screen resulted in cancers detected at a later stage, then the cost per person per 10 years of not doing screening exceeds \$1000.

In the distant future, direct screening colonoscopy or gene-based screening tests may prove to be feasible, acceptable, and effective. In the meantime, the best hope of reducing the great mortality, morbidity, and economic loss from colorectal cancer is to promote widespread FOBT and flexible sigmoidoscopy screening. In clinical trials and in the individual experience of many practicing physicians, this approach appears to be feasible, highly effective, and affordable and could reduce the colorectal cancer mortality rate by more than 50%.⁸ The challenge that now confronts us is to ensure adequate compliance for screening by both the general public and by primary clinicians, who are in the best position to perform preventive medical services.

To promote compliance for screening, the American Digestive Health Foundation launched the DHI Colorectal Cancer Campaign during Digestive Disease Week 1996. Patterned after the very successful DHI Ulcer Campaign, this program is designed to increase awareness of the public, primary clinicians, and managed care groups of the impact of colorectal cancer in the United States and the value of screening. Using a creative public promotion program, knowledgeable volunteers from our membership, and productive liaisons with other interested groups such as the American Cancer Society and the Center for Disease Control and Prevention, this campaign will not only benefit the 70 million Americans at risk for colorectal cancer but will also reinforce the appropriate leadership position of our subspecialty in digestive health. The American public has footed the bill for most of the extensive research that shows the value of screening

for colorectal cancer. We believe it is now time to translate the results of this investigation into real benefits for our society. We urge all gastrointestinal specialists to help with this important effort by informing your colleagues, your patients, and their families about the new USPSTF screening recommendations.

BERNARD LEVIN, M.D.

*M. D. Anderson Cancer Center
Houston, Texas*

JOHN H. BOND, M.D.

*Department of Veterans Affairs Medical Center
Minneapolis, Minnesota*

References

1. Guide to clinical preventive services. 2nd ed. Report of the U.S. Preventive Services Task Force. Washington, DC: Department of Health and Human Services, 1995.
2. U.S. Preventive Services Task Force recommends colorectal cancer screening. *ASGE News* 1996; 3:2.
3. Winawer SJ, Bond JH. Fecal occult blood test screening trials. In: Cohen AM, Winawer SJ, eds. *Cancer of the colon, rectum and anus*. New York: McGraw-Hill, 1995:279.
4. Mandel JS, Bond JH, Church TR, Snover DC, Bradley M, Schuman LM, Ederer F. Reducing mortality from colorectal cancer by screening for fecal occult blood. *N Engl J Med* 1993; 328:1365.
5. Winawer SJ, Flehinger BJ, Schottenfeld D, Miller DG. Screening for colorectal cancer with fecal occult blood test and sigmoidoscopy. *J Natl Cancer Inst* 1993; 85:1311-1318.
6. Selby JV, Friedman GD, Quesenberry CP, Weiss NS. Effect of fecal occult blood testing on mortality from colorectal cancer: a case-control study. *Ann Intern Med* 1993; 118:1.
7. Wahrendorf J, Robra B-P, Wiebelt H, Shore KM. Effectiveness of colorectal cancer screening: results from a population-based case-control evaluation in Saarland, Germany. *Eur J Cancer Prev* 1993; 2:221.
8. Bond JH. Fecal occult blood testing for colorectal cancer: can we afford not to do this? *Gastroenterol Clin North Am* 1997 (in press).
9. Selby JV, Friedman GD, Quesenberry CP Jr, Weiss NS. A case-control study of screening sigmoidoscopy and mortality from colorectal cancer. *N Engl J Med* 1992; 326:653-657.
10. Newcomb PA, Norflee RG, Storer BE, Surawicz TS, Marens PM. Screening sigmoidoscopy and colorectal cancer mortality. *J Natl Cancer Inst* 1992; 84:1572-1575.
11. Rex CK, Lehman GA, Ulbright TM, Smith JJ, Hawes RH. The yield of a second screening flexible sigmoidoscopy in average-risk persons after one negative examination. *Gastroenterology* 1994; 106:593-595.
12. Levin B, Murphy B. Revision in American Cancer Society recommendations for the early detection of colorectal cancer. *CA Cancer J Clin* 1992; 42:296.
13. Winawer SJ, St John DJ, Bond JH, Rozen P, Burt RW, Waye JD, Kronborg O, O'Brien MJ, Bishop DT, Kurtz RC, Shike M, Swaroop S, Levin B, Fruhmorgen P, Lynch HT. Prevention of colorectal cancer: guidelines based on new data. *Bull WHO* 1995; 73:7.
14. Czaja R, McFull SL, Warnecke RB, Ford LF, Kaluzny AD. Preferences of community physicians for cancer screening guidelines. *Ann Intern Med* 1994; 120:602-608.
15. Mandel JS, Bond JH, Bradley M, Snover DC, Church TR, Williams S, Watt G, Schuman LM, Ederer F, Gilbertsen V. Sensitivity, specificity and positive predictivity of the Hemoccult test in screening

- for colorectal cancers: the University of Minnesota's Colon Cancer Control Study. *Gastroenterology* 1989; 97:597-600.
16. Kewenter J, Engaras B, Haglind E, Jensen J. Value of retesting subjects with a positive Hemoccult in screening for colorectal cancer. *Br J Surg* 1990; 77:1349.
 17. Allison JE, Tekawa IS, Ransom LJ, Adrain AL. A comparison of fecal occult blood tests for colorectal cancer screening. *N Engl J Med* 1996; 334:155.
 18. Van Dam J, Bond JH, Sivak MV. Fecal occult blood screening for colorectal cancer. *Arch Intern Med* 1995; 155:2389.
 19. Rex DK, Lehman GA, Ulbright TM, Smith JJ, Pound DC, Hawes RH, Helper DJ, Wiersema MJ, Langefeld MS, Li W. Colonic neoplasia in asymptomatic persons with negative fecal occult blood tests: influence of age, gender, and family history. *Am J Gastroenterol* 1993; 88:825-831.
 20. Foutch PG, Mai H, Pardy K, Disario JA, Manne RK, Kerr D. Flexible sigmoidoscopy may be ineffective for secondary prevention of colorectal cancer in asymptomatic, average-risk men. *Dig Dis Sci* 1991; 36:924-928.
 21. Lieberman DA, Smith FW. Screening for colon malignancy with colonoscopy. *Am J Gastroenterol* 1991; 86:946-951.
 22. Ransohoff DF, Lang CA. Screening for colorectal cancer. *N Engl J Med* 1991; 325:37.
 23. Bond JH, Levin B. Colorectal cancer screening: the battle may be lost, but the war must be won. *ASGE News* 1995; 3:6.
 24. Wagner JL, Herdman RC, Wadhwa S. Cost-effectiveness of colorectal cancer screening in the elderly. *Ann Intern Med* 1991; 115:807.
 25. Brown ML. Letter to the editor. *N Engl J Med* 1993; 329:1352.
 26. Wagner JL, Tunis S, Brown M, Ching A, Almeida R. The cost effectiveness of colorectal cancer screening in average-risk adults. In: Young G, Levin B, eds. *Prevention and early detection of colorectal cancer*. London: Saunders, 1996:321-356.
 27. Lieberman DA. Cost-effectiveness model for colon cancer screening. *Gastroenterology* 1995; 109:1781-1790.
-
- Address requests for reprints to: John H. Bond, M.D., Department of Veterans Affairs Medical Center, One Veterans Drive, Minneapolis, Minnesota 55417.**
- © 1996 by the American Gastroenterological Association
0016-5085/96/\$3.00**