



Prevention & Early Detection of Colorectal Cancer

A CRICO DECISION SUPPORT TOOL

Created: 2004
Revised: 2006, 2010
Current: 2014

crico

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A DECISION SUPPORT TOOL

COLORECTAL CANCER is the second leading cause of cancer-related death in the United States. It is also among the most common types of cancer cited in diagnosis-related malpractice claims naming CRICO-insured physicians. Common causal factors underlying missed or delayed colorectal cancer diagnoses include:

- a physician—often due to a narrow diagnostic focus—fails to order diagnostic testing or provide ongoing monitoring of a patient who exhibits worrisome symptoms, including rectal bleeding, or for signs such as unexplained iron deficiency anemia;
- a physician whose practice fails to track compliance with and results from ordered screening tests—including stool cards, flexible sigmoidoscopies, and colonoscopies; and
- a primary care provider fails to follow routine cancer screening guidelines for colorectal cancer.

To address these risk issues, CRICO convened a task force of primary care providers and gastroenterologists to develop a colorectal cancer decision support tool 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.⁶⁻⁹

3. Offer appropriate screening modalities according to patient risk and patient preference; and¹⁰⁻¹³
4. Identify the advantages and disadvantages of each selected screening modality.¹⁰⁻¹³

Prevention and Early Detection of Colorectal Cancer is based on national colorectal cancer screening and clinical practice guidelines¹¹⁻¹⁹ and is a decision-support tool which should not be construed as a standard of care.

Risk Management for Patients ≥ age 40 with Rectal Bleeding

1. Aggressively and completely investigate the cause of rectal bleeding, regardless of the patient's family history.
2. Do not test for occult blood, as this may delay the ordering and completion of a colonoscopy.

Risk Management for Colorectal Cancer Screening

3. Average risk patients (age 50–75) with no history of colon cancer or adenomas—who have had a negative screening colonoscopy—should be screened again after 10 years.
4. Recognize increased risk of colorectal cancer for patients who are black, obese, heavy alcohol users, smokers, or have a history of non-gastrointestinal malignancies treated with chemotherapy or radiation.^{24–28}
5. Before ordering a screening colonoscopy or flexible sigmoidoscopy for a patient > age 75, discuss the risk and benefits, taking into consideration the patient's general quality of life and life expectancy.^{29–31}
6. Routine screening is, generally, not recommended for patients > age 85.
7. Discuss screening options with the patient and document the discussion and the patient's preference in the medical record.
8. Single, in-office FOBT via digital exam is not adequate screening.³²
9. Recognize that the quality of bowel preparation may modify screening intervals. A split dose of prep is considered most effective. Oral sodium phosphate should not be used as a preparation for colonoscopy, given the small but definite risk of renal failure.^{33–35}
10. Track and document screening tests and results.
11. Follow up with the patient on all positive results. Document follow-up testing and/or referral recommendations.
12. Coordinate care and clarify roles and responsibilities among providers. Communicate the follow-up plan to the patient and the responsible providers.

CRICO's Colorectal Cancer Diagnosis-related Cases

8 cases filed 2008–2012;
\$9.8 million total incurred losses
 (i.e., aggregate of expenses, reserves, and payments on open and closed cases).

PHYSICIAN DEFENDANTS NAMED

4	gastroenterology
4	general medicine
1	family practice
1	general surgery

PATIENT AGE

1	30–39 years
3	40–49
2	50–59
1	60–69
1	unknown

BREAKDOWNS IN THE PROCESS OF CARE

STEP	# CASES	TOTAL INCURRED
1. Patient seeks care	0	0
2. History/physical/evaluation	3	\$2,890,000
3. Order of diagnostic/lab tests	5	\$6,130,000
4. Performance of tests	0	0
5. Interpretation of tests	1	\$2,200,000
6. Receipt/transmittal of test results	1	\$1,040,000
7. Physician follow up with patient	2	\$2,080,000
8. Referral management	1	\$1,080,000
9. Patient compliance with follow-up plan	2	\$2,080,000

A case may involve multiple breakdowns.

ADHERENCE ACROSS CRICO WITH THE COLORECTAL CANCER DECISION SUPPORT TOOL

A review of medical records for patients who sought care by a CRICO-insured provider for a complaint of rectal bleeding indicates the following rates of adherence with the recommendations embedded in this guideline (N=1,370 records reviewed 2007–2011)

GUIDELINE	RECORDS SHOWING ADHERENCE
Capture personal history of predisposing colorectal cancer	89%
Capture family history of colorectal cancer	50%
Recommendations for patients less than 40	65%
Recommendations for patients 40–49	69%
Recommendations for patients age 50 and above	61%

Malpractice Case Examples

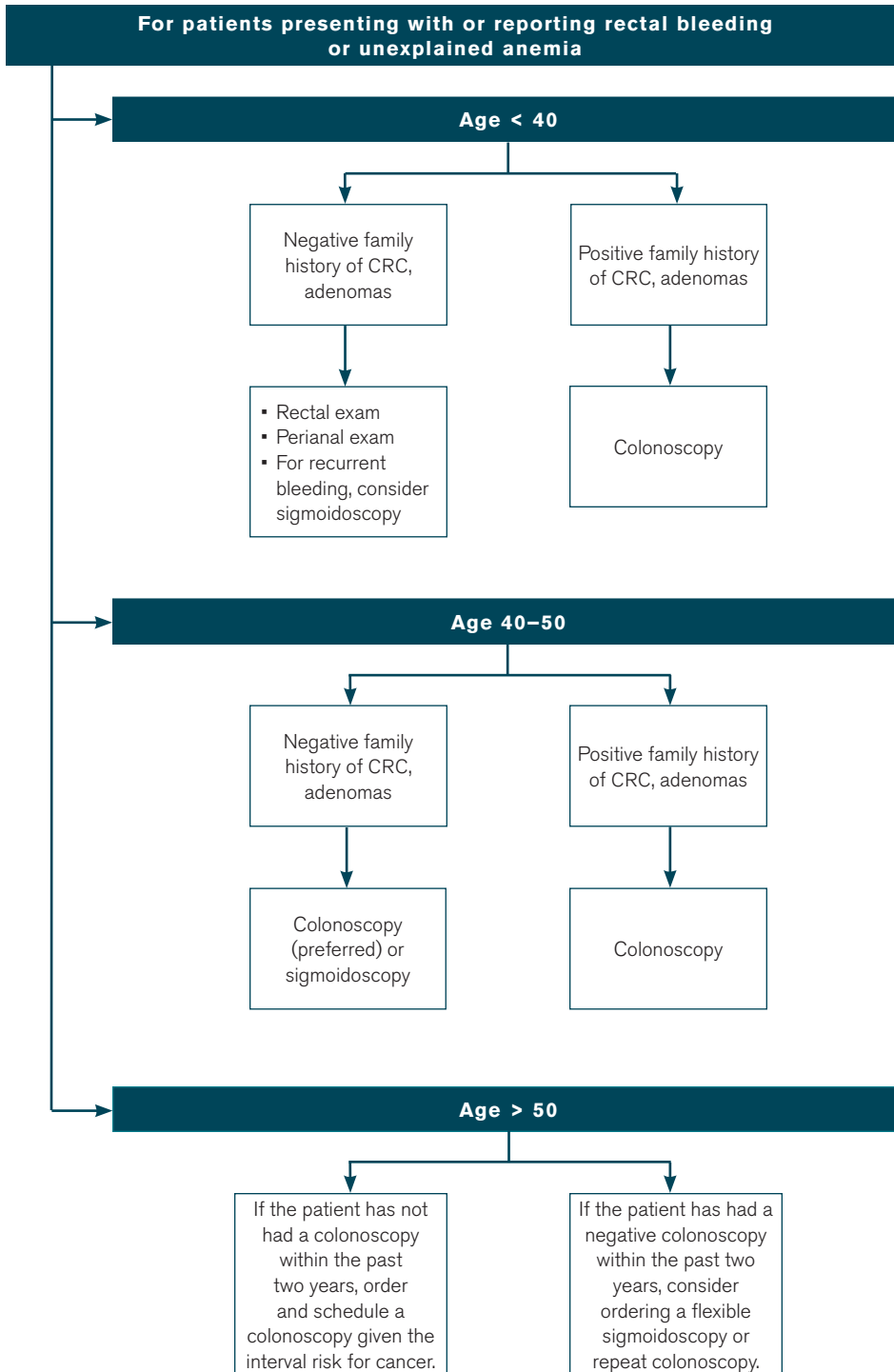
- A 69-year-old woman with no prior CRC screening, whose sister died of colorectal cancer, presents with anemia. No work-up for her anemia is done. Four years after anemia noted, the patient dies of metastatic colon cancer.
 - *Fully work up anemia, including family history.*
- A 55-year-old woman with 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.
 - *Rectal bleeding requires a full work up.*
- A 52-year-old man with rectal bleeding and recent 25lb weight loss is not referred for colonoscopy because the one he had performed a year prior was negative. A month after being treated for hemorrhoids, a flexible sigmoidoscopy and biopsy reveals invasive cancer. The patient dies the following year.
 - *Interval cancers—often due to an inadequate prior procedure—should be considered in light of persistent complaints.*
- 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. The patient dies of metastatic colon cancer.
 - *Full visualization with CT colonography is mandated for a patient with a history of adenomas and an incomplete colonoscopy.*

Key Factors in Colorectal Cancer Malpractice Cases

- Patients with rectal bleeding 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

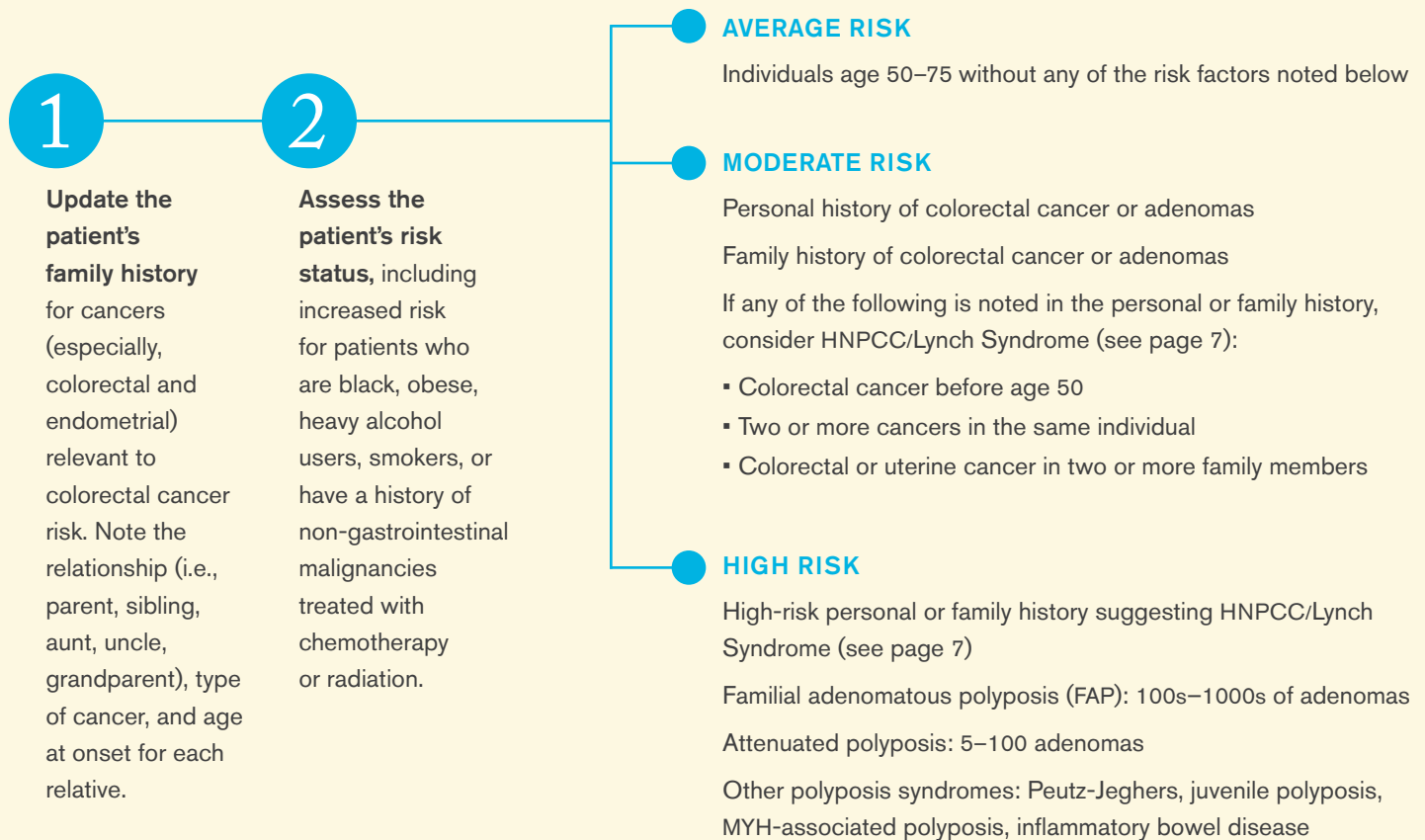
Patients with Symptoms

Assess the patient for relevant symptoms (e.g., rectal bleeding; or for signs such as unexplained iron deficiency anemia*) and review history of pertinent diagnostic testing. Your clinical expertise and shared decision making are key to developing an appropriate plan for each patient.

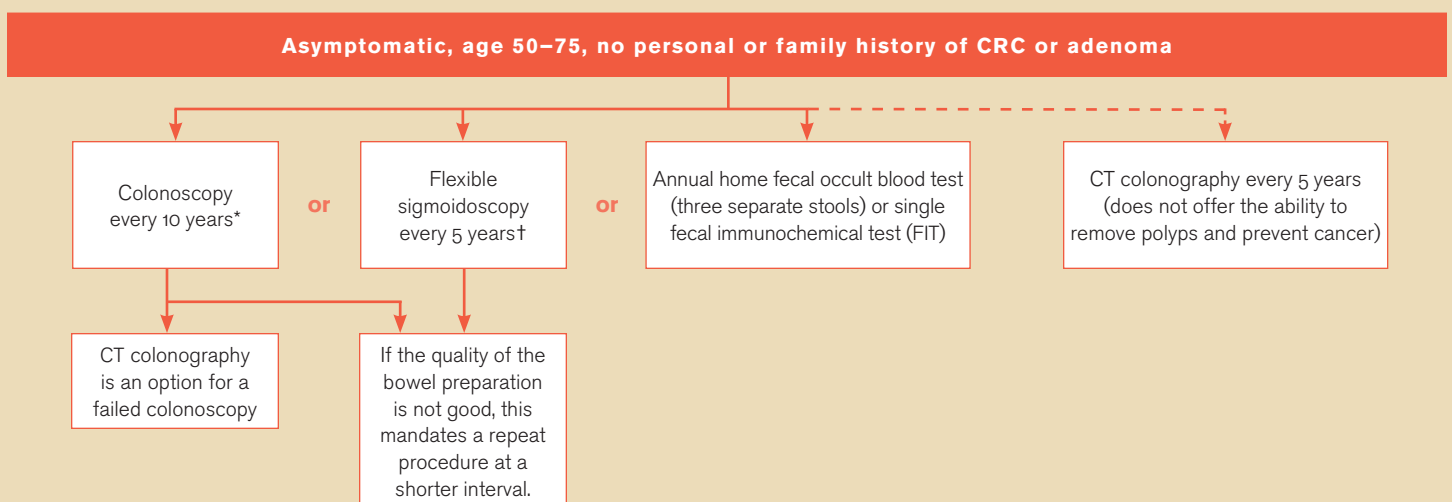


*Colonoscopy is only part of the workup for patients with iron-deficiency anemia.

Screening Patients without Symptoms

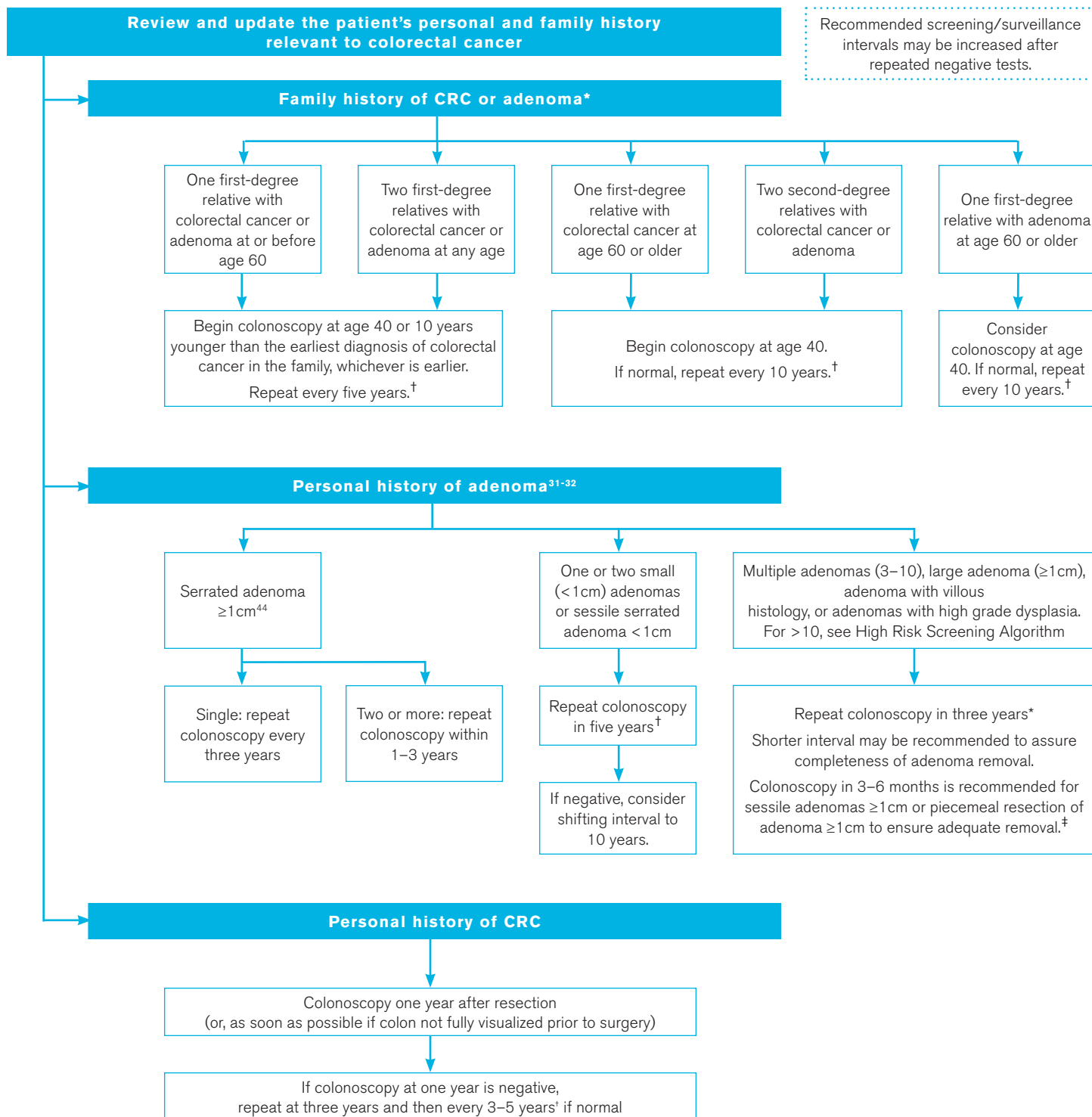


Patients at Average Risk



* Suggested intervals for screening procedures are based on a good or excellent bowel preparation for colonoscopy or sigmoidoscopy. The success of the procedure in reaching the cecum is essential for a completed colonoscopy.³⁷

Patients at Moderate Risk

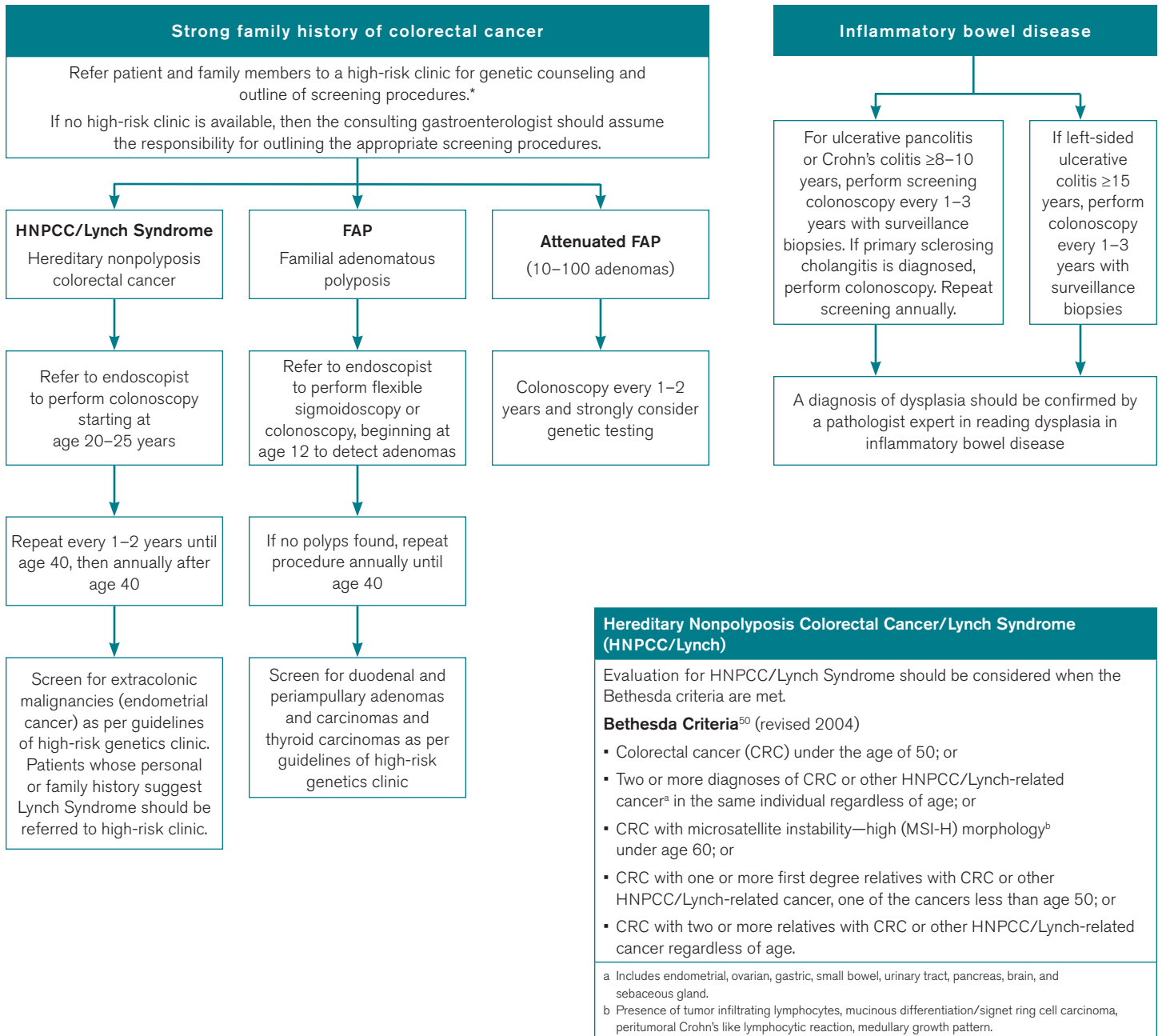


* Consider genetic syndromes such as HNPCC/Lynch Syndrome. If there are multiple or early colon cancers or adenomas in the family. Refer to the High Risk Screening Algorithm.

†Suggested intervals for screening procedures are based on the quality of the bowel preparation and the success of the procedure in reaching the cecum.³⁷ 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.³⁷⁻⁴⁵

‡An early follow-up colonoscopy is recommended when the endoscopist and/or pathologist is not certain that all adenomatous tissue was completely removed, or the pathologist notes worrisome features and recommends an early re-evaluation and biopsy of the polyp site.⁴⁶⁻⁴⁹

Patients at High Risk



* If the index case is positive by genetic testing for HNPCC/Lynch Syndrome or FAP, and the family member (patient) is negative, then the screening recommendations should be guided by the patient's personal history.

Advantages and Disadvantages of Colorectal Cancer Screening Options¹⁵⁻¹⁷

A shared decision-making process for selecting a screening modality is a key to patient compliance and timely detection and treatment.

HOME TESTS: FOBT & FIT

Low to moderate sensitivity

Evidence

Large randomized controlled trials demonstrate a decrease in CRC mortality of up to 33 percent.^{12-13, 51-53}

Annual fecal occult blood test (FOBT) is 24 percent sensitive for advanced adenomas or colorectal cancer.⁵⁴

Annual fecal immunochemical tests (FITs) use antibodies to detect human hemoglobin, and are not affected by diet or medications.^{13, 55-57}

FIT significantly improves the sensitivity and specificity to 91 percent and 88 percent respectively for colorectal cancer detection.⁵⁵

Change to FIT slightly increased colon cancer screening rates.⁵⁸

The rate of positive results from FIT does not decrease after repeated colorectal cancer screening, but the positive predictive value of the FIT for advanced neoplasia and for colorectal cancer is significantly lower among second-round participants who tested negative in the first round.⁵⁹

Advantages

Easy, safe, convenient

FIT detects colon cancer and advanced adenomas with increased sensitivity compared with the FOBT.

FOBT: heat stability is excellent and cost is less compared to other methods.

Disadvantages

FIT and FOBT must be repeated annually to be beneficial.

Standard FOBT requires dietary restrictions and multiple samples.

Positive tests require colonoscopy and (possibly) other testing.

The Hemoccult Sensa II™ is more sensitive, but has a lower specificity compared with Hemoccult II™.

FIT vary in sensitivity and specificity.⁵⁷

Requirement for three day testing with FOBT is less convenient than the single day for FIT.

FLEXIBLE SIGMOIDOSCOPY

Moderate sensitivity and specificity

Evidence

Two randomized controlled trials, one from the United Kingdom and one from the United States, documented a decrease in mortality for distal colorectal cancer of about 50 percent after 11 years of follow-up when an initial screening flexible sigmoidoscopy is performed.²⁰⁻²¹

Flexible sigmoidoscopy detects 70–80 percent of all CRC and large adenomas.⁶⁰

Approximately two percent of patients with normal findings on flexible sigmoidoscopy have a significant lesion in the proximal colon.⁶⁰⁻⁶¹

The risk of perforation is less than 1 in 1,000.⁶²⁻⁶³

Advantages

Safer and more convenient than colonoscopy

Takes about 10 minutes to perform and is usually well-tolerated without sedation

Most patients can drive home alone or return to work following the procedure.

Disadvantages

Requires bowel preparation with enemas

If adenomas found, further testing with colonoscopy is required to visualize the complete colon and remove polyps

Does not visualize most of the colon; some lesions will be missed

COLONOSCOPY

High sensitivity and specificity

Evidence

In cross-sectional screening studies, colonoscopy is more sensitive than FOBT, or flexible sigmoidoscopy combined with FOBT, for detecting large adenomas and CRC.⁶⁰⁻⁶¹

Evidence from the National Polyp Study shows that patients who had adenomas removed during participation in the study had a 53 percent reduction in mortality from colon cancer over a median of 15.8 years. This supports the hypothesis that colonoscopic removal of adenomatous polyps prevents death from colorectal cancer and this prevention is long term.¹⁸

The benefit of colonoscopy is significant for decreasing mortality from left-sided colorectal cancer but not as strong for right-sided cancers.^{11, 48-49}

In U.S. studies, the overall risk of perforation was approximately 2 in 1,000, but lower if polypectomy was not performed.⁶²⁻⁶³ The risk for perforation increases with increasing age and the presence of two or more comorbidities.⁶²

Withdrawal time of the colonoscopist (> six minutes is recommended) has been correlated with the number of adenomas found in one study⁶⁴ but not in another.⁶⁵

The endoscopist's adenoma detection rate is an independent predictor of the risk of interval colorectal cancer and is considered a major quality indicator for the colonoscopic procedure.⁴¹

Advantages

Colonoscopy has the ability to detect and remove polyps at the time of the initial examination. Polypectomy has been shown to decrease colon cancer mortality.¹⁸

Enables direct visualization of the entire colon when evidence—via landmarks—indicates the cecum was reached

Disadvantages

Colonoscopy requires an orally administered bowel preparation.

The exam takes about 30 minutes plus additional recovery time.

Patients need to be escorted home and are advised not to go back to work the same day if sedation is given.

Unlike home stool testing and sigmoidoscopy, no randomized trials of colonoscopy have shown benefit in decreasing CRC mortality. Observational studies show a benefit of ~50 percent decrease in mortality that is similar to randomized studies of sigmoidoscopy.

Mortality from proximal colon cancer, as compared to left-sided colorectal cancer, may be affected to a lesser degree by the performance of screening colonoscopy.^{11, 43}

CT COLONOGRAPHY (“VIRTUAL COLONOSCOPY”)^{66–70}

High sensitivity and specificity

Evidence

In a study of asymptomatic adults, CT colonographic screening identified 90 percent of patients with colon cancer or adenomas 10mm or larger in diameter.^{66–67} Laxative-free colonography has been reported, but is not routinely available.⁶⁸

CT colonography does not offer the ability to remove polyps and prevent cancer.

CT colonography should not be a modality of choice for high-risk patients with polyp syndromes or inflammatory bowel disease given its inability to detect flat lesions with accuracy or to remove polyps.

Recently MR colonography has also been shown to detect colon cancers and polyps with accuracy.⁷⁰

Advantages

Fast (10–15 minute), noninvasive imaging of the entire colon⁶⁹

Sedation is not required; patients may drive home or return to work the same day.

Some patients find CT colonography to be more acceptable than standard colonoscopy.

Detection of some significant extra-colonic findings (mostly abdominal aortic aneurysms and renal cell carcinomas)

Disadvantages

Variability in sensitivity based on technique and experience of the radiologists

Requires bowel preparation similar to colonoscopy (at present)

Requires a rectal tube to insufflate air into the colon, which can cause cramping

Exposure to radiation

Abnormal findings require a standard colonoscopy

Can miss small and flat adenomas

Detection of some incidental extra-colonic findings may lead to additional testing that otherwise would not have been done.



The entire CRICO *Prevention & Early Detection of Colorectal Cancer*, along with related information and links, is available at www.rmhf.harvard.edu/guidescolorectal

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Physician-Patient Discussion and Take-home Points Related to Colorectal Cancer Detection

PATIENT-DETECTED RECTAL BLEEDING

The cause of rectal bleeding should be investigated to resolution, regardless of the patient's age, or personal or family medical history. A single, in office FOBT via digital exam is not an adequate assessment.

GENETIC TESTING

Patients with a complex personal or family history of colorectal cancer should be referred—along with family members—to a high-risk clinic (if available) for genetic counseling and development of their ongoing screening plans.

PREVENTION AND EARLY DETECTION OF COLORECTAL CANCER

Periodic screening and aggressive follow up of key symptoms can reduce a patient's likelihood of developing later stage colorectal cancer. Discuss the benefits and limitations of screening and the importance of reporting to you any symptoms (e.g., rectal bleeding, anemia, change in bowel habits). Patients should understand that, while early detection of colorectal cancer can significantly reduce the risk of mortality, health care providers cannot guarantee a cure based on the timing of the diagnosis. Patients may need to be educated as to the subtleties of research data, and discrepancies in findings among various studies.

RISK OF COLORECTAL CANCER FOR PATIENTS YOUNGER THAN AGE 50

Ten percent of colorectal cancers occur in patients less than age 50: approximately eight percent between ages 40–50; two percent occur in patients younger than 40.⁷¹ Other than an age of greater than 50 years, definite risk factors for an increased risk for colon cancer include having a family history of colorectal cancer, black race, obesity, heavy alcohol use, and smoking.

RISK OF INTERVAL COLORECTAL CANCER FOR PATIENTS WITH A SCREENING HISTORY

For patients > age 50 who present with symptoms in the months or years following a negative colonoscopy, explain that:

- if the colonoscopy was more than two years prior, a colonoscopy is recommended;
- if the colonoscopy was less than two years prior, was completed successfully, and was negative, then a repeat colonoscopy—or sigmoidoscopy—should be considered.

COLORECTAL CANCER SCREENING FOR ASYMPTOMATIC PATIENTS > AGE 75

Before ordering a screening colonoscopy or flexible sigmoidoscopy for a patient > age 75, discuss the risks and benefits, taking into account the patient's general quality of life. Routine screening is not recommended for patients over age 85, as the risks outweigh the benefits.

SCREENING OPTIONS

Patients respond best to a definitive recommendation from their primary care provider regarding the need for colorectal cancer screening and the most appropriate modality. As necessary, discuss and document the advantages and disadvantages of the relevant screening modes. Confirm with patients that they fully understand what's involved for each relevant modality. When you and the patient agree to a screening plan, confirm that the appointment has been made.

BOWEL PREP

For patients scheduled for colonoscopy or sigmoidoscopy, emphasize the importance of the bowel prep—including the fact that a poor prep reduces the ability to detect cancerous polyps and increases the likelihood that a repeat procedure will be necessary sooner than when the bowel prep is good.

TEST RESULTS

- Explain to the patient how test results will be communicated to him or her and (if appropriate) other clinicians.
- To ensure notification of test results, employ a system to track ordered tests through the receipt and communication to the patient.
- Document any conversations with patients regarding the reported results.

FOLLOW UP

- Make follow-up or test appointments before the patient leaves your office.
- Physicians and patients share responsibility for follow up; explain to your patients your tracking and compliance system (contacting patients a day or two before their follow-up appointments can reduce noncompliance).
- Track all referrals to ensure that you are receiving a timely report from the specialist.
- Ask the Gastroenterology Department or other specialist to notify your office of patients who do not keep scheduled appointments. Document all patient no-shows or cancellations.
- If a patient refuses follow up, explain the risks of not having a recommended diagnostic test or procedure. Note the patient's refusal for follow up in the record; consider using an informed refusal form signed by the patient.

DOCUMENTATION

- Update and document the patient's personal and family history, and any physical examination; enter, in quotes, the patient's complaints (if any).
- During each visit, update the patient's risk factor assessment and your recommendations for screening based on that patient's current risk for developing colorectal cancer.
- Consider using a problem list to highlight patients with a positive family history of colorectal cancer.