

March 2008

Frequently Asked Questions (FAQ)

1. What are the new recommended guidelines for early detection of colorectal cancer?

Based on an expert panel's review of the historic and recent evidence, the following tests are acceptable options for the early detection of colorectal cancer and adenomatous polyps for asymptomatic, average risk adults aged 50 years and older:

Tests That Detect Adenomatous Polyps and Cancer

Flexible sigmoidoscopy (FSIG) every 5 years, or
Colonoscopy (CSPY) every 10 years, or
Double contrast barium enema (DCBE) every 5 years, or
CT colonography (CTC) every 5 years

Tests That Primarily Detect Cancer

Annual guaiac-based fecal occult blood test (gFOBT) with high test sensitivity for cancer, or
Annual fecal immunochemical test (FIT) with high test sensitivity for cancer, or
Stool DNA test (sDNA) with high sensitivity for cancer, interval uncertain

2. What is new and significant in these guidelines?

There are significant updates to the guidelines for colorectal cancer screening.

- Two new tests are now recommended as options for colorectal cancer screening. They are stool DNA (sDNA) and computerized tomographic (CT) colonography.
- For the first time, screening tests are grouped into categories based on performance characteristics: those that primarily detect cancer early and those that can also detect precancerous polyps. Tests that primarily detect cancer early are fecal (stool) tests, including guaiac-based and immunochemical-based fecal occult blood tests (gFOBT & FIT), and stool DNA tests (sDNA). Tests that detect both precancerous polyps and cancer include flexible sigmoidoscopy, optical colonoscopy, double contrast barium enema, and computerized tomographic (CT) colonography. It is the strong opinion of the expert panel that *colon cancer prevention* should be the primary goal of colorectal cancer screening. Exams that are designed to detect both early cancer and precancerous polyps should be encouraged if resources are available and patients are willing to undergo an invasive test.

- In addition, the updated guidelines establish a sensitivity threshold for recommended tests - all screening tests should have evidence in the medical literature documenting their ability to detect the majority of cancers present at the time of testing. Tests which do not meet this standard should not be used.
- Historically, the Society's guidelines for the early detection of colorectal cancer have emphasized options, and in an effort to enhance access to and uptake of screening, the updated guidelines will continue to do so. The Society maintains that the best test is the one you get that is *done well*.

3. What are the major changes to these guidelines compared with previous reviews?

One significant change is the grouping of colorectal cancer screening methods into those that primarily identify cancer and those that both detect cancer and precancerous polyps, with a preference for those tests that can both detect cancer and prevent it by detecting premalignant polyps, which can then be removed.

Another change is the panel's recommendation that options for screening must be able to detect the majority of cancers present at the time of testing. This criterion is based on expert opinion, and the following considerations:

- First, recent evidence has revealed an unacceptably wide range of sensitivity among some gFOBT strategies, with some practices and tests performing so poorly that the large majority of cancers are missed at the time of screening.
- Second, a test like gFOBT that demonstrates poor test sensitivity, but good program sensitivity, depends on high rates of adherence with regular screening. However, many patients have only one test and do not return for annual programmatic testing, and there is a lack of systems to ensure or facilitate adherence with recommended regular screening intervals.

For these reasons, the panel concluded that physicians and institutions should select stool blood tests that have been shown in the scientific literature to detect the majority of prevalent colorectal cancers in an asymptomatic population. If there is not evidence that an available test has met that benchmark, it should not be offered to patients for colorectal cancer screening.

The panel also added two new tests as acceptable options: CT colonography every 5 years, and sDNA testing (for which the optimal screening interval is currently unknown).

Finally, the panel eliminated the previously recommended preference for a combined approach using gFOBT or FIT every year *plus* flexible sigmoidoscopy every 5 years; in the revised guideline flexible sigmoidoscopy every 5 years is sufficient without the addition of annual gFOBT or FIT.

4. What topics did the current guideline review cover?

The latest guideline review reassessed the evidence for colorectal cancer screening tests that fall broadly into two categories:

Tests that are more likely to detect both cancer and premalignant polyps

Tests in this category are structural exams, including flexible sigmoidoscopy (FSIG), optical colonoscopy (CSPY), double contrast barium enema (DCBE), and computerized tomographic (CT) colonography. The higher likelihood of polyp detection with the use of these tests substantially increases opportunities for removal of polyps and the associated prevention of colorectal cancer.

Tests that are primarily effective at finding cancer early

Fecal (stool) tests include: guaiac-based and immunochemical-based fecal occult blood tests (gFOBT & FIT), and stool DNA test (sDNA). These tests primarily identify the existence of colorectal cancer. Some precancerous polyps may be detected by these tests, providing an opportunity to remove them and prevent colorectal cancer, but the opportunity for prevention is both limited and incidental and can not be the primary goal of colorectal cancer screening with these tests.

The panel also sought to address a number of quality issues related to each form of testing, as well as concerns about the complexity of offering multiple screening options to adults, and the degree to which the range of testing options, performance, costs, and demands on patients poses a significant challenge for shared decisions. An overriding goal of this update is to provide a practical guideline for physicians and the public to assist with informed decision making related to colorectal cancer screening.

5. What is the primary outcome of the review?

The expert panel believes that colon cancer prevention should be the primary goal of colorectal cancer screening. Screening tests that are designed to detect both early cancer and adenomatous polyps should be encouraged if resources are available and patients are willing to undergo an invasive test. These tests include flexible sigmoidoscopy, optical colonoscopy, air-contrast barium enema and CT colonography.

6. What are the early detection guidelines for those at increased risk for colorectal cancer?

In this update of the colorectal cancer screening guidelines, we have focused on screening in average risk adults and have not reviewed recent literature on colorectal cancer screening or surveillance among individuals at increased and high risk. Individuals at increased risk due to a history of adenomatous polyps, a personal history of curative-intent resection of colorectal cancer, or a family history of either colorectal cancer or colorectal adenomas diagnosed in a first-degree relative before age 60, or high-risk, due to a history of inflammatory bowel disease of significant duration, or the presence of one of two hereditary syndromes should continue to follow recommendations issued previously by the American Cancer Society or USMSTF. The current guidelines update includes tables summarizing the recommendations for those at increased risk.

7. If structural tests such as colonoscopy can prevent cancer, why not recommend only these tests?

These tests require bowel preparation and an office or hospital visit, and have various levels of risk to patients. They also have limitations, greater patient requirements for successful completion, and potential harms. The panel also recognized that some patients will not want to undergo an invasive test that requires bowel preparation, may prefer to have screening in the privacy of their home, or may not have access to the invasive tests due to lack of coverage or local resources.

8. What are the benefits and limitations of the fecal tests?

The primary advantage of these tests is that collection of fecal samples for blood or DNA testing can be performed at home, without bowel preparation. Fecal occult blood tests are also inexpensive on a per test basis when compared to other screening methods. However, these tests are less likely to lead to cancer prevention compared with the invasive tests; they must be repeated at more frequent intervals to be effective; and if the test is positive, colonoscopy is required. Patients choosing to be screened with fecal tests should also be comfortable with a cancer detection program that will not prevent most colon cancers. It must also be recognized that some stool tests (particularly older versions of guaiac-based tests) do not detect the majority of cancers present at the time of testing, and should therefore not be used for colorectal cancer screening.

If patients are not willing to have annual testing or to have colonoscopy if the test is positive, or if available fecal tests have not been shown in the medical literature to achieve the recommended cancer detection threshold, fecal testing programs will not be effective and should not be recommended.

9. Why is sDNA now recommended, and what are its strengths and limitations?

sDNA testing is a relatively new method of colorectal cancer screening. Cancer cells that contain altered DNA are continuously shed into the large bowel and passed in the feces, and this altered DNA can be isolated and identified through this screening test. In previous assessments, both the American Cancer Society and the U.S. Multi-Society Task Force concluded that data were insufficient to recommend screening with sDNA for average risk individuals. Based on the accumulation of evidence since the last update of these guidelines in 2003, there is sufficient data to conclude that sDNA testing meets the threshold criterion of detecting the majority of prevalent and incident cancers at the time of testing.

Advantages of this method are that sDNA testing has acceptable sensitivity for colorectal cancer, is not dependent on the detection of occult blood, which is intermittent, and requires only a single episode of stool collection. sDNA also is noninvasive, and lacks physical harm. Patient and provider acceptance of this technique appears to be high.

A clear limitation of sDNA testing is that test sensitivity is based on a panel of markers that appears to identify most, but not all, colorectal cancers. Further, it is not known what proportion of advanced adenomas is identified with the current commercially available version of the stool DNA test. Patients therefore need to be informed that the current test will detect some but not all cancers and some polyps. Also, there is uncertainty about how positive results without evidence of advanced lesions or cancer on follow-up colonoscopy should be interpreted by patients, and whether or not these patients require a different plan for on-going surveillance. Other potential limitations that have considerable implications for cost-effectiveness are the unit cost of the test, which is considerably higher than the other stool tests, and the frequency with which the test should be performed, which is uncertain.

10. Why is the sDNA re-testing interval described as “uncertain”

There are currently no observational data upon which to base a recommendation for appropriate screening intervals. Although the manufacturer of the currently available commercial test recommends a 5-year interval for routine screening, such an interval was judged by the committee to be appropriate only for a test that has very high sensitivity for both cancer and adenomatous polyps – a standard that has not been documented for sDNA testing. In the only large population study of sDNA completed to date, the sDNA test had better performance than the comparison gFOBT for the detection of cancer and advanced adenomas, but the detection rate still was not dissimilar to that of a high sensitivity gFOBT or FIT, for which current repeat testing recommendations range between 1 and 2 years.

11. Why is CT colonography now recommended?

Recent data suggest CTC is comparable to optical colonoscopy for the detection of cancer and polyps of significant size when state-of-the-art techniques are applied. Provided that advanced, proven techniques are employed in the clinical setting, CTC is included in the guidelines as an option for colorectal cancer screening and prevention in average-risk adults age 50 years and older.

12. What are CT colonography’s strengths and limitations?

CTC provides a time efficient procedure with minimal invasiveness. No sedation or recovery time is required, nor is a chaperone needed to provide transportation after the procedure. Time permitting, patients can return to work on the same day.

Several limitations of CTC exist. Since it is an “image-only” test, patients with polyps of significant size will require colonoscopy to remove the polyps. CTC also requires the same full bowel preparation and restricted diet as optical colonoscopy, which may decrease patient adherence. While same-day polyp removal can be offered without the need for additional preparation, this requires coordination between medical specialists (radiologists and endoscopists) and facilities (radiology departments and endoscopy

suites). Reimbursement for CTC is limited, although 47 states now offer Medicare reimbursement for diagnostic CTC for certain clinical indications (typically limited to patients who have had an incomplete optical colonoscopy).

Potential harms from CTC are related to the procedural risks associated with bowel preparation, colonic distention, and radiation exposure due to CT scanning. The risks associated with bowel preparation are similar to those for optical colonoscopy. Because CTC is a minimally invasive test, the risk for colonic perforation due to distention is low. In addition to views of the colon, CTC also captures images of the abdomen and pelvis. Abnormalities outside the colon are commonly identified, and a significant proportion of these abnormalities require additional evaluation, with associated costs and risks to patients.

13. How expensive are the tests recommended in the guidelines? Are they covered by insurance?

Costs of these different tests vary widely based not only on the type of test but also other fees (e.g.: administration fees, office visit, etc.). With the exception of the newly added tests – CTC and sDNA – Medicare and most insurers already cover most or all colorectal cancer screening tests. Based on the recommendations from this multi-organizational panel and those of other organizations it is conceivable that many major insurance plans will begin to cover the added tests (CTC and sDNA). As a result, these updated guidelines have a real possibility of contributing to greater access to colorectal cancer screening tests.

14. What is the American Cancer Society doing to increase access to colorectal cancer screening?

The recommendations from this multi-organizational panel and those of other organizations are likely to lead to additional test coverage by Medicare and most insurers, contributing to greater access to colorectal cancer screening tests.

In support of the Society's efforts to reduce colon cancer incidence and mortality, its sister advocacy organization, American Cancer Society Cancer Action Network (ACS CAN) advocates at the state and federal levels to ensure responsible health policies that help improve access to colon cancer testing and treatment.

- At the federal level, ACS CAN is working to pass legislation that would establish a program administered by the Centers for Disease Control and Prevention (CDC) that would provide vital colon cancer screenings, treatment and follow-up services to low-income, uninsured and underinsured men and women ages 50-64.
- ACS CAN is also working to ensure that more Medicare beneficiaries take advantage of these lifesaving screening tests. These efforts include advocating for legislation that would waive Medicare co-pays for all colon cancer screening tests

and extend the eligibility period for the Welcome to Medicare visit (in which doctors may recommend colon cancer and other screenings to their patients) from six months to one year. Additionally, ACS CAN is advocating for legislation that would give the U.S. Secretary of Health and Human Services the authority to have new screenings covered by Medicare once the United States Preventive Services Task Force approves them. Efforts are also underway to collaborate with Medicare Quality Improvement Organizations at the national and regional level to implement and evaluate interventions designed to increase screening among Medicare beneficiaries.

- ACS CAN is also working in partnership with the Society at the state level to pass laws that would require private health insurance plans to cover the full range of colon cancer screenings. Currently, 22 states and the District of Columbia guarantee such coverage, as does Medicare.

In addition to advocacy efforts, the Society has been engaged in strong outreach efforts to health plans and medical providers, and created a number of tools to assist them in educating their patients about colorectal cancer. The Society has also developed both PSA and paid advertising campaigns to raise public awareness of colorectal cancer and the benefits of screening, and to encourage individuals to talk with their doctors about screening.

15. How will these guidelines help reduce deaths from colorectal cancer?

Screening of average risk individuals can reduce colorectal cancer mortality by detecting cancer at an early curable stage, and by detecting and removing advanced neoplasia. No screening test is perfect – either for cancer detection or polyp detection. Each test has advantages, limitations and risks. Patient preferences and availability of resources play an important role in the selection of screening tests. This update of the guidelines for colorectal cancer screening have placed an emphasis on the value of preventing colorectal cancer, sought to address the importance of test sensitivity in the presence of low rates of programmatic screening, and attempted to provide improved guidance about test characteristics to referring clinicians. It is our hope that these new recommendations facilitate increased rates of colorectal cancer screening, and that referring clinicians find these new guidelines ease some of the challenges they have experienced in promoting colorectal cancer screening to their patients.

16. What is the history behind these guidelines?

Beginning in 1980, the American Cancer Society first issued formal guidelines for colorectal cancer screening in average risk adults. Since then, the Society has periodically updated its colorectal cancer guidelines, and other organizations also have issued recommendations for colorectal cancer screening, most notably the U.S. Preventive Services Task Force and the U.S. Multi-Society Task Force on Colorectal Cancer (USMSTF; comprised of the American College of Gastroenterology, the American Gastroenterological Association and the American Society for Gastrointestinal

Endoscopy). Since 1997, the organizational guidelines for average risk adults have grown increasingly similar, and now largely represent a broad consensus on the value, options, and methods for periodic screening for colorectal cancer.

In response to a recommendation from the National Colorectal Cancer Roundtable Quality Assurance Committee, the American Cancer Society, the U.S. Multi-Society Task Force, and the American College of Radiology (ACR) agreed to collaborate on an update of each organization's guidelines. It was agreed that the guidelines would be developed through a process of collective deliberation between experts from the three organizations and that the completed guideline would then be reviewed and approved by each organization.