

FluFOBT Implementation Guide

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Acknowledgments

The American Cancer Society would like to thank Michael Potter, MD, former National Colorectal Cancer Roundtable (NCCRT) Steering Committee member and current chair of the NCCRT Professional Education and Practice Task Group, and his colleagues (at UCSF, the San Francisco Department of Public Health, and Kaiser Permanente) and funders (ACS, CDC, and NCI), for developing and demonstrating the effectiveness of FluFOBT interventions. We thank FluFOBT project coordinators La Phengrasamy, MPH, Vicky Gomez, MPH, and Tina Yu for developing and field-testing many of the program materials and procedures included in this Implementation Guide. We would also like to thank Holly Wolf, PhD, MSPH, NCCRT Steering Committee member and chair of the NCCRT Policy Action Task Group, and her team at the Colorado Colorectal Screening Program for organizing FluFOBT.org Web site materials into a model implementation guide.

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INTRODUCTION

The American Cancer Society FluFOBT program (the Program) is intended to assist community health centers in increasing colorectal cancer (CRC) screening. It has been demonstrated in the medical literature that offering and providing take-home fecal occult blood tests (FOBTs and FITs) to patients at the time of their annual flu shot increases CRC screening rates.^{1,2,4}

Colorectal cancer is the third leading cause of cancer death among men and women in the United States (US).⁸ An estimated 142,820 cases of colon and rectal cancer are expected to occur in 2013, with an estimated 50,830 deaths.

In 2010, 59.1% of adults 50 years of age and older reported use of either an FOBT or an endoscopy test within recommended time intervals. However, rates remain substantially lower in uninsured individuals and those with lower socioeconomic status.

Compelling data from the Centers for Disease Control and Prevention (CDC) suggest that CRC screening reduces the incidence and mortality from colorectal cancer. The CDC detailed a study concerning CRC screening data gathered from the 2002-2010 Behavioral Risk Factor Surveillance System surveys, in addition to incidence and mortality data gathered from the United States Cancer Statistics. Significant findings from this study were: CRC incidence and mortality rates declined 13% and 12% (approximately 66,000 cases and 32,000 deaths) respectively from 2003 to 2007, and screening prevented approximately half of the expected CRC cases (33,000) and deaths (16,000) during this same time frame.^{6,7} Those screened for CRC increased 13% from 2002 to 2010. This study demonstrates that prevention and early detection of CRC through screening can decrease the incidence of and mortality from this disease.⁷ However, in 2010 one in three adults between the ages of 50 and 75 years of age were still not up-to-date with screening recommendations.⁶

The American Cancer Society has developed this implementation guide to include:

- Background and evidenced-based information/education regarding the Program and the benefits of FluFOBT
- Patient eligibility criteria for colorectal cancer screening
- Patient education about colorectal cancer and the importance of screening
- Steps on setting up a FluFOBT program in your health center
- Staff training regarding the implementation of a FluFOBT program for your center
- Tracking tools to manage your FluFOBT program

BACKGROUND INFORMATION AND EDUCATION

FluFOBT BACKGROUND

The FluFOBT program is an efficient and effective way to increase colorectal cancer screening. Flu shot clinic staff provide take-home fecal occult blood test (FOBT) kits to patients due for colorectal cancer screening when they get their annual flu shot. Patients due for colorectal cancer screening through FOBT are 50 and older and have not had an FOBT in the past year or a colonoscopy in the past 10 years. The FluFOBT program is a population-based method, which has been shown to increase screening rates in a variety of settings, including community health centers.^{1,3,4}

An FOBT is a colorectal cancer screening test for patients 50 and older that must be done annually to be effective.⁸ There are two types of FOBTs currently used for colorectal cancer screening, the guaiac-based FOBT and the immunochemical FOBT, more commonly known as an FIT. The Program will refer to both tests more broadly as FOBTs. Either a high-sensitivity guaiac-based FOBT or an FIT is appropriate for the FluFOBT program.

The patient completes the FOBT by collecting a small stool sample in the privacy of their home and returning the test to their doctor's office (or sending the kit to the lab) for processing. The test detects small amounts of blood in the stool that may result from colorectal cancer or precancerous colon polyps. If the test is positive, a colonoscopy is then required to determine the source of the bleeding.

Clinics can use this guide as a resource to plan and implement an independent FluFOBT program.



WHY HAVE A FluFOBT PROGRAM?

(Information in this section is provided with permission by Michael Potter, MD, and FluFOBT.org.)

Some Reasons to Try!

1. Annual colorectal cancer screening tests are underused:

Colorectal cancer is the third leading cause of cancer death among both men and women in the United States, but most of these deaths could be prevented with routine screening. The least invasive, least expensive form of screening involves annual home stool tests, using either guaiac-based fecal occult blood tests (FOBT) or fecal immunochemical tests (FIT). If done yearly and with good follow up, FIT or FOBT can catch cancer early when it can often be treated successfully. Colorectal cancer screening programs that emphasize the use of FIT and FOBT as initial screening tests can be similarly effective to programs that emphasize more invasive tests, such as colonoscopy.

2. Annual flu shot activities are an opportunity to reach many people who need colorectal cancer screening:

Each fall, millions of Americans get flu shots. Many of these people are also at risk for colorectal cancer. Annual flu shot campaigns are an opportunity to reach this at-risk group with screening.

3. FOBT kits can be given to patients by flu shot clinic staff:

Many flu shot campaigns are run by nurses, pharmacists, or medical assistants. A prepared health care team can develop simple systems to provide a home FOBT or FIT kit to all eligible patients and in doing so can free up time for busy providers to address other pressing health concerns.

4. FluFOBT programs increase colorectal cancer screening rates:

FluFOBT programs have resulted in major improvement in colorectal cancer screening rates in a variety of clinical settings. The program can be implemented and sustained with limited resources. In addition, FOBT and FIT screening methods are well-accepted by patients and lead to higher screening rates.

5. FluFOBT programs can be a first step toward other innovative, preventive health and screening programs:

Success with FluFOBT programs can lead to other practice innovations. For example, once the health center has a successful FluFOBT program, they may decide to add other services to flu shot activities, such as mammogram or smoking-cessation referrals.

6. FluFOBT programs can help health centers meet important performance goals:

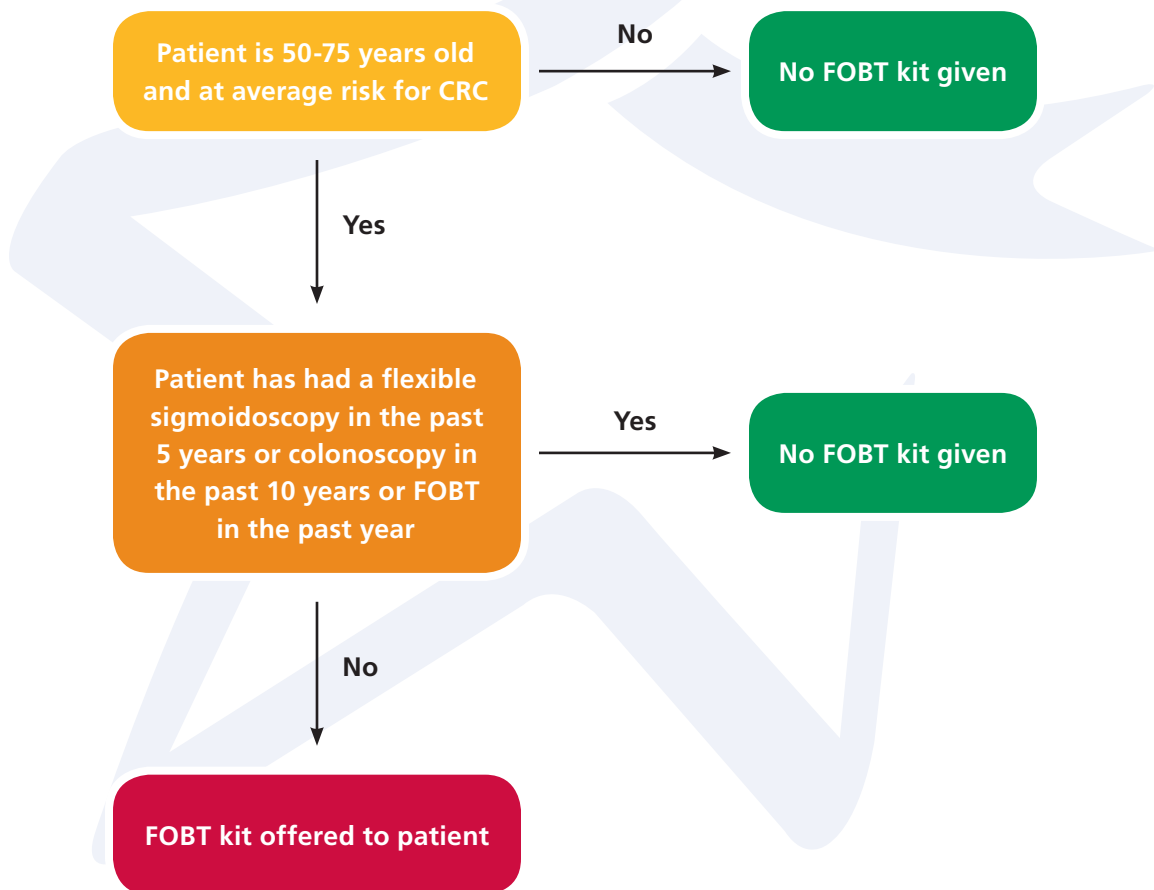
As of 2012, the Health Resources and Services Administration has added a colorectal cancer screening measure to the Clinical Quality Core Measure Set of performance measures annually tracked and reported by health centers. FluFOBT programs support the health center in meeting HRSA performance measures and Patient-Centered Medical Home standards.

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COLORECTAL CANCER SCREENING ELIGIBILITY

Clinics will give FOBT kits to all eligible average-risk patients coming in for their flu vaccine who are between 50 and 75 years of age and have not been screened for colorectal cancer via colonoscopy in the past 10 years or FOBT in the past year. If there is a positive FOBT test result, the patient will then need a colonoscopy as part of the post-screening diagnostic process. Patients over 75 should have a conversation with their doctor about whether colorectal cancer screening is appropriate before being offered a colorectal cancer screening test.

When to offer an FOBT kit:





COLORECTAL CANCER SCREENING RECOMMENDATIONS

The following is based on recommendations for colorectal cancer early detection from the American Cancer Society and the US Preventive Services Taskforce. More information can be found at cancer.org/colonmd.

American Cancer Society Recommendations

Average-risk patients 50 years of age and older should be routinely screened for colorectal cancer. There are several screening tests for colorectal cancer that when done at recommended intervals are effective at reducing colon cancer mortality, including:

- Colonoscopy every 10 years
- FOBT or FIT every year
- Flexible sigmoidoscopy every five years
- Double-contrast barium enema every five years
- CT colonography (virtual colonoscopy) every five years
- Stool DNA test

US Preventive Services Taskforce Recommendations

- Colonoscopy every 10 years
- FOBT or FIT every year
- Flexible sigmoidoscopy every five years, preferably with FOBT every three years



Quality Issues in Stool Testing

There is no evidence that stool samples obtained from asymptomatic patients on digital rectal examination can be used to detect colorectal cancer. Therefore, all FOBT (whether guaiac or immunochemical) should be performed on specimens collected at home, and according to manufacturers' test instructions.

If the results of an FOBT are positive (abnormal), a colonoscopy should be done. For more information on stool test quality issues, refer to Appendix C, page 23.

Average Risk vs. Increased Risk

The FluFOBT program is primarily an outreach program for average-risk patients. Health centers should develop both population-screening programs (such as FluFOBT) for average-risk patients AND tailored approaches to identify and refer increased-risk or high-risk patients.

For complete information on colorectal cancer screening recommendations, including guidelines for higher-risk patients, refer to Appendix B: American Cancer Society Guidelines on Screening and Surveillance for the Early Detection of Colorectal Adenomas and Cancer in People at Increased Risk or at High Risk on page 21.



PATIENT EDUCATION

(Information in this section is provided with permission by Michael Potter, MD, and FluFOBT.org.)

COLORECTAL CANCER AND FOBT: FACTS AND TALKING POINTS TO USE WITH PATIENTS

Facts about colorectal cancer and screening:

- Colorectal cancer is the third leading cause of cancer death among both men and women in the United States.
- More than 50,000 Americans die of colorectal cancer each year.
- Colorectal cancer is often preventable with screening.
- Early detection and treatment can save lives.
- Seven out of 10 people diagnosed with colorectal cancer have no symptoms.
- There are more than one million colorectal cancer survivors in the United States.
- Colorectal cancer screening is recommended for adults 50 years of age and older.

Facts about FOBT and FIT kits

- These tests work by detecting small, invisible amounts of blood that can come from colon polyps or early colorectal cancer.
- If done every year, they can help find polyps and cancers before they become life-threatening.
- Studies have shown that high-quality FOBT kits, if done correctly and with proper follow up, can be similarly effective to colonoscopy for most people to detect cancer.
- Stool should be collected at home and returned to the health center or mailed into the lab.
- If the FOBT results are abnormal, a colonoscopy should be performed.
- If your patients choose to get screened with FOBT, they need to do it every year, just like a flu shot.

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Talking Points for Use with Patients

- We have something extra to offer you today!
- It looks like you are due for a home colon test.
- Colon cancer screening can save lives.
- Just like a flu shot, all our doctors and nurses recommend home colon tests every year.
- It's easy – you can do it in the privacy of your home and bring it back or mail it in.

Reminders after Giving the Kit to Patients

- Put the kit in the bathroom so it will be there when you need to use it.
- Try to complete the kit in the next few days if possible.
- Write the collection dates on each completed kit.
- Mail the kit in or bring it to the health center as soon as possible after you finish collecting the stool.
- Call us if you have a problem with the kit.
- Talk to your doctor if you have any other questions about FOBT.



HOW TO SET UP YOUR FluFOBT PROGRAM

(Information in this section is provided with permission by Michael Potter, MD, and FluFOBT.org.)

Setting up a FluFOBT program is not hard, but it does require some careful planning and staff training before you start.

1. PUT YOUR FluFOBT TEAM TOGETHER.

Select a FluFOBT champion to coordinate your efforts.

This will usually be a nurse or other member of the medical team who works closely with the clinicians and the manager of your health center.

Select your FluFOBT team members and staffing levels.

FluFOBT team members can be nurses, medical assistants, or other health workers who enjoy working with patients and can be trained to provide flu shots and/or FOBT kits to patients. Also include staff members who can help track kit return rates and monitor project data.

Depending on your setup, you may have each team member carry out all aspects of the FluFOBT process with patients (e.g., give flu shots, assess FOBT eligibility, provide patient education, and distribute FOBT kits), or you may divide up the tasks.

To implement a FluFOBT program, you may need to adjust your staffing levels. If you have a high-volume clinical site, you may need to assign one or more additional persons above what you usually need for flu shot season to help assess patient eligibility and dispense FOBT kits.

Help your FluFOBT team to be successful.

To make sure that the program runs smoothly, start your planning process early, and involve your team members in the planning process.

Once you have settled on the details of your program and who will be involved, set a date for a final walkthrough and training session. This session should take place one or two weeks before the start of your program.

The walkthrough and training should include checking supplies and systems for assessing patient eligibility, and providing FOBT. Assign at least one experienced team member who knows all aspects of the program to be on hand each day to help supervise and offer guidance to team members who are less experienced. Develop a coverage system for lunch breaks and a backup plan to solve logistical challenges as they arise.

2. CHOOSE TIMES AND PLACES FOR FluFOBT, AND ADVERTISE THEM.

When to Start

The best time to start a FluFOBT program is when you usually begin dispensing flu shots. The first several days and weeks of flu shot activities can be busy, but this is also the time when you have the opportunity to reach the largest number of patients who may be due for colorectal cancer screening.

Where to Do It

You can do FluFOBT programs wherever you provide flu shots, but the approach used may differ depending on the nature of your venue, your available resources, and your relationships with your patients.

FluFOBT programs are easiest to implement within integrated health care settings. For example, you could have them in settings with immediate access to documentation about prior screening history and with systems to provide test results to primary care clinicians and to refer patients with abnormal tests to get follow up.

FluFOBT programs can be implemented during dedicated FluFOBT clinics or integrated within routine primary care office visits.

Advertise it.

The first step is to meet with the people who work within your organization, including clinicians, managers, and all of your staff members, and inform them that you are doing a FluFOBT program so they can be ready to support you and help you reach out to patients.

How you announce the program to your patients depends on your resources. You may choose to pass out flyers announcing the FluFOBT program dates, send postcards, provide an automated phone call announcement, or place information about the program on your Web site or in a health center newsletter.

Important information to give to patients can include the following:

- Dates and times of your program
- Who should come in for their flu shot
- Explain that patients between 50 and 75 years of age who come in for flu shots will be offered a home colorectal cancer screening kit if they are eligible.
- Provide a motivational message such as “Colon cancer screening can save lives!”



3. DESIGN PATIENT-FLOW AND LINE-MANAGEMENT PLAN

Offer FluFOBT before giving flu shot.

Planning patient-flow issues in advance will help your program run smoothly. In busy settings, there may be a FluFOBT line. When there is a line, the most efficient way to reach everyone who needs colorectal cancer screening is usually to provide FOBT before providing flu shots. Waiting until after giving flu shots to offer FOBT may be less efficient, since patients usually expect to leave immediately after getting their flu shot.

Assess eligibility for flu and FOBT.

Most experienced flu shot clinics already have established protocols for screening patients with allergies to egg or poultry products or other contraindications to flu shots.

Annual FOBT should be considered for all adults 50 to 75 years of age. Patients who have had a colonoscopy in the past 10 years will not need an annual FOBT.

Therefore, the goal is to offer FOBT to the following patients:

- Between 50 and 75 years of age
- No colonoscopy in the past 10 years
- No FOBT in the past year

For patients who are registered users of your health center, this information may be found in electronic health records or in a health maintenance log sheet in the patient's paper medical chart. Team members who are unfamiliar with where to find this information may need training from a physician or clinic manager.

When information about colorectal cancer screening is not available in the medical record, you can ask patients 50 to 75 years of age to tell you if they did a home stool test for colorectal cancer screening in the past year or a colonoscopy in the past 10 years, and offer FOBT to those who are due for screening based on their answers.

If there is no information in the medical record and patients are uncertain about when they had their last tests, you may still consider offering FOBT if it seems possible that they have not had testing in the recommended time intervals, or these patients can be referred to a clinician to clarify their screening status. Patients over 75 years of age should discuss their screening eligibility with their clinician.

One time-saving approach for clinics with electronic health records is to print out a list of registered patients who are due for FOBT at the beginning of the flu shot season, and use it as a reference to select appropriate patients for FOBT as they come in for their flu shots.



4. DEVELOP SYSTEMS TO SUPPORT FOLLOW UP OF DISPENSED FOBT KITS.

Consider ease of test completion when selecting an FOBT kit.

There are many FIT and FOBT kits on the market. When possible, select a kit that does not require the patient to restrict their diet or medication regimen for several days before they collect their specimen. It is easiest for patients to complete a test that they can take home and complete without special preparation or delay (see Appendix E, page 26).

Ideally, use kits that will be processed in a lab that can link results directly to the health center's electronic health record to facilitate project evaluation.

Provide clear instructions for completing and returning kits.

Most test kits come with manufacturers' recommended instructions, and they can be given to patients as part of the FOBT kit.

You may want to include additional instructions (such as multilingual instructions, simpler instructions for low-literacy patients, a special reminder to date the kit when completed, and/or a phone number to call if they have questions) if you believe this would be helpful.

Provide a return envelope for kits to be mailed back to your clinic or to the lab.

Most test kits come with return envelopes to allow the kits to be mailed back to your clinic for processing.

If patients will be allowed to mail kits back, providing envelopes with paid postage will increase your return rates on dispensed FOBT kits.

Consider reminder phone calls and/or postcards to encourage test completion by those who are given FOBT kits.

Typically, less than 50% of people who are given FOBT kits will return them without reminders. Providing reminders within two weeks of providing patients with a home FOBT kit can increase return rates.

Assist patients with abnormal FOBT results in getting a colonoscopy and additional treatment when needed.

Develop a system to get FOBT results to both the patient and their primary care physician.

Patients with normal FOBT results should receive the message that this is good news and that they should repeat the test in a year. Their primary care clinicians should also receive these results.



Patients with abnormal FOBT results should be called and told that they must have a colonoscopy to check for polyps or cancer. Primary care clinicians should also be alerted of abnormal FOBT results so they can participate as needed in arranging for a diagnostic colonoscopy for the patient.

Keep a log of patients with abnormal test results, and check it periodically to verify that everyone on the list has gotten needed follow up.

Consider what the treatment options are in your community to determine a path to treatment if necessary.

5. IMPLEMENT YOUR PROGRAM: FINAL PREPARATIONS

Gather your supplies well in advance.

Order flu shots and FOBT kits with return envelopes and/or stamps.

Written patient education materials, posters, and algorithms for your team are available for duplication in this implementation guide or downloadable from FluFOBT.org. Identify materials suitable for your patient population (language, reading level) in the weeks before beginning your FluFOBT program. If you have specific needs in this area, talk with your local American Cancer Society representative for assistance.

Two Weeks before FluFOBT Activities Start

Recheck to be sure you have all your supplies.

Do a walkthrough with your FluFOBT team.

Consider doing a role play with your FluFOBT team, checking your workflow and procedures for providing flu shots, colorectal cancer screening information, and FOBT kits.

First Day of Your FluFOBT Program

Whatever happens on the first day, don't give up – FluFOBT programs get easier with experience.

FluFOBT Checklist

(See Appendix F, page 27)

Congratulate yourselves for getting to this point!

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STAFF TRAINING FOR YOUR FluFOBT PROGRAM

(Information in this section is provided with permission by Michael Potter, MD, and FluFOBT.org.)

Setting up a FluFOBT program requires training for the staff that will be interacting directly with your patients. The training you provide will depend on the way you organize your program and the type of staff that are involved.

For example, if your health center is already experienced in providing FOBT kits to patients without a doctor's order, your team may not need very much training at all. However, if your team has never provided FOBT kits in the past, more training will be needed.

THE FIVE KEY ELEMENTS TO INCLUDE IN YOUR TRAINING:

1. Information about the importance of both flu shots and colorectal cancer screening

Your staff should know a few facts about flu shots and colorectal cancer screening:

Facts about flu and flu shots:

- Flu is often mild, but can be a very serious illness.
- The CDC estimates that between 3,000 and 49,000 Americans die of complications from the flu each year.
- Flu shots are one of the best tools to prevent people from getting the flu.
- Flu shots are safe when administered as directed.
- Flu shots do not cause the flu.
- Flu shots are recommended for everyone over 6 months of age.

More information about flu and flu shots can be found on the CDC's seasonal flu Web site at cdc.gov/flu/index.htm.



Facts about colorectal cancer and screening:

- Colorectal cancer is the third leading cause of cancer death among men and women in the United States.
- More than 50,000 Americans die of colorectal cancer each year.
- Early detection and treatment can save lives.
- There are more than 1 million colorectal cancer survivors in the United States.
- Colorectal cancer screening is recommended between 50 and 75 years of age.

More information about colorectal cancer and colorectal cancer screening can be found on the American Cancer Society Web site at cancer.org/colonmd.

2. Information about how to organize your workflow efficiently

- In most clinical settings, it is best to offer FOBT before the administration of flu shots.
- It is also important to give consideration to how your space is organized so that it will be comfortable for patients and staff.
- If you have a busy, high-volume setting, you will want to have someone dedicated to managing the flu shot line to keep things running smoothly.
- You may also want to set up a separate station for FOBT kits several feet in front of the station where flu shots are being offered.
- If you are providing the FluFOBT program during primary care visits, or in a lower-volume setting with limited space, you may want to provide FOBT kits and flu shots together at the same clinic station.
- Make sure to select all of your patient education materials in advance, and have your work stations well stocked with FOBT kits and flu shots so that your team is well-prepared.



3. Assess eligibility for flu shots and FOBT without waiting for a doctor's order.

The CDC has developed detailed free training programs for health professionals and clinic staff that provide flu shots. These can be accessed at cdc.gov/flu/index.htm.

Patients are eligible for colorectal cancer screening with FOBT if they are between 50 and 75 years of age and also have had:

- No FIT or FOBT in the past year
- No colonoscopy in the past 10 years
- No personal history of Crohn's disease or ulcerative colitis*
- No personal or family history of colorectal cancer or adenomatous polyps*

** Patients with these risk factors and those over 75 years of age should be referred to a clinician to discuss colorectal screening.*

All patients with an abnormal FOBT should be referred for colonoscopy to check for polyps or cancer.

Eligibility for FOBT may be determined by reviewing clinic charts or your electronic health record.

- One time-saving approach for clinics with electronic health records is to print out a list of patients who are due for FOBT at the beginning of the flu shot season, and use it as a quick reference to select appropriate patients for FOBT as they come in for their flu shots.
- When clinic charts or electronic health records are not available, the clinic staff can ask the patient about prior FOBT and colonoscopy procedures.
- As long as the patient is reasonably certain that they have not completed a recent FOBT kit and that they have not had a colonoscopy in the past 10 years, it is reasonable to offer an FOBT kit with their flu shot.



4. Talking to patients about FOBT and how to complete the test

Colorectal cancer screening is a serious topic, but patients are usually receptive to hearing about it, especially when the conversation is kept simple and light. What you say to patients will depend on how your FluFOBT program is set up and what type of kit you provide to patients.

- Effective points to make to patients may include phrases like this:
 - We have something extra to offer you today!
 - It looks like you are due for a home colon test.
 - Colon cancer screening can save lives.
 - Just like the flu shot, all our doctors and nurses recommend home colon tests.
 - It's very easy and you can do it in the privacy of your home and mail it in.
 - We'll make sure the results get to your doctor.
- Patients who accept the kit should be given additional written material and instructions.
- If the patient is unfamiliar with FOBT, it can be helpful to take a moment to show them the kit and offer simple instructions with a visual aid or a brief instructional video.

5. Information about how to record your work and provide follow up of FOBT kits provided to patients

For tracking purposes, you will want to keep a record of which patients were given FOBT (see Appendix H, page 32).

- This information can be recorded on a log sheet where flu shots are also recorded.
- This list can be useful to determine test return rates and to provide reminders to patients who have not yet returned their kits.
- The log sheet can also be used to gather information to track and arrange follow up of abnormal test results.



SUMMARY

Although often a preventable disease, colorectal cancer (CRC) is the third leading cause of cancer deaths among men and women in the United States.⁵ In addition, while unpredictable, flu-associated deaths in the US range from 3,000 to 49,000 people per year.⁵ Screening for CRC and vaccination for flu both help reduce the incidence of these conditions. Research has demonstrated that a FluFOBT program is an efficient and effective way to increase colorectal cancer screening that can improve screening rates in a variety of settings.^{1,2,4} FluFOBT programs reach many patients who may otherwise not have an opportunity to receive screening.

This implementation guide will assist your health center in setting up and implementing your FluFOBT program easily and successfully. If you have any questions or concerns about the program, please refer to FluFOBT.org or contact your local American Cancer Society representative.

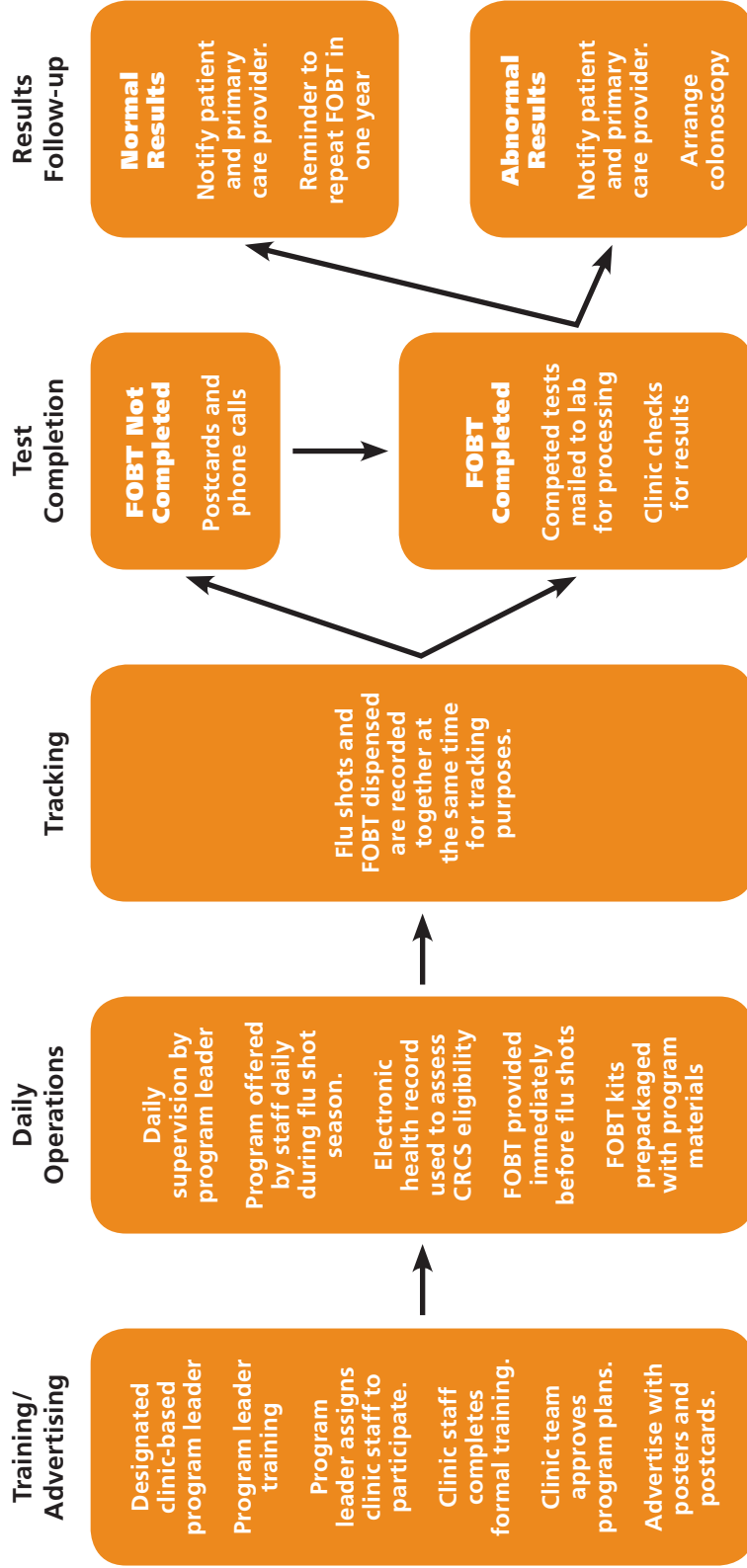
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APPENDIX A: FluFOBT Components and Logic Model

GOAL: Increase CRC screening rates by offering home FOBT to eligible patients during annual flu shot activities.

CORE FUNCTIONAL COMPONENT: Standing orders for clinic staff to offer flu shots and FOBT together for patients aged 50-75 seen during flu shot season

TARGET CLINICAL SETTINGS AND POPULATIONS: Community health centers where flu shots are provided and where FOBT is the primary test for average risk CRCs



Program Materials

- Pre-addressed mailing pouches
- Pre-stamped mailing pouches
- FOBT tracking and follow-up log sheets
- Mailed FluFOBT program announcements
- FluFOBT program clinic posters
- Multilingual materials explaining the importance of FOBT

- Patient-flow algorithm
- Patient-eligibility algorithm
- Script to explain FOBT to patients during flu shot visits
- Visual aids to explain FOBT
- Multilingual clinic video to explain FOBT
- Multilingual patient instructions on FOBT completion

APPENDIX B:

Colorectal Cancer Screening Recommendations for People at Increased or High Risk

Individuals at increased or high risk of colorectal cancer should begin colorectal cancer screening before age 50 or be screened more often. The following conditions make the risk higher than average:

- A personal history of colorectal cancer or adenomatous polyps
- A personal history of inflammatory bowel disease (ulcerative colitis or Crohn’s disease)
- A strong family history of colorectal cancer or polyps
- A known family history of a hereditary colorectal cancer syndrome such as familial adenomatous polyposis (FAP) or hereditary non-polyposis colon cancer (HNPCC)

The table below suggests screening guidelines for those with *increased or high risk* of colorectal cancer based on specific risk factors. Some people may have more than one risk factor.

American Cancer Society Guidelines on Screening and Surveillance for the Early Detection of Colorectal Adenomas and Cancer in People at Increased Risk or at High Risk			
INCREASED RISK – Patients With a History of Polyps on Prior Colonoscopy			
Risk Category	Age to Begin	Recommended Test(s)	Comment
People with small rectal hyperplastic polyps	Same as those at average risk	Colonoscopy, or other screening options at same intervals as for those at average risk	Those with hyperplastic polyposis syndrome are at increased risk for adenomatous polyps and cancer and should have more intensive follow up.
People with 1 or 2 small (less than 1 cm) tubular adenomas with low-grade dysplasia	5 to 10 years after the polyps are removed	Colonoscopy	Time between tests should be based on other factors such as prior colonoscopy findings, family history, and patient and doctor preferences.
People with 3 to 10 adenomas, or a large (1 cm +) adenoma, or any adenomas with high-grade dysplasia or villous features	3 years after the polyps are removed	Colonoscopy	Adenomas must have been completely removed. If colonoscopy is normal or shows only 1 or 2 small tubular adenomas with low-grade dysplasia, future colonoscopies can be done every 5 years.
People with more than 10 adenomas on a single exam	Within 3 years after the polyps are removed	Colonoscopy	Doctor should consider possibility of genetic syndrome (such as FAP or HNPCC).
People with sessile adenomas that are removed in pieces	2 to 6 months after adenoma removal	Colonoscopy	If entire adenoma has been removed, further testing should be based on doctor’s judgment.

American Cancer Society Guidelines on Screening and Surveillance for the Early Detection of Colorectal Adenomas and Cancer in People at Increased Risk or at High Risk - Continued

INCREASED RISK – Patients With Colorectal Cancer

Risk Category	Age to Begin	Recommended Test(s)	Comment
People diagnosed with colon or rectal cancer	At time of colorectal surgery, or can be 3 to 6 months later if person doesn't have cancer spread that can't be removed	Colonoscopy to view entire colon and remove all polyps	If the tumor presses on the colon/rectum and prevents colonoscopy, CT colonoscopy (with IV contrast) or DCBE may be done to look at the rest of the colon.
People who have had colon or rectal cancer removed by surgery	Within 1 year after cancer resection (or 1 year after colonoscopy to make sure the rest of the colon/rectum was clear)	Colonoscopy	If normal, repeat exam in 3 years. If normal then, repeat exam every 5 years. Time between tests may be shorter if polyps are found or there is reason to suspect HNPCC. After low anterior resection for rectal cancer, exams of the rectum may be done every 3 to 6 months for the first 2 to 3 years to look for signs of recurrence.
Colorectal cancer or adenomatous polyps in any first-degree relative before age 60, or in 2 or more first-degree relatives at any age (if not a hereditary syndrome)	Age 40, or 10 years before the youngest case in the immediate family, whichever is earlier	Colonoscopy	Every 5 years
Colorectal cancer or adenomatous polyps in any first-degree relative age 60 or older, or in at least 2 second-degree relatives at any age	Age 40	Same options as for those at average risk.	Same intervals as for those at average risk.

HIGH RISK

Risk Category	Age to Begin	Recommended Test(s)	Comment
Familial adenomatous polyposis (FAP) diagnosed by genetic testing, or suspected FAP without genetic testing	Age 10 to 12	Yearly flexible sigmoidoscopy to look for signs of FAP; counseling to consider genetic testing if it hasn't been done	If genetic test is positive, removal of colon (colectomy) should be considered.
Hereditary non-polyposis colon cancer (HNPCC), or at increased risk of HNPCC based on family history without genetic testing	Age 20 to 25 years, or 10 years before the youngest case in the immediate family	Colonoscopy every 1 to 2 years; counseling to consider genetic testing if it hasn't been done	Genetic testing should be offered to first-degree relatives of people found to have HNPCC mutations by genetic tests. It should also be offered if 1 of the first 3 of the modified Bethesda criteria is met. ¹
Inflammatory bowel disease: - Chronic ulcerative colitis - Crohn's disease	Cancer risk begins to be significant 8 years after the onset of pancolitis (involvement of entire large intestine), or 12-15 years after the onset of left-sided colitis.	Colonoscopy every 1 to 2 years with biopsies for dysplasia	These people are best referred to a center with experience in the surveillance and management of inflammatory bowel disease.

APPENDIX C:

Clinician’s Reference: Fecal Occult Blood Testing (FOBT) for Colorectal Cancer Screening

CLINICIAN’S REFERENCE: FECAL OCCULT BLOOD TESTING (FOBT) FOR COLORECTAL CANCER SCREENING

Guidelines from the American Cancer Society, the US Preventive Services Taskforce, and others recommend high-sensitivity fecal occult blood tests (FOBT) as one option for colorectal cancer screening. This document provides state-of-the-science information about guaiac-based FOBT and fecal immunochemical tests (FIT).

- ★ Colorectal cancer screening with FOBT has been shown to decrease both incidence and mortality in randomized controlled trials.
- ★ High-sensitivity FOBT detects colorectal cancer at relatively high rates.
- ★ Modeling studies suggest that the years of life saved through a high-quality FOBT screening program are essentially the same as with a high-quality colonoscopy-based screening program.
- ★ Access to colonoscopy and other invasive tests may be limited or non-existent for many patients. In addition, some adults prefer less invasive tests.

All of these elements make FOBT a reasonable choice for patients.

Recent advances in stool blood screening include the emergence of new tests and improved understanding of the impact of quality factors on testing outcomes.

Two main types of FOBT are available – guaiac-based FOBT and FIT

Guaiac-based FOBTs have been the most common form of stool tests used in the US. Modern high-sensitivity forms of the guaiac test (such as Hemoccult Sensa) have much higher cancer and adenoma detection rates* than older tests (Hemoccult II and others).

Guaiac-based FOBT version	Sensitivity for cancer	Sensitivity for adenomas
Hemoccult Sensa (high-sensitivity)	50% – 79%	21% – 35%
Hemoccult II	13% – 50%	8% – 20%

These differences are so significant that screening guidelines now specify that only high-sensitivity forms of guaiac-based tests (like Hemoccult Sensa) should be used for colorectal cancer screening. Hemoccult II and similar older guaiac tests should no longer be used for colorectal cancer screening.

FITs also look for hidden blood in the stool, but these tests are specific for human blood and guaiac tests are not. There are many brands of FIT sold in the US, and there is no consensus that one brand is superior to another. There is evidence that patient adherence with FIT may be higher than with guaiac FOBT; this may be a result of preparation needed by patients (no dietary and medication restrictions, only 1 or 2 specimens required with some brands).

FIT and guaiac-based FOBT	Sensitivity for cancer	Sensitivity for adenomas
Immunochemical tests (FIT)	55% – 100%	15% – 44%
High-sensitivity guaiac-based FOBT (Hemoccult Sensa)	50% – 79%	21% – 35%

When done correctly FIT and high-sensitivity guaiac-based FOBT have similar performance*; both are significantly better than Hemoccult II and similar older tests.

*Sensitivities cited are based on review of studies that used colonoscopy as the reference standard to determine FOBT performance characteristics.



CLINICIAN'S REFERENCE: FECAL OCCULT BLOOD TESTING (FOBT) FOR COLORECTAL CANCER SCREENING

The American Cancer Society, the US Preventive Services Taskforce, and other organizations endorse the use of either a high-sensitivity guaiac-based fecal occult blood test (FOBT) or a fecal immunochemical test (FIT) for screening, within the context of a high-quality stool-based screening

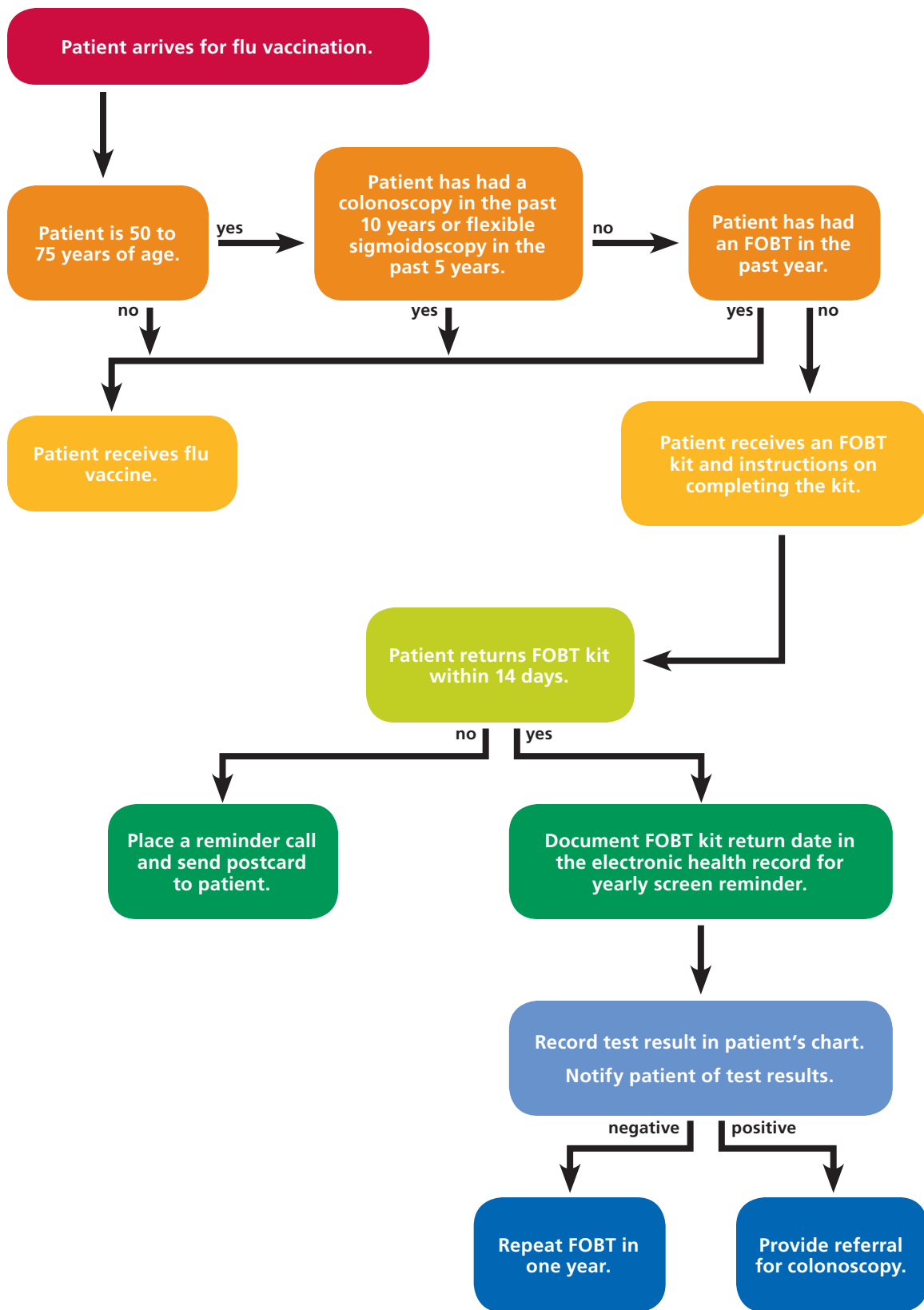
Characteristics of high-quality stool-based screening programs

<i>High-quality programs</i>	<i>Rationale</i>
Use only high-sensitivity guaiac-based FOBTs (such as Hemoccult Sensa) or fecal immunochemical tests (FIT).	Sensitivity for cancer is 2-3 times higher with FIT or high-sensitivity guaiac tests when compared to older stool guaiac tests (such as Hemoccult II) in most studies.
Eliminate the use of Hemoccult II and other older forms of guaiac-based FOBT.	Sensitivity for cancer is less than 25% in many studies of Hemoccult II (compared to sensitivity of >50% for FIT and highly sensitive guaiac-based tests)
Never use in-office FOBT at the time of digital rectal exam as a screening test for colorectal cancer.	Studies have shown that a guaiac FOBT obtained on a single stool sample obtained at the time of in-office digital rectal exam may miss up to 95% of cancers and significant adenomas. There is no evidence that this would be an appropriate method for collection of stool for FIT either.
Perform tests only on stool specimens collected by patients at their home; the number of specimens to be collected and the collection process should follow manufacturers' recommendations.	Studies that demonstrated decreases in incidence and mortality with FOBT screening utilized home collection and analysis of specimens based on manufacturers' instructions.
Repeat stool tests annually.	One-time FIT or highly sensitive guaiac tests may miss up to 50% of cancers (and a higher proportion of adenomas). Annual testing significantly improves lesion detection over time.
Follow up all patients who have a positive stool test with colonoscopy.	Stool-based screening results in decreased incidence and mortality only when screen-detected abnormalities are assessed and managed appropriately.

For additional information, please visit ncrt.org/about/provider-education/crc-clinician-guide/ and cancer.org/colonmd.



APPENDIX D: FluFOBT Flow Chart



APPENDIX E: FIT and FOBT Brands

The American Cancer Society and the National Colorectal Cancer Roundtable do not endorse any FIT or FOBT brand or product. However, we do encourage use of high-sensitivity tests to detect blood in the stool, per consensus guidelines. There are a number of FOBT and FIT brands available. For your convenience, we are listing Web sites for a few brands that are widely used in the United States. All of the brands listed are effective, but they differ somewhat in how they must be handled and processed. The Web sites listed all include information for health professionals and instructions for patients. For specific questions about individual tests, we recommend that you contact the manufacturers directly.

Inclusion on this list does not imply endorsement by the American Cancer Society.

- **Hemoccult Sensa (Beckman Coulter):** This is a high-sensitivity guaiac FOBT kit that requires samples from three consecutive bowel movements collected after 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 before it comes into contact with the toilet water. It is manually developed either in your clinic or in your clinic laboratory.

· https://www.beckmancoulter.com/wsrportal/wsrportal.portal?_nfpb=true&_windowLabel=UCM_RENDERER&_urlType=render&wlpUCM_RENDERER_path=%2Fwsr%2Fdiagnostics%2Fclinical-products%2Frapid-diagnostics%2Fhemoccult-sensa%2Findex.htm

- **Hemoccult ICT (Beckman Coulter):** This is a FIT kit that usually requires two stool samples and does not require any dietary or 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 before it comes into contact with the toilet water. It is manually developed either in your clinic or clinic laboratory.

· <https://www.beckmancoulter.com/wsrportal/wsr/diagnostics/clinical-products/rapiddiagnostics/hemoccult-ict/index.htm>

- **InSure FIT (Quest Laboratories):** This test requires two stool samples and does not require any dietary or medication restrictions. It uses a collection method that involves the use of two long brushes to simplify stool collection. The brush is used to collect a sample of stool and toilet water, which is then placed on a collection card. The InSure test kits come in versions that can be sent to a commercial laboratory for automated development or that can be developed on site by in your clinic or clinic laboratory.

· <http://www.insuretest.com/index.php>

- **OC FIT-Check (Polymedco):** This test can be provided as a one- or two-sample kit. The collection method involves poking the stool with a probe and placing the collection probe into a small tube, which is mailed into the laboratory. The stool is probed before it comes into contact with the toilet water. The OC FIT-Check test kits come in versions that can be sent to a hospital laboratory for automated development or that can be developed on site in your clinic or clinic laboratory.

· <http://www.polymedco.com/>

APPENDIX F:

Checklist for Running a FluFOBT Program

Assemble your team and involve everyone in the planning process.

Designate a champion/coordinator.

Select team members.

- Clinicians
- Medical assistants
- Nurses
- Health workers who can be trained to provide flu shots and FOBT kits

Plan specific roles and tasks for each member of the team.

Plan and implement your program.

Staff Training

- Educate staff on facts regarding flu shots and CRC screening.
- Help familiarize them with the procedure of completing the FOBT kit that they will distribute to patients.
- Make sure they are comfortable with explaining the procedure of completing the FOBT kit to patients.
- Organize and practice the workflow until it runs smoothly.
- Help familiarize staff with eligibility and tracking practices.

Patient Flow

- Decide which staff will work with “flu shot only” patients and “FluFOBT” patients.
- Determine how patients will be guided to the “flu shot only” versus the “FluFOBT” areas.
- Provide the FOBT kits before providing flu shots.

Assessing Eligibility

- Have eligibility algorithm posted.
- Develop a system for easy access to patient records/electronic health record
- Consider offering FOBT if it seems possible that the patient may not have received screening in the recommended intervals.

Designate dates, times, and locations.

Advertise, advertise, advertise.

Develop systems to support tracking and follow up.

Develop log sheets.

Develop tracking sheets for normal and abnormal FOBT

- Enter positive or normal result
- Notify patient and doctor whether positive or normal
- If normal, remind them to come in again next year

Finish preparations for your FluFOBT program.

- Gather an ample supply of flu shots and FOBT kits with return envelopes/stamps.
- Gather ample patient education materials/directions for FOBT.

Don't forget reminder calls and/or postcards to patients to return their FOBT kits.

APPENDIX G:

Action Plan Guideline

Overview Action Plan Guideline for FluFOBT Program Activities

(See Checklist for Running a FluFOBT program, Appendix F, page 27.)

Action Item	Staff Responsible	Date to Be Completed	Notes	Complete
Identify clinic staff lead.				
Identify staff who will provide patient information, assess patient pilot project eligibility, and distribute FOBT/FIT kits.				
Identify staff responsible for tracking kit returns, processing and reporting results.				
Identify staff responsible for a reminder system for kits that are not returned (calls, postcards).				
Plan for staff training (dates and impact on schedules).				
Plan for clinician/provider training (dates and impact on schedules).				
Purchase flu vaccines.				
Purchase FOBT/FIT kits. <ul style="list-style-type: none"> Identify the FOBT/FIT test brand that will be used. 				
Identify/prepare/print/order patient education materials: <ul style="list-style-type: none"> Prepare pilot project patient talking points utilizing the materials found on FluFOBT.org. Prepare educational materials: (1) hardcopy handouts in needed languages and (2) verbal scripts. Consider reading levels of materials. Make sure that test kit manufacturer's instructions are culturally and reading-level appropriate for your patient population, or prepare a written explanation for patients of how to complete and return the test kit and when to return the kit, in all needed languages (request assistance from Society if needed). Create or adapt existing reminder postcard in needed languages. Prepare a script for the follow-up phone call. 				

Action Item	Staff Responsible	Date to Be Completed	Notes	Complete
<p>Identify/print/order promotional materials for use in the clinic setting (refer to FluFOBT.org Web site):</p> <ul style="list-style-type: none"> • Create or adapt posters/clinic materials in needed languages. • Identify where materials will be posted. • Decide if additional venues for FluFOBT promotion, outside of the clinic setting, are needed. 				
<p>Prepare protocol for determining patient eligibility for the pilot project:</p> <ul style="list-style-type: none"> • Define tools to be used by staff for patient-risk assessment (average risk vs. high risk). • Utilize patient eligibility algorithm. (Society resource) 				
<p>Develop clinic flow plan for implementing FluFOBT:</p> <ul style="list-style-type: none"> • Select an FOBT/FIT kit storage area easily accessible when flu vaccinations are given. • Decide if project log sheets (flu vaccination, FOBT/FIT kit distribution, and tracking form) will be kept in hard copies or through EHRs. • Identify staff person(s) who will collect and document program data. • Determine if alert should be placed in EHR to signify pilot participant. • Outline your process to assure closing the “testing/results loop” (test order entered; patient returns completed kits to the clinic; clinic sends to lab; lab returns results to the clinic; patient is informed of results); consider patients in for flu shot only vs. other reasons who also (by the way) want a flu shot and are eligible for FOBT kit. 				
<p>Create a process for tracking kit returns, processing and reporting results:</p> <ul style="list-style-type: none"> • Decide how follow up will be documented in the EHR. • Describe how patient will be informed of results. • For patients with positive results, develop a follow-up plan for referral to diagnostic follow up (colonoscopy). 				

Action Item	Staff Responsible	Date to Be Completed	Notes	Complete
<p>Create a process for tracking kit returns, processing and reporting results:</p> <ul style="list-style-type: none"> • Decide how follow up will be documented in the EHR. • Describe how patient will be informed of results. • For patients with positive results, develop a follow-up plan for referral to diagnostic follow up (colonoscopy). 				
<p>Create a reminder system process for patients who do not return kits:</p> <ul style="list-style-type: none"> • Verify patient's mailing address and phone number. • Consider asking patients to self-address a HIPPA-compliant fold-over postcard reminder that can be mailed to them if their kit is not returned within 2 weeks. • Review log sheets weekly to ensure patients are returning test kits within 2 weeks after receiving a kit. • Send a postcard or call the patient if kit is not returned within the 2-week time frame. 				
<p>Determine process for collecting input from frontline clinic staff and patients on what is working and not working with regard to program implementation and follow up:</p> <ul style="list-style-type: none"> • Modify processes as needed based on staff and patient input. 				
<p>Schedule regular meetings with Society staff for updates and technical assistance once flu vaccination season begins:</p> <ul style="list-style-type: none"> • Hold a conference call or brief meeting after the first full week of FluFOBT implementation to assess needs or any process changes. • Determine how frequently the staff lead would like to hold conference calls and/or have site visits. 				
<p>Report interim data (includes baseline) to the Society.</p>				
<p>Submit final report/data to the Society.</p>				<p>On or before 2/15/14</p>

APPENDIX H:

FluFOBT Tracking Tool

Telephone Script

Hello. This is <Member Name> calling from <Health Center Name>.


Our records indicate you have received a stool test kit, called an FOBT kit, that has not yet been returned. Please complete your FOBT kit and mail it back to us.

An FOBT kit screens for evidence of blood in your stool, which is an early detector for colon cancer. Finding colon cancer early is key to saving lives.


If you would like another FOBT kit mailed to you, please press one now.

APPENDIX I: Advertising

Sample patient education poster (visit FluFOBT.Org for current materials)



Flu and Colon Cancer Can Often Be Prevented!

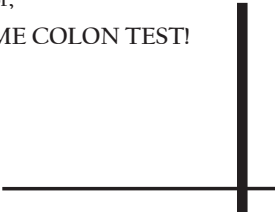


- ◆ Just like the FLU,
COLON CANCER can often be PREVENTED, and also TREATABLE and BEATABLE when found EARLY!

- ◆ Colon screening is recommended for healthy men and women aged 50 to 75.
- ◆ One recommended colon screening test is a yearly test that can be done at home.
- ◆ Other recommended colon tests include:
Colonoscopy every 10 years or Flexible Sigmoidoscopy every 5 years

- ◆ YEARLY HOME STOOL TESTS ARE EASY TO DO!
- ◆ YEARLY HOME STOOL TESTS COULD SAVE YOUR LIFE!

- ◆ If you are due for colon screening today and have a regular doctor,
WE WOULD LIKE TO OFFER YOU A FREE HOME COLON TEST!



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