



American Cancer Society FluFIT Implementation Guide



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Introduction

The American Cancer Society FluFIT program (the Program) is intended to assist primary care clinics and other health care settings in increasing colorectal cancer (CRC) screening. It has been demonstrated in the medical literature that offering and providing take-home fecal occult blood tests and fecal immunochemical tests (gFOBTs and FITs) to patients at the time of their annual flu shot increases CRC screening rates.^{1,2,3}

Colorectal cancer (CRC) is the second-leading cause of cancer death when men and women are combined in the United States.⁴ An estimated 135,430 cases of colon and rectal cancer are expected to occur in 2017, with an estimated 50,260 deaths.⁴

In 2015, 63% of adults 50 years of age and older reported use of either a stool-based CRC screening test (FOBT) or an endoscopy test within recommended screening intervals.⁵ However, CRC screening rates remain substantially lower in uninsured individuals and those with lower socioeconomic status.

What is 80% by 2018?

The 80% by 2018 colorectal cancer screening initiative is a nationwide movement in which more than 1,500 organizations have committed to reducing colorectal cancer as a major public health problem. The goal of the initiative, which is led by the American Cancer Society, the Centers for Disease Control and Prevention, and the National Colorectal Cancer Roundtable, is to have 80% of adults ages 50 and older screened for colorectal cancer by 2018.

Increasing CRC screening rates to 80% by 2018 would reduce CRC incidence rates by 17% and mortality rates by 19% during short-term follow-up and by 22% and 33%, respectively, during extended follow-up. These reductions would amount to a total of 277,000 averted new cancers and 203,000 averted CRC deaths from 2013 through 2030.⁶

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

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

Visit [Steps for Increasing Colorectal Cancer Screening Rates: A Manual for Community Health Centers](#) for more information on best practices, templates, and tools for increasing CRC screening in community health centers.

Background Information and Education

FluFIT Background

A guaiac-based fecal occult blood test (gFOBT) or fecal immunochemical tests (FIT) is a stool-based colorectal cancer screening test for average-risk patients 50 years of age and older that must be done annually to be effective.⁴ There are two types of stool tests currently used for colorectal cancer screening, the guaiac-based FOBT (gFOBT) and the fecal immunochemical test (FIT). Either a high-sensitivity guaiac-based FOBT or a FIT is appropriate for the Program, which has come to be known simply as the FluFIT Program.

Colorectal cancer or adenomatous polyps often result in small amounts of blood in the stool. This blood is usually not visible to the naked eye (therefore described as “occult” or hidden). Stool tests, such as gFOBT and FIT, detect these trace amounts of blood. The patient completes the

gFOBT/FIT test by collecting a 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. If the test indicates that blood is present, a colonoscopy is needed to determine the source of the bleeding. **It is imperative that every patient with a positive gFOBT/FIT result gets a colonoscopy to determine the source of the positive finding and to rule out cancer.**

The FluFIT Program is an innovative and effective way to increase colorectal cancer screening in primary care settings. When men and women come in for their annual flu shot, health center staff provide either a take-home gFOBT kit or FIT kit to those who are also due for colorectal cancer screening. The Program is a population-based intervention that has been shown to increase screening rates in a variety of clinical settings.^{1,7}

Why Have a FluFIT Program?

In a 2013 FluFOBT pilot study in 5 federally qualified health centers, four of the five clinics experienced an increase in the clinic’s colorectal cancer screening rate in the pilot year. Clinic staff felt that implementing the FluFOBT program resulted in greater awareness of the importance of CRC screening among all staff as well as patients. Changes in annual screening rates between 2012 and 2013 ranged from a 4% increase, to about a 9% increase. The return rate for the FOBT kits ranged from 33% to 83% across the five pilot sites, with an average return rate across sites of 54%. The percentage of patients receiving reminders to return their kits ranged from 35% to 100%.

Some Reasons to Try!

- 1. Colorectal cancer screening tests are underused:** Colorectal cancer is the second-leading cause of cancer death when men and women are combined in the States,⁴ 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 (gFOBT) or fecal immunochemical tests (FIT). If done yearly and with appropriate follow-up, high-sensitivity FIT or gFOBT can help find some polyps (which, when removed, can prevent cancer), or catch cancer early when it can often be treated successfully. Modeling studies have found that high-quality colorectal cancer screening programs that emphasize the use of high-sensitivity FIT and gFOBT as initial screening tests can be similarly effective at helping save lives as 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. FIT or gFOBT 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 gFOBT or FIT kit to all eligible patients and in doing so can free up time for busy clinicians to address other pressing health concerns.
- 4. FluFIT programs increase colorectal cancer screening rates:** FluFIT programs have resulted in major improvements in colorectal cancer screening rates in a variety of clinical settings. The programs can be implemented and sustained with limited resources. In addition, gFOBT and FIT screening methods are well-accepted by patients and lead to higher screening rates.
- 5. FluFIT programs can be a first step toward other innovative, preventive health and screening programs:** Success with FluFIT programs can lead to other practice innovations. For example, once the health center has a successful FluFIT program, they may decide to add other services to flu shot activities, such as mammogram or smoking cessation referrals.
- 6. FluFIT programs support improvement efforts to meet important performance goals:** Colorectal cancer screening performance measures are often included in quality reporting programs. These include the new CMS Merit-based Incentive Payment program (MIPS), some state Medicaid quality programs, Healthcare Effectiveness Data and Information Set (HEDIS), and the Uniform Data System (UDS), which are reported annually by community health centers to HRSA. FluFIT programs can help increase CRC screening rates and support meeting quality improvement goals.

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 Task Force (USPSTF). Visit cancer.org/colonmd for more information.

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, which when done at recommended intervals are effective at reducing colorectal cancer mortality, including:

- Guaiac-based fecal occult blood test (gFOBT) or fecal immunochemical test (FIT) with high test sensitivity to cancer every year*
- Colonoscopy every 10 years
- FIT-DNA test with high sensitivity to cancer, every 3 years based on manufacturer's recommendation
- Flexible sigmoidoscopy every 5 years*
- Double-contrast barium enema every 5 years*
- CT colonography (virtual colonoscopy) every 5 years*

*Highly sensitive versions of stool-based tests should be used, with testing performed on a specimen collected at home per manufacturer recommendations. A gFOBT or FIT done during a digital rectal exam in the doctor's office is not adequate for CRC screening. If any of these tests are positive, the patient should have a colonoscopy to complete the screening process. **If the patient does not get a colonoscopy after having a positive stool test, they have not completed the screening process. A colonoscopy is needed to find out why they had a positive test.**

US Preventive Services Task Force Recommendations

The USPSTF recommends screening for colorectal cancer beginning at 50 years of age and continuing until 75 years of age.

- gFOBT or FIT every year
- Colonoscopy every 10 years
- FIT-DNA every 3 years per manufacturer instructions
- CT colonography every 5 years
- Flexible sigmoidoscopy every 5 years, or option of flexible sigmoidoscopy every 10 years, plus FIT every year





Quality Issues in Stool Testing

There is no evidence that stool samples obtained from asymptomatic patients on digital rectal examination can be used to reliably detect colorectal cancer, and neither the American Cancer Society nor the USPSTF guidelines endorse this form of testing. Therefore, all gFOBT or FIT should be performed on specimens collected at home and according to manufacturers' test instructions.

If the result of a gFOBT or FIT is positive, a colonoscopy should be done.

The Program is primarily an outreach service for average-risk patients. Health centers should develop both population screening programs (such as FluFIT) 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: Colorectal Cancer Screening Recommendations for People at Increased or High Risk, page 21.

The American Cancer Society does not endorse any FIT or gFOBT brand or product.

There are many high-sensitivity FIT brands and one highly sensitive gFOBT available. For your convenience, the following table lists FIT and gFOBT available in the US, with published evidence regarding sensitivity and specificity for cancer detection. For more information on stool test quality issues and data on documented test performance and more detailed information about various FIT and gFOBT brands, see the [Clinician's Reference: Stool-based Tests for Colorectal Cancer Screening](#). All of the brands listed have evidence of effectiveness, but differ in how they must be handled and processed. The manufacturers' websites for these tests include information for health professionals and instructions for patients. For specific questions about individual tests, visit the manufacturers' websites or contact them directly. Hemoccult II and generic low-sensitivity stool tests are no longer recommended for CRC screening.

Choosing a Stool Test ^{9,10,11,12,13}

Fecal immunochemical tests (FITs) look for hidden blood in the stool and are specific for human blood while older guaiac-based tests are not. FIT results are not impacted by food or medication. It is important to note that not all FITs

are equally effective. As of July 2016, there are 26 FDA-cleared FITs available for purchase in the US. However, most do not have published data on their performance for detection of CRC.

The following table includes FITs that are available for purchase in the US and have published performance data:

Fecal Immunochemical Tests (FIT)		
Brand Name	Manufacturer	Number of stool samples required
OC-Auto FIT * and OC-Light S FIT	Polymedco	1
Quick-View iFOB	Quidel	1
Hemosure One-Step iFOB Test	Hemosure, Inc.	1 or 2
InSure	Clinical Genomics	2
Hemoccult ICT	Beckman Coulter	2 or 3

*Used with OC-Sensor DIANA and OC-Auto Micro 80 automated analyzers

Guaiac-based FOBTs are the most common form of stool tests used in the US. Modern high-sensitivity forms of the guaiac test have much higher cancer and adenoma detection rates than older tests, resulting in fewer missed cancers. Screening guidelines now specify that only high-sensitivity forms of guaiac-based tests (like

Hemoccult II SENSAs) should be used for colorectal cancer screening. Hemoccult II and similar older guaiac tests should not be used for colorectal cancer screening. Hemoccult II SENSAs is the only high-sensitivity guaiac-based FOBT available for purchase in the US for which published performance data are available.

Guaiac-Based FOBT (gFOBT)		
Brand Name	Manufacturer	Number of stool samples required
Hemoccult II SENSAs	Beckman Coulter	3

FIT-DNA is a stool test that looks for mutations associated with cancer and adenomas that are sometimes found in colon and rectal cells excreted in the stool. Cologuard is the only stool DNA test currently marketed in the US that combines testing for DNA markers with a high-quality FIT (thus the designation “FIT-DNA”). FIT-DNA is not likely to be

commonly used as part of FluFIT programs because it is recommended for use only once every three years, and it may require additional workflows beyond those described in this guide. It is mentioned here because it is included in current evidence-based screening recommendations.

FIT-DNA		
FIT-DNA Brand Name	Manufacturer	Number of stool samples required
Cologuard	Exact Sciences	1*

*Requires collection of an entire bowel movement

For more information about choosing a stool test, including current evidence on sensitivity and specificity for various tests, see the [Clinician’s Reference: Stool-based Tests for Colorectal Cancer Screening](#).

Colorectal Cancer Performance Measures

FluFIT programs can help support ongoing quality-improvement efforts in your setting, as well as meeting requirements for patient-centered medical home recognition and other quality-reporting programs. For example, community health centers annually report CRC screening rates as part of the Health Resources and Services Administration's (HRSA) Uniform Data System (UDS), and CRC screening is also part of the measure set for the CMS Quality Payment Program (QPP). Commercial health plans may also monitor CRC screening rates through the Healthcare Effectiveness Data and Information Set (HEDIS). Current quality measures are consistent with evidence-based recommendations such as described in the following copy.

[Colorectal Cancer Screening Performance Measure \(CMS 130v6\)](#): Percentage of adults 50-75 years of age who had appropriate screening for colorectal cancer defined by any one of the following criteria:

- Guaiac-based fecal occult blood test (gFOBT) or FIT during the measurement period
- Flexible sigmoidoscopy during the measurement period or the four years prior to the measurement period
- Colonoscopy during the measurement period or the nine years prior to the measurement period
- FIT-DNA during the measurement period or the two years prior to the measurement period
- CT colonography during the measurement period or the four years prior to the measurement period

New Resources

Follow-up for Positive gFOBT/FIT:

[Paying for Colorectal Cancer Screening Patient Navigation Toolkit](#)

[CDC Replication Manual on Colorectal Cancer Screening Patient Navigation](#)

Patient Education

Colorectal Cancer and Stool-based Screening Tests

Facts about colorectal cancer and screening:

- Colorectal cancer (CRC) is the second-leading cause of cancer death when men and women are combined in the United States.⁴
- Approximately 50,000 Americans die of colorectal cancer each year.
- Finding polyps, finding cancer early (called early detection), and treatment can save lives.
- Seven out of 10 people diagnosed with colorectal cancer have no symptoms.
- Colorectal cancer is often preventable with testing of people who have no symptoms, often called screening. Note: patients may understand the terms “test” or “testing” more easily than the word “screening.”
- 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 gFOBT 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 if done correctly and with proper follow-up, screening with high-quality gFOBT or FIT can be similarly effective to colonoscopy for preventing deaths from colorectal cancer.
- The tests are done at home and returned to the health center or mailed to the lab.
- If the gFOBT or FIT results are positive, a colonoscopy must be performed. **If the patient does not get a colonoscopy after having a positive stool test, they have not completed the screening process. A colonoscopy is needed to find out why they had a positive test.**
- If your patients choose to get screened with gFOBT or FIT, they need to do it every year, just like a flu shot.
- Each patient should receive clear instructions about the test that you provide. (See the [flufit.org](https://www.flufit.org) website for test instructions and videos on multiple tests in a variety of languages.)

Talking points for use with patients:

- We have something extra to offer you today!
- It looks like you are due for a home colorectal cancer test.
- Testing for colorectal cancer (also called screening) can save lives.
- Just like a flu shot, all our doctors and nurses recommend home colorectal cancer 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 any questions or a problem with the kit.
- Talk to your doctor if you have any other questions about the kit.

New Resources That Support Communication

Promoting 80% by 2018 communications:

- [80% by 2018 Communications Guidebook: Effective messaging to reach the unscreened – *New 2017 update!*](#)
- [Hispanics/Latinos and Colorectal Cancer Companion Guide](#)
- [Asian Americans and Colorectal Cancer Companion Guide – *New!*](#)

How to Set Up Your FluFIT Program

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

1. Put your FluFIT team together.

Select a FluFIT 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 FluFIT team members and staffing levels.

FluFIT 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 give FIT kits to patients. Also include staff members who can help track kit return rates and monitor project data.

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

To implement a FluFIT 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 people above what you usually need for flu shot season to help assess patient eligibility and dispense FIT kits.

Help your FluFIT team to be successful.

To make sure that the FluFIT 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 FIT. Assign at least one experienced team member who knows all aspects of the Program to be on hand each day both during designated flu shot clinics and during routine clinic appointments when a flu shot might be given (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.

Important Reminders:

- Use your full team, including front desk staff, medical assistants, and nurses, to the fullest extent possible.
- Clinics should confirm screening policy and train staff well in advance of the initiative.
- Ensure all participating staff have been trained on the FIT kit, and that there are sufficient staff to provide FIT kits to patients.
- Consider making reminder phone calls in place of or in addition to mailed reminders.
- Conduct follow-up calls in two weeks to allow patients time to return the kits. As a result, time will only be spent on those who need a reminder.

2. Choose times and places for FluFIT, and advertise them.

When to Start

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

You can do FluFIT 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.

FluFIT 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 every patient with a positive test result to get follow-up.

FluFIT programs can be implemented during dedicated flu shot 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 FluFIT 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 about the FluFIT Program dates, send postcards, provide an automated phone call announcement, or place information about the Program on your website 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 “Colorectal cancer screening can save lives!”



3. Design a patient-flow and line-management plan.

Offer FIT before giving flu shot.

Planning patient-flow issues in advance will help your program run smoothly. See Appendix D (page 24) for example of a clinical work flow.

In busy settings, there may be a flu shot line. When there is a line, the most efficient way to reach everyone who needs colorectal cancer screening is usually to provide gFOBT or FIT before providing flu shots. Waiting until after giving flu shots to offer gFOBT or FIT may be less efficient, since patients usually expect to leave immediately after getting their flu shot.

Assess eligibility for flu and FIT.

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

- No FIT or gFOBT in the past year
- No colonoscopy in the past 10 years
- No flexible sigmoidoscopy in the past 5 years
- No FIT-DNA in the past 3 years
- No CT colonography in the past 5 years
- No personal history of Crohn's disease or ulcerative colitis*
- No family history of genetic syndrome such as HNPCC or FAP*
- 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.

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 or one of the other recommended tests for colorectal cancer screening. Offer gFOBT or FIT 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 gFOBT or FIT 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. Many patients who are older than 75 years of age may still benefit from screening. These patients should discuss the benefits and limitations of screening (based on their overall health status) with their clinician.

One time-saving approach for clinics with electronic health records is to develop a report of registered patients who are due for gFOBT or FIT at the beginning of the flu shot season and use it as reference to select appropriate patients for gFOBT or FIT as they come in for their flu shots.

Tools & Resources

[EHR Best Practice Workflow and Documentation Guide to Support Colorectal Cancer Screening Improvement with eClinicalWorks](#)

Electronic Medical Records Report

The Use of Electronic Health Records in Optimizing the Delivery of Colorectal Cancer Screening in Primary Care Report is designed to help both the doctor who already has an electronic medical record and one who is considering buying one. The report includes a list of electronic health record features that are needed to improve the delivery of CRC screening. [Click here to download a PDF.](#)

4. Develop systems to support follow-up of dispensed FIT kits.

In addition to selecting a high-sensitivity guaiac-based test or FIT, consider ease of test completion when selecting an FIT kit.

There are many FIT and gFOBT 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 [Clinician's Reference: Stool Based Tests for Colorectal Cancer Screening](#)). See the [NCCRT's "Implementing FIT" webinar](#) for more information on selecting a tool-based test.

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 ongoing quality improvement in your center and project evaluation.

Provide clear instructions for completing and returning kits.

Most test kits come with manufacturers' recommended instructions, which can be given to patients as part of the gFOBT or FIT kit.

Depending on the needs of your patient population, you may want to include additional instructions, such as multilingual instructions, [examples of supplemental patient instructions](#), a special reminder to date the kit when completed, and/or a phone number to call if they have questions.

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. Be sure to include the correct mailing address on the return envelopes.

If patients will be allowed to mail gFOBT or FIT kits back, providing postage-paid envelopes will increase your return rates on dispensed kits.

Strongly consider reminder phone calls and/or postcards to encourage test completion by those who are given gFOBT or FIT kits.

Typically, less than 30% of people who are given gFOBT or FIT kits will return them without reminders. Telephone reminders may lead to a higher return rate than mailed reminders, although both increase return rates. Send reminders two weeks after dispensing the test if the kit has not been returned within that time.

Assist patients with a positive gFOBT or FIT result with referral for colonoscopy. A positive gFOBT or FIT should not simply be repeated; every positive test requires a follow-up colonoscopy. Health center staff and clinicians should also be prepared to coordinate access to any treatment needed as a result of colonoscopy findings.

Develop a system to communicate both normal and positive gFOBT/FIT results to both the patient and their primary care clinician.

Patients with normal gFOBT or FIT results should receive the message that this is good news and that they should repeat the test in a year. The results should be documented in the patient's chart, and their primary care clinicians should also be notified.

Patients with positive gFOBT or FIT results should be notified and referred for colonoscopy to check for polyps or cancer. Positive results and date of colonoscopy referral should be documented in the patient's chart. The primary care clinician should be alerted of all positive results so they can provide patients with an appointment or referral for a diagnostic colonoscopy.

Keep a log of patients with positive gFOBT or FIT results. Monitor this log periodically to verify that all patients have completed the recommended follow-up colonoscopy. Be familiar with treatment resources in your community to determine a path to treatment in the rare cases where cancer or other major problems are found through screening and follow-up exams.



5. Implement your program: Final preparations.

Gather your supplies well in advance.

Order flu vaccine and gFOBT or FIT 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 the [flufit.org](https://www.flufit.org) website. Identify materials suitable for your patient population (language, reading level) in the weeks before beginning your FluFIT program. If you have specific needs in this area, talk with your local American Cancer Society representative for assistance.

Congratulate yourselves for implementing a FluFIT program in your community!

Two Weeks before FluFIT Activities Start

Double check to be sure you have all your supplies ready. Do a walkthrough with your FluFIT team.

Consider doing a role play with your FluFIT team, checking your workflow and procedures for providing flu shots, colorectal cancer screening information, and gFOBT or FIT kits.

First Day of Your FluFIT Program

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

Use the Action Plan Guideline (Sample) (See Appendix D, page 24.)

Staff Training for Your FluFIT Program

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

For example, if your health center is already experienced in providing gFOBT or FIT 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 gFOBT or FIT kits in the past, more training will be needed.

The Five Key Elements to Include in Your Training(s):

1. Information about the importance of both flu shots and colorectal cancer screening, including the need for both to be repeated annually

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.⁸
- 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

Visit the CDC's seasonal flu website at [cdc.gov/flu/](https://www.cdc.gov/flu/) for more information about flu and flu shots.

Facts about colorectal cancer and screening:

- Colorectal cancer (CRC) is the second-leading cause of cancer death when men and women are combined in the United States.⁴
- Approximately 50,000 Americans die of colorectal cancer each year.
- Early detection and treatment can save lives.
- There are more than one million colorectal cancer survivors in the United States.
- Colorectal cancer screening is recommended for people between 50 and 75 years of age.

Visit the American Cancer Society website at [cancer.org/colonmd](https://www.cancer.org/colonmd) for more information about colorectal cancer and colorectal cancer screening.

2. Information about how to organize your workflow efficiently

- In most clinical settings, it is best to offer gFOBT or FIT before the administration of flu shots.
- It is also important to consider 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 gFOBT or FIT kits several feet in front of the station where flu shots are being offered.
- If you are providing the FluFIT Program during primary care visits, or in a lower-volume setting

with limited space, you may want to provide gFOBT or FIT kits and flu shots together at the same clinic station.

- Make sure to have your work stations well stocked with patient education materials, gFOBT or FIT kits, and flu shots so that your team is well prepared.

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

Visit [cdc.gov/flu/index.htm](https://www.cdc.gov/flu/index.htm) for detailed free training programs for health professional and clinic staff that provide flu shots.

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

- No FIT or gFOBT in the past year
- No colonoscopy in the past 10 years
- No flexible sigmoidoscopy in the past 5 years
- No FIT-DNA stool test in the past 3 years
- No CT colonography in the past 5 years
- No personal history of Crohn's disease or ulcerative colitis*
- No family history of genetic syndrome such as HNPCC or FAP*
- 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 positive gFOBT or FIT results should be referred for colonoscopy to check for polyps or cancer. **If the patient does not get a colonoscopy after having a positive stool test, they have not completed the screening process. A colonoscopy is needed to find out why they had a positive test.**

Eligibility for gFOBT or FIT 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 FIT at the beginning of the flu shot season, and use it as a quick reference to select appropriate patients for gFOBT or FIT 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 gFOBT or FIT and colonoscopy procedures.
- As long as the patient is reasonably certain that they have not completed a recent gFOBT or FIT kit and that they have not had a colonoscopy in the past 10 years, it is reasonable to offer a gFOBT or FIT kit with their flu shot.

4. Talking to patients about FIT 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 FluFIT program is set up and what type of kit you provide to them.

- 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 colorectal cancer test.
 - Colorectal cancer testing can save lives.
 - Just like the flu shot, all our doctors and nurses recommend home colorectal cancer 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 gFOBT or FIT, it can be useful 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 given follow-up of FIT kits given to patients

For tracking purposes, you will want to keep a record of which patients were given gFOBT or FIT. Visit flufit.org/program-materials for a sample log sheet and a positive test result tracking form.

- This information can be recorded on a log sheet where flu shots are also recorded.
- This log 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 positive test results.

Summary

Although often a preventable disease, colorectal cancer (CRC) is the second-leading cause of cancer death when men and women are combined in the United States.⁴ In addition, while unpredictable, flu-associated deaths in the US range from 3,000 to 49,000 people per year.⁸ Screening for CRC and vaccination for flu both help reduce the incidence of these conditions. Research has demonstrated that a FluFIT program is an efficient and effective way to increase colorectal cancer screening, which can improve screening rates in a variety of settings.^{1,2,3} FluFIT programs reach many patients who otherwise may not have an opportunity to receive screening.

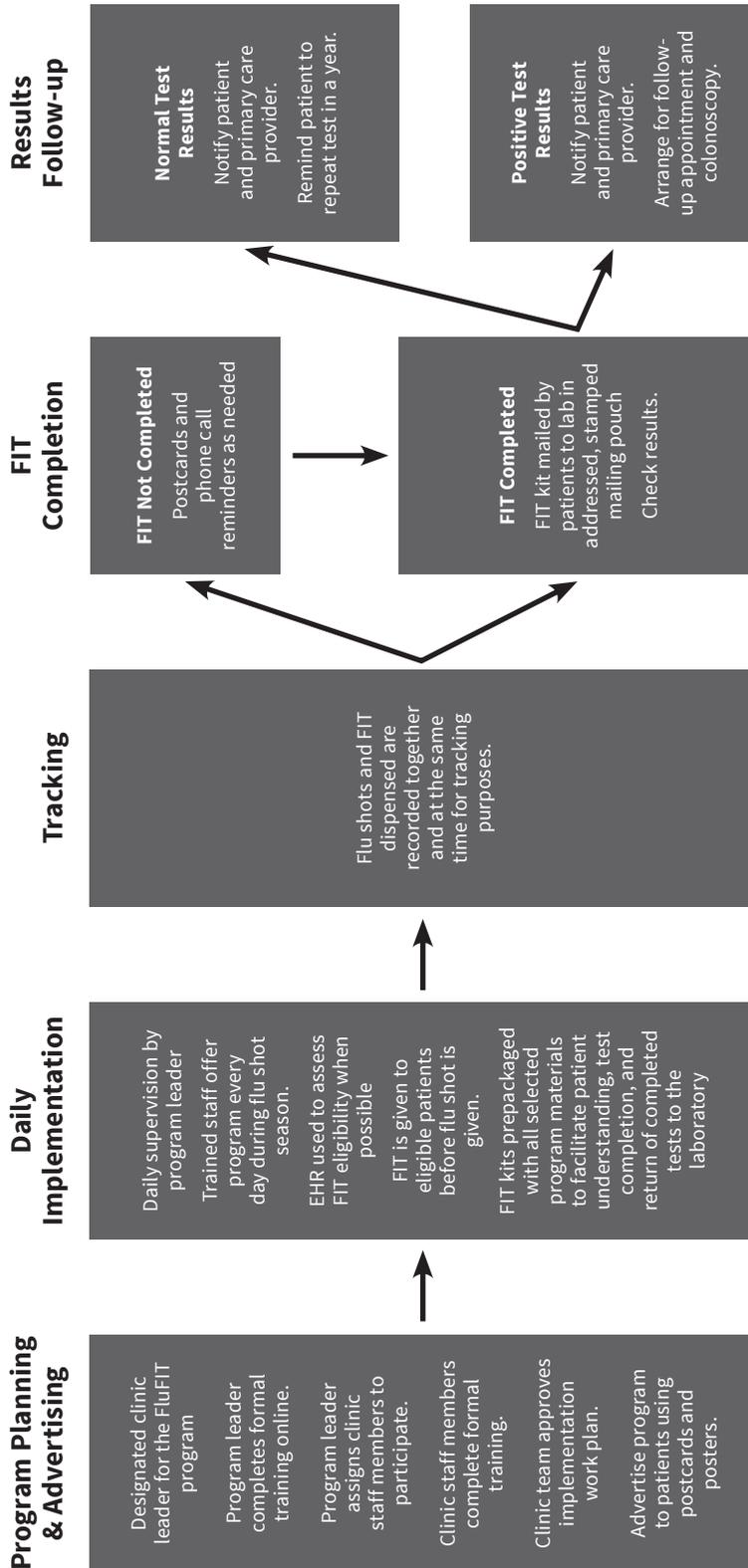
This implementation guide will assist your health center in setting up and implementing your FluFIT program easily and successfully. If you have any questions or concerns about the Program, please refer to cancer.org/colonmd or contact your local American Cancer Society representative or call **1-800-227-2345** and ask to speak to your local American Cancer Society office.

Appendix A: FluFOBT Components and Logic Model

GOAL: Increase colorectal cancer screening rates by offering home gFOBT or FIT to eligible patients during annual flu shot activities.

CORE FUNCTIONAL COMPONENT: Standing orders to allow non-physician clinic staff to offer flu shots and gFOBT or FIT together to any clinic patient or health care client 50 to 75 years of age who is seen during flu shot season

TARGET CLINICAL SETTINGS AND POPULATIONS: Community health centers, pharmacies, managed care organizations, and other health care settings where flu shots are provided and where gFOBT or FIT is offered for average-risk colorectal cancer screening



Sample Program Implementation Materials

- Mailed FluFIT program announcements
- Clinic posters to advertise FluFIT program Algorithm for FluFIT program patient flow
- Algorithm to use EHR to assess FIT eligibility
- Script to introduce/explain FIT with flu shots to patients
- Visual aids to use when offering FIT to patients
- Multilingual materials to explain why FIT is important
- Multilingual FIT completion instructions
- Multilingual video instructions
- Preaddressed FIT mailing pouches
- Prestamped FIT mailing pouches
- FluFIT log sheet to record flu shots and FIT dispensed

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 50 years of age 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

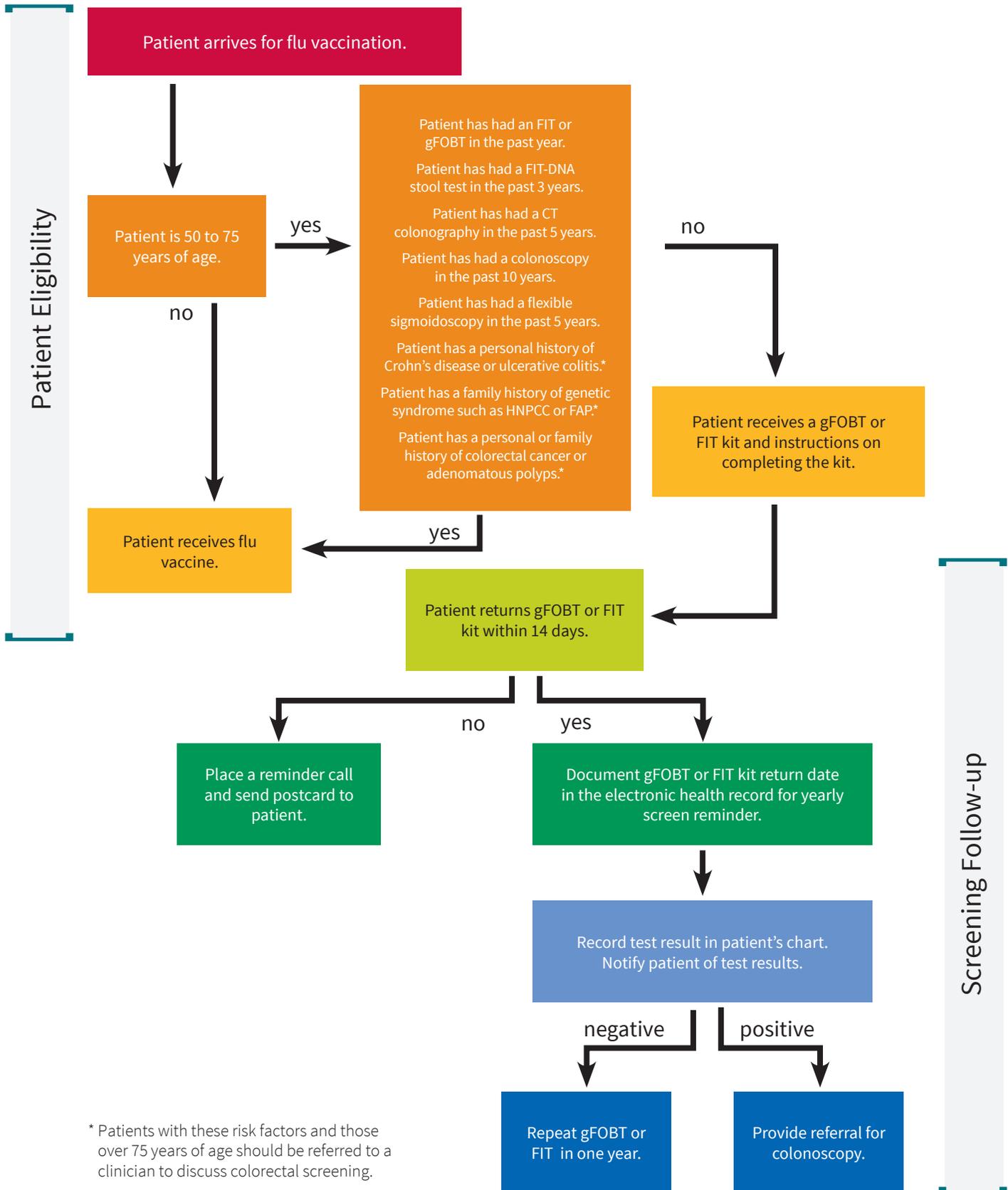
INCREASED RISK – Patients With a History of Polyps on Prior Colonoscopy

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: FluFIT Flow Chart



Appendix D:

Action Plan Guideline (Sample)

Overview Action Plan Checklist for FluFIT Program Activities

Action Item	Staff Responsible	Date to Be Completed	Notes	Complete
Identify clinic staff lead.				
Identify clinic support staff.				
Identify staff who will provide patient information, assess patient project eligibility, and distribute gFOBT/FIT kits.				
Identify staff responsible for tracking kit returns, as well as processing and reporting results.				
Identify staff responsible for a reminder system for kits that are not returned (calls, postcards).				
Plan for and conduct staff training (dates and impact on schedules).				
Purchase flu vaccines.				
Purchase gFOBT/FIT kits. <ul style="list-style-type: none"> Identify the gFOBT/FIT test brand that will be used. 				
Identify/prepare/print/order patient education materials: <ul style="list-style-type: none"> Prepare patient selling/talking points utilizing the materials found on FluFIT.org website. Prepare patient selling/talking points utilizing the materials found on FluFIT.org website. Prepare educational materials: (1) hard-copy handouts in needed languages; and (2) verbal scripts. Consider reading levels of materials. Make sure that test kit manufacturers' 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 American Cancer 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 FluFIT.org website):</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 FluFIT promotion, outside of the clinic setting, are needed. 				
<p>Prepare protocol for determining patient eligibility for this intervention:</p> <ul style="list-style-type: none"> • Define patient risk assessment (average risk versus high risk). • Use patient eligibility algorithm, which can be found in Steps for Increasing Colorectal Cancer Screening Rates: A Manual for Community Health Centers. 				
<p>Develop clinic flow plan for implementing FluFIT:</p> <ul style="list-style-type: none"> • Select a gFOBT/FIT kit storage area easily accessible when flu vaccinations are given. • Decide if project log sheets (flu vaccination, gFOBT/FIT kit distribution, and tracking form) will be kept in hard copies or through EHR. • Identify staff person(s) who will collect and document program data. • Determine if alert should be placed in EHR to signify pilot participant. • Assure a process is in place to close 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 versus other reasons who also (by the way) want a flu shot and are eligible for gFOBT/FIT 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 a positive result, 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 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 that are on file. • Document if the patient is comfortable in having a message left on an answering machine. • 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 assure patients are returning test kits within 2 weeks after receiving them. • Call the patient if the kit is not returned after 2 weeks. • If a call is not possible, send a postcard to the patient if the kit is not returned within the 2-week timeframe. • Identify a protocol for “lost to follow-up” when a patient does not return a kit after multiple contacts. 				
<p>Determine process for collecting input from frontline clinic staff and patients on what is working – and what is not working – regarding program implementation and follow-up:</p> <ul style="list-style-type: none"> • Modify processes as needed based on staff and patient input. 				
<p>Provide ongoing technical assistance once flu vaccination season begins:</p> <ul style="list-style-type: none"> • Hold a conference call or brief meeting after 1 full week of FluFIT implementation to assess needs or any process changes. • Determine how frequently the staff lead(s) would like to hold conference calls and/or have site visits or additional training. 				

Appendix E:

FluFIT Tracking Tools

Data Report Form Template

This data form can be used to collect information on baseline and follow-up colorectal cancer screening rates, as well as track distribution and return of gFOBT and FIT kits.

Baseline Screening Rate Data should be recorded at project start and should include dates of January 1 through June 30 of the implementation year of the FluFIT Program (e.g., if implementation of FluFIT is in the fall-winter; baseline would be reported for January 1-June 30 of the calendar year). If you are implementing the Program in one or a subset of clinics in your system, report numbers for that subset. If you are implementing the Program system-wide, report numbers for the entire system.

Project Report Data should be tracked during the implementation period of the Program. Please indicate the time period of project implementation.

Implementation Screening Rate Data should be recorded following the completion of the implementation of the Program and should include dates of July 1 through December 31 of the implementation year.

Optional Section. Additional data can be reported if desired. In this section, you can report post-screening data, including the number of colonoscopies performed for patients who had a positive gFOBT or FIT, the number of patients with adenomatous polyps removed, and the number of cancer cases identified during the Program. This data can be reported through a six-month post-implementation period, through June 30 of the year following the Program implementation.

FluFIT Data Report

Agency Name:
Person Completing the Form:
Project Location (City/State):

Baseline Screening Rate Data: (January 1 through June 30 of Implementation Year)	
Total patients 51-74 in clinic/system in baseline time period	
Number of patients 51-74 up to date with colorectal cancer screening in baseline time period	
Number of individuals 51-74 who received flu shot in baseline time period	

Project Report Data: (Specify Time Period of FluFIT Project Implementation)	
Number of patients 51-74 receiving flu shot	
Number of patients 51-74 receiving gFOBT/FIT kit	
Number of patients returning gFOBT/FIT kit	
Number of patients receiving reminder communication	
Number of normal gFOBT/FIT results	
Number of abnormal gFOBT/FIT results	

Implementation Screening Rate Data: (July 1 through December 31 of Implementation Year)	
Number of patients 51-74 up to date with colorectal cancer screening in implementation period	

Optional Section

Long-term Follow-up (through June 30 of Year Following Implementation)	
Number of patients who received colonoscopy following abnormal gFOBT/FIT results	
Number of patients with at least one adenomatous polyp removed	
Number of cancer cases identified	

Telephone Script

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

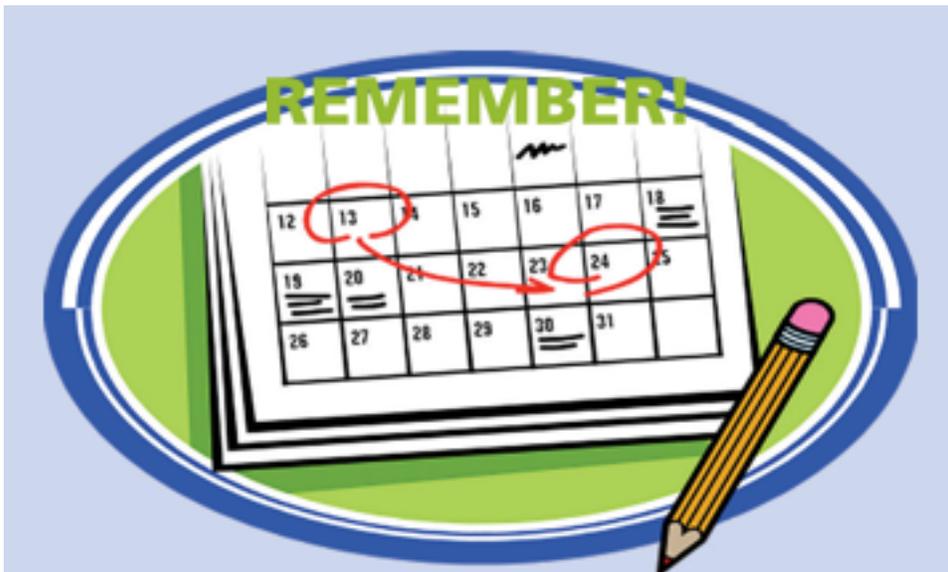
Our records indicate you have received a colorectal cancer screening stool test kit that has not yet been returned. Please complete your stool test kit, and mail it back to us.

A colorectal cancer screening stool test kit screens for evidence of blood in your stool, which can be an early sign of colorectal cancer. Finding colorectal cancer early is key to saving lives.

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

Sample Reminder Postcard

(visit flufit.org for current materials)



Greetings from [name of health care facility]!

When you came in to get your flu shot, we gave you a home colorectal cancer screening test kit. If you already completed it, thank you!

If you haven't done your home colorectal stool test yet, please do so and send it back to us as soon as possible.

Thank you very much!

[Insert signature of the patient's PCP or of the medical director of the clinic here]

[Insert Clinic Address and Logo here]

Appendix F:

Elements of a Successful FluFIT Program

Clinics should:

- Conduct regular staff meetings about the Program, particularly to make sure clinicians are all on board.
- Use the medical assistants (MAs) and nurses to the fullest extent possible for identifying eligible patients, providing education, and implementing standing orders for gFOBT or FIT test distribution.
- Confirm the standing-orders policy well in advance of the initiative. If necessary, additional training should be provided to medical assistants/nurses to ensure they feel empowered to educate patients and distribute gFOBT or FIT kits. Determine how to best use the EHR to generate lists of eligible patients in advance.
- If implementing a flu shot clinic, ensure all participating staff have been trained on the gFOBT or FIT kit and that there are sufficient staff to provide the kits.
- Flu shot visits are short: it may be more efficient to have a staff member other than the nurse offer the gFOBT or FIT kit and provide instructions.
- Track the gFOBT or FIT kit return rate.
- Consider reminder phone calls in place of or in addition to mailed reminders if the kit is not returned within two weeks. This ensures that time is spent only on those who need a reminder.
- Ensure colonoscopy follow-up of all positive gFOBT or FIT test results.

Appendix G: Advertising

Sample Patient Education Poster

The poster on the left is a sample patient education poster for general colorectal cancer screening.

The poster on the right is a FluFIT custom poster for event promotion.

Visit cancer.org/colonmd and look for the Printable Resources for Your Clinical Practice section to download a copy of these posters. Visit flufit.org for additional promotional materials.



American Cancer Society

You can help prevent **colorectal cancer.**

If you're 50 or older, talk to a health care provider about getting screened for colorectal cancer.

Colorectal cancer is one of the leading causes of cancer death in men and women, yet it can often be prevented or found at an early stage, when it's small and easier to treat, with regular screening.

Preventing colorectal cancer or finding it early doesn't have to be expensive. There are simple, affordable take-home tests available. Get screened. Call your health care provider today.

To learn more about colorectal cancer, visit the American Cancer Society's website at cancer.org or call us at **1-800-227-2345**. We're here when you need us – 24 hours a day, 7 days a week.

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Written January 2017

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American Cancer Society

Get tested!
It can save your life.

Like the flu, colorectal cancer can be prevented and treated most successfully when it's found early.

If you are 50 years of age and older, talk to your health care provider about getting tested for colorectal cancer.

LOCAL FLUFIT EVENT:
Month xx, xxxx | 00:00 a.m. – 00:00 p.m.
Location | Street Address, City, State, Zip

To learn more about colorectal cancer, call 1-800-227-2345.

cancer.org | 1.800.227.2345

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FluFIT Research and Related Publications

Information about colorectal cancer screening in Diverse Practice Settings

[Potter MB. Strategies and resources to address colorectal cancer screening rates and disparities in the United States and globally. Annual Review of Public Health. 2013;34:413-429.](#)

Managed Care Settings

[Potter MB, Somkin CP, Ackerson LM, et al. The FLU-FIT program: An effective colorectal cancer screening program for high volume flu shot clinics. Am J Manag Care. 2011;17\(8\):577-583](#)

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Community Health Centers

[Sarfaty M, Doroshenk M, Hotz J, et al. Strategies for expanding colorectal cancer screening at community health centers. CA Cancer J Clin. 2013;63\(4\):221-231.](#)

[Walsh JM, Gildengorin G, Green LW, Jenkins J, Potter MB. The FLU-FOBT program in community clinics: Durable benefits of a randomized controlled trial. Health Educ Res. 2012; 27\(5\):886-894.](#)



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