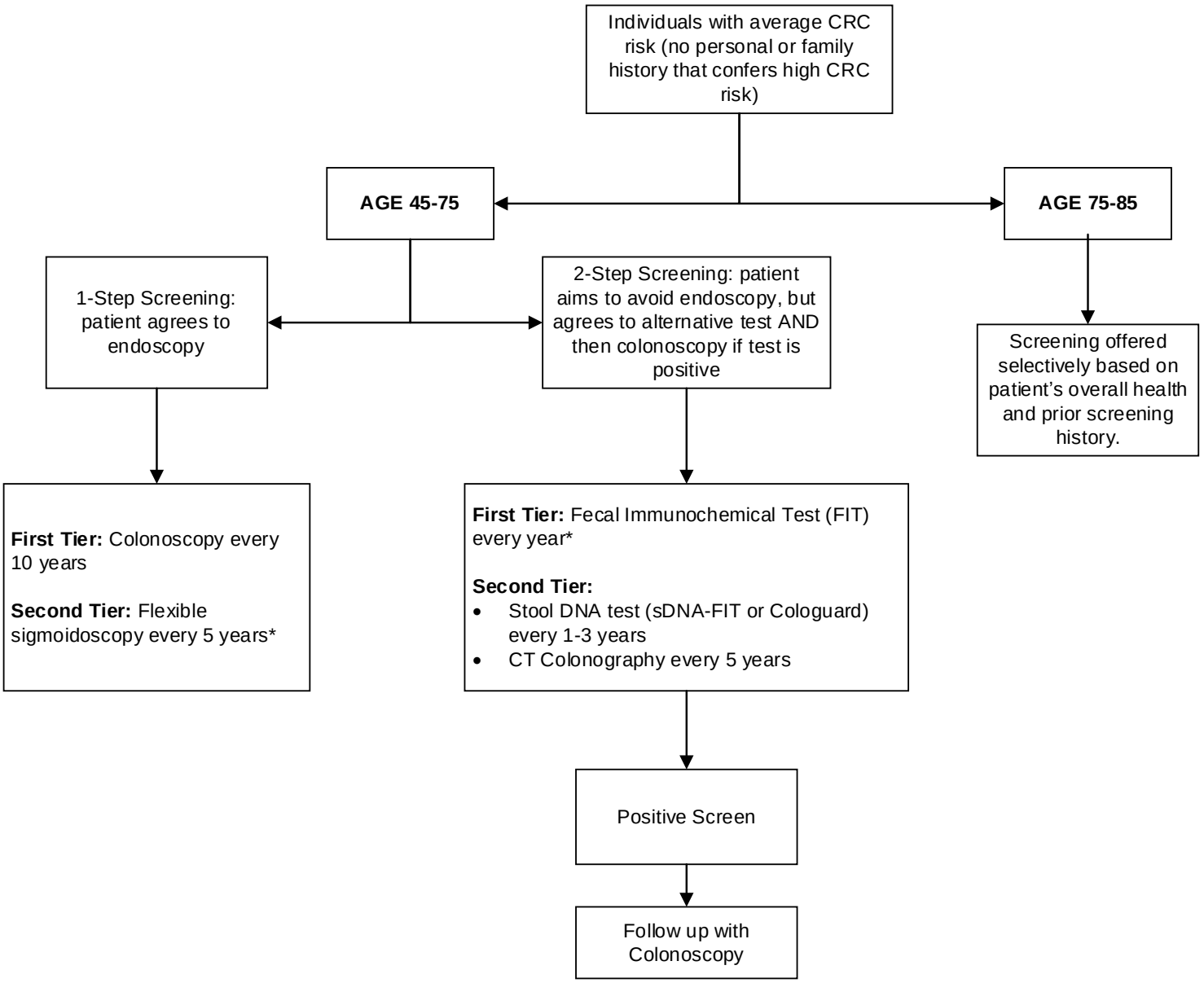
Clinical Pathways Program

Guideline: Colorectal Cancer (CRC) Screening, Oupatient

Updated: November 2021

Clinical algorithm:



*Hybrid option: Tier 2 flex sig every 10 years + FIT every 1 year

Clinical pathway/guideline summary

CLINICAL PATHWAY/GUIDELINE NAME: Colorectal Cancer (CRC) Screening Guidelines

PATIENT POPULATION AND DIAGNOSIS: Average risk individuals aged 45-75

APPLICABLE TO: All Spectrum Health Sites

BRIEF DESCRIPTION: The guideline outlines recommended practice for colorectal cancer screening in average risk patients aged 45-75.

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OWNING EXPERT IMPROVEMENT TEAM (EIT): Colorectal/Endoscopy

MANAGING CLINICAL PRACTICE COUNCIL (CPC): Digestive Health

CPC APPROVAL DATE: January 2022

OTHER TEAM(S) IMPACTED: Primary Care, Preventative Health

IMPLEMENTATION DATE: N/A

LAST REVISED: November 2021

FOR MORE INFORMATION, CONTACT: Andrew Shreiner MD

Clinical pathways clinical approach

TREATMENT AND MANAGEMENT:

These recommendations apply only to average risk individuals based on personal and family history.

New in 2021, the recommended age for screening has expanded to 45 to 75 years old. Screening for those 75 to 85 years old can be offered selectively based on the patient's overall health and prior screening history.

Screening tests fall into 1-step or 2-step approaches, and screening tests at Spectrum are ranked in 2 tiers based on performance features, costs, and practical considerations.

Two approaches for recommended screening tests include:

- 1-step testing: These tests involve direct examination of the colon and are generally used every 5 to 10 years. These tests allow for tissue biopsy to diagnose cancer AND polyp removal to prevent cancer.
- 2-step testing: These tests involve indirect examination of the colon and are generally used every 1 to 5 years. These tests look for signs of colorectal cancer with imaging or

stool tests. If these tests are positive, then the 2nd step requires colonoscopy for direct examination of the colon with possible tissue biopsy and/or polyp removal.

Tier 1:
Colonoscopy (1-step test) is the preferred modality for screening. It has been clearly shown to reduce mortality and has the highest life years gained compared to other methods of colon cancer screening. It can detect early cancers and also prevent cancer by removing pre-cancerous lesions.

Fecal immunochemical test (FIT) (2-step test) is the preferred modality for those aiming to avoid colonoscopy. However, patients and providers should understand that a positive FIT should be followed up with colonoscopy.

Tier 2:
Second-tier tests include 2-step tests: CT colonography every 5 years, stool DNA test (sDNA-FIT or Cologuard) every 1-3 years, or high-sensitivity guaiac-based fecal occult blood test (HSgFOBT) annually; or 1-step flexible sigmoidoscopy every 5 years. (Hybrid approach with annual FIT + flexible sigmoidoscopy is also an option.)

Not recommended at this time: digital rectal exam, capsule endoscopy, serum tests (Septin-9), or urine tests.

Supplemental Discussion

Screening for colorectal cancer has been proven to save lives. Every patient who meets age criteria should be screened for CRC. We recommend a sequential approach where the preferred test is recommended first and, if declined, a second test is recommended with a goal of completing some form of CRC screening that is acceptable to the patient and the provider. In accordance with the U.S. Multi-Society Task Force (MSTF) on CRC screening and in keeping with the typical approach in the U.S., we recommend offering colonoscopy first and then FIT second. Patients and providers who place greater emphasis on higher single-time testing efficacy would choose colonoscopy, while patients and providers who place greater emphasis on the risks of colonoscopy may choose FIT. Second-tier tests can also be considered.

At this time, we have changed our recommendations to begin CRC screening at age 45 yrs and continue until age 75 yrs, reflecting changes in guidelines produced by the American Cancer Society (ACS) in 2018 and the U.S. Preventative Services Task Force (USPSTF) in 2021. The ACS gave a *qualified recommendation* to begin average risk CRC screening at age 45 yrs, and the USPSTF has recommended with *moderate certainty* that there is a net benefit to CRC screening in those 45-49 yrs old. Recommendations to screen those 50-75 yrs old are *strong recommendations* felt to confer *substantial* benefit. The decision to screen for CRC cancer between age 75 and 85 years of age is an individual one taking into account the patient's overall health, life expectancy, and prior screening history.

Based on published evidence, SHMG Clinical Excellence Council has defined the optimal test for CRC screening as colonoscopy. Colonoscopy has the ability to detect pre-cancerous polyps and remove them, thus preventing cancer. Relative to other screening tests, colonoscopy is far superior in the detection of conventional adenomas <1 cm in size and serrated class lesions. It also has the highest sensitivity, averts the most cancer deaths, and has the most life-years

gained per 1000 individuals screened. Colonoscopy involves bowel preparation, usually some form of sedation, and insertion of a long flexible tube through the entire colon. The absolute risk rates of colonoscopy are very low when performed by skilled operators. Colonoscopy should be performed every 10 years for average risk patients when a high quality normal exam is reported.

If patients prefer to avoid colonoscopy if possible, then we recommend a yearly FIT as the preferred alternative. FIT is a stool-based test with one-time sensitivity for cancer of ~80% (Ann Intern Med 2014; 160: 171–81). In the event of a positive FIT test, patients should undergo colonoscopy. Drawbacks include lower sensitivity for advanced pre-cancerous polyps, the need for annual testing, and stress related to false-positive tests while awaiting colonoscopy.

Second-tier alternative screening tests may be considered. CT colonography every 5 years requires bowel preparation, oral and rectal contrast, and radiation exposure, and CT colonography is less sensitive than colonoscopy for polyp detection, requires follow-up colonoscopy if polyps are detected, and may lead to additional and unnecessary diagnostic testing if there are extra-colonic findings. Flexible sigmoidoscopy every 5 years requires enema preparation, usually some form of sedation, and insertion of a flexible tube into the distal colon, and sigmoidoscopy is inferior to colonoscopy due to not evaluating the proximal colon where polyps and cancer also occur. The sDNA-FIT (Cologuard) detects more advanced adenomas than FIT, but it has a lower specificity (more false positive results) compared to FIT and is less cost effective than FIT (Gastroenterology 2016; 151:427–439). After the fecal occult blood blood test was replaced by FIT in screening guidelines, annual HSgFOBT has reappeared in current guidelines though it is noted to likely have lower accuracy and be harder to administer than other stool-based tests.

Routine digital rectal exams are not sufficient for colorectal cancer screening.

Septin9 DNA test (Epi proColon) is a blood test that has recently become available but **is not currently recommended for colorectal cancer screening.** The SEPT9 DNA test has lower sensitivity and specificity than the other tests. It only has a sensitivity of 48% for detecting colorectal cancer per the USPFT guidelines and even lower for advanced adenomas. In addition, its specificity is 16 points lower than the FIT test and at a higher cost. This blood test is recommended annually but there is no long term data on this test. The significance of a positive SEPT9 DNA test with a negative colonoscopy is unknown at this time. For reporting purposes, SEPT9 does not meet HEDIS criteria for colorectal cancer screening and thus will not improve our quality performance measures for Medicare and other payers.

References:

1. Davidson et al. JAMA 2021;325(19):1965-1977 (USPSTF guideline)

2. Rex et al. Gastrointestinal Endoscopy 2017;8(1):18-33 (MSTF guideline, including ACG, AGA, ASGE)

3. Wolf et al. CA Cancer J Clin 2018;68:250–281 (ACS guideline)