Mailed FIT Implementation Guide







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here were 141,074 new colorectal cancer (CRC) cases and 52,163 deaths due to CRC in the United States in 2018, according to cancer statistics kept by the CDC. CRC screening is an effective way to reduce CRC incidence and mortality, but about one-third of eligible U.S. adults are not screened as recommended.

Mailing fecal immunochemical tests (FITs) to the homes of adults who are due for screening is a proven and cost-effective way to increase screening rates. Because the test is mailed, it is easy for patients to complete it at home: one meta-analysis of seven randomized, controlled trials found that mailed FIT outreach programs could increase screening rates by 28 percentage points. (1)

The 2021 United States Preventive Services Task Force guidelines have lowered the recommended starting age for adult screening from age 50 to age 45, making even more adults eligible for screening. Mailed FIT outreach programs can help to address the resulting increased demand, and mailed FIT outreach has been shown to work well across diverse underserved, rural, and city-based healthcare settings.

It takes collaboration among multiple organizations and teams to implement an effective mailed FIT outreach program, including primary care clinics or health plans, to send and receive mailed FIT kits to and from patients; laboratories, to process FIT kits; colonoscopy providers, to follow up on abnormal FIT results; patient navigators, to support follow-up processes; and electronic health record system vendors and information technology personnel, to manage FIT data and create useful tracking reports. This guide provides step-by-step instructions for implementing a mailed FIT outreach program that leverages the strengths of all team members.

This guide recognizes the contributions of researchers, clinicians, colorectal cancer survivors, and frontline workers in helping to establish and improve the design and operation of mailed FIT outreach programs.

As authors and reviewers of the guide, we want to share these evidence-based practices to help you increase colorectal cancer screening in your community. Together, we can all work to increase colorectal cancer screening rates and save lives.

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Kaiser Permanente is recognized as one of America's leading health care providers and not-for-profit health plans. Kaiser Permanente is dedicated to care innovations, clinical research, health education, and improving community health. Kaiser Permanente currently serves 12.5 million members in 8 states and the District of Columbia.

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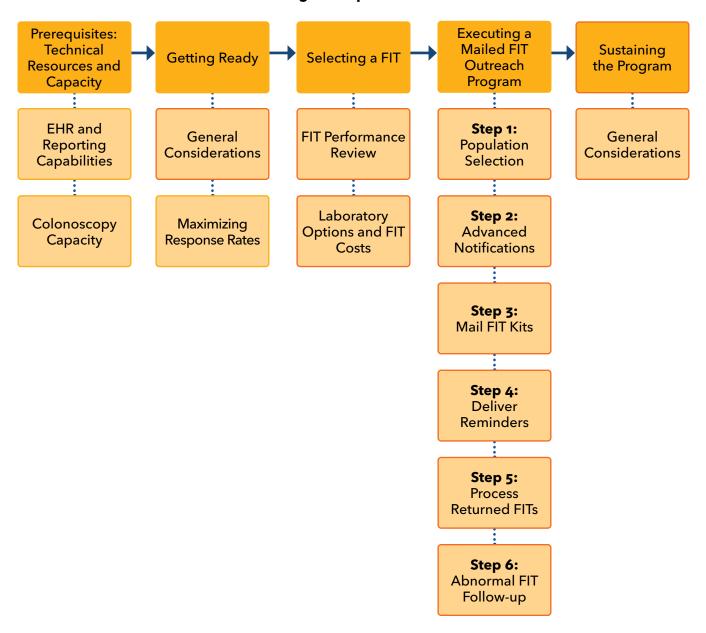
Mailed FIT Outreach Guide for Clinics and Health Plans

Overview of the Implementation Guide

This guide is a roadmap for how health systems and other entities can design and carry out mailed fecal immunochemical test (FIT) outreach programs, including information on key partnerships and what to have in place before launching a program. The goal of this guide is to provide clinic and health system administrators and staff with the information needed to make informed decisions and successfully implement a mailed FIT outreach program.

Colorectal cancer (CRC) screening rates can be increased through effective partnerships among health systems, health departments, payers, vendors, and community organizations based on trusted relationships and strong infrastructure. (2) Many clinics and health plans have leveraged their resources to collaborate on CRC screening for cancer prevention. Throughout this guide, you will find blue boxes that provide examples of specific ways that clinics and health plans have collaborated to increase CRC screening rates through mailed FIT outreach programs for adults who are due for CRC screening.

Overview of the Mailed FIT Outreach Program Implementation Process



Importance of CRC Screening Programs

CRC is the second leading cause of cancer deaths in the United States. The likelihood of surviving five years after a CRC diagnosis is 90% when cancer is detected in early stages, 69% when detected in a regional stage, and 8% for when detected at an advanced stage. High screening rates are the best way to increase early detections. CRC screening can be achieved through various screening tests, including colonoscopy, sigmoidoscopy, C.T. colonography, FIT, or a multi-target stool DNA-FIT test.

Despite the effectiveness of early detection, many age-eligible adults in the United States are not screened on the timeline recommended by current guidelines: only 68.8% of eligible adults who participated in the 2018 Behavioral Risk Factor Surveillance System Survey were up to date for CRC screening. (3) Screening rates are particularly low for certain groups, such as adults without a high school diploma, those with low incomes, and those without health insurance. Rates are also disproportionately low among recent immigrants, those with no usual source of health care, and Hispanic/Latino people. Screening rates are also lower among people who live in rural areas than among people who live in cities. (4-6)



CRC incidence is also increasing in people younger than age 50. In 2020, an estimated 17,930 people younger than 50 were diagnosed with new CRC cases, and 3,640 people younger than 50 died of CRC. (7) Evidence supports starting regular CRC screening before age 50 to increase early detections and improve patients' chances of survival. Accordingly, the new 2021 United States Preventive Services Task Force guidelines have lowered the starting age for adult screening from age 50 to age 45. (8) This change will result in an even larger number of adults who are not up to date with screening recommendations.

Barriers to accessing CRC screening contribute to low screening rates and disparities across population subgroups, such as those noted above. Common barriers to colonoscopy include being unable to take time off work, lacking transportation to the clinic, and not understanding or disliking the preparatory steps for colonoscopy (clearing out the colon). In addition, crises and natural disasters, such as wildfires, snowstorms, and pandemics, can hinder or delay access to CRC screening, while the importance of timely screening and follow-up for abnormal results remains constant. To address low screening rates, health systems should adapt and find ways to address barriers to access and to continue preventive cancer screening services during times of crisis, especially in medically underserved communities.

Some effective strategies for increasing screening rates include sending reminders to patients whose electronic health records (EHR) indicate they are due for screening; outreach via social media; and increasing the use of at-home screening methods. (9-10) Another option that has proven effective is to use mailed FIT outreach programs that enable people to do the tests conveniently at home and mail kits back for laboratory analysis. Patients with abnormal FIT results must then have a follow-up colonoscopy to ensure early detection and prevention of cancer. (9)

Advantages of Mailed FIT Outreach Programs

We are getting [FIT] kits in the hands of everyone who is eligible for a kit, [instead of relying on them coming in for a clinic visit]. That is the strength. -Project Lead

FIT screening offers a convenient, minimally invasive at-home alternative to colonoscopy and is thus an important component of any CRC screening program. The use of the multi-target stool DNA-FIT test (Cologuard) is also increasing, but is not currently as accessible as FIT and colonoscopy. Research has shown that promoting multiple options for screening, including complementing in-clinic offerings of FIT and colonoscopy with mailed FIT outreach, maximizes participation in CRC screening. (11)

Mailing FIT kits directly to patients is an evidence-based and effective way to screen more patients for colorectal cancer. Advantages of mailed FIT outreach programs include:

- Mailed FIT outreach programs have consistently been shown to improve rates of CRC screening. (1, 12)
- Mailed FIT outreach is a *population-based strategy that lessens the burden on primary care physicians* to recommend screening during office visits. It overcomes limitations of opportunistic screening and can be conducted in coordination with in-clinic screening efforts.
- Mailed FIT outreach programs may *help address health disparities*: some studies have shown that these programs elicit as good a response, or better, from Spanish-speaking patients as from English-speaking patients. (13, 14)
- Patients appreciate alternatives to a screening colonoscopy, and the outreach makes them feel "cared for" by their clinic or health plan. (15)
- Mailed FIT outreach programs are cost-effective. (16, 17)

Overview of Evidence Provided in this Implementation Guide

The evidence provided in this guide is based on two recent primary sources. The first source is the five-year STOP CRC pragmatic trial of mailed FIT outreach in federally qualified health centers (2013-2018). The second source is the 2019 CDC-sponsored Mailed FIT Summit, which evaluated the findings of more than 75 research studies on the use of mailed FIT outreach to increase CRC screening and follow-up colonoscopy completion rates. Best practices identified at this Summit are highlighted throughout the text and resources to support best practices are provided in the Appendix.

The 2018 STOP CRC Study

The STOP CRC study was a collaboration between Kaiser Permanente Northwest, Kaiser Permanente Washington, and OCHIN (formerly the Oregon Community Health Information Network, now renamed to OCHIN). The study investigated whether the use of mailed FIT outreach, together with follow-up colonoscopy for abnormal FIT results, could increase CRC screening rates above those obtained with the



usual care approach of opportunistic screening within 26 federally qualified community health center clinics in Oregon and California. The findings showed a significant improvement in CRC screening rates and an overall FIT return rate of 21%. Findings from the study were published in JAMA Internal Medicine. (18)

The program had three key steps. First, EHR reports were used to identify patients who were due for CRC screening, who were then mailed an introductory (advance notification) letter. Second, a few weeks later, patients were mailed FIT kits for completion. Third, a few weeks after the kits were mailed, non-completer patients were mailed a reminder letter encouraging them to complete and return their kits. Because this was a pragmatic trial and these steps were implemented by clinic staff, not all non-completer patients received reminder letters.

Key Findings of the STOP CRC Project

Mailed FITs were acceptable to both patients and providers. Some clinic staff were initially worried that patients would not want to receive a FIT by mail or be confused when they received it, but both patients and providers had positive reactions to the mailed FIT outreach program.

Clinics could reach more patients for CRC screening. Among the 13 clinics that implemented the program in the first year, the rate of FIT return ranged from 11% – 36% (21% overall response rate). More than 6,000 FITs were completed. FIT returns were higher for clinics that sent reminders after the FIT test was mailed.

The 2019 CDC Mailed FIT Summit

In June 2019, the CDC convened a meeting of subject matter experts and stakeholders to identify best practices and key components of successful mailed FIT outreach programs. The meeting was structured around nine key topics that were identified as important for successful mailed FIT outreach program implementation. More than 75 relevant research studies were evaluated to inform the Summit findings. An accompanying journal article published in CA: A Cancer Journal for Clinicians described the Summit goals, process, and findings in detail. (19)

Key Findings from the June 2019 CDC Mailed FIT Summit

- **1.** Data management infrastructure should be used to identify eligible patients and track them through each step of the outreach process.
- 2. Advance notifications (primers) such as texts, telephone calls, and printed mailings sent before mailed FIT are associated with higher effectiveness. Primer letters should be brief and easy to read, and the signatory should be tailored based on the setting.
- **3.** A high-quality, 1-sample FIT should be used, with instructions that are simple and address challenges that may lead to failed laboratory processing, such as notation of collection date.
- 4. Reminders delivered to initial non-completers should be used to increase the FIT return rate.
- **5.** Protocols and procedures to follow up abnormal FITs with colonoscopy, such as patient navigation services, should be in place before implementing a mailed FIT program.

Summit participants concluded that mailed FIT is an effective and efficient strategy with great potential for increasing CRC screening in diverse health care settings.

Prerequisites: Technical Resources and Capacity



Both the STOP CRC study and the Mailed FIT Summit noted the importance of data infrastructure that can identify eligible patients and track each step in the outreach process, from the delivery of an advance notification through abnormal FIT follow-up. Moreover, successful program implementation and sustainment requires a program champion and organizational support for the work, including sufficient funding and external policies (such as quality reporting requirements) that support an ongoing commitment. Sufficient colonoscopy capacity and staffing resources are also needed to support program success. The table below outlines best practices for data infrastructure identified at the Mailed FIT Summit.

Best practices for data infrastructure based on the Mailed FIT Summit

At a minimum, a data infrastructure should:

- Identify eligible patients for mailed outreach
- Track key steps in the screening process (mailings sent, FIT results, and FIT result communication to patients and providers)

An ideal infrastructure should also:

- Track steps in the navigation to colonoscopy for abnormal FIT
- Allow for repeat invitation for patients with normal results
- Accommodate tracking of reimbursement if applicable

EHR and Reporting Capabilities

Clinics and health plans can use a variety of technical tools and resources to track and report information used in mailed FIT outreach programs. These tools and resources can vary by site. For example, different health centers in the STOP CRC study used different resources depending on the specific EHR system they used.

In the EPIC EHR system, the Reporting Workbench feature can be used to find and track patients who are eligible for CRC screening. This feature can generate EHR reports of patients due for each step in the outreach process (introductory letter, FIT kit, or reminders). Also in EPIC, the Health Maintenance feature can be used to track patient-level preventive health data. This tool can automatically update records based on completed EHR fields (such as a laboratory order for a FIT) and can also be manually updated to include historical colonoscopies.

In the AllScripts EHR system, EHR reports can be created that list patients due for screening. Staff can export these reports and manage the mailed FIT outreach program using a spreadsheet or database program, such as Excel.

IMPORTANCE OF PARTNERSHIPS

A regional collaboration to increase CRC screening rates was initiated by the <u>Great Plains Quality Innovation Network (GPQIN)</u> in Kansas, Nebraska, North Dakota, and South Dakota. GPQIN facilitated a regional learning and action network, hosted webinars, and provided technical assistance to support evidence-based systems change interventions at 57 clinics. All 43 clinics that track their screening rates have reported increases, with one screening 84% of eligible patients. (20) <u>See the GPQIN achievement award at NCCRT.org</u>.

In STOP CRC, customized EHR reports were created to identify people who were due for each step in the mailed FIT outreach process (see *Example EHR and Tracking Reports, Detailed Report Definitions, below*).

Example EHR and Tracking Reports

Detailed Report Definitions. The STOP CRC EHR Report Definitions can be used to help customize a mailed FIT outreach program. These include essential and optional fields as well as exclusion and inclusion codes.

Colonoscopy Report Example. The STOP CRC Colonoscopy Report can systematically search scanned files to identify individuals who received colonoscopies that were not recorded in coded EHR fields.

Monitoring Report Example. The STOP CRC Monitoring Report provides the data that allows staff to assess the success of the program over time.

Implementation Tracking Report Example. The STOP CRC Implementation Tracking Report provides a snapshot of what is happening with letters and mailed and returned FITs, allowing clinics to track response rates to the mailings.

IMPORTANCE OF PARTNERSHIPS

In Milwaukee, Wisconsin, an academic health center partnered with local community groups to increase CRC screening rates among Black adults. They formed the Milwaukee Regional Cancer Care Network, which used evidence-based interventions, education, training, and tools to improve health outcomes. They doubled their cancer screening rate by using FIT and establishing clear patient navigator roles. (21)

Colonoscopy Capacity

When considering a Mailed FIT outreach program, clinics must ensure that demand from high abnormal FIT results will not exceed available capacities, resulting in longer wait times for follow-up colonoscopy. Wait times of 6 months or longer are considered too long. However, abnormal result rates of the most reliable FIT tests are only about 4%-8%, so the needed additional capacity is incrementally small. The following tables show calculations of colonoscopy capacity required based on expected returned FIT rates of 25% and 50% and abnormal result rates of 5%.

Colonoscopy capacity required by return rate and mailing size*				
	Assuming 25% FIT return rate		Assuming 50% FIT return rate	
N patients mailed FIT	N kits returned	Expected N abnormal tests (5%) (maximum N needing colonoscopy)	N kits returned	Expected N abnormal tests (5%) (maximum N needing colonoscopy)
10,000	2500	125	5000	250
1000	250	12.5	500	25
500	125	6.25	250	12.5
200	50	2.5	100	5

^{*}Assumes 5% abnormal test result rate

Other Types of Capacity and Resources

In addition to ensuring sufficient colonoscopy capacity, clinics or health plans must have sufficient staffing resources to deliver the program, and clinic-based programs should have a training plan to ensure that staff are comfortable promoting FIT testing. Clinics and health plans must have sufficient laboratory capacity and staff to support tracking completed FITs and to ensure that patients with an abnormal FIT result are informed of their results and supported in getting a follow-up colonoscopy. The table below outlines additional clinical capacity and technical resources identified by STOP CRC as necessary to successfully implement a mailed FIT outreach program.

AREA	CAPACITY AND READINESS CRITERIA
1 Staffing capacity	Even if a health plan/clinic uses a vendor to mail FIT kits, they still must have enough staff to do the work of preparing and reviewing the list of eligible patients, answering questions, and tracking outcomes (see <u>Building a Team</u>).
2 Clinical staff FIT knowledge	Leadership and providers should understand how offering mailed FIT can complement in-clinic offers for CRC screening. Mailed FIT outreach program rollout should include a training plan. Providers, nurses, medical assistants, and staff must be comfortable promoting FIT.
3 Laboratory interface/capacity	Health plans/clinics should establish an interface with a laboratory that processes FITs, or work with an internal laboratory, to establish protocols for FIT returns. Plans should be in place for how to handle samples missing collection dates. The laboratory must also carefully avoid sending out expired or nearly expired FITs.
4 Follow-up	Health plans/clinics should have enough staffing to receive completed FITs by mail and enter laboratory orders, provide FIT results for patients, and follow established processes for post-FIT activities (e.g., schedule follow-up colonoscopies) as needed.

IMPORTANCE OF PARTNERSHIPS

AltaMed Health Services delivers care to almost 300,000 residents in underserved Hispanic/Latino and multi-ethnic neighborhoods throughout Southern California. AltaMed's health centers increased screening through the use of provider and staff training, electronic point-of-care reminders, standing medical orders, follow-up on colonoscopy referrals, outreach to patients by phone, screening goals, and a provider incentive program. Between 2012 and 2017, AltaMed increased its screening rates from 39% to 67%. (22) See the AltaMed achievement award at NCCRT.org.

AltaMed Health Services recently partnered with Kaiser Permanente Northwest to implement text message and live phone call enhancements to their Mailed FIT outreach program; these enhancements will further improve FIT return rates. (23, 24)

Getting Ready



General Considerations

Customizing Your Mailed FIT Outreach Program

The mailed FIT outreach program is highly adaptable to individual clinics and health plans and their EHRs. The following "big picture" themes and questions are helpful in customizing a program:

- Define priorities and targets: What is your goal?
- Select a strategy or two: What will you do to reach your goal?
- Engage partners: Who will help you?
- Gather resources and tools: What resources and tools do you need? Which do you have available?

Implementation Process Steps

When rolling out new interventions, it is recommended that clinics or health plans make small, incremental changes and use a Plan-Do-Study-Act (PDSA) cycle to minimize disruption and achieve optimal results. (25) PDSA cycles are beneficial for any improvement project because they provide the opportunity to test a change on a small scale, study the outcomes, and improve the process. A PDSA evaluation is a useful way to assess the process and the staffing approach and identify ways to reach subgroups of patients who have lower rates of FIT kit return.

Building a Team

Staffing levels for cleaning up EHR data in advance of the program launch and establishing workflows and the basics of mailing should not be underestimated. Clinics need leadership support, EHR experts, and a team dedicated to getting the project off the ground. Clinics have had success working with partners or external vendors to support mailed FIT outreach programs. (26)

Here is an overview of recommended team member roles and responsibilities:

RESPONSIBILITIES	Executive leadership	Champion	Operations/ Q.I. lead	EHR expert	Frontline staff	Laboratory personnel
Project vision, prioritization, communication, resources, staffing	\checkmark					
Intervention workflow design, assigning roles	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark
EHR functionality, tracking reports		\checkmark	\checkmark	\checkmark		
Training, elbow support			\checkmark	\checkmark	\checkmark	
Oversight, performance management			\checkmark			
Processing returned FITs or designing workflow with an external laboratory			\checkmark			✓

For more information on gathering a team and creating an overall CRC screening strategy, see the American Cancer Society Colorectal Cancer Screening manual: https://nccrt.org/Steps-Guide.



Enhancing other in-clinic activities, particularly patient and staff education

Educating patients and staff at every level about CRC in general and mailed FITs in particular is extremely important to the success of the mailed FIT outreach program. STOP CRC clinics repeatedly said they wanted to inform patients about mailed FITs with the goal of improving response rates and reducing patient questions. Key facts to communicate in a patient educational campaign include:

- What colorectal cancer is
- Why CRC screening is important
- That FIT is an approved and accepted alternative to colonoscopy
- That FIT screening needs to be done annually
- That it is safe to send fecal samples through the mail
- That FIT screening is easy and can be done at home with no dietary preparation
- That a follow-up colonoscopy is needed if a FIT result is abnormal
- That FIT is usually free (depending on insurance coverage), and that resources may be available to help pay for colonoscopy if one is needed



TIP: Ongoing patient education is important! Use visual aids or videos to emphasize that FIT is an annual test and that a follow-up colonoscopy is needed if the test result is abnormal.

Figure 1. Sample Educational FIT Display



Centralized vs. Distributed Staffing

The mailed FIT outreach program can be implemented by a single centralized team that handles all reporting, mailing, and receipt of FITs, or by smaller groups at each clinic that handle these elements individually for their patient populations. Most STOP CRC clinics found that a centralized approach worked best, because it freed frontline clinic staff from the burden of mailing FITs in addition to delivering direct patient care. Many clinic systems used EHR or data specialists to run patient reports and generate patient communications. Some groups had medical assistants temporarily place laboratory orders for the technical support team. Others used standing orders in the EHR to accomplish this. In some cases, physician panels reviewed lists of patients due for screening and returned the lists to a centralized administrative team that conducted the mailing.

A distributed staffing model may be preferable if the mailed FIT outreach program complements in-clinic FIT distribution - for example, if staff primarily hand out kits in the clinic and only mail kits to patients who do not get them during a visit. However, coordination between in-clinic and mailed FIT distribution could also be done electronically using real-time reports (as in STOP CRC) or by care teams updating mailing lists to remove patients who are reached in the clinic.



TIP: Establish a workflow and identify who will be responsible for requesting medical records from other facilities for historical colonoscopies. Front desk teams may need to handle duties such as receiving FITs and updating address information.

Chart Cleaning and Scrubbing

EHRs and claims data do not always capture all previous colonoscopies. Scrubbing EHR records to ensure they are fully updated can prevent unnecessary mail-outs to and calls from patients who have already been screened, minimizing unnecessary expenses. Mailed FIT outreach programs can still be successful even if EHR records cannot be fully scrubbed.

There are several ways to improve documentation of prior CRC screenings:

- **Colonoscopy report EHR tool** Automated EHR functions can systematically search scanned colonoscopy reports to identify scanned documents with "colo" or "colonoscopy" in the Comment field and no recorded colonoscopy in EHR-coded fields.
- **Claims review** Claims review can improve data captured from specialty service providers. Clinic staff should contact their health insurance plans and ask for claims data on prior colonoscopies for their patient list.
- **Manual scrub** Once a list of patients due for screening is generated using EHR codes, the team can manually review the EHR records to check for prior CRC screening.
- **Ask the patient during mailed FIT outreach** The mailed FIT primer letter can ask patients about their prior screening history and request that they call their clinic to update their records.



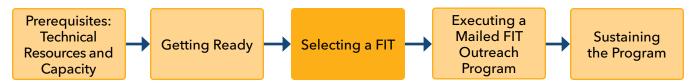
TIP: Create systems to coordinate the mailed outreach program with in-clinic FIT distribution. This can minimize patient confusion and reduce duplication of efforts. All clinic staff and leadership should be aware of the mailed FIT program and notified when mailed-FIT outreach occurs, either by email or through the EHR system.

Clinics can use their EHR tools to generate an initial list of patients who meet screening criteria and export this list to Excel for scrubbing. At the end of the scrub process, clinics can mail FITs to those who are identified as due for screening and follow up with the other patients as needed (e.g. to ensure that abnormal FITs were followed up).

Some clinics chose to divide scrubbing and mailing work by physician or patient's birth month. Thus, rather than run a global report for all patients in the clinic, they sorted patients into groups and worked to reach out to one group of patients each month.

TIP: Make sure you have sufficient staff for initial data cleaning and scrubbing. While scrubbing for historical colonoscopies can be labor-intensive, once past records are cleaned, the outreach efforts will be streamlined. Some clinics found a 10% increase in patients who had already been screened by recording historical information, which helped them meet their targets. They were also able to pinpoint the sources of gaps in documentation processes (such as not getting completed colonoscopy information) and address those gaps to improve colonoscopy data collection in the future. Consider the optimal frequency for scrubbing in your setting and determine staffing accordingly.

Selecting a FIT Kit



The mailed FIT outreach program can be implemented with a variety of kits, but some are easier for patients to complete and return. The selection of a FIT kit depends on laboratory processing capabilities and balancing the simplicity of the test with the accuracy of its results in a given population.

Key considerations for selecting a FIT kit based on Mailed FIT Summit

There is limited evidence concerning which FIT kit characteristics promote a successful response to FIT outreach, defined by returning the kit and also having a sample that can be processed.

Some key considerations for selecting a FIT for mailed outreach include:

- Quality and performance characteristics
- One-sample kits are better for mailed FIT programs than multi-sample kits due to ease and potential for higher response rates
- FITs that allow for batch processing with automation may be preferred
- The cost of tests or mailing
- Where the FIT will be processed (on-site, internal laboratory, or outside laboratory)

FIT Performance

All FITs are not created equal. They vary in both sensitivity and specificity (consistency of producing a normal result when cancer is absent). A <u>recent report by the National Colorectal Cancer Roundtable</u> summarized the performance characteristics of commonly used FITs. (27)

Because FITs test for human blood and lower gastrointestinal blood loss, FIT results are not influenced by food or medications, and most require only one or two stool samples. They have higher sensitivity (ability to find cancer when it is present) than guaiac-based tests (e.g. high sensitivity fecal occult blood tests) and are generally easier for patients to use.

FIT Costs

The cost [of mailing kits] is so minimal. And the folks who have insurance, you know, the reimbursement from them covers the cost for the few uninsured folks. And so ... the cost of the test ... and the processing ... [is], not a huge financial barrier.

-Operations Lead

Because CRC screening is recommended by the U.S. Preventive Services Task Force (A or B), tests are covered under the Preventive Services Mandate of the Affordable Care Act. This means that patients who have health care insurance cannot be charged for screening.

Medicare covers stool testing once every 12 months for patients age 50 and older if patients have an order from a doctor, physician assistant, nurse practitioner, or clinical nurse specialist. (28) Note that the age will soon be reduced to age 45 to align with current CRC screening guidelines. Most Medicare-enrolled adults younger than age 65 are dual-eligible beneficiaries (enrolled in both Medicare and Medicaid). (29)

Many laboratories provide FITs to clinics for free because they will be paid when the tests are returned for laboratory processing. If a selected laboratory does not offer free FITs, be sure to ask them about this option. If the health system is processing FITs in-house, calculate how much it costs to purchase and process the tests. The table below gives an example of potential FIT costs and expected reimbursement

Sample profit and loss calculation for FIT mailing program with internal laboratory

Mailing Program Variable	Cost each	Total Amt
Number of Kits		2000
Cost of Kits to clinic*	\$3.00	\$6,000.00
Postage to Mail Kits**	\$2.65	\$5,300.00
Return Postage (based on 30% return)	\$2.65	\$1,590.00
Total Initial Investment		\$12,890.00
Expected Return*	30.00%	600
Expected Insured	90.00%	540
Expected Return on Insured	\$25.00	\$13,500.00
Total Profit & Loss for Laboratory		\$610.00

^{*}Based on kits used in the STOP CRC study; kits are most often offered at no charge when an external laboratory is processing the kits and receiving the reimbursement.

NOTE: Clinics typically pay for the outbound postage, so this might be free for the laboratory

IMPORTANCE OF PARTNERSHIPS

St. Vincent de Paul Medical Center is a free clinic located in Phoenix, Arizona. The clinic had not practiced preventive medicine prior to 2015. To increase CRC screening rates, the clinic started a quality improvement project and developed a FIT program. Staff used best practices such as destigmatizing screening tests, using standing orders, standardizing protocols, implementing a patient registry, and sending regular reminders. The clinic was able to then reach or surpass 80% CRC screening rates between 2016 and 2021. (30) See the St. Vincent de Paul achievement award at NCCRT.org.

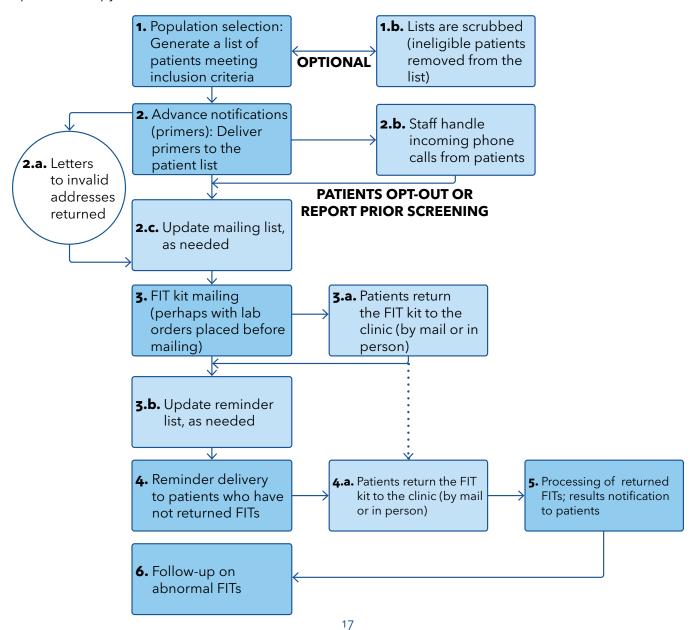
^{**}Postage based on 2016 rates to mail O.C. Auto Kits.

Executing a Mailed FIT Outreach Program



Program Workflow

The figure below shows the steps in the mailed FIT outreach process. The clinic or health plan generates of list of eligible patients, the list is scrubbed (if clinics or health plans opt to do so), and advance notifications (in the form of a letter, text message, or phone call) are sent. Staff handle incoming phone calls from patients and update the mailing list, removing the names of patients found to have an invalid address (if the advance notification was a letter). The FIT kit is mailed, and patients mail or drop off the completed FIT to the laboratory or clinic. A reminder list is generated and reminders are delivered to eligible patients. Completed FITs are processed, patients are notified, abnormal FIT results are tracked, and patients with abnormal test results are assisted in getting a follow-up colonoscopy.



IMPORTANCE OF PARTNERSHIPS

The <u>Healthy Aging Partnerships in Prevention Initiative</u> was created to increase cancer screening uptake in Black and Hispanic/Latino communities in South Los Angeles for adults aged 50 and over. Through this initiative, community health centers and community-based organizations increased their capacity to deliver clinical preventive services, including cancer screening. The initiative also demonstrated how existing resources could be utilized to increase the uptake of those services. (31)

Step 1: Population Selection

Before executing the mailed FIT outreach program, clinics should identify active patients who are eligible for screening, based on the clinic's definition of their outreach population (see *Outreach to Unestablished Patients* below).

To determine the total population due for CRC screening, clinics can use HEDIS or UDS criteria, including the variables below:

- Ages 45-75
- No FIT laboratory result in the last year
- No colonoscopy in last 9 years
- No prior diagnosis of colorectal cancer (codes 153.XX, 154. XX, 197.5X, and V10.05), colectomy (codes V15.29, V45.89), or inflammatory bowel disease
- Viable mailing address on file (K50-K52)

There may be additional criteria for some populations, such as:

- Visit to clinic in the previous year (or some other time window)
- PCP or birthday month (for smaller mailing groups)

Limiting the Program to a Smaller Target Population

For some STOP CRC clinics, the expense of mailing FITs to the entire population due for screening was too high, so they chose to limit the program in one of the following ways:

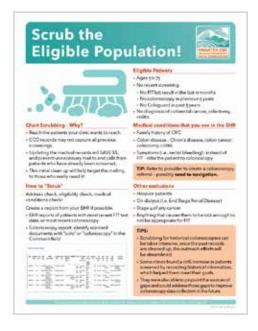
- Selecting patients with a clinic visit in the previous 6 months rather than a year.
- Mailing only to patients who had completed prior FIT testing.

Outreach to Unestablished Patients

Some individuals who are part of a clinic's population (such as those assigned by Medicaid) may not have seen a care provider at the clinic in the past year. The STOP CRC protocol limited mailing lists to patients who had been seen in the last year. This approach means some patients were not contacted, but also ensured that insurance information and consent-to-treat forms were likely to be current for patients being mailed FITs.

As a clinic decides whether and how to conduct outreach to patients who are not established at the clinic, they might consider the following options:

- Mail FITs only to patients who have an assigned provider and have been seen in the last year (or two). This practice ensures current insurance information and that patients are likely to receive care at the clinic.
- Ask patients to drop off kits in the clinic. When they do so, front desk personnel can be trained to gather insurance information and set them up with a new patient appointment.



- Have an intake specialist call patients to establish care. This outreach can include scheduling an appointment and instructing the patient to bring a completed FIT to the appointment.
- Mail FITs to the entire list of eligible patients and reach out to those who return the FIT to update insurance coverage information.

Health plans often reach out directly to their members regarding CRC screening and mailed FITs. Large health plans can manage outreach more efficiently, saving clinics time and money. Clinics and health plans can coordinate patient outreach so that patients receive reminders through multiple channels. (32)

Step 2: Advance Notifications (Primers)

An introductory letter or email (<u>see Resources</u> for examples) tells patients why they need CRC screening and that they will soon be mailed a FIT (or that a FIT is included in the same mailing). Benefits of this letter include:

- Helping clinics identify patients who have invalid addresses before spending money on mailing FITs.
- Prompting patients to call to report that they have already had CRC screening or schedule other types of CRC screening if they prefer it.
- Preparing patients to complete the test.

Requesting a deadline for the return of the kits

Emerging research suggests that having a deadline for return may improve response rates. The deadline could be referred to on the introductory envelope, in the invitation letter, or both. (32) Language such as "Please return within 7 days" could be used.

Advance notification text messages or live phone calls

A recent study showed that advanced notification live phone calls were particularly effective for adults who had no evidence of prior FIT testing. In this never-screened group, a live phone call led to a 30% FIT return rate, compared to a 15% return rate in patients who received an advance notification text message. (23) Moreover, the live call was helpful in increasing patient awareness about CRC and answering any questions they might have, overcoming patients' forgetfulness to complete the FIT, and providing an opportunity for clinic staff to update the EHR with correct address information or help establish the patient with a clinician, if needed. Patients reported that phone calls led to them feeling 'cared for' by clinic staff. (23, 33)



TIP: Text messages (with or without linked videos), automated phone calls, or live phone calls can be used in place of introduction letters. Some clinics have also developed educational fotonovelas (visual print narratives) that can be viewed on a cell phone.

Returned letters

If an introductory letter was returned due to an incorrect address or for another reason, STOP CRC clinics documented the return using the messaging feature of the EHR. That patient was not included in the STOP CRC eligibility reports until the address was updated. When the clinic received updated address information, staff would update it in the EHR, remove the prompt excluding the patient from reports, and generate a new letter for that patient.

Handling Phone Calls

Each STOP CRC clinic set up staffing and a process for handling phone calls from patients in response to the introductory letters. Call center staff should be alerted when the letters are sent, and the clinic manager should communicate with these staff to be sure they can answer patients' questions.

In STOP CRC, automated EHR tools were employed to assist with incoming phone calls. When a call came in, call center staff entered STOP CRC as the reason for the call, which automatically triggered a tool that had common actions to be taken in response to a mailed FIT call. Even if the clinic has an automated tool, staff still require training to be able to handle calls.

Call center and medical staff should be equipped to handle the following types of calls:

- Patient request for a new FIT kit.
- Patient questions about the FIT, including why they were mailed a screening test (<u>STOP CRC FAQ</u> for responses to common questions and answers).
- Patient has already had CRC screening, such as a colonoscopy. In this case, staff should record the prior screening in the EHR.
- A patient is ineligible for a FIT mailing due to a terminal or serious illness. In this case, the clinic staff should modify their EHR record to indicate the condition so that the patient is excluded from eligibility reports. Automated EHR tools can help with this process.

The National Colorectal Cancer Roundtable has great resources for customizing messages to different populations. The NCCRT's 2019 Colorectal Cancer Screening Messaging Guidebook: Recommended Messages To Reach The Unscreened (34) describes the rationale, attitudes, and motivations for getting screened for colorectal cancer, and includes market research-tested messages. The Hispanics/Latinos and Colorectal Cancer Companion Guide (35) and Asian Americans and Colorectal Cancer Companion Guide (36) introduce market research about the unscreened from these populations and include tested messages in Spanish and several Asian languages.

Best practices for primers based on Mailed FIT Summit

While additional research is needed, there is some evidence that advanced notification primers contribute meaningfully to the success of mailed FIT outreach. Local context should be considered, letters should be pilot-tested, and feedback on letter content should be solicited from target populations when possible.

Instead of or in addition to letters, primers may include text messages, live telephone calls, automated telephone calls, and/or postcards delivered *before* the FIT test mailing.

Introductory letters should be brief (one page or less), written at a low literacy level, and include the following elements:

- Branding from the patient's clinical home (clinic letterhead, provider or clinic leader signature)
- Information about the out-of-pocket cost of the test (or that the test is free)
- A telephone number to contact for questions
- A suggested time frame for response
- Instructions and encouragement for completing the FIT and general information about CRC screening (optional; it may be preferable to include separate print and graphical instructions for test completion within the mailed FIT packets, including in multiple languages)

Step 3: Mail FIT Kits

About two weeks after the introductory letter is mailed, clinics should generate a new report of patients who should be mailed the FIT kit. This report should exclude:

- Patients whose introductory letters were returned and for whom no updated addresses were found.
- Patients who called to decline participation.
- Patients who called to report prior CRC screening.

The FIT kit should be mailed together with instructions (see <u>Customizing FIT instructions</u>), a return envelope, and a FIT Insert explaining what the FIT kit is and why patients are receiving it (<u>see Resources</u> for wordless Instructions and FIT Insert samples).



TIP: Check the expiration dates of the FITs before they are mailed out in bulk; ensure that FITs are mailed at least six months before the expiration date.

Preparing FIT Kits for Laboratory Mailing

Before putting FIT kits into mailing envelopes, staff may need to prepare return envelopes (<u>see Mailing and Receiving FIT Kits</u> for FIT return and postage options).

Once materials were printed and laboratory orders were placed, STOP CRC clinic staff followed these steps to mail the FIT kits:

- Affix a FIT label printed from the EHR with patients' medical record number and Date of Birth fields filled in over existing labels on the test vials. Staff in some clinics highlighted the collection date field with a yellow highlighter (see nearby image). (37)
- Replace the instructions that come with the FIT package with the instruction page used by the program. If a laboratory requisition needs to be included with the completed FIT, place this form in the envelope.
- 3. Attach patient mailing address labels and verify a match between the mailing label, the test vial labels, and (if applicable) the laboratory requisition form.





- 4. If patients are to mail FITs to the clinic, clinic staff will need to affix a stamp and an address label with the clinic's address, or use USPS-approved preprinted business reply envelopes. If completed FIT kits are to be mailed directly to the laboratory, the laboratory may provide business reply envelopes with the laboratory address. If patients are to return the FITs in person, a sticker should be placed on the outside of reply envelopes to instruct patients to bring the FIT back to the clinic.
- 5. Stamp and mail the FIT packages.



TIP: For STOP CRC, the EHR automatically documented that the FIT had been mailed when the test was ordered. In the absence of an automated tool, staff should have a workflow in place to document and track the mailing.

FITs returned due to incorrect address

If a FIT was returned due to an incorrect address, STOP CRC clinics documented this using the messaging feature of the EHR. Patients whose FITs were returned were not included in STOP CRC eligibility reports until their address was updated. If a new address was obtained and entered into the EHR, clinic staff placed the laboratory order again and re-sent the kit.

Best practices for FIT kit instructions based on Mailed FIT Summit

FIT Kit instructions should:

- Be simple, with strong consideration given to wordless instructions
- Include separate print and graphical instructions for test completion within the mailed FIT packets, including in multiple languages
- Address the challenge of adequate stool collection and ensure that participants provide the collection date to avoid failed processing of returned FITs

I think the advantage of introducing it on a small scale is that we can just get all our supports in place and get kind of the physicians' real endorsement of the process. And then once we have that, and we've got our team and all of our kind of logistics in place, then spreading to other clinics is far easier. —Quality Improvement Manager

Customizing FIT instructions

The instructions accompanying FITs are often complicated and hard to follow. For this reason, it is helpful to include a simplified version of FIT instructions in the mailing.

STOP CRC created wordless instructions for three popular, evidence-based FITs (available at www.mailedfit.org under Program Materials). A partnership with Ontario Cancer Care led to the simply worded instructions seen in the box to the right. The Insure instructions (image on far right) are also bilingual (English/Spanish).





Wordless or simply worded pictorial instructions are particularly important for populations who have difficulty reading detailed or complex instructions. (38) In addition, laboratory orders require that the sample collection date be recorded on the collection device, so the mailed FIT instructions should emphasize the importance of properly recording the date.

l've had patients come...when I was rooming them say, oh, I got an abnormal FIT kit, and it turned out I didn't have colon cancer, or I did, but the fact that they got checked out, they're very thankful to the provider... —Quality Improvement Lead

IMPORTANCE OF PARTNERSHIPS

In Baltimore City, Maryland, partnerships among local health departments, hospitals, and the American Cancer Society facilitated the successful implementation of a collaborative screening outreach program targeting uninsured and low-income residents. Successful tactics included the use of template contracts, quality assurance protocols, case management procedures, and a screening database. (39)

Mailing Options

Mailed FIT outreach programs should include a structure for mailing and receiving kits and for optimizing response rates. Clinics will need to make the following decisions about their mailing structures:

One-time mailing vs. staggered mailing

As mentioned above, while some clinics will find it easiest to do one or two large mailings per year, clinics with many patients due for screening may choose to divide their patient lists into smaller groups and conduct staggered mailings to evenly distribute staffing needs as well as demand for patient follow-up colonoscopy referrals. Clinics with seasonal, temporary staffing help, such as interns, might consider having these personnel handle large mailings.

Including introductory letter with kit vs. separately

Some STOP CRC clinics chose to send introductory letters with the kits themselves rather than mailing them before mailing FIT kits as outlined in the workflow above. This approach reduces the amount of staffing needed for printing and mailing tasks and saves postage costs. However, it does not prepare patients for the mailing nor alert them to the importance of CRC screening, and is associated with lower return rates. Postage and staffing cost savings could be offset by the lower response costs and unopened kits (with higher postage costs than letters) being returned because of outdated or inaccurate addresses. A decision of whether to send introductory letters before or with FIT kits may depend on clinic capacity, expected accuracy of patient addresses, and expected response rates.

Mailed vs. in-person FIT returns

Some STOP CRC clinics chose to have patients return their FIT kits in person. In-person returns eliminate reply postage costs and allow clinic staff to verify and update patient information, including insurance status information, before placing the laboratory order. The downside of in-person returns is patient inconvenience, especially in rural areas where clinics might be far away or patients might not have easy transportation options. These factors may reduce response rates.

Envelopes and postage options

With mailed FITs, response rates are much higher if postage is prepaid on reply mailers. Many laboratories supply business reply envelopes that are pre-stamped and pre-addressed to the labs. If opting to have FITs returned to the clinic, stamp all outbound reply envelopes, or work directly with the laboratory or FIT manufacturer to get business reply envelopes printed with the clinic's address. The advantage of envelopes pre-printed with postal codes is that postage is paid only on the returned FITs, but this often requires setup time and approvals from the laboratory and post office. If sending a large volume of kits, it is worth getting business reply envelopes set up in advance. Branding envelopes and labeling them as time-sensitive or providing a deadline for return may also help promote the opening of mailings and FIT returns.



TIP: Be sure to work with the post office to ensure that postage rates are correct for both mailing out and returning FITs and that there are no barriers to timely delivery. Postage was more complicated than anticipated for a number of clinics during the STOP CRC rollout, resulting in additional staff time to correct problems. Lower-cost bulk rates also may be available.

Step 4: Reminders

About 2-3 weeks after FIT kits are mailed, clinics should send a reminder to those who have not returned the test. Meta-analyses have shown incremental increases in stool testing from using reminder letters (3% increase) or live telephone calls (6% increase). (19)

In STOP CRC clinics, the process for sending reminder letters was similar to the introductory letter workflow. Clinics ran a report that excluded invalid addresses and patients who had opted out or who had already completed the screening. They selected patients from the report to receive the letter, chose the Reminder Letter template, and printed out the letters in batches for mailing (or emailed the letters, for those who had indicated this was their preference).



TIP: Personalize phone calls as much as possible by referencing the patient's clinic or provider and/or using a familiar recorded voice (for automated calls). If possible, ensure that the patient's caller ID shows a local area code.

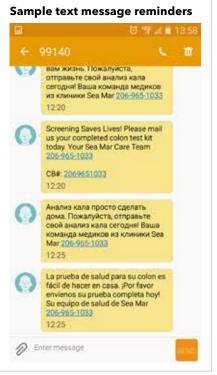
Other Reminders: Phone Calls, Text Messages

In addition to mailed or emailed reminders, some clinics have used telephone calls or text messages to remind people to return their FITs. Phone calls take more staff time and are more expensive than text messages, which are less costly but may take more data infrastructure to set up.

Telephone calls and text messages can be made by clinic staff or a vendor. If using a vendor, set up a call or text script, define parameters for the times at which reminders are to be delivered, and develop tracking and reporting protocols to produce reports on the total number of patients contacted, whether patients were reached, and how each call or text was handled (transferred to a live person, etc.).

A comparative effectiveness study of Mailed FIT outreach reminders found that Spanish-preferring adults had higher return rates than English-preferring adults following reminders (34.1% vs. 22.4%). (40) In addition, the most effective communication mode varied by language preference: Spanish-preferring adults had the highest rate of return following a combination of automated and live phone calls, while English-preferring adults had the highest return rates following live phone calls alone. Further research is needed to

identify successful communication modes, including videos and fotonovelas, to more effectively reach underserved populations.



Best practice for Mailed FIT reminders based on Mailed FIT Summit

Reminders (postcards, text messages, mailed letters, or automated or live telephone calls, with or without patient navigation) lead to small to moderate increases in stool test uptake.

While additional research is warranted, the following is recommended for reminders:

- Implement at least one type of reminder after mailed outreach among initial non-completers to increase FIT return rates.
- Clinic staff who make reminder calls should know a patient's health history, be knowledgeable about CRC screening, and be able to communicate to the patient's physician.

Step 5: Process Returned FITs

A laboratory order may be placed in tandem with FIT mailing, or it can be placed once a completed FIT is returned to the clinic. The order may need to include laboratory requisitions to process the FIT once it is returned.

Some EHRs, like Epic, have the option to place a batch of FIT orders at the same time (see <u>Example EHR and Tracking Reports, Detailed Report Definitions</u> for specifications on Bulk Ordering FITs). This process was developed and used in STOP CRC.

FIT returns tend to be staggered over about 3 months, with the majority of returns coming within 4 weeks of invitation. Depending on the size of the population, laboratory processing location, type of FIT used, and other variables, clinics have the following options for receiving and processing FITs:

- 1. Have patients return FIT kits to the clinic and process them at an internal laboratory. This process is the most streamlined for clinics who have the necessary laboratory capacity and do not have an existing relationship with an external laboratory that handles FIT testing. If clinic staff receive returned FIT kits from patients, staff should check for a sample collection date on each collection device as it is returned and request the date from the patient if necessary.
- 2. Have patients mail their FIT kits to an external laboratory. This workflow requires some way of creating and printing laboratory requisitions before FIT kits are mailed. In the Epic EHR system primarily used in the STOP CRC study, clinics needed to create a laboratory appointment for each patient receiving a FIT before they were able to place a laboratory order. The printed laboratory requisitions could then be included in the package mailed to the patient.
- 3. Have patients return the FIT kits to the clinic, where clinic staff create laboratory requisitions for completed kits and send kits to an external lab. This option enables a clinic to place laboratory orders after sending FIT kits. Depending on the EHR, you may need to create a laboratory appointment for each patient who returns a FIT, but not for patients who do not return FITs.

Laboratory Billing

Laboratory billing for FIT testing requires up-to-date insurance status information or federal poverty level (FPL) information, values that are generally updated during in-person clinic visits. If clinics are unable to pay for testing of uninsured patients, they will need to have up-to-date FPL information for uninsured patients. Some STOP CRC clinics chose to call all patients due for screening to attempt to update the FPL field information in the EHR; others were able to determine whether the FPL field had been updated within the year and used the recorded information when this was the case. Clinics should evaluate where they can get updated FPL information if needed.

IMPORTANCE OF PARTNERSHIPS

Dr. Cynthia Yoshida is the medical lead of the <u>University of Virginia Cancer Center Colorectal Cancer Screening Program</u>. She developed a program that improved access to quality CRC screening for employees, patients, and underserved Virginia communities. Dr. Yoshida and her team created a free CRC screening program that served 400 uninsured patients in rural areas. She and her team also established partnerships with gastroenterology practices to provide free or lower-cost follow-up colonoscopies for patients with abnormal findings after FITs. (41) <u>See Dr. Yoshida's achievement award at NCCRT.org</u>.

Step 6: Abnormal FIT Follow-up

Entering FIT Results into the EHR

Typically, FIT results come electronically to the EHR through a laboratory interface, and the provider or care team is notified that results have been added to the record. It is important to determine how patients will be notified of results.



TIP: It is important to standardize the placement of the results information on the patient chart. This practice includes both FIT results and colonoscopy reports. Clinics should create a workflow to verify that colonoscopy was completed and documented in the medical chart.

Follow-up for Abnormal FIT Results

Before FITs are mailed out, a follow-up protocol should be in place to ensure a timely response to abnormal FIT results. Delaying colonoscopy 6 to 9 months after abnormal results may lead to significantly worse colorectal outcomes than timely colonoscopies within 30 days. (42) Follow-up colonoscopy should ideally occur within 90 days of the abnormal result.

The protocol should clearly define and track four steps: informing patients of their results, scheduling and completing a colonoscopy, returning colonoscopy results to the patient, and scheduling a treatment consultation if cancer is found. When designing a follow-up protocol, it is important to ensure that colonoscopy capacity is sufficient to meet demands for services.

Interventions that may help to moderately increase completion rates of follow-up colonoscopies include designating a single staff member to perform follow-up referral and patient support activities;

Who notifies patients of normal and abnormal results?

- Registered Nurse
- Licensed Practicing Nurse
- Provider PCP
- Specialist's Office

What is the preferred method of contact?

- Phone
- Letter
- Patient Portal

generating patient tracking lists 30, 60, and 90 days after abnormal results; standardizing outreach protocols for patient navigators; mailing certified letters to unresponsive patients; and adopting a quality metric goal to achieve greater than 80% completion of follow-up colonoscopy within 90 days of abnormal results. (43, 44)

IMPORTANCE OF PARTNERSHIPS

Esperanza Health Centers provides high-quality healthcare services to underserved communities in Southwest Chicago. Esperanza started implementing a team-based model in 2016 to increase CRC screening rates. The model uses an integrated three-person team comprised of a care coordinator, a medical assistant, and a provider that works with each patient to optimize care. Screening rates increased from a 2015 baseline rate of 43% to 69% in 2016. The health centers reached and maintained 80% screening rates between 2017 and 2019. During COVID-19, care teams focused on delivering frequent reminders and FITs with prepaid return envelopes. (45) See the Esperanza achievement award at NCCRT.org.

Best practice for Abnormal FIT follow-up based on Mailed FIT Summit

Effective strategies for ensuring abnormal FIT follow-up include:

- Implementing protocols and procedures to ensure completion of diagnostic colonoscopy after an abnormal stool test
- Use of patient navigators (note: patient navigation, by itself, may not be sufficient to promote timely follow-up colonoscopy completion without system-level strategies)
- Multicomponent strategies (note: more data is needed to understand the effectiveness and feasibility of these strategies in more settings)

Sustaining the program over time



Sustaining a mailed FIT outreach program over time can take careful planning. Research shows that people who have previously completed FIT testing are much more likely than those who have never completed testing to respond to mailed FIT outreach. (18, 46) Some programs have shown greater effectiveness from one year to the next as processes become streamlined and patients become more accustomed to receiving FITs by mail. Nevertheless, questions remain about how best to optimize programs so that they can be easily sustained over time. Some programs have stratified patients so that easy, low-cost prompts or reminders are delivered to patients who are familiar with testing, and higher-intensity outreach is used for patients who are new to FIT testing and may experience reluctance or be unaware of their need for testing. (23)

The key to sustainment is securing adequate resources (funding and staffing) and having external policies that expand patient access to care services and that promote health system/health plan reporting and goal-setting toward reaching established benchmarks. Partnerships across sectors can also create opportunities for long-term sustainment. The Mailed FIT Summit identified several strategies to successfully sustaining the program over time (see below).

Best practice for program implementation and sustainability based on Mailed FIT Summit

Strategies that have been shown to help ensure the sustainability of mailed FIT outreach over time include:

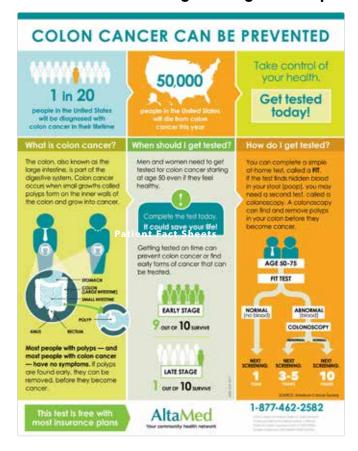
- A reliable funding mechanism to deliver mailed outreach components
- Organizational alignment (leadership engagement and dedicated staff)
- An organized, well-defined, and well-documented screening approach with explicit policies and standard workflows for how the screening should be performed and for identifying target populations
- An oversight process, with a management team responsible for implementation
- A quality assurance structure with a dedicated quality improvement team to enhance implementation
- Tracking for complications of screening, abnormal FIT follow-up, and cancers detected
- Consideration of private health plans and Medicare and Medicaid managed care programs that may benefit from tracking, monitoring, and reporting CRC screening metrics

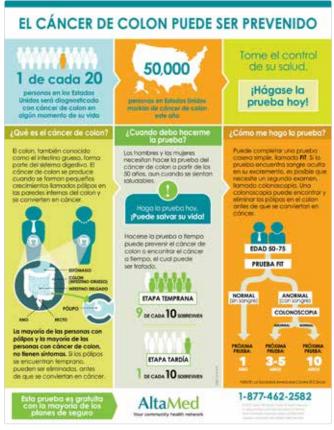
Resources

Patient materials that were used in recent mailed FIT outreach programs can be found at www.mailedfit.org under Program Materials. Available materials include the following:

- Introductory & Reminder Outreach
 - Letters
 - Text messages
 - Phone call scripts
- FIT Materials
 - Wordless instructions
 - Letters to be mailed with the FIT
- Patient Education
 - Fact sheets
 - Videos
- Patient Navigation
 - Training materials
 - Videos
- Data Tracking and Reports
- Executing the Program
 - Implementation Guide
 - Workflows

Patient Fact Sheets: Images of English and Spanish versions

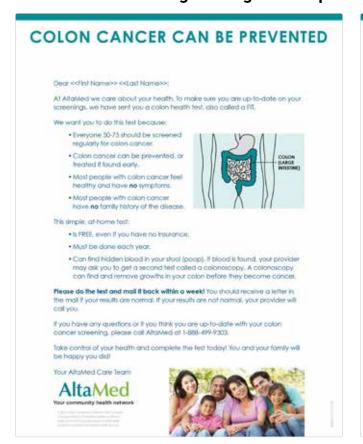








Patient Fact Sheets: Images of English and Spanish versions





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Appendices

Appendix A. Possible Adaptations to a Mailed FIT Outreach Program

Program Component	Potential Adaptations
Population to receive program	 All eligible patients/enrollees Adults with a given insurance type (e.g., Medicaid/ dual Medicaid-Medicare insured) Adults with a given prior screening history (e.g., those who have/have not completed a prior FIT) Adults who opt in, based on phone calls or email outreach
Identification of eligible adults and obtainment of accurate contact information	 Obtain updated contact and enrollment information from patient/enrollee Run eligible patient list through the US Postal Service address verification process Reconcile address lists from multiple sources (health record, claims data, hospital ER admissions)
Introductory outreach	 Introduction letters (possible phone call to adults with invalid addresses) Live or automated phone calls (possible letter to non-working phone numbers) Text messages (additional adaptations: interactive, with or without linked videos) Fotonovelas Emails
FIT mailing	 Special packaging (brightly colored envelopes) Highlight sample collection date on FIT label or packaging FIT kit insert
FIT instructions	Wordless instructionsText message with link to video instructions
FIT reminders	 Live or automated phone calls Text messages (additional adaptations: interactive, with or without linked videos) Letters/ postcards Fotonovela Emails
Follow-up to abnormal FIT results	 Patient education about the possible need for follow-up colonoscopy in FIT materials/messages Registry to track patients with abnormal FIT results Direct referral to colonoscopy Provider reminders / provider audit and feedback Replacement of pre-procedure visit with phone call In-house gastroenterology provider Patient navigation

Appendix B. Using Dot Phrases to Track Reminder Calls in the EHR

Consistency in and standardization of patient messages are helpful for tracking purposes. The table below presents examples of phrases staff at one clinic used to track their calls. By using 'dot phrases' such as ".lm", staff were able to quickly enter standardized phrases in the EHR, such as "Voicemail reminder left for the patient regarding outstanding FIT order. Expecting a call back to the CRC Program at xxx-xxxx."

When do I use it?	Dot phrase	Message body
You left a message for the patient	.lm	Voicemail reminder left for the patient regarding outstanding FIT order. Expecting a call back to the CRC Program at xxx-xxxx.
Patient confirmed receipt of FIT and said when they'd mail it	.pc	Confirmed: Patient is aware of colon health screening and will mail FIT promptly.
Patient reports that they need a replacement FIT	.frep	Second FIT: Patient is aware of colon health screening and will mail replacement FIT promptly.
Patient reports they never received a FIT and want one	.onf	Order without FIT: Patient is aware of colon health screening and will mail FIT promptly.
Patient states that they would not like to do the test	.re	Refusal: Patient would not like FIT screening at this time. Please revisit the importance of colon cancer screening at the next office visit.
Unable to speak with or leave a message due to incorrect number, no voicemail.	.npc	Unable to contact or leave a message with the patient regarding outstanding FIT laboratory order. If the patient calls, please forward to the CRC Program at xxx-xxxx.
Patient reports they had a colonoscopy	.co	Colonoscopy was reported by the patient from (facility name, year). Records request initiated on (date).
Patient transferred care	.tc	Transferred Care: Patient stated that they have transferred care.

Appendix C. Colorectal Cancer Screening Rate Measures

The table below shows how CRC screening is defined across various reporting systems, including the Government Performance and Results Act (GPRA), the Health Care Effectiveness Data and Information Set (HEDIS), the Uniform Data System (UDS), and the National Quality Forum (NQF). More information on measuring CRC screening rates if provided by the Centers for Disease Control and Prevention. (47)

Measure	Reporting Period	Performance Measure	Appropriate Screening Definition
Government Performance and Results Act (GPRA).	July 1-June 30.	Proportion of clinically appropriate patients 45 through 75 years of age who have received colorectal screening.	Fecal occult blood test (FOBT) or fecal immunochemical test (FIT) during the reporting period; flexible sigmoidoscopy in the past 5 years; or colonoscopy in the past 10 years.*
Health Care Effectiveness Data and Information Set (HEDIS).	January 1-December 31. Measures reported to National Committee for Quality Assurance (NCQA) annually in June.	Percentage of adults 45-75 years of age who had appropriate screening for colorectal cancer.	Fecal occult blood test (FOBT) or fecal immunochemical test (FIT) during the measurement year; flexible sigmoidoscopy during or 4 years before the measurement year; FIT-DNA test during or 2 years before the measurement year; CT colonography during or 4 years before the measurement year; or colonoscopy during or 9 years before the measurement year. *
Uniform Data System (UDS).	January 1-December 31. Measures reported to Health Resources and Services Administration (HRSA) annually in February.	Percentage of patients 45-75 years of age who had appropriate screening for colorectal cancer.	Fecal occult blood test (FOBT) or fecal immunochemical test (FIT) during the measurement year; flexible sigmoidoscopy during or 4 years before the measurement year; FIT-DNA test during or 2 years before the measurement year; CT colonography during or 4 years before the measurement year; or colonoscopy during or 9 years before the measurement year.**
National Quality Forum (NQF)- Endorsed Measure.	January 1- December 31.	Percentage of adults 45-75 years of age who had appropriate screening for colorectal cancer.	Fecal occult blood test (FOBT) or fecal immunochemical test (FIT) during the measurement year; flexible sigmoidoscopy during or 4 years prior to the measurement year; FIT-DNA test during or 2 years before the measurement year; CT colonography during or 4 years before the measurement year; or colonoscopy during or 9 years before the measurement year. *

^{*} Updates to the colorectal cancer screening GPRA, HEDIS and NFQ metrics exclude individuals age 65 and older who have an advanced illness and frailty or who live long-term in nursing home settings. (48, 49)

^{**} Updates to the colorectal cancer screening UDS metric exclude individuals age 66 and older who have an advanced illness and frailty or who lived in an institution for more than 90 days during the measurement period. (50)

Appendix D. EHR Codes to Identify Eligible Adults

INCLUSION/EXCLUSION CRITERIA	DEFINITION/ CODES
INCLUSIONS	
AGE 45-75	Greater than or equal to 45 AND less than or equal to 75 at time of query
VITAL STATUS	Patient is alive
EXCLUSIONS	
PREVIOUS COLONOSCOPY	9140 (Referral), 44388-44392, 44394, 44397, 45355, 45379- 45385, 45387, 45391-45392, 848008 (HIE Colonoscopy Procedure), G0105, G0121, HX0060
FIT/FOBT	82270, 82271, 82272, 82274, G0328, G0394, LC908, LP926, LP1081, LP1398, LS652, LS885, LS900, LS901, LS902, LS912, LS932, LS944, LS945, LS990, LS992, LV414, LV472, LV510, LV705, LV877, LV908, LV919, LV1433, LV1542, LV1576, LV1684, LV1737, LV1804, LV2180, LV2301, LV2856, LV3193, LV3415, LV3509, LV3803, LV4289, LX063, LV5546, LV5550, LV5554
SIGMOIDOSCOPY	45330, 45331, 45332, 45333, 45334, 45335, 45337, 45338, 45340, 45341, 45342, 45345, G0104
COLORECTAL CANCER	C18.1, C18.2, C18.0, C18.3, C18.4, C18.5, C18.6, C18.7, C18.8, C18.9, C19.X, C20.X, C21.8, Z85.048, Z85.038, C78.5
COLORECTAL NEOPLASM	D49.0
TOTAL COLECTOMY	Z90.49
ALZHEIMER'S/DEMENTIA	G30.9, F02.80, G30.1, G30.8, E85.89, G30.0, F01.51, F01.50, F03.90
HOSPICE CARE	Z ₅ 1.5
ASSISTED LIVING	Z59.3

^{*}Additional potential exclusion codes are: colorectal polyp (K63.5); adenoma by biopsy (D12.6); family history of colorectal cancer (Z80.0); inflammatory bowel disease (K52.9, K50.90 (Crohn's), K51.90, K51.00 (Ulcerative colitis), Z87.19); metastatic cancer (C85.83, B27.09, C71.9 (diagnosis of glioblastoma), C25.9 (diagnosis of pancreatic cancer), C45.9 (diagnosis of mesothelioma), C34.9 (diagnosis of lung cancer), C15.9 (diagnosis of esophageal cancer), C24.0 (diagnosis of liver and bile duct cancer); and screening contraindicated (based on Preventive Health Tracking Tool (i.e. Health Maintenance in Epic)).

Mailed FIT Resources and Templates

The following Mailed FIT Resource Guide provides additional resources identified during a Landscape Analysis of Mailed FIT screening conducted by Leavitt Partners in 2020 under the direction of the CDC and the NACDD on behalf of the Mailed FIT Summit leaders. The document highlights currently available mailed FIT resources and templates. Some of this information was published in the report "Mailed Fecal Immunochemical Test Outreach for Colorectal Cancer Screening: Summary of a Centers for Disease Control and Prevention-Sponsored Summit." Of the 200+ resources identified during the analysis, duplicates were removed, and only those resources developed after 2010 were included in the list below.

The NACDD and the Mailed FIT Summit Advisory Committee would like to acknowledge the work of <u>Leavitt Partners</u> in conducting the Landscape Analysis and creating this valuable best practices resource.

Data Infrastructure			
General Trackers	Health Plan Trackers		
Contact Sheet by the Against Colorectal Cancer in Our Neighborhoods (ACCION) program Sample SQL Database by the Fecal Immunochemical Test (FIT) and Colonoscopy Outreach: Products program	BeneFIT Data Tracking Form Instructions by Kaiser Permanente Center for Health Research (KPCHR) BeneFIT Health Plan Tracking Sheet by KPCHR BeneFIT Health Plan Vendor Tracking Sheet by KPCHR		

Flu-FIT and FOBT Trackers

Sample Flu-FIT and FOBT Log Sheet and Tracking Form for Abnormal FIT (links on the website) by UCSF

FIT Kit Selection

Fact Sheet

<u>Clinician's Reference: Stool-Based Tests for CRCS</u> by American Cancer Society

Advanced Notification Primers			
Call Scripts	Text Messages		
<u>Automated Telephone Message Script</u> by KPCHR Outreach Call/Voicemail Scripts (<u>English</u> , <u>Spanish</u>) by Kaiser Permanente	Text Message Primer (<u>English and Spanish</u>) by KPCHR		
Brochures/Pamphlets	Letters		
Patient education resources (poster 1-English, poster 2-English, poster 3 - Spanish, poster 4 - multiple languages) by UCSF Screening options brochure by the Smart Options for Screening (SOS) program	Introductory letter in English and Spanish by KPCHR Incentive letter in English and Spanish by KPCHR Patient outreach letter (English, Spanish, Chinese and Russian) by the STOP CRC program at KPCHR FIT Kit invitation letter by the FIT and Colonoscopy Outreach program Educational patient letter in English and Spanish by the PROMPT program at KPCHR FIT Letter (in 32 languages) by Cancer Care Ontario		

FIT Kit Instructions			
OC FIT Instructions	InSure FIT Instructions		
Here's How to Use Your FIT Test by MetroHealth 1-page FIT Instructions (English) (Spanish) by UCLA Health	InSure ONE Fit Instructions (<u>English and Spanish</u>) by KPCHR		
3-page FIT Instructions (<u>English</u>) (<u>Spanish</u>) by UCLA Health			
FIT Instructions (<u>in 32 languages</u>) by Cancer Care Ontario			
<u>Graphical FIT Instructions</u> by Cancer Care Ontario and KPCHR			
OC FIT Instructions (<u>English</u>) (<u>Spanish</u>) (<u>Vietnamese</u>) (<u>Russian</u>) (<u>Chinese</u>) (<u>Hindi</u>) by UCSF			
OC-Light Kit Instructions, by KPCHR			

Video Instructions

FIT test video instructions (English and Spanish) by KPCHR

FIT and FOBT Instructional Videos for Patients (<u>available in this link</u>) in English, Spanish, Cantonese, Mandarin, Vietnamese, Russian, Korean, Llokand, Hmong, and Tagalog by UCSF

Mailed FIT Reminders	
Call Scripts	Letters
Reminder Call Scripts (<u>English and Spanish</u>) by KPCHR	Patient reminder letter by KPCHR
Reminder Call Scripts (<u>English, Spanish, and Russian</u>) by KPCHR	
Automated Call Reminder text (English and Spanish) by KPCHR	
Health Plan Call Script by the SOS program	
Postcards	Flyers
Postcard Reminder (<u>English and Spanish</u>) by KPCHR	Mailed Reminder Flyer by the Department of Veterans Affairs

Abnormal FIT Follow-Up

Letters

<u>Abnormal FIT test follow-up letter</u> by KPCHR (also includes follow-up from normal FIT test)

Abnormal and Normal FIT results notification letters in English and Spanish by the ACCION program

<u>Abnormal</u> and <u>Normal</u> FIT results notification letters in English and Spanish by the FIT and Colonoscopy Outreach program

Letter to patient's provider on FIT test results by the ACCION program

RN Positive FOBT/FIT Checklist by the SOS program

Program Implementation and Sustainability		
Note: Many of the resources in this section were developed for specific programs.		
Workflows	Implementation Guides	
FIT: Patient in Clinic Workflow by KPCHR Direct-Mailed FIT: Intro Letter & Patient Opt-Out	Program Implementation Guide by the SOS program	
Workflow by KPCHR Direct-Mailed FIT: Ordering FIT & Results Receipt by KPCHR	FIT and Colonoscopy Outreach Implementation Guide by the Putting Public Health Evidence in Action program	
<u>Direct-Mailed FIT: Incoming Calls</u> by KPCHR <u>Direct-Mailed FIT: FIT Results Review</u> by KPCHR	Program Implementation Guide by the Colorectal Cancer Education, Screening, and Prevention Program (CCESP)	
Execute FIT Kit Screening Program by KPCHR	<u>FluFIT Implementation Guide</u> by the American Cancer Society	
FIT Strategy Workflow by the FIT and Colonoscopy Outreach program		
Guides/Workflows for Health Plans	Program Follow-Up Material	
How to Implement a Mailed FIT Colorectal Cancer Screening Program: A Guide for Health Plans by KPCHR	Nine-Month Follow-Up Brief Questionnaire by the Family CARE (Colorectal Cancer Awareness and Risk Education) project	
<u>Health Plan Model Advantages and Challenges</u> by KPCHR		
<u>Health Plan: Direct Mailed FIT Workflow</u> by KPCHR		
Patient Education		
Factsheets/Brochures	Infographics	
Mailed FIT Q&A (English and Spanish) by KPCHR	Colon Screening Path infographic by KPCHR	
One-page FLUFIT advertisement by the American Cancer Society, CHAD, and NCCRT	Get Screened Medical Office Flyer by KPCHR	

