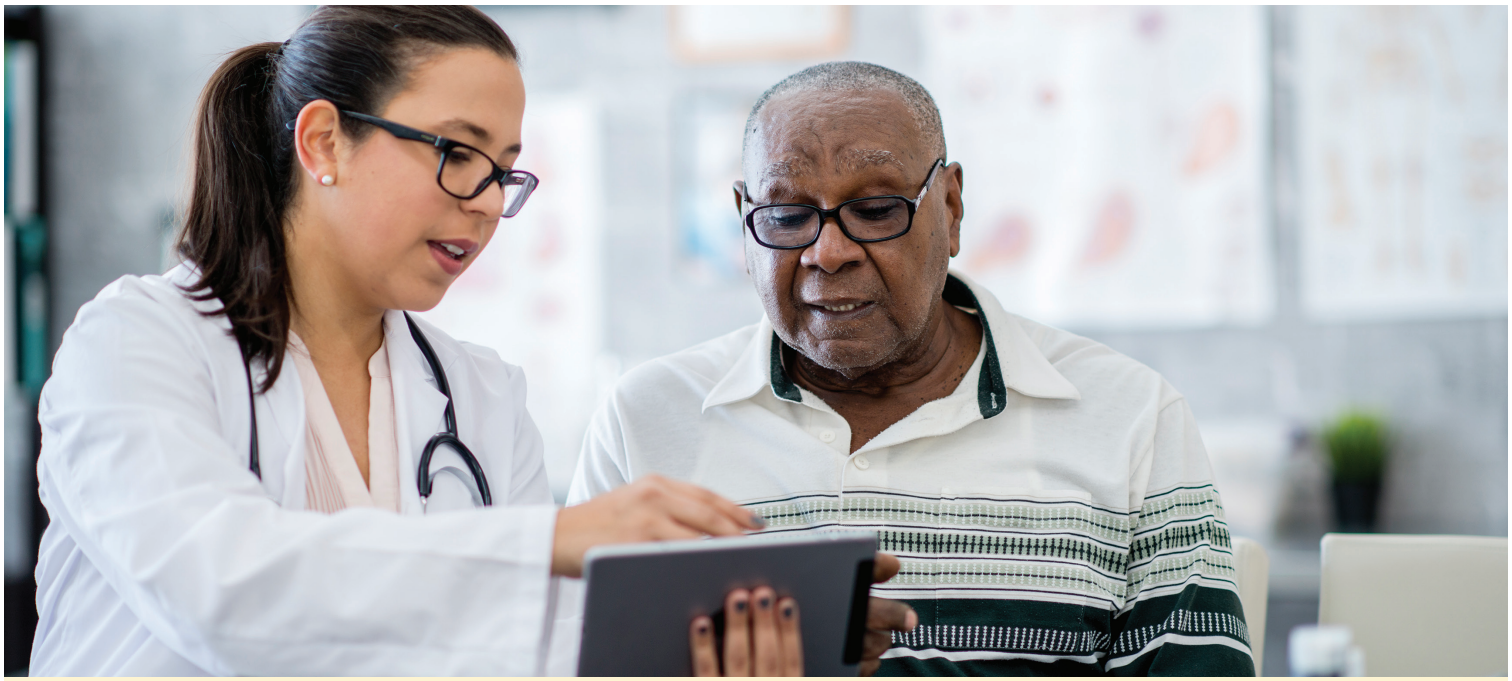


Prevention & Early Detection of Colorectal Cancer

A CRICO DECISION SUPPORT TOOL

crico

CBS 2019

Colorectal Cancer Screening

Discuss screening options with the patient and document the discussion and the patient's preference in the medical record.

- 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.
- Recognize increased risk of colorectal cancer for patients who are African-American, obese, heavy alcohol users, smokers, or have a history of non-gastrointestinal malignancies treated with chemotherapy or abdominal radiation.[1–7]
- Before ordering a screening colonoscopy or flexible sigmoidoscopy for patients age 75–84, discuss the risk and benefits, taking into consideration the patient's general quality of life, prior screening history, and life expectancy.[8–10]
- Screening is not recommended for patients > age 85.
- Single, in-office fecal occult blood test via digital exam is not adequate screening.[11]
- 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.[12–15]
- Track and document screening tests, prep adequacy, and results.
- Follow up with the patient on all positive results. Document follow-up testing and/or referral recommendations, including for tests/appointments reported as not completed.

ABOUT THE GUIDELINE

Prevention and Early Detection of Colorectal Cancer is a CRICO decision support tool for the evaluation of colorectal health and the care of a patient with a colorectal complaint. It is intended for use by clinicians providing primary care. It should not be construed as the standard of care; care plans for individual patients must be based on the provider's professional judgment.

Prevention and Early Detection of Colorectal Cancer

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.

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 kits, flexible sigmoidoscopies, and colonoscopies;
- a primary care provider (PCP) fails to follow colorectal cancer screening guidelines;
- miscommunication between PCP, specialist, and patient regarding poor bowel preparation/limited evaluation; and
- inadequate coordination of ongoing screening, surveillance, or treatment.

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 family or personal history of colorectal cancer or advanced adenomas;[16–18] and

   High Risk Patients who have a genetic colorectal cancer syndrome or inflammatory bowel disease.[19–26]
3. Offer appropriate screening modalities according to patient risk and patient preference; [27–30]
4. Identify the advantages and disadvantages of each selected screening modality;[27–30] and
5. Confirm that patients adequately complete required bowel cleanouts.[31]

Prevention and Early Detection of Colorectal Cancer is based on national colorectal cancer screening and clinical practice guidelines and is a decision-support tool which should not be construed as a standard of care. Health care providers are advised to consider differences in screening recommendations among peer organizations (e.g., the United States Preventive Services Task Force, the U.S. Multi-Society Task Force, and the American Cancer Society).[28–30, 32–40.]

Lessons from Medical Malpractice Cases

Malpractice Case Examples

- Eleven months after a normal colonoscopy, a 52-year-old male presented to his GI with a 25lb weight loss and rectal bleeding. Due to the recent (normal) colonoscopy, the GI treated the patient for hemorrhoids. Four weeks later, with worsening symptoms, the patient underwent sigmoidoscopy and was diagnosed with invasive cancer.
  - ***Screening intervals are guidelines to be measured against the patient's constellation of symptoms.***
  - ***Relying on previously normal findings may lead to narrow diagnostic focus.***

- 61-year-old female underwent a screening colonoscopy following a "fair" prep, but the endoscopist could not proceed past the sigmoid colon due to patient's discomfort. The aborted procedure was documented as normal and a 10-year screening interval was indicated. Six years later, the patient was diagnosed with metastasized sigmoid cancer.
  - ***Screening intervals should reflect the quality of bowel prep and the success of the procedure. An inadequate bowel prep or limited procedure renders a colonoscopy as incomplete.***

- 42-year-old male with unexplained weight loss and multiple complaints of rectal bleeding was treated for hemorrhoids over 13 months before a referral to Gastroenterology revealed advanced stage T3 cancer.
  - ***Consider a differential diagnosis for patients with hemorrhoids, especially with repeated complaints.***

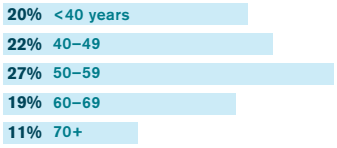
- 38-year-old female, whose father died of colon cancer at age 53, was seen by her PCP for episodic care, including complaints of rectal bleeding, over a 13-month period (she never returned stool cards). Five months after her initial rectal bleeding complaint, colonoscopy revealed invasive stage T3 colon cancer.
  - ***All patients with rectal bleeding and first degree family history of CRC should undergo colonoscopy.***

COLORECTAL CANCER DIAGNOSIS-RELATED CASES

447 cases filed 2008–2017

PHYSICIAN DEFENDANTS NAMED

PATIENT AGE



BREAKDOWNS IN THE PROCESS OF CARE

STEP	PERCENT CASES
1. Patient notes problem/seeks care	1%
2. History/physical	10%
3. Patient assessment/evaluation of symptoms	30%
4. Diagnostic processing	28%
5. Order of diagnostic/lab test	38%
6. Performance of tests	3%
7. Interpretation of tests	13%
8. Receipt/transmittal of test results	3%
9. Physician follow up with patient	25%
10. Referral management	24%
11. Provider-provider communication	13%
12. Patient compliance with follow-up plan	24%

A case may involve multiple breakdowns.

Source: CRICO Comparative Benchmarking System

KEY FACTORS IN COLORECTAL CANCER MALPRACTICE CASES

1. Patient with rectal bleeding did not receive a prompt diagnostic evaluation
2. Over-reliance on previously normal findings may lead to narrow diagnostic focus
3. Breakdowns in screening protocol
4. Primary care provider fails to refer symptomatic patient to specialist
5. Breakdowns in diagnostic test ordering, scheduling
6. Scheduled test not performed
7. Patient's informed refusal not documented
8. Ordering or follow-up of screening/diagnostic procedures inadequately documented
9. Narrow diagnostic focus, failure to establish differential diagnosis
10. Abnormal finding not adequately evaluated
11. Clinician does not convey to the patient the importance of keeping appointments for testing and follow up
12. Multiple providers fail to coordinate care of a shared patient and communicate important information to patient and each other
13. Patient is not notified of test results

Patient Safety and Risk Management Recommendations

PATIENTS AGE <50 WITH RECTAL BLEEDING

Mismanagement of patients with self-reported rectal bleeding is among the most common factors in allegations of missed colorectal cancer diagnoses.

- Aggressively and completely investigate the cause of rectal bleeding, regardless of the patient's personal or family history.[41]
- Evidence that incidence of colorectal cancer is increasing among adults <50 suggests due vigilance for younger patients who present with symptoms such as rectal bleeding and/or abdominal pain.[42]
- Do not test for occult blood, as this may delay the ordering and completion of a colonoscopy.

COLLECTING A MEANINGFUL HISTORY

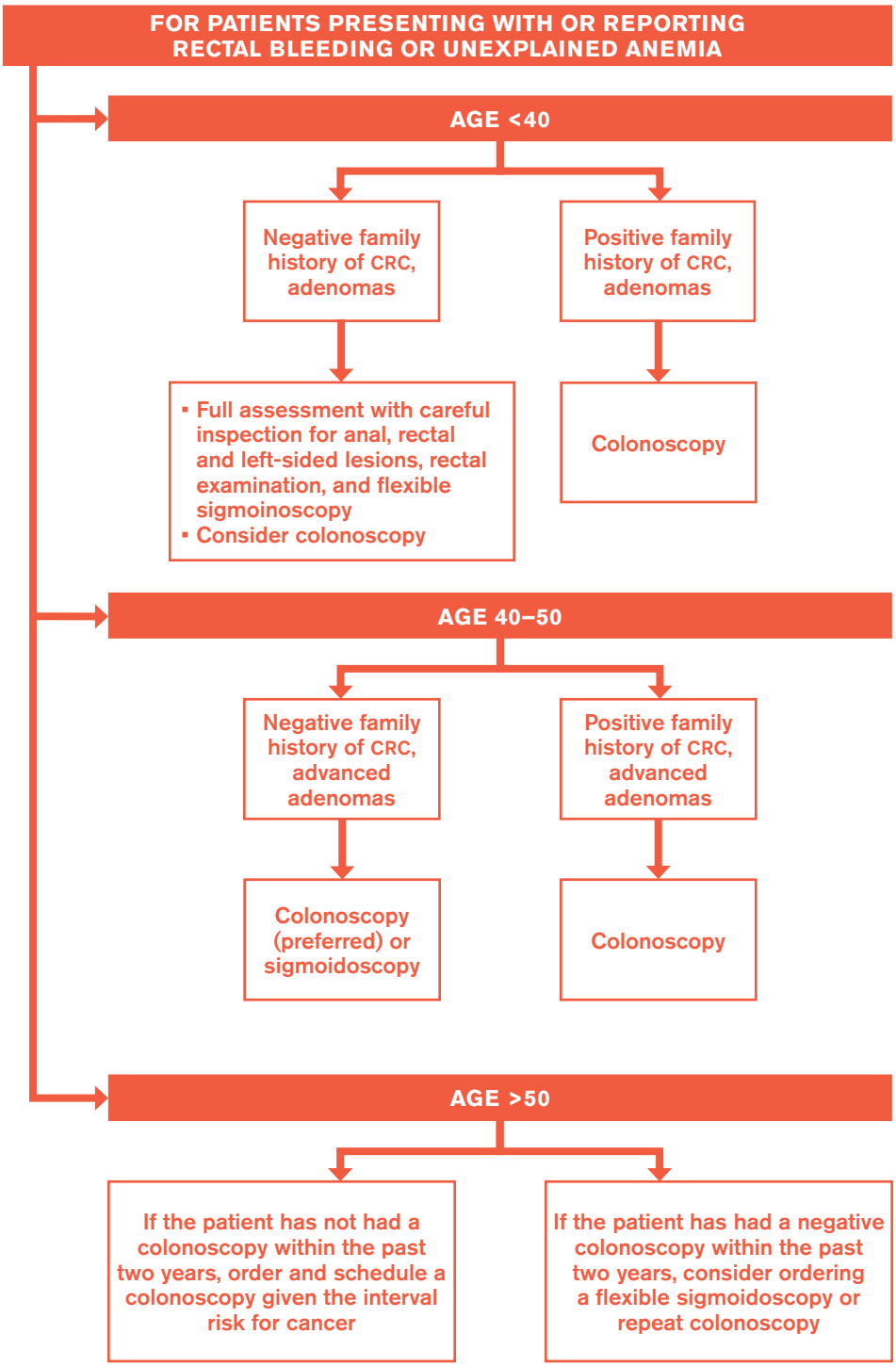
An updated patient and family history should precede selection of screening initiation, modality, and follow up. Obtaining an accurate family history is critical to determining if a patient has a genetic predisposition to the development of adenomas or cancer.

- A family history indicative of prior polyps (i.e., not specifically adenoma) is typically not adequate to determine the appropriate starting period for colon cancer screening or the appropriate surveillance interval.
- Current guidelines recommend that advanced* polyps or a family history of colon cancer should prompt screening colonoscopy at an earlier age and more frequent surveillance intervals. If a patient is uncertain if a family member's adenomas were "advanced," document accordingly.
- Additionally, family histories of polyposis syndromes or genetic cancer risks may necessitate earlier colon cancer screening and shorter intervals between surveillance colonoscopies.
- In general, patients with a family history of colorectal cancer or advanced adenomas should begin screening at age 40 or 10 years earlier than the age of the relative at the time of diagnosis.
- Patients treated with chemotherapy or abdominal radiation for non-gastrointestinal malignancies (e.g., childhood cancer survivors) are at significantly increased risk for the development of colorectal cancer.

*Adenomas considered advanced: a) ≥1cm in diameter, or b) <1cm in diameter with ≥25 percent villous features or high-grade dysplasia.

Assessing 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.



The incidence of colorectal cancer in younger patients.[42–48]

- Recent studies indicated that incidence of colorectal cancer is increasing among adults under age 50, often presenting with rectal bleeding and /or abdominal pain.
- Rectal bleeding in patients under age 40 should not be attributed to hemorrhoids without an adequate work up, including history, rectal exam, perianal exam, and sigmoidoscopy. Colonoscopy may be considered.

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

Screening Patients without Symptoms

1

Update the patient's family history for cancers (especially colorectal and endometrial) relevant to colorectal cancer risk. Note the relationship (i.e., parent, sibling, aunt, uncle, grandparent), type of cancer, and age at onset for each relative.

2

Assess the patient's risk status. Consider patients who are African-American, obese, heavy alcohol users, smokers, or have a history of non-gastrointestinal malignancies treated with chemotherapy or abdominal radiation to be at increased risk for colorectal cancer. Initiation of screening at age 45 should be considered.

AVERAGE RISK

Individuals age 50–75 without any of the risk factors noted below

MODERATE RISK

Personal history of colorectal cancer or adenomas

Personal history of non-gastrointestinal malignancies treated with chemotherapy or abdominal radiation

Family history of colorectal cancer or advanced adenomas

If any of the following is noted in the personal or family history, consider Lynch syndrome (see page 8):

- 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

Personal or family history suggesting Lynch syndrome

Familial adenomatous polyposis (FAP): 100s–1,000s of adenomas

Attenuated polyposis: 10–100 adenomas

Inflammatory Bowel Disease

Other polyposis syndromes: Peutz-Jeghers, juvenile polyposis, MYH-associated polyposis (see page 9)

Bowel Preparation

The adequacy of the colonoscopy preparation is key to a high-quality colon cancer screening program. For patients with inadequate prep, discontinue the procedure and order a repeat colonoscopy within one year.

- Provide written, age and reading-level appropriate, instructions.
- The Gastroenterology office or Endoscopy unit should have systems to manage patient questions about bowel preparation and document any related education.
- A split-dose bowel prep provides better preparation success.[15] The preparation is started the night prior to the procedure, then a second dose is taken 4–6 hours before the scheduled colonoscopy time. For patients who fail to clean the colon adequately, a more extended bowel prep (over two days) should be considered. The regimen for an extended bowel prep should be provided by the gastroenterologist.
- Consider using a low-residue diet prior to the procedure
- Endoscopists should always rate and document the bowel prep. Ideally a scoring system should be used (e.g., Boston Bowel Prep Scale)[31] or adequate /inadequate. Adequate indicates that lesions 5mm or greater should have been seen.

Screening Intervals

The diagnosis of colorectal cancer in the interval between a negative screening and the next scheduled screening is a major challenge for providers and patients. Such interval diagnoses are more susceptible to an allegation of negligent care.

- Interval recommendations following a normal colonoscopy or flexible sigmoidoscopy should be guided by the adequacy of the bowel prep, with an inadequate prep repeated within one year and an adequate prep at routine intervals.[49]
- The gastroenterologist must document the recommended interval.
- Primary care providers should question the interval if it is not documented.

Coordination of Care

Patient safety relies on multiple providers clarifying roles and responsibilities to each other and to the patient. Communicate the follow-up plan (including screening intervals) to the patient and the responsible providers.

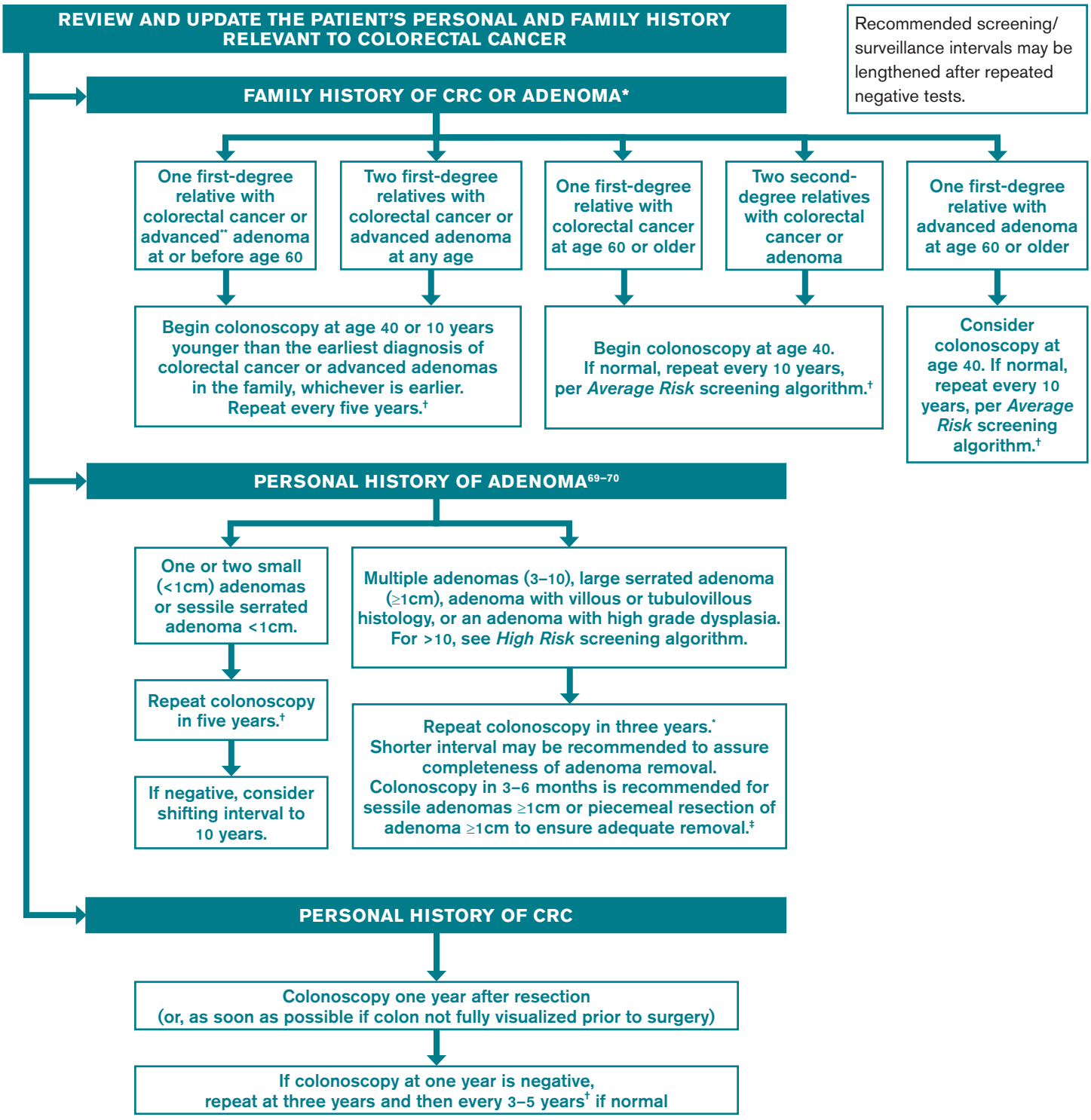
Patients at Average Risk

ASYMPTOMATIC, AGE 50–75, NO PERSONAL OR FAMILY HISTORY OF CRC OR ADENOMA

Intervals for procedures requiring bowel preparation are based on a prep rated "adequate." The success of the procedure in reaching the cecum is essential for a completed colonoscopy.[15] An "inadequate" bowel prep mandates a repeat procedure at a shorter interval.

TIER 1	ADVANTAGES	DISADVANTAGES
Colonoscopy: every 10 years[28, 36, 50–55]	Has the ability to concurrently detect and remove polyps Polypectomy has been shown to decrease colon cancer mortality	Requires bowel preparation Takes about 30 minutes plus recovery time Patients need to be escorted home
FIT (fecal immunochemical test): annually[29–30, 56–64]	Easy, safe, convenient (single sample) Not affected by diet or medications Detects colon cancer and advanced adenomas with increased sensitivity (91%) over fecal occult blood test (24%)	Must be repeated annually to be beneficial Positive tests require colonoscopy
TIER 2		
CT Colonography: every 5 years[65]	10–15 minute noninvasive imaging of the entire colon Sedation is not required; patients may drive home or return to work the same day	Variability in sensitivity based on radiologist Requires bowel preparation similar to colonoscopy Abnormal findings require a standard colonoscopy
FIT/DNA (Cologuard): every 3 years[50, 66]	Stool-based assay: non-invasive, safe, easy High sensitivity for colon cancer (92%) Can be performed every three years	10 percent false positive rate Sensitivity for adenomas is lower (17% for any adenoma, 42% for advanced adenoma) Abnormal findings require a standard colonoscopy
Flexible sigmoidoscopy: every 5–10 years[67–68]	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. Detects 70–80 percent of all CRC and large adenomas	Requires bowel preparation with enemas Detection of adenomas requires colonoscopy Does not visualize most of the colon; some lesions may be missed
TIER 3		
Capsule colonoscopy: every 5 years	No sedation Imaging without an invasive procedure	Bowel prep more extensive than for colonoscopy Reprep and colonoscopy required following abnormal findings Not routinely available

Patients at Moderate Risk



* Consider genetic syndromes such as Lynch syndrome, if there are multiple or early colon cancers or adenomas in the family. Refer to the *High Risk* screening algorithm.

** Adenomas considered advanced: a) ≥1cm in diameter, or b) <1cm in diameter with ≥25 percent villous features or high-grade dysplasia.

† Suggested intervals for screening procedures are based on the quality of the bowel preparation and the success of the procedure in reaching the cecum.[15] 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.[49–50, 71–76]

‡ 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 the endoscopist recommends an early re-evaluation and biopsy of the polyp site.[51–52, 77–78]

Patients at High Risk

STRONG FAMILY HISTORY OF COLORECTAL CANCER

Refer patient and family members to a high-risk clinic for genetic counseling, genetic testing, and outline of screening procedures.*
If no high-risk clinic is available, then the consulting gastroenterologist should assume the responsibility for outlining the appropriate screening procedures.

Lynch Syndrome

Refer to endoscopist to perform colonoscopy starting at age 20–25 years

Repeat every 1–2 years until age 40, then annually after age 40

Screen for extracolonic malignancies (endometrial cancer) as per guidelines of high-risk genetics clinic. Patients whose personal or family history suggests Lynch syndrome should be referred to high-risk clinic.

Familial adenomatous polyposis (FAP)

Refer to endoscopist to perform flexible sigmoidoscopy or colonoscopy, beginning at age 12, to detect adenomas

If no polyps found, repeat procedure annually until age 40

Screen for duodenal and periampullary adenomas and carcinomas and thyroid carcinomas as per guidelines of high-risk genetics clinic

Attenuated FAP (10–100 adenomas)

Colonoscopy every 1–2 years

Consider other, less common syndromes* based on clinical presentation, family history, polyp histology (page 9)

INFLAMMATORY BOWEL DISEASE[79]

For ulcerative pancolitis or Crohn's colitis ≥8–10 years, perform screening colonoscopy every 1–3 years with surveillance biopsies. If primary sclerosing cholangitis is diagnosed, perform annual surveillance colonoscopy.

If left-sided ulcerative colitis ≥15 years, perform colonoscopy every 1–3 years with surveillance biopsies

A diagnosis of dysplasia should be confirmed by a pathologist expert in reading dysplasia in inflammatory bowel disease

LYNCH SYNDROME[80]

Evaluation for Lynch syndrome should be considered when the:

1. Bethesda criteria are met

   Bethesda Criteria[81] (revised 2004)

   - Colorectal cancer (CRC) under the age of 50; or
   - Two or more diagnoses of CRC or other Lynch-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 first degree relative with CRC or other Lynch-related cancer, one of the cancers onset < age 50; or
   - CRC with two or more relatives with CRC or other Lynch-related cancer regardless of age.
2. IHC testing for DNA-MMR protein on colorectal tumor tissue is abnormal
3. A predictive model (e.g., MMRpredict, MMRPro, PREMM) suggests a high risk of a mutation

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.

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

Hereditary Gastrointestinal Polyposis and Nonpolyposis Syndromes

CONDITION	GENES (INHERITANCE)	KEY CLINICAL FEATURES
Polyposis syndrome		
Familial adenomatous polyposis (FAP)	APC (AD)	100s–1,000s of colonic adenomatous polyps Duodenal/periampullary adenomas Onset in teenage years Prophylactic proctocolectomy is standard
Attenuated FAP	APC (AD)	<100 colonic adenomas, onset in adulthood
MYH-associated polyposis	MUTYH (AR)	Wide range in number of colon adenomas (few–1,000s)
Polymerase proofreading-associated polyposis	POLD1, POLE (AD)	5–100 colon adenomas; Increased risk of endometrial cancer
Peutz-Jeghers Syndrome	STK11 (AD)	Peutz-Jeghers type hamartomatous polyps Perioral macular pigmentation High risk of colon, gastric, pancreatic, breast, and gynecologic cancers
Cowden Syndrome	PTEN (AD)	Multiple hamartomatous polyps High risk of thyroid cancer, breast cancer
Bannayan-Riley-Ruvalcaba	PTEN (AD)	Multiple hamartomatous polyps Macrocephaly Developmental delay
Juvenile polyposis	BMPR1A, SMAD4 (AD)	Multiple juvenile polyps Increased risk of colon cancer Hereditary hemorrhagic telangiectasia phenotype in some SMAD4 families
Serrated polyposis	Unknown	Multiple sessile serrated adenomas (at least five serrated polyps proximal to sigmoid colon, two of which are >1cm in size)
Nonpolyposis syndrome		
Lynch	MLH1, MSH2, MSH6, PMS2, EPCAM (AD)	High risk of colon and endometrial cancer Absence of multiple polyps Most common hereditary colon cancer syndrome

AD autosomal dominant

AR autosomal recessive

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 fecal occult blood test via digital exam is not an adequate assessment.

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.[82] Other than an age of greater than 50 years, definite risk factors for an increased risk for colon cancer include being African-American, having a strong family history of colorectal cancer (see page 7), obesity, heavy alcohol use, and smoking. Patients treated with chemotherapy or abdominal radiation for non-gastrointestinal malignancies (e.g., childhood cancer survivors) are at a significantly increased risk for the development of colorectal cancer.

GENETIC TESTING

Regardless of age, patients with a complex personal 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.

RISK OF INTERVAL COLORECTAL CANCER FOR PATIENTS WITH A SCREENING HISTORY

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

- if the colonoscopy was more than two years prior, a repeat 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 75–84, discuss the risks and benefits, taking into account the patient's general quality of life and prior screening history. Screening is not recommended for patients over age 85, as the risks generally outweigh the benefits.

SCREENING OPTIONS

Patients respond best to a definitive recommendation from their primary care providers 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 (see page 6). 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 PREPARATION

Emphasize with the patient the importance of a good bowel preparation—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 usually recommended. Be prepared for patient questions about bowel preparation (e.g., nurse navigators, on- and off-hour call-in systems).

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 by 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 adherence system (contacting patients a day or two before their follow-up appointments can reduce nonadherence).
- 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 the patient's problem list to highlight patients with a positive family history of colorectal cancer.

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