

## OHSU HEALTH SYSTEM OFFICE OF CLINICAL INTEGRATION AND EVIDENCE-BASED PRACTICE

### COLORECTAL CANCER SCREENING GUIDELINE

***Incidence:*** Colorectal cancer is the second leading cause of cancer death in the United States. In 2016, an estimated 134,000 persons will be diagnosed with the disease, and about 49 000 will die from it.<sup>[1]</sup> Colorectal cancer is most frequently diagnosed among adults aged 65 to 74 years; the median age at death from colorectal cancer is 68 years.<sup>[1]</sup>

***Benefits of Screening and Early Detection:*** There is convincing evidence that screening for colorectal cancer in adults aged 50 to 75 years reduces colorectal cancer mortality.<sup>[2]</sup> At this time, no head-to-head studies exist to demonstrate that any specific screening strategy is more effective than others. In addition, the tests have varying levels of evidence supporting their effectiveness, and each test has different strengths and limitations. About one-third of eligible adults in the United States have never been screened for colorectal cancer<sup>[3]</sup>, and offering choices in colorectal cancer screening strategies may increase screening uptake.<sup>[4]</sup>

The benefit of early detection of and intervention for colorectal cancer declines after age 75 years. Among older adults who have been previously screened for colorectal cancer, there is, at best, a moderate benefit for continued screening during the ages of 76 to 85 years. However, adults in this age group who have never been screened for colorectal cancer are more likely to benefit than those who have been previously screened.<sup>[2]</sup> The time between detection and treatment of colorectal

cancer and realization of a subsequent mortality benefit can be substantial. As such, the benefit of early detection of and intervention for colorectal cancer in adults 86 years and older is at most small.

To date, no method of screening for colorectal cancer has been shown to reduce all-cause mortality in any age group.<sup>[5, 6]</sup>

***Harms of Screening and Early Intervention:*** The harms of screening for colorectal cancer in adults aged 50 to 75 years are small.<sup>[2]</sup> The majority of harms result from the use of colonoscopy, either as the screening test or as follow-up for positive findings detected by other screening tests. The rate of serious adverse events from colorectal cancer screening increases with age.<sup>[5]</sup> Thus, the harms of screening for colorectal cancer in adults 76 years and older are small to moderate.

#### ***Definitions:***

***Average Risk:*** Non-African American patients aged 50 years or older with no personal history of CRC or adenomas, no inflammatory bowel disease, and with a negative first-degree family history for CRC.

***Increased Risk:*** African American patients or patients with a personal or first-degree family history of CRC or advanced adenomas, or patients with inflammatory bowel disease.

### ***Clinical Practice Recommendations***

#### **Screening in asymptomatic non-African American individuals $\geq$ 50 years old at average risk for colorectal cancer**

The United States Preventive Services Task Force (USPSTF) recommends screening adults aged 50 to 75 years.<sup>[2]</sup> The USPSTF found no head-to-head studies demonstrating that any of these screening strategies are more effective than others. Varying levels of evidence support each test's effectiveness, and each test has its own strengths and limitations. This led the USPSTF to recommend all screening tests, with the belief that any method of screening is more beneficial than no screening at all.<sup>[2]</sup> The OHSU Health System agrees with this approach, but to assist patients and providers in determining the most appropriate screening test, the OHSU Health System developed a ranking of colorectal cancer screening tests based on the 2017 Multi-Society Task Force's tiered approach.<sup>[7]</sup> This tiered approach takes into consideration test performance, adverse events, patients' needs, and local availability. Although the Preferred Option tests are chosen for their sensitivity and/or cost-effectiveness of screening, the tiered approach allows the opportunity to offer other tests if a patient declines a Preferred Option test.



Preferred Options includes colonoscopy every 10 years (*strong recommendation; moderate-quality evidence*)<sup>[7]</sup> or annual fecal immunochemical test (FIT) (*strong recommendation; moderate-quality evidence*)<sup>[7]</sup>. If a patient declines colonoscopy and FIT, move sequentially to Alternative Option tests of CT colonography every 5 years (*conditional recommendation; low-quality evidence*)<sup>[7]</sup>, or FIT-fecal DNA every 3 years (*conditional recommendation; low-quality evidence*)<sup>[7]</sup>, or flexible sigmoidoscopy every 10 years (or every 5 years) (*strong recommendation; high-quality evidence*)<sup>[7]</sup>.

<b>OHSU Health System’s ranking of colorectal cancer screening tests</b>	
<b>Preferred Options</b>	<ul style="list-style-type: none"> <li>Colonoscopy every 10 years (<i>moderate-quality evidence</i>)<sup>[7]</sup></li> <li><b>OR</b></li> <li>Annual fecal immunochemical test (FIT) (<i>moderate-quality evidence</i>)<sup>[7]</sup></li> </ul>
<b>Alternative Options</b>	<ul style="list-style-type: none"> <li>CT colonography every 5 years (<i>low-quality evidence</i>)<sup>[7]</sup></li> <li><b>OR</b></li> <li>FIT-fecal DNA every 3 years (<i>low-quality evidence</i>)<sup>[7]</sup></li> <li><b>OR</b></li> <li>Flexible sigmoidoscopy every 10 years (or every 5 years) (<i>high-quality evidence</i>)<sup>[7]</sup></li> </ul>
<i>Available tests not currently recommended</i>	<ul style="list-style-type: none"> <li>Capsule colonoscopy every 5 years (<i>low-quality evidence</i>)<sup>[7]</sup></li> <li>SEPT9 (<i>low-quality evidence</i>)<sup>[7]</sup></li> </ul>

#### **PRACTICE IMPLICATIONS FOR OHSU Health System:**

- If a patient’s first preferred screening test is negative, providers will receive follow-up reminders to alert patients when the next test is due (e.g., yearly for FIT test).
- If a patient’s preferred screening test is positive, referral will automatically be sent to Gastroenterology with a notification sent to the patient’s primary care physician.
- If a patient receives a positive FIT test and then a follow-up colonoscopy, there should no longer be reminders sent for FIT testing.
- Panel Management should be established to oversee quality measurement of OHSU’s colorectal cancer screening program, provide data support to monitor program, and conduct ongoing audits for quality assurance and improvement purposes.

#### **Shared-decision making**

When determining which colorectal cancer screening test is most appropriate for a patient, utilize shared-decision making that focuses on Preferred Option tests of colonoscopy or FIT as first choice. If a patient declines a Preferred Option test, offer patients Alternative Option screening test recommendations of CT colonography, or FIT-fecal DNA every 3 years, or flexible sigmoidoscopy.

#### **High-risk patients**

OHSU Health System endorses the Multi-Society Task Force 2017 recommendations for high-risk patients:

##### For patients with family history of colorectal cancer and polyps<sup>[7]</sup>:

- Persons with one first-degree relative with CRC or a documented advanced adenoma diagnosed at age <60 years or with two first-degree relatives with CRC and/or documented advanced adenomas at any age should undergo colonoscopy every 5 years beginning 10 years younger than the age at which the youngest first-degree relative was diagnosed or age 40, whichever is earlier (*conditional recommendation, low-quality evidence*).<sup>[7]</sup>
- Persons with one first-degree relative diagnosed with CRC or a documented advanced adenoma at age ≥60 years should begin screening at age 40. The options for screening and the recommended intervals are the same as those for average-risk persons (*conditional recommendation, very-low quality evidence*).<sup>[7]</sup>

- Persons with one or more first-degree relatives with a documented advanced serrated lesion (SSP or traditional serrated adenoma  $\geq 10$  mm in size or an SSP with cytologic dysplasia) should be screened according to above recommendations for persons with a family history of a documented advanced adenoma (*conditional recommendation, very-low-quality evidence*).<sup>[7]</sup>
- Persons with one or more first-degree relatives with CRC or documented advanced adenomas, for whom a colonoscopy is recommended, should be offered annual FIT if they decline colonoscopy (*strong recommendation, moderate-quality evidence*).<sup>[7]</sup>

Patient considerations regarding age and colorectal cancer risk<sup>[7]</sup>:

- Screening should begin in African Americans at age 45 years (*conditional recommendation, very-low-quality evidence*).<sup>[7]</sup>
- Adults age <50 years with colorectal bleeding symptoms (hematochezia, unexplained iron deficiency anemia, melena with a negative upper endoscopy) should undergo colonoscopy or an evaluation sufficient to determine a bleeding cause, initiate treatment, and complete follow-up to determine resolution of bleeding (*strong recommendation, moderate-quality evidence*).<sup>[7]</sup>
- Persons who are up-to-date with screening and have negative prior screening tests, particularly colonoscopy, may consider stopping screening at age 75 years or when life expectancy is less than 10 years (*conditional recommendation, low-quality evidence*).<sup>[7]</sup>
- Persons without prior screening should be considered for screening up to age 85, depending on consideration of their age and comorbidities (*conditional recommendation, low-quality evidence*).<sup>[7]</sup>

**PRACTICE IMPLICATIONS FOR OHSU Health System:**

- Utilize clinical scoring system annually with patients that includes family history and symptoms. Family history and symptoms should be captured discreetly in the medical record.

## **Quality Measures:**

### **Process**

- Percentage of patients aged 50-75 years who had appropriate screening for colorectal cancer
- Percentage of patients aged 50-75 years receiving a screening colonoscopy without biopsy or polypectomy and with an adequate prep who had a recommended follow-up -interval of 10 years for repeat colonoscopy documented in their colonoscopy report
- Percentage follow-up for positive screenings for other modalities
- Percentage of patients  $\geq 50$  years old with  $\geq 1$  conventional adenoma or sessile serrated polyp or colorectal cancer detected during screening colonoscopy
- Percentage of patients  $\geq 18$  years old receiving a surveillance colonoscopy, with a history of a prior adenomatous polyp(s) in previous colonoscopy findings, who had an interval of  $\geq 3$  years since their last colonoscopy
- Utilization of shared decision making tool
- Utilization of clinical scoring system
- Positive test referrals received

### **Outcome**

- Patient satisfaction with CRC screening

## References

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**Guideline Preparation**

This guideline was prepared by the Office of Clinical Integration (CI) and Evidence-Based Practice (EBP) in collaboration with content experts at Oregon Health and Science University.

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**Development Process**

This guideline was developed using the process outlined in the CI and EBP Manual (2016). The review summary documents the following steps:

1. Review Preparation
  - PICO questions established
  - Evidence search confirmed with content experts
2. Review of Existing Internal and External Guidelines
  - Literature Review of Relevant Evidence
3. Critically Analyze the Evidence
4. Summarize the Evidence by preparing the guideline, and order sets

- Materials used in the development of the guidelines, review summaries and content expert team meeting minutes are maintained in a CF Pain and Anxiety Management EB review manual with the Office of CI and EBP.

**Evaluating the Quality of the Evidence**

Published clinical guidelines were evaluated for this review using the **University of Pennsylvania’s Trustworthy Guideline Rating Scale**. The summary of these guidelines are included in the evidence summary. The rating scale is based on the Institute of Medicine’s “Standards for Developing Trustworthy Clinical Practice Guidelines” (IOM), as well as a review of the AGREE Enterprise and Guidelines International Network domains. This scale evaluates a guideline’s transparency, conflict of interest, development group, systematic review, supporting evidence, recommendations, external review and currency and updates. The purpose of this scale is to focus on the weaknesses of a guideline that may reduce the trust a clinical user can have in the guideline, and distinguish weaknesses in documentation (e.g. guideline does not have a documented updating process) from weaknesses in the guidance itself (e.g. recommendations are outdated).

**The GRADE (Grading of Recommendations, Assessment, Development and Evaluation)** criteria were utilized to evaluate the body of evidence used to make clinical recommendations. The table below defines how the quality of the evidence is rated and how a strong versus conditional recommendation is established. The evidence summary reflects the critical points of evidence.

Recommendation	
<b>STRONG</b>	Desirable effects clearly outweigh undesirable effects or vice versa
<b>CONDITIONAL</b>	Desirable effects closely balanced with undesirable effects
Quality	Type of Evidence
<b>High</b>	Consistent evidence from well-performed RCTs or exceptionally strong evidence from unbiased observational studies
<b>Moderate</b>	Evidence from RCTs with important limitations (e.g., inconsistent results,



	methodological flaws, indirect evidence, or imprecise results) or unusually strong evidence from unbiased observational studies
<b>Low</b>	Evidence for at least 1 critical outcome from observational studies, from RCTs with serious flaws or indirect evidence
<b>Very Low</b>	Evidence for at least 1 critical outcome from unsystematic clinical observations or very indirect evidence

deemed appropriate for the guideline’s intended use. Guidelines are reviewed and updated as necessary every 2 to 3 years within the Office of CI and EBP at OHSU. Content Expert Teams will be involved with every review and update.

**Conflict of Interest**

None of the content expert team members has any affiliations or financial involvement that conflicts with the material presented in this guideline.

**Disclaimer**

Guideline recommendations are made from the best evidence, clinical expertise and consensus, in addition to thoughtful consideration for the patients and families cared for within the Integrated Delivery System. When evidence was lacking or inconclusive, content experts made recommendations based on consensus. Expert consensus is implied when a reference is not otherwise indicated.

The guideline is not intended to impose standards of care preventing selective variation in practice that is necessary to meet the unique needs of individual patients. The physician must consider each patient and family’s circumstance to make the ultimate judgment regarding best care.

**Recommendations**

Recommendations for the guidelines were directed by the existing evidence, content experts, and consensus. Patient and family preference were included when possible. When evidence is lacking, options in care are provided in the guideline and the order sets that accompany the guideline.

**Approval Process**

Guidelines are reviewed and approved by the Content Expert Team, Office of CI and EBP, Knowledge Management and Therapeutics Committee, Professional Board, and other appropriate hospital committees as