



CRICO/RMF COLORECTAL CANCER SCREENING ALGORITHM

A DECISION SUPPORT TOOL
FOR PRIMARY CARE PROVIDERS

Created: 2004
Revised: 2006



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COLORECTAL CANCER IS THE SECOND MOST COMMON TYPE OF CANCER cited in malpractice claims naming CRICO-insured physicians. General medicine physicians are named most frequently in such cases. Common causal factors underlying missed or delayed colorectal cancer diagnoses include:

- a primary care provider fails to follow routine cancer screening guidelines for colorectal cancer;
- a physician who recommends or orders screening tests—including stool cards, barium enemas, flexible sigmoidoscopies, and colonoscopies—fails to track compliance and the test results;
- a physician pursues a narrow diagnostic focus, resulting in a delay in ordering tests for patients who exhibit worrisome symptoms, including rectal bleeding or weight loss; or signs such as anemia; and
- a physician fails to provide ongoing monitoring and diagnostic testing of a symptomatic patient who exhibits worrisome symptoms, including rectal bleeding or weight loss; or signs such as anemia.

To address these risk issues, CRICO/RMF convened a task force of primary care providers and gastroenterologists to develop a Colorectal Cancer Screening Algorithm. As a decision support tool, the Algorithm is designed to help clinicians:

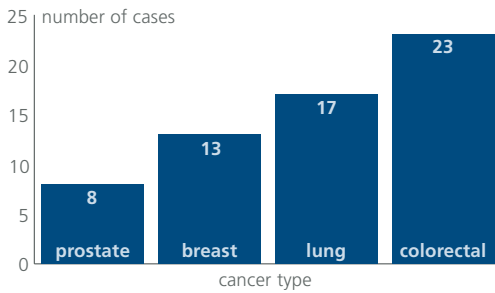
1. Assess patients for colorectal cancer risk factors, particularly family history;
2. Stratify a patient's risk for colon cancer into one of three groups;
 - Average Risk Patients** who are asymptomatic, over age 50, with no personal or family history of colorectal cancer or adenomas,
 - Moderate Risk Patients** who have a family¹ or personal history of colorectal cancer or adenomas, and
 - High Risk Patients** who have a genetic colorectal cancer syndrome²⁻⁵ or inflammatory bowel disease.⁶⁻⁸
3. Offer appropriate screening modalities according to patient risk and patient preference; and
4. Identify the advantages and disadvantages of each selected screening modality.

The CRICO/RMF Colorectal Screening Algorithm is based on national colorectal cancer screening and clinical practice guidelines⁹⁻¹⁴ and is a decision-support tool which should not be construed as a standard of care.

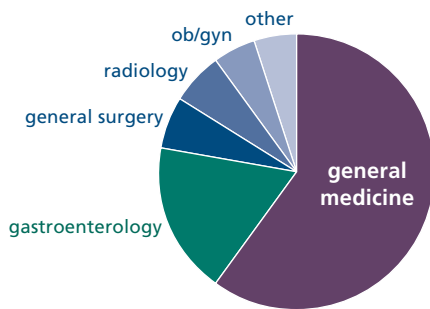
Risk Management for Colorectal Cancer Screening

1. Discuss screening options with the patient and document the discussion and the patient's preference in the clinical record.
2. Single, in-office FOBT digital exam is not adequate screening.¹⁵
3. Track and document screening tests and results.
4. Recognize that the quality of the bowel clean out may modify screening intervals.
5. Follow up on all positive results.
6. Coordinate care with the specialist to clarify roles and responsibilities among providers.
7. Document follow-up testing recommendations.
8. Communicate the follow-up plan to the patient and the responsible providers.

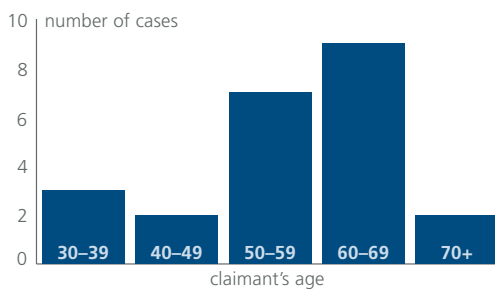
CRICO Cases Filed from 2001–2005 Involving Cancer Diagnoses



Physicians Named in CRICO Cases (1996–2005) Involving Diagnosis of Colorectal Cancer (N=63 defendants)



Cases Involving Colorectal Cancer Diagnosis Asserted 2001–2005 (N=23)



Cost of Malpractice Claims Alleging a Missed or Delayed Diagnosis of Colorectal Cancer

	cases opened 2001–2005	cases closed 2001–2005
incurred losses	\$27 million	\$13.3 million
expenses	\$1.6 million	\$1.2 million

Malpractice Case Examples

Case 1

A 69-year-old woman with no prior CRC screening, whose sister died of colorectal cancer, presents with anemia. No work-up for her anemia is done. Four years after anemia noted, the patient dies of metastatic colon cancer.

Case 2

A 55-year-old woman with no history of screening presents with rectal bleeding, which her physician attributes to hemorrhoids. One year later, flexible sigmoidoscopy shows cancer of the rectum. The patient dies of metastatic rectal cancer.

Case 3

A 64-year-old man with no history of screening presents with a hematocrit of 35 percent. His physician does not order iron studies or any other work-up. Three years later, metastatic sigmoid cancer is discovered.

Case 4

A 69-year-old man with recurrent adenomas, including a villous adenoma, undergoes an incomplete colonoscopy (despite multiple attempts). Repeat colonoscopy is recommended in two years. Additional visualization of the colon is not done. Three years later, a 7cm malignant lesion is found in his proximal transverse colon by barium enema. The patient dies of metastatic colon cancer.

Key Factors in Colorectal Cancer Malpractice Cases

- Patients with symptoms did not receive a prompt diagnostic evaluation
- Routine screening not recommended
- Routine screening ordered but not followed up
- Diagnostic test ordered, but not scheduled
- Diagnostic test scheduled, but not performed
- Ordering or follow-up of screening or diagnostic procedures not documented
- Narrow diagnostic focus
- Abnormal finding not adequately evaluated
- Clinician does not convey to the patient the importance of keeping appointments for testing and follow-up
- Multiple providers for the same patient fail to properly communicate important information
- Patient is not notified of test results
- Informed refusal not documented
- Important clinical information missing from clinical note

Colorectal Cancer Risk Assessment Checklist

Step 1: Assess the patient for relevant symptoms (e.g., rectal bleeding or weight loss; or for signs such as anemia) and review history of pertinent diagnostic testing.

Presentation	Action
Patient <40 years old with rectal bleeding	<ul style="list-style-type: none"> ■ If family history is negative for colorectal cancer or adenomas, consider flexible sigmoidoscopy or other modality for visualization of the colon. ■ If family history is positive for colorectal cancer or adenomas, strongly consider colonoscopy.
Patient age 40–50 with rectal bleeding	<ul style="list-style-type: none"> ■ If family history is negative for colorectal cancer or adenomas, consider colonoscopy for visualization of the colon. At a minimum, perform a flexible sigmoidoscopy. ■ If family history is positive for colorectal cancer or adenomas, order and schedule colonoscopy.
Patient ≥50 years old with rectal bleeding	<p>Review family history and check the date (and success*) of the patient’s most recent screening.</p> <ul style="list-style-type: none"> ■ If the patient has not had a colonoscopy within the past two years, order and schedule a colonoscopy. ■ If the patient has had a negative colonoscopy within the past two years, order a flexible sigmoidoscopy.

* Verify the quality of the bowel preparation and the success of the procedure.

Step 2: Family history: determine and update the patient’s family history for cancers (especially, colorectal and uterine) relevant to colorectal cancer risk.

Relationship (i.e., parent, sibling, aunt, uncle, grandparents)	Type of Cancer	Age at Onset

Step 3: Assess the patient’s risk status.

Average Risk

For recommended algorithm, see Page 3

- Individuals age 50 or older without any of the risk factors noted below
- Average risk patients with concerning symptoms including rectal bleeding or anemia require a prompt diagnostic workup including colonoscopy

Moderate Risk

For recommended algorithm, see Page 4

- Personal history of colorectal cancer or adenomas
- Family history of colorectal cancer or adenomas
- If any of the following is noted in the personal or family history, consider **Hereditary Nonpolyposis Colorectal Cancer (HNPCC)** (see Table 1):
 - Colorectal cancer before age 50
 - Two or more cancers in the same individual
 - Colorectal or uterine cancer in two or more family members

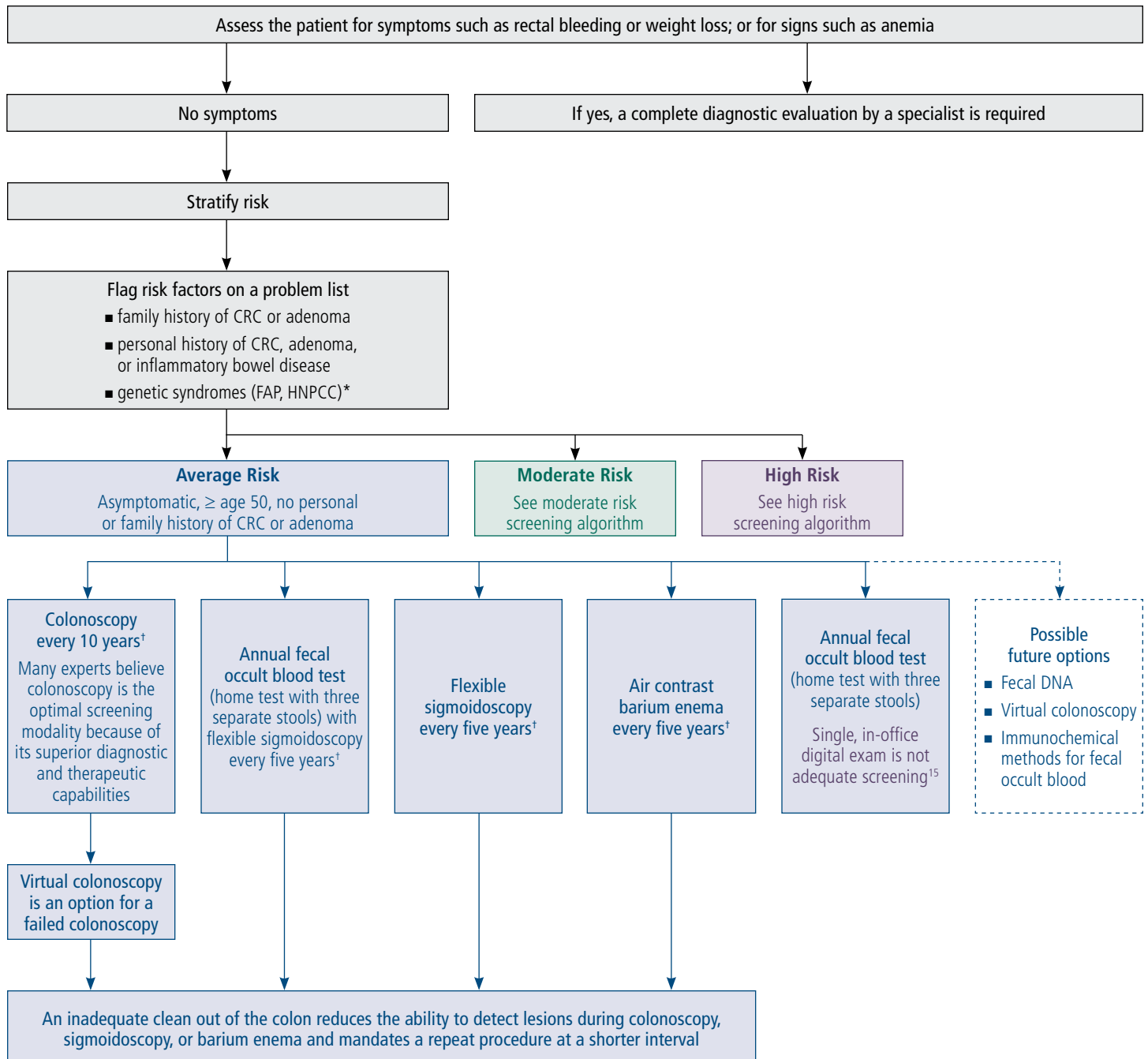
High Risk

For recommended algorithm, see Page 5

- High-risk personal or family history suggesting HNPCC (see Table 1)
- Familial adenomatous polyposis (FAP): 100s–1000s of adenomas
- Attenuated polyposis: 5–100 adenomas
- Other polyposis syndromes: Peutz-Jeghers, Juvenile Polyposis
- Inflammatory bowel disease

Table 1 Genetic Syndromes	
<p>Hereditary Nonpolyposis Colorectal Cancer (HNPCC) Should be considered when either the Amsterdam or Bethesda criteria are met</p>	<p>Amsterdam Criteria¹⁶</p> <p>Three relatives with colorectal cancer (one a first-degree relative of the others), and:</p> <ul style="list-style-type: none"> ■ at least two successive generations affected, and ■ at least one colorectal cancer case diagnosed before age 50
	<p>Bethesda Criteria¹⁷ (revised 2004)</p> <ul style="list-style-type: none"> ■ Colorectal cancer (CRC) under the age of 50; or ■ Two or more diagnoses of CRC or other HNPCC-related cancer^a in the same individual regardless of age; or ■ CRC with microsatellite instability—high (MSI-H) morphology^b under age 60; or ■ CRC with one or more first degree relatives with CRC or other HNPCC-related cancer, one of the cancers less than age 50; or ■ CRC with two or more relatives with CRC or other HNPCC-related cancer regardless of age <p><small>a Includes endometrial, ovarian, gastric, small bowel, urinary tract, pancreas, brain, and sebaceous gland. b Presence of tumor infiltrating lymphocytes, mucinous differentiation/ signet ring cell carcinoma, peritumoral Crohn’s like lymphocytic reaction, medullary growth pattern.</small></p>
<p>Familial Adenomatous Polyposis (FAP)</p>	<p>Individuals with:</p> <ul style="list-style-type: none"> ■ more than 100 colonic adenomas, or ■ multiple adenomas and a relative with known FAP

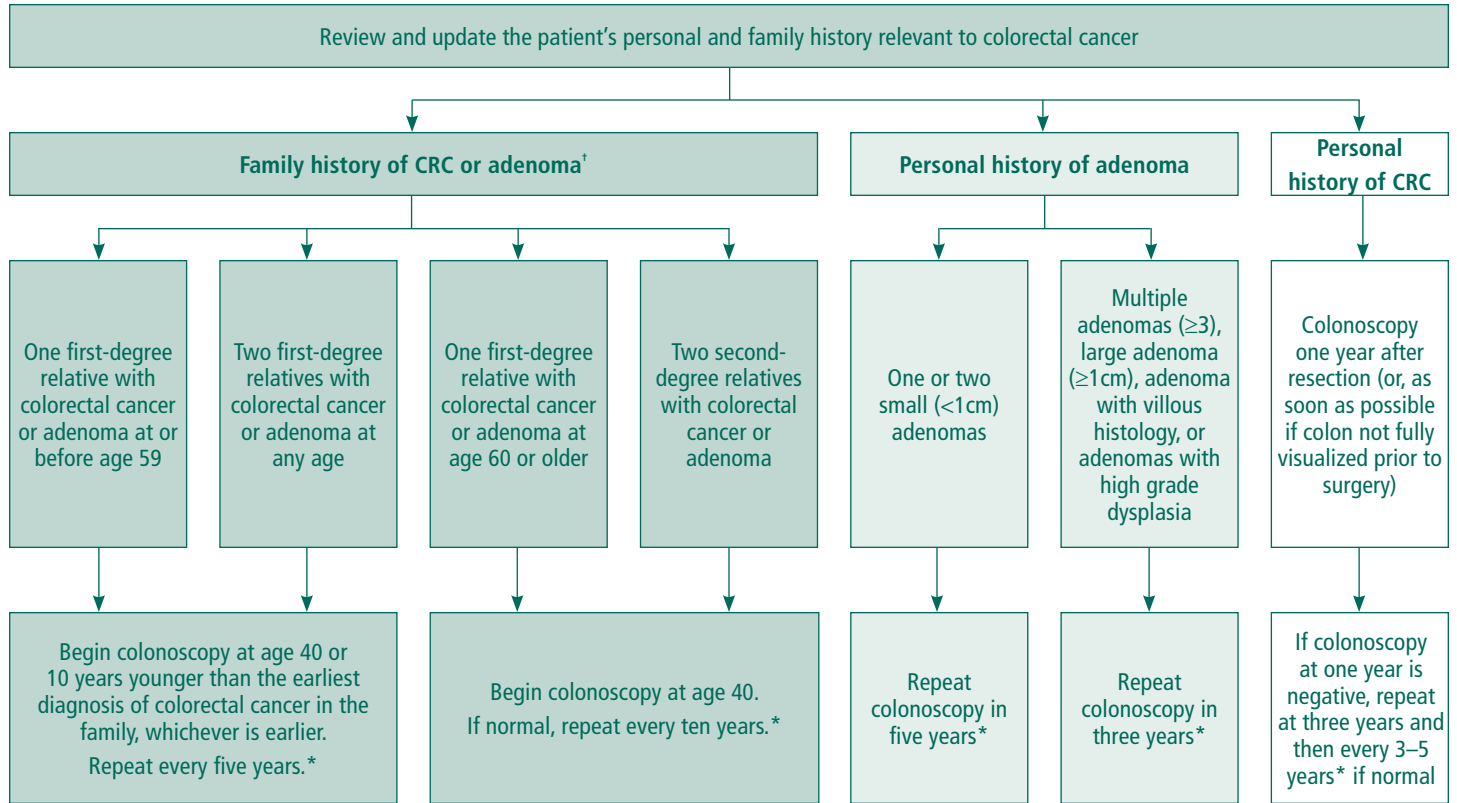
Colorectal Cancer Screening Recommendation for Individuals at Average Risk (asymptomatic patients age 50 years or older)



* See Table 1, Page 2.

† Suggested intervals for screening procedures are based on a complete visualization during colonoscopy or sigmoidoscopy.

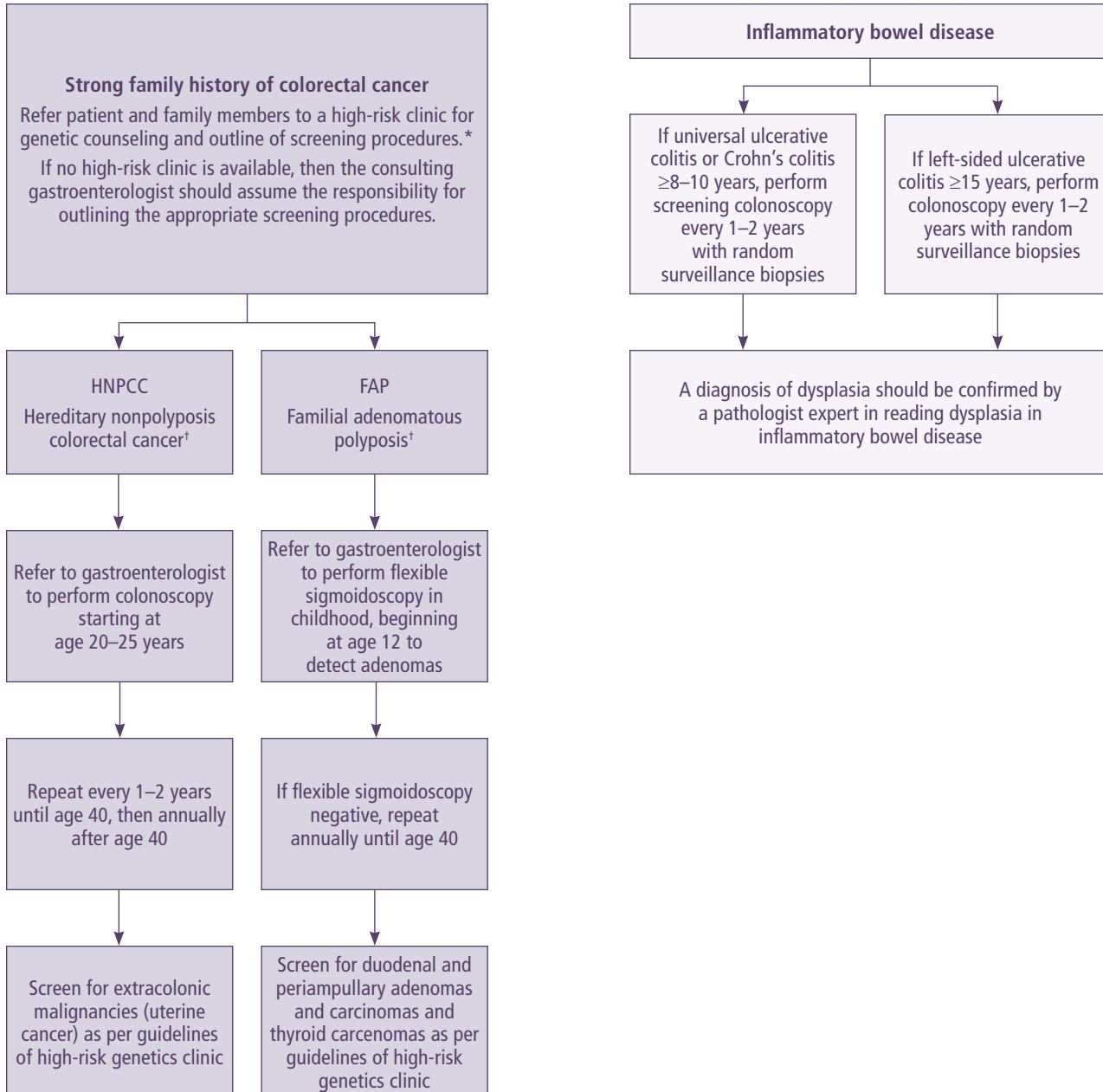
Colorectal Cancer Screening and Surveillance Recommendations for Individuals at Moderate Risk



* Suggested intervals for screening procedures are based on a complete visualization during colonoscopy or sigmoidoscopy. An inadequate clean out of the colon reduces the ability to detect lesions during either colonoscopy or sigmoidoscopy and mandates a repeat procedure at a shorter interval.

† Consider genetic syndromes such as HNPCC if there are multiple or early colon cancers or adenomas in the family. Refer to the High Risk Screening Algorithm.

Colorectal Cancer Screening Recommendations for Individuals at High Risk



* If the index case is positive for HNPCC or FAP, but the family member (patient) is negative, then the screening recommendations should be modified according to the patient’s personal history.

[†] See Table 1, Page 2

Advantages and Disadvantages of Colorectal Cancer Screening Options

Screening Modality	Advantages	Disadvantages
Fecal Occult Blood Test (FOBT)	<p>Easy, safe, convenient</p> <hr/> <p>Strong evidence from three large randomized controlled trials demonstrates a decrease in CRC mortality of up to 33 percent when used annually.^{18–20} Immunochemical FOBT may significantly improve its performance.²¹</p>	<p>Should be repeated annually.</p> <p>Requires certain dietary restrictions: rare red meat, horseradish, turnips, vitamin C.</p> <p>No direct visualization of the colon.</p> <p>All positive tests require colonoscopy and (possibly) other testing.</p> <p>Low to moderate sensitivity and specificity.</p> <hr/> <p>Only 24 percent sensitive for advanced adenomas or colorectal cancer.²²</p>
Flexible Sigmoidoscopy	<p>Safer than colonoscopy. The risk of perforation is less than 1 in 1000.^{23–24}</p> <p>More convenient than colonoscopy; takes about 10 minutes to perform.</p> <p>Usually well-tolerated without sedation, so patients may drive home alone and may return to work following the procedure.</p> <hr/> <p>Evidence from three well-designed studies suggests a decrease in CRC mortality of about 60 percent overall and 70 percent from distal CRC.^{25–27}</p> <p>Flexible sigmoidoscopy detects 70–80 percent of all CRC and large adenomas.²⁸</p>	<p>Requires bowel preparation with enemas.</p> <p>Usually repeated every five years.</p> <p>Finding an adenoma requires further testing via colonoscopy.</p> <hr/> <p>Does not visualize the entire colon, so some lesions will be missed. Approximately two percent of patients with normal findings on flexible sigmoidoscopy have a significant lesion in the proximal colon.^{28–29}</p>
FOBT and Flexible Sigmoidoscopy	<p>Combination testing with annual FOBT plus flexible sigmoidoscopy every five years may provide a small additional benefit over flexible sigmoidoscopy alone and is widely practiced.</p> <hr/> <p>In a large, prospective trial, the addition of FOBT to one-time flexible sigmoidoscopy increased detection of advanced adenomas and CRC from 70 to 76 percent.²⁸</p>	<p>Includes the disadvantages of either test alone plus the need to comply with two tests.</p> <hr/> <p>Very little outcomes data are available to support combination testing. In a single, nonrandomized trial, CRC mortality was marginally lower with combined screening versus FOBT alone over 5–11 years of follow-up.³⁰</p>
Colonoscopy	<p>Many experts believe colonoscopy is the optimal screening modality because of its superior diagnostic and therapeutic capabilities.</p> <p>Direct visualization of the entire colon.</p> <p>Allows for removal of polyps at the same time as the initial diagnostic exam.</p> <p>Because sedation is used, the procedure is typically well tolerated.</p> <hr/> <p>Reduction in CRC mortality in FOBT trials is attributable to follow-up diagnostic colonoscopy.</p> <p>National Polyp Study showed a 76–90 percent reduction in CRC incidence with colonoscopy and removal of all visualized polyps compared to historical controls over six years of follow-up.³³</p> <p>In cross-sectional screening studies, colonoscopy is more sensitive than FOBT, or flexible sigmoidoscopy combined with FOBT, for detecting large adenomas and CRC.^{28–29}</p>	<p>Requires an orally administered bowel preparation.</p> <p>Patients need to be escorted home and are advised not to go back to work the same day.</p> <p>The exam takes about 30 minutes plus recovery time.</p> <p>Safe, but not as safe as flexible sigmoidoscopy. The overall risk of perforation is approximately 2 in 1,000 but lower if polypectomy is not performed.^{23–24, 31–32}</p> <hr/> <p>No randomized controlled trials directly assessing the impact of colonoscopy on CRC mortality are currently available.</p>

Screening Modality	Advantages	Disadvantages
Barium Enema	<p>Sedation is not required.</p> <p>Safe; the complication rate is approximately 1 in 10,000.³⁴⁻³⁵</p> <p>In a large, retrospective study, the sensitivity of barium enema for CRC was 83 percent.³⁶ Other studies support the conclusion that barium enema is reasonably sensitive for detecting CRC.³⁷⁻³⁹</p>	<p>Requires bowel preparation similar to colonoscopy.</p> <p>Abnormal findings require further testing via colonoscopy.</p> <p>Exposure to radiation.</p> <p>Barium enema misses many adenomas. In the National Polyp Study, the sensitivity of barium enema for large polyps (>1cm) was not much greater than 50 percent.⁴⁰</p> <p>No controlled trials evaluate its effectiveness for CRC screening.</p> <p>Uncommonly used for screening (currently).</p>
CT Colonography (“Virtual Colonoscopy”)	<p>Noninvasive imaging of the entire colon.</p> <p>Safe; the risk of perforation is probably similar to barium enema, given the need for air insufflation with a rectal tube.</p> <p>Sedation is not required, so patients can drive home.</p> <p>Some patients find CT colonography to be more acceptable than standard colonoscopy.</p> <p>Detection of some significant extra-colonic findings (mostly abdominal aortic aneurysms and renal cell carcinomas).</p> <p>Fast; the procedure takes 10–15 minutes.</p> <p>In a single trial of 1,233 asymptomatic adults using 3-D imaging and fecal tagging, CT colonography was as sensitive as standard colonoscopy (>90 percent) for polyps >8mm.⁴¹</p>	<p>Abnormal findings require further testing with a colonoscopy. Few centers are set up to do this on the same day.</p> <p>Currently requires bowel preparation similar to colonoscopy.</p> <p>Requires a rectal tube to insufflate air into the colon, which can cause cramping. Some studies report that CT colonography is more uncomfortable than standard colonoscopy.⁴¹</p> <p>Currently not covered by insurance for screening (unless colonoscopy failed).</p> <p>Exposure to radiation.</p> <p>New technology that is not currently recommended by any national group for CRC screening.</p> <p>Can miss some small and flat adenomas.</p> <p>Detection of some incidental extra-colonic findings may produce anxiety in both the patient and physician and lead to additional testing that otherwise would not have been done.</p> <p>In several studies, CT colonography was only moderately sensitive and specific, and there was high interobserver variability.⁴²⁻⁴⁴</p>
Fecal DNA	<p>Safe, noninvasive, performed at home.</p> <p>Better than FOBT for detecting invasive colorectal cancer (52 percent versus 13 percent).⁴⁵</p>	<p>Detected only 18 percent of significant adenomas.⁴⁵</p>

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