Screen to Prevent (STOP) Colon Cancer Implementation Guide

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Mailed FIT Program Implementation: Guide for Clinics

Importance of CRC Screening Programs

Colorectal cancer is the second-leading cause of cancer deaths, even though early detection is extremely effective. When colorectal cancer is detected early, the likelihood of surviving five years is 90%. Survival drops to 69% for cancers that are diagnosed at regional stages, and to 8% when found at an advanced stage.

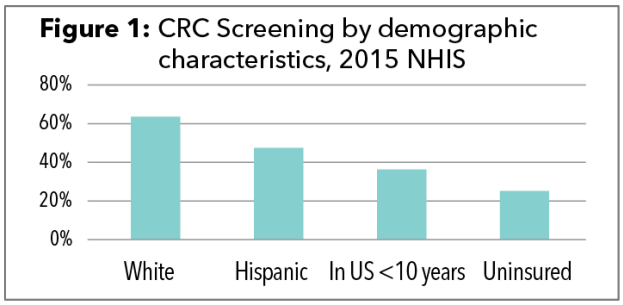


Figure 1: CRC Screening by demographic characteristics, 2015 NHIS

Despite the effectiveness of early detection, many age-eligible adults in the United States are not current with guidelines for colorectal cancer screening. A national survey in 2016 showed that 33% of adults aged 50 to 75—nearly 28 million people—were not up to date with screening.[1] Screening rates are particularly low for certain groups, such as adults with little schooling, low incomes, or no health insurance. Rates were also disproportionately low among recent immigrants, those with no usual source of care, and Hispanics **(see Figure 1).**

Fecal Immunochemical Testing vs. Colonoscopy

This project promotes the use of fecal immunochemical tests (FITs) for colorectal cancer screening. While colonoscopy is considered the gold standard by many professional organizations, it may not be optimal for primary screening for all patients. Fecal testing is an important component of a colon screening program.

- **Colonoscopy access can be limited.** Endoscopic capacity can be limited in some geographic regions, procedure costs can be high, and access can be limited. FITs are non-invasive, the cost is low, and for most people, the test is easy to do.
- **Fecal testing is as effective as colonoscopy.**[2] Modeling studies show that routine use of fecal testing and colonoscopy can equally reduce mortality from colorectal cancer.

Screening test	Mortality reduction*
Colonoscopy every 10 years	65%
FIT every year	64%
Flex sigmoidoscopy every 5 years	59%
Flex sigmoidoscopy every 5 years plus FIT every 3 years	66%

*reduction in mortality over 10 years by each type of screening test

- **Fecal testing your population leads to fewer colonoscopies.** A population-based FIT approach leads to fewer colonoscopies which can ease capacity limits in some geographic regions.
- **Patients prefer fecal testing to colonoscopy.** Fecal testing requires no bowel preparation, it is done in the privacy of home, and there is no need for time off work or assistance getting home after the procedure. Notably, patients with an abnormal FIT result will still need colonoscopy as follow-up to prevent colon cancer or find it in an early, treatable stage.
- **Fecal testing can find early signs of colon problems.** Patients who screen positive on a FIT have a 5% chance of having colorectal cancer; dedicating colonoscopy resources to this "high risk" group can save more lives.

"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

Advantages of Mailed FIT Programs

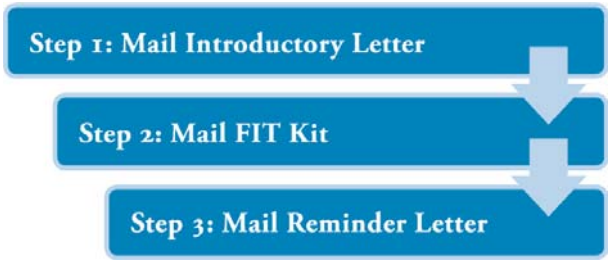
Mailing FIT kits directly to patients, is an evidence-based, effective way to get more patients screened for colorectal cancer.

Here are some advantages of mailed FIT programs:

- Mailed FIT programs have consistently been shown to improve rates of colorectal cancer screening (effect sizes 7%-40%).
- Mailed FIT programs can help clinics meet quality goals and statewide metrics (such as the Coordinated Care Organization metric for colorectal cancer screening in Oregon).
- Mailed FIT is a population-based strategy that relieves the burden on primary care physicians to do outreach during office visits. It overcomes limitations of opportunistic screening, and can happen in coordination with in-clinic screening efforts.
- Mailed FIT programs may help address health disparities: some studies have shown that direct-mail programs elicit as good a response, or better, from Spanish-speaking patients as English-speaking patients[3,4].
- Patients appreciate alternatives to screening colonoscopy, and the outreach makes them feel "cared for" by their health center.

Overview of STOP CRC Program

Screen to Prevent Colon Cancer (STOP CRC) is a research project that investigated *whether mailing FITs to patients raised colorectal cancer screening rates* in federally qualified health centers (FQHCs).



The project was led by scientists and physicians at the Kaiser Permanente Center for Health Research, Kaiser Permanente Washington Research Institute, and OCHIN. This high-impact pragmatic study involved 26 FQHC clinics in Oregon and California. (A pragmatic trial is one that evaluates the effectiveness of interventions in real-life practice conditions.)

STOP CRC was a data-driven program that used reports embedded in an electronic health record (EHR) system to identify patients due for colorectal screening and mail FIT kits to them.

The program has three main steps. First, clinic staff run a report that lists all patients due for screening and use the report to *mail an introductory letter* to each patient. A few weeks later, clinics *mail FIT kits* to the list of patients due for screening. Then a few weeks after the kits have been mailed, clinics *mail a reminder letter* to anyone who has not returned a kit.

The research team built a system directly into the clinical EHR. The care that patients received at the clinics complemented and reinforced this automated program.

What STOP CRC showed about mailing FITs to patients:

- **was acceptable to both patients and providers.** Some clinic staff initially were worried that patients would not want to receive a FIT by mail or would be confused when they received it, but both patients and providers had positive reactions to the Mailed FIT Program.
- **could reach more patients for colorectal cancer screening.** Responses to the mailed FITs ranged from about 11%-36%. Over 6,000 FITs were completed in the first year of the program, which was about a 25% overall response rate. Responses were higher for clinics that sent additional reminders after the initial FIT test was mailed.

Overview of Implementation Guide

The STOP CRC Implementation Guide discusses clinic capacities needed to run the Mailed FIT Program and decisions clinic administrators and staff must make along the way.

The guide describes the Mailed FIT Program and how to orient a clinic to the program. Clinics that implemented the STOP CRC program needed to address technical, workflow, and policy questions before launching it. This guide is intended to address these questions.

Prerequisites: Clinic Capacity and Technical Resources

The Mailed FIT Program can be adapted easily to a variety of clinic organizational structures. The table below outlines the areas of clinical capacity and technical resources needed to implement a Mailed FIT Program.

Area	Capacity and Readiness Criteria
Leadership prioritization	Clinic and organizational leaders must have a desire to implement the program, prioritize it, and establish improvement targets for colorectal cancer screening rates. They should be able to identify an internal champion who is enthusiastic and has the support of the organization's leaders.
Staffing capacity	Clinics need enough staff to do the work, answer questions, and take calls. They need well-trained EHR and data reporting staff. (See *Building a Team*.)
FOBT/FIT	The program can be implemented with a variety of FIT brands (see *Selecting a FIT Kit*). Staff and leadership should know the differences among FIT options.
EHR & reporting capabilities	The Mailed FIT Program can be implemented using a variety of EHR and reporting platforms. There is a need for experienced EHR staff with the ability to create or customize reports on people due for colorectal cancer screening. (See *Detailed Report Definitions*.)
Clinical staff FIT knowledge	Leadership and providers should understand the differences in adherence to screening by FIT and colonoscopy in their clinical setting. There should be a training plan for FIT rollout. Providers, nurses, MAs, and staff must be comfortable promoting FIT.
Lab interface/capacity	Clinics should establish an interface with the laboratory that processes FITs, or work with their internal lab, to establish protocols for FIT returns. Labs must be able to provide FIT tests in bulk for mailing (either for free or at a reasonable cost) and sufficient capacity to process the tests.
Colonoscopy capacity	Clinics should have sufficient capacity to perform colonoscopies for patients who screen positive on the FIT, or partner with organizations that provide colonoscopy services. (Needed capacity is relatively small: *see Colonoscopy Capacity below*.)
Testing the uninsured	Clinics should develop a plan for fecal testing among uninsured patients.
Follow-up	Clinics should have enough staffing to receive completed FITs by mail and enter lab orders; provide FIT results for patients; and follow established processes for post-FIT activities (e.g., schedule follow-up colonoscopies).

Technical Resources

Eight health centers that participated in the STOP CRC study used Epic version 2010 (Vernona, WI), then upgraded to the 2014 version. The clinics were able to store patient-level preventive health data in an Epic-based tool called Health Maintenance. Health Maintenance had the ability to automatically update based on completed EHR fields (such as a resulted laboratory order for a fecal test), and be updated manually (such as by entering a historical colonoscopy).

For the STOP CRC project, Reporting Workbench (RWB) was used to find and track patients eligible for colorectal cancer screening. RWB is a feature in Epic to allow clinical staff and providers to generate real-time reports to pull lists of patients directly from the EHR. Reports showed patients due for colorectal cancer screening and due for outreach mailings (introductory letter, FIT kit, or reminder letter), and clinic staff used those reports to mail the appropriate materials.

In addition, another health system implemented the STOP CRC program using the AllScripts EHR system. After running an initial report from their EHR listing screening-eligible patients, staff exported the report to Excel and managed the process using Excel instead of creating custom EHR reports.

Colonoscopy Capacity

Many clinics considering the Mailed FIT Program are concerned they do not have the capacity to conduct follow-up colonoscopy. However, positivity rates of the most reliable FIT tests are only about 5%-10%. Here is a sample colonoscopy calculation based on 25% and 50% expected returned FITs:

25% FIT RETURN RATE

Colonoscopy capacity requirements at 10% and 5% positivity rates for varying mailing size				
# of patients mailed FIT	Number of kits returned at **25%** response rate	Positivity rate	Expected abnormal tests	# of colonoscopies required at 90% referral rate
10,000	2500	10%	250	225
10,000	2500	5%	125	113
1000	250	10%	25	23
1000	250	5%	12.5	11
500	125	10%	12.5	11
500	125	5%	6.25	6
200	50	10%	5	5
200	50	5%	2.5	2

50% FIT RETURN RATE

Colonoscopy capacity requirements at 10% and 5% positivity rates for varying mailing size				
# of patients mailed FIT	Number of kits returned at **50%** response rate	Positivity rate	Expected abnormal tests	# of colonoscopies required at 90% referral rate
10,000	5000	10%	500	450
10,000	5000	5%	250	225
1000	500	10%	50	45
1000	500	5%	25	23
500	250	10%	25	23
500	250	5%	12.5	11
200	100	10%	10	9
200	100	5%	5	5

Getting Ready

General Considerations

The Mailed FIT Program is highly adaptable to individual clinics, as well as to 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: How will you reach it?
- Engage partners: Who will help you?
- Gather resources and tools: What resources/tools do you have available?

For more information on gathering a team and creating an overall CRC screening strategy, see the ACS Colorectal Cancer Screening manual: http://nccrt.org/wp-content/uploads/0305.60-Colorectal-Cancer-Manual_FULFILL.pdf

Before implementing the Mailed FIT Program, clinic staff and administration should consider a number of variables, primarily:

- How best to define their clinic's "active" patients (see *Determining Patients Eligible for Screening*)
- How to organize mailings (for example, one large mailing or several smaller mailings by patient's birthday month or physician teams)
- Whether their clinic's EHR colonoscopy data needs to be updated before implementation (to avoid mailing to people who have had a colonoscopy that might not be recorded properly in the EHR data)
- Which staff members will run the eligible patient reports
- Which staff members can address EHR issues
- Which staff members can process and send the mailings
- How to staff and handle incoming calls generated by the mailings (including which phone number to include on the letters and mailed materials)
- Whether to culturally tailor the letters and FIT kit instructions
- How the clinic will handle payment for test processing for uninsured patients and laboratory billing
- Whether the lab can handle supplying and processing a bulk mailing of FIT tests

See *Program Design Options* (below) for more details and decisions that should be made before implementation.

When rolling out new interventions, we recommend clinics make small, incremental changes and use a Plan-Do-Study-Act (PDSA) cycle to ease disruption and achieve optimal results. PDSA cycles are beneficial for any clinic improvement project because they provide the opportunity to test the change on a small scale, study the outcomes, and improve the process. We recommend a PDSA evaluation to assess the process, the staffing approach, and reach those patients who do not return the FIT kits.

Building a Team

Staffing levels to clean up EHR data in advance of the program launch and to establish 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.

TIP: Prior to implementation, clinic leadership must be committed to CRC screening, specifically the FIT, and clinics should have a clinician champion who is educated about the FIT and has influence. We recommend educational training for leaders and providers, who can then present facts about the FIT and the different types of screening available.

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

WHO	WHAT
Executive Leadership (Operations and Medical Directors) **Site Ops Managers and Lead Clinicians**	Project vision, prioritization, communication, resources, staffing
Cross-Clinic Operations QI Lead **Frontline Staff** **EHR Expert** **Clinical Champion** **Site Manager**	Intervention workflow design, role specifications
QI Lead **Cross-clinic EHR and Data Experts** **Clinical Champion**	EHR functionality: point of service, tracking reports
QI Lead **Cross-clinic EHR and Data Experts** **Frontline Staff**	Training: Ops and EHR lead, elbow support for staff
Site Manager **Cross-Clinic Operations QI Lead**	Oversight, performance management
Lab Personnel	Processing returned FITs, designing in-house lab processing or workflow with external lab

Centralized vs. Distributed Staffing

The Mailed FIT Program can be implemented with a centralized team that handles all reporting, mailing, and receipt of FITs, or with smaller groups that handle their own patient populations. Most STOP CRC clinics found that a centralized approach worked best because it freed frontline clinic staff from having to handle mailing duties in addition to direct patient care. Many clinic systems used EHR or data specialists who ran patient reports and generated patient communications. Some groups had medical assistants temporarily place lab orders for the technical support team. Others used standing orders in the EHR to accommodate that, and some physician panels reviewed the lists of patients due for screening and returned the list to the centralized administrative team for the mailing itself.

A distributed staffing model may be preferable if the Mailed FIT Program complements in-clinic FIT distribution, i.e., a system whereby staff hands out kits in the clinic and the clinic mails kits to patients who did not get them during the visit. Or care teams might scrub the mailing lists to remove patients they are reaching in clinic

TIP: Establish which actions will be the responsibility of medical assistants and clinical teams, and which will fall to central staff (such as following up in the EHR vs. requesting medical records from other facilities for historical colonoscopies). The front desk team may also need to handle duties such as receiving FITs and updating address information.

Determining Patients Eligible for Screening

Before executing the Mailed FIT Program, clinics should identify active patients who are eligible for screening. Active patients are those who are part of a health center's population (such as those assigned by Medicaid) and have visited the clinic to see a care provider within the previous year. STOP CRC reports limited the mailing lists to active patients. (Note that the population your clinic ultimately chooses for mailed outreach might include additional qualifications; see *Decisions About Target Population*.)

Point-of-Care Staff Offering FITs During Visit
Is a pre-visit scrub standardized and implemented?
Is your staff trained to provide FIT kits and answer questions?
Do administrative and medical staff know their responsibilities?

To determine the total population due for CRC screening, STOP CRC used the following criteria:

- Ages 50-75
- No FIT lab result in the last year, and possibly no FIT kit ordered in the previous 6 months; this would indicate patients had already been part of an outreach
- No referral to colonoscopy in past year
- No colonoscopy in previous 9 years
- No diagnosis of colorectal cancer, colectomy, colitis, or end-stage renal disease

Chart Cleaning and Scrubbing

EHRs do not always capture all previous colonoscopies because many are performed in outside facilities. Updating EHRs will prevent unnecessary mail to and calls from patients who have already been screened. This initial cleanup will prevent unnecessary clinic expense by targeting the intervention to those who most need it.

There are several ways to document prior colonoscopies:

- **Colonoscopy report –** Reports can systematically search scanned colonoscopy reports. They can 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 on specialty services. Clinic staff should contact their health insurance plans and ask for claims data on prior colonoscopies for their patient list.
- **Scrub –** Using a list of patients due for screening, scrub the EHR records to check for prior CRC screening. Snapshot reports that provide CRC information at a glance can augment manual searches.

Sample Scrub Tool and Process

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. We created a sample Excel file for use by clinics.

At the end of the scrub process, clinics will mail FITs to everyone appropriate for mailing, and follow up with the other patients as needed.

TIP: Be sure to staff for data cleaning and scrubbing. While scrubbing for historical colonoscopies can be labor intensive, once the past records are cleaned up, the outreach efforts will be streamlined. Some clinics found a 10% increase in patients screened by recording historical information, which helped them meet their metric targets. They were also able to pinpoint the sources of gaps (such as not getting the completed colonoscopy information) and could address those gaps to improve colonoscopy data collection in the future.

TIP: Some clinics that chose to mail their FITs monthly scrubbed their eligible patient list each time to make sure it was accurate. Consider the frequency that works best for scrubbing the charts and determining the appropriate staffing.

Determining the Target Population for Mailing

In the STOP CRC project, clinics could run a report (using the Reporting Workbench tool embedded within their OCHIN EHR systems) that identified patients who were eligible for a FIT mailing. In addition to the eligible clinical criteria listed earlier, eligible patients also needed to meet all of the following criteria:

- Have a viable address
- Have a primary care physician (PCP) assigned to a clinic, or if no PCP was listed in the EHR, patients whose last visit was at that clinic
- Were seen at the clinic in the previous 12 months

Additionally, some clinics chose to divide the work by physician team or by patient's birthday month. Thus, rather than run a global report for all the patients in a clinic, they further sorted patients and worked in smaller batches.

Outreach to Unestablished Patients

Patients may be part of a health center's population (such as those assigned by Medicaid), but have not been in to see a care provider in the last year. The STOP CRC reports limited the mailing lists to patients who have been seen in the last year. This means some patients will not be reached, but also ensures that billing information and consent-to-treat forms are current for patients being mailed FIT kits.

Here are some options to consider:

- Mail only to patients who have an assigned PCP and have been seen in the last year (or two). This ensures current insurance information and that patients are likely receiving care at the clinic.
- Use an intake specialist to call patients to establish care. Such outreach to new patients can include scheduling an appointment and having the patient bring the completed FIT with them.
- Mail FIT kits to the entire list and reach out to patients who return the FIT to update insurance coverage information.

Limiting the Program to a Smaller Target Population

Some STOP CRC clinics felt that 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.

Program Design Options

Mailed FIT programs should be designed to include a structure for mailing and receiving kits and for optimizing response rates.

Mailing and Receiving FIT Kits

One-time mailing vs. staggered mailing

Clinics with many patients due for screening may divide their patient lists into small groups for staffing purposes as well as for patient follow-up colonoscopy referrals. Other clinics may do one or two large mailings. Clinics with seasonal temporary staffing help, such as interns, might consider having these personnel handle one large mailing. Whichever approach is desired, it is helpful to know that FIT returns tend to be staggered over about 3 months' time.

Including introductory letter with kit vs. separately

Many STOP CRC clinics chose not to send introductory letters (see *Introductory Letters* below) before mailing FIT kits, instead including them with the FIT kit itself. Such an approach reduces the amount of staffing needed for printing and stuffing envelopes, and saves postage. However, it does not prepare patients for the mailing nor alert them to the importance of CRC screening. As well, postage savings could be offset by unopened kits (with higher postage costs than letters) being returned because of invalid addresses. Selection of this option depends on clinic capacity, accuracy of patient addresses, and response rates.

Mailed FITs vs. in-person returns

Some STOP CRC clinics chose to have patients return their FIT kits in person to ensure they had the correct patient information before placing the lab order. In general, the clinics were worried about patients who were not established with a PCP, and those who had not been in recently enough to have updated insurance information. 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. While response rates may be higher with mailed FITs, in-person returns eliminate reply postage costs and allow clinic staff to verify and update patient information (i.e. insurance status).

Envelopes and postage options

With mailed FITs, response rates are much higher if postage is prepaid on reply mailers. Many labs supply business reply envelopes that are pre-stamped and pre-addressed to the labs.

In many cases, STOP CRC clinics opted to have FITs returned to the clinic (instead of the lab), which helped with quality control and reduced staffing needs for placing lab orders (see *Mailing the FITs*). In this case, stamp all the outbound reply envelopes or work directly with the lab and/or FIT manufacturer to get actual business reply envelopes printed. The advantage of business reply envelopes pre-printed with postal codes is postage is paid only on the FITs that are returned. But this often requires setup time and approvals from the lab and post office. If sending a large volume of mailing, it is worth getting business reply envelopes set up in advance.

TIP: Be sure to work with the post office to make sure that postage rates are correct for both mailing out and returned FIT postage. Postage was more complicated than anticipated for a number of clinics during rollout, resulting in additional staff time to correct the postage amounts.

Maximizing Response Rates

There should be reporting in place to monitor response rates. Typically, a data analyst pulls the response rate monthly so the team knows how the mailing is going. Also, if there is a PDSA in place, as recommended, data specialists should isolate the PDSA population to measure effects.

"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." - QI

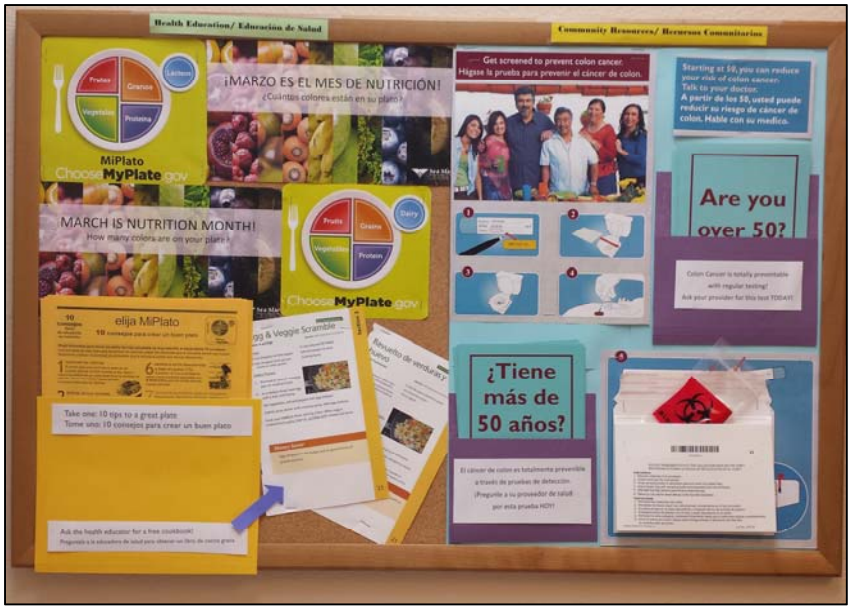
Enhancing other in-clinic activities, particularly patient and staff education

Educating patients and staff at every level about colorectal cancer in general and mailed FITs specifically is extremely important to the success of the Mailed FIT Program. STOP CRC clinics repeatedly said they wanted to prime the wheel for this type of mailing and hopefully improve response rates and reduce patient questions. The key facts to communicate in a patient educational campaign are:

- Definition of colorectal cancer
- Colorectal cancer screening is important
- FIT as an approved/accepted option in addition to colonoscopy
- FIT screening needs to be done yearly
- It is safe to send fecal samples in the mail
- FIT screening is easy and you can do it at home with no special diet
- FIT needs colonoscopy follow-up for positive results
- FIT is free (if this is the case), and resources may be available to help pay for colonoscopy if one is needed

TIP: In addition to patient education, make sure providers and all clinical staff know what the FIT is, its reliability, and how to pitch the FIT relative to colonoscopy. Use educational presentations at provider meetings, grand rounds, or team meetings.

Figure 1. Sample Educational FIT Display



Customizing letters and FIT instructions

The instructions accompanying FIT kits are often complicated and hard to follow. For this reason, it is helpful to include a simplified version of FIT instructions in the mailing. The STOP CRC project created wordless instructions for three popular, evidence-based FITs (found at www.mailedfit.org under Program Materials). The National Colorectal Cancer Roundtable has some great resources for customizing messages to different populations (www.nccrt.org). In particular, the Tested Messages to Reach the Unscreened and the Hispanics/Latinos and Colorectal Cancer Companion Guide has tested messaging for colorectal cancer screening[5,6].

Delivering additional reminders to increase return rates

Some clinics decided to have clinic staff call patients who had received a FIT and remind them to return the kits. Other clinics used an external phone vendor to send automated phone calls or text messages to people who did not return their FIT tests. If using an outside vendor for phone or text reminders, develop a tracking process, set up the call script, and define parameters for when calls are made. See *Follow-up and Tracking: Other Reminders* for details.

Offering an incentive for a returned FIT or completed screening

While the evidence is mixed for offering incentives for returned FITs, some health centers have offered incentives for patients who returned their FITs. If opting to provide incentives, include information about the incentive in the outreach letter. It is also important to have a process for tracking returns and providing incentives, either at the point of return (if people are returning in clinic) or by mail later. Be sure customer support call centers have all the information about the incentives (such as how long they take to be sent) because patients will call with questions.

"I've had patients come…when I was rooming them say, oh, I got a positive 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..." - QI

Selecting a FIT Kit

The Mailed FIT 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 involves lab-processing capabilities or arrangements, and balancing the simplicity of the test with the accuracy of its results in a given population.

FIT Kit Selected and Providers Able to Support FIT
Are you already using a FIT? Are FIT processes standardized and are staff trained?
Lab Interface for FIT Processing Is Established
Will you use an internal or external lab? How will tests arrive at the lab? How are lab orders placed and who puts in the orders? How are results returned? Are they automatically updated in the EHR, or is there a manual step to get results from lab to EHR? Has Lab interface been tested where applicable?

TIP: If your staff is new to FIT, ensure that everyone on the team is up to speed on FIT testing before launching the mailing program.

FIT Performance Review

FITs are specific for human blood and for lower GI bleeds. FIT results are not influenced by food or medications and most require one or two stool samples. They have a higher sensitivity than guaiac-based tests and are generally easier for patients to use.

All FITs are not created equal. The FDA clears guaiac FOBTs and FITs only for "detection of blood." A recent study found 56 FITs cleared for use in the United States and 23 currently marketed. Only one-fourth of FDA-cleared FITs have published data on their performance (for detection of adenomas and cancer). The FDA is updating its criteria.

The following chart shows the positivity and sensitivity of different FIT tests.

FIT test	% positive [a]	Sensitivity [b]	Evaluated in large numbers
OC-Auto	3.3 – 6.0%	88%	√
OC-Light	8.4 – 14.2%	88 – 96%	√
Insure	4.6 – 5.6%	87.5%	√
Hemoccult ICT	3.2 – 9.0%	82 – 98%	√
Hemosure	7.2%	55%	√
Consult Diagnostics	Not available	Not available	
QuickVue	Not available	Not available	
One-Step +	Not available	Not available	

[a] Positivity rate is the proportion of test that have a positive result.

[b] Sensitivity is the proportion of actual positives correctly identified (e.g. % of patients with colorectal cancer who are correctly identified as having the condition).

FIT Costs and Lab Options

"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. " -COO

Apart from test performance, two additional factors should be considered when selecting a FIT:

- Where the kit will be processed (on-site, internal lab, or outside laboratory)
- Cost of the tests and/or mailing

Because colorectal cancer screening, specifically colonoscopy and high-sensitivity fecal testing (as well as FIT-DNA, CT Colonography and sigmoidoscopy), is recommended by the U.S. Preventive Services Task Force, tests are covered under the Preventive Health Mandate of the Affordability Care Act. This means that patients who have health care insurance cannot be charged for screening. Become acquainted with state and local laws and regulations.

Many labs provide the FIT for free because they will be paid when the tests are returned for lab processing. If the selected lab is not providing free FITs, be sure to ask them about this option. If the health system is processing the FITs in-house, calculate how much it costs to purchase the tests and the processing costs. Below is a sample of the costs of mailing 2,000 kits and reimbursement for processing returned kits as part of a Mailed FIT Program.

Sample profit and loss calculation for FIT mailing program with external lab

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 Lab		$610.00

*Estimated cost based on kits used in STOP CRC

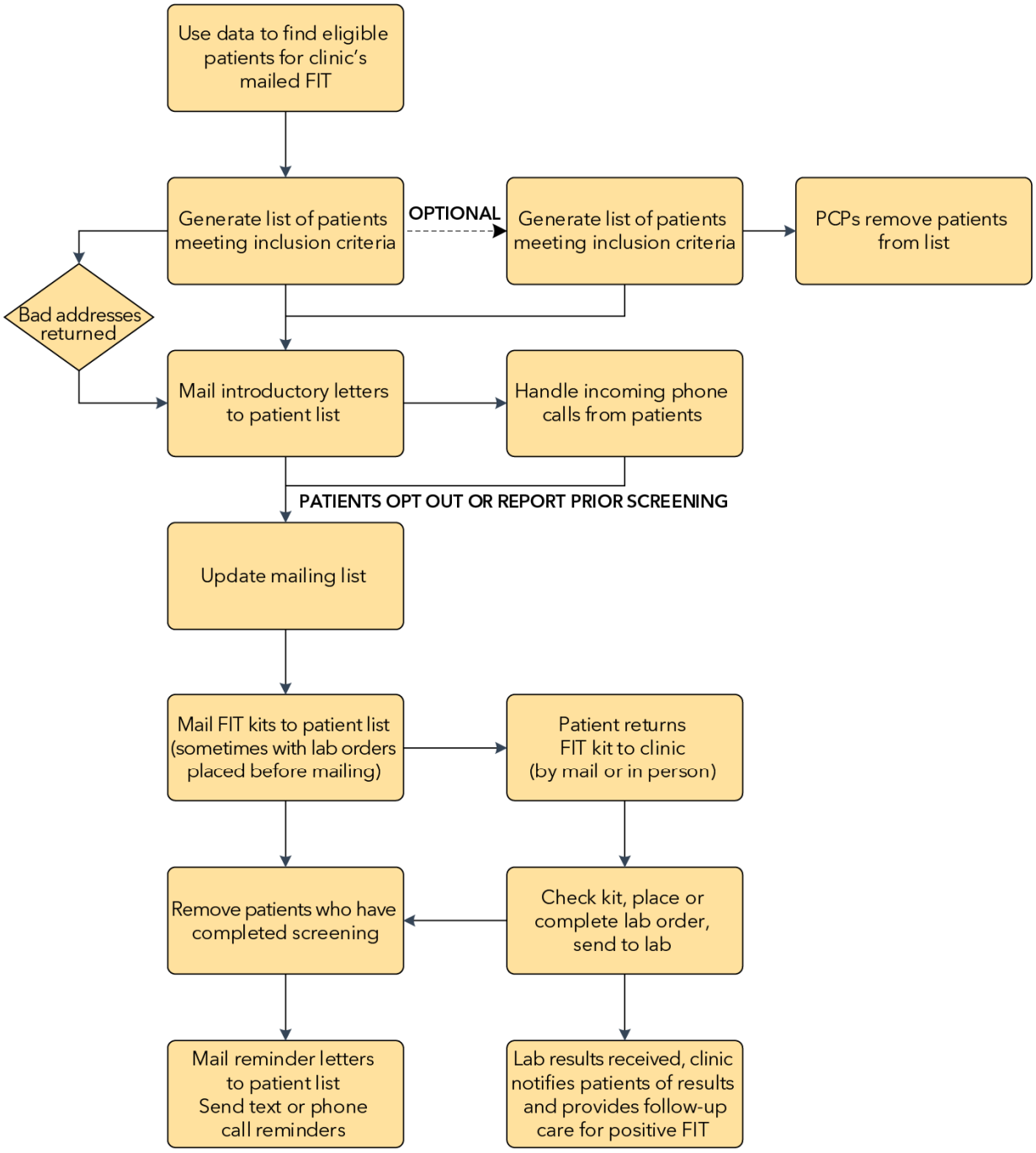
**Postage based on 2016 rates to mail OC Auto Kits. Return rate based on STOP CRC average.

NOTE: Clinics typically pay for the outbound postage, so this might be free for the lab processing the kits.

Execute FIT Kit Screening Program

Overview of Program Workflow

The sample workflow, below, shows the steps in the Mailed FIT Program. These steps include selecting patients for the mailng, mailing an introductory letter, mailng a FIT kit, mailing reminder letters or delivering othere types of reminders (e.g. phone calls, text messages), and processing returned FIT kits. The STOP CRC EHR tools support the Mailed FIT Program activities by automatically generating up-to-date lists of patients who are due for each step.



Population Selection

Generally speaking, patient criteria are:

- Ages 50-75
- No FIT lab result in last year
- No colonoscopy in previous 9 years
- No diagnosis of colorectal cancer (patients who have or had colorectal cancer codes [153.XX, 154.XX, 197.5X, and V10.05), colectomy codes (V15.29, V45.89), or colitis or end-stage renal disease
- Viable address

In addition, depending on what target population is selected (see *Decisions about Target Population),* there may be additional filters, such as:

- Visit in the previous year (or 6 or 18 months)
- PCP or birthday month (for smaller mailing groups)
- FIT completed in prior years

Introductory Letters

The introductory letter (see *Patient Materials* for examples) tells patients why they need colorectal cancer screening and that they will be mailed a cancer testing kit soon. Mailing the letter:

- Helps clinics find patients who have invalid addresses.
- Prompts patients to call to report that they have already had colorectal cancer screening or schedule other types of colorectal cancer screening, if they prefer it.
- Prepares patients to complete the test.

In the STOP CRC program, clinics mailed the introductory letter at least 2-3 weeks before the FIT kit was mailed. Clinic timing varied based on staffing for the next mailing, the ability to respond to questions, and postal speed (to ensure there was time to identify invalid addresses before the FITs were mailed).

Introductory letters were generally signed by a clinic's providers (or the entire provider team), or a medical director for the larger clinics that did centralized mailings. Another option is to sign the letters with a simple "Your Care Team."

Staff responsible for sending introductory letters will need to list all patients eligible for a mailed FIT. They will want to carefully validate or review reports to ensure they are pulling the correct lists.

In STOP CRC, the communications features of the EHR were tied directly to the report of patients eligible to receive a FIT. Thus, clinic staff ran an eligible report, then selected the patients in the report to receive a paper letter or an email based on their communication preferences. STOP CRC clinics followed these steps when sending introductory letters to their population.

1. Run a *STOP CRC – Eligible Patients* report to list everyone who meets eligibility criteria and has not received an introductory letter in the previous 11 months.

2. Select all patients in the report. Some clinics with large populations filtered the report into smaller, more manageable batches, such as by patient birth month or PCP name.

3. Click a button to open the EHR functionality that allows generation of letters or email communication to patients.
4. Select a reason for the letter (i.e., Health Promotion), and choose the STOP CRC Introduction Letter template that was pre-loaded by the EHR team.
5. Send letters to batch printing. The communications function in the EHR automatically documented that the Introductory Letter had been mailed. A similar process enabled staff to email patients who opted for electronic communications from the clinic.
6. Collect the printed letters, which contain a name/address block positioned to show through the window of a window envelope, and mail them.

TIP: Before mailing introductory letters, your clinic may want to scrub the charts to ensure the list of eligible patients is accurate (see *Scrubbing Charts*).

TIP: For this kind of reporting and communications feature to work, the printer must be able to accommodate a large batch of letters. With STOP CRC, batch printing initially was set up to run nightly, but simple mistakes caused significant delays in the workflow. If you plan to print during the day, make sure beforehand that the printer is not being used for time-sensitive activities.

Returned Letters

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

Incoming Phone Calls

Each STOP CRC clinic set up staffing and a process for handling phone calls that patients made in response to the introductory letters. The call center should be alerted when the letters are sent. As well, the clinic manager should communicate with customer service staff to be sure they are able to answer patients' questions.

In STOP CRC, automated EHR tools were employed to assist with incoming phone calls. When a call came in, clinic 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 should be able to handle calls.

The call center and medical staff were equipped to handle the following types of calls:

- Patient requests a new FIT kit.
- Patient has questions about the FIT, including why they were mailed a screening test. (See *Patient FAQ* for common questions and answers.)
- Patient has already had colorectal cancer screening, such as a colonoscopy. In this case, as staff record the prior screening in the EHR, medical staff will need to determine the follow-up interval for the patient's next CRC screening based on the colonoscopy results. The automated tool can transfer the call to the correct personnel and open the correct location in the EHR to make these updates.

- A patient is ineligible for a FIT mailing due to a terminal or serious illness. In this case, the clinic staff modified their EHR record to indicate the condition that would exclude them from the eligible reports. Again, the automated tool helped open the correct EHR window.

Mailing FIT Kits

About two weeks to a month after the introductory letter was mailed, STOP CRC clinics generated a new report of patients who should be mailed the FIT kit. Other clinics generated a FIT mailing list by scrubbing the charts each time and selecting a small number of patients to whom a FIT should be mailed. The FIT mailing report process is dependent on workflow decisions.

The FIT mailing list should exclude:

- Patients whose introductory letters were returned and no updated addresses was found.
- Patients who called to decline.
- Patients who called to report prior colorectal cancer screening.

Mailing the FIT kit is more complex than mailing the introductory letter because the mailing includes the FIT kit, a return envelope, and instructions. The STOP CRC study developed wordless instructions for several of the most common FIT kits available so they could be sent to multilingual patient populations. Clinics also included another, shorter letter with the FIT explaining what it was and why patients were receiving it. (See *Patient Materials* for Wordless Instructions and FIT Letter samples.)

FIT Lab Orders

A lab order should be placed in tandem with the FIT kit mailing. The order may need to include lab requisitions to process the FIT once it is returned. FITs can either be processed in a clinic's internal laboratory or sent to an outside laboratory. This difference will affect the process. Depending on the size of the population, lab processing location, the FIT itself, and other variables, clinics have the following options:

1. *Have patients return FIT kits to the clinic and process them at an internal lab.* While this process is the most streamlined, many clinics do not have that lab capacity or already have an existing relationship with an external lab that handles their FIT testing.
2. *Have patients mail their FIT kits to an external lab.* Note that this workflow requires some way of creating and printing a laboratory requisition *before* the FIT kits are mailed. In the Epic EHR system used in the STOP CRC study, clinics needed to create a lab appointment for each patient receiving a FIT kit and then they were able to place a lab order. The lab requisitions are included in the mailing package to the patient. Depending on the clinic and population size, this approach might not be manageable due to staffing constraints. (It is necessary to place orders for all the FITs mailed instead of only the FITs completed and returned to clinic.)
3. *Have patients return the FIT kits to the clinic; clinic staff then creates a lab requisition for completed kits, and sends the kit on to an external lab.* Depending on the EHR, you may need to create some type of lab appointment for each patient, but the number of patients was limited to only those returning FITs. This option enables a clinic to send the FIT kits and place the lab order later.
4. *Use or develop a batch lab ordering process for the EHR system that enables staff to place multiple lab orders at once for a population.* Some EHRs, like Epic, have the option to mail a batch of kits at the same time. (See *Detailed Report Definitions* for specifications on Bulk Ordering FIT Labs.)

TIP: In preparation for the mailing, estimate how many FITs you will mail and place an order for the FITs with your lab. Keep in mind that labs might not always be able to handle large orders quickly.

TIP: Check the expiration dates of the FITs that are received at your clinic. Perform a quality check on the FITs delivered by labs before they are mailed out in bulk.

Preparing FIT Kit for Mailing

Before stuffing FIT kits into mailing envelopes, prepare reply envelopes unless using those that come with the FIT kits (see *Decisions about Workflow* for FIT return and postage options). If patients are to return FITs to the clinic, it will probably be necessary to affix a new address label and stamp the business reply envelopes that go with the FITs (unless using USPS-approved, preprinted business reply envelopes). If patients are to return the FITs in person, we recommend putting a sticker on the outside of the reply envelopes instructing patients to bring the test back to the clinic.

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

1. Affix a FIT label (printed from the EHR data with patients' medical record number and Date of Birth fields) over the existing labels on the test vials.

TIP: The labels provide a line for the patient to write the date he or she took the sample. Staff in some clinics highlighted this line with a yellow highlighter.

2. Use wordless instructions rather than those that came in the FIT package. Clinic staff removed these instructions from the packaging and discarded them before shipping the test. They folded the wordless instructions in half and inserted them into the patient mailing envelope that contained the test vials and supplies. If a lab requisition was being included with the mailed kit, they folded the requisition form and placed it in the envelope to be returned with the completed FIT test cards.
3. Attach patient mailing address labels. Staff verified a match between the mailing label, the test vial labels, and (if applicable) the lab requisition form.
4. Stamp and mail the FIT packages.

TIP: For STOP CRC, the EHR automatically documented that the FIT test had been mailed when the lab was ordered. Without an automated tool, staff should have a process for documenting and tracking the mailing.

Returned FITs

If a FIT was returned due to an incorrect address, STOP CRC clinics documented it in the messaging feature of the EHR. That patient was not included in the STOP CRC eligible reports until the address was updated. If a new address is obtained and entered into the EHR, clinic staff placed the lab order again and resent the kit.

Laboratory Billing

Laboratory billing for a FIT is reliant on up-to-date insurance status information or federal poverty level (FPL) information, a value that is generally updated during in-person clinic visits. (However, if the clinic chooses to pay for uninsured patients, FPL information is not needed.) Among STOP CRC clinics that needed FPL for billing purposes, some clinics chose to reach out to all their patients due for screening and update their FPL, and others were able to determine that the FPL had been updated within the year and used the recorded information. Clinics should evaluate how they are handling billing and where they are getting updated FPL information, if needed.

TIP: Many STOP CRC clinics had lab billing issues with the first few FITs that were processed. Be sure to confirm that the lab is correctly billing for the processing of the FITs. You will want to ensure that your patients are not being sent a bill they should not receive.

Follow-up and Tracking

Reminder Letters

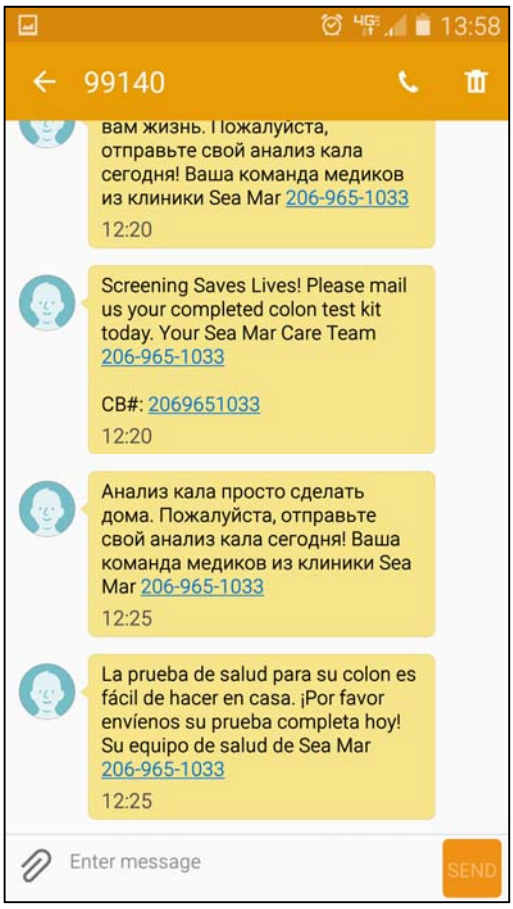
About 2-3 weeks after FIT kits are mailed, clinics should send a reminder letter to those who have not returned the test.

In STOP CRC clinics, the process was similar to the introductory letter workflow. Clinics ran a report that excluded invalid addresses and patients who had opted out or 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.

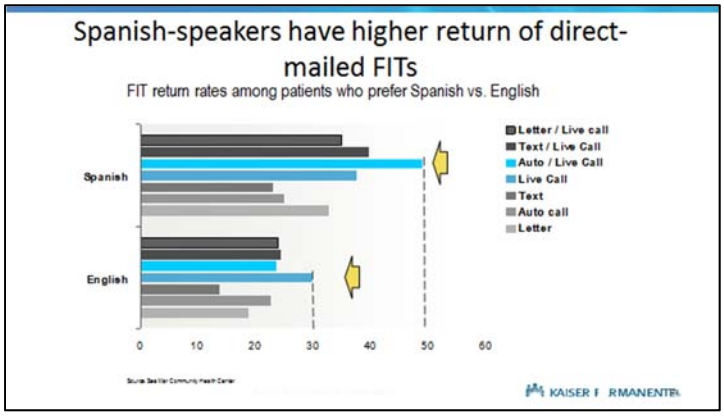
The process would be similar for those who opt to receive email communications instead of a paper mailing. These patients would receive an email generated using the Reminder Letter template for the text.

Other Reminders: Phone Calls, Text Messages

In addition to mailed or email reminders, some clinics used phone calls or text messaging to remind people to return their FIT tests (see sample).



Phone calls can be made by clinic staff or a vendor. Vendors can provide either automated reminder calling or text messaging services to remind patients to return their FITs. The figure below shows the relative success of these reminders for Spanish- and English-speaking patients. If selecting a vendor, develop tracking and reporting protocols. The STOP CRC clinic that used an external vendor had the vendor produce reports on the total number of patients called, and whether they were contacted or not reached, and how the call was handled (automated call only, transferred to a live person, etc.).



Sample Reminder Call Report

Consistency in and standardization of patient messages are helpful for tracking purposes. Following are examples of the phrases staff at one clinic used to track their calls. In this clinic, staff needed to begin the subject with "CRC REMINDER CALL" for the call to be pulled into the CRC Screening Report (example above).

Subject	Dot	Message Body	When do I use this?
CRC Reminder Call 1	.lm	Voicemail reminder left for patient regarding outstanding FIT order. Expecting a call back to the CRC Program at xxx-xxxx.	You left a message for the patient
CRC Reminder Call 1	.pc	Confirmed: Patient is aware of colon health screening and will mail FIT promptly.	Patient confirmed receipt of FIT and says when they'll mailed it
CRC Reminder Call 1	.frep	Second FIT: Patient is aware of colon health screening and will mail replacement FIT promptly.	Patient reports that they need a replacement FIT
CRC Reminder Call 1	.onf	Order without FIT: Patient is aware of colon health screening and will mail FIT promptly.	Patient reports they never received a FIT and want one
CRC Reminder Call 1	.re	Refusal: Patient would not like FIT screening at this time. Please revisit the importance of colon cancer screening at next office visit.	Patient states that they would not like to do the test
CRC Reminder Call 1	.npc	Unable to contact or leave message with patient regarding outstanding FIT lab order. If patient calls, please forward to the CRC Program at xxx-xxxx.	Unable to speak with or leave a message due to incorrect number, no voicemail.
CRC Reminder Call 1	.co	Colonoscopy reported by patient from (facility name, year). Records request initiated on (date).	Patient reports they had a colonoscopy
CRC Reminder	.tc	Transferred Care: Patient stated that they have transferred care.	Patient transferred care

Processing Returned FITs and Follow-up

Typically, FIT results come electronically to the EHR through a lab 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.

All positive FITs should be followed up with a colonoscopy. Before FITs are mailed, a referral process should be in place, including a way to quality-check that referrals are being made and completed by the patient.

TIP: It is very important to standardize placement of the FIT results and the colonoscopy reports in the patient charts. In many cases, STOP CRC clinics were notified a colonoscopy was completed, but needed to gather the actual results to update the medical chart for a patient.

Who notifies patients of *normal* and *abnormal* results?

Medical Assistant

Registered Nurse

Licensed Practicing Nurse

Panel Manager

Provider – PCP

Specialist Office

What is the preferred method of contact?

Patient Materials

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

- Introductory Letters
- FIT Letter
- Wordless Instructions
- Reminder Letter
- Reminder Phone Call Scripts
- FIT Results Letters
- Patients' Frequently Asked Questions

Technical Specifications for EHR and Tracking Reports

Detailed Report Specifications

https://research.kpchr.org/Portals/0/Docs/project%20websites/STOPCRC/implementation-guide/STOP-CRC-Detailed-Report-Definitions.pdf

EHR reports can help run a mailed FIT program, including optional and essential fields and exclusion and inclusion codes.

Colonoscopy Report Sample

https://research.kpchr.org/Portals/0/Docs/project%20websites/STOPCRC/implementation-guide/Colonoscopy-Report.pdf

Reports can systematically search scanned colonoscopy reports. They can identify scanned documents with “colo” or “colonoscopy” in the comment field, and no recorded colonoscopy in EHR-coded fields.

Monitoring Report Sample

https://research.kpchr.org/Portals/0/Docs/project%20websites/STOPCRC/implementation-guide/Monitoring%20Report.pdf

Implementation Tracking Report Samples

https://research.kpchr.org/Portals/0/Docs/project%20websites/STOPCRC/implementation-guide/Implementation-Tracking-Report-Sample.pdf

For monitoring purposes, the Implementation Tracking Report provides a snapshot of what is happening with letters and mailed and returned FITs. It is important to have a way to show response rates to the mailings.

References

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