

# **Toolkit for the System Approach to Tracking and Increasing Screening for Public Health Improvement of Colorectal Cancer Intervention**

These materials enable implementation of the System Approach to Tracking and Increasing Screening for Public Health Improvement of Colorectal Cancer (SATIS-PHI/CRC) intervention. This toolkit includes materials for planning the intervention, identifying a central entity to manage the program, educating medical practices about the program, and communicating with patients.

The toolkit was prepared for the Agency for Healthcare Research and Quality (AHRQ) by the CNA Health ACTION Partnership for SATIS-PHI/CRC under Contract No. HHS290200600014, Health Care Systems for Tracking Colorectal Cancer Screening Tests, Task Order 290-06-0014-1.

## **Disclaimer and Copyright Information**

The authors of this report are responsible for its content. Statements in this report should not be construed as endorsement by the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, or the U.S. Department of Health and Human Services. This document is in the public domain and may be used without permission.

Prepared by: Daniel M. Harris, Ph.D., and Amanda E. Borsky, M.P.P., CNA; Brian Stello, M.D., Melanie Johnson, M.P.A., and Nancy Gratz, M.P.A., Lehigh Valley Health Network; Mona Sarfaty, M.D., Ronald Myers, Ph.D., Randa Sifri, M.D., James Cocroft, M.A., and Martha Kasper-Keintz, Sc.M., Thomas Jefferson University

For more information about implementation of the SATIS-PHI/CRC, contact the CNA Health ACTION Partnership at: [CHAP@CNA.ORG](mailto:CHAP@CNA.ORG) or at CNA Health ACTION Partnership, CNA, 4825 Mark Center Drive, Alexandria, VA 22311.

AHRQ Publication No. 11-0016  
December 2010

# Contents

I. Introduction	1
Purpose	1
Intended Users	2
Rationale and Supporting Evidence for SATIS-PHI/CRC	2
Overview of Toolkit Contents	3
II. Background	6
Overview of the Task Order for SATIS-PHI/CRC Development	6
Description of the SATIS-PHI/CRC Intervention	6
Description of the Intervention Setting, Transferability to Other Settings, and the Central Entity	8
Intervention Findings	11
III. Intervention Steps and Tools	13
Step 1: Recruit Practices	13
1.a-1 Information Packet for Participating Practices	15
Step 2: Conduct Academic Detailing	20
2.a-1 Preintervention Survey of Clinicians and Practice Staff	22
2.a-2 Practice Focus Group Guide (Preintervention)	29
2.a-3 Key Informant Interview Guide (Pre-Intervention)	32
2.b-1 Academic Detailing Slides	35
2.b-2 Web Links to CRC Screening Guidelines From ACS/U.S. Multi-Society Task Force/ACR and USPSTF	45
2.b-3 Screening Tracking Sheet for Practices	46
2.c-1 Academic Detailing Booster Letter	47
Step 3: Identify Eligible Patients	49
3.a-1 Sample Programming Criteria for Initial Electronic Record Review	52
Step 4: Mail Screening Information and Materials	53
4.a-1 Introduction Letter to Patients With Instructions for Completing SEA Form	56
4.a-1 Introduction Letter to Patients With Instructions for Completing SEA Form (Spanish)	57
4.a-2 Screening Eligibility Assessment (SEA) Form (Spanish)	59
4.b-1 Invitation to Screen Letter to Patients (Version 1 – Kit Enclosed)	61
4.b-3 Web Links to CDC Patient Information on CRC Screening	65
4.b-4 Stool Test Kit Request Card	66
4.c-1 Letter to Patient for Responding to Stool Test Kit Requests	67
4.d-2 Reminder Letter to Patients (Version 2 – Request Card)	70
4.d-2 Reminder Letter to Patients (Version 2 – Request Card) (Spanish)	71
Step 5: Track Patient Screening and Results	72
5.a-1 Master Patient Database Elements	74
5.d-1 Chart Audit Review Form	76
Step 6: Provide Feedback to Practices	79
6.a-1 Feedback Form for Stool Test Positive	80
6.a-2 Feedback Form for Stool Test Negative	81
6.b-1 Feedback Form for CDE	82
Assessment	83

A.1-2 Practice Focus Group Guide (Postintervention)	86
A.2-1 Key Informant Interview Guide (Postintervention)	90
A.3-1 Patient Focus Group Guide	92
IV. References	101

## I. Introduction

According to the Centers for Disease Control and Prevention (CDC) and United States Cancer Statistics (USCS) data, colorectal cancer (CRC) is the “second leading cancer killer” in the United States among cancers affecting both men and women. It is also one of the most commonly diagnosed cancers. In 2006, 139,127 people (70,270 men and 68,857 women) were diagnosed with CRC, and 53,196 people (26,801 men and 26,395 women) died from it (USCS, 2010). According to CDC, when CRC is found and treated early, survival is high (90 percent). However, many colorectal cancers are not found early due to low screening rates.

### Purpose

The System Approach to Tracking and Increasing Screening for Public Health Improvement of Colorectal Cancer (SATIS-PHI/CRC) intervention is a population-based, system-level redesign of the way CRC screening and followup are conducted in a network of primary care practices. It was implemented by the following members of the CNA Health ACTION Partnership (CAN): CNA (a nonprofit research and analysis company), the Lehigh Valley Health Network and its associated physician-hospital organization (LVPHO), and Thomas Jefferson University. The project was part of a task order funded by the Centers for Disease Control and Prevention (CDC) under the Accelerating Change and Transformation in Organizations and Networks (ACTION) program of the Agency for Healthcare Research and Quality (AHRQ).

The purpose of this toolkit is to inform potential new users about the SATIS-PHI/CRC intervention and CNA’s experiences implementing it. CNA developed the toolkit consistent with research findings about effective CRC screening programs and techniques. SATIS-PHI/CRC is intended to assist primary care practices to better provide guideline-based preventive health care to their age-appropriate patients, who are at average risk for CRC and who are not up to date in their screening. It assists practices in encouraging, facilitating, and providing screening. It also helps educate both clinicians and patients about CRC screening.

This toolkit is designed to facilitate the spread of the SATIS-PHI/CRC intervention. Therefore, this toolkit includes tools, process guidelines, tips (based on implementation lessons learned), and evidence of the intervention’s effectiveness.

#### ***What Is SATIS-PHI/CRC?***

- Population-based, system-level redesign for conducting CRC screening and followup in primary care practices
- Assists primary care practices in providing guideline-based CRC screening
  - Providing, facilitating, and encouraging screening
- Educates both clinicians and patients about CRC screening

## **Intended Users**

The primary intended users of this toolkit are potential adopters of the intervention. They include integrated delivery systems, independent practice associations or foundations, multisite primary care practice networks, insurers, accountable care organizations (ACOs), regional health information organizations (RHIOs), and State and local public health agencies and related entities.

This toolkit may also be of interest to those who can inform and influence potential new users, or those who may be interested in the intervention and findings for purposes of conducting followup research. These users may also be interested in incorporating intervention elements into other CRC screening efforts or developing next generation versions of the intervention.

## **Rationale and Supporting Evidence for SATIS-PHI/CRC**

SATIS-PHI/CRC is based on the premise that busy primary care practices could benefit from assistance in carrying out population-based screening programs (Zapka, 2008). A central entity provides this assistance by:

- Identifying patients who are eligible for but not up to date in their CRC screening.
- Sending invitations to be screened and screening information and material to those patients.
- Tracking whether patients get screened.
- Sending reminders to those who do not screen and then issuing reminders to the practices to follow up with screened patients.

SATIS-PHI/CRC was modeled largely after interventions developed by researchers at Thomas Jefferson University (Myers, et al. 2007; Myers, et al. 2004, Myers, et al. 2001).

The major components of SATIS-PHI/CRC are supported by recent literature. CNA incorporated a central entity to identify and communicate with eligible patients. Michael Pignone, M.D., a clinician and researcher with the University of North Carolina, Chapel Hill, medical school observed that most health care systems do “not have the ability to identify and then mass communicate with people who are not up to date with screening. ... more systems need to develop that kind of capability” (quoted in Pinkowish, 2009). CNA’s central entity performs these functions for primary care practices. The central entity also conducts academic detailing about CRC screening at participating practices and provides information about CRC and screening to eligible patients of these practices.

Educating both the provider and patient about the importance of CRC screening has been shown to be effective in increasing screening in patients (Levy, 2007; Geller, 2008; Zapka, 2008). Receiving information and recommendations for CRC screening from their health care provider, particularly their primary care provider, has been found to be a predictor of patients getting screened (Carcaise-Edinboro, 2008; Griffith, 2008; Sarfaty, 2007; Zajac, 2010). Therefore, all mailed communications to patients from the central entity are sent on behalf of the providers in each patient’s primary care practice (e.g., all letters are signed by all providers in the practice) rather than coming from the central entity itself. Mailed communications have been shown to be

effective (Vernon, 1997; Snell & Buck, 1996). In one study comparing mailed reminders to patients and electronic reminders to physicians, the mailed reminders were more effective in increasing population-based screening rates (Sequist, et al., 2009).

Patients have varying preferences for CRC screening modalities (DeBourcy, et al, 2008; Hawley, et al., 2008), and opportunities for screening can be lost if patients are not given a choice of modality, especially when it comes to offering colonoscopy only. Thus, CNA provided patients with a choice between colonoscopy and a less invasive test they could use themselves at home, a stool test kit. The fact that colonoscopies may be a barrier to screening can be seen in a story that appeared in the Wall Street Journal in July 2009 (Matthews). A company that mandated that all employees get certain exams and tests within a year or lose their insurance coverage excluded colonoscopy from the list of requirements because, according to the company's vice president for human resources, colonoscopies were "too intrusive" and mandating them might "create a lot of resistance and resentment."

Finally, since "failures to inform patients or to document informing patients of abnormal outpatient test results are common" (Casalino, et al., 2009), CNA built in a feedback mechanism to remind providers to properly follow up with patients regarding test results. CNA also provided tools to assist practices and clinicians to track and document patient notification and followup.

## **Overview of Toolkit Contents**

The SATIS-PHI/CRC toolkit includes the following:

- A background description of the intervention and requirements for a central entity administering it.
- The intervention steps.
- Tips, based on lessons learned implementing the steps.
- Each step's corresponding tools.

Tables 1 and 2 list the tasks associated with each of the six intervention steps and with the optional assessment step, respectively, along with their corresponding tools. Section 3 of the toolkit provides more information about the steps and copies of each tool.

**Table 1. Intervention Steps and Implementation Tools**

Intervention Protocol Steps	Intervention Implementation Tools
<b>Step 1: Recruit Practices</b>	
1.a. Recruit primary care practices to participate in intervention	1.a-1. Information packet for participating practices describing the intervention, their roles and responsibilities, instructions for receiving stool test kits from patients and sending them to the clinical lab for processing (note: copies of the patient mailings should also be sent to the practices – see Step 4 materials)
1.b. Recruit a stool test kit supplier and a clinical lab to process/develop kits	N/A
<b>Step 2: Conduct Academic Detailing</b>	
2.a. Administer baseline CRC screening survey, focus groups, and interviews in participating practices*	2.a-1. CRC screening preintervention survey for participating practices* 2.a-2. CRC screening preintervention focus group guide for participating practices* 2.a-3. CRC screening preintervention key informant interview guide for participating practices*
2.b. Conduct preintervention academic detailing	2.b-1. Academic detailing PowerPoint slides 2.b-2. Web link to most recent screening guidelines on CRC from the American Cancer Society (ACS), U.S. Multi-Society Task Force on Colorectal Cancer, and American College of Radiology (ACR), and the U.S. Preventive Services Task Force (USPSTF) 2.b-3. Screening tracking sheet for participating practices
2.c. Conduct academic detailing boosters as needed	2.c-1. Sample academic detailing booster letter
<b>Step 3: Identify Eligible Patients</b>	
3.a. Execute initial electronic record review	3.a-1. Sample programming criteria for initial electronic record review
3.b. Review returned screening eligibility assessment (SEA) forms to identify additional ineligible and opt-outs*	N/A
<b>Step 4: Mail Screening Materials to Eligible Patients</b>	
4.a. Mail introduction and SEA form*	4.a-1. Introduction letter to patients with instructions for completing the SEA form* 4.a-2. SEA form*
4.b. Mail screening invitation, educational materials, and stool test materials <sup>†</sup> : <i>Version 1: Stool test kit enclosed</i> <i>Version 2: Request card for stool test kit enclosed</i>	4.b-1. Letter to patients ( <i>Version 1</i> ) 4.b-2. Letter to patients ( <i>Version 2</i> ) 4.b-3. Web link to CDC patient information on CRC (English and Spanish version) 4.b-4. Reply card for requesting stool test kit ( <i>Version 2</i> )
4.c. Respond to requests for stool test kits <sup>‡</sup>	4.c-1. Cover letter to patients
4.d. Mail reminder letter to unscreened patients	4.d-1. Reminder letter to patients ( <i>who received a stool test kit</i> ) <sup>†</sup> 4.d-2. Reminder letter to patients ( <i>who received a stool test kit request card</i> ) <sup>†</sup>
4.e. Mail subsequent reminder letter to unscreened patients*	N/A

<b>Intervention Protocol Steps</b>	<b>Intervention Implementation Tools</b>
<b>Step 5: Track Screening</b>	
5.a. Conduct “evidence of screening” electronic record review	5.a-1. Master patient database elements
5.b. Conduct one or more subsequent “evidence of screening” electronic record reviews*	N/A
5.c. Conduct “evidence of complete diagnostic evaluation” (CDE) followup electronic record review	N/A
5.d. Conduct chart reviews for patients lacking definitive electronic record information*	5.d-1. Chart audit review form
<b>Step 6: Provide Feedback to Practices/Clinicians</b>	
6.a. Provide feedback to practices and clinicians about screening results	6.a-1. Feedback form for stool test positive 6.a-2. Feedback form for stool test negative
6.b. Provide feedback to practices and clinicians about CDE	6.b-1. Feedback form for CDE

\* This step or tool is optional.

† These two versions are alternatives; either can be used for all patients or some patients can receive one version and the remainder can receive the other version, depending on the availability of stool test kits.

‡ This step is only implemented if stool test kit request card is used (Step 4.b Version 2).

**Table 2. Assessment Protocol Step and Tools**

<b>Assessment Protocol Step</b>	<b>Assessment Tools</b>
A.1. Focus groups with practice clinicians and staff (postintervention)*	A.1-1 Sample postintervention practice survey (same as 2.a-1)* A.1-2. Sample postintervention practice focus group guide
A.2. Informal interviews with practice staff (postintervention)*	A.2-1. Sample postintervention key informant interview guide
A.3. Patient focus groups (postintervention)*	A.3-1. Sample postintervention patient focus group guide *

\* This step or tool is optional.

## II. Background

### Overview of the Task Order for SATIS-PHI/CRC Development

CNA developed this toolkit as part of an AHRQ ACTION task order involving a population-based case study. It was designed to assess how easily a health system redesign intervention shown to improve colorectal cancer (CRC) screening rates and rates of diagnostic followup for positive screens in one clinical setting could be transferred to another setting. The goal was to achieve similar rate improvements.

The components of the SATIS-PHI/CRC intervention are based on prior studies conducted by project staff at Thomas Jefferson University (TJU) (Myers, 2007; Myers, 2001; Myers, 2004), which demonstrated the following:

- A targeted outreach intervention to patients in a large urban academic practice improved CRC screening rates.
- A feedback intervention to providers in practices affiliated with a large, for-profit managed care organization improved diagnostic follow-up for positive screens.

This project built on the cited studies and examined both:

- The process of implementing the SATIS-PHI/CRC intervention in the Lehigh Valley Physician-Hospital Organization (LVPHO) network of community-based practices (how and how well the intervention could be implemented).
- The outcome of the intervention (the degree to which it could achieve similar rate improvements for both CRC screening and followup in this different setting).

### Description of the SATIS-PHI/CRC Intervention

The SATIS-PHI/CRC intervention is designed to:

- Influence the behavior of primary care providers and their patients regarding CRC screening and followup through targeted communications.
- Facilitate the screening and followup process through improved eligibility identification and screening tracking systems.

The SATIS-PHI/CRC intervention has the following features:

- **Uses system-level redesign.** It is a population-based, system-level redesign of the way CRC screening and followup are conducted in a network of primary care practices. It is intended to assist these practices to better provide guideline-based preventive health care to their age-appropriate patients (50 through 79 years old) who are at average risk for CRC.
- **Provides system support to CRC screening.** It assists practices in providing population-based CRC screening that follows recommendations and guidelines jointly issued in 2008 by the American Cancer Society, U.S. Multi-Society Task Force on Colorectal Cancer,

and American College of Radiology (Leven, et al., 2008) and in 2008 by the U.S. Preventive Services Task Force (USPSTF, 2008).

- **Provides a mechanism for identifying patients in need of CRC screening.** It provides a mechanism for identifying patients who are eligible for but not up to date in their CRC screening, contacting such patients on behalf of their physician's practice to encourage and facilitate recommended screening, tracking screening results, and facilitating patient notification and appropriate followup through feedback to providers.
- **Provides a mechanism for CRC screening.** It also provides a facilitating mechanism for patients to undergo screening. Although the Multi-Society and USPSTF guidelines identify a range of acceptable screening modalities, in an effort to avoid possibly confusing patients with too many choices, SATIS-PHI/CRC limits the choice to only two: (1) a less invasive modality patients can perform themselves at home (stool test) and (2) a more invasive modality requiring a physician-performed procedure (colonoscopy).
- **Educates clinicians and practice staff.** Using academic detailing and performance feedback forms, it seeks to educate clinical providers and other staff in participating practices about recommended CRC screening and followup procedures.
- **Educates patients.** Using mailed information, it seeks to educate targeted patients of participating practices about the importance of and need for CRC screening and about the various types of recommended screening modalities.

**Key Features of SATIS-PHI/CRC:**

- Uses system-level redesign
- Provides system support to CRC screening
- Provides a mechanism for identifying patients in need of CRC screening
- Provides a mechanism for CRC screening
- Educates clinicians and practice staff
- Educates patients

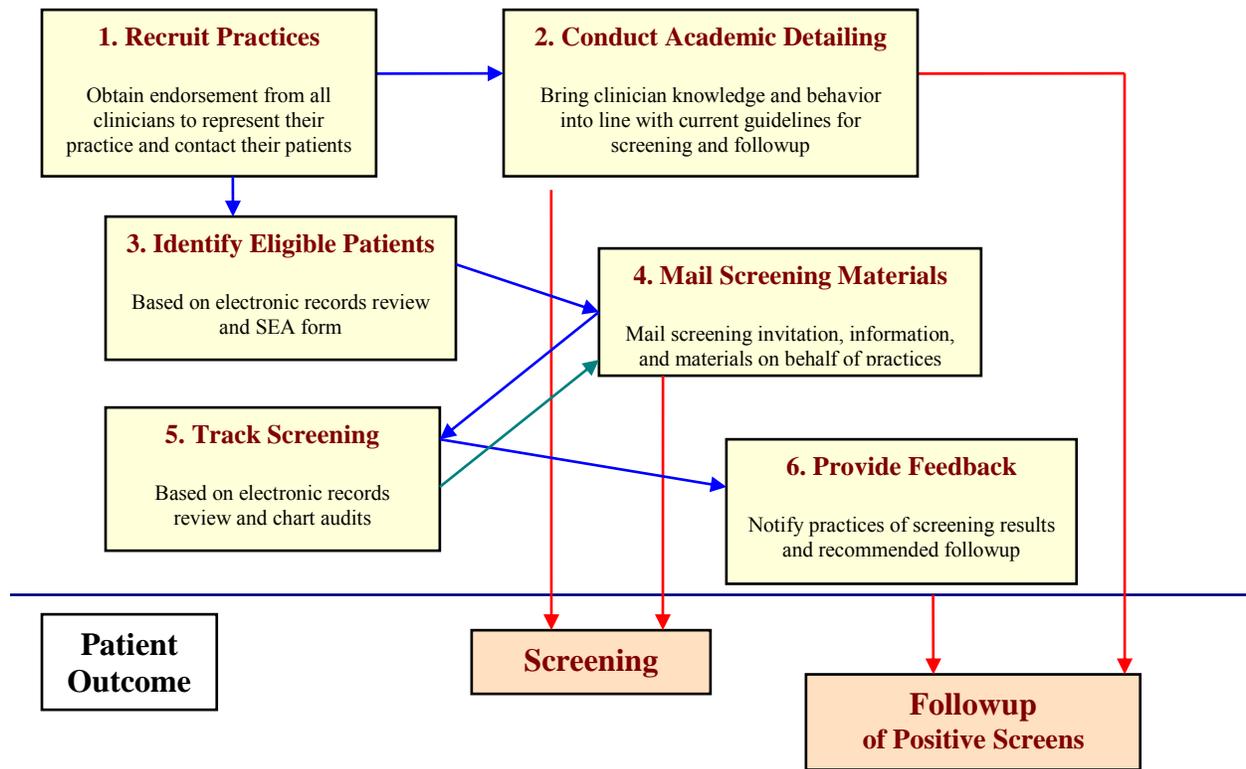
The two educational components (educating clinicians and staff and educating patients) are aimed at informing and changing the behavior of clinicians and practice staff and their patients. Educating both the provider and patient about the importance of CRC screening has been shown to be effective in increasing screening in patients (Levy, 2007; Geller, 2008; Zapka, 2008). The practice/clinician component consists of academic detailing and performance feedback, whereas the patient component consists of mailed information about CRC and screening.

Figure 1 presents the conceptual framework for the six steps of SATIS-PHI/CRC that are conducted by the central entity:

- Step 1 brings primary care practices and their patients into the intervention.
- Step 2 seeks to influence the screening knowledge and behavior of providers within those practices and, along with Step 6, to influence followup knowledge and behavior. By educating and influencing providers, Step 2 also seeks to ensure that providers will influence the screening behavior of their patients.

- Step 4 more directly seeks to influence patient screening. The remaining steps facilitate the process.
- Step 3 identifies patients who are eligible (based on prevailing screening guidelines) to receive the Step 4 screening materials.
- Step 5 tracks patient screening and results. Those with no evidence of being screened receive a reminder Step 4 mailing, whereas the practices of those patients with evidence of screening are notified of screening results and receive feedback regarding recommended followup through Step 6.

**Figure 1. Framework for S ATIS-PHI/CRC**



## **Description of the Intervention Setting, Transferability to Other Settings, and the Central Entity**

### ***Intervention Setting***

The health system setting for this project was the LVPHO formed in 1993 by the Lehigh Valley Health Network (LVHN) and the Greater Lehigh Valley Independent Practice Association (GLVIPA). The PHO, which offers a preferred provider organization health insurance plan, had an interest in value-based health care and sees preventive care, including CRC screening, as a means to that end. The LVPHO, in conjunction with the Eastern Pennsylvania Inquiry Collaborative Network (EPICNet, a practice-based research network [PBRN] of primary care practices affiliated with LVHN), was the central entity for this implementation of SATIS-PHI/CRC.

### ***Transferability to Other Systems/Settings***

Based on assessment findings and lessons learned, CNA believes that the SATIS-PHI/CRC can be a transferable intervention that can improve CRC screening and followup. It is most transferable to health care system settings with a central entity that:

- Is motivated to take the lead in organizing and implementing the effort.
- Has easy access to up-to-date and reasonably complete electronic records.
- Understands and accepts the time and resource commitment needed to undertake the intervention.
- Has experience with large, targeted, population-based mailings to patients (either by conducting such mailings themselves or outsourcing them to reliable contractors).
- Has strong relationships with its affiliated primary care practices.

Environmental conditions most supportive of successful implementation include (1) a sufficient number of willing colonoscopy providers serving the medical service areas participating in the intervention to accommodate any increased demand for colonoscopies resulting from the intervention and (2) no other competing population-based initiatives occurring in the service area or at the participating practices that could detract from the support and attention needed to implement the SATIS-PHI/CRC intervention.

CNA's experience with SATIS-PHI/CRC also demonstrates that this intervention can be successfully implemented in a wide range of practices. These include practices that are more closely and less closely affiliated with the central entity and those that have and do not have fully functional electronic medical record (EMR) systems. However, the central entity would need access to sufficient other electronic records (in particular claims or other evidence of medical services provided to patients) for practices without fully functional EMR systems. Participating practices can also enhance implementation if they are dedicated to population-based preventive health in general and have strong leaders who support the SATIS-PHI/CRC intervention effort. A clinical champion who supports the effort can also help.

### ***Central Entity***

The intervention is intended to be conducted by a central entity, such as a health care delivery system or insurer, affiliated with a network of primary care practices on behalf of and in conjunction with those practices. The central entity completes the six implementation steps highlighted in Figure 1 and described in detail in Section 3. In addition, the central entity can implement an optional assessment step that is described in Section 3.

#### ***Intervention and Assessment Steps for the Central Entity:***

- Recruit practices
- Conduct academic detailing
- Identify eligible patients
- Mail screening materials
- Track screening
- Provide feedback
- Conduct assessment (optional)

To conduct the SATIS-PHI/CRC intervention, the central entity needs to meet the following eight requirements:

1. **Determine patient eligibility.** It must be able to centrally and electronically determine likely eligibility based on the guideline recommendations.
2. **Contact patients.** It must be able to contact patients on behalf of the practices to confirm their eligibility, invite them to be screened, and remind them if they have not responded after a period of time.
3. **Track patient responses and screening.** It must be able to track patient response to the invitation and to screening results.
4. **Contact clinicians with screening results.** It must be able to provide results to practice clinicians and remind them of appropriate recommended followup for positive screening findings.
5. **Obtain funding.** It must be willing to fund or find funding for the intervention.<sup>i</sup>
6. **Recruit stool test kit suppliers.** It must identify one or more suppliers of stool test kits and one or more clinical laboratories to process them (the processing labs may also be the suppliers in many cases).
7. **Establish relationship with a clinical lab.** It must have or develop a business associate relationship with the clinical labs or use a lab it operates to allow the lab to report screenings and results to the central entity.
8. **Work with colonoscopy providers.** It should be able to notify colonoscopy providers (identified by the participating practices) that this screening program will take place and when it will occur, and that they should expect a potential increase in requests for screenings. This last condition is recommended rather than strictly required.

***Requirements for the Central Entity:***

- Determine patient eligibility
- Contact patients
- Track patient responses and screening
- Contact clinicians with screening results
- Obtain funding
- Recruit stool test kit suppliers
- Establish relationship with a clinical lab
- Work with colonoscopy providers

---

<sup>i</sup> This funding is minimal considering the potential public health benefit to be derived. It is primarily for conducting electronic reviews of records, mailing material to patients, and providing stool test kits for those patients preferring to be screened by stool testing.

## Intervention Findings

CNA successfully implemented the intervention in the LVPHO/EPICNet setting and generally improved CRC screening rates. However, a number of factors hindered implementation and likely caused lower than expected screening rates. These included:

- **Lack of implementation infrastructure.** The LVPHO/EPICNet central entity lacked some elements of the ideal implementation infrastructure (in particular, electronic records systems set up for public health population-based patient outreach programs). It also lacked experience implementing a program of this size based at the central entity rather than the practices.
- **Time of economic uncertainty.** CNA implemented the intervention during a time of economic uncertainty and limitations, resulting in fewer staff resources available for implementation at both the central entity and the practices. They also had to change the intervention protocol to accommodate a decision by the stool test kit supplier to restrict the number of free kits it would make available. Thus, the kit could only be sent directly to a small subsample of patients; most patients had to request a kit by mailing a request card.
- **Primary care transformations.** The implementation timeframe was also during a time of change among primary care practices in the Lehigh Valley that affected both their electronic medical record systems and their ability to focus on the SATIS-PHI/CRC intervention.
- **Implementation delays.** Implementation delays shortened the period available for observing screening and followup.
- **Colonoscopy provider shortages.** Shortages of colonoscopy providers in the Lehigh Valley to accommodate an increase in demand for screening likely depressed observed screening and followup rates during the shortened observation period.

These factors affected CNA's ability to fully eliminate ineligible patients from the rate denominators and to fully identify completed screenings (especially colonoscopies) for the rate numerators, leading to low observed screening rates.

Despite these implementation shortcomings, CNA found significantly greater odds of patients of intervention practices than of control practices being screened during the observation period. This finding persisted even after controlling for age, gender, and various practice attributes, including the completeness of the tracking data available. Factors increasing the odds of being screened included receiving the stool test kit directly rather than having to request it and having commercial insurance.

The observed screening rate was substantially lower than in the previous study on which CNA modeled the patient outreach elements of SATIS-PHI/CRC. But when CNA more closely approximated the research conditions of that earlier study, the rate more closely approximated that study's rate. In particular, when stool test kits were sent directly to patients rather than request cards and when CNA included only patients responding to the baseline screening eligibility assessment (SEA) survey in the analysis, rates were more comparable.

Evidence showed that 786 patients were screened: 682 (8.6 percent) from intervention practices and 104 (3.9 percent, or 4.7 percent with an adjusted denominator needed for comparison purposes) from control practices. Of those 786 screens, 363 were by stool test (almost all of the others were by colonoscopy). Only 8 were positive (abnormal); CNA could not ascertain the results of an additional 18.

CNA tracked the followup experience of the 26 patients with positive or inconclusive screens for evidence of complete diagnostic examinations. Their small number precluded any meaningful assessment of the intervention's effectiveness in improving followup rates. A comparison of the pre- and postintervention survey of intervention practices suggests that the academic detailing element of SATIS-PHI/CRC was somewhat effective in educating providers about current CRC screening guidelines.

Overall, implementation of the SATIS-PHI/CRC intervention in the LVPHO/EPICNet setting demonstrates that CNA (1) successfully implemented the SATIS-PHI/CRC intervention in a setting that differed from those that prevailed in studies on which CNA based development of SATIS-PHI/CRC and (2) achieved comparable effectiveness in improving the odds of screening among guideline-eligible patients who were not up to date in their screening. Furthermore, CNA extracted a set of "lessons learned" from their implementation experience that could help others to successfully implement SATIS-PHI/CRC in their settings and to achieve comparable outcomes. These lessons learned are presented as tips in the toolkit.

### **III. Intervention Steps and Tools**

This section describes each of the six main intervention steps and then describes the optional assessment step. Each intervention and assessment step includes what the step entails, provides instructions for implementing it, and offers tips about it and how to avoid potential pitfalls (based on implementation lessons learned). This section also identifies possible alternative ways of carrying out various steps and what would be needed to make such alternatives practical. In addition, the text notes where various steps may be considered optional and under what circumstances a user may or may not want to apply one of those steps. After each intervention step is described, the appropriate corresponding intervention tools are provided (e.g., forms, letters to patients, academic detailing material).

The tools are based on the materials used for CNA's intervention, but they can be tailored and revised as appropriate for each organization that implements the intervention. In addition, some tools include language that was specific to CNA (e.g., participation was voluntary since it was part of a study) that may not be appropriate for each setting. Text in the tools indicates where materials can be personalized (e.g., insert your organization's name here). We suggest that you review the tools and make any appropriate changes.

#### **Step 1: Recruit Practices**

##### ***Description***

The first step of the SATIS-PHI/CRC intervention is recruiting primary care practices to participate. This component consists of encouraging primary care practices affiliated with the central entity to participate by providing the practices information about:

- The importance of CRC screening.
- The nature of the intervention and the evidence it is based on.
- The benefits to them and their patients of participating.
- The intervention requirements for them and their patients.

As the central entity recruits the practices, it is important for the central entity to clearly explain to the practices what is involved with the intervention and what is expected of the practices. Presenting the practices with a step-by-step process guide (Tool 1.a-1) can help them better understand the SATIS-PHI/CRC intervention.

In addition to recruiting practices, the central entity needs to consider whether it wants to involve a stool test kit supplier. This decision will likely vary depending on the type of organization that acts as the central entity. The central entity can choose to bear the upfront cost or negotiate with a clinical laboratory or other supplier to bear the cost of supplying kits for either all eligible patients or only those patients who request them through an enclosed request card. As a third alternative, the central entity can send the kit to patient groups it especially wants to target and send request cards to all other eligible patients. While insurance companies usually reimburse for the cost of kits when they are processed, unused or unprocessed kits are most likely not reimbursed by insurance companies.

## **Tips**

- **Making sure practices are aware of their role.** We suggest providing the practices with detailed written documentation of the practice's role in the intervention so that the practice office manager, staff, and clinicians understand who is supposed to do what and when. Therefore, we suggest using a step-by-step instruction packet to outline exactly what the practice and provider should do during each step of the process (Tool 1.a-1).
- **Sustaining practice involvement.** We suggest staying engaged with the recruited practices during the time it takes to recruit all participating practices, identify eligible patients, and prepare the Invitation to Screen mailing to patients. While practice priorities will always be shifting and loss of practices from the intervention during this time may be inevitable, maintaining engagement with practices can help minimize this loss.
- **Sustaining support of a stool test kit supplier.** When you recruit a stool test kit supplier, be sure that the supplier understands the financial implications of supplying kits. This is especially the case if the supplier is a clinical laboratory that expects to recoup the cost of supplying the tests by charging patients or their insurers for developing and processing returned kits. You should work with such a supplier to ensure that it has a realistic estimate of the proportion of supplied kits that are likely to be returned.

## **Tools (Step 1)**

### **1.a-1 Information Packet for Participating Practices**

#### **Colorectal Cancer Screening: A Process Guide for Practices**

##### **Introduction**

Thank you for participating in this intervention. This process guide explains the System Approach to Tracking and Increasing Screening for Population Health Improvement of Colorectal Cancer (SATIS-PHI/CRC) intervention and your practice's role in this intervention. Your effort here will help improve colorectal cancer care within your practice.

SATIS-PHI/CRC is a population-based, system-level redesign of colorectal cancer screening and followup in primary care practices. SATIS-PHI/CRC is intended to assist primary care practices to better provide guideline-based preventive health care to their age-appropriate patients. It assists practices in encouraging, facilitating, and providing screening. It also helps educate clinicians and patients about colorectal cancer screening.

This effort may be your first time participating in population-based health care. On your behalf, we will contact all the patients in your practice ages 50-79 and of average risk and invite them into an evidence-based screening program. You may receive questions from patients about the process and about colorectal cancer screening. This guide is meant to help clarify the process and answer patient questions. You should also review the 2008 evidence-based guidelines for colorectal cancer screening published by the (1) American Cancer Society, U.S. Multi-Society Task Force on Colorectal Cancer, and American College of Radiology and (2) U.S. Preventive Services Task Force (USPSTF).

In addition to this overview, we have also included copies of the letters that we will send your patients, as well as a Screening Tracking Sheet that can help your practice track patient screening. [ATTACH ALL MATERIALS REFERENCED IN THIS DOCUMENT AND CREATE A CD FOR ELECTRONIC COPIES]

Below is an outline of the information included in this packet:

- Introduction
- Part I: Recommended Screening Guidelines
- Part II: Initial Records Review
- Part III: Baseline Practice Survey (Optional)
- Part IV: Academic Detailing and Optional Baseline Practice Focus Group
- Part V: Patient Screening Eligibility Assessment Mailing (Optional)
- Part VI: Patient Invitation to Screen Mailing
- Part VII: Responding to Patient Screening Requests
- Part VIII: Patient Reminder Mailing(s)
- Part IX: Tracking Patient Screening
- Part X: Postintervention Practice Survey and Focus Group (Optional)
- Part XI: Patient Focus Group (Optional)

## **Part I: Recommended Screening Guidelines**

We are using the March 2008 guidelines from ACS/U.S. Multi-Society Task Force/ACR, which have been widely endorsed and adopted over the past year. A detailed version of the guidelines is at: <http://caonline.amcancersoc.org/cgi/content/full/58/3/130>.

We are also using the 2008 guidelines from the USPSTF. A brief summary chart is attached. The summary chart is available at: <http://www.ahrq.gov/clinic/uspstf08/colocancer/colosum.htm>.

We find that many physicians think colonoscopy is the only successful screening method for colorectal cancer. Some may be unaware that several methods of screening are known to be effective, including stool blood testing. In fact, colorectal cancer screening by stool blood testing remains the only method of screening proven in randomized clinical trials.

In a population effort, it is important to offer effective screening options to all patients. This is why we are providing patients with information about effective screening methods along with an immunochemical stool blood test kit. Patients who receive only a recommendation for colonoscopy often go without screening because of fears about the test; this prevents them from participating in other effective screening measures.

## **Part II: Initial Records Review**

We will review your current electronic databases (claims, billing, and/or electronic medical record) to establish your current documented screening rate. Most of this review will be external to the practice. However, we may ask for clarification from the practice.

## **Part III: Baseline Practice Survey (Optional)**

You may have already completed the preintervention practice survey before receiving this document, or if not, you should complete it prior to the Academic Detailing session. It should be completed by every member of your practice. It will tell us what their current beliefs and processes are about colorectal cancer screening, as well as telling us a little bit about them as members of the medical team.

## **Part IV: Academic Detailing and Optional Baseline Practice Focus Group**

After the survey, but before any patients are contacted, we will come to your office to review the basics of this SATIS-PHI/CRC intervention and of current guidelines (i.e., hold an Academic Detailing session). We may also ask questions to clarify how your practice perceives colorectal cancer screening. Afterward, we will stay to answer questions. We may get back in touch with you later to clarify your information.

## **Part V: Patient Screening Eligibility Assessment Mailing (Optional)**

The daily work of hectic practices, or missing communication from specialists, may have prevented documentation for all patients whose screening is current. In addition, some patients may decline screening. We will send your patients a brief letter asking them to let us know if they are ineligible to be screened but slipped through the documentation process. We will also

ask for some brief demographic information. We will collect all of this information. If we discover any patients who are not screened, we will pass their information back to you as they provided it so that you can update their chart.

At this stage, some patients may call you with questions. They may want to verify that this mailing did indeed come from your practice. In this case, we would appreciate your verification of the eligibility assessment's legitimacy.

Patients may also want to update you on their screening status or they may express a desire not to be screened. In this case, please encourage them to respond to the Screening Eligibility Assessment as instructed. We will provide you with the necessary information about patients who have been screened.

The Screening Eligibility Assessment is attached.

#### **Part VI: Patient Invitation to Screen Mailing**

At this point, we will send all patients who remain eligible to be screened an invitation to participate in screening. This mailing will contain (1) an invitation, (2) information on colorectal cancer screening and methods from the Centers for Disease Control and Prevention, (3) a request slip for an immunochemical stool test kit with instructions [REVISE THIS STATEMENT IF YOU ARE SENDING PATIENTS A STOOL TEST KIT DIRECTLY (VERSION 1), RATHER THAN A STOOL REQUEST CARD (VERSION 2)] and (4) a list of colonoscopy providers whom you recommend.

The invitation endorses multiple methods of effective screening. This includes the stool test kit as well as colonoscopy. Some patients will call and ask for help scheduling a colonoscopy. Some will return the stool test kit to your office. Rarely, someone may ask about a less common method of screening.

If a patient calls for your advice and you prefer to recommend a specific test, please feel free to do so. However, it is important to understand that patients may prefer to choose the effective means of screening that works best for them.

The Invitation to Screen is attached.

#### **Part VII: Responding to Patient Screening Requests**

If a patient requests a colonoscopy, please refer the patient using your current process.

If a patient returns a stool test kit, it is to be processed through [INSERT HERE: NAME OF YOUR NETWORK'S LABORATORY SERVICE]. It is important to use [INSERT HERE: YOUR LAB'S NAME] for these kits, as they will help us track results and ensure the safety of your patients. [INSERT HERE: YOUR LAB'S NAME] has provided a short form to return kits to the lab for processing. Please feel free to use it. You can also call the lab for specimen pickup at [INSERT HERE: LAB CONTACT PHONE NUMBER].

Patient safety and the appropriate followup of patients' screening results are our top priority. Any positive stool test requires a followup colonoscopy, and we want to ensure that all patients who have a positive test return to your practice for that care. [INSERT HERE: YOUR LAB'S NAME] will provide us with the results of each patient's stool blood test so that we can follow up with you.

Although the immunochemical stool test kit is easier to use than the old guaiac kits, some may be unsuitable for developing. In this case, we will remind you of the affected patients so that you can inform them and provide an additional kit if the patient wants to repeat the test. If you need a new kit, please call [INSERT HERE: CONTACT PHONE NUMBER]. Please identify the name of the practice and the name of the patient, including Social Security Number.

The stool test kit will identify the patient by a unique number (the number below the lab return address). We will give you the number with the decoded names in a spreadsheet. By matching this number to the patient on the spreadsheet, you can identify any stool test kit.

SAMPLE STOOL TEST KIT LABEL

SATIS-PHI/CRC [INSERT PRACTICE NAME] [INSERT PRACTICE ADDRESS] ABC00001
--

In this example, the patient's unique ID is ABC00001. Matching the number to the name shows that Patient ID ABC00001 is Jane Doe.

Patient ID	SSN	Name	Street	City	State	Zip Code
ABC00001	123-45-6789	Jane Doe	5 Main St.	Allentown	PA	18101
ABC00002	987-65-4321	John Doe	2 West St.	Coplay	PA	18243

If a stool test kit is returned and cannot be properly developed, please contact us with the patient's name and patient ID number. We will send the patient a replacement kit. We would like you to contact your patient by phone to let the patient know the test needs to be repeated and that a new kit is on the way.

The contents of the Invitation to Screen mailing are attached, including more information on the immunochemical stool blood test kit.

**Part VIII: Patient Reminder Mailing**

We will send a simple reminder letter to all patients who do not respond to the initial mailing. If necessary, we may send a second reminder mailing to patients.

A copy of the reminder letter is attached.

### **Part IX: Tracking Patient Screening**

At this point, we will track the results of all patients who are screened. We will specifically track all positive results to the point of followup colonoscopy and subsequent treatment if necessary.

A document called the Screening Tracking Sheet is attached and included on your CD. This document can serve as a simple registry if you want to track your patient results. Personnel from the central entity can show you how to use this tool. It is for your use if you choose. You may already have another method of tracking results you are comfortable with, which makes the Screening Tracking Sheet unnecessary.

Patients who screen positive will require your support and encouragement as their primary care provider to ensure that they receive appropriate care. We will ask you about each positive result to see that the patient has benefited from followup.

### **Part X: Postintervention Practice Survey and Focus Group (Optional)**

We may ask you to repeat the initial survey to assess what may be different about your practice after the intervention. We may also conduct a final focus group to clarify and reflect on your experience.

### **Part XI: Patient Focus Group (Optional)**

We may contact some of your patients to ask them to share their experience of colorectal cancer screening. This task will occur late in the intervention, so we will let you know when patients are being contacted. Some patients may call you to verify the legitimacy of our contact.

## **Step 2: Conduct Academic Detailing**

### ***Description***

The practice/clinician educational component of the SATIS-PHI/CRC intervention consists of an academic detailing session at each participating practice conducted by staff of the central entity. The detailers use informational material, primarily consisting of PowerPoint slides, for a presentation to practice clinicians and staff (Tool 2.b-1). The presentation describes the intervention and provides information about currently recommended CRC screening and followup guidelines (Tools 2.b-1 and 2.b-2).

Detailers also distribute and explain the use of a screening tracking sheet developed for this intervention to be used by practices that do not already have an effective means of tracking screening tests (Tool 2.b-3). Detailers stress the importance of tracking screening, notifying all patients of screening results whether normal or abnormal, and following up on positive screens.

As needed, the central entity can also conduct followup academic detailing. This need may arise from information collected from an optional survey and focus group of clinicians and other practice staff regarding their perceptions of and behavior performing CRC screening and followup. It also may arise from information found in record reviews (Step 3) or from current events (e.g., changes in guideline recommendations). Detailers can develop an academic detailing “booster” containing material targeted at clarifying misperceptions or nonrecommended screening and followup behaviors (Tool 2.c-1).

The optional practice survey should be distributed and collected prior before the academic detailing session, as the survey is intended to collect baseline information about the practices and should not be influenced by information disseminated during the detailing session (Tool 2.a-1). The optional focus groups should also be conducted before the central entity disseminates information about the intervention (Tool 2.a-2). If the focus group will be conducted during the same session as the academic detailing, it should be held at the beginning of the detailing session. Key informant interviews can also be conducted to obtain additional information not collected during the focus groups (Tool 2.a-3). The Assessment section has more information about these optional tools.

### ***Tips***

- **Understanding clinicians’ preferences.** Physicians may not agree with the new CRC screening guidelines. For example, a physician in CNA’s intervention thought colonoscopy was the only acceptable screening method and that other methods recommended by the current guidelines were not correct, especially stool testing. If you find clinicians with similar preferences, talk with them about their concerns and stress the acceptability of all recommended screening modalities. We also suggest emphasizing the recommended screening modalities in the academic detailing session.
- **Setting expectations.** It may not always be clear to practice staff, especially physicians, that agreeing to participate in the intervention includes agreeing to attend the academic detailing session (with its optional embedded focus group component) and to complete the optional survey of CRC beliefs and behaviors. We suggest reminding the practices and their physicians of this requirement when scheduling the academic detailing sessions. If you conduct the optional practice survey and focus group, we also suggest reminding

clinicians and practice staff that you will need to collect the survey before the academic detailing session to avoid confounding of results.

**Tools (Step 2)**

**2.a-1 Preintervention Survey of Clinicians and Practice Staff**

[INSERT HERE: HEALTH SYSTEM LOGO]

**Health Care Systems for Increasing and Tracking  
Colorectal Cancer Screening Tests**

**Physicians and Other Clinicians - Complete Sections A To D.**

**All Other Staff - Complete Section C Only.**

<p><b>Anonymous ID</b> _____</p> <p><b>Role in the Practice:</b></p> <p><input type="checkbox"/> Physician</p> <p><input type="checkbox"/> Other clinician (CRNP, PA)</p> <p><input type="checkbox"/> Other clinical staff (specify) _____</p> <p><input type="checkbox"/> Other office staff (specify) _____</p> <p><b>Practice ID</b> _____</p> <p><b>Date</b> ____/____/____ (MM/DD/YYYY)</p>
--

**CONFIDENTIALITY:** [INSERT HERE: CONFIDENTIALITY STATEMENT]

## A. Colorectal Cancer Screening Practices (Physicians and Other Clinicians)

This section asks about different approaches to colorectal cancer screening. Please respond based on how you **actually** practice, even if this differs from how you would prefer to practice.

**A-1.** How **frequently** do you recommend the following tests for colorectal cancer screening to your asymptomatic, average-risk patients age 50 and older?

Check one box on each line.

Tests	Very frequently	Somewhat frequently	Not frequently	Never
A. Colonoscopy	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
B. Stool test alone				
Fecal occult blood test (FOBT)	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
Fecal immunochemical test (FIT)	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
Stool DNA test	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
C. Other				
Flexible sigmoidoscopy	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
Virtual colonoscopy (CT colonography)	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
Double contrast barium	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
Digital rectal exam	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

**A-2.** How **effective** do you believe the following tests are in reducing colorectal cancer mortality in asymptomatic, average-risk patients age 50 and older?

Check one box on each line.

Tests	Very effective	Somewhat effective	Not effective	Don't know
A. Colonoscopy	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
B. Stool test alone				
Fecal occult blood test (FOBT)	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
Fecal immunochemical test (FIT)	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
Stool DNA test	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
C. Other				
Flexible sigmoidoscopy	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
Virtual colonoscopy (CT colonography)	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
Double contrast barium	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
Digital rectal exam	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

## B. Case Scenarios (Physicians and Other Clinicians)

We would like your thoughts about the followup of these two hypothetical patients.

**B-1.** Your office is involved in a colorectal cancer screening program that involves sending **stool tests** to patients age 50 and older. Patients may complete and return stool test cards to a central lab for processing. Your office is informed of an abnormal screening test result for one of your patients.

What would you routinely do when you are informed that a patient has a positive stool test result?

Would you recommend . . .

**Check all that apply:**

- 1  Repeat stool test?
  - 2  Flexible sigmoidoscopy?
  - 3  Colonoscopy?
  - 4  Double contrast enema?
  - 5  Other? (Specify)
- 

**B-2.** Your office is involved in a colorectal cancer screening program that offers **flexible sigmoidoscopy** to patients age 50 and older. Patients may undergo a screening flexible sigmoidoscopy examination. Your office is informed of an abnormal test result for one of your patients.

What would you routinely do when you are informed that a patient has an **abnormal flexible sigmoidoscopy result**?

Would you recommend . . .

**Check all that apply:**

- 1  Stool test?
  - 2  Repeat flexible sigmoidoscopy?
  - 3  Colonoscopy?
  - 4  Double contrast enema?
  - 5  Other? (Specify)
-

### C. Colorectal Cancer Screening Process in Your Office (Physicians, Other Clinicians, and ALL Other Staff)

This section asks about how the colorectal cancer screening process occurs in your office. Please respond based on how this process **actually** works in your practice, even if this differs from how you would prefer things to work.

**C-1.** For screening **stool tests**, who in your practice actually performs the activity involved in each step below?

Check all that apply.

	I do it	Another person does it (specify job title)	No one does it	Don't know
A. Gives stool test cards to the patient	1 <input type="checkbox"/>	2 <input type="checkbox"/> _____	3 <input type="checkbox"/>	4 <input type="checkbox"/>
B. Contacts nonresponders to stool test	1 <input type="checkbox"/>	2 <input type="checkbox"/> _____	3 <input type="checkbox"/>	4 <input type="checkbox"/>
C. Gives stool test results to patient	1 <input type="checkbox"/>	2 <input type="checkbox"/> _____	3 <input type="checkbox"/>	4 <input type="checkbox"/>
D. Refers patients with positive stool test for followup	1 <input type="checkbox"/>	2 <input type="checkbox"/> _____	3 <input type="checkbox"/>	4 <input type="checkbox"/>
E. Schedules followup for positive stool test patients	1 <input type="checkbox"/>	2 <input type="checkbox"/> _____	3 <input type="checkbox"/>	4 <input type="checkbox"/>
F. Contacts followup no-shows	1 <input type="checkbox"/>	2 <input type="checkbox"/> _____	3 <input type="checkbox"/>	4 <input type="checkbox"/>
G. Reschedules no-shows for followup	1 <input type="checkbox"/>	2 <input type="checkbox"/> _____	3 <input type="checkbox"/>	4 <input type="checkbox"/>

**C-2.** For screening **flexible sigmoidoscopy**, who in your practice actually performs the activity involved in each step below?

Check all that apply.

	I do it	Another person does it (specify job title)	No one does it	Don't know
A. Orders screening flexible sigmoidoscopy	1 <input type="checkbox"/>	2 <input type="checkbox"/> _____	3 <input type="checkbox"/>	4 <input type="checkbox"/>
B. Schedules flexible sigmoidoscopy	1 <input type="checkbox"/>	2 <input type="checkbox"/> _____	3 <input type="checkbox"/>	4 <input type="checkbox"/>
C. Contacts flexible sigmoidoscopy no-shows	1 <input type="checkbox"/>	2 <input type="checkbox"/> _____	3 <input type="checkbox"/>	4 <input type="checkbox"/>
D. Reschedules no-shows for flexible sigmoidoscopy	1 <input type="checkbox"/>	2 <input type="checkbox"/> _____	3 <input type="checkbox"/>	4 <input type="checkbox"/>

**C-3.** For screening **colonoscopy**, who in your practice actually performs the activity involved in each step below?

Check all that apply.

	<b>I do it</b>	<b>Another <u>person</u> does it (specify job title)</b>	<b>No one does it</b>	<b>Don't know</b>
A. Orders screening colonoscopy	1 <input type="checkbox"/>	2 <input type="checkbox"/> _____	3 <input type="checkbox"/>	4 <input type="checkbox"/>
B. Schedules colonoscopy	1 <input type="checkbox"/>	2 <input type="checkbox"/> _____	3 <input type="checkbox"/>	4 <input type="checkbox"/>
C. Contacts colonoscopy no-shows	1 <input type="checkbox"/>	2 <input type="checkbox"/> _____	3 <input type="checkbox"/>	4 <input type="checkbox"/>
D. Reschedules no-shows for colonoscopy	1 <input type="checkbox"/>	2 <input type="checkbox"/> _____	3 <input type="checkbox"/>	4 <input type="checkbox"/>

## D. Background of Your Patients and Yourself (Physicians and Other Clinicians Only)

**D-1a** During the past 12 months, how **many** (number) newly diagnosed colorectal cancer patients have you **personally** seen in your practice? An estimate is fine.

|\_\_\_\_\_| newly diagnosed colorectal cancer patients

**D-1b** During the past 12 months, how many (number) newly diagnosed colorectal adenomatous polyp patients have you **personally** seen in your practice? An estimate is fine.

|\_\_\_\_\_| newly diagnosed colorectal adenomatous polyp patients

**D-2a** During the past 12 months, approximately what **percentage (%)** of your newly diagnosed colorectal cancer patients was diagnosed because they had a symptom (e.g., hematochezia, weight loss, abdominal pain, or bloating)? An estimate is fine.

|\_\_\_\_\_|% of newly diagnosed colorectal cancer patients

**D-2b** During the past 12 months, approximately what **percentage (%)** of your newly diagnosed colorectal adenomatous polyp patients was diagnosed because they had a symptom? An estimate is fine.

|\_\_\_\_\_|% of newly diagnosed colorectal adenomatous polyp patients

**D-3a** During the past 12 months, approximately what **percentage (%)** of your newly diagnosed colorectal cancer patients was diagnosed because they had a positive FOBT result? An estimate is fine.

|\_\_\_\_\_|% of newly diagnosed colorectal cancer patients

**D-3b** During the past 12 months, approximately what **percentage (%)** of your newly diagnosed adenomatous polyp patients was diagnosed because they had a positive FOBT result? An estimate is fine.

|\_\_\_\_\_|% of newly diagnosed colorectal adenomatous polyp patients

**D-4.** On average, how many patients do you see each week?

1  Fewer than 100

2  100-124

3  125-149

4  150 or more

**D-5.** What is your date of birth? \_\_\_\_/\_\_\_\_/\_\_\_\_ (MM/DD/YYYY)

**D-6.** What is your gender? 1  Male 2  Female

**D-7.** Do you consider yourself to be Hispanic or Latino? 1  Yes 2  No

**D-8.** Do you consider yourself to be . . .

Check all that apply:

- 1  American Indian or Alaska Native
- 2  Asian
- 3  Black or African American
- 4  Native Hawaiian or Other Pacific Islander
- 5  White

**D-9.** Do you as an individual have an affiliation with a medical school or nursing school, such as adjunct, clinical, or other faculty appointment?

- 1  Yes (Specify the medical or nursing school) \_\_\_\_\_
- 2  No

**D-10. Physicians only** -- What is your **primary** medical specialty?

Check one box:

- 1  Family medicine
- 2  General practice
- 3  General internal medicine
- 4  Obstetrics/gynecology
- 5  Other (specify) \_\_\_\_\_

**D-11. Physicians only:** Are you board certified in that specialty?

- 1  Yes 2  No

**D-12a. Physicians only:** In what year did you graduate from medical school? |\_|\_|\_|\_| (4-Digit Year)

**D-12b. Other clinicians only:** In what year did you receive your highest clinical degree?  
|\_|\_|\_|\_| (4-Digit Year)

**Thank you for sharing this information  
with us.**

[INSERT HERE: INFORMATION ON HOW, WHERE, AND BY WHOM SURVEYS WILL  
BE COLLECTED]

## **2.a-2 Practice Focus Group Guide (Preintervention)**

### **SATIS-PHI/CRC Preintervention Practice Focus Group Guide**

#### INTRODUCTION

Hello. My name is \_\_\_\_\_ and I am the moderator for today's 30 minute group discussion. My colleague, \_\_\_\_\_, is here to take notes and help the session run smoothly. Our main purpose today is to discuss colorectal cancer screening in your practice.

#### MODERATOR INFORMATION

[INSERT HERE: INTRODUCE YOUR ORGANIZATION AND WHY YOU ARE CONDUCTING THIS FOCUS GROUP]

As part of our work, we are speaking with physicians, other clinicians, clinical staff, and office staff who were part of our intervention. Your input is important to help us understand how to implement an intervention designed to increase colorectal cancer screening and tracking.

#### ACKNOWLEDGMENT

I want to thank you for coming in today to talk with us and for fitting this session into your already busy schedules.

#### DISCLOSURES

The session is being recorded in audio to make sure our notes accurately reflect our discussion with you. It's not important who says what; I only care what gets said. Does anyone have concerns about taping this session?

Notes will also be taken during the discussion today, but they will not include any identifying information about the group's participants.

#### INFORMED CONSENT

Your decision to participate is voluntary. Before we begin, I would like to hand out this consent form for you all to sign, if you still would like to participate in our discussion. [Hand out informed consent, and collect after obtaining signatures]

- Are there any questions about your participation?
- If you do not want to participate, please take this time to gather your things and leave the room. We appreciate your interest.

## GUIDELINES

A few guidelines before we start:

1. What **you say in this room stays in this room**. As I already mentioned, all information discussed today will be held in confidence. So, please feel comfortable in speaking openly and candidly with us.
2. Please talk one at a time.
3. Talk in a voice as loud as mine.
4. **Avoid side conversations** with your neighbors; but it is okay to “piggy back” on comments others have made. Just be sure to talk loud enough so the whole group can participate.
5. Make sure everyone has a chance to talk.
6. There is **no one point of view**, so please allow all points of view to be heard.
7. Say what **you believe**. It doesn't matter whether anyone agrees with you.

## QUESTIONS

Are there any other questions before we begin?

## SELF-INTRODUCTIONS

Before we begin, does everyone know each other? [If not, have participants introduce themselves with first names only]

## QUESTIONS

### **Theme 1: Understanding Current Guidelines**

1. What guidelines for colorectal cancer screening do you follow?
2. What guidelines for colorectal cancer screening followup do you use?
3. How do you keep up to date with changes to the guidelines?
4. Are you familiar with the recent update of the guidelines?
  - If so, can you describe the new guidelines?
5. How do you manage conflicting or confusing statements between the guidelines?

### **Theme 2: Patient Awareness**

9. How aware do your patients seem to be regarding colorectal cancer screening?
  - What does this vary with (e.g., age, gender, culture)?
10. Do you think your patients are aware of the 2008 ACS/U.S. Multi-Society Task Force/ACR and USPSTF Screening Guidelines?
11. How do your patients get information about colorectal cancer screening?

### **Theme 3: Screening Activities**

12. To whom do you recommend colorectal cancer screening?
13. To whom do you recommend colorectal cancer screening followup?
14. How much time do you spend making the recommendations?
15. Do you offer the patient a range of acceptable screening choices?
16. What percentage of patients agree to be screened?
17. If your patients have an initial positive colorectal cancer screen, what percentage of patients agree to receive appropriate colorectal cancer screening followup?
18. What are the barriers that prevent you from making a recommendation?
19. What are the barriers to patient acceptance?
20. What are the facilitators to patient acceptance?
21. Do you think this practice's current colorectal cancer screening process has an economic impact on the practice?
  - Describe to me how you think it economically affects the practice.
    - What do you think are some positive effects?
    - What do you think are some negative effects?
22. Do you think this practice's current colorectal cancer screening process has an impact on the practice's reputation?
  - Describe to me how you think it affects the practice's reputation.
    - What do you think are some positive effects?
    - What do you think are some negative effects?

### **Theme 4: Process Improvement**

23. What would help improve the way colorectal cancer screening is made available to your patients?
24. How could tracking of patient screening be improved?
25. How could tracking of CRC followup be improved?

## **2.a-3 Key Informant Interview Guide (Pre-Intervention)**

### **SATIS-PHI/CRC Preintervention Informal Interview Protocol**

**Name (Interviewee):**

**Location:**

**Address**

**Telephone No.:**

**Fax No.:**

**E-Mail:**

**Date:**

**Interviewer:**

**Note to interviewer:** The purpose of these informal interviews is to gather additional information or to provide clarification and followup to issues that were discussed (or not discussed) during a previous practice focus group. The interview script below includes questions that may or may not be asked, as it will serve as a guide rather than a script for the interviews.

[INSERT HERE: EXPLAIN WHY YOU ARE CONDUCTING THIS INTERVIEW]

Your decision to participate in this interview is voluntary. You may refuse to take part, or choose to stop, at any time. A decision to refuse to take part or to stop being a part of our discussion will not have a negative impact on you in any way. All information discussed today will be held in our confidence. Information you provide will be summarized and reported with the responses of others and will not be linked to you or any individual. There is no direct benefit from being interviewed; however, taking part may help identify strategies to improve colorectal cancer screening and followup in the future.

Do you have any questions about your participation in this interview? If you do not want to participate, please let me know at this time.

## QUESTIONS

**Note: Questions with an asterisk are higher priority.**

### Practice Perceptions

1. Does the practice have a mechanism to regularly schedule time to discuss medical processes and procedures?
2. Does the practice have an office policy toward the following (and please describe):
  - Colorectal cancer (CRC) screening?
  - CRC followup?
  - Reminding patients to get screened?
  - Patient chart audits?
  - Patient education?
3. \* How is new information, such as new colorectal cancer screening guidelines, disseminated throughout the practice?
4. \* Tell me about what kind of bottlenecks and/or challenges, if any, you experience in your colorectal cancer screening process?
  - In your CRC tracking process?
5. Describe to me how your practice identifies patients who are eligible for screening?

### If not already disclosed in #2 and if time permits

6. Can you walk me through the process in your practice for colorectal cancer screening?
  - Can you describe to me what is done at each step and who is responsible?
7. Can you walk me through the process in your practice for tracking colorectal cancer screening results?
8. Describe to me what happens if someone responsible for a step in the process is not available?
9. How are lab results communicated within the practice?

### Fact-Based Questions (if not obtained elsewhere)

10. How would you characterize your practice?
  - Probe: Would you say it is: a solo practice, a practice with one other physician, a single-specialty group practice, a multispecialty group practice?
11. How many providers do you have in your practice?
  - How many support staff?
  - What types of facilities do you have available in your practice (e.g., exam rooms, x-rays)?

12. Can you describe to me the general patient population you serve (e.g., patient demographics)?
  - Are there providers at your practice who can communicate with patients whose first language is not English?
  - What are some of the main secondary languages spoken by patients and providers?
  - Are translator services available to patients?
13. What types of insurance do you accept?
14. If electronic medical records are used in your practice, describe to me how they are used.
15. What percentage of your patients are insured and uninsured?
16. What percentage of your patients are covered by managed care plans, such as an HMO or PPO?
17. What percentage of your patients are over 50 years of age?

### **Conclusion**

18. Before we end are there any issues or topics that I have not brought up today that you would like to address?

\*\*\* Thank you very much for taking the time to talk with me today.\*\*\*

## 2.b-1 Academic Detailing Slides

**Note:** A sample slide design is shown but any template can be used. The first slide is shown with no design. You might want to insert a logo or other design features.

# System Approach to Tracking and Increasing Screening for Population Health Improvement of Colorectal Cancer (SATIS-PHI/CRC)

[INSERT HERE: ORGANIZATION NAME AND STAFF]

## Objectives

---

- After this academic detailing session, you will be able to:
  - Identify current trends in colorectal cancer screening.
  - Understand the SATIS-PHI/CRC intervention.
  - Identify recommended colorectal cancer screening modalities for patients of average risk, using the:
    - Joint Guideline from the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology, and
    - U.S. Preventive Services Task Force (USPSTF) Guideline.

2

## Burden of Colorectal Cancer

---

- CRC is third most common cancer but the second-leading cause of cancer mortality.
- 98% of physicians report that they screen for colorectal cancer.
- However, less than 60% of eligible patients are screened.

3

## Effective Colorectal Cancer Screening

---

- An effective colorectal screening program includes:
  - Your recommendation,
  - An office policy,
  - An office reminder system,
  - An effective communication system, and
  - A tracking system.

4

## SATIS-PHI/CRC Intervention

- Population-based, system-level redesign for conducting colorectal screening and followup in primary care practices.
- Assists primary care practices with providing guideline-based CRC screening.
  - Providing, facilitating, and encouraging screening.
- Educates both clinicians and patients about colorectal screening.

5

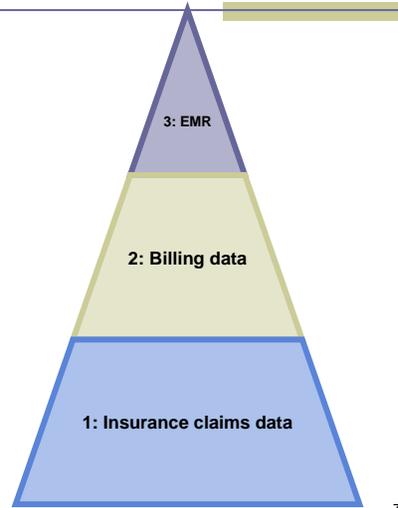
## SATIS-PHI/CRC Process

- Scheme will allow central entity to track both the patients and the effectiveness of the systems:
  - Identify patients who have no recent confirmation of colorectal cancer screening from electronic databases.
  - Under your recommendation, invite those patients to be screened in concordance with ACS/U.S. Multi-Society Task Force/ACR and USPSTF guidelines.
  - Send those patients back through your practice for care decisions related to screening.
  - Track screening results and give reminders to your patients and feedback to your practice.

6

## Databases for Identifying Patients

- Depending on available electronic data, the central entity identifies patients from the following sources:
  - Electronic medical record (EMR)
  - Billing data
  - Insurance claims data



## Steps to Identify Patients

- The central entity identifies eligible patients by conducting a query of the database to identify all patients ages 50-79.
- The central entity then eliminates those whose data include the following information:
  - Up-to-date screening, by any acceptable method.
  - A prior history of colorectal cancer or colorectal cancer risk (e.g., history of adenomatous colon polyps).
  - A history of high risk (e.g., primary relative with colorectal cancer or known high-risk condition such as ulcerative colitis).

8

## Mailings to Patients

- Come from the patient's primary care practice but are sent by the central entity. .
- Screening eligibility assessment (optional).
- Invitation to screen letter with:
  - Information on CRC screening methods, including fact sheet from the Centers for Disease Control and Prevention (CDC),
  - Information on accessing screening tests in their network, and
  - A stool blood testing kit (optional) or a return card to request a kit.
- Reminder letters to nonrespondents.

9

## Screening Process

- Patients will be referred back to the practice for:
  - Screening questions,
  - Referrals, and
  - Followup of screening.
- Patients will be able to request a stool blood testing kit from the central entity.
  - Developing will be done by an approved laboratory for tracking purposes.
- Central entity will track results via reviews of EMR, billing, insurance claims, and other data sources.

10

## Followup of Positive Stool Test Screens

- Primary care providers should recommend that positive stool test screens be followed up with a diagnostic colonoscopy.
- The central entity will provide the practice with:
  - A list of all negative screens.
  - A list of all positive screens needing diagnostic followup.
  - A form for tracking and documenting followup of diagnostic colonoscopies for patients with positive stool tests.
- **REMEMBER:** All positive stool blood tests should be recommended for diagnostic colonoscopy. There are no assumptions of false positive tests.

11

## Tracking Screening

- Primary care practices should have an office process to track their patients' screening through the Screening Tracking Sheet or another existing method.
- At minimum, should track:
  - Patient name,
  - Screening modality,
  - Screening date,
  - Screening result,
  - Patient notification of result,
  - Followup recommended, if applicable,
  - Followup received, or documentation of patient refusal to follow up, if applicable,
  - Followup date, if applicable,
  - Followup result, if applicable,
  - Patient notification of followup result, if applicable, and
  - Medical reason for exclusion of any patient, if applicable.

12

## Sources of Colorectal Cancer Guidelines

- **A Joint Guideline from the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology**

*CA Cancer J Clin* 2008; 58:130-160

Available at:

<http://caonline.amcancersoc.org/cgi/content/full/58/3/130>

- **The U.S. Preventive Services Task Force (USPSTF) 2008**

Available at:

[www.ahrq.gov/clinic/uspstf08/colocancer/colosum.htm](http://www.ahrq.gov/clinic/uspstf08/colocancer/colosum.htm)

13

## Colorectal Cancer Guidelines

- Most important facilitator of screening is a recommendation from the doctor.
- Guidelines focus on tests that primarily detect cancer and polyps (prevention) and those that primarily detect cancer.
- All recommended tests have at least a 50% rate of true positives when performed correctly.
- Availability of appointments, insurance coverage, patient risk, and patient preference can all play a role in an individual patient's choice of screening modality.

14

## Tests That Find Cancer and Polyps

- Colonoscopy
  - Virtual colonoscopy (CT colonography)\*
  - Flexible sigmoidoscopy
  - Double-contrast barium enema\*
- Note: Each test has a recommended frequency when screening patients of average risk.
- \* This test is not part of the USPSTF recommendation for colorectal cancer screening.

15

## Tests That Find Cancer

- Fecal occult blood test (FOBT) (guaiac)
  - Fecal immunochemical test
    - In use for SATIS-PHI/CRC intervention
  - Stool DNA test\*
- Note: Each test has a recommended frequency when screening patients of average risk.
- \* This test is not part of the USPSTF recommendation for colorectal cancer screening.

16

## Ineffective Tests

- Digital rectal exam (DRE) and a single, office-performed stool blood test are **not** recommended for colorectal screening by the ACS/U.S. Multi-Society/ACR or USPSTF guidelines.

17

## Reminder: Important Facts About Stool Testing

- All patients who have a single positive stool blood test should be referred for diagnostic colonoscopy.
- No positive stool test should be considered a false positive.
- Digital rectal exam and in-office stool blood testing are **not** recommended for colorectal screening.

18

# Questions?

- Any questions?

## **2.b-2 Web Links to CRC Screening Guidelines From ACS/U.S. Multi-Society Task Force/ACR and USPSTF**

A Joint Guideline from the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology. CA Cancer J Clin 2008; 58:130-160

Available at:

<http://caonline.amcancersoc.org/cgi/content/full/58/3/130>

U.S. Preventive Services Task Force. Screening for colorectal cancer: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med 2008 Nov 4;149(9):627-37. Epub 2008 Oct 6.

Available at:

<http://www.ahrq.gov/clinic/uspstf08/colocancer/colosum.htm>

<http://www.annals.org/content/149/9/627.full>



## 2.c-1 Academic Detailing Booster Letter

Dear Colleague:

As you may know, we surveyed providers in your office on their colorectal cancer (CRC) screening practices. This was for an intervention that involves your practice along with other practices in the [INSERT HERE: YOUR ORGANIZATION NAME]. We want to alert you that we discovered patterns in some practices that are **NOT** supported by current guidelines.

Please note:

- Digital rectal exam and in-office stool blood testing is NOT recommended for CRC screening by any guidelines.
- Take-home stool blood testing IS ACCEPTABLE as a CRC screening test. This can be either fecal occult blood testing (FOBT) or fecal immunochemical testing (FIT) annually.
- Patients with any positive at-home stool test should be referred for colonoscopy.

Current guidelines on screening are enclosed.

If you have any questions, please contact [INSERT HERE: CONTACT NAME AND PHONE NUMBER].

## 2.c-1 Academic Detailing Booster Enclosure

### American Cancer Society Guidelines – Colorectal Cancer Screening\*

Beginning at age 50, both men and women at average risk for developing colorectal cancer should use one of the screening tests below. The tests that are designed to find both early cancer and polyps are preferred.

#### Tests that find polyps and cancer:

- Flexible sigmoidoscopy every 5 years\*
- Colonoscopy every 10 years
- Double contrast barium enema every 5 years\*
- CT colonography (virtual colonoscopy) every 5 years\*

#### Tests that mainly find cancer

- Fecal occult blood test (FOBT) every year\*· \*\*
- Fecal immunochemical test (FIT) every year\*, \*\*
- **Stool DNA test (sDNA), interval uncertain\***

\* Colonoscopy should be done if any test results are positive.

\*\* An FOBT or FIT done with a digital rectal exam is NOT adequate for screening. If FOBT or FIT is used as a screening test, use the take-home multisample.

### U.S. Preventive Services Task Force Recommendations†

- The USPSTF recommends screening for colorectal cancer using fecal occult blood testing, sigmoidoscopy, or colonoscopy in adults, beginning at age 50 years and continuing until age 75 years. The risks and benefits of these screening methods vary.
- The USPSTF recommends against routine screening for colorectal cancer in adults ages 76 to 85 years. There may be considerations that support colorectal cancer screening in an individual patient.
- The USPSTF recommends against screening for colorectal cancer in adults older than age 85 years.
- The USPSTF concludes that the evidence is insufficient to assess the benefits and harms of computed tomographic colonography and fecal DNA testing as screening modalities for colorectal cancer.

---

\* [www.cancer.org/docroot/PED/content/PED\\_2\\_3X\\_ACS\\_Cancer\\_Detection\\_Guidelines\\_36.asp](http://www.cancer.org/docroot/PED/content/PED_2_3X_ACS_Cancer_Detection_Guidelines_36.asp).

† [www.uspreventiveservicestaskforce.org/uspstf/uspcolo.htm](http://www.uspreventiveservicestaskforce.org/uspstf/uspcolo.htm).

### Step 3: Identify Eligible Patients

#### **Description**

Eligible patients are initially identified through a review of available electronic records. Such records can include claims records, billing records, electronic medical or health records, and patient registries. Ideally information in these records should be verified and made up to date by using a brief screening eligibility assessment (SEA) form of those patients identified as eligible through the records review (Tool 4.a-2).

This SEA form is optional, but we suggest using it, if possible. It helps ensure that the central entity only targets patients who are truly eligible and not those who may only appear to be eligible based on records with missing, incomplete, incorrect, or out-of-date information. Such patients may become annoyed if sent screening material in error or may decide to get screened even though they do not meet guidelines for screening.

The following are eligibility criteria for including patients in the SATIS-PHI/CRC intervention (Tool 3.a-1):

- Being age 50 through 79.
- Being a current patient of a participating practice (having had at least one visit to the practice within the previous 2 years).
- Being of average risk for colorectal cancer (having no previous diagnosis of CRC, colorectal polyps, or inflammatory bowel disease and no family history of CRC diagnosed before age 60).
- Having a complete mailing address on file.
- Not being up to date in CRC screening according to prevailing guidelines. These guidelines currently include not having had (1) a colonoscopy within the previous 10 years, (2) a flexible sigmoidoscopy or double contrast barium enema x-ray within the previous 5 years, or (3) a stool test (e.g., a fecal occult blood test [FOBT], a fecal immunochemical test [FIT], or similar stool test) within the previous year.

Information about eligible patients should be entered into a “master patient database” (Tool 5.a-1). The format of this database can vary, depending on each organization’s existing information technology infrastructure. At a minimum, it should include the following:

- Patient’s name and mailing address.
- Unique patient identification number.<sup>iv</sup>
- Patient’s age or date of birth.
- information indicating whether the patient would be ineligible for the intervention (e.g., evidence of prior diagnosis of CRC or polyps or inflammatory bowel disease, evidence of family history of CRC diagnoses before age 60, evidence of recent prior CRC screening test, not a patient of the practice).

---

<sup>iv</sup> Assigning a unique patient identification number to patients can be useful for confidentiality and Health Insurance Portability and Accountability Act (HIPAA) concerns.

- Name of the practice the patient attends.

Additional patient information can also be entered in this database, such as the patient's gender and the patient's primary language. Recording the patient's primary language can especially be helpful if sending language-appropriate materials to patients. This information, as well as other demographic information, can be collected from the optional SEA form.

The master patient database will then be used for tracking patient screening, as described in greater detail in Step 5. Such tracking includes recording patient response to the intervention, screening results for those choosing to be screened, indications of patient notification of screening results, and indications of followup to screenings.

Followup electronic reviews are conducted before various subsequent steps in the intervention that require identifying patient response to the intervention material or results of screenings. These are described in more detail below under tracking patient response and screening results (Step 5).

### **Tips**

- **Timing.** Try not to schedule electronic record reviews during or in the weeks following open enrollment periods, because records may not be up to date for patients. During open enrollment, patients may be changing insurance plans or primary care practices. In addition, data system personnel at health plans, who may be required to assist with the record review, will likely be too busy updating records with open enrollment data to support the intervention during those times.
- **Complications of extracting data.** You may need to build in extra time for electronic record reviews to accommodate inexperienced data system staff at practices or other entities from which information needs to be extracted. Staff responsible for managing and extracting data from the source data systems do not always have the necessary experience or expertise to easily identify and produce lists of patients eligible for the intervention. Further, these systems are not always set up to produce such lists or to provide the kinds of data needed (e.g., identifying which primary care practice a patient is affiliated with or finding evidence of prior colorectal cancer screening or other disqualifying conditions in the records) and require special programming.

You may need to (1) accommodate competing demands on electronic data systems and on data management and programming staff, (2) supplement existing report generation programs with revised programs needed for the data extraction, (3) respond to Health Insurance Portability and Accountability Act (HIPAA) concerns of data management staff, and (4) accommodate and overcome missing data and data ambiguities, especially in electronic medical records. Roth (2009) and West (2009) both note that obtaining information from electronic health records is complicated and difficult. Roth found that quality indicator data for colorectal cancer are especially problematic. We suggest considering these potential complications when planning your record review.

- **Data cleaning.** Regardless of all the precautions you take to ensure receiving clean data, you should plan to set aside time and resources to further clean them. Data cleaning may require a significant amount of additional manual effort. For example, the format of

patient names received from different systems may be inconsistent or may not be compatible with producing mailing labels, requiring manual reformatting of names.

- **Staggered patient mailings.** If you encounter delays in receiving and cleaning data for patients of some practices but have complete clean data for patients of other practices, you can consider staggering your patient mailings. You can mail material to patients of practices with complete data while continuing to obtain and clean data from other practices. If you choose this option, we suggest tracking in the master patient database which patients received the mailing and when to ensure that all patients received the mailing (as you will be sending patients the mailings at various intervals). In addition, you may want to track which patients received the mailings and when, regardless of whether you have to send the mailings with a staggered start.

## Tools (Step 3)

### 3.a-1 Sample Programming Criteria for Initial Electronic Record Review

#### Electronic Records Review Programming Criteria

##### Eligibility Criteria

- 1 Age 50-79
- 2 Visit to practice within 2 years
- 3 Complete mailing address (first and last name, street address, city, State, ZIP Code)
- 4 No diagnosis of CRC or polyps or inflammatory bowel disease (refer to Table 1, ICD-9 Codes for Excluded Diagnoses)
- 5 No family history of CRC diagnosis before age 60
- 6 No recent CRC tests (refer to Table 2, Excluded Procedure Codes)
  - Stool blood test within 1 year
  - Sigmoidoscopy within 5 years
  - Barium enema within 5 years
  - Colonoscopy within 10 years

**Table 1. ICD-9 Codes for Excluded Diagnoses**

Diagnosis	ICD-9 Codes
Malignant neoplasms	153.0 – 154.8
Benign neoplasms	211.3 – 211.4
Colorectal and intestinal neoplasms	159, 197.5, 197.8, 211.9, 230.3 – 230.4, 230.7, 235.2, 239.0
Regional enteritis (including Crohn's disease)	555.0 – 555.9
Ulcerative colitis	556.0 – 556.9
History of colon polyps	V12.72

**Table 2. Excluded Procedure Codes**

Procedure	CPT Codes	HCPCS Codes	ICD-9 Codes
Stool blood test	82270, 82274	G0107, G0328	V76.51
Sigmoidoscopy	45330-45335, 45337-45342, 45345	G0104	45.24, 45.42
Barium enema	74270, 74280	G0106, G0120, G0122	
Colonoscopy	44388-44394, 44397, 45355, 45378-45387, 45391, 45392	G0105, G0121	45.22, 45.23, 45.25, 45.43

**Key:** CPT = Current Procedure Terminology; HCPCS = Healthcare Common Procedure Coding System; ICD-9 = International Classification of Diseases, 9<sup>th</sup> edition.

## **Step 4: Mail Screening Information and Materials**

### ***Description***

This step consists of several mailings to patients:

1. Optional screening eligibility assessment (SEA) survey form.
2. Invitation to screen.
3. Followup reminder (including an optional second reminder).

Recent studies have found that minorities are more likely to be screened when the information is presented in a manner they can read and understand (Carcaise-Edinboro, 2008; Natale-Pereira, 2008). Therefore, if the intervention is to be implemented in a community that has a significant population that speaks or reads a non-English language, we highly recommend that all mailed material be sent in both English and the other languages. The CNA implementation of the SATIS-PHI/CRC had a large Spanish-speaking population, so most of the patient mailing materials included in this toolkit are in both English and Spanish.

In addition, recent studies have found that receiving information and recommendations for CRC screening from a health care provider can be a predictor of patient screening (Carcaise-Edinboro, 2008; Griffith, 2008; Sarfaty, 2007). Therefore, although the central entity mails the patient letters (on behalf of the practice), we suggest that the provider sign all mailings so that the patient clearly identifies this effort with his or her provider. In addition, all mailings should be printed on practice letterhead.

### **Optional SEA Form**

As noted, use of the SEA form is optional, although it is recommended. Its primary intent is to identify patients who appear to be eligible based on the initial record review but who are, in fact, ineligible. SATIS-PHI/CRC includes this step to help compensate for the current state of most electronic records. The information contained in them required to determine eligibility is often incomplete, inaccurate, or not up to date. The SEA form gives patients an opportunity to identify themselves as ineligible and to report the reason for their ineligibility.

The central entity conducting the intervention can then change the status of such a patient in the master patient database from eligible to ineligible and indicate the reason. The central entity can also inform the practice with which such a patient is affiliated of the need to update its records on this patient or to further confirm with the patient the validity of the self-identified ineligibility. If a patient identifies himself or herself to be ineligible due to above-average risk for CRC (e.g., through a family history of CRC), the central entity should inform that patient's practice. The practice can then initiate a conversation with that patient to be diligent about receiving CRC testing more often than recommended for average-risk patients.

If the central entity is willing to accept the results of the initial electronic record review as determinative, it can omit the SEA form. The central entity may have great confidence in the validity of the electronic records from which it determines eligibility or it may decide that the cost and effort involved in mailing and processing the SEA form outweigh the benefit. We do not recommend this plan but leave it to the central entity adopting the intervention to make this choice.

If the central entity decides to use the SEA, all patients who are identified as being potentially eligible by the initial electronic record review should be sent the optional first mailing consisting of the following two items:

1. Letter from the primary care practice with which they are affiliated explaining the importance of CRC screening and informing them of the practice's participation in a screening program (Tool 4.a-1), and
2. SEA form, requesting information about their eligibility and demographics (Tool 4.a-2).

The SEA form asks patients to indicate whether they consider themselves to be ineligible for the intervention (i.e., identify themselves as ineligible by checking one or more listed reasons that would make them ineligible). The form also requests demographic information about the patient not otherwise ascertainable through the available electronic records. Such information includes race/ethnicity, preferred language, marital status, educational level, and perceived health status. The SEA form also provides a check box for patients to indicate that they do not want to participate in the intervention (i.e., that they do not want to receive subsequent information about CRC screening or this screening program). A telephone number is provided (for the central entity) for opting out of the screening program intervention if a patient does not want to respond by the SEA form.

#### **Invitation to Screen Mailing**

The central entity next sends an invitation to screen to all patients deemed to be eligible by electronic record review and possibly the SEA mailing (note that if the central entity omits the SEA mailing, the invitation becomes the first rather than the second mailing). The invitation consists of:

1. A letter from the patient's primary care practice inviting the patient to be screened (Tools 4.b-1 and 4.b-2).
2. Educational material regarding CRC and screening (a brochure that describes the benefits of CRC screening and the alternative screening modalities consistent with the 2008 Multi-Society and USPSTF guidelines) (Tool 4.b-3).
3. A list of colonoscopy providers to whom clinicians in the patient's practices refer, along with those providers' addresses, phone numbers, and other contact information (additional information such as type of insurance accepted may be included if it is available).
4. Either a stool test kit or a request card that the patient can mail back to request a kit (Tool 4.b-4).
5. A self-addressed stamped envelope for returning either the kit or the card to the practice.\*

If the invitation is the first mailing (i.e., the SEA mailing is omitted), the invitation should also include language from the introductory letter from practice clinicians (Tool 4.a-1).

---

\* Depending on the relationship between the central entity and the laboratory, patients may be able to mail completed stool test kits directly to the laboratory for processing, or they may have to send the kits to the practice (who in turn send them to the lab).

The central entity should also tailor the invitation letter to whether a stool test kit or a request for a kit is enclosed with this mailing (we refer to these options as Versions 1 and 2, respectively). If the central entity decides to send kits only to those requesting one through a mail-back request card for all or some of the patients in the screening program, it should periodically mail kits to patients requesting them at short enough intervals that patients do not have to wait too long to receive them (Tool 4.c-1). The central entity can also update its master patient database to indicate which patients have requested a kit and when it was mailed to them. When the central entity sends patients the stool test kits, it should include instructions for completing the kit that are specific to the type of kit used.

### **Reminder Mailings**

In conjunction with tracking patient responses and screening, the central entity sends one or more reminders to patients in the database who remain eligible for screening (i.e., those for whom no disqualifying information has been received) and no evidence of screening is found (Tools 4.d-1 and 4.d-2). The central entity can decide to stop after only one reminder or send one or more subsequent reminders. This decision should be based on considerations of cost and expected increased screening response.

### **Tips**

- **Preparation of mailing materials.** It was time and labor intensive to conduct the patient mailings. Depending on the size of the patient population and the staff resources available from the central entity, we suggest using a separate contractor who specializes in large-scale mailings to send and track the patient mailings. HIPAA issues should be considered when making this decision as well.
- **Use of SEA.** The SEA form can be very useful for identifying patients who are not eligible and who do not want to participate. Some patients can also use the SEA form as a way to indicate their sometimes strong desire to not continue receiving any additional screening information.
- **Patient response.** Patients do not always return requested information (e.g., SEA form) in a timely manner. In addition, patients can be frustrated by receiving information when they indicate they do not want to participate. If you choose to use the SEA form, we suggest waiting a sufficient amount of time before sending the invitation to screen. You can judge what a “sufficient amount of time” is by monitoring the rate of return of SEA forms and waiting until that rate drops off significantly. We also recommend adding a suggested timeline in patient mailing materials, indicating a deadline for patients to respond.

## ***Tools (Step 4)***

### **4.a-1 Introduction Letter to Patients With Instructions for Completing SEA Form**

Date

Honorific First Last

Address

City, State, ZIP

Dear Honorific First Last:

My practice, along with others in the [INSERT HERE: ORGANIZATION NAME], will soon begin participation in a research study to increase the rate of colorectal cancer screening among patients. We are making an effort to invite only those who currently need screening.

You may have had screening, but it was not captured in our records. If this is so, please complete the enclosed Screening Eligibility Assessment.

We ask that you complete the Patient Information section whether or not you choose to take part in this screening. Your responses to the questionnaires will be kept confidential and your participation is strictly voluntary.

Please return the Screening Eligibility Assessment along with the Patient Information in the enclosed, stamped envelope in one week.

If you do not wish to receive further contact about colorectal cancer screening, you may also call [INSERT HERE: CONTACT PHONE NUMBER].

Sincerely,

#### **4.a-1 Introduction Letter to Patients With Instructions for Completing SEA Form (Spanish)**

### **CARTA DE CLASIFICACIÓN DE ELEGIBILIDAD**

Fecha

Antenombre Primero Apellido

Domicilio

Ciudad, Estado, Código Postal

Estimado(a) Primero Apellido:

Mi consultorio, junto con otros en [INSERT HERE: ORGANIZATION NAME], empezará pronto a participar en un proyecto para incrementar el número de pruebas para detectar cáncer colorrectal entre los pacientes. Estamos haciendo un esfuerzo para invitar únicamente a aquellos que actualmente necesitan la prueba de detección.

Es posible que usted se haya hecho la prueba de detección, pero no fue captado en nuestros registros. Si es así, por favor llene el formulario de Evaluación de elegibilidad para la prueba de detección.

Le pedimos que llene la Sección B si usted elige o no tomar parte en la prueba de detección. Sus respuestas a los cuestionarios serán confidenciales y su participación es estrictamente voluntaria.

Por favor devuelva en el transcurso de una semana Evaluación de elegibilidad para la prueba de detección junto con la Información del paciente, en el sobre que se incluye con estampilla de correo prepagada.

Si usted no desea recibir más comunicación acerca de la prueba de detección de cáncer colorrectal, puede también llamar al [INSERT HERE: CONTACT PHONE NUMBER].

Atentamente,

<MÉDICOS DE LA PRÁCTICA>

## 4.a-2 Screening Eligibility Assessment (SEA) Form

### Colorectal Cancer Screening Eligibility Assessment

We are evaluating a new program for men and women who are 50-79 years of age and are eligible for colorectal cancer screening. You are receiving this form because our records show that you may be eligible for this program. Your answer to Section A of this form will help us determine your eligibility.

If you are eligible, in the next few weeks, we will send information to you about colorectal cancer screening and this program **unless** you check the box in Section C to tell us you do not want to receive this information. Whether or not you are eligible for this program, please answer the questions about yourself in Section B. When you have completed this form, please return it in the postage paid envelope provided.

#### A. I may not be eligible for colorectal cancer screening through this program because:

*(Check all that apply)*

- I am *not* between 50 and 79 years of age.
- I had a recent screening test (a colonoscopy in the last 10 years, a stool blood test at home in the last year, a flexible sigmoidoscopy in the last 5 years, or a barium enema x-ray in the last 5 years).
- I have previously been diagnosed as having colorectal cancer.
- Other reason (Specify) \_\_\_\_\_

#### B. Please answer the following questions about yourself.

##### B1. Do you consider yourself to be Hispanic or Latino?

- Yes
- No

##### B2. Do you consider yourself to be:

*(Check all that apply)*

- American Indian or Alaskan Native
- Asian
- Black or African American
- Native Hawaiian or Pacific Islander
- White
- Other \_\_\_\_\_

##### B3. Are you:

- Single
- Married
- Divorced, separated, or widowed

##### B4. Which language do you prefer to speak?

- English
- Spanish
- Other

##### B5. What is your highest level of education?

- Some high school
- High school graduate or GED
- Some college or Associate's degree
- College degree or above

##### B6. How would you describe your health?

- Poor
- Fair
- Good
- Very Good
- Excellent

#### Please do not send me information about colorectal cancer screening or this program.

(Note: If you do not want to receive this information, you may call [INSERT HERE: CONTACT PHONE NUMBER] and leave a message. Please identify yourself using the survey number below rather than your name.)

Survey No.

## 4.a-2 Screening Eligibility Assessment (SEA) Form (Spanish)

### Evaluación de elegibilidad para la prueba de detección de cáncer colorrectal

Estamos evaluando un nuevo programa para hombres y mujeres entre 50-79 años de edad y que son elegibles para la prueba de detección de cáncer colorrectal. Usted está recibiendo este formulario porque nuestros registros muestran que podría ser elegible para este programa. Su respuesta a la Sección A de este formulario nos ayudará a determinar su elegibilidad.

Si usted es elegible, en las próximas semanas, le enviaremos información acerca de la prueba de detección de cáncer colorrectal y de este programa, **a menos** que marque la casilla en la Sección C para decirnos que no desea recibir esta información. Si usted es o no elegible para este programa, por favor responda a las preguntas sobre su persona en la Sección B. Cuando haya llenado este formulario, por favor devuélvalo en el sobre proporcionado con estampilla de correo prepagada.

#### 1. Yo podría no ser elegible para la prueba de detección de cáncer colorrectal a través de este programa porque: *(Marque UtodasU las que apliquen)*

- No tengo entre 50 y 79 años de edad.
- Tuve una prueba de detección reciente (una colonoscopia en los últimos 10 años, una prueba de sangre en las heces en casa en el último año, una sigmoidoscopia flexible en los últimos 5 años o una radiografía de enema opaco en los últimos 5 años).
- He sido previamente diagnosticado de tener cáncer colorrectal.
- Otro motivo (Especifique) \_\_\_\_\_

#### 2. Por favor responda a las siguientes preguntas sobre usted.

##### B1. ¿Se considera usted hispano o latino?

- Si
- No

##### B4. ¿Qué idioma prefiere usted hablar?

- Inglés
- Español
- Otro

##### B2. ¿Se considera usted:

*(Marque todas las que apliquen)*

- Indio americano o nativo de Alaska
- Asiático
- Negro o afro americano
- Nativo hawaiano o isleño del Pacífico
- Blanco
- Otro \_\_\_\_\_

##### B5. ¿Cuál es su grado más alto de educación?

- Algo de preparatoria
- Graduado de la preparatoria o GED
- Algo de universidad o grado asociado (2 años)
- Título universitario o más alto

##### B3. ¿Es usted:

- Soltero
- Casado
- Divorciado, separado, o viudo

##### B6. ¿Cómo describiría usted su salud?

- Mala
- Regular
- Buena
- Muy Buena
- Excelente

#### Por favor no me envíen información acerca de la prueba de detección de cáncer colorrectal o de este programa.

(Nota: Si usted no desea recibir esta información, puede también llamar al *[INSERT HERE: CONTACT PHONE NUMBER]* y dejar un mensaje. Por favor identifíquese usando el número de encuesta que aparece abajo en lugar de usar su nombre.)

**Encuesta No.**

#### **4.b-1 Invitation to Screen Letter to Patients (Version 1 – Kit Enclosed)**

Date:

Honorific First Last  
Address  
City, State, ZIP

Dear Honorific First Last:

I am writing you to let you know some important information about colon cancer screening. Colon cancer is the nation's second leading cause of cancer-related deaths. With appropriate screening tests, colon cancer can be prevented or detected early, when it can be cured. Colon cancer screening is recommended medical care by many national organizations, including the American Cancer Society.

Our practice is working as part of a research study sponsored by the [INSERT HERE: SPONSOR NAME, IF APPLICABLE] to develop a colon cancer screening program that reaches out to patients. Based on a review of your medical records, you are eligible to be screened for colon cancer. I would like you to participate in the screening.

Enclosed is a stool test kit. Please complete the kit and return it to my office in the enclosed envelope for developing. Or, if you choose, you may schedule a colonoscopy for screening. Information on colonoscopy is enclosed, as is a list of doctors who do colonoscopy and are used by other patients of my practice. You may schedule a colonoscopy directly or contact my office if you need advice or a referral.

If you want to speak about colon cancer screening, please schedule an appointment with me or call my office.

If you returned the Eligibility Form and have already been screened, or did not wish to be screened, it may have arrived too late to prevent this mailing. If so, please disregard this letter.

Please note that colorectal cancer screening is covered by the major health insurance companies in [INSERT STATE]. Call your insurance carrier if you have questions.

As we are reaching out to you as part of a study, your participation is voluntary. If you choose to be screened, we are accepting your participation as consent to participate in this study. Only the minimal amount of information needed to follow the results of your screening will be gathered, and it will be kept confidential. You may be asked to participate in a focus group at the end of this study to help us understand its impact.

Sincerely,

<PRACTICE PHYSICIANS>

#### **4.b-1 Invitation to Screen Letter to Patients (Version 1 – Kit Enclosed) (Spanish)**

Fecha:

Antenombre Primero Apellido

Domicilio

Ciudad, Estado, Código Postal

Estimado(a) Primero Apellido:

Le escribo para darle información importante acerca de la prueba de cáncer del colon. El cáncer del colon es la segunda causa principal de muertes por cáncer en la nación. Con pruebas apropiadas de detección, se puede prevenir o detectar temprano el cáncer del colon, cuando todavía se puede curar. La detección del cáncer del colon es parte del cuidado médico que recomiendan muchas organizaciones nacionales, tales como la Sociedad Americana del Cáncer.

Nuestra consultoría forma parte de un estudio de investigación auspiciado por the [INSERT HERE: SPONSOR NAME, IF APPLICABLE] para crear un programa de detección de cáncer del colon que logre llegar a los pacientes. Hemos revisado sus registros médicos y usted es elegible para recibir una prueba de detección de cáncer del colon. Me gustaría que usted participe en la prueba de detección.

Incluido está el paquete para prueba de heces. Por favor hágase la prueba como se indica en el paquete y devuélvalo a mi oficina en el sobre incluido para análisis. Si elije hacerse una colonoscopia para su detección, por favor llame a nuestra oficina si necesita una recomendación. Adjunto encontrará información sobre la colonoscopia. Para su conveniencia, se incluye una lista de colonoscopistas a quienes recomendamos con frecuencia. Usted no está obligado(a) a usar un colonoscopista de esta lista.

Si usted desea hablar acerca de la detección de cáncer del colon, por favor haga una cita conmigo o llame a mi oficina.

Tenga en cuenta que la prueba de detección del cáncer colorectal está cubierto por las principales compañías de seguros de salud en [INSERT STATE]. Llame a su seguro si usted tiene preguntas.

Estamos contactándole como parte de un estudio y su participación es voluntaria. Al elegir hacerse la prueba de detección, aceptamos su participación como consentimiento para participar en este estudio. Se recolectará únicamente la cantidad mínima de información necesaria para dar seguimiento a los resultados de su prueba de detección y ésta será mantenida de forma confidencial. Puede que se le pida participar en una sesión de grupo al final de este estudio para ayudarnos a entender su impacto.

Atentamente,

<MÉDICOS DE LA PRÁCTICA>

#### **4.b-2 Invitation to Screen Letter to Patient (Version 2 - Request Card)**

Date

Honorific First Last

Address

City, State, ZIP

Dear Honorific First Last:

I am writing to let you know some important information about colon cancer screening. Colon cancer is the nation's second leading cause of cancer-related deaths. With appropriate screening tests, colon cancer can be prevented or detected early, when it can be cured. Colon cancer screening is recommended medical care by many national organizations, including the American Cancer Society.

Our practice is working as part of a research study sponsored by the [INSERT HERE: SPONSOR NAME, IF APPLICABLE] to develop a colon cancer screening program that reaches out to patients. Based on a review of your medical records, you are eligible to be screened for colon cancer. I would like you to participate in the screening.

Enclosed is information on effective methods of colorectal cancer screening. Please read the information to understand the screening tests. If you want to speak about colon cancer screening, please schedule an appointment with me or call my office.

If you choose, you may schedule a colonoscopy for screening. Information on colonoscopy is enclosed, as is a list of doctors who do colonoscopy and are used by other patients of my practice. You may schedule a colonoscopy directly or contact my office if you need advice or a referral.

You may choose to perform an annual stool blood test. If so, please return the enclosed form, and we will send a stool test kit to you. Follow the instructions in the kit and return the completed kit to my office.

If you returned the Eligibility Form and have already been screened, or did not wish to be screened, it may have arrived too late to prevent this mailing. If so, please disregard this letter.

Please note that colorectal cancer screening is covered by the major health insurance companies in [INSERT STATE]. Call your insurance carrier if you have questions.

As we are reaching out to you as part of a study, your participation is voluntary. If you choose to be screened, we are accepting your participation as consent to participate in this study. Only the minimal amount of information needed to follow the results of your screening will be gathered, and it will be kept confidential. You may be asked to participate in a focus group at the end of this study to help us understand its impact.

Sincerely,  
<PRACTICE PHYSICIANS>

#### **4.b-2 Invitation to Screen Letter to Patient (Version 2 - Request Card) (Spanish)**

Fecha

Antenombre Primero Apellido

Domicilio

Ciudad, Estado, Código Postal

Estimado(a) Primero Apellido:

Le escribo para darle información importante acerca de la prueba de cáncer del colon. El cáncer del colon es la segunda causa principal de muerte por cáncer en la nación. Con pruebas apropiadas de detección, se puede prevenir o detectar temprano el cáncer del colon, cuando todavía se puede curar. La detección del cáncer del colon es parte del cuidado médico que recomiendan muchas organizaciones nacionales, tales como la Sociedad Americana del Cáncer.

Nuestro consultorio forma parte de un estudio de investigación auspiciado por the [INSERT HERE: SPONSOR NAME, IF APPLICABLE] para crear un programa de detección de cáncer del colon que logre llegar a los pacientes. Hemos revisado sus registros médicos y usted es elegible para recibir una prueba de detección de cáncer del colon. Me gustaría que usted participe en la prueba de detección.

Incluida está la información sobre métodos efectivos para la detección del cáncer colorrectal. Favor lea la información para comprender las pruebas de detección. Si desea hablar sobre la detección de cáncer del colon, favor haga una cita conmigo o llame a mi consultorio.

Si usted desea, puede hacerse una colonoscopia para su detección. Adjunto encontrará información sobre la colonoscopia y una lista de colonoscopistas a quienes recomendamos con frecuencia. Usted no está obligado(a) a usar un colonoscopista de esta lista. Usted puede hacer su cita para la colonoscopia directamente o llame a mi consultorio si necesita ayuda o una recomendación.

Otra opción que puede elegir es una prueba anual de sangre en las heces. Si desea hacerse esta prueba, favor devolver el formulario adjunto y le enviaremos un paquete para la prueba de heces. Siga las instrucciones en el paquete y devuelva el paquete completo a mi consultorio.

Si usted devolvió el formulario de elegibilidad y ya se ha hecho la prueba de detección, o no desea hacerse la prueba de detección, favor no haga caso a esta carta.

Tenga en cuenta que la prueba de detección del cáncer colorectal está cubierto por las principales compañías de seguros de salud en [INSERT STATE]. Llame a su seguro si usted tiene preguntas.

Estamos contactándole como parte de un estudio y su participación es voluntaria. Al elegir hacerse la prueba de detección, aceptamos su participación como consentimiento para participar en este estudio. Se recolectará únicamente la cantidad mínima de información necesaria para dar seguimiento a los resultados de su prueba de detección y ésta será mantenida de forma confidencial. Puede que se le pida participar en una sesión de grupo al final de este estudio para ayudarnos a entender su impacto.

Atentamente,

<MÉDICOS DE LA PRÁCTICA>

#### **4.b-3 Web Links to CDC Patient Information on CRC Screening**

CDC Screen for Life Basic Facts on Screening (English)

[http://www.cdc.gov/cancer/colorectal/pdf/Basic\\_FS\\_Eng\\_Color.pdf](http://www.cdc.gov/cancer/colorectal/pdf/Basic_FS_Eng_Color.pdf) (PDF, 321 KB) [[PDF Help](#)]

Pruebas de detección de cáncer colorrectal (Spanish/Español)

[http://www.cdc.gov/cancer/colorectal/pdf/SFL\\_SpanishFS\\_2c.pdf](http://www.cdc.gov/cancer/colorectal/pdf/SFL_SpanishFS_2c.pdf) (PDF, 463 KB) [[PDF Help](#)]

#### **4.b-4 Stool Test Kit Request Card**

##### **REQUEST FOR STOOL TEST KIT**

Patient Name <Mail Merge>

I wish to receive a stool test kit. I know that a stool blood test should be performed annually and understand that a positive (abnormal) test result should be followed up with a colonoscopy.

STUDY ID# <Mail Merge>

Side 2:

REQUEST FOR STOOL TEST KIT

[INSERT HERE: RETURN ORGANIZATION NAME AND ADDRESS]

STUDY ID# <Mail Merge>

#### **4.c-1 Letter to Patient for Responding to Stool Test Kit Requests**

Date

Honorific First Last

Address

City, State, ZIP

Dear Honorific First Last:

Enclosed is the Stool Blood Test Kit you requested. Instructions for completion are also enclosed in English and in Spanish.

Stool blood testing is an effective method of colorectal cancer screening when done yearly and when any positive stool blood tests are followed up by a colonoscopy.

To complete the kit, follow the enclosed instructions. Be sure to label the test cards with your name and return the completed kit to this office. We will route the completed kits for developing.

Sincerely,

<PRACTICE PHYSICIANS>

#### **4.d-1 Reminder Letter to Patients (Version 1 - Kit Enclosed)**

Dear Patient:

Several weeks ago, information was sent to you about colorectal cancer screening and you were invited to be screened.

As of yet, the practice has not received a completed stool blood test kit from you. This may mean you chose to have a colonoscopy. It may also mean you forgot to complete and return the stool blood test kit you received.

If you did forget to complete the stool blood test kit, please take this opportunity to complete it at your earliest convenience and return it to the office in its envelope for developing.

As we are reaching out to you as part of a study, your participation is voluntary. Only the minimal amount of information needed to follow the results of your screening will be gathered, and it will be kept confidential.

Sincerely,

#### **4.d-1 Reminder Letter to Patients (Version 1 - Kit Enclosed) (Spanish)**

Estimado(a) Paciente:

Hace varias semanas, se le envió a usted información acerca de la prueba de cáncer colorrectal y se le invitó a ser examinado.

A la fecha, el consultorio no ha recibido de su parte el paquete completo del examen de heces. Esto puede significar que eligió someterse a una colonoscopia. También esto puede significar que se le olvidó completar y devolver el paquete del examen de heces que recibió.

Si a usted se olvidó completar el paquete del examen de heces, por favor tome esta oportunidad para completarlo a su más pronta conveniencia y devuélvalo a la oficina en el sobre para su análisis.

Debido a que le estamos contactando como parte de un estudio, su participación es voluntaria. Se recolectará únicamente la cantidad mínima de información necesaria para dar seguimiento a los resultados de su prueba de detección y todo será mantenido de forma confidencial.

Atentamente,

#### **4.d-2 Reminder Letter to Patients (Version 2 – Request Card)**

Dear Patient:

Several weeks ago, information was sent to you about colorectal cancer screening and you were invited to be screened.

As of yet, the practice has not received a completed stool blood test kit from you. This may mean you chose to have a colonoscopy. It may also mean you forgot to return the request for a stool blood test kit.

If you did forget to return the request for a stool blood test kit, please take this opportunity to return it at your earliest convenience. If you have chosen to have a colonoscopy, please contact us if you need help scheduling this test.

As we are reaching out to you as part of a study, your participation is voluntary. Only the minimal amount of information needed to follow the results of your screening will be gathered, and it will be kept confidential.

Sincerely,

#### **4.d-2 Reminder Letter to Patients (Version 2 – Request Card) (Spanish)**

Estimado(a) Paciente:

Hace varias semanas, se le envió a usted información acerca de la prueba de cáncer colorrectal y se le invitó a ser examinado.

A la fecha el consultorio no ha recibido de su parte el paquete completo del examen de heces. Esto puede significar que usted eligió someterse a una colonoscopia. También esto puede significar que se le olvidó devolver la solicitud para recibir el examen de heces.

Si a usted se olvidó de devolver la solicitud para el examen de heces, por favor tome esta oportunidad para devolverlo a su más pronta conveniencia. Si usted ha elegido una colonoscopia, por favor, póngase en contacto con nosotros si necesita ayuda para la programación de esta prueba.

Debido a que le estamos contactando como parte de un estudio, su participación es voluntaria. Se recolectará únicamente la mínima cantidad de información necesaria para el seguimiento a los resultados de su prueba y todo será mantenido de forma confidencial.

Atentamente,

## Step 5: Track Patient Screening and Results

### **Description**

After a reasonable period of time and periodically thereafter, the central entity conducts a followup electronic record review to look for evidence of screening (in particular, a stool test or colonoscopy, but evidence of screening by other guideline-supported modalities should be looked for as well). The central entity also reviews reports received from the clinical lab processing stool test kits for evidence of screening and results and updates its master patient database accordingly (Tool 5.a-1). Results from this tracking are used for sending out reminders and preparing feedback reports to the practices.

The intervention also uses two other tracking mechanisms. First, practices track the screening of their own patients and periodically generate reports that the central entity can use to update the master patient database. Tracking can be done with the screening tracking sheet provided at the academic detailing sessions (Tool 2.b-3) or with internal tracking mechanisms already in place.

Second, especially for practices without electronic medical records, central entity staff may request access to select patient charts to conduct audits looking for evidence of screening and possible needed followup (Tool 5.d-1). Such chart audits would only be performed in instances where electronic evidence of screening and followup is inconclusive and only if the audits would not violate HIPAA requirements. Audits can also be performed on electronic charts, especially when screening information may be entered in various text fields in the record that require a manual review.

### **Tips**

- **Using a clinical champion.** To help encourage practices to track their patient screening and to help instill the importance of CRC screening and tracking, we feel that it may be helpful to have a clinical “champion” at each practice to help ensure that the clinical tracking tools are used. This champion, along with a practice management staff member, can also serve as a liaison between the practice and the central entity.
- **Recording SEA data.** It can be time and labor intensive to code and capture SEA results for the master patient database. We suggest establishing a codebook or exploring the use of a scannable SEA form. A scannable form will help minimize manual data entry and increase the speed, and perhaps accuracy, of data entry.
- **Tracking Screening and Followup.** Practices may not use the screening tracking sheet. Each practice may have its own methods of tracking patient screening or may not be able to maintain additional records. In addition, it is difficult to determine from electronic records whether a followup colonoscopy (i.e., complete diagnostic exam was performed on stool test-positive patients. A screening colonoscopy and a diagnostic colonoscopy are not easily distinguishable in electronic records. The central entity may need to conduct a manual review of the record and chart notes to distinguish between them. Because tracking patient screening is important, we suggest working with the practices to determine how they can best monitor their patient screening.
- **Arrange lab record review.** As mentioned, we suggest establishing an agreement with the clinical laboratory processing the stool tests so that they will be able to inform the central entity directly of the stool test screening result. This helps the central entity track

patient screening and screening results. The central entity should consider potential HIPAA issues when establishing this agreement.

## **Tools (Step 5)**

### **5.a-1 Master Patient Database Elements**

#### **SATIS-PHI/CRC Master Patient Database Elements**

Below is a list of key elements that we suggest you use to implement and track the SATIS-PHI/CRC intervention. These elements can be incorporated into a separate database, or they can be obtained from your existing electronic record infrastructure. Items marked with a † are optional, but we suggest that you try to record and track them.

If you plan to conduct an assessment of the SATIS-PHI/CRC intervention, we strongly recommend collecting all of these data elements as well as others that may be unique to your setting. You may also find it helpful to track the dates of many of these data elements (e.g., mailing dates, request dates, and notification dates). This will help you establish an “analytical database” that can be useful for assessment purposes.

#### **Patient Elements**

- Patient name
- Patient identification code\*
- Patient mailing address
- Date of birth of patient and/or age of patient
- Practice name
- Reason for ineligibility (i.e., evidence of prior diagnosis of CRC or polyps or inflammatory bowel disease, evidence of family history of CRC diagnosis before age 60, evidence of recent prior CRC screening test, not a patient of the practice)
- Sex<sup>†</sup>
- Race<sup>†</sup>
- Ethnicity<sup>†</sup>
- Marital status<sup>†</sup>
- Insurance status<sup>†</sup>
- Mailed invitation to screen<sup>†</sup>
- Mailed reminders<sup>†</sup>
- Requested stool test kit<sup>†</sup>
- Sent stool test kit to requesting patient<sup>†</sup>
- Stool test completed
- Patient notified of stool test result
- Stool test result
- Complete diagnostic exam (CDE) recommended (i.e., followup colonoscopy recommended)
- CDE completed
- CDE patient notified
- CDE result
- Colonoscopy scheduled
- Colonoscopy completed

- Patient notified of colonoscopy result
- Colonoscopy result
- Other screening completed (e.g., flexible sigmoidoscopy or barium enema)
- Other screening patient notified
- Other screening result

#### **SEA Form Elements<sup>†</sup>**

- Mailed SEA<sup>†</sup>
- Responded to SEA<sup>†</sup>
- Reason for ineligibility (Section A response)<sup>†</sup>
- Ethnicity (Section B1 response)<sup>†</sup>
- Race (Section B2 response)<sup>†</sup>
- Marital status (Section B3 response)<sup>†</sup>
- Language preference (Section B4 response)<sup>†</sup>
- Education (Section B5 response)<sup>†</sup>
- Health status (Section B6 response)<sup>†</sup>
- Opt-out (Section C response)<sup>†</sup>

#### **Practice Elements**

- Practice name
- Practice identification code\*
- Practice affiliation<sup>†</sup>
- Practice geographic location (e.g., urban, rural)<sup>†</sup>
- Presence of electronic medical record in the practice<sup>†</sup>
- Practice size (e.g., large, small)<sup>†</sup>
- Practice specialty (e.g., general internal medicine, family medicine)<sup>†</sup>

\* Identification numbers can be useful for addressing HIPAA and other privacy and confidentiality concerns.

<sup>†</sup> Optional data elements.

## 5.d-1 Chart Audit Review Form

### CRC Screening Chart Audit Form

**Instructions:** Use this form to document information on each of four colorectal cancer screening tests (stool test, flexible sigmoidoscopy, barium enema x-ray, and colonoscopy) found in the medical chart. Each test has its own section for you to document your findings.

- If there is no evidence of a given test being performed, check “no” to the first question for that test and skip to the next section.
- If a given test was performed more than once since date indicated, document the most recent test.
- For each type of test performed, document the date of the test, its result, its reason, and where in the chart (or elsewhere) you found the information.

Auditor _____	Audit Date ____/____/____
Patient Study ID # _____	Patient Transferred [ ]
Practice ID # _____	Patient Deceased [ ]
<b>PATIENT DEMOGRAPHICS</b>	
Patient Gender:	[ ] Male [ ] Female [ ] Missing/Unknown
Preferred Language:	[ ] English [ ] Spanish [ ] Other [ ] Missing/Unknown
Marital Status:	[ ] Single [ ] Married [ ] Divorced, Separated, Widowed [ ] Missing/Unknown
Ethnicity:	[ ] Hispanic or Latino [ ] Non-Hispanic or Non-Latino [ ] Missing/Unknown
Race (Check all that apply):	
[ ] American Indian or Alaska Native	
[ ] Asian	
[ ] Black or African American	
[ ] Native Hawaiian or Other Pacific Islander	
[ ] White	
[ ] Other (specify _____)	
[ ] Missing	





## Step 6: Provide Feedback to Practices

### **Description**

The central entity notifies participating practices of positive (abnormal) and negative (normal) stool test screenings and coaches them on notifying patients about screening results and how to follow up on them (Tools 6.a-1 and 6.a-2, respectively). The central entity also provides a form to practices for tracking and documenting followup complete diagnostic examinations (CDEs)\* for patients with positive (abnormal) stool test screening results (Tool 6.b-1).

The stool test abnormal and normal forms inform the practices and clinicians about how they are expected to respond to the respective results. Practices are expected to respond to a positive stool test by recommending a CDE for the patient (i.e., a followup colonoscopy). Practices are expected to respond to negative stool tests by notifying patients and informing them that the guidelines recommend that they be rescreened every 12 months.

In addition, the CDE feedback form facilitates tracking and followup of positive screens. The CDE feedback form identifies patients in need of a CDE and reminds providers of recommended CDE procedures. It also requests that providers document (1) that patients have been advised to have a CDE and what type of modality was recommended, (2) the date the CDE was scheduled and completed, and (3) the results of the CDE as well as any additional comments. This information can then become part of the patient's record.

### **Tips**

- **Encouraging use of CDE feedback form.** It can be difficult to get clinicians to complete and return the CDE feedback form. As previously noted, we suggest that in the future the central entity have a clinical “champion” at each practice, in addition to the office manager. If each practice has a clinical point of contact, he or she may be better suited to encourage fellow clinicians to use these clinical tracking tools.

---

\* Also referred to as followup colonoscopy to a positive stool test screen.



**6.a-2 Feedback Form for Stool Test Negative**

**Colorectal Cancer Screening Feedback Form for FIT Negative Patients**

<DATE>

Below is a list of patients in your practice who participated in the SATIS-PHI/CRC screening program and had a NEGATIVE fecal immunochemical test (FIT-) result. The date of the result is included.

Patient status was determined on the basis of a medical record review and inspection of administrative data.

All patients with a NEGATIVE FIT (FIT-) result should be notified of this result and informed that the U.S. Multi-Society Task Force guidelines recommend that they should be rescreened every 12 months.

If you have any questions related to the information provided here, please call our office at [INSERT HERE: CONTACT PHONE NUMBER].

Sincerely,

[INSERT HERE: CONTACT NAME]

<b>Patient Name</b>	<b>ID Number</b>	<b>FIT+ Result Date</b>	<b>CDE Status</b>

**6.b-1 Feedback Form for CDE**

**Complete Diagnostic Evaluation (CDE)\* of the Colon as Followup to a Positive Fecal Immunochemical Test**

Listed below are the names of your patients who had a recent positive fecal immunochemical test (FIT+) when screened for colorectal cancer. We previously notified you that these patients were FIT+ and reminded you that the U.S. Multi-Society Task Force guidelines recommend a complete diagnostic evaluation (CDE) of the colon with either colonoscopy (Cx) or a combination of flexible sigmoidoscopy plus double contrast barium enema (FS+BE) as followup. We ask that you complete this form with as much information as you currently have about the CDE for each of these patients.

Use the Comments column at the right to indicate any special circumstances as to why a CDE was not recommended or scheduled.

All dates should follow MM/DD/YYYY format.

<b>Patient Name</b>	<b>Date CDE Recommended</b>	<b>CDE Modality Recommended (Cx/FS/BE)</b>	<b>Date CDE Scheduled</b>	<b>Date CDE Completed</b>	<b>CDE Results (Normal/Abnormal)</b>	<b>Comments</b>

**After Completing This Form, Please Return It To:**

[INSERT RETURN ORGANIZATION NAME, ADDRESS, AND CONTACT INFORMATION]

---

\* Recommended procedures for CDE include (1) colonoscopy or (2) flexible sigmoidoscopy plus double-contrast barium enema.

## Assessment

### ***Description of Optional Assessment Step***

As previously noted, central entities may decide to assess their implementation of the SATIS-PHI/CRC intervention. To conduct such an assessment, we suggest that you use an evaluation framework that has both process evaluation and outcome evaluation components such as the Practical, Robust Implementation and Sustainability Model (PRISM) (Feldstein and Glasgow, 2008).

PRISM contains a contextual domain that allows you to gain a better understanding of the context in which the intervention takes place and how that context likely affected your ability to implement SATIS-PHI/CRC with fidelity and achieve intended outcomes. This contextual domain includes such factors as the external environment of your implementation setting, the organizational characteristics of that setting, and the setting's implementation and sustainability infrastructure. It also contains an outcome domain that allows you to assess whether and to what degree you achieved the intervention's intended outcomes of:

- Reaching eligible patients,
- Being adopted by target practices,
- Being implemented with fidelity, and
- Improving screening and followup rates.

PRISM incorporates the RE-AIM outcome factors of reach, effectiveness, adoption, implementation, and maintenance (Glasgow, et al., 1999). Please refer to CNA's final report to see how they used this framework in their assessment of implementing SATIS-PHI/CRC (Harris and Borsky, 2010).

For more information about CNA's experiences assessing the SATIS-PHI/CRC, please contact the CNA Health ACTION Partnership at [CHAP@CNA.ORG](mailto:CHAP@CNA.ORG) or at CAN Health ACTION Partnership, 4825 Mark Center Drive, Alexandria, VA 22311.

Several optional tools may be useful for this assessment. These tools include the following data collection instruments:

- A practice survey.
- Practice interview guide.
- Focus group guides for both practices and patients.

These tools can be useful for better understanding the perspectives of the clinicians, practice staff, and patients regarding CRC screening and their experience with the SATIS-PHI/CRC intervention.

Fielding these instruments and analyzing their results requires additional staff time and is not directly related to implementing the intervention. However, if your organization has the additional personnel and wants to better understand the effectiveness of your implementation, we suggest using these tools. If your organization conducts an assessment, we also recommend

reviewing some recommended research protocol and assessment techniques (Babbie, 2004; Campbell and Stanley, 1963; Perceman and Curran, 2006; Krueger and Casey, 2009).

### ***Practice Assessment***

These assessment tools can be fielded before the intervention to ascertain baseline perspectives, and they can also be fielded after the intervention. To collect the baseline information, we suggest conducting the practice surveys (Tool 2.a-1) and practice focus groups (Tool 2.a-2) prior to Step 2. However, the interviews (Tool 2.a-3) should be conducted after Step 2 to gather information about additional questions and information that was not uncovered during the focus groups.

To collect postintervention information, we suggest conducting the practice surveys, practice focus groups, and practice interviews after Step 6 is complete (Tools 2.a-1, A.1-2, and A.2-1, respectively). The central entity can then compare the pre and post data collections to ascertain whether perspectives, knowledge, and reported behavior have changed.

### ***Patient Assessment***

The central entity can also conduct patient focus groups postintervention (Tool A.3-1). Focus groups can be held separately with a sample of patients who were screened and had negative findings and with a sample of patients who were screened and had positive findings.\* Focus groups can also be held with patients who were not screened (nonresponders). The central entity can also decide to combine groups and to use only appropriate parts of the guides as needed.

Using the PRISM and RE-AIM frameworks and data gathered from focus groups, key informant interviews, and practice surveys can be helpful for assessing the contextual domain of your implementation of SATIS-PHI/CRC. In addition, screening outcomes can be assessed by analyzing the master patient database. If you plan to conduct such an assessment, we suggest collecting the optional data elements listed in the Master Patient Database Elements Tool (Tool 5.a-1). These optional elements can be useful for analytical purposes. For example, you could calculate the screening rate (number of screens/number of eligible patients) separately for men and women, and separately for older and younger patients. You could also conduct analyses to predict which elements were significantly associated with screening (e.g., conduct logistic regression or other statistical analyses).

### ***Tips***

- **Obtaining assessment approvals.** Be certain to obtain any Institutional Review Board (IRB) approvals required by your organization before undertaking any assessment data collections. Check with your IRB to see whether your assessment activities will require its prior approval. Check with your legal department as well regarding HIPAA requirements.

---

\* If conducting a focus group with positive screen patients, we suggest making sure that all such patients had a subsequent negative followup colonoscopy or CDE. We also suggest making sure that patients understand that this is a focus group for an intervention and not part of a support or therapeutic group.

- **Encouraging practice respondents.** Clinicians and practice staff may be less likely to respond to the postintervention survey than the preintervention survey. We suggest maintaining communication with clinicians and practice staff and establishing expectations for participation to encourage them to remain engaged throughout the duration of the intervention.
- **Encouraging patient respondents.** It may also be difficult to recruit patients for focus groups, especially patients who did not respond to the intervention. We suggest starting patient recruitment early and considering combining various types of patients into a single focus group, if needed.
- **Collecting analytical data.** If you conduct an assessment of the SATIS-PHI/CRC intervention, we suggest that you collect the additional optional data elements and others relevant to your setting, listed in the Master Patient Database Elements tool (Tool 5.a-1). If conducting an assessment, it will be important to track which patients received what mailing and when, and it will also be important to track more demographic-related information. We also suggest collecting additional information about each patient's practice so that you can assess what practice-related factors influenced patient screening (e.g., presence of an electronic medical record, size of the practice, practice geographic setting, practice affiliation, and practice specialty).

## **Tools (Assessment)**

### **A.1-2 Practice Focus Group Guide (Postintervention)**

#### **SATIS-PHI/CRC Postintervention Practice Focus Group Guide**

##### INTRODUCTION

Hello. My name is \_\_\_\_\_ and I am the moderator for today's 30-minute group discussion. My colleague, \_\_\_\_\_, is here to take notes and help the session run smoothly. Our main purpose today is to discuss colorectal cancer screening in your practice.

##### MODERATOR INFORMATION

[INSERT HERE: INFORMATION ON WHY YOU ARE CONDUCTING THIS FOCUS GROUP]

Your practice participated in this intervention, and we would like to talk with you about the intervention and how you think it may have affected you, this practice, and the practice's patients. Your input is important to help us understand how the intervention functioned and what we can do to improve it.

##### ACKNOWLEDGMENT

I want to thank you for coming in today to talk with us and for fitting this session into your already busy schedules.

##### DISCLOSURES

The session is being recorded in audio to make sure our notes accurately reflect our discussion with you. It doesn't matter who says what; I only care what gets said. Does anyone have concerns about taping this session?

Notes will also be taken during the discussion today, but they will not include any identifying information about the group's participants.

##### INFORMED CONSENT

Your decision to participate is voluntary. Before we begin, I would like to hand out this consent form for you all to sign, if you still would like to participate in our discussion. [Hand out informed consent, and collect after obtaining signatures]

- Are there any questions about your participation?
- If you do not want to participate, please take this time to gather your things and leave the room. We appreciate your interest.

## GUIDELINES

A few guidelines before we start:

1. What you say in this room stays in this room. As I mentioned, all information discussed today will be held in confidence. So please feel comfortable in speaking openly and candidly with us.
2. Please talk one at a time.
3. Talk in a voice as loud as mine.
4. Avoid side conversations with your neighbors, but it is okay to “piggy back” on comments others have made. Just be sure to talk loud enough so the whole group can participate.
5. Make sure everyone has a chance to talk.
6. There is no one point of view, so please allow all points of view to be heard.
7. Say what you believe. It doesn’t matter whether anyone agrees with you.

## QUESTIONS

Are there any other questions before we begin?

## SELF-INTROS

Before we begin, does everyone know each other? [If not, do self-intros with first names only]

## QUESTIONS

### **Theme 1: Overall Impression of/Satisfaction With the Intervention**

1. Describe to me your overall impression and level of satisfaction with this colorectal cancer screening intervention?
  - What do you understand this intervention to be? [**NOTE:** Briefly describe the intervention if it appears subjects don’t have a good understanding of it]
  - What do you think worked well?
  - What do you think didn’t work well?

### **Theme 2: Perceived Impact of the Intervention on You (especially targeted to clinicians)**

2. How, if at all, would you say the intervention affected you or your behavior regarding CRC screening and followup?
3. Has this intervention affected your understanding of CRC screening guidelines?
4. Has this intervention affected your understanding of appropriate CRC screening followup procedures?
5. Has this intervention affected which patients you recommend CRC screening to or how you recommend it or talk with them about it [the nature or content of your discussions]?
6. Has this intervention affected which patients you recommend a CDE followup to or how you recommend it or talk with them about it [the nature or content of your discussions]?
7. Has the intervention affected how often you recommend CRC screening or CDE?
8. Are there any other ways this intervention affected you or your behavior regarding CRC screening and followup?

### **Theme 3: Perceived Impact on Patients**

9. As part of the intervention we conducted, we sent your eligible\* patients information on CRC screening and an invitation to be screened.
  - Did patients contact you or the practice about the intervention or any of the materials we sent them? Also, did patients talk with you about the intervention or materials during any office visits?
    - If yes, what did they ask about or want to know?
    - What did you tell them?
  - How, if at all, did the intervention appear to influence your patients' awareness of or attitude toward CRC and screening for it?
  - How, if at all, did the intervention appear to influence their behavior?
  - Do you think either the intervention or the new 2008 Colorectal Cancer Screening Guidelines played a role in their decision about getting screened?
10. What do you think your patients thought of the intervention material and the screening invitation? How satisfied or dissatisfied did they appear to be with it?

### **Theme 4: Perceived Impact on the Practice**

11. In general, how, if at all, did the intervention affect this practice?
12. Who, if anyone, in this practice did it affect? How did it affect them?
13. How, if at all, do you see this intervention benefiting or having positive effects on this practice? [**Probe** for economic, reputational, efficiency, or other types of benefits]
14. How, if at all, do you see this intervention negatively affecting this practice? [**Probe** for economic impact, reputation, interference with processes, overuse of providers' or staff's time, or other types of negative effects]

### **Theme 5: Process Improvement and Maintenance**

15. Describe to me what it was like to adopt and implement this intervention in your practice.
  - What were the interventions' strengths?
  - What were the interventions' weaknesses?
16. Based on your experience, if we wanted to introduce this CRC screening intervention into other practices:
  - What, if anything, would you suggest we do differently and why?
  - What, if anything, would you suggest we do the same and why?

---

\* If anyone asks, eligibility criteria were: average-risk patients (no known personal or family risk factors for CRC), age 50-79, with no evidence of up-to-date screening (as defined by current screening guidelines for CRC), a known mailing address, and a visit to the practice within 2 years.

- What, if anything, would you suggest we do to improve the way this screening intervention affects:
  - Practitioners/clinicians? Practice staff?
  - The practice overall?
  - The practice's patients?
- 17. How, if at all, do you see this intervention and your experience with it having changed your and this practice's approach to CRC screening and followup? [**Probe:** What, if anything, from the intervention have you or this practice adopted to use on your own? If nothing was already adopted, what would be required for you and your practice to adopt this intervention approach on your own in the future?]
- 18. If we were to come to you in a year or so and ask you and this practice to once again participate in a screening effort using this intervention approach, would you or would you not agree to participate again? Why?
- 19. Would you encourage other primary care practices or other organizations that work with practices to adopt this intervention approach on their own? Why?
- 20. Would you encourage other primary care practices to participate in screening programs that use this intervention approach? Why?

## **A.2-1 Key Informant Interview Guide (Postintervention)**

### **SATIS-PHI/CRC Postintervention Informal Interview Protocol**

**Name (Interviewee):**

**Location:**

**Address:**

**Telephone No.:**

**Fax No.:**

**E-Mail:**

**Date:**

**Interviewer:**

**Note to interviewer:** The purpose of these informal interviews is to gather additional information or to provide clarification and followup to issues that were discussed (or not discussed) during a previous practice focus group. The interview script below includes questions that may or may not be asked, as it will serve as a guide rather than a script for the interviews.

[INSERT HERE: EXPLAIN WHY YOU ARE CONDUCTING THIS INTERVIEW]

Your decision to participate in this interview is voluntary. You may refuse to take part, or choose to stop, at any time. A decision to refuse to take part or to stop being a part of our discussion will not have a negative impact on you in any way. All information discussed today will be held in confidence. Information you provide will be summarized and reported with the responses of others, and will not be linked to you or any individual. There is no direct benefit from being interviewed; however, taking part may help identify strategies to improve colorectal cancer screening and follow-up in the future.

Do you have any questions about your participation in this interview? If you do not want to participate, please let me know at this time.

## QUESTIONS

\* Indicates questions of a higher priority.

1. \* In general, can you tell me what you thought about the colorectal cancer screening intervention?
  - How do you think it worked in terms of increasing colorectal cancer screening?
  - How do you think it worked in terms of increasing screening followup?
2. \* What were some of the things that you think made the intervention work well in your practice (e.g., facilitators)?
  - Was there anything that specifically worked well to increase screening?
  - Was there anything that specifically worked well to increase followup?
3. \* What were some things that you think did *not* work so well in your practice (e.g., barriers)?
  - Was there anything specifically that did *not* work well to increase screening?
  - Was there anything specifically that did *not* work well to increase followup?
4. How did the practice handle questions or visits from patients?
  - Did the practice experience an increase in phone calls and visits from patients inquiring about the screening?
5. How did the staff respond to patients' questions about the project or about colorectal cancer screening in general?
  - Did they feel like they were knowledgeable enough about the intervention (e.g., was enough information provided to them)?
6. \* Tell me about whether you think the practice will continue with the intervention in the future?
7. If you've seen an increase in colorectal cancer screening and followup, describe to me whether you think this increase is sustainable. Why or why not?
8. Are there any stories that you find particularly memorable (no names) with respect to the intervention that you'd like to share?
9. \* What do you think could have been done to improve the intervention?
  - Do you think anything could have been done to improve the following intervention components?
    - Academic detailing
    - Chart audits
    - CDE performance feedback form
    - Coordination with the lab
    - Provider understanding
    - Practice staff understanding
    - Perception of patient satisfaction
10. Before we end, are there any issues or topics that I have not brought up today that you would like to address?

\*\*\*Thank you very much for taking the time to talk with me today.\*\*\*

### A.3-1 Patient Focus Group Guide

#### **SATIS-PHI/CRC Intervention Patient Focus Groups: Negative Screening Focus Group (A)**

**Moderator Instructions:** After patients (who are part of the intervention practices) sign in, they will be given a name label with identifier (A = negative screen, B = positive screen, C = nonresponders). The appropriate separate groups (A, B, C) will then convene, and the group moderator will read the script below.

The announcement of gift cards should be given at the end of the session.

#### INTRO

Hello. My name is \_\_\_\_\_ and I am the moderator for today's 2-hour group discussion. My colleague, \_\_\_\_\_, is here to take notes and help the session run smoothly. Our main purpose today is to discuss colorectal cancer screening recommendations.

#### MODERATOR INFO

[INSERT HERE: FOR WHOM AND WHY YOU ARE CONDUCTING THIS FOCUS GROUP]

As part of our work, we are speaking with individuals who were part of our intervention and received a recommendation for colorectal cancer screening. Your input is important to help us understand how to increase colorectal cancer screening.

#### ACKNOWLEDGMENT

I want to thank you for coming in today to talk with us and for fitting this session into your already busy schedules.

#### DISCLOSURES

The session is being recorded in audio to make sure our notes accurately reflect our discussion with you. It doesn't matter who says what; I only care what gets said. Does anyone have concerns about taping this session?

Notes will also be taken during the discussion today, but they will not include any identifying information about the group's participants.

#### INFORMED CONSENT

Your decision to participate is voluntary. Before we begin, I would like to hand out this consent form for you all to sign, if you still would like to participate in our discussion. [Hand out informed consent, and collect after patients sign]

- Are there any questions about your participation?
- If you do not want to participate, please take this time to gather your things and leave the room. We appreciate your interest.

## GUIDELINES

A few guidelines before we start:

1. What **you say in this room stays in this room**. As I mentioned, all information discussed today will be held in confidence. So please feel comfortable speaking openly and candidly with us.
2. Please talk **one at a time**.
3. Talk in a **voice as loud as mine**.
4. **Avoid side conversations** with your neighbors, but it is okay to “piggy back” on comments others have made. Just be sure to talk loud enough so the whole group can participate.
5. Make sure **everyone has a chance to talk**.
6. There is **no one point of view**, so please allow all points of view to be heard.
7. Say what **you believe**. It doesn't matter whether anyone agrees with you.

## QUESTIONS

Are there any other questions before we begin?

## SELF-INTROS

Let's start off by introducing yourself to the group and tell us:

- Your first name.
- Your favorite vacation spot.

## QUESTIONS

1. Everyone here participated in the colorectal cancer screening intervention. What did you all think about it?
  - What were its strengths?
  - What were its weaknesses?
2. Who do you think is supposed to receive colorectal cancer screening?
  - Before receiving our letter, did you think you should get screened?
  - Are you familiar with the 2008 Colorectal Cancer Screening Guidelines from the ACS/U.S. Multi-Society Task Force/ACR and USPSTF?
3. Describe to me how often, if at all, you get screened for colorectal cancer.
4. How did you feel about the colorectal cancer screening information that was sent to you a few months ago?
  - Did you think the information was clear? Easy to understand?
  - What did you like about the information?
  - What did you not like about the information?

5. Tell me what motivated you to receive the recommended colorectal cancer screening?
  - Was this something you intended to get before receiving the letter?
  - Was this something you decided to get after you received the letter?
6. After you received the screening, how were you informed of results?
  - Were you informed of the need for repeat screening in the future?
7. Describe to me what you thought about the process of responding to participate in this intervention.
8. Describe to me what you thought about the overall process of getting your screening.
9. Describe to me what you thought about the overall process of being notified about the screening results.
10. If you received a similar invitation in the future, tell me whether you would respond and get screened or not?
  - Tell me more.
11. If your doctor's office were to participate in another screening intervention program, what would you advise they do...
  - Differently, and why?
  - The same, and why?
12. Before we end, are there any issues or topics that I have not brought up today that you would like to address?

\*\*\*As a way to thank you for participating in today's focus group, we have some gift cards for you [distribute gift cards]. Thank you again for taking the time to talk with us today.\*\*\*

### A.3-1 Patient Focus Group Guide

#### **SATIS-PHI/CRC Intervention Patient Focus Groups: Positive Screening Focus Group (B)**

**Moderator Instructions:** After patients (who are part of the intervention practices) sign in, they will be given a name label with identifier (A = negative screen, B = positive screen, C = nonresponders). The appropriate separate groups (A, B, C) will then convene, and the group moderator will read the script below.

**Note:** We suggest that only patients with a subsequent negative followup colonoscopy (i.e., a complete diagnostic exam) be included in Focus Group B for positive screen patients. Patients with an unknown or positive follow up screen should not be included in the focus group. Patients should also understand that these focus groups are to discuss their experiences with the SATIS-PHI/CRC intervention and that they are not part of a support or therapeutic group.

The announcement of gift cards should be given at the end of the session.

#### INTRO

Hello. My name is \_\_\_\_\_ and I am the moderator for today's 2-hour group discussion. My colleague, \_\_\_\_\_, is here to take notes and help the session run smoothly. Our main purpose today is to discuss colorectal cancer screening recommendations.

#### MODERATOR INFO

[INSERT HERE: FOR WHOM AND WHY YOU ARE CONDUCTING THIS FOCUS GROUP]

As part of our work, we are speaking with individuals who were part of our intervention and received a recommendation for colorectal cancer screening. Your input is important to help us understand how to increase colorectal cancer screening.

#### ACKNOWLEDGMENT

I want to thank you for coming in today to talk with us and for fitting this session into your already busy schedules.

#### DISCLOSURES

The session is being recorded in audio to make sure our notes accurately reflect our discussion with you. It doesn't matter who says what; I only care what gets said. Does anyone have concerns about taping this session?

Notes will also be taken during the discussion today, but they will not include any identifying information about the group's participants.

## INFORMED CONSENT

Your decision to participate is voluntary. Before we begin, I would like to hand out this consent form for you all to sign, if you still would like to participate in our discussion. [Hand out informed consent, and collect after patients sign]

- Are there any questions about your participation?
- If you do not want to participate, please take this time to gather your things and leave the room. We appreciate your interest.

## GUIDELINES

A few guidelines before we start:

1. What **you say in this room stays in this room**. As I mentioned, all information discussed today will be held in confidence. So please feel comfortable speaking openly and candidly with us.
2. Please talk **one at a time**.
3. Talk in a **voice as loud as mine**.
4. **Avoid side conversations** with your neighbors, but it is okay to “piggy back” on comments others have made. Just be sure to talk loud enough so the whole group can participate.
5. Make sure **everyone has a chance to talk**.
6. There is **no one point of view**, so please allow all points of view to be heard.
7. Say what **you believe**. It doesn't matter whether anyone agrees with you.

## QUESTIONS

1. Everyone here participated in the colorectal cancer screening intervention. What did you all think about it?
  - What were its strengths?
  - What were its weaknesses?
2. Who do you think is supposed to receive colorectal cancer screening?
  - Before receiving our letter, did you think you should get screened?
  - Are you familiar with the 2008 Colorectal Cancer Screening Guidelines from the ACS/U.S. Multi-Society Task Force/ACR and USPSTF?
3. Describe to me how often, if at all, you get screened for colorectal cancer?
4. How did you feel about the colorectal cancer screening information that was sent to you a few months ago?
  - Did you think the information was clear? Easy to understand?
  - What did you like about the information? What did you not like about the information?

5. Tell me what motivated you to receive colorectal cancer screening?
  - Was this something you intended to get before receiving the letter?
  - Was this something you decided to get after you received the letter?
6. After you received the screening, how were you informed of results?
  - Were you informed of the need for repeat screening in the future?
7. Describe to me what you thought about the process of responding to participate in this intervention.
8. Describe to me what you thought about the overall process of getting your screening.
9. Describe to me what you thought about the overall process of being notified about the screening results.
  - What did you think about the timeliness of being notified of the results?
  - Tell me about how satisfied or unsatisfied you were with the way you were notified.
  - Tell me about your experience discussing the results with your provider.
10. Describe to me your experience of arranging a CDE.
  - What did you think about the timeliness of arranging a CDE?
  - During the process, were your questions about the CDE answered?
11. If you received a similar invitation in the future, tell me whether you would respond and get screened or not.
  - Tell me more.
12. If your doctor's office were to participate in another screening intervention program, what would you advise they do...
  - Differently, and why?
  - The same, and why?
13. Before we end, are there any issues or topics that I have not brought up today that you would like to address?

\*\*\*As a way to thank you for participating in today's focus group, we have some gift cards for you [distribute gift cards]. Thank you again for taking the time to talk with us today.\*\*\*

### **A.3-1 Patient Focus Group Guide**

#### **SATIS-PHI/CRC Intervention Patient Focus Groups: Nonresponder Focus Group (C)**

**Moderator Instructions:** After patients (who are part of the intervention practices) sign in, they will be given a name label with identifier (A = negative screen, B = positive screen, C = non-responders). The appropriate separate groups (A, B, C) will then convene, and the group moderator will read the script below.

The announcement of gift cards should be given at the end of the session.

#### **INTRO**

Hello. My name is \_\_\_\_\_ and I am the moderator for today's 2-hour group discussion. My colleague, \_\_\_\_\_, is here to take notes and help the session run smoothly. Our main purpose today is to discuss colorectal cancer screening recommendations.

#### **MODERATOR INFO**

[INSERT HERE: FOR WHOM AND WHY YOU ARE CONDUCTING THIS FOCUS GROUP]

As part of our work, we are speaking with individuals who were part of our intervention and received a recommendation for colorectal cancer screening. Your input is important to help us understand how to increase colorectal cancer screening.

#### **ACKNOWLEDGMENT**

I want to thank you for coming in today to talk with us and for fitting this session into your already busy schedules.

#### **DISCLOSURES**

The session is being recorded in audio to make sure our notes accurately reflect our discussion with you. It doesn't matter who says what; I only care what gets said. Does anyone have concerns about taping this session?

Notes will also be taken during the discussion today, but they will not include any identifying information about the group's participants.

#### **INFORMED CONSENT**

Your decision to participate is voluntary. Before we begin, I would like to hand out this consent form for you all to sign, if you still would like to participate in our discussion. [Hand out informed consent, and collect after patients sign]

- Are there any questions about your participation?
- If you do not want to participate, please take this time to gather your things and leave the room. We appreciate your interest.

## GUIDELINES

A few guidelines before we start:

1. What **you say in this room stays in this room**. As I mentioned, all information discussed today will be held in confidence. So please feel comfortable speaking openly and candidly with us.
2. Please talk **one at a time**.
3. Talk in a **voice as loud as mine**.
4. **Avoid side conversations** with your neighbors, but it is okay to “piggy back” on comments others have made. Just be sure to talk loud enough so the whole group can participate.
5. Make sure **everyone has a chance to talk**.
6. There is **no one point of view**, so please allow all points of view to be heard.
7. Say what **you believe**. It doesn't matter whether anyone agrees with you.

## QUESTIONS

1. Are you familiar with screening tests for colorectal cancer screening?
  - Who do you think is supposed to receive colorectal cancer screening?
  - Who do you think does not need to be screened for colorectal cancer?
  - Describe to me whether you think you are someone who should receive colorectal cancer screening.
  - Are you familiar with the 2008 Colorectal Cancer Screening Guidelines from the ACS/U.S. Multi-Society Task Force/ACR and USPSTF?
2. Have you received colorectal cancer screening before?
  - If so, when? How were you screened? Describe to me what influenced your decision to be screened.
  - If you haven't received colorectal cancer screening before, describe to me why you were not and what influenced your decision not to be screened.
3. Do you recall receiving an invitation in the mail a few months ago suggesting that you get screened for colorectal cancer?
  - How did you feel about the colorectal cancer screening information that was sent to you?
    - Did you think the information was clear? Easy to understand?
    - What did you like about the information?
    - What did you not like about the information?
  - What influenced your decision to not participate?

4. Specifically in terms of this intervention, if it were conducted again and you received another invitation to get screened, what could be done differently to help encourage you to receive screening?
  - Do you feel there was a need for better information?
  - Do you feel there was a need for more personalized information?
  - Do you feel there was a need for more colorectal cancer screening choices (beyond stool blood test and colonoscopy)?
  - Do you feel you should have received direct contact from your provider?
  - Anything else?
5. Before we end, are there any issues or topics that I have not brought up today that you would like to address?

\*\*\*As a way to thank you for participating in today's focus group, we have some gift cards for you [distribute gift cards]. Thank you again for taking the time to talk with us today.\*\*\*

## IV. References

Babbie E. The practice of social research. 10<sup>th</sup> ed. Belmont, CA: Wadsworth/Thomson Learning; 2004

Campbell D and Stanley J. Experimental and quasi-experimental designs for research. Boston: Houghton Mifflin; 1963.

Carcaise-Edinboro P, Bradley CJ. Influence of patient-provider communication on colorectal cancer screening. *Med Care* 2008;46(7):738-45.

Casalino LP, Dunham D, Chin MH, et al. Frequency of failure to inform patients of clinically significant outpatient test results. *Arch Intern Med* 2009;169(12):1123-29.

DeBourcy AC, Lichtenberger S, Felton S, et al. Community-based preferences for stool cards versus colonoscopy in colorectal cancer screening. *J Gen Intern Med* 2008;23(2):169-74.

Feldstein AC, Glasgow RE. A practical, robust implementation and sustainability model (PRISM) for integrating research findings into practice. *Jt Comm J Qual Patient Saf* 2008;34(4):228-43.

Geller BM. Increasing patient/physician communications about colorectal cancer screening in rural primary care practices. *Med Care* 2008;46(9):S36-S43.

Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM Framework. *Am J Public Health* 1999;89(9):1322-7.

Griffith KA, McGuire DB, Royak-Schaler R, et al. Influence of family history and preventive health behaviors on colorectal cancer screening in African Americans. *Cancer* 2008;113(2):276-85.

Harris DM, Borsky AE. Health care systems for tracking colorectal cancer screening tests: final report on the System Approach to Tracking and Increasing Screening for Public Health Improvement of Colorectal Cancer (SATIS-PHI/CRC) Intervention (Prepared by CNA Health ACTION Partnership under Contract No. HHS290200600014). Rockville, MD: Agency for Healthcare Research and Quality; 2010. AHRQ Publication No. 11-0016-1-EF.

Krueger RA, Casey MA. Focus groups: a practical guide for applied research. 4<sup>th</sup> ed. Thousand Oaks, CA: Sage Publications; 2009.

Levin B, Lieberman DA, McFarland B, et al. Screening and surveillance for the early detection of colorectal cancer and adenomatous polyps, 2008: A Joint Guideline from the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology. *CA Cancer J Clin* 2008;58(3):130-60. Available at: <http://caonline.amcancersoc.org/cgi/content/full/58/3/130>.

Levy BT, Nordin T, Sinift S, et al. Why hasn't this patient been screened for colon cancer? An Iowa research network study. *J Am Board Fam Med* 2007;20(5):458-68.

- Mathews AW. When all else fails: forcing workers into healthy habits. Wall Street Journal 2009;July 12. Available at:  
<http://online.wsj.com/article/SB10001424052970203577304574274102603258642.html>.
- Myers RE, Sifri R, Hyslop T, et al. A randomized controlled trial of the impact of targeted and tailored interventions on colorectal cancer screening. *Cancer* 2007;110(9):2083-91.
- Myers RE, Turner B, Weinberg D, et al. Complete diagnostic evaluation in colorectal cancer screening: research design and baseline findings. *Prev Med* 2001;33:249-60.
- Myers RE, Turner B, Weinberg D, et al. Impact of a physician-oriented intervention on followup in colorectal cancer screening. *Prev Med* 2004;38:375-81.
- Natale-Pereira A. Barriers and facilitators for colorectal cancer screening practices in the Latino community: perspectives from community leaders. *Cancer Control* 2008 April;15(2):157-65.
- Perceman E, Curran SR. A handbook for social science field research: essays and bibliographic sources on research design and methods. Thousand Oaks, CA: Sage Publications; 2006.
- Pinkowish MD. Promoting colorectal cancer screening: which interventions work? *CA Cancer J Clin* 2009;59(4):215-7.
- Roth CP, Lim YW, Pevnick JM, et al. The challenge of measuring quality of care from the electronic health record. *Am J Med Qual* 2009;24(5):385-94.
- Sarfaty M, Myers RE. The effect of HEDIS measurement of colorectal cancer screening on insurance plans in Pennsylvania. *Am J Manag Care* 2008;14(5):277-82.
- Sarfaty M, Wender R. How to increase colorectal cancer screening rates in practice. *Cancer* 2007;57(6):354-66.
- Sequist TD, Zaslavsky AM, Marshall R, et al. Patient and physician reminders to promote colorectal cancer screening. *Arch Intern Med* 2009;169(4):364-71.
- Snell JL, Buck EL. Increasing cancer screening: a meta-analysis. *Prev Med* 1996;25:702-7.
- U.S. Cancer Statistics Working Group. United States cancer statistics: 1999–2006 incidence and mortality Web-based report. Atlanta: Centers for Disease Control and Prevention and National Cancer Institute; 2010. Available at: <http://www.cdc.gov/uscs>.
- U.S. Preventive Services Task Force. Screening for colorectal cancer: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med* 2008;149(9):627-37.
- Vernon SW. Participation in colorectal cancer screening: a review. *J Natl Cancer Inst* 1997;89:1406-22.
- West SL, Blake C, Liu Z, et al. Reflections on the use of electronic health record data for clinical research. *Health Informatics J* 2009;15(2):108-21.

Zajac IT, Whibley AH, Cole SR, et al. Endorsement by the primary care practitioner consistently improves participation in screening for colorectal cancer: a longitudinal analysis. *J Med Screen* 2010;17(1):19-24.

Zapka J. Innovative provider- and health system-directed approaches to improving colorectal cancer screening delivery. *Med Care*. 2008 Sep;46(9 Suppl 1):S62-7.