Colorectal Cancer Screening Guideline Issue Brief Updated May 30th, 2018



Issue Summary

The American Cancer Society has updated its colorectal screening guideline, which have been published in CA: A Journal for Clinicians and are accessible here.

This document is intended to: provide general background information for NCCRT Members and 80% partners, help NCCRT members and partners talk about the guidelines in an informed manner, and answer common questions about the new guideline.

If you have additional questions or concerns not addressed in this document, please contact Mary Doroshenk, NCCRT director at mary.doroshenk@cancer.org

Key Points

The American Cancer Society has updated its colorectal cancer screening guideline. The new recommendations state:

- If you're age 45 or older, you should start getting screened for colorectal cancer.
- Several types of tests can be used. Talk to your health care provider about which ones might be good
 options for you and to your health insurance provider about your coverage.
- No matter which test you choose, the most important thing is to get tested.

KEY MESSAGES

What Has Changed in the New Guideline and Why

The American Cancer Society lowered their colorectal cancer screening recommended starting age to 45.

- The ACS guideline was changed, based in part, on new data showing rates of colorectal cancer are increasing in younger populations.
- The American Cancer Society updated the guideline to save more lives by finding colorectal cancer early, when treatment is more likely to be successful and by detecting and removing polyps, which contributes to the prevention of colorectal cancer.
- The current guideline differs from the previous guideline in the starting age, an emphasis on choice of tests for screening, and age-specific recommendations about when to stop screening.
- The previous recommendation said begin screening at age 50.
- While the previous guideline expressed a preference for screening tests that not only detected cancer, but also directly helped prevent it through removal of precancerous polyps, the new guideline does not prioritize among screening test options, instead emphasizing patient preferences and choice. Also, the

- new guideline does not include double-contrast barium enema as an acceptable CRC screening option.
- The new guideline stresses that when a screening test (other than colonoscopy) comes back positive, that test must be followed with a timely colonoscopy, in order to complete the screening process.
- Details about the new guideline and additional resources can be found on cancer.org.

The New Guideline – For People at Average Risk

The new guideline recommends that adults aged 45 and older at average risk* of colorectal cancer undergo regular screening with either a high-sensitivity stool-based test or a structural (visual) exam.

- People who are in good health and with a life expectancy of more than 10 years should continue regular colorectal cancer screening through the age of 75.
- For people ages 76 through 85, the decision to be screened should be based on a person's preferences, life expectancy, overall health, and prior screening history.
- People over 85 should no longer get colorectal cancer screening.
- ACS recommends that people talk to their health care provider about screening and which tests might be good options for them.
 People should also contact their insurance provider about their insurance coverage for colorectal cancer screening.

The New Guideline – Screening Test Options

The new guideline recommends several test options for colorectal cancer screening.

- There are some differences between these tests individuals will wish to consider, but the most important thing is to get screened, no matter which test you choose.
- Colorectal cancer screening can be done either with a sensitive test that looks for signs of cancer in a person's stool (a stoolbased test), or with an exam that looks at the colon and rectum (a visual exam).
- Stool-based tests:
 - o Fecal immunochemical test (FIT) every year
 - Highly sensitive guaiac-based fecal occult blood test (HSgFOBT) every year
 - Multi-targeted stool DNA test (mt-sDNA) every 3 years
- Visual (structural) exams of the colon and rectum:
 - Colonoscopy every 10 years
 - CT colonography (CTC) (virtual colonoscopy) every 5 years
 - o Flexible sigmoidoscopy (FS) every 5 years
- If a person chooses to be screened with a test other than colonoscopy, any abnormal test result should be followed up with a timely colonoscopy in order to complete the screening process.
- Patients are encouraged to talk to their health care provider about which tests might be good options for them and talk to their insurance provider about insurance coverage.
- The American Cancer Society has materials to help facilitate conversations between clinicians and patients about selecting an option for CRC screening. The materials will be available on cancer.org/colonmd

For People at High Risk

People at increased or high risk* of colorectal cancer might need to start

*People at increased or high risk of colorectal cancer includes people with: a strong family history of colorectal cancer or certain

colorectal cancer screening before age 45, be screened more often, and/or get specific tests.

types of polyps; personal history of colorectal cancer or certain types of polyps; personal history of inflammatory bowel disease (ulcerative colitis or Crohn's disease); a known family history of a hereditary colorectal cancer syndrome such as familial adenomatous polyposis (FAP) or Lynch syndrome (also known as hereditary non-polyposis colon cancer or HNPCC); or a personal history of radiation to the abdomen (belly) or pelvic area to treat a prior cancer.

- The American Cancer Society does not have screening guidelines specifically for people at increased or high risk of colorectal cancer. However, some other professional medical organizations, such as the US Multi-Society Task Force on Colorectal Cancer (USMSTF), do put out such guidelines. These guidelines are complex and are best discussed with your health care provider.
- ACS recommends that people at increased or high risk talk to their health care provider who can suggest the best screening option and determine what type of screening schedule you should follow, based on your individual risk.

Common Questions

1. How does the new guideline differ from the guideline published in 2008?

In the new guideline, the American Cancer Society recommends that people at average risk of colorectal cancer start regular screening at age 45 (instead of starting at age 50 as recommended in the previous guideline). This can be done either with a test that looks for signs of cancer in a person's stool (a stool-based test), or with a visual exam of the inside of the colon and rectum (also called a structural exam).

People who are in good health and with a life expectancy of more than 10 years should continue regular colorectal cancer screening through the age of 75. For people ages 76 through 85, the decision to be screened should be based on a person's preferences, life expectancy, overall health, and prior screening history. People over 85 should no longer get colorectal cancer screening.

While the previous guideline expressed a preference for screening tests that not only detected cancer, but also directly helped prevent it through removal of precancerous polyps, the new guideline does not prioritize among screening test options. Also, the new guideline no longer includes double-contrast barium enema as an acceptable CRC screening option. Finally, the new guideline stresses that when a screening test (other than colonoscopy) comes back positive, that test must be followed with a timely colonoscopy, in order to complete the screening process.

2. What tests does the American Cancer Society recommend in the new guideline?

The American Cancer Society recommends that any of the following screening test options be used. It is important to note that if a person chooses to be screened with a test other than colonoscopy, any abnormal test result should be followed up with a timely colonoscopy in order to complete the screening process.

- a. Stool-based tests:
 - Fecal immunochemical test (FIT) every year
 - High-sensitivity guaiac-based fecal occult blood test (HSgFOBT) every year
 - Multi-target stool DNA test (mt-sDNA) every 3 years
- b. Visual (structural) exams of the colon and rectum:

- Colonoscopy every 10 years
- CT colonography (CTC) (virtual colonoscopy) every 5 years
- Flexible sigmoidoscopy (FS) every 5 years

3. Why did ACS lower the recommended age to start screening, and why does that differ from the United States Preventive Services Task Force (USPSTF) recommendation?

The ACS looked closely at increasing incidence in younger adults, with emphasis on a recent study by ACS researchers showing rising incidence in younger birth cohorts expected to carry over as they age. This study had not yet been published when the USPSTF updated their CRC recommendations. With incidence increasing in younger adults, the Guideline Development Group concluded that screening should now begin at age 45 instead of age 50, resulting in more lives saved from colorectal cancer.

4. How was the data on rising CRC rates in younger individuals and the modeling papers sufficient evidence for changing the guidelines?

We have had strong evidence supporting the use of the recommended screening tests for many years. However, most studies on CRC screening include only adults aged 50 years and older because for many years this has been the recommended age to start screening. Because there is strong evidence of the benefit of screening, microsimulation modeling can be used to evaluate different screening strategies. The ACS commissioned a modeling study that extended a previous analysis conducted for the 2016 United States Preventive Services Task Force (USPSTF) screening recommendations. When models were adjusted to reflect increased incidence in younger adults, screening beginning at age 45 had a favorable balance of benefit to burden, and there was an improvement in life years gained compared with starting screening at age 50.

5. What should consumers do if their health plan won't start covering colorectal cancer screening until age 50?

While ACS has updated its guidelines to call for colorectal cancer screening to begin at age 45, health insurance plans may not yet cover the screening test for those in that age range. This could result in out-of-pocket expenses.

The Affordable Care Act requires insurance coverage without cost-sharing based on recommendations issued by the United States Preventive Services Task Force (USPSTF). The USPSTF last updated its recommendations in 2016, and recommends individuals begin screening at age 50. While insurers could choose to offer coverage of colorectal cancer screening tests earlier, they are not currently required to do so.

The ACS and ACS CAN are working aggressively to educate insurers, lawmakers, and other stakeholders on the rising rates of CRC among younger individuals, the evidence in support of screening for individuals aged 45-49, and the importance of expanding insurance coverage of screening for this age group.

Additionally, several states have laws in place that require health plans under their jurisdiction to cover colorectal cancer screening according to the American Cancer Society guidelines (non-ERISA plans). The National Conference of State Legislatures (NCSL) provides a state-by-state analysis of screening coverage, including which states use American Cancer Society guidelines for coverage requirements, and can be <u>found here</u>. ACS CAN is providing information to insurance commissioners and Medicaid directors in those states to educate them about the CRC guidelines change.

Consumers should understand what options their insurance policy will cover and what out-of-pocket expenses they may incur should they begin screening at age 45. Consumers should also understand that there are many screening options, and they may find some screening options more affordable than others, if they need to pay out of pocket before health plans have an opportunity to modify their coverage.

6. What impact will these guidelines have on insurance coverage? And what impact will insurance coverage have on the guidelines?

The Affordable Care Act requirements for preventive services coverage by insurance come from recommendations made by four expert medical and scientific bodies – the U.S. Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices (ACIP), the Health Resources and Services Administration's (HRSA's) Bright Futures Project, and the Institute of Medicine (IOM) committee on women's clinical preventive services. As these expert bodies make recommendations for clinical preventive services, payers are then required to cover those services. While many health plans are not obligated by law to cover screening based on ACS recommendations, some still may choose to do so to make their plans more appealing to employers and consumers. Additionally, several states have laws in place that require certain health plans under their jurisdiction to cover colorectal cancer screening according to the American Cancer Society guidelines (non-ERISA plans). ACS CAN is providing information to insurance commissioners in those states to educate them about the CRC guidelines change.

7. Will ACS and ACS CAN employee benefits provide coverage to match these new guidelines? Cigna will cover colorectal screenings at age 45. Kaiser coverage requirement will remain age 50 at least for the remainder of 2018.

8. How common is colorectal cancer at ages 45-49?

While colorectal cancer is still relatively uncommon in this age group, there has been a 51% increase in colorectal cancer among those under 55 since 1994. The starting age is being reduced by only 5 years, and the underlying age-specific incidence in this age groups should be viewed in comparison to adults aged 50-54 years. Since many colorectal cancers are found through screening, and screening is far less common in adults in their 40s than those in their 50s (17.8% vs. 45.3%), the true underlying risk in adults aged 45-49 years is likely closer to the risk in adults ages 50 to 54 than the most recent age-specific rates would suggest. The modeling analysis that was done for this guideline update, which incorporated the increased incidence data, showed a favorable balance of benefit to burden for screening beginning at age 45, thus finding that screening was efficient beginning at age 45 and resulted in an improvement in life years gained. It is also worth noting that benefits in the model were based on both early cancer detection and prevention resulting from the detection and removal of polyps.

9. Why didn't ACS recommend starting screening at age 40?

The modeling analysis that was done looked at strategies for starting screening at age 40 and showed a considerably less favorable balance of benefit to burden. The incidence of CRC and years of life lost in adults aged 40 to 44 are measurably less than in those 45 to 49. ACS will continue to watch for trends in incidence and mortality, as well as additional evidence on screening in younger populations for consideration in future guideline updates.

Having said that, the ACS and the members of the National Colorectal Cancer Roundtable are very concerned about the trend of increasing incidence of CRC among *all* younger adults and are working to spur action to improve diagnosis of young onset colorectal cancer diagnosis in the short term and spur research to better understand why this is happening and what to do about it in the long term. Through the auspices of the NCCRT's Family History and Early Onset Task Group, the ACS short term priorities are to: educate medical professionals about young adult CRC, develop better risk assessment tools for medical practices, and prompt conversations between family members about family history of both CRC and colorectal polyps, as we work to spur research in this area. Finally, adults of all ages should see a doctor if they experience symptoms, such as blood in the stool or unexplained weight loss.

10. If other organizations recommend a screening age of 50, why did ACS change the age?

The American Cancer's Society's recommendations are based on evidence of the effectiveness of

screening, a new analysis of the trends in increased incidence in younger adults, and modeling studies incorporating the more recent data. The change in the recommendation is in response to the growing disease burden in younger adults, and it expands the opportunity to save lives.

11. Why not just recommend colonoscopy for everyone? Isn't colonoscopy the 'gold standard?'

Given the evidence that adults vary in their test preferences, the guidelines development committee emphasized that screening utilization and adherence could be improved by offering a choice of tests. While colonoscopy are sometimes called the 'gold standard,' it mostly has that label because it is used to evaluate the performance of other screening tests. However, in day-to-day use, it is not perfect, and the evidence shows that if adults are adherent to annual FOBT with a high-sensitivity test, long-term outcomes are similar to those that are estimated to be achieved with colonoscopy. The ACS has developed materials to support conversations between clinicians and patients to facilitate selecting a screening test based on individual preferences and availability and access to screening test options.

12. Why does ACS recommend a screening cut off age?

The screening cut-off age recommendation is based on analysis of the benefits and harms for available screening tests. The harms of screening and diagnostic colonoscopy include bleeding, perforation, complications of anesthesia, and hospitalization. These risks are greater in the elderly and the risk increases with increasing comorbidity burden. Adults aged 76-84 can make an individualized decision about screening during a shared decision-making discussion with their health care provider. After age 85 years, the potential harms of screening outweigh the potential benefits.

13. How will the new guideline impact minority populations?

Some guidelines making bodies have recommended CRC screening for African Americans starting at age 45 for some time now. Lowering the starting age overall is expected to benefit not only the segments of the population who suffer disproportionately from CRC – African Americans, Alaska Natives, and American Indians – but also those individuals otherwise considered to be at average risk. Moreover, epidemiological trends in cohorts as young as those born in 1990 suggest that the higher risk of developing CRC will be a persistent concern for decades to come.

14. How does this the new recommendation impact the effort to screen 80% of adults by 2018?

The shared goal to screen 80% of adults for colorectal cancer by 2018 screening targeted adults age 50 or older, and the effort to achieve 80% screening will be measured for the 50+ age group, not the 45+ age group. With only 6 months remaining in 2018, it is unrealistic to expect a significant uptake in screening in the new age groups to which the new recommendation apply; further, at this point, the major measures that track CRC screening rates, measure CRC screening rates for those 50 or older. Having said that, the ACS and its partners have been concerned about the low screening rates for those in the 50 to 54 age range, which are currently under 50%, significantly behind older age groups. Attention directed to the release of the new guideline may contribute to heightened understanding of the burden of CRC and the value and importance of screening for all recommended age groups. The ACS and the NCCRT are planning to launch a new colorectal cancer screening campaign in 2019 and want to hear from NCCRT members and partners about how to take the new guideline into account.

15. What does the new recommendation mean for the National Colorectal Cancer Roundtable and its members?

The NCCRT considers itself a "guidelines agnostic" organization, meaning that the NCCRT recognizes the fact that NCCRT members abide by different evidence-based recommendations for colorectal cancer screening. The shared mission of the NCCRT is to leverage efforts and save lives by working together to increase colorectal cancer screening, and that commitment accommodates all guidelines for CRC screeningGoing forward NCCRT materials will reflect both the ACS guidelines and the USPSTF recommendation to the extent possible, given that the latter is the basis for minimum insurance coverage

under the ACA. We'll be using this disclaimer, as needed for materials that have not yet been updated to reflect the new ACS guidelines: *This resource does not reflect the new 2018 ACS guideline for colorectal cancer.* We welcome NCCRT member advice on how the new recommendation should fit into the NCCRT's overall strategic plan. For systems that choose to start recommending screening at 45, we'd like to learn from you about how the new guideline was s received and any advice for others who may wish to do the same. Most importantly, we do not want the differing ages at which to begin CRC screening to become a reason for inaction.

16. Don't we need to do a better job screening the currently recommended age group, not make it even harder (to reach 80% of the population) by extending the age range?

The spirit of the 80% goal is to reduce the morbidity and mortality associated with CRC in all age groups at risk; screening at the earlier age, in a population with demonstrated increased risk greater than previously known, will help to do just that.

17. Does the United States have the capacity and financial resources to screen millions of new patients? While cost, coverage, and reimbursement may be important considerations for individuals when making decisions about screening tests, resource use and cost are not used by the American Cancer Society as decision-making criteria for development of recommendations. Prior and recent analyses of national resources show that there is sufficient capacity to accommodate a younger age to begin CRC screening.

18. Why was barium enema removed as a type of screening in the guidelines?

The utilization of barium enema as a CRC screening test in the U.S. is very low; while there has been limited evidence for its effectiveness and performance in screening, we previously retained the barium enema because it may have been the only visual exam available in some communities. However, the combination of continued decline in availability and increasing availability of a superior radiologic screening option (CTC) led the ACS guidelines committee to choose to remove barium enema from the list of options.

19. Why do we continue to include flexible sigmoidoscopy and guaiac stool tests?

Although very few adults are screened with flexible sigmoidoscopy, some of the best evidence we have of the effectiveness of screening in reducing deaths from colorectal cancer comes from randomized trials of flexible sigmoidoscopy. The ACS guidelines committee chose to keep it as an option, based on the sound foundation of evidence of benefit, and because there may be some areas of the country where it is the only structural exam accessible to patients. Where flexible sigmoidoscopy is not available, we do not expect referring physicians to discuss it as an option.

The performance of different types and brands of stool tests varies widely. Though the use of older, low-sensitivity guaiac-based tests is not recommended, some high-sensitivity guaiac-based tests have performance characteristics that are similar to FIT. Additionally, the relatively low cost of HSgFOBTs compared with FIT may result in increased access to screening in some low-resource settings.

20. When should people at high risk for colorectal cancer be screened?

The American Cancer Society does not have screening guidelines specifically for people at increased or high risk of colorectal cancer. People at increased or high risk of colorectal cancer might need to start colorectal cancer screening before age 45, be screened more often, and/or get specific tests. This includes people with:

- a. A strong family history of colorectal cancer or certain types of polyps (see <u>Colorectal Cancer</u> <u>Risk Factors</u>)
- b. A personal history of colorectal cancer or certain types of polyps
- c. A personal history of inflammatory bowel disease (ulcerative colitis or Crohn's disease)

- d. A known family history of a hereditary colorectal cancer syndrome such as familial adenomatous polyposis (FAP) or Lynch syndrome (also known as hereditary non-polyposis colon cancer or HNPCC)
- e. A personal history of radiation to the abdomen (belly) or pelvic area to treat a prior cancer
- f. Anyone with these risk factors should speak with their health care provider about when they should begin screening and how often they should be screened.