

Screening for Colorectal Cancer: Optimizing Quality

Primary Care Version Part 2



PART 2:

**DELIVERING HIGH-QUALITY STOOL
BLOOD TESTING IN PRIMARY CARE**

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Topics to Be Covered

Stool Blood Testing

- ❑ The importance of offering stool blood testing
 - Advantages of stool blood testing
 - Many patients prefer stool blood testing
- ❑ Developing a high-quality stool testing program
 - Selecting an effective test
 - Tests to avoid, tests to use
 - High-sensitivity guaiac tests (HS-gFOBT), immunochemical tests (FIT)
 - Stool collection at home, NOT in-office
 - Identifying eligible patients
 - Patients who should not receive FOBT / FIT

Topics to Be Covered

- ❑ Developing a high-quality stool testing program (continued)
 - Training staff to communicate with patients
 - Providing appropriate instructions
 - Assuring high test completion rates
 - Assuring high-quality test handling and processing
 - Following up abnormal tests
 - Assuring annual test completion

Pop Quiz

Why is it important to offer stool blood testing as an option for screening?

Stool Blood Testing Remains Important in the “Age of Colonoscopy”

- ❑ Colonoscopy is now the most frequently used screening test for CRC.
- ❑ However, when provided annually to average-risk patients with appropriate follow-up, stool occult blood testing with high-sensitivity tests can provide *similar reductions in mortality compared to colonoscopy and some reduction in incidence.*

Advantages of Stool Blood Testing

Stool blood testing

- Is less expensive.
- Can be offered by any member of the health team.
- Requires no bowel preparation.
- Can be done in privacy at home.
- Does not require time off work or assistance getting home after the procedure.
- Is non-invasive and has no risk of causing pain, bleeding, bowel perforation, or other adverse outcomes.

Colonoscopy is required only if stool blood testing is abnormal.

Many Patients Prefer Home Stool Testing

- ❑ Diverse sample of 323 adults given detailed side-by-side description of FOBT and colonoscopy*
 - **53% preferred FOBT.**
 - Almost half felt very strongly about their preference.
- ❑ 212 patients at four health centers in Texas rated different screening options with different attributes**
 - 37% preferred colonoscopy.
 - **31% preferred FOBT.**

*[Community-based Preferences for Stool Cards versus Colonoscopy in Colorectal Cancer Screening](#)

**[Preferences for colorectal cancer screening among racially/ethnically diverse primary care patients](#)

Many Patients Prefer Home Stool Testing

- ❑ Nationally representative sample of 2,068 Veterans Administration patients given brief descriptions of each screening mode*
 - 37% preferred colonoscopy.
 - **29% preferred FOBT.**

- ❑ Racially diverse sample of 525 average-risk patients at two safety-net ambulatory care sites in Boston given an interactive decision aid for CRC screening**
 - 59% preferred colonoscopy.
 - **26% preferred FOBT.**
 - Patients who preferred FOBT were less likely to have their preferred test ordered than those who preferred colonoscopy (35% vs. 85%) and more likely to have no test ordered (31% vs. 15%).

*[Colorectal cancer screening mode preferences among US veterans](#)

**[Aid-Assisted Decision Making and Colorectal Cancer Screening: A Randomized Controlled Trial](#)

Many Patients Prefer Home Stool Testing

- Randomized clinical trial in which 997 ethnically diverse patients in San Francisco community health centers received different recommendations for screening
 - Colonoscopy recommended 38% completed colonoscopy
 - **FOBT recommended:** **67% completed FOBT**
 - **Colonoscopy or FOBT:** **69% completed a test**

Many Patients Prefer Home Stool Testing

- ❑ Some patients may forgo ANY colorectal cancer screening if they are not offered a home stool blood testing alternative to colonoscopy.
- ❑ Clinical evidence indicates that selecting annual stool blood testing instead of colonoscopy is a reasonable choice for average-risk patients.
- ❑ However, patients who select stool blood testing must also be prepared to accept follow-up colonoscopy if the stool blood test is abnormal.

How Should Patient Preferences Influence Practice?

- ✓ To maximize the number of patients who get screened, stool blood tests need to be offered as a screening option alongside colonoscopy for average-risk screening in all primary care settings.
- ✓ All primary care practices need to develop *systems of care* to ensure that stool blood tests are offered at appropriate time intervals, with high-quality instructions and attention to follow-up of abnormal results.

There Is More to Stool Blood Testing Than Handing Out Kits!

The next slides outline procedures to follow to develop a high-quality stool blood testing program.

Other complementary resources include a tool kit from the National Colorectal Cancer Roundtable.

[Tools & Resources – How to Increase Colorectal Cancer Screening Rates in Practice: A Primary Care Clinician’s Evidenced-Based Toolbox and Guide](#)

Developing a High-Quality Home Stool Testing Program That Works

1. Select an effective test.
2. Identify eligible patients.
3. Train staff to communicate with patients.
4. Provide appropriate test instructions.
5. Ensure high test completion rates.
6. Ensure high-quality test processing.
7. Follow up abnormal test results with colonoscopy.
8. Ensure annual test completion.

Pop Quiz

Is screening with a standard
guaiac-based test like
Hemoccult II a good way
to screen for CRC?

Step 1: Select an Effective Test

- ❑ One of the most important considerations when selecting a test is its sensitivity.
- ❑ Use tests with sensitivity for cancer of at least 50% with a single test kit.
 - High-sensitivity guaiac tests (HS-gFOBT)
 - Fecal immunochemical tests (FIT)



Screening and Surveillance for the Early Detection of Colorectal Cancer and Adenomatous Polyps, 2008: A Joint Guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology

Screening for Colorectal Cancer: U.S. Preventive Services Task Force Recommendation Statement

Step 1: Select an Effective Test

Standard guaiac tests* should not be used.

- ❑ Sensitivity for cancer is less than 50% with a single test kit.
- ❑ The USPSTF and joint ACS/US Multi-Society Task Force/ACR guidelines ***do not recommend the use of these low-sensitivity tests.***

*Standard guaiac tests include Hemoccult II®** and similar tests.

**Use of trade names is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

Step 1: Select an Effective Test

High-Sensitivity Guaiac Tests (HS-gFOBT)

- Sensitivity of at least 50% for cancers on a single test kit.
- Hemoccult II SENZA[®]* is an example of a high-sensitivity guaiac test (HS-gFOBT) that is in use in the United States.
 - Estimated sensitivity for cancer: 64–80%**
 - Estimated specificity for cancer: 87–90%**

*Use of trade names is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

**[Screening for Colorectal Cancer: A Targeted, Updated Systematic Review for the U.S. Preventive Services Task Force](#)

Step 1: Select an Effective Test

High-Sensitivity Guaiac Tests (HS-gFOBT)

- ❑ Require stool samples collected on 3 different days after up to 7 days of dietary and medication restrictions.
- ❑ Each stool specimen is collected by using a collection stick to take samples from two different areas of stool from each bowel movement. The stool should be collected on the paper provided, before it comes into contact with the toilet water. The kit is manually processed in the clinic or lab.
- ❑ Average Medicare reimbursement: \$4.48 per test.

Step 1: Select an Effective Test

Fecal Immunochemical Tests (FITs)

In general, FITs are easier to use and more likely to be completed by patients than guaiac tests.

- ❑ No need for dietary or medication restriction.
- ❑ Most FIT require samples from only 1 or 2 consecutive bowel movements.

Step 1: Select an Effective Test

Fecal Immunochemical Tests (FITs)

- ❑ FITs cost slightly more than guaiac tests, but arrangements can be made to reduce or eliminate up-front costs for clinical practices. Also, FITs are usually reimbursed at a higher rate than guaiac tests.
- ❑ Average Medicare reimbursement: \$21.86 for each completed FIT.

Step 1: Select an Effective Test

Not all FITs are the same.

- ❑ Different FITs use different collection methods and require varying numbers of samples.
- ❑ Some FITs can be processed in an office setting (point-of-care tests).
- ❑ Some FITs use a machine or analyzer to measure hemoglobin.
- ❑ Different tests have different hemoglobin cutoff values to define an abnormal test.
 - Lower cutoff values lead to higher sensitivity but lower specificity, thereby increasing number of patients needing a colonoscopy.

Step 1: Select an Effective Test

Not all FITs have been tested rigorously.

Criterion for choosing a FIT:

Use a FIT that has been evaluated in clinical practice and for which data on performance in the peer-reviewed literature show at least 50% sensitivity for cancer.

Step 1: Select an Effective Test

A recent systematic review compared results of studies on performance characteristics of different FITs.

Looked at studies done in average-risk asymptomatic patients with an appropriate reference standard (colonoscopy or ≥ 2 years of follow-up)

- ❑ Included several studies of Polymedco FITs, one study of Hemoccult ICT[®],* and studies of FITs not available in U.S.
- ❑ For included studies:
 - Range of sensitivity for cancer: 56%–100%.**
 - Range of specificity for cancer: 83%–97%.**

Excluding studies of FITs that have been discontinued.

*Use of trade names is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services

**[Accuracy of Fecal Immunochemical Tests for Colorectal Cancer: Systematic Review and Meta-analysis](#)

Step 1: Select an Effective Test

At this time, the brand of FIT that has been most extensively tested and is available in the United States is OC FIT-CHEK^{®*} (Polymedco):

- Provided as a one-sample kit in most cases. The collection method involves inserting the probe several times into the stool to a point on the probe just above the ridges and placing the collection probe into a small tube. The stool is probed before it comes into contact with the toilet water.

- Test processing can be manual or automated
 - Manual: OC-Light^{®*} – point-of-care assay
 - Estimated sensitivity for cancer: 93%
(95% CI, 83%–97%)
 - Automated: OC-Auto^{®*} – uses an automated analyzer



[Accuracy of Fecal Immunochemical Tests for Colorectal Cancer: Systematic Review and Meta-analysis](#)

*Use of trade names is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services

Pop Quiz

Is performing a stool blood test using a stool sample collected during a DRE a good way to screen your patient?

Remember: Stool Collection Should Be Done AT HOME!

- ❑ Stool collected on digital rectal exam may not be sufficient or sufficiently representative of stool collected from a complete bowel movement.
- ❑ There is ***no evidence*** that any type of stool blood testing is sufficiently sensitive when used on a stool sample collected during a rectal exam.
- ❑ Therefore, ***HS-gFOBT and FIT should be completed by the patient at home, and NOT as an in-office test.***

Step 2: Identify Eligible Patients

- ❑ Use electronic patient data when possible.
- ❑ Primary target: **average-risk** adults aged 50–75.
 - Average-risk adults aged 76–85 on a case-by-case basis.
 - Consider screening if not up-to-date with screening and life expectancy at least 5–10 years.
- ❑ Many patients at higher than average risk should be screened with colonoscopy rather than HS-gFOBt or FIT.

Pop Quiz

Should you recommend an interim stool blood test to an average-risk patient who had a normal colonoscopy several years ago?

Step 2: Identify Eligible Patients

There is no evidence for performing an interim HS-gFOBT or FIT for average-risk patients with a negative high-quality colonoscopy within the preceding 10 years.

Step 2: Identify Eligible Patients

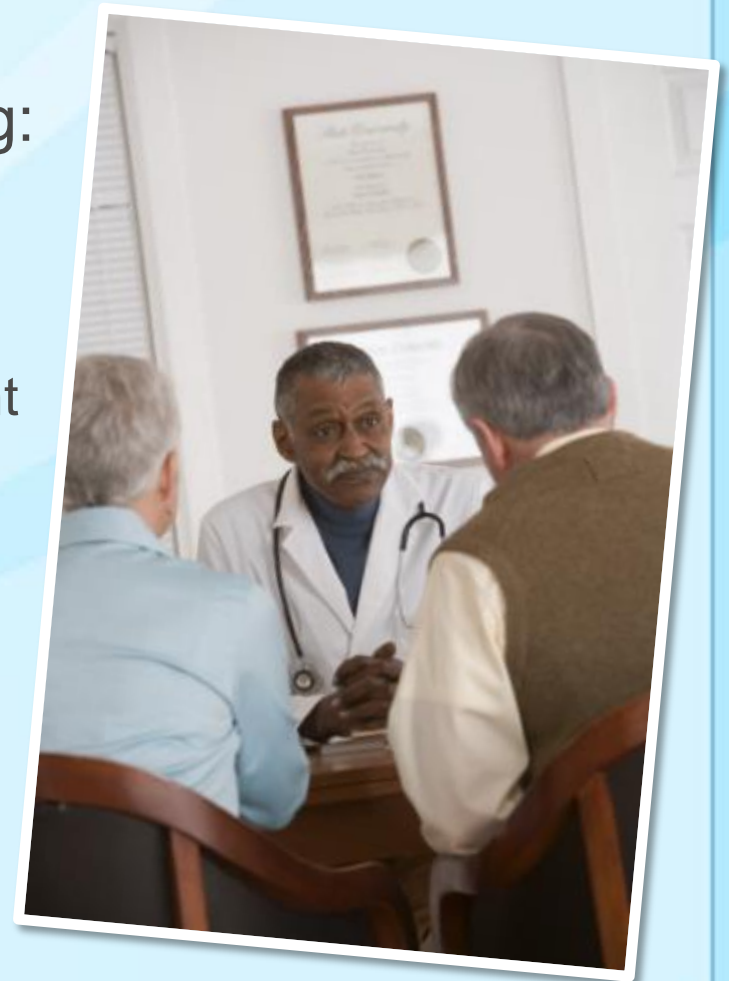
Remember: Risk Assessment Is Important!

Clinic outreach programs that emphasize HS-gFOBT or FIT distribution must have a system to identify and refer higher-than-average risk patients for colonoscopy when indicated.

Step 3: Train Staff to Communicate with Patients

Train clinicians and staff so that they know and feel comfortable explaining:

- ❑ Why screening is important for the clinic population.
- ❑ Why HS-gFOBt and FIT are important and useful options for colorectal cancer screening.
- ❑ Testing intervals and the importance of follow-up of abnormal test results.

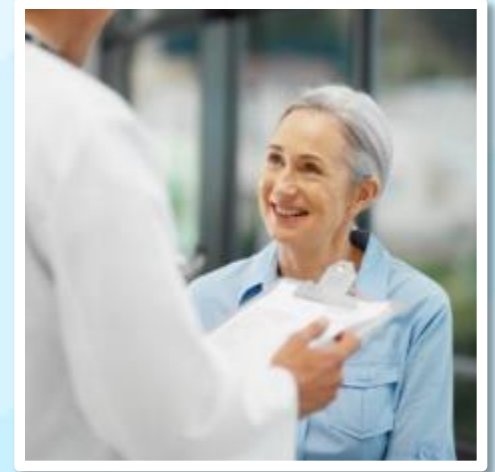


Step 3: Train Staff to Communicate with Patients

Develop, tailor, and practice scripts to generate enthusiasm for screening among staff and patients.

For example:

- ❑ “This easy test could save your life!”
- ❑ “The test is not painful and can be done in the privacy of your own home!”
- ❑ “We want to be sure that everyone in our community has a chance to take advantage of colorectal cancer screening.”
- ❑ “All our doctors recommend this test.”



Using Patient Navigators to Improve Adherence and Quality of Screening

- ❑ Recent studies have demonstrated the effectiveness of patient navigators in improving screening adherence.
- ❑ Patient navigators are trained, culturally sensitive health care workers who provide individualized assistance to patients, families, and caregivers to help overcome health care system barriers and facilitate timely access to high-quality health care.
- ❑ Patient navigators can assist at many points in the screening process, including:
 - Getting patients scheduled for screening.
 - Explaining the technique for completing FOBT/FIT tests or for bowel preparation for colonoscopy.
 - Assuring patient understanding and completion of testing.
 - Addressing patient barriers (for example, need for an escort, language, transportation).
 - Assuring the patient receives test results from the provider promptly.
 - Scheduling and preparing for follow-up procedures.
 - Identifying treatment resources and support networks when needed.

Step 4: Provide Appropriate Instructions

- ❑ A well-trained staff is essential.
- ❑ Clinicians and staff should review manufacturer instructions carefully and follow them as closely as possible.
- ❑ Adjust written instructions for language and literacy, using low-literacy versions, simplified translations, or visual aids.
- ❑ Demonstrate the technique to collect the specimen, date the specimen, and return the specimen promptly to the laboratory (video instructions may be helpful).

Step 4: Provide Instructions Using Appropriate Language

- ❑ Brief, low-literacy videos in multiple languages explaining the importance of screening and the general principles of guaiac and immunochemical test completion have been developed and posted on the Internet:
[Community Engagement and Health Policy Videos](#)
- ❑ Other low-literacy and multilingual print materials are often available from kit manufacturers, CRC screening advocacy groups, or on the Internet.

Step 4: Provide Instructions Using Appropriate Language

Examples of written instructions for the Polymedco FIT:

- English
- Spanish
- Chinese
- Vietnamese
- Russian

Note: Those who choose to use these instructions should check with their patient population to make sure they are appropriate and that final versions used follow manufacturer's specifications.

Step 5: Ensure High Test Completion Rates

In-reach Methods

- ❑ Use electronic point-of-care reminders.
- ❑ Involve staff in addition to the PCP in the process of identifying eligible patients and offering HS-gFOBT/FIT.
- ❑ Waiting room videos, posters, or brochures may help. CDC's *Screen for Life* campaign offers a variety of [materials](#).

Step 5: Ensure High Test Completion Rates

- ❑ Provide kits during nurse visits, flu shot clinics (FLU-FIT), or other regular types of clinic visits, not just during primary care visits!
- ❑ Explore and consider interventions from the National Cancer Institute's "Research-Tested Intervention Programs" for colorectal cancer screening, some of which address issues of targeted in-reach and outreach.

Step 5: Ensure High Test Completion Rates

- ❑ Outreach methods
 - Use electronic health registries.
 - Mail invitations with or without test kits.
 - Use personal or automated phone call invitations.

- ❑ Test completion reminders
 - Send by telephone or mail within 2–3 weeks of receipt of test kit.

Step 6: Ensure High-Quality Test Handling and Processing

- ❑ Verify date of collection with patient if not written on sample, if feasible.
- ❑ Use trained, experienced personnel to develop and report the test kits.
- ❑ Send to a central laboratory for processing when possible to ensure good quality control.
- ❑ Monitor test positivity rates and investigate unexpected fluctuations.

Step 6: Ensure High-Quality Test Handling and Processing

To reduce the risk of false-negative results, patients should be advised to:

- ❑ Carefully follow manufacturer's instructions.
- ❑ Return kits promptly, within the test kit brand recommendations.
- ❑ Avoid storing kits at high temperatures before and after test completion because of possibility of hemoglobin degradation.
 - Seasonal variations in FIT positivity rates have been observed.
 - Companies are working to improve buffers to reduce deterioration at high temperatures.

Step 7: Follow-Up Abnormal Test Results

- ❑ **Refer all patients with an abnormal stool blood test for colonoscopy because this may indicate the presence of a significant polyp or cancer.**
- ❑ Navigate patients to colonoscopy with referrals, telephone and mailed reminders, and assistance with scheduling.
- ❑ Collaborate with the endoscopist to ensure prompt and proper follow-up.

Step 8: Ensure Annual Test Completion

- Use registries and outreach systems (mail and telephone) to remind and provide testing to patients who do not come in for a visit every year.
- Provide consistent messages about the importance of annual test completion at the time the test is provided and again at the time test results are given.

Quality Screening Must Be a Priority

Assess numbers and rates of:

- Eligible patients.
- Test kits provided.
- Test kits returned and processed.
- Test kits rejected by laboratory.
- Abnormal test results.
- Colonoscopy for abnormal results.
- Sustained annual participation.

Remember: Refer for Colonoscopy If HSgFOBT or FIT Is Abnormal!

Do not repeat an abnormal HS-gFOBT or FIT.

- ❑ A normal result on a repeat HS-gFOBT or FIT does not rule out polyps or cancer.
- ❑ Abnormal screening with HS-gFOBT or FIT should be evaluated further by direct visualization of the colon with colonoscopy.
- ❑ Abnormal HS-gFOBT or FIT should NOT be followed with other less definitive tests, such as flexible sigmoidoscopy, barium enema, or CT colonography.

Summary: To Develop a High-Quality Stool Blood Testing System...

1. Select an effective HS-gFOBT or FIT, and have patients complete it **at home**.
2. Identify eligible patients.
3. Train staff to communicate with patients.
4. Provide appropriate test instructions.
5. Ensure high test completion rates.
6. Ensure high-quality test processing.
7. Follow up abnormal test results with colonoscopy.
8. Ensure annual test completion.

Thanks for viewing Part 2

**The following slides are not part of this presentation,
but rather serve as links for users.**

Risk Stratification to Ensure Appropriate Screening and Surveillance*

- ❑ **Average Risk**
 - No signs or symptoms of CRC.
 - None of the risk factors below.

- ❑ **Increased Risk**
 - Family history of CRC or adenomas in a first-degree relative or CRC in two second-degree relatives.
 - Personal history of adenomas, certain serrated polyps, or CRC.

- ❑ **High Risk**
 - Inflammatory bowel disease: chronic ulcerative colitis or Crohn's colitis.

- ❑ **Highest Risk**
 - Confirmed or suspected genetic syndromes (FAP, HNPCC).

*The term “surveillance” is used for testing patients with a personal history of colorectal adenomas, certain serrated polyps, or cancer. “Diagnostic testing” is appropriate for patients with signs or symptoms.

Screening Patients with a Family History

- If patient has either:
 - CRC or adenomas* in a first-degree relative diagnosed at **age ≥ 60** OR
 - Two second-degree relatives with CRC



Begin screening at age 40 with any test recommended for average risk; repeat at usual intervals based on type of test and findings.**

- If patient has either:
 - CRC or adenomas* in a first-degree relative diagnosed **before age 60** OR
 - Two or more first-degree relatives diagnosed at any age (with family history not suggestive of genetic syndrome)



Colonoscopy every 5 years starting at age 40, or 10 years before the youngest case in the family was diagnosed, whichever comes first.**

*Our expert opinion is that this applies to relatives with advanced adenomas (adenomas that are ≥ 1 cm, villous, or with high-grade dysplasia)only, recognizing that this information is often unavailable.

**The evidence base for these guidelines was not strong and some aspects are controversial.

Screening and Surveillance for the Early Detection of Colorectal Cancer and Adenomatous Polyps, 2008: A Joint Guideline from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology