

American Cancer Society Guidelines for Screening and Surveillance for Early Detection of Colorectal Polyps and Cancer: Update 1997

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Background

In 1997 approximately 131,000 Americans will be diagnosed with colorectal cancer and about 55,000 will die from this disease.¹ Colorectal cancer is second only to lung cancer as a cause of death from

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The ACS Detection and Treatment Advisory Group on Colorectal Cancer consisted of the following members: Bernard Levin, MD (Chair);* Tim Byers, MD, MPH (Vice-Chair);* Donald Anthony, MD; Debra Broadwell-Jackson, PhD, RN; Randall Burt, MD; Jerome DeCosse, MD; Gerald Dodd, MD;* Julian Duttera, MD; John Fazekas, MD; Cecilia Fenoglio-Preiser, MD; Stanley Hamilton, MD; Edward Mansour, MD; Richard Nelson, MD; Jerry Olshan, DO; Michael Paglia, MD; Mary Elizabeth Roth, MD; David Rothenberger, MD;* Robert Schweitzer, MD; Mary Simmonds, MD; Marion Nadel, PhD (CDC liaison); Robert Smith, PhD (ACS staff).*

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cancer in the United States. Without preventive actions, about 6% of Americans will develop colorectal cancer sometime in their lives. Recent research, however, has contributed to a growing consensus that early detection methods can prevent a substantial proportion of the suffering and mortality from colorectal cancer.^{2,3} The same methods used to detect colorectal cancers at early, curable stages can also aid physicians in the identification and removal of adenomas, which give rise to colorectal cancer. Methods for early detection can therefore actually prevent colorectal cancer.

Development of Guidelines

The American Cancer Society issues guidelines for practitioners and the general public for both clinical practices and lifestyle behaviors that can reduce suffering and mortality from cancer. Since 1980 the ACS has recommended screening for colorectal cancer.⁴ The current recommendation, updated in 1992, calls for everyone over age 50 who is at average risk to be screened with annual fecal occult blood testing and sigmoidoscopy every 3 to 5 years and for those at higher risk to seek a recommendation from their physician.⁵

Because of new findings that have strengthened the evidence of benefit from screening people at average risk and

because of the need for more specific guidance for those at higher risk, the ACS has determined that these guidelines now need to be updated.

The ACS Detection and Treatment Advisory Group on Colorectal Cancer developed the new guidelines using an inclusive process, based on the best scientific evidence available. Late in 1995, the Advisory Group met to review the scientific evidence and to set general principles for guideline development. The Group identified four scientific and clinical issues that it regarded as important in the formation of these new guidelines:

1. Evidence was growing about the benefits of early detection of colorectal cancer and of adenomatous polyp removal.

2. Evidence was inconclusive regarding the relative clinical effectiveness of the alternative methods for early detection of colorectal cancer and adenomatous polyps.

3. Advances in cancer genetics and findings from epidemiologic studies had identified increasing numbers of people as being at high risk for colorectal cancer, yet the previous ACS guidelines did not provide specific recommendations for anyone other than those at average risk.⁴

4. Despite the existing ACS guidelines most adults in the United States were not being screened for colorectal cancer.

The Advisory Group developed the new guidelines by a process based on the following four principles:

1. Wide input and consensus among the medical specialties would be sought.

2. Specific advice would be offered when scientific data could support specific methods, and a range of acceptable options would be offered when scientific data were insufficient to contrast alternative effective methods.

3. Different recommendations would be considered for those at different levels of risk.

4. The guidelines would be clear enough for widespread clinical use but

also flexible enough to allow for tailoring of approaches to meet individual needs.

Draft guidelines were developed in mid-1996 and circulated to various organizations for comments and suggestions. Based on those suggestions, the guidelines were then revised in early 1997 and approved by a vote of the ACS Board of Directors in March 1997.

Definitions of Early Detection Methods

Fecal occult blood testing (FOBT) refers to the implementation of the protocol of collecting and testing six samples from three consecutive stools of a patient following a specified diet.⁶ The published FOBT trials used the Hemoccult II method (SmithKline Diagnostics, San Jose, CA),⁷⁻⁹ but other methods are now in development.¹⁰ A positive fecal occult blood test should be followed by colonoscopy.

Digital rectal examination refers to the inspection and palpation of the anus and lower rectum.

Flexible sigmoidoscopy refers to the direct visual examination of the lower third to half of the colorectum by a trained examiner using a flexible 60-cm endoscope after satisfactory cleansing of the descending and sigmoid colon. A positive finding on sigmoidoscopy should be followed by colonoscopy.

Total colon examination refers to either of two procedures carried out by a trained examiner after a satisfactory cleansing of the entire colorectum. One procedure is *colonoscopy*, direct visual examination of the entire colorectum (to the cecum) using a colonoscope. The other procedure is *double-contrast barium enema*, radiologic examination of the entire colorectum by instilling both barium and air to define the contours of the colorectal mucosa. A positive finding on double-contrast barium enema should usually be followed by endoscopy.

1997 ACS Colorectal Cancer Screening Guidelines

The new ACS guidelines for the early detection of colorectal adenomas and colorectal cancer are summarized in the Table. Following is a brief explanation of the main features of the recommendations.

PEOPLE AT AVERAGE RISK

Approximately 70 to 80% of all colorectal cancers occur among people at "average risk."³ Average risk is defined by exclusion as anyone who is not otherwise defined as being at increased risk (as defined below). There are no factors yet identified that would place a person at lower than "average" risk for an initial approach to screening.

Everyone should begin colorectal cancer screening by age 50 by one of two methods, annual FOBT with sigmoidoscopy every 5 years or a total colon examination, either by colonoscopy (every 10 years) or by double-contrast barium enema (every 5 to 10 years). Digital rectal examination should be performed at the time of the sigmoidoscopy or the total colon examination, that is, every 5 to 10 years. Although there may be benefits of more frequent digital rectal examination for other purposes (e.g., for examination of the prostate in men or as part of the bimanual pelvic examination in women), there is no added benefit in detecting anal or rectal neoplasia by digital rectal examination more often than every 5 to 10 years.

The choice of colonoscopy or double-contrast barium enema can be made on an individual basis, depending on factors such as the local availability of trained clinicians who can offer a high-quality examination and cost. A supplementary double-contrast barium enema may be needed if a colonoscopic examination fails to reach the cecum, and a supplementary colonoscopy may be

needed if a double-contrast barium enema identifies a possible lesion or does not adequately visualize the rectosigmoid area. Double-contrast barium enema is usually less expensive than colonoscopy, but colonoscopy provides a direct visualization of lesions, which can then be sampled for biopsy or excised during the same procedure. For those who elect a periodic total colon examination for screening, there is no need for annual FOBT.

PEOPLE AT MODERATE RISK

Approximately 15 to 20% of colorectal cancers occur among people at moderate risk.³ The genetic events leading to colorectal cancer are rapidly becoming understood.¹¹ Colorectal adenomas are clearly the precursor lesions for almost all colorectal cancers, and adenomas are usually present for several years before they develop into cancer.¹² People who are diagnosed as having adenomatous polyps should have colonoscopic removal of all polyps from the colorectum. A total colon examination should then be repeated in 3 years. If adenomatous polyps have not recurred at the time of the 3-year examination, surveillance by total colon examination should be repeated every 5 years thereafter if the original polyp was 1 cm or larger or contained villous histology. If the original polyp was smaller than 1 cm, however, if it did not contain villous histology, and if the 3-year examination is negative, the patient can thereafter return to "average-risk" recommendations.

A family history of either colorectal cancer or colorectal adenomas increases the risk of developing colorectal cancer. In general, the closer the familial relationship, the younger the age of onset, and the larger the number of affected family members, the greater is the risk.¹³ Thus, risk is especially high for an individual if a first-degree relative (parent, sibling, or offspring) has had a colorectal

ACS Guidelines for Screening and Surveillance for Early Detection of Colorectal Polyps and Cancer*

Risk Category	Recommendation†	Age to Begin	Interval
AVERAGE RISK			
All people 50 years or older who are not in the categories below	One of the following: FOBT plus flexible sigmoidoscopy‡ or TCE§	Age 50 Age 50	FOBT every year and flexible sigmoidoscopy every 5 y Colonoscopy every 10 y or DCBE every 5-10 y
MODERATE RISK			
People with single, small (<1 cm) adenomatous polyps	Colonoscopy	At time of initial polyp diagnosis	TCE within 3 y after initial polyp removal; If normal, as per average risk recommendations (above)
People with large (≥1 cm) or multiple adenomatous polyps of any size	Colonoscopy	At time of initial polyp diagnosis	TCE within 3 y after initial polyp removal; if normal, TCE every 5 y
Personal history of curative-intent resection of colorectal cancer	TCE§	Within 1 y after resection	If normal, TCE in 3 y; if still normal, TCE every 5 y
Colorectal cancer or adenomatous polyps in first-degree relative younger than 60 y or in two or more first-degree relatives of any ages	TCE	Age 40 or 10 y before the youngest case in the family, whichever is earlier	Every 5 y
Colorectal cancer in other relatives (not included above)	As per average risk recommendations (above); may consider beginning screening before age 50		
HIGH RISK			
Family history of familial adenomatous polyposis	Early surveillance with endoscopy, counseling to consider genetic testing, and referral to a specialty center	Puberty	If genetic test positive or polyposis confirmed, consider colectomy; otherwise, endoscopy every 1-2 y
Family history of hereditary non-polyposis colon cancer	Colonoscopy and counseling to consider genetic testing	Age 21	If genetic test positive, or if patient has not had genetic testing, colonoscopy every 2 y until age 40 y, then every year
Inflammatory bowel disease	Colonoscopies with biopsies for dysplasia	8 y after the start of pancolitis; 12-15 y after the start of left-sided colitis	Every 1-2 y

*Approximately 70-80% of cases are from average-risk individuals, approximately 15-20% are from moderate-risk individuals, and 5-10% are from high-risk individuals. Topical rectal examination should be done at the time of each sigmoidoscopy, colonoscopy, or DCBE.

†Annual FOBT has been shown to reduce mortality from colorectal cancer, so it is preferable to no screening; however, the ACS recommends that annual FOBT be accompanied by flexible sigmoidoscopy to further reduce the risk of colorectal cancer mortality.

‡TCE includes either colonoscopy or DCBE. The choice of procedure should depend on the medical status of the patient and the relative quality of the medical examinations available in a specific community. Flexible sigmoidoscopy should be performed in those instances in which the rectosigmoid colon is not well visualized by DCBE. DCBE would be performed when the entire colon has not been adequately evaluated by colonoscopy.

§This assumes that a preoperative TCE was done.

DCBE = double-contrast barium enema; FOBT = fecal occult blood testing; TCE = total colon examination; y = years.

cancer or an adenomatous polyp diagnosed before age 60 years or if more than one first-degree relative has been affected at any age. Individuals with a single first-degree relative diagnosed with a colorectal cancer or an adenomatous polyp after age 60, however, or with affected relatives who are not first-degree relations can be considered to be at average risk, although it may be prudent to begin screening before the age of 50 years.

PEOPLE AT HIGH RISK

Approximately 5 to 10% of all colorectal cancers occur among people at high risk.³ Most of those defined as being at high risk for colorectal cancer have one of two hereditary syndromes or inflammatory bowel disease.

Familial adenomatous polyposis syndrome (FAP) is a genetic condition that affects 1 in 10,000 people. FAP is caused by a mutation in the APC gene on chromosome 5.¹¹ People with this condition develop hundreds of colorectal polyps and will almost certainly develop colorectal cancer unless the colon is removed.

Hereditary non-polyposis colorectal cancer syndrome (HNPCC) is a genetic condition that can also cause colorectal cancer among many people in a family even though multiple polyps are not present. HNPCC is caused by mutations in mismatch repair genes located on chromosome 2, 3, or 7.¹¹ HNPCC has been classically defined as colorectal cancer in three or more family members, two of whom are first-degree relatives of the third, involving people in at least two generations, and with one person diagnosed with colorectal cancer before age 50 years. However, other variants of this classic pedigree clearly exist. Individuals with genetic mutations that can lead to HNPCC are also at high risk for cancers of the ovary, uterus, ureter, pancreas, and stomach. Genetic tests are now available to detect the mutations that lead to FAP and HNPCC and should be considered,

with appropriate counseling, for people with family histories suggestive of these conditions.

Both ulcerative colitis and Crohn's disease that affects the colorectum greatly increase risk for colorectal cancer beginning 8 years after the onset of colorectal symptoms. Management is by careful endoscopic surveillance for colonic dysplasia and prophylactic colectomy.

Comment

These new ACS guidelines for colorectal cancer screening are comparable to guidelines released by two other organizations within the past year.^{2,3}

In 1996 the US Preventive Services Task Force (USPSTF) issued revised guidelines for clinical preventive services.² Those guidelines called for annual FOBT beginning at age 50. The success of a large randomized, controlled trial in reducing colorectal cancer mortality by 33% was the basis of the USPSTF recommendation.⁷ Since then, two European trials also have shown benefits from FOBT.^{8,9} The USPSTF also recommended sigmoidoscopic screening, though it did not specify a frequency because no randomized trials testing sigmoidoscopy had yet been completed.² The USPSTF criteria for making recommendations depend largely on findings from randomized trials. A randomized, controlled trial is now under way to measure the benefits of sigmoidoscopic screening, but results will not be known for several years.¹⁴

The ACS recommends that flexible sigmoidoscopy be done every 5 years to complement annual FOBT. One reason for the ACS recommendation is related to a well-documented set of recommendations issued in February 1997 by an interdisciplinary task force originally convened by the Agency for Health Care Policy Research (AHCPR).³ This Task Force was supported not only by AHCPR but also by the American Gastroenterological Association, the Ameri-

can Society for Gastrointestinal Endoscopy, the American College of Gastroenterology, the American Society of Colon and Rectal Surgeons, and the Society of American Gastroenterologic Endoscopic Surgeons. The Task Force called for universal screening for everyone after age 50 years, offered a set of reasonable options for screening methods, and specified recommendations for different levels of risk. These new ACS guidelines for colorectal cancer screening are nearly identical to the AHCPR Task Force guidelines.

One of the Task Force options is limited to annual FOBT testing for those at average risk for colorectal cancer. The ACS recommendation to always add periodic sigmoidoscopic examinations to the annual FOBT is an important difference between the ACS and the AHCPR Task Force recommendations. The ACS has made this recommendation for three reasons: the benefits from the FOBT trials⁷⁻⁹ were the result of the diagnostic endoscopies that followed positive FOBT tests,¹⁵ other studies have shown substantial risk reduction from sigmoidoscopic examinations,^{16,17} and flexible sigmoidoscopy is now widely available and safe and can be offered at a reasonable cost. Although trials have shown that FOBT alone as a screening method can reduce colorectal cancer mortality by 15 to 33%,⁷⁻⁹ the benefits derived from FOBT in these trials were the result not of the FOBT per se but of the subsequent colonoscopic examinations that led to polypectomy or to the early identification of colorectal cancers.¹⁵ The simulation models presented by the AHCPR Task Force estimate a 20% reduction in mortality from adding sigmoidoscopy every 5 years to annual FOBT,³ and two case-control studies suggest an even greater benefit from sigmoidoscopy.^{16,17} The ACS therefore recommends sigmoidoscopic examinations every 5 years as a reasonable way to intensively monitor the left side of the colorectum for neoplasia

while using annual FOBT to monitor the entire colon for bleeding.

The option of using total colon examination as a primary screening method is an important feature of both the AHCPR Task Force recommendations and the new ACS guidelines. Although randomized trials of total colonic examinations have not yet begun (and hence measures of their effectiveness will not be made for at least 10 years), the ACS committee believes that the indirect evidence for benefit and efficiency is compelling and that both benefit and efficacy would probably improve if future costs declined and availabilities improved with greater demand.

The ACS committee discussed the operational performance of various age cut-points. Because cut-points for age are arbitrary in most publications, the ACS committee decided to recommend a common age of "before age 60 years" to define familial risk. This is the same as the AHCPR Task Force cut-point for polyps but 5 years higher (and thus more inclusive) than the Task Force cut-point for cancer. Minor differences in the cut-points are less important than the concept of identifying elevated risk by family history, then beginning screening at an earlier age.

Future developments will improve the already impressive benefits of the early detection methods we now have in place in many clinical centers. FOBT methods will probably improve and be refined. The clinical implications of rehydration of Hemoccult II slides (resulting in high sensitivity but lower specificity) have resulted in an appreciation of the need for newer tests, such as Hemoccult Sensa (SmithKline Diagnostics, San Jose, CA) and immunochemical tests for human hemoglobin. The use of different types of fecal occult blood tests in combination is also under study. Even genetic testing for mutations present in colonic cells excreted in feces is technically possible,¹⁸ and improved imaging techniques

using modalities such as spiral CT with three-dimensional reconstruction of the colonic images may be useful for early detection.¹⁹ These new ACS guidelines for screening and surveillance for the early detection of colorectal polyps and cancer should be useful for clinicians and the general public. These guidelines will be updated in the future as new scientific data become available.

Summary

In the past, differences in opinion among professional groups about colorectal can-

cer screening have been a barrier to colorectal cancer prevention. It is clear that screening for colorectal cancer is currently practiced by fewer than 20% of American adults.²⁰ However, a growing consensus now exists that even though we do not yet have trial data to compare precisely the various methods for screening, there is now both a compelling case for screening and a reasonable set of methods that clinicians and patients can consider. By applying the knowledge we already have, it is likely that most of the deaths from colorectal cancer in the United States could be prevented. **CA**

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