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

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Prepared by:

Daniel M. Harris, Ph.D., and Amanda E. Borsky, M.P.P.
CNA

With contributions from members of the CNA Health ACTION Partnership for SATIS-PHI/CRC:

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

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Executive Summary

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.

This report summarizes the experience of the CNA Health ACTION (Accelerating Change and Transformation in Organizations and Networks) Partnership in implementing and assessing a health care intervention to increase CRC screening and followup. The System Approach to Tracking and Increasing Screening for Public Health Improvement of Colorectal Cancer (SATIS-PHI/CRC) was a demonstration project conducted in primary care practices in the Lehigh Valley of Pennsylvania. The practices were affiliated with the Lehigh Valley Physician-Hospital Organization (LVPHO) and the Eastern Pennsylvania Inquiry Collaborative Network (EPICNet). This report also contains a description of our dissemination plans and efforts to date to spread the uptake of this intervention to other health care settings.

The project was funded by the Centers for Disease Control and Prevention (CDC). It was carried out as a task order (Contract No. HHSA290200600014, Task Order No. 290-06-0014-1) under the ACTION program of the Agency for Healthcare Research and Quality (AHRQ) between October 2007 and July 2010. We implemented the intervention in early 2009, and it ran through February 2010.

SATIS-PHI/CRC is a population-based system-redesign intervention designed to improve CRC screening rates and rates of diagnostic followup for positive screens. We based the major components of SATIS-PHI/CRC on prior studies developed in other settings. We used a case study approach, informed by the PRISM (Practical, Robust Implementation and Sustainability Model) framework, to determine whether we could:

- Implement SATIS-PHI/CRC in the Lehigh Valley setting,
- Increase screening and followup rates, and
- Achieve rate improvements similar to those previously reported.

SATIS-PHI/CRC is a six-step intervention that assists primary care practices in providing population-based CRC screening. Screening follows recommendations and guidelines jointly issued in 2008 by the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology and by the U.S. Preventive Services Task Force. This intervention seeks to influence the behavior of primary care providers and their patients regarding CRC screening and followup through targeted communications. It also is designed to facilitate the screening and followup process through improved eligibility identification and screening tracking systems.

The intervention is intended to be conducted by a central entity, such as a health care delivery system, accountable care organization, or insurer, affiliated with a network of primary care practices on behalf of and in conjunction with those practices. Intervention steps include:

1. Recruiting primary care practices to participate;
2. Conducting academic detailing to inform and influence the behavior of practice clinicians and other staff;
3. Identifying patients of participating practices who are guideline eligible for, but not up to date in, CRC screening;
4. Mailing information and reminders to patients regarding CRC screening and material facilitating screening;
5. Tracking patient screening and followup of positive screens; and
6. Providing feedback to practices regarding patients who were screened and recommended for followup.

LVPHO, in conjunction with EPICNet, served as the central entity for our implementation study. We recruited 26 EPICNet practices to participate in the study: 20 practices to receive the intervention, 5 to act as controls not receiving the intervention, and 1 to be the site of a pilot of the intervention. We used purposive assignment to allocate practices to the intervention or control group to ensure a satisfactory mix of practice attributes in each group. We reviewed available electronic records (claims, billing, and electronic medical records) to identify eligible patients. We supplemented this record review with eligibility information provided by patients responding to a screening eligibility assessment (SEA) brief survey form that we mailed to them.

We identified 7,965 patients from intervention practices and 2,662 patients from control practices who met criteria for inclusion in our study. We further randomly assigned the 2,347 patients of two intervention practices to receive alternate versions of mailed screening materials (470 received a stool test kit and 1,877 received a mail-back card for requesting a kit) to estimate the effect of receiving a kit versus a card on screening rates. We reviewed electronic records and reports from a clinical laboratory that processed stool test kits, supplemented by audits of a sample of patients, to track screening and followup. We also conducted a short survey of participating practices, focus groups, and key informant interviews with each practice, as well as focus groups with a sample of patients of intervention practices to inform our assessment of our implementation effort and its outcome.

Overall, we were able to successfully implement the SATIS-PHI/CRC intervention in the LVPHO/EPICNet setting and generally achieve an effect on improving CRC screening rates that was comparable to previous intervention studies. However, we identified a number of factors that hindered implementation and that were a likely cause of lower than expected screening rates. The LVPHO/EPICNet central entity lacked some elements of the ideal implementation infrastructure. In particular, the central entity did not have electronic records systems set up for public health population-based patient outreach programs or experience implementing a program of this size based at the central entity rather than the practices.

We implemented the intervention during a period of economic uncertainty and limitations, resulting in fewer staff available for implementation at both the central entity and the practices.

We also had to change the intervention protocol to accommodate the decision of the stool test kit supplier to restrict the number of kits it would make available free of charge. We thus could only send the kit directly to a small subsample of patients; the large majority of patients had to request a kit from us by mailing back a request card. The implementation timeframe was also a period of change and transformation among primary care practices in the Lehigh Valley that affected both their electronic medical record (EMR) systems and their ability to focus on the SATIS-PHI/CRC intervention.

These factors affected our ability to fully eliminate ineligible patients from our rate denominators and to fully identify completed screenings (especially colonoscopies) for our rate numerators, leading to low observed screening rates. Implementation delays shortened the period available for observing screening and followup. Shortages of colonoscopy providers in the Lehigh Valley to accommodate an increase in demand for screening likely depressed observed screening as well as followup rates during the shortened observation period.

Despite these implementation shortcomings, we found that the odds of being screened during the observation period were significantly greater among patients of intervention practices than control practices. 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.

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

We found evidence of 786 patients being 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), of which only 8 were positive (abnormal); we could not ascertain the results of an additional 18. We tracked the followup experience of these 26 patients for evidence of complete diagnostic examinations; however, 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, our assessment of our implementation of the SATIS-PHI/CRC intervention in the LVPHO/EPICNet setting demonstrates that we were able to:

1. Successfully implement the SATIS-PHI/CRC intervention in a setting that differed from those that prevailed in studies on which we based our development of SATIS-PHI/CRC; and

2. Achieve comparable effectiveness in improving the odds of becoming screened among guideline-eligible patients not up to date in their screening.

Further, we were able to extract a set of "lessons learned" from our implementation experience that could help others to successfully implement SATIS-PHI/CRC in their settings and to achieve comparable effectiveness outcomes. We describe these lessons learned in this report and introduce the implementation toolkit we developed to assist those who want to implement the intervention. This toolkit contains descriptions of how to implement each of SATIS-PHI/CRC's steps. It also has implementation tips based on our lessons learned and tools for each step (e.g., forms, materials to mail to patients, patient eligibility criteria, and practice recruitment and academic detailing material). We then describe our current efforts to disseminate the intervention through presentations at professional meetings, publication of papers, and involvement with health care delivery systems and with clinical and policy working groups.

Based on our assessment findings and our lessons learned, we believe 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:

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

For successful implementation, it is important to have 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. In addition, it is best not to have other competing population-based initiatives in the service area or at the participating practices that could detract from the support and attention needed to implement SATIS-PHI/CRC.

Our experience with SATIS-PHI/CRC also demonstrates that this intervention can be successfully implemented in a wide range of practices. These include those that are more closely and less closely affiliated with the central entity and those that have and do not have fully functional 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 patents) for practices without fully functional EMR systems. Successful implementation would also be enhanced if participating practices are dedicated to population-based preventive health in general and have strong leadership supportive of the SATIS-PHI/CRC intervention effort. In addition, it helps to have a clinical champion for the intervention.

1. 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.

Project Overview

This project sought to assess whether, to what extent, and how easily a health system redesign intervention could increase CRC screening and followup. The intervention was called the System Approach to Tracking and Increasing Screening for Public Health Improvement of Colorectal Cancer (SATIS-PHI/CRC) and was implemented in a network of primary care practices.
The project was funded by the Centers for Disease Control and Prevention (CDC). It was carried out as a task order under the ACTION (Accelerating Change and Transformation In Organizations and Networks) program of the Agency for Healthcare Research and Quality (AHRQ) between October 2007 and July 2010. We implemented the intervention in early 2009, and it ran through February 2010.

SATIS-PHI/CRC is a population-based system-redesign intervention designed to improve CRC screening rates and rates of diagnostic followup for positive screens. We based the major components of SATIS-PHI/CRC on prior studies conducted by project staff at Thomas Jefferson University (TJU) (Myers, et al., 2007; Myers, et al., 2004; Myers, et al., 2001). Those studies showed that a targeted outreach intervention to patients in a large urban academic practice improved CRC screening rates. They also indicated that a feedback intervention to providers in practices affiliated with a large, for-profit managed care organization improved diagnostic followup for positive screens. We used a case study approach, informed by the PRISM (Practical, Robust Implementation and Sustainability Model) framework, to determine whether we could:

1. Implement SATIS-PHI/CRC in a different setting,
2. Increase screening and followup rates, and
3. Achieve rate improvements similar to those previously achieved by the TJU research team.

The health system setting for this project is the Lehigh Valley Physician-Hospital Organization (LVPHO) affiliated with 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, has an interest in value-based health care and sees preventive care, including CRC screening, as a means to that end. This project builds on the cited prior studies and examines both the process of implementing the SATIS-PHI/CRC intervention in the LVPHO network of practices and the outcome of the intervention.

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

- 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 the practices to better provide guideline-based preventive health care to their patients ages 50 through 79 years old who are at average risk for CRC.
- It assists practices to provide population-based CRC screening that follows recommendations and guidelines jointly issued in 2008 by the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology (Leven, et al., 2008) and also in 2008 by the U.S. Preventive Services Task Force (USPSTF, 2008).
- 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 recommended screening, tracking screening results, and facilitating patient notification and appropriate followup through feedback to providers.
- 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).
- 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.
- 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.

We designed the SATIS-PHI/CRC intervention between October 2007 and early July 2008. Our design effort included updating our initial environmental scan of CRC screening interventions, developing goals and objectives for the intervention, designing an implementation plan, and planning for the assessment of the intervention. The intervention we designed includes six component steps:

1. Recruit primary practices to participate in the intervention,
2. Conduct academic detailing in these practices,
3. Identify patients of these practices who are eligible to receive the intervention materials,
4. Mail the screening intervention materials to them,
5. Track resulting patient screening and results, and
6. Provide feedback to the participating practices regarding screening results for their patients and recommended, guideline-supported followup.

Pilot and Intervention Protocol

Because this project included an assessment of the intervention that entailed human subjects research, it required Institutional Review Board (IRB) approval. In addition, the assessment and several steps in the intervention process required data collection. The project was conducted under a task order contract with the Federal Government, so we had to obtain Paperwork Reduction Act clearance from the Office of Management and Budget (OMB) prior to any data collection. Once we received approval from the LVHN and TJU IRBs for the assessment study, we worked with AHRQ to obtain OMB clearance to collect data for this project.

Steps 2 and 3 of the intervention process included surveying practice staff to ascertain baseline screening knowledge, attitudes, and practices. These steps also involved accessing and reviewing electronic records to identify patients eligible to receive the intervention. Thus, we needed to obtain OMB clearance before we could implement those steps. We began developing material for the OMB submission in late January 2008 and received written clearance in early December of that year.

In addition to developing, implementing, and then assessing the implementation and outcomes of the SATIS-PHI/CRC intervention, this project required us to develop materials for dissemination based on our experiences with the intervention. The dissemination materials were to include our findings, lessons learned, and a toolkit that could all be used by other health care systems interested in adopting this intervention to improve CRC screening and followup rates. Figure 1.1 presents a timeline for the implementation, assessment, and dissemination phases of this project.

To allow us to move forward on gaining experience with the intervention and its assessment while we awaited OMB clearance, the project's Task Order Officer granted permission for us to pilot test the IRB-approved intervention and assessment protocol in one primary care practice. We got permission on the condition that we not use any data collected during the pilot in any publication, presentation, or external report, whether separately or combined with data collected during the main intervention. We could, however, use lessons learned during the pilot to revise and refine the main intervention, and we were encouraged to do so by the Task Order Officer and the project's Technical Advisors from CDC.

We conducted the pilot test of the intervention between late June 2008 and March 2009. We recruited all of the practices for the pilot (1 practice) and the full intervention (25 practices) concurrently at the beginning of the pilot test period. We then began the pilot while waiting for OMB clearance. The pilot was well underway when we received OMB clearance in December 2008.

The pilot and the full intervention overlapped during the first few months of 2009, allowing us to begin the full intervention with lessons learned from the early steps in the pilot. Later, we incorporate further lessons learned from later steps in the pilot. This approach avoided having to wait until the pilot was fully completed before beginning the full intervention and helped us compensate for unanticipated delays due to the OMB clearance process.

To further expedite the intervention, we divided participating intervention practices into two waves for Steps 3 and 4. That way, we did not have to wait until we could access and review electronic records from practices whose records were difficult to work with before we moved ahead with nonproblematic practices. We also selected two Wave 2 practices as sites to introduce a variation of the intervention. The intervention period ended in February 2010.

The assessment began with preintervention surveys, focus groups, and key informant interviews with intervention practices concurrently with implementing step 2 of the intervention (academic detailing). Tracking screening and followup for outcome assessment purposes began and was conducted concurrently with the tracking performed for step 5 of the intervention. However, it continued past the end of the intervention period to allow us to identify screening and followup that occurred during the intervention period but did not show up in electronic records until after the close of that period. Assessment data collection also included postintervention surveys and focus groups, as well as chart audits.

We developed a dissemination plan between the beginning of June and the end of August 2009. We developed draft dissemination material between the beginning of August and the end of October 2009 and finalized it between May and July 2010. We conducted some dissemination activities before preparing this report in July 2010 and planned to continue these activities for several months past the formal period of performance of the task order.

Figure 1.1. Timeline for Implementation, Assessment, and Dissemination of the SATIS-PHI/CRC Intervention

Intervention Steps and Assessment Activities	2008	2009												2010			
	Jun-Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr
Intervention																	
Pilot test the intervention																	
Step 1: Recruit practices																	
Receive OMB clearance under the PRA																	
Step 2: Schedule and conduct academic detailing																	
Step 3: Identify eligible patients - initial electronic records review - Wave 1																	
Step 3: Identify eligible patients - initial electronic records review - Wave 2																	
Step 4: Mail screening materials - intro and SEA Form - Wave 1																	
Step 4: Mail screening materials - intro and SEA Form - Wave 2																	
Step 3: Identify eligible patients - review SEA Forms - Wave 1																	
Step 3: Identify eligible patients - review SEA Forms - Wave 2																	
Step 4: Mail screening materials - invitation and request card - Wave 1																	
Step 4: Mail screening materials - invitation, request card, and kit - Wave 2																	
Step 4: Mail screening materials - kits sent to those requesting them*																	
Step 5: Track screening - electronic records review																	
Step 4: Mail screening materials - reminder - Waves 1 and 2																	
Step 6: Provide feedback																	
Assessment																	
Administer preintervention practice surveys, focus groups, and interviews																	
Track screening and followup - electronic records review																	
Conduct postintervention practice surveys and focus groups																	
Control practice surveys and focus groups																	
Conduct postintervention patient focus groups																	
Conduct chart audits																	
Conduct implementation staff focus group																	
Dissemination																	
Develop dissemination plan																	
Develop draft dissemination products and tools																	
Implement dissemination plan; conduct dissemination activities																	→

***** Note: For ethical reasons, we continued to honor requests for kits that we received after the end of the intervention period but did not count them in the assessment.

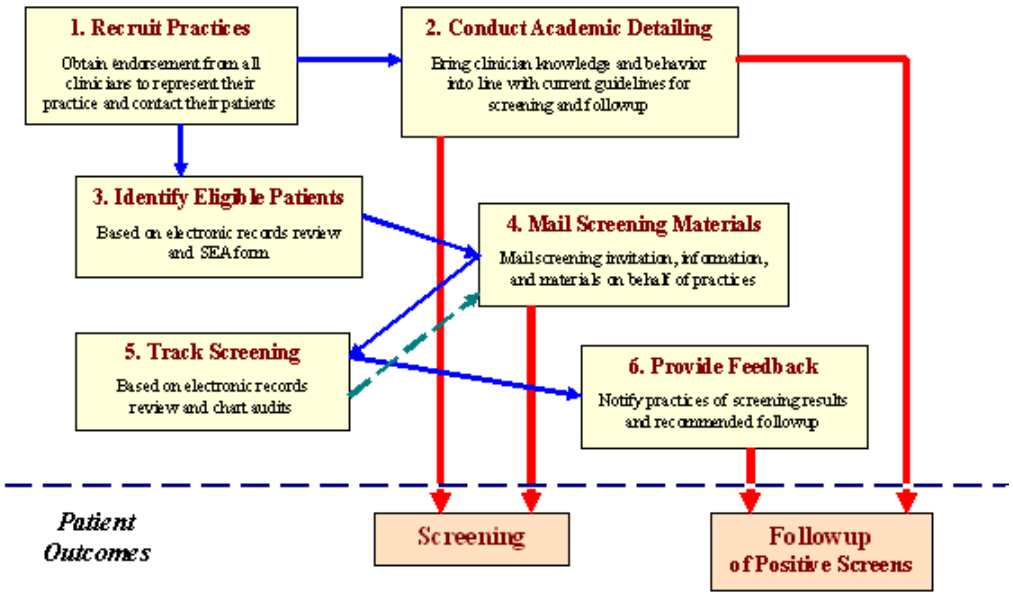
Overview of the Intervention

The System Approach to Tracking and Increasing Screening for Population Health Improvement of Colorectal Cancer (SATIS-PHI/CRC) intervention seeks to (1) influence the behavior of primary care providers and their patients regarding CRC screening and followup through targeted communications and (2) facilitate the screening and followup process through improved eligibility identification and screening tracking systems. Figure 1.2 presents the framework for the six steps of SATIS-PHI/CRC.

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 as well. 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 patients with no evidence of being screened receive a reminder Step 4 mailing whereas the practices of patients with evidence of screening are notified of screening results and receive feedback regarding recommended followup.

Figure 1.2. Framework for a System Approach to Tracking and Increasing Screening for Population Health Improvement Regarding Colorectal Cancer (SATIS-PHI/CRC)



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. Because the central entity will contact patients on behalf of practices participating in the intervention, the first step is to recruit practices to participate in the intervention and obtain the consent of all clinicians in each practice to represent them and to contact their patients.

The central entity then conducts academic detailing at each participating practice to bring clinicians and staff up to date on current screening and followup guidelines, inform them about the screening information and materials the central entity will send to their patients, and ask them to support the intervention effort by encouraging their patients to respond positively to the invitation to be screened. (The central entity can also conduct an optional survey of the practices to ascertain baseline knowledge and behavior prior to the academic detailing session in order to better tailor the session to the practices.)

During Step 3, the central entity accesses and reviews electronic billing, claims, and medical records available through participating practices or cooperating insurance plans. This review is used to identify patients who appear to be eligible (meet the guideline-based criteria) for screening by age, prior screenings, and personal and family medical history. The central entity then mails those who appear to be eligible an introductory letter with a screening eligibility assessment (SEA) form for patients to fill out to confirm their eligibility or identify themselves as not eligible.

At the central entity's discretion, the SEA form can include an option for patients to opt out of receiving further information or materials. Those who continue to be eligible (and do not opt out) receive a second mailing with information about CRC and various screening modalities supported by the intervention at the central entity's discretion (we elected to support at-home stool testing by fecal immunochemical testing [FIT] and colonoscopy). If an at-home screening test is part of the intervention, this mailing also includes either a test kit or a mechanism, such as a mail-in request card, to request one.

The central entity then tracks electronic records to identify who does and does not get screened (Step 5). After allowing an appropriate time to elapse, the central entity mails reminders to nonscreeners (this cycle can be repeated more than once at the central entity's discretion). Step 5 tracking continues to identify results of screening tests. The central entity then provides feedback (Step 6) to practices and their clinicians regarding results for their patients and recommended followup procedures for negative (normal) and positive (abnormal) or inconclusive results.

Scope and Outline of the Report

The stated purpose of this ACTION task order project was "to design, implement, assess, and disseminate a redesign of important health care delivery system processes in CRC screening in order to increase their efficiency while sustaining or improving their value to patients" (quoted from the Request for Task Order for this project released on July 3, 2007). The scope of this report covers all aspects of this purpose. In it, we describe (1) the SATIS-PHI/CRC intervention we designed and implemented to improve CRC screening and followup, (2) our experience and

the lessons learned from implementing it, (3) our assessment of it, and (4) our current and planned dissemination activities to encourage the spread and uptake of the intervention.

A major emphasis of this report is the intervention assessment. We devote a section to describing our assessment approach and design and another section to reporting our assessment findings. The scope of the assessment is broader than simply evaluating the effect or outcome of the intervention. It also encompasses an assessment of the implementation of the intervention. Since the intent of this project is to learn about the intervention implementation process as well as the intervention's effect, the assessment reflects this intent by assessing both process and outcome.

We previously submitted a series of deliverables under this ACTION task order contract that (1) updated the environmental scan we provided in our proposal for this project, (2) outlined our goals and objectives for our health system intervention approach to improve CRC screening and tracking, (3) presented our plan for implementing this intervention for primary care practices affiliated with the LVPHO, (4) described our plan for assessing the implementation process and its outcomes, (5) delineated our dissemination plan for facilitating the spread and uptake of the intervention, (6) presented a preliminary report of our work under this contract, and (7) provided our draft dissemination products and tools. This current report further documents our work and presents our overall experience and findings related to our implementation of the intervention and our assessment of its outcome. It draws on, refers to, and occasionally summarizes information contained in the previous deliverables but primarily provides information on our more recent work and findings.

At the time of our preliminary report in early October 2009, we had (1) fully completed Steps 1 through 3 of the intervention, (2) completed the initial and followup mailings of Step 4 but were continuing to mail stool test kits to patients who requested one, (3) completed an initial round of Step 5 tracking and were continuing to track screening and followup, and (4) had just begun Step 6 feedback to practices (see Figure 1.1 for a timeline of the implementation of the intervention and its assessment). As Figure 1.1 indicates, we continued to send requested stool test kits, track screening and followup, and provide feedback through February 2010. We began our postintervention data collection for the assessment in February 2010 and continued to collect assessment data through the end of April. The scope of this report, then, describes our experience implementing the full intervention, our methods for assessing the intervention, our assessment findings, and our dissemination plan and activities.

The following section of this report presents a detailed description of the SATIS-PHI/CRC intervention, including a rationale for the intervention, the role of a central entity to implement it, and descriptions of its components, our experience implementing them, and lessons learned from that experience that could help others to adopt and implement SATIS-PHI/CRC. The next section then presents our assessment plan and methodology. It first introduces the assessment framework we adopted (the Practical, Robust Implementation and Sustainability Model, or PRISM) and then describes our assessment research design. Finally, it describes our sources of data for the assessment, our assessment outcome measures, and the patient and provider attribute data we used in our assessment of the intervention. That section is followed by our assessment findings. Following the PRISM framework, these findings include an assessment of

the context in which we implemented the intervention as well as an evaluation of the implementation process and the intervention's outcome.

We then turn to a discussion of our dissemination activities, including (1) a review of our dissemination plan, (2) a description of the contents of our intervention toolkit, and (3) a discussion of our recent, ongoing, and planned dissemination activities. We end this report with a Conclusions section in which we summarize our assessment results and our lessons learned regarding implementing the intervention and then discuss the transferability of the intervention to other system settings. In particular, based on our assessment and lessons learned, we identify the conditions and attributes of central entities and practices that we believe are needed for a successful adoption and implementation of the SATIS-PHI/CRC intervention.

2. Description of the Intervention

In this section, we first present a rationale and supporting evidence for the SATIS-PHI/CRC intervention. We then describe the role of a central entity in implementing it. We next provide a detailed description of each of the six component steps of the intervention (recruit practices, conduct academic detailing, identify eligible patients, mail screening information and materials, track patient screening and results, and provide feedback to practices) and our experience implementing them. We include the lessons we learned from implementing the intervention in the setting of the Lehigh Valley Physician-Hospital Organization and the ambulatory practices of its affiliated primary care providers. In the accompanying toolkit, we turn our lessons learned into "tips" to end users who may be interested in adopting the intervention.

Reviewing Figures 1.1 (the intervention timeline) and 1.2 (the SATIS-PHI/CRC framework) while reading this section may be useful.

Rationale and Supporting Evidence

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). We provide this assistance by having a central entity identify patients who are eligible for but not up to date in their CRC screening, send invitations to be screened and screening information and material to those patients, track whether patients get screened, send reminders to those who do not screen, and then issue reminders to the practices to follow up with screened patients. We modeled SATIS-PHI/CRC largely after the interventions developed by TJU researchers (Myers, et al., 2007; Myers, et al., 2004; Myers, et al., 2001).

The major components of SATIS-PHI/CRC are supported by recent literature. We 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). We conducted academic detailing about CRC screening at participating practices and provided information about CRC and screening for it 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, et al., 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 becoming screened (Carcaise-Edinboro and Bradley, 2008; Griffith, et al., 2008; Sarfaty and Wender, 2007; Zajac, et al., 2010). Therefore, all the mailed communications to patients were sent by the central entity on behalf of the providers in each patient's practice. For example, all letters were 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 and 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. Therefore, we provided patients with a choice between colonoscopy and a less invasive test they could use themselves at home (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 (Mathews). A company that mandated that all employees would have to 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), we built in both a feedback mechanism to remind providers to properly follow up with patients regarding test results and tools to assist practices and clinicians to track and document patient notification and followup.

The Central Entity

The SATIS-PHI/CRC system intervention is intended to be conducted by a central entity that has a relationship or affiliation with a formal or informal network of primary care practices. Examples of such a relationship or affiliation with practices include:

- Practices owned or operated by an integrated delivery network,
- Practices affiliated with or members of a PHO or independent practice association (IPA),
- Practices that provide care to the defined population for which an accountable care organization (ACO) is responsible,
- Practices that have a contractual relationship with a health insurance plan,
- Practices that are part of a centrally owned multilocation group practice,
- Practices affiliated with or members of a communitywide regional health information organization (RHIO), and
- Practices located in the jurisdiction of a county or municipal public health agency.

The central entity conducting the intervention in each of these examples would be the delivery network, the PHO or IPA, the ACO, the insurance plan, the group practice, the RHIO, or the public health agency, respectively.[i] In each instance, the entity conducting the intervention acts centrally on behalf of the practices to institute a population-based screening program for the practices' patients who are eligible, according to prevailing guidelines, to be screened based on their age, personal and family medical history, and previous screening history. [ii]

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[i] In appropriate circumstances, a single large primary care practice with a sizable patient population could institute this intervention on its own by acting as the central entity.

[ii] Although this intervention specifically targets CRC screening, the same general approach could be used for screening for other conditions or for other appropriate preventive services such as immunizations as long as there is a central entity able to meet the requirements stated below and there exists evidence-based and generally accepted guidelines recommending who should and should not receive the service. Thus, SATIS-PHI/CRC could become, for example, SATIS-PHI/DM for diabetes mellitus screening or SATIS-PHI/HTN for hypertension screening.

The central entity for this implementation of the SATIS-PHI/CRC intervention was the LVPHO in conjunction with Eastern Pennsylvania Inquiry Collaborative Network (EPICNet, a practice-based research network [PBRN] of primary care practices affiliated with LVHN).

To conduct this intervention, the central entity must be able to meet the following eight requirements:

- Be able to centrally and electronically determine likely eligibility based on the guideline recommendations,
- 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 screened after a period of time,
- Be able to track patient response to the invitation and to screening results,
- Be able to feed back results to practice clinicians and remind them of appropriate recommended followup for positive screening findings,
- Be willing to fund or find funding for the intervention,[iii]
- Identify one or more suppliers of stool test kits and one or more clinical laboratories to process them (the processing lab may also be the supplier in many cases),
- Have or develop a business associate relationship with the clinical lab—or use a lab it operates—to allow the lab to report screenings and results to the central entity, and
- Be able to notify colonoscopy providers identified by participating practices as those to whom they refer that this screening program will take place and when and that they should expect a potential increase in requests for screenings (this last condition is recommended rather than strictly required).

In addition, since we conducted the intervention as part of a study to assess its feasibility, transferability, and effectiveness, we performed research-related central entity activities, including obtaining Institutional Review Board (IRB) approval, collecting pre- and postintervention data needed to assess the intervention, expanding the demographic information collected from patients for use in evaluating the intervention, and conducting focus groups with practice staff and patients. Central entities adopting this intervention would generally not need to perform these additional activities unless they wanted to assess the intervention in their settings. Such central entities would need to consult with their IRBs to determine whether the assessment phase would require review and approval.

Step 1: Recruit Practices

Description

The first step of the intervention is to recruit primary care practices to participate. This component consists of encouraging primary care practices affiliated with the central entity to participate by providing them information about the importance of CRC screening and the prevailing low rate of screening, the nature of the intervention and the evidence it is based on,

[iii] This funding is minimal considering the potential public health benefit to be derived. It is primarily required 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.

the benefits to them and their patients of participating, and the requirements of them and their patients for participation.

In addition to recruiting practices, the central entity must also consider whether it wants to involve a stool test kit supplier. The central entity can choose to bear the cost or negotiate with a clinical laboratory or other test kit supplier to bear the cost of supplying kits for all eligible patients or only those patients who request them through the enclosed request card. As a third option, the central entity can send the kit to patient groups it especially wants to target and send request cards to all other eligible patients.

Our Experience

Our research design protocol specified that we purposefully recruit 25 primary care (family medicine and general internal medicine[iv]) practices from among the 111 such practices affiliated with the LVPHO and then purposively assign them to intervention and control arms (20 intervention and 5 controls). We classified practices based on five attributes:

1. Size (smaller practices with one to three clinicians and larger practices with more than three clinicians).
2. Affiliation or ownership (LVHN-operated hospital clinics, LVHN-owned practices of the Lehigh Valley Physician Group [LVPG], independent practices affiliated with Medical Associates of the Lehigh Valley [MATLV], and unaffiliated independent practices).
3. Specialty (family medicine and general internal medicine).
4. Location within the Lehigh Valley area (urban, rural, suburban).
5. Presence or absence of an electronic medical record system.

Using a purposive recruitment process, we successfully recruited 25 practices that included adequate representation of each type of practice.

We then assigned the practices to the intervention and control arms based on target quotas for the five distinct attributes to ensure equitability between the two arms. The attribute that we gave the highest priority to ensure equal distribution between the intervention and control arms was practice size. We felt this was one of the most important practice characteristics that could influence screening.

Following assignment, but before the start of the intervention, 5 intervention practices dropped out of the study,[v] leaving us with 15 intervention and 5 control practices participating. We decided not to recruit replacement practices, as the randomization of the practices had already occurred and we were following an "intention to treat" research design. The net result of this decision, however, is that fewer patients were exposed to the intervention.

[iv] We excluded pediatric practices since their patient populations do not meet the age eligibility requirements (50-79) for average-risk CRC screening.

[v] We list the reasons these practices cited for dropping out in our discussion of adoption of the intervention.

For a practice to be eligible to participate, it had to be located in either Lehigh or Northampton County in Pennsylvania and a family medicine or general internal medicine practice. All participating practices agreed to participate in the study. The practices involved their patients in the study intervention as part of normal clinical care based on recommended screening guidelines.

We completed practice recruitment in November 2008. Intervention and control group assignment occurred once recruitment was complete.

We recruited a stool test supplier for the intervention to help facilitate screening. This supplier was the LVHN clinical laboratory (Health Network Laboratory, or HNL) that also would process and develop the stool tests. During the pilot, substantially fewer patients of the pilot practice chose to be screened by stool testing than initially expected. Based on the results of the pilot, HNL decided it would not be financially feasible to donate kits for all patients in the full intervention. HNL said it could not recoup the expense of the kits by processing and charging patients' insurance plans for a sufficient number to cover the costs of donating the kits.

In order to avoid charging patients for the cost of the kits, we negotiated an agreement with the lab to donate kits for patients who had a high likelihood of using them. We thus modified our full intervention protocol so that kits would be sent only to those patients who requested one using a request card enclosed with the invitation-to-be-screened mailing. We also arranged for the lab to donate some additional kits so that we could mail a subset of patients in two practices the kit directly, rather than the card. We felt the ease of screening might influence patients' decision to screen.

Lessons Learned

- Because five practices dropped out of the intervention before its start, the most important lesson learned is to stay engaged with the practices between the time you recruit them and the time you send the first mailing to their patients. While practice priorities will always be shifting and loss of practices from the intervention may be inevitable, maintaining engagement with the practices can help minimize this loss.
- While finding a stool test kit supplier was not the focus of this step, we learned some lessons during our pilot in terms of recruiting a supplier. When recruiting a stool test kit supplier, we recommend ensuring that the supplier is realistic in its understanding of the financial implications of supplying kits before agreeing to supply them. Since a clinical laboratory was the supplier for our implementation of SATIS-PHI/CRC, it planned to cover the cost of providing the kits by charging for developing those returned for testing. To break even, it required a certain percentage of kits to be returned. When the lab realized, based on its experience with the pilot, that fewer kits were likely to be returned than needed, it informed us that it could not continue to participate unless we could guarantee a higher rate of return. This condition resulted in our needing to revise the SATIS-PHI/CRC protocol by requiring most patients to request a kit before one would be sent to them. Even after insurance reforms associated with the recently passed Patient Protection and Affordable Care Act (P.L. 111-148) go into effect, this financial consideration will continue to apply.

- It is necessary to provide the practice 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. For the full intervention, we created a step-by-step instruction booklet to send to practices that outlined exactly what the practice and provider should do during each step of the process. This booklet also included a more detailed explanation of the lab's processing of stool test kits and a shortened form for practices to use when sending kits to the lab for processing. This approach proved very helpful for the full-intervention practices.

Step 2: Conduct Academic Detailing

Description

The practice/clinician educational component of this intervention consists of an academic detailing session at each participating practice conducted by staff of the central entity. The detailers use informational material developed by this Task Order's staff (included as part of the dissemination kit produced for this Task Order). This material primarily consists of slides and notes for a detailing presentation to practice clinicians and staff. The presentation describes the intervention and provides information about currently recommended CRC screening and followup guidelines. Detailers also distribute and explain the use of a screening tracking spreadsheet developed for this intervention to be used by practices that do not already have an effective means of tracking screening tests. Detailers stress the importance of tracking screening, notifying patients of screening results, 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 of clinicians and other practice staff regarding their perceptions of and behavior performing CRC screening and followup. It also may arise from record reviews (discussed below) or current events (e.g., changes in guideline recommendations). Detailers can develop an academic detailing "booster" containing material targeted at clarifying misperceptions or pointing out nonrecommended screening and followup behaviors that are revealed through the survey or focus groups.

Our Experience

We scheduled academic detailing sessions with each of the intervention practices at times that were most convenient for practice staff and clinicians. However, end-of-year holidays and busy schedules resulting from the winter cold and flu season resulted in scheduling delays and thus delays in completing these sessions. The academic detailing was not completed until the end of March 2009.

Prior to academic detailing at a practice, we distributed CRC screening surveys to the practice and requested that all staff complete them and have them available for collection prior to or at the beginning of the detailing session. We adopted this approach to avoid confounding preintervention baseline survey results by allowing staff to use information presented in the detailing session to respond to survey questions. For the same reason, we conducted a short focus group to learn about the practice's prevailing screening procedures before beginning the detailing portion of the session. We audio recorded the focus group portions of the sessions and later transcribed them for analysis.

It is important to note that the Multi-Society Task Force and the USPSTF revised their CRC guidelines late in 2008 and the revised guidelines were relatively new to clinicians. We intended the detailing to serve as a way to ensure that all clinicians were aware of the updates. We did not provide academic detailing to control practices as detailing is a component of the intervention and controls were not to be exposed to intervention components. Nothing, however, prevented clinical staff at control practices from reading the revised guidelines on their own, especially as these guidelines received coverage in publications aimed at clinicians.

Early results from analyzing the preintervention practice survey revealed that a not-insignificant percentage of clinicians at intervention practices held screening beliefs and engaged in screening behaviors that were not in accordance with the prevailing guidelines. To address this finding, we developed an academic detailing "booster" that was e-mailed and mailed to clinicians at the 15 intervention practices. This booster was designed to reemphasize which screenings were recommended and to differentiate between an in-office stool test done during a digital rectal exam (which is not recommended) and the use of an annual multisample at-home stool test (which is recommended). The booster also emphasized that positive tests should be followed up by colonoscopy (and not by a repeat stool test or flexible sigmoidoscopy).

Lessons Learned

During our pilot, we learned four key lessons regarding the academic detailing that affected how we implemented this step in the full intervention. Our lessons learned included the following:

- Some physicians may not agree with the new recommended CRC screening guidelines. During the pilot, we encountered a physician who believed that colonoscopy is the only acceptable screening modality and that other modalities recommended by the current guidelines are not correct, especially stool testing. We were concerned that his belief, if he communicated it to his patients, could negatively affect the intervention's ability to get his patients screened, especially if they were uncomfortable with colonoscopy and would prefer stool testing. We talked with him about his concerns and about the efficacy of stool testing as a screening modality. For the full intervention, we stressed the acceptability of all recommended screening modalities and noted that including both stool testing and colonoscopy to accommodate patient preference could increase screening rates.
- It was not always clear to practice staff, especially physicians, that participating in the intervention included agreeing to attend the academic detailing sessions (with the embedded focus group component) and to complete the survey of CRC beliefs and behaviors. For the full intervention, we reminded the practices and their physicians of this agreement before distributing the surveys and conducting the academic detailing sessions. This reminder helped alleviate the issue, but we still were not able to have all practice staff attend the academic detailing sessions.
- It was not clear to all practice staff that they needed to complete the survey before the academic detailing session. (We wanted to avoid having them answer questions about CRC screening after they had been detailed about prevailing recommended guidelines, thus confounding the results of the baseline [preintervention] survey). For the full intervention, we emphasized that surveys had to be completed before the detailing

session and that completed surveys would be collected at the beginning of the session. We also allowed a short time at the beginning of the session prior to providing information regarding current guidelines for any practice staff without a completed survey to complete one.

Step 3: Identify Eligible Patients

Description

Identifying eligible patients ideally involves two components: (1) conducting electronic record reviews, and (2) reviewing returned SEA forms to identify additional ineligibles and opt-outs. This latter step is optional, but we recommend doing it, if possible, as it helps ensure that the central entity is only targeting patients who are truly eligible and not ineligibles who might become frustrated or annoyed by receiving screening materials.

Reviews of electronic records (claims, billing, and medical records) are conducted at several points during the intervention. An initial review is conducted to identify patients of participating practices who appear to be eligible for receiving intervention material. Eligibility criteria are:

- Being ages 50 through 79,
- Being a current patient of the practice (having had at least one visit to the practice within the previous 2 years),
- Being of average risk for colorectal cancer (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, and
- Not being up to date in CRC screening according to guidelines (not having had a colonoscopy within the previous 10 years, a flexible sigmoidoscopy or double contrast barium enema within the previous 5 years, or a fecal occult blood test (FOBT), FIT, or similar stool test within the previous year).

Patients deemed ineligible after the initial record review are excluded from receiving the intervention and do not receive any of the patient mailings. At this time, an SEA form could be mailed to patients to further clean the data of ineligibles and patients who do not want to receive any more screening information. Patients deemed eligible after this initial review are entered into a master patient database used to track:

- Patient response to the intervention,
- Screening results for those subsequently choosing to be screened,
- Patient notification of screening results, and
- Followup to screenings.

In addition, the master patient database can be used to store eligibility information from the SEA. It also can include demographic information about each patient gleaned from medical records and responses to the SEA form (described in greater detail below under mailing intervention material to patients). In addition, the master patient database can include information about the primary care practice with which a patient is affiliated.

Followup electronic reviews are conducted prior to various subsequent steps in the intervention that require identifying patient response to the intervention material or results of screenings. We describe these in more detail below under tracking patient response and screening results.

Our Experience

We identified patients in intervention and control practices as being potentially eligible for average-risk CRC screening (and hence eligible for the intervention) by an initial electronic record review using expanded eligibility criteria. These criteria excluded patients insured through one of the Blue Cross Blue Shield products conducting a CRC screening program of their own. Patients deemed eligible by record review were then entered into a master patient database and were tracked through the various stages of the intervention screening process, including tracking responses to the SEA mailing.

As previously described, we collected the required electronic data for the record review from LVPHO, MATLV, LVPG, and LVHN. The electronic data systems included:

- Claims submitted for payment to LVPHO by providers at participating practices for health care provided to patients insured through an LVPHO insurance product.
- Bills for health care provided at participating practices to patients insured through any private insurance product (LVPHO or non-LVPHO), any public program (Medicare or Medicaid), or self-insured (self-pay); and patient electronic medical records at practices with EMR systems accessible to project staff. Acting in a HIPAA-compliant manner,[vi] LVHN study personnel merged each entity's data to develop a central database for this study. This database contained information on all participating practice patients identified as potentially eligible for the intervention.

Prior to the reminder mailing (mailing 3) and at several other points during the intervention period, we conducted electronic record reviews to assess evidence of CRC screening. We also conducted several additional reviews in conjunction with the intervention assessment to identify patients who were screened or had a followup test performed.

Lessons Learned

During both the pilot and full intervention, we learned several key factors that affect the ability to conduct electronic record reviews successfully. These factors include the following:

- We received OMB clearance close to the end of calendar year 2008, which affected the timing of our intervention. We had to delay data extraction until the source data systems could update and stabilize in response to end-of-year open enrollment-associated changes in patient insurance selection and provider/practice changes resulting from insurance plan switching. Scheduling record reviews during or in the weeks following open enrollment periods is not a good idea because records are not up to date and data systems and personnel have other priorities.

[vi] Medical practices must comply with the provisions of the Health Insurance Portability and Accountability Act regarding patient records.

- Staff responsible for managing and extracting data from the source data systems did not always have the necessary experience or expertise to easily produce the lists of patients eligible for the intervention. In addition, these systems were not always set up to produce such lists or to provide the kinds of data we needed (e.g., identifying which primary care practice a patient was affiliated with or finding evidence of prior CRC screening in the records) and required special programming. We needed to learn how to (1) accommodate competing demands on electronic data systems and data management and programming staff, (2) supplement existing report generation programs with revised programs that met the requirements of the data extraction, (3) respond to HIPAA concerns of data management staff who had not been part of early decisionmaking and HIPAA reviews, and (4) accommodate and overcome missing data and data ambiguities, especially in electronic medical records. We did not experience these problems to this extent with the pilot site. These lessons learned were not unique to this study. Other recent studies (Roth, et al., 2009; West, et al., 2009) note that obtaining information from electronic health records is complicated and difficult. In particular to colorectal cancer, Roth, et al. (2009) found that quality indicator data are especially problematic.
- Even after we received source data for the record review, data cleaning required a significant amount of additional manual effort (i.e., more time and internal resources than originally anticipated). For example, the format of patient names received from some of the source systems was not compatible with producing mailing labels, requiring us to manually reformat the names. All of these issues caused further delay to the start of our intervention. In response to these unanticipated delays, we decided to stagger the start of the intervention. We sent an initial wave of mailings to patients of practices for which data cleaning and formatting issues were resolved and waited to send a second wave of mailings to patients of the remaining practices for which data problems remained. We describe this situation in greater detail in the following section.

Step 4: Mail Screening Information and Materials

Description

This step consists of several mailings to patients:

1. Screening Eligibility Assessment (SEA) brief survey form.
2. Invitation to be screened.
3. Followup reminder.
4. Optional second reminder.

If the intervention is to be implemented in a community that has a significant population who speaks a non-English language, we highly recommend that all mailed material be sent in both English and the other language.

All patients in the intervention practices who are identified as being potentially eligible by the initial electronic record review are sent a first mailing consisting of a letter from the primary care practice with which they are affiliated. This mailing explains the importance of CRC screening, informs them of the practice's participation in a screening program, and requests that they complete the enclosed form (the SEA form). The SEA form asks patients to indicate

whether they consider themselves to be ineligible for the intervention (i.e., self-identify as ineligible by checking one or more listed reasons that would make them ineligible). It also asks them to provide additional demographic information about themselves 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 use 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). There is also a telephone number provided (that goes to the central entity) for opting out of the screening program if a patient does not want to respond by the SEA form.

As previously noted, use of the SEA form is optional, although 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. This step is included to help compensate for the current state of most electronic records. The information contained in them that is required to determine eligibility is often outdated, incomplete, inaccurate, or missing.

The SEA form gives patients an opportunity to self-identify 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. Such information can also be used by practices to initiate a conversation with patients who identify themselves as ineligible due to above-average risk to be more diligent about receiving CRC testing than 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 this entity may decide that the cost and effort involved in mailing and processing the SEA form outweighs the benefit gained since it can be a time-intensive effort. We recommend against this but leave it up to the central entity adopting the intervention.

A secondary intent of the SEA form is to collect demographic data not otherwise available. The central entity can use this information to assess screening response rate and results by demographic group and plan subsequent educational or outreach programs targeted specifically to appropriate groups. Again, if the central entity does not want to include this function in the intervention, it can omit the step.

All patients deemed to still be eligible following the SEA mailing are sent an invitation to be screened. If the central entity omits the SEA mailing, the invitation becomes the first rather than the second mailing.

The invitation mailing consists of:

- A letter from the patient's primary care practice inviting the patient to be screened,
- 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),
- A list of colonoscopy providers to whom practice clinicians refer,
- Either a stool test kit or a request card that the patient can mail back to request a kit, and
- A self-addressed stamped envelope for returning either the kit or the card.

If the invitation mailing is the first mailing (i.e., the SEA mailing was omitted), the invitation letter also provides the introduction to the screening program from the initial letter accompanying the SEA form. The invitation letter is also tailored to whether a stool test kit or a request for a kit is enclosed.

If the central entity conducting the intervention is using stool test kit request cards for all or some of the patients in the screening program, it periodically mails kits to patients requesting them. It also updates its master patient database to indicate which patients have requested a kit.

In conjunction with tracking patient response to the screening invitation (described below), 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). The central entity can decide to stop after only one reminder or to send one or more subsequent reminders. This decision will be based on considerations of cost, expected increased response, and patient reaction.

Our Experience

All material sent to patients was bilingual, in English and Spanish. Approximately 11 percent of the population of the Lehigh Valley is Hispanic or Latino, many of whom speak Spanish as their primary language. We felt it was important to provide written material in a language they would be more comfortable with than English. Further, 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, et al., 2008; Nguyen, et al., 2010).

Mailing 1: Screening Eligibility Assessment

We sent an introductory mailing to all patients in the intervention practices who were identified as being potentially eligible by the electronic record review. This mailing contained a letter from their primary care practice regarding the importance of CRC screening and an SEA form. This form asked them to verify their eligibility and to provide additional demographic information about themselves not otherwise ascertainable through the available electronic records.

We did not send this mailing to patients in the control practices. Receiving information and recommendations for CRC screening from a health care provider has been found to be a predictor of screening. Thus, we considered this mailing to be a component of the intervention

and did not want to expose members of the control group to it lest it stimulate a portion of them to be screened and thus confound the intervention assessment.

The SEA form provided an opportunity for patients to self-identify as ineligible and indicate a reason for their ineligibility. We coded such patients as ineligible in our master patient database and included their reason. The SEA form also provided a mechanism for patients to inform us that they did not want to receive any further information about CRC screening, which we considered to be an indication of their desire to opt out of the intervention. We coded them as opt-outs in the master patient database. We did not require patients to opt in because this is a population-based public health intervention designed to reach out to the eligible unscreened population. We included in the intervention all patients who did not return an SEA form, as we had no indication from them that they were either ineligible or wanted to opt out.

We initially planned to postpone the first intervention mailing until the completion of the initial electronic record review for all participating practices even though we were experiencing delays in obtaining and cleaning source data. We were able to resolve these issues for 8 of the 15 intervention practices by the end of April but continued to experience problems with the remaining 7 practices. At that point, we decided to conduct the mailings in two successive waves. Wave 1 consisted of the eight practices for which the electronic record review was complete; Wave 2—mailed several weeks later[vii]—consisted of the remaining seven practices.

Mailing 2: Invitation To Be Screened

We sent the invitation to be screened to all patients who did not opt out or indicate they were ineligible for the intervention through the SEA form, or who did not have their first mailing returned as undeliverable. As noted, due to financial constraints on the clinical laboratory supplying stool test kits for this study and the lower than expected return-for-processing rate for kits mailed in the intervention pilot, we modified our protocol for this mailing. Instead of mailing kits to all recipients as we did for the pilot, we required recipients to return a card—enclosed with the mailing—requesting a kit.

We wanted to test the effect of the change in protocol and thus devised a small substudy embedded within the main study. This substudy allowed us to estimate the relative effectiveness of two different methods of providing stool test kits to patients (enclosed with the invitation vs. sent in response to a request). We sought and received agreement from the lab to supply up to 550 kits for direct mailing to a subset of patients. We selected the two largest practices in Wave 2 for this substudy (N = 2,036 and 373 eligible patients, respectively). We separately randomly selected a proportional subset of each practice's patients to be sent the stool kit rather than the card (totaling 500 patients across the two practices). By restricting this substudy to only two practices and then separately randomizing patients, we were able to estimate the effect of the two versions of the protocol controlling for the effect of practice setting.

[vii] The Wave 2 mailing was subsequently further delayed in the LVHN mailroom due to temporarily misplacing it prior to actually putting it into the Postal Service mail.

We used two versions of the letter from the practices for this substudy. The letter for those patients receiving the request card protocol explained the procedure to follow for mailing back the card to request a kit. The letter for those patients receiving the kit directly explained the procedure for using and returning the kit to their physician's practice. To avoid confusion among patients, we sent all patients of these practices who shared a common address (i.e., patients within the same household) the same version of the invitation mailing. Thus, if one eligible patient member of a household was randomly selected to receive the stool test kit directly, then all eligible patient members of that household received that version of the mailing. This procedure increased the number of patients receiving the kit directly to 540. Our assessment of the intervention now includes a comparison of screening rates for the two different protocols for distributing stool test kits within the two selected intervention practices.

We sent this second mailing in two waves to match the waves of the first mailing in order to give all recipients adequate time to complete and return the SEA form before we prepared mailing lists for the second mailing. Wave 1, completed during mid-July, consisted of patients sent a stool test kit request card. We split Wave 2 between those receiving the stool test kit request card (Wave 2a, sent in early August) and those receiving the stool test kit directly (Wave 2b, sent at the end of July).

Mailing 3: First Reminder Mailing

After we conducted an electronic record review to assess evidence of screening, patients with no evidence of screening were sent a reminder letter by study personnel on behalf of the patient's practice. Our goal was to further stimulate and encourage patient screening (Hudson, et al., 2007). Mailing three was completed at the end of August.

Mailing 4: Second Reminder Mailing

We considered sending a second reminder mailing (fourth mailing) to further encourage and increase CRC screening; however, we decided not to do so in response to requests from several practices who had received complaints from patients about study contact. The practices informed us that patients complained about receiving mailings for screenings that they either did not want or did not need. Apparently, the data in the electronic records were more incomplete or faulty than we had anticipated and did not adequately identify ineligible patients.

Our protocol specified that we would send intervention material to all patients not opting out who otherwise appeared to be eligible; thus, we inadvertently sent material to some ineligible patients who did not return their SEA forms notifying us of their ineligibility. Similarly, although we provided an opportunity and a means for patients to opt out, many who did not want to participate apparently did not inform us of their desire to opt out. Given that we did not want to alienate either the practices or their patients, we decided to cancel the second reminder.

We believe this issue could have been minimized had the electronic records contained more accurate information. A recent study by Schneider, et al. (2008) found that administrative data often underestimate receipt of CRC screening.

Lessons Learned

We learned several key lessons from the patient mailings, including the following:

- The patient mailings were time and labor intensive. For the full intervention, we anticipated this situation and extended mailing timelines and assigned additional staff to accommodate requirements for printing, assembling, and mailing all the materials. Even taking this into account, we experienced delays in sending out the mailing materials. Part of this problem was based on the time required to ensure that each letter uniquely identified a specific patient, which then was matched to the mailing label. Depending on the size of the patient population and the staff resources available from the central entity, we recommend 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.
- Patients do not always return requested information (e.g., SEA form) in a timely manner. For the full intervention, we revised the patient mailing letters so that they more explicitly requested that patients complete and return the SEA form within a specific time period. We also allowed more time for receiving completed forms.
- The SEA form was very useful for identifying patients who were not eligible and who did not want to participate. Some patients used the SEA form to "vocalize" their desire to not continue receiving any additional screening information. We believe that if they had not had this opt-out modality, then the practices would have received more phone calls from frustrated patients.
- Patients can complete an SEA form indicating they are ineligible or want to opt out and then choose to get screened. It is important to consider whether you want to consider such patients to be eligible and whether you want to consider their screens as "successes," as this affects your tracking records and methods.

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), reviews reports received from the clinical lab processing stool test kits for evidence of screening and results, and updates its master patient database accordingly. Results from this tracking are used for sending 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. They can track screening either through the screening tracking spreadsheet provided to them at the academic detailing sessions or through internal tracking mechanisms they already have in place. They then periodically generate reports that the central entity can use to update the master patient database. Second, especially for practices without electronic medical records, central entity staff may request access to select patient charts in order to conduct audits looking for evidence of screening and possible needed followup. Such chart

audits would only be performed when electronic evidence of screening and followup is inconclusive and only if they would not violate HIPAA requirements.

Our Experience

Using the electronic data systems, we tracked evidence of screening and followup at several intervals during the study. This allowed us to monitor both the number of patients being screened and the methods by which they were being screened. We updated the master patient database with tracking information as we received it.

We tried to collect screening tracking spreadsheets and internal tracking mechanisms from each practice; however, we found that the practices did not use the screening tracking sheet and they were not able to share their own internal tracking mechanisms. Therefore, we were not able to use this information for tracking patients.

We did conduct chart audits on a sample of charts from the intervention and control practices. The protocol we used for the chart audits follows:

- For intervention practices:
    - In practices with approximately 50 or fewer patients included in the study (where we could only access limited electronic data for identifying intervention-eligible patients), we conducted chart audits for all patients included in the study.
    - In the remaining practices, each with substantially more than 50 intervention-eligible patients included in the study, we set a target of auditing a 6 percent sample of study patient charts. To facilitate reaching this target within each of these practices, we drew a 12 percent random sample of their study patient charts. Starting at the top of each randomized list, we conducted audits of available usable charts until we reached a quota of approximately 6 percent for each practice (upwardly rounded to the next whole number; e.g., 6% of 520 = 31.2, upwardly rounded to 32).
- For control practices:
    - In practices with approximately 50 or fewer patients included in the study (where we could only access limited electronic data for identifying intervention-eligible patients), we conducted chart audits for all patients included in the study.
    - In the remaining practices, each with substantially more than 50 intervention-eligible patients included in the study, we set a target of auditing an 8 percent sample of study patient charts. To facilitate reaching this target within each of these practices, we drew a 16 percent random sample of their study patient charts. Starting at the top of each randomized list, we conducted audits of available usable charts until we reached a quota of approximately 8 percent for each practice (upwardly rounded to the next whole number; e.g., 8% of 540 = 43.2, upwardly rounded to 44).

We used a higher target for control practices than for intervention practices to partly compensate for having less complete data for control practices.

Lessons Learned

We learned several valuable lessons regarding patient tracking, including the following:

- From the pilot, we learned that in addition to updating the master patient database with information related to eligibility for the intervention and each of the various mailings, patient response, and screening results and followup, it would be useful to track patients through the flow of intervention steps. In addition, information to support the tracking of patients was not always available through the source data systems we were using. For the full intervention, we developed an intervention flowchart for internal tracking purposes that accounted for each patient being passed from one intervention step to the next. We also developed a Screening Tracking Sheet for use by practices without an existing internal tracking system. However, we experienced difficulties using these tools. The intervention flowchart was not always compatible with the electronic data systems and therefore the information available in our master patient database, so it was difficult to populate this flow chart. As noted, we also found that practices did not use the Screening Tracking Sheet. We sent the Screening Tracking Sheet to the office manager of each practice. We feel that it may also be helpful to have a clinical "champion" at each practice to help ensure that clinical tracking tools are used.
- During the pilot, we learned that the lab did not have an established process to review its electronic records for evidence of screening. For the full intervention, we requested that the lab establish such a process. The lab used this process for the full intervention without any problems.
- We learned that it was time and labor intensive to code and capture SEA results for the master patient database. For the full intervention, we developed a codebook and coding instructions for the SEA data and created an electronic database for them that could be subsequently merged into the master patient database. This data coding and tracking was still time consuming. In the future, we recommend exploring the use of a scannable SEA form. This will help minimize manual data entry and increase the speed, and perhaps accuracy, of the data entry.
- We also learned that it can be very difficult to determine from the electronic records whether a complete diagnostic evaluation (CDE) was performed on patients with positive stool tests. In fact, we had to manually review the charts of nearly all patients with positive stool tests to uncover evidence of CDE. Colonoscopy can be performed as either a screening test or as diagnostic followup for an abnormal finding from a stool test or other screening procedure. But in many cases, a screening colonoscopy and a diagnostic colonoscopy were not easily distinguishable in the electronic record. This ambiguity required a manual review of the record and chart notes to resolve. When even a manual review of the patient record could not provide unambiguous resolution, we assumed that if a patient had both a stool test and a colonoscopy during the intervention observation period, the colonoscopy would be a CDE rather than a screen.

Step 6: Provide Feedback to Practices

Description

The central entity notifies participating practices of normal (negative) and positive (abnormal) stool test screenings and coaches them on notifying patients about screening results and how to follow up on them. The central entity also provides a form to practices for tracking and documenting followup CDEs for patients with positive stool test results.

Practices are expected to respond to a negative stool test by notifying the patient and informing the patient that the guidelines recommend that they be rescreened every 12 months. Practices are expected to respond to a positive stool test by recommending a CDE for the patient. 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) advice to patients to have a CDE and what type of modality was recommended, (2) date the CDE was scheduled and completed, and (3) results of the CDE as well as any additional comments. This information can then become part of the patient's record.

Our Experience

We sent the appropriate feedback forms to the practices at several interim points during the assessment period of the study. We did this on an ongoing basis, based on when new screening results were uncovered:

1. We sent the stool test positive form to each practice that had patients with a positive stool test result. The form reminded the practice that these patients should have a followup test and what types of tests were recommended.
2. We sent the stool test negative form to each practice that had patients with a negative stool test result. The form reminded the practice that these patients should be notified of their negative result and that they should be screened again in 1 year.
3. We sent the CDE feedback form to practices with patients who had a positive stool test result (along with form 1). This form was a tracking tool, where clinicians could track the appropriate followup steps. The CDE feedback form asked that the clinician return the completed form to the study. However, we did not receive any completed forms. We contacted the practice manager at several points regarding collecting the CDE feedback forms without success.

Lessons Learned

It was difficult to get clinicians to complete and return the CDE feedback form. As noted, we recommend that 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.

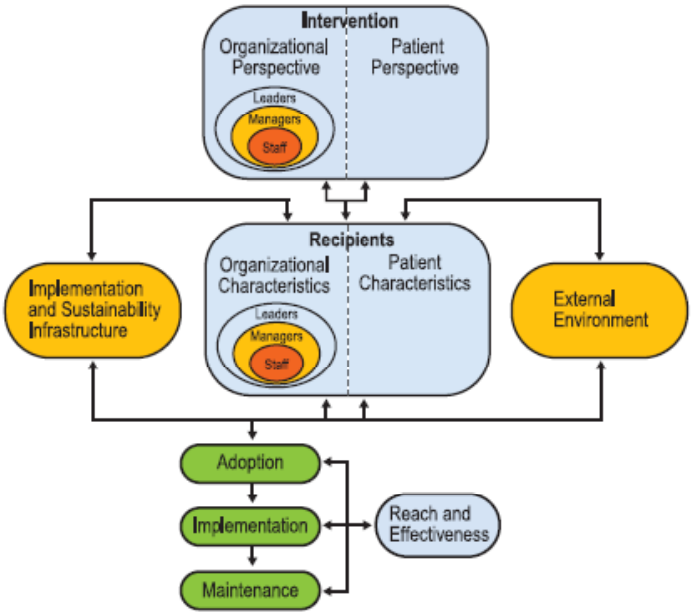
3. Assessment Plan and Methodology

We selected the Practical, Robust Implementation and Sustainability Model (PRISM) (Feldstein and Glasgow, et al., 2008) as a framework to guide our evaluation. This framework highlights factors that affect the outcome of an intervention or program (context domain elements) and incorporates measures of success (outcome domain elements). The framework can be used to guide the design and development of programs or interventions as well as to assess their implementation and outcome.

PRISM Model

When used as a guide to development, the PRISM framework identifies design elements and internal and external considerations that should be addressed and provides a set of questions to help developers address them. When using the framework as a guide to assess performance and outcome, evaluators can use the same elements and considerations to ascertain how they affected performance. Evaluators can also use the incorporated RE-AIM outcome measures of Reach, Effectiveness, Adoption, Implementation, and Maintenance (Glasgow, et al., 1999) to gauge the program's or intervention's impact. Figure 3.1, from Feldstein and Glasgow (2008), illustrates the various elements of PRISM and their interrelationships.

Figure 3.1. Elements of the PRISM Model



Source: Feldstein and Glasgow, 2008.

The context domain of the PRISM model consists of four elements: intervention, external environment, implementation and sustainability infrastructure, and recipients. The Intervention element includes the nature and design of the intervention from the perspective both of the organization in which it is delivered or implemented and of the patient receiving it. From the organization's perspective, PRISM suggests the organization consider such factors as the degree of readiness the intervention requires, the usability and adaptability of the intervention to

organizational conditions, and the burden the intervention places on the organization. From the patient's perspective, factors to consider include the patient centeredness of the intervention, the degree to which the intervention provides choices and addresses access and other barriers, and the burden (complexity and cost) the intervention places on the patient.

Considerations under External Environment include market forces and conditions, prevailing health care regulations and policies, and community resources. Implementation and Sustainability Infrastructure refers to such factors as having a dedicated implementation and sustainability team, training and support for implementers and adopters, and a flexible implementation and sustainability plan.

Like Intervention, the Recipient element has an organizational and a patient component. The organizational component refers to characteristics of an organization that may affect its ability to successfully deliver or implement the intervention. It includes such factors as organizational culture, clinical leadership, data and decision support, and systems of care. The patient component refers to characteristics of patients that may affect the intervention's ability to be successful with them. It includes such factors as demographics (especially age and gender), socioeconomics (especially education and insurance status), health status, and health knowledge and beliefs.

Each of the four context domain elements affect the intervention's performance, which is evaluated within PRISM's outcome domain consisting of the five RE-AIM elements (Reach, Effectiveness, Adoption, Implementation, and Maintenance). As shown in Figure 3.1, the context domain affects the latter three elements, which in turn affect the former two. Taken together, these five elements "represent the overall public health impact of a program or policy" (Belza, et al.).

Adoption refers to the participation rate among potential settings and "intervention agents" for implementing or delivering an intervention and the representativeness of those settings and agents. A key concern for adoption is whether the intervention can be adopted by a wide range of settings or whether only those with certain characteristics (such as strong financial resources or a functioning electronic medical record) adopt it. Implementation refers to both the fidelity of implementation (the degree to which the implemented intervention matches the intended intervention) and the consistency of implementation across settings and agents. Maintenance applies both to intervention settings (the extent to which an intervention becomes institutionalized into the settings' routine) and to intervention recipients (the long-term effects of the intervention on those exposed to it in terms of intended outcomes and quality of life).

Reach refers to the participation rate among potential or targeted recipients of the intervention and the representativeness of those who participate. Like Adoption, a key concern for Reach is whether all segments across a wide range of targeted participants will actually participate in an intervention or whether only those with certain kinds of characteristics (such as financial resources) will participate. Finally, Effectiveness refers to an intervention's outcome—its ability to achieve its intended (positive) impact without additionally causing (negative) unintended effects or adverse consequences.

Assessment Design

We assessed the PRISM context domain as it relates to our implementation of the SATIS-PHI/CRC intervention by gathering information about:

1. Perspectives of participating practices and patients regarding the intervention.
2. Prevailing conditions and events occurring in the external environment that could affect the implementation or outcome of the intervention.
3. Relevant infrastructure at the intervention's central entity (LVPHO and EPICNet) and at participating primary care practices to carry out and sustain the implementation.
4. Characteristics of participating practices and of the intervention patient population that also could affect the intervention's implementation or outcome.

We took a descriptive and often qualitative approach to assessing the context domain, seeking to understand the various contextual elements and how they likely affected implementation and outcome.

We assessed the PRISM outcome domain for SATIS-PHI/CRC—its overall public health impact—through a mixture of the same descriptive approach as above for Adoption, Implementation, and Maintenance. We took a more quantitative quasi-experimental approach for Reach and Effectiveness. This method is in keeping with the requirement stated in our task order contract directing us to use (1) quasi-experimental methods to evaluate the intervention's impact comparing pre- and postintervention measures at intervention and comparison (control) practice sites and (2) qualitative methods to evaluate the implementation process.

We conducted a quasi-experimental evaluation of the SATIS-PHI/CRC intervention with patients of 20 primary care practices assigned to either of two intervention arms or to the control arm. Assignment was by a mixture of cluster allocation of practices to either the intervention (15 practices) or control (5 practices) arm and subsequent randomization of patients within two selected intervention practices to the two intervention arms: receive a mailing with a card to be mailed back to request a stool test kit or receive a mailing with the kit enclosed.

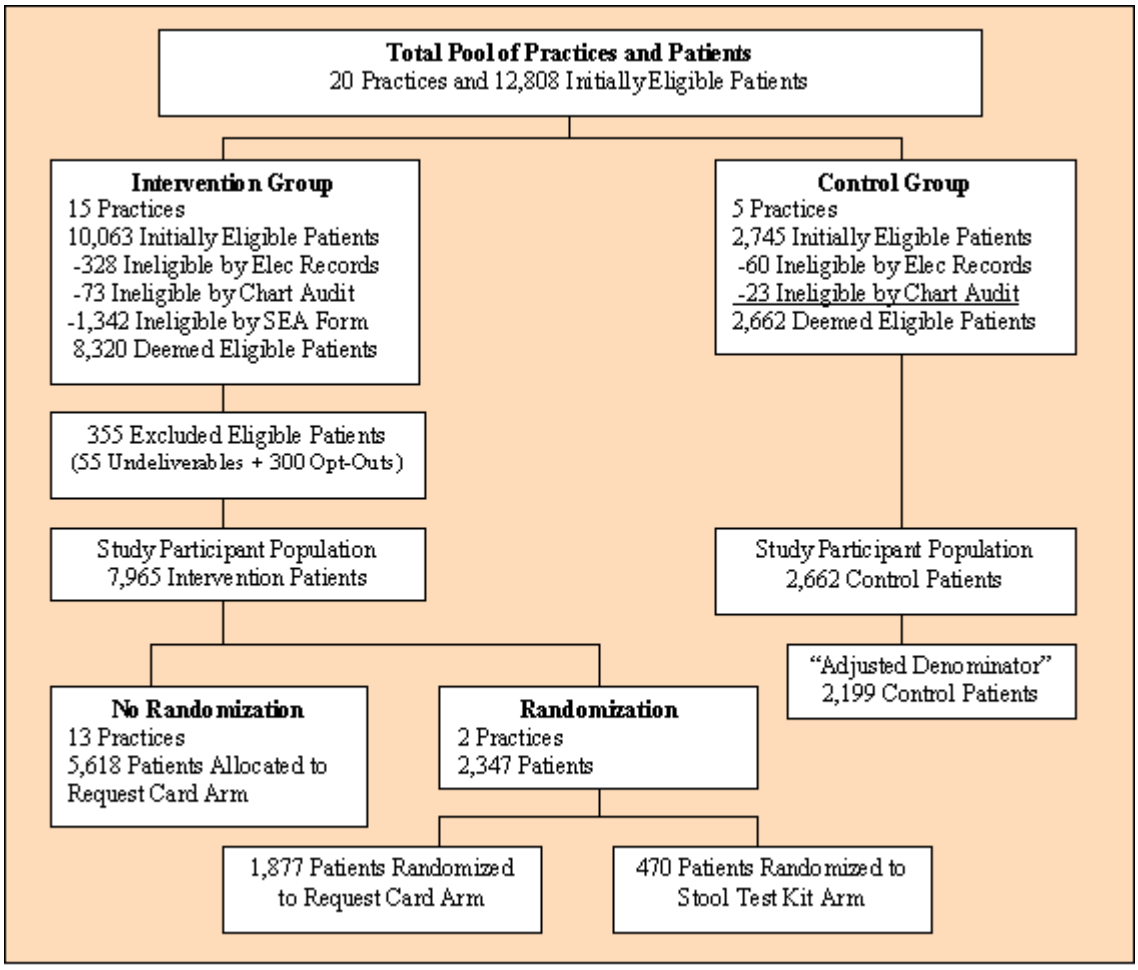
We initially recruited 26 practices: one to serve as a pilot site[viii] and the remaining 25 to be assigned to either the intervention or control arm. We assigned 20 practices to the intervention arm and 5 to the control arm; however, 5 intervention practices dropped out after assignment but before the start of the intervention, reducing the number of intervention practices to 15. We discuss this loss of intervention practices further below under Adoption.

Figure 3.2 presents the cluster allocation and randomization process, along with the number of practices and patients at each step in the process. We had more information for intervention patients (from the SEA form, undeliverable addresses, and opt-outs) than we did for control patients. To compensate, we "adjusted" the number of control patients to use as the denominator

[viii] The pilot was solely used to gain experience with the intervention and to identify weaknesses in our implementation plan that could be addressed before the full intervention. We reported our experience, lessons learned, and findings in our Preliminary Report of Findings, submitted to AHRQ in September 2009.

of screening rates when comparing intervention and control groups for several outcome evaluation analyses. This adjustment removed a proportional number of control patients as intervention patients excluded by this additional information.

Figure 3.2. Flow of Participating Practices and Patients Through the SATIS-PHI/CRC Intervention Study



To be included in the intervention evaluation study, practices and patients had to meet the inclusion/exclusion criteria discussed below.

Practice Eligibility Criteria

To be eligible to participate in the study, practices had to be:

1. Affiliated with the LVPHO and a member of EPICNet,
2. A primary care practice that treated adults of both genders (family or general internal medicine, but not pediatrics or obstetrics), and
3. Located in either Lehigh County or Northampton County, Pennsylvania.

A total of 111 practices met these criteria.

In addition, all of the clinicians at a given practice had to consent to participate for that practice to be eligible for inclusion. This criterion was necessary because we could not uniquely associate patients of a practice with the specific clinicians who were their primary providers. Since the intervention called for mailing material to a practice's patients on behalf of their providers as part of their health care, and we wanted to ensure that their providers consented and gave us permission, all of the practice's clinicians had to consent.

We further purposively recruited practices to ensure an adequate mix by:

- Affiliation (LVHN residency clinic, LVPG practice, MATLV practice, or unaffiliated independent practice),
- Size (three or fewer clinicians or more than three clinicians),
- Specialty (family practice or general internal medicine),
- Location (urban, suburban, or rural), and
- Presence or absence of an electronic medical record (EMR) system.

Patient Eligibility Criteria

We identified initially eligible patients by reviewing electronic claims records of patients insured through the LVPHO and electronic billing records and EMR information available from participating practices. To be initially eligible to participate in the study, patients had to be:

1. Current patients of participating practices (had a visit to a participating practice within the 2 years immediately preceding the start of the intervention[ix]),
2. Age eligible (ages 50 through 79),
3. At average risk for developing CRC (not having had either a diagnosis of CRC or a personal or family history predisposing one to CRC),
4. Free from other complicating colorectal or gastrointestinal conditions (e.g., Crohn's disease or ulcerative colitis), and
5. Not up to date on CRC screening (not having had a CRC stool test within the past year, a flexible sigmoidoscopy or double contrast barium enema x ray in the past 5 years, or a colonoscopy within the past 10 years).[x]

In addition, since the intervention involved mailing materials to patients, they had to have a valid mailing address in at least one of the electronic data sources we reviewed. Finally, since a commercial Blue Cross plan serving the Lehigh Valley implemented a CRC screening campaign for its covered patients, we excluded patients with this coverage from our pool of initially eligible patients. This exclusion avoided possible confounding of the SATIS-PHI/CRC intervention effect and the Blue Cross campaign effect.

[ix] We defined the start of the intervention for patients to be the mailing of the introductory letter and SEA form. If a patient had a visit to more than one participating practice in the previous 2 years, we associated that patient with the practice visited most recently.

[x] We based the age, average risk, complicating condition, and screening history criteria on recent CRC screening guidelines (U.S. Preventive Services Task Force, 2008; Levin, et al., 2008).

We subsequently deemed initially eligible patients to be ineligible if:

1. We discovered evidence from subsequent electronic record reviews or chart audits that patients did not meet eligibility criteria,
2. Intervention patients responding to the SEA form indicated they were not eligible, or
3. The SEA form was undeliverable.

Finally, we excluded eligible intervention group patients if they exercised the opt-out option on the SEA form or the invitation to be screened mailing was undeliverable.

Data Sources

We used six types of data to conduct the intervention assessment: electronic records, Health Network Laboratories (HNL) stool test reports, chart audits, the SEA form, a survey of participating practices, and focus groups and informal interviews. Data from several of these sources are integral to the actual implementation of the SATIS-PHI intervention and we used them for the implementation as well as for the assessment. We describe here how we used them for the assessment (Section 2 of this report describes how we used them for the implementation).

Electronic Records

We used electronic records to identify eligible patients and as one of three sources of data to track CRC screening and followup. Electronic records consisted of billing records, LVPHO claims, and EMRs. Since the PHO served as the central entity for the SATIS-PHI/CRC intervention, we had access to claims data for all 20 participating practices. This data source provided information on health care received by covered patients regardless of who the provider was (i.e., the care or service did not have to be provided by a participating practice to be included). However, the LVPHO insurance plans only cover a small proportion of Lehigh Valley patients and are employer-based plans.

To gain access to a wider range of patients for this intervention and its assessment, including Medicare and Medicaid patients and self-pay/uninsured patients, we supplemented PHO claims data with the two other electronic record sources. EMR data provided the most complete and clinically rich data but not all participating practices had EMR systems. Of those that did have them, there were several we were not able to access. If EMR data were not available to us, we used billing data. Billing data are the least informative source of electronic data. We could use billing data to identify potentially eligible patients but they were not useful for tracking screening and followup because the primary care practices did not bill for the CRC tests and diagnostic procedures we tracked.

Table 3.1 presents the electronic data sources we were able to access and use for each of the practices participating in the intervention study and the number of PHO insured and other patients from each practice included in the study. Practices are identified with three-character codes. The first character identifies whether the practice is in the control (C) or an intervention (I) arm of the study. The second character identifies the affiliation of the practice (A for independent practices receiving practice business services from LVHN, H for LVPG practices,

M for MATLV practices, S for unaffiliated independent practices, and U for LVHN hospital clinics). The third character identifies the order in which we recruited the practice. Discontinuities in third characters (e.g., IHA to IHD) indicate where initially recruited practices subsequently dropped out of the study after assignment to study arm.

Three control practices (CHA, CHB, and CUA) and seven intervention practices (IHA, IHE, IHF, IHH, IHI, IUA, and IUB) have the most complete data as we were able to use both PHO claims and EMR data for them. For the two remaining control practices (CMA and CSA) and five of the remaining eight intervention practices (IMB, IMD, ISB, ISC, and ISD), we were only able to use claims data. Thus, we were only able to include PHO patients from those practices in the study. The remaining three intervention practices (IAA, IHD, and ISA) have the least complete data as we were only able to use their claims and billing records.

As we describe below, we used clinical laboratory reports of stool tests from HNL to track stool test screenings from all practices; thus, incomplete electronic record data from some of the practices is not problematic for stool tests. However, it is problematic for both colonoscopy screens and diagnostic followups. Therefore, we omit practices IAA, IHD, and ISA, which have the most incomplete colonoscopy data, from analyses of colonoscopy intervention effects.

Table 3.1 also illustrates the difficulty we experienced identifying patient eligibility. After using the available electronic records to identify patients with visits to participating practices within the previous 2 years, we sorted the records by age to identify those who were age eligible. All of the electronic data sources were useful for these two initial sorts. However, identifying eligibility status for the average risk, complicating condition, and screening history criteria was more problematic, especially when EMR data were not available. We also could not identify PHO insurance status for practice ISA; we only know that we included both PHO-insured and other patients from that practice in the study.

Once we established current patient status and age eligibility, we considered patients to be eligible unless we found disqualifying evidence for them. Thus, inability to identify patients who should have been disqualified as ineligible is a greater problem than declaring eligible patients to be ineligible based on the available electronic records data. This problem causes the denominators for our screening rates to be overestimated, resulting in rates being underestimated. Since this condition varies between practices based on available data sources, we include data source as a statistical control variable in various outcome analyses.

Table 3.1. Electronic Data Sources Used and Patients Included in the SATIS-PHI/CRC Study, by Participating Practice

Practice ID	Electronic Data Sources			Patients Included in Study		
	EMR	PHO Claims	Billing	PHO	Non-PHO	All
Control Practices						
CHA	✓	✓		1	747	748
CHB	✓	✓		17	881	898
CMA		✓		51	0	51
CSA		✓		35	0	35
CUA	✓	✓		0	930	930
Intervention Practices						
IAA		✓	✓	24	1,981	2,005
IHA	✓	✓		9	424	433
IHD		✓	✓	9	505	514
IHE	✓	✓		71	1,149	1,220
IHF	✓	✓		17	346	363
IHH	✓	✓		14	1,008	1,022
IHI	✓	✓		50	446	496
IMB		✓		48	0	48
IMD		✓		19	0	19
ISA		✓	✓	Yes	Yes	342
ISB		✓		55	0	55
ISC		✓		5	0	5
ISD		✓		27	0	27
IUA	✓	✓		31	1,087	1,118
IUB	✓	✓		1	297	298

HNL Stool Test Reports

As part of the study's agreement and protocol with Health Network Laboratories, the lab would not only serve as the supplier and processor of FIT tests, but would also provide test results to LVPHO study personnel and to the test ordering clinician.[xi] LVPHO study personnel would then record the test and results in the deidentified master patient database for analysis.

[xi] Patient instructions accompanying the FIT stool test kit directed patients to return the competed kit to their primary care physician's practice, which would then write an order from the patient's physician to the lab to process the kit. HNL then reported the test result to the ordering clinician and periodically sent study personnel affiliated with LVPHO a list of patients tested and their results. HNL also provided information to study personnel on patients of control practices.

Chart Audits

For tracking the screening of study-eligible patients, as well as further determining eligibility, we supplemented information gained from electronic record reviews and HLN with chart audits for a sample of patients (the toolkit accompanying this report includes the chart audit form). This was a labor-intensive data collection requiring us to actively read charts for evidence of screening or eligibility. We followed a chart audit protocol developed by the study team in conducting the audits.

Study staff at LVPHO arranged to access a sample of charts of study patients from intervention and control practices. Some of these charts were electronic (from one of the several EMR systems used by practices participating in the study) and others were on paper. Regardless of medium, study staff read the relevant portions of the charts looking for evidence either of ineligibility or screening and followup.

Within the study's resource limits of time and money to devote to chart audits, we set a target of charts to audit for each practice (Table 3.2). As described above, we targeted a 100 percent sample for practices with close to 50 or fewer study patients (resulting from only being able to access limited electronic data to identify potential eligibles). We targeted a 6 percent sample of study patients at all other intervention practices and an 8 percent sample of study patients at all other control practices.

We targeted a somewhat higher sampling percentage for control practices to help compensate for having less complete data for them from some other sources. To compensate for not being able to access a sampled chart due to unavailability during the time period allotted to chart audits, we drew samples double the target at practices not being sampled at 100 percent (e.g., 12 percent for intervention practices and 16 percent for control practices). We further decided that as long as we had drawn these extra charts, we would conduct audits somewhat above the set targets for at least some of the practices if they could be done within the study's time and funding limitations. Thus, we had some audit completion rates above 100 percent.

Table 3.2 presents the chart audit completion rates for intervention and control practices. With the exception of two intervention practices (IAA and IMB) and one control practice (CSA), all completion rates were above 90 percent, and those for nine practices exceeded 100 percent. We conducted 849 audits, of which 96 resulted in identifying seemingly eligible patients who were, in fact, not eligible. From the remaining audits, we identified 28 additional screened patients (23 intervention patients and 5 control patients) whose screening was not detected through the other two data sources.

Table 3.2. Chart Audit Completion Rate, by Intervention and Control Practice

Control Practices			
ID	**Targeted**	**Completed**	**Completion Rate (%)**
CHA	46	50	108.7
CHB	56	57	101.8
CMA	61	57	93.4
CSA	43	22	51.2
CUA	57	62	108.8
Intervention Practices			
ID	**Targeted**	**Completed**	**Completion Rate (%)**
IAA	119	47	39.5
IHA	27	35	129.6
IHD	30	30	100.0
IHE	76	83	109.2
IHF	23	27	117.4
IHH	62	62	100.0
IHI	33	38	115.2
IMB	55	42	76.4
IMD	23	21	91.3
1SA	22	22	100.0
ISB	56	55	98.2
ISC	5	8	160.0
ISD	30	29	96.7
IUA	69	73	105.8
IUB	24	29	120.8

SEA Form

The primary purpose of the Screening Eligibility Assessment (SEA) form was to be a source of data for determining patient eligibility (the toolkit accompanying this report includes the SEA form). Section A of the survey asked patients whether they considered themselves to be ineligible for the intervention study based on age, being up to date on CRC screening, having had a previous CRC diagnosis, or not being a patient of the practice. In addition to this primary purpose, we used the SEA form to gather supplementary information about patients (race, ethnicity, marital status, language spoken, education, and perceived health status) not consistently available from other sources. We also used the form to allow patients to opt out of the intervention study.

Table 3.3 presents the response rate to the mailed SEA form by participating intervention practice (the SEA form was not mailed to control practice patients). The overall response rate was 27.9 percent (2,810 responses out of 10,063 forms mailed). Although the central entity mailed the forms following the same protocol to all the practices, response rates nevertheless varied considerably among practices. Response rates ranged from a low of 21.4 percent, 21.8 percent, and 21.9 percent among patients of practice IAA, IUA, and IUB, respectively, to a high of 45.0 percent and 66.7 percent among patients of practice ISA and IMD, respectively. We were unable to account for this wide variation. Based on responses to the SEA form, we eliminated 1,342 patients as ineligible; an additional 300 opted out.

The SEA form also provided supplementary data for 1,131 eligible intervention practice patients out of a total of 7,965 such patients included in the study, or a response rate for eligible patients of 14.2 percent. This rate varied by practice from a low of 0.0 percent and 8.3 percent among patients of practices ISC and IAA, respectively, to a high of 22.9 percent and 52.6 percent among patients of practice IMB and IMD, respectively.

Table 3.3. SEA Form Response Rate, by Intervention Practice

Practice ID	Number Mailed	Responses Received	Response Rate (%)	Responses from Eligible	Number of Eligibles	Eligible Reponse Rate (%)
IAA	2,421	518	21.4	166	2,005	8.3
IHA	501	127	25.3	66	433	15.2
IHD	655	229	35.0	99	514	19.3
IHE	1,551	453	29.2	206	1,220	16.9
IHF	440	126	28.6	65	363	17.9
IHH	1,299	435	33.5	190	1,022	18.6
IHI	683	221	32.4	83	496	16.7
IMB	64	22	34.4	11	48	22.9
IMD	36	24	66.7	10	19	52.6
1SA	524	236	45.0	69	342	20.2
ISB	66	18	27.3	10	55	18.2
ISC	8	3	37.5	0	5	0.0
ISD	35	9	25.7	4	27	14.8
IUA	1333	291	21.8	117	1,118	10.5
IUB	447	98	21.9	35	298	11.7
Total	10,063	2,810	27.9	1,131	7,965	14.2

Survey of Practice Providers and Staff

We fielded a survey to all practice providers and staff (both clinical and nonclinical) at the intervention and control practices to ascertain prevailing beliefs and behaviors regarding CRC screening and followup. We conducted these surveys both pre- and postintervention for the intervention practices, and once in the control practices (the toolkit accompanying this report includes the survey form; we used the same form for the pre, post, and control surveys). We administered the preintervention practice survey of providers and staff in the intervention practices to gather data regarding the current CRC screening environment at each practice. We then administered the survey again postintervention to ascertain changes in behavior or attitudes resulting from the intervention.

In addition, we distributed the survey in the control practices late in the intervention period to gather comparison information similar to the baseline information gathered from intervention practices. All surveys were completely anonymous and were assigned a unique random ID by practice. Due to IRB restrictions and the anonymous nature of the survey, we were not able to link the pre and post responses by individual respondents.

To collect the preintervention information, we sent the practice survey to practice administrators for distribution to all clinical and nonclinical staff in the practice prior to the academic detailing sessions and focus groups at the intervention practices. We then collected all practice surveys prior to the start of the academic detailing session and focus groups. We hoped that by

distributing and collecting the survey prior to the academic detailing sessions and focus groups, we would minimize response bias (as this was a baseline assessment of current practices). To obtain the postintervention information, we sent the practice survey to the practice administrators prior to the final debrief session. We collected the completed surveys prior to the start of the debrief, when the postintervention focus groups were conducted.

For the control practices, we also distributed the practice surveys to the practice administrators and collected them prior to the start of the focus group. We did not conduct any debrief sessions with the control practices, as we plan to disseminate the toolkit and intervention materials to them at the conclusion of the study.

The content of the practice survey included the exact same questions for the preintervention, postintervention, and control data collections. The survey included the following topics:

1. What types of screening modalities do clinicians recommend?
2. What types of screening modalities do clinicians believe are effective?
3. What types of followup do clinicians recommend to positive screenings?
4. Who performs the various steps of the screening process within the practice?

Topics one through three were for clinicians and physicians only, while topic four was for physicians, other clinicians, and all other staff. The final section of the survey included demographic questions for all respondents.

The number of responses and response rates we received to the practice survey varied by practice and by the survey group (i.e., preintervention, postintervention, and control). Tables 3.4, 3.5, and 3.6 show the number of surveys distributed and received for the pre- and postintervention surveys and the number of surveys received for the control practice surveys. Overall, across the intervention practices for the preintervention survey, we received 205 completed surveys for a 71.9 percent response rate. For the postintervention survey, we received 135 completed surveys for a 47.4 percent response rate. For the control practices, we received 45 completed surveys. For the postintervention and control practice surveys, when we saw the lower than expected response rates, we attempted to recontact the practices to obtain additional completed surveys. However, we were not able to increase our response rates.

Table 3.4. Preintervention Survey Respondents and Response Rates, by Practice

Practice	Number of Respondents				Number of Surveys Distributed	Response Rate
	M.D. Provider	Other Provider	Nonprovider Staff	Total		
IAA	2	1	6	9	13	69.2%
IHA	4	0	8	12	13	92.3%
IHD	1	1	5	7	8	87.5%
IHE	7	0	27	34	38	89.5%
IHF	0	0	3	3	7	42.9%
IHH	4	0	18	22	24	91.7%
IHI	6	1	11	18	22	81.8%
IMB	1	0	6	7	10	70.0%
IMD	0	0	3	3	5	60.0%
ISA	2	1	8	11	17	64.7%
ISB	4	0	13	17	22	77.3%
ISC	3	0	16	19	21	90.5%
ISD	2	0	11	13	14	92.9%
IUA	10	1	11	22	62	35.5%
IUB	3	0	5	8	9	88.9%
Total	49	5	151	205	285	71.9%

Table 3.5. Postintervention Survey Respondents and Response Rates, by Practice

Practice	Number of Respondents				Number of Surveys Distributed	Response Rate
	M.D. Provider	Other Provider	Nonprovider Staff	Total		
IAA	1	1	0	2	13	15.4%
IHA	3	0	6	9	13	69.2%
IHD	1	1	4	6	8	75.0%
IHE	3	0	18	21	38	55.3%
IHF	0	0	2	2	7	28.6%
IHH	2	0	15	17	24	70.8%
IHI	7	0	1	8	22	36.4%
IMB	2	0	3	5	10	50.0%
IMD	1	0	3	4	5	80.0%
ISA	3	0	7	10	17	58.8%
ISB	4	0	9	13	22	59.1%
ISC	2	0	11	13	21	61.9%
ISD	4	0	6	10	14	71.4%
IUA	4	0	4	8	62	12.9%
IUB	1	1	5	7	9	77.8%
Total	38	3	94	135	285	47.4%

Table 3.6. Control Survey Respondents and Response Rates, by Practice

Practice	Number of Respondents			Number of Surveys Distributed	Response Rate
	Provider	Nonprovider Staff	Total		
CHA	0	5	5	9	55.6%
CHB	0	8	8	11	72.7%
CMA	4	10	14	21	66.7%
CSA	0	10	10	10	100.0%
CUA	1	7	8	16	50.0%
Total	5	40	45	67	67.2%

Focus Groups and Informal Interviews

We conducted the focus groups both before the intervention and after the intervention at each of the 15 intervention practices and at one time near the end of the intervention period at each of the 5 control practices. The intended populations for the focus groups were all the providers and clinical and nonclinical staff of each practice. As with the practice survey, there was no sampling or selection process; we invited all providers and staff. We obtained informed consent from all focus group participants.

We conducted preintervention focus groups during the academic detailing sessions, but prior to when the detailing actually began to ensure accurate baseline information (that would be unaffected by the information disseminated during the detailing). The purpose of these focus groups was to collect information to establish a baseline. We conducted postintervention focus groups during debrief sessions that occurred at each intervention practice at the end of the intervention period. The postintervention focus groups assessed satisfaction with the intervention and identified changes in attitudes and behaviors regarding screening and followup. They also identified changes in management of normal and abnormal screening tests resulting from the intervention.

We also conducted focus groups at the control practices late in the intervention period using the preintervention focus group guide to gather information similar to the baseline information gathered from intervention practices. We conducted them late in the intervention period to avoid introducing any information that could influence the control practices usual CRC screening or followup practices.

We used the same focus group guide for the preintervention and control practices in order to obtain baseline information. We asked participants the following types of questions:

1. What screening guidelines do they use?
2. How aware do they think their patients are regarding the importance of CRC screening?
3. How often and when do they recommend CRC screening to patients?
4. How can CRC screening and tracking be improved.

For the postintervention focus groups, we asked participants the following types of questions:

1. How satisfied were they with the intervention?
2. How did they feel the intervention affected their practice and themselves?
3. How did they feel the intervention affected their patients?
4. What was it like to adopt the intervention?
5. What could have improved the intervention?

Attendance at each of the focus groups varied, depending on the practice.

Key Informant Interviews

We conducted brief key informant interviews with selected providers and staff at intervention practices to ascertain additional baseline information about procedures and systems for screening results. These interviews collected information from selected knowledgeable practice personnel who provided information related to the practice as a whole. The interviews also allowed us to obtain answers to questions that remained unanswered or unclear based on the data received from the focus groups and survey. We did not conduct postintervention key informant interviews with practice staff or interviews at the control practices, as we were able to collect all necessary information from these focus groups and surveys.

Interview topics included:

1. How are screening guidelines disseminated throughout the practice?
2. What are some of the practice policies and procedures for CRC screening?
3. How does the practice identify patients eligible for screening?
4. How does the practice use an EMR to track screening?
5. What are the patient demographics of the practice?
6. What types of insurance does the practice accept?
7. What are some other unique characteristics of the practice?

The number of interviews conducted during the preintervention period varied by practice.

Patient Focus Groups

We conducted postintervention patient focus groups to better understand the intervention from the patient's perspective. We conducted two focus groups with patients at two distinct sites, primarily patients who had received the intervention. We recruited patients based on all eligible patients from the site and obtained informed consent from all participants.

The focus group topics included the following four key areas:

1. What was the patient perception and knowledge about CRC screening?
2. What did the patient think about the intervention (what worked and what did not work well)?
3. What were some patient motivators and barriers?
4. What else could have been done to further the screening objective?

Eleven individuals participated in these two discussions. Ten had received screening as the result of the intervention; one had not.

Informal Conversation With LVHN

In addition to the practice focus groups, we conducted a conversation with study members of the LVHN to gather information about their impressions of the intervention and its implementation and outcome. During our informal conversation with LVHN project staff, we discussed the following topics:

1. How did the LVHN/LVPHO context affect the intervention?
2. How representative was this intervention to others that the network has participated in?
3. What aspects of the intervention worked well, and which did not work well?
4. Would they recommend introducing this intervention to the other practices in the network?
5. How would they describe the practices' levels of participation?

Three people participated in this informal discussion.

Outcome Measures

The PRISM intervention evaluation framework has two types of overall outcome measures: the reach of the intervention into the target patient population and the effectiveness of the intervention. For this study, we defined reach as the number, proportion, and representativeness of eligible patients of intervention practices who participated in the study. For our purposes, participation means that the eligible patient did not opt out and had a valid (deliverable) mailing address that permitted us to mail intervention materials to them. We measured representativeness by comparing participating eligible intervention patients with those who opted out or had undeliverable mailing addresses. We also measured the representativeness of the study population by comparing the distribution of study patients of intervention and control practices to that of all LVPHO patients ages 50-79.

We identified and measured several kinds of intervention effects. SATIS-PHI/CRC seeks to improve patient screening and followup both through encouraging and facilitating patients to become screened and through academic detailing to providers and other practice staff regarding evidence-based screening guidelines (as shown in Figure 1.2). We sought to assess the effect of the intervention on these outcomes.

We measured the effect of the intervention on patient screening by comparing the rate and likelihood (odds) of intervention patients being screened to that of control patients being screened during an 8-month observation period. The observation period followed the mailing of the invitation to be screened letter and accompanying screening information and materials. We separately compared each intervention study arm (receiving a card to request a stool test kit and receiving the stool test directly without having to request it) to the control arm for being screened by stool test, by colonoscopy, and by any modality. We also compared the two intervention arms to each other within the two practices with randomized patients.

We measured variation in effect size among intervention patients classified by several individual and practice-level attributes to assess what kinds of patients the intervention was most likely able to affect. In addition, we estimated the effect size comparing intervention and control patients adjusting for the effects of these attributes to assess whether the intervention effect persisted even after controlling for them. We corrected for possible clustering effects of assigning patients to the intervention and control study arms by practice and also estimated effect size adjusting for several sources of possible measurement error. In particular, we adjusted the screening rate denominator for control practice patients in several analyses to compensate for not having eligibility data from the SEA form for them. We also sought to assess the possible impact of incomplete screening tracking data on effect size for screening.

We conducted practice-level analyses, examining variation in screening rates by practice, to assess both the degree of variation and whether intervention practices generally had higher rates than control practices. We looked at whether there was more variation between groups (intervention practices vs. control practices) than within groups. Finally, we assessed possible negative consequences of patient screening by examining the results of diagnostic colonoscopies done as a followup to positive or abnormal stool test screens.

In addition to the intervention's effect on patient screening, we assessed its effect on followup of positive screens. For purposes of this assessment, we defined followup as performing a guideline-consistent complete diagnostic evaluation (CDE) in response to a positive or abnormal stool test. As there were only a few positive stool tests within the study population during the observation period, we were only able to do a minimal analysis of this effect.

We measured the effect of the academic detailing portion of the intervention on providers and practices by comparing results of the preintervention and postintervention survey of intervention practices. Since we only conducted a preintervention survey of control practices, we could not assess pre-post differences within these practices nor compare them with pre-post differences in intervention practices. We defined a positive intervention effect to be a movement in responses away from beliefs and behaviors not supported by guidelines and toward those that are guideline supported. In particular, we assessed changes in the proportion of clinician respondents who recommended nonsupported screening modalities to their patients, believed that nonsupported modalities were effective, and followed up positive stool tests and flexible sigmoidoscopies with nonsupported procedures.

We also assessed the impact of the intervention on clinician attitudes toward fecal immunochemical tests (FITs), which were one of the two screening modalities offered to patients through the intervention. We examined changes in pre-post responses to recommending the FIT and believing it to be effective. In addition, we compared pre- and postintervention responses to evaluate any impact of the intervention on whether various steps in the screening process for stool tests and colonoscopy were performed within intervention practices.

Patient and Practice Attributes

We sought to understand how outcome screening rates varied by patient and practice attributes. We also sought to determine whether and how these attributes affect intervention effect size for screening rates. Patient attribute data came from the electronic records we reviewed to

determine eligibility and from responses to the SEA form (for those intervention patients who returned an SEA form with this information; control patients did not receive an SEA form). Electronic records provided age (date of birth), gender, and primary insurance coverage.[xii] The SEA form provided marital status,[xiii] perceived health status, and education.[xiv]

We calculated age as of the start of the intervention from date of birth and then coded the result into a series of age categories. We coded insurance coverage into the categories of commercial, Medicare, Medicaid, and self-pay/uninsured. The data from electronic records were relatively complete. Out of 7,965 intervention patients, only 343 cases (4.3 percent), 2 cases (0.03 percent), and 683 cases (8.6 percent) were missing data for gender, age, and insurance coverage, respectively.

For the 2,662 control patients, no cases were missing gender data and only 19 cases (0.7 percent) were missing age data; however, all 2,662 were missing insurance data. Thus, we could not include insurance coverage in analyses involving control patients. Data from the SEA form, on the other hand, were much less complete (and nonexistent for control patients). Marital status data, even after supplementation from electronic records, was available for only 48.4 percent of intervention patients. Perceived health status and education were only available for 13.7 percent.

LVHN study staff provided practice attribute data for the LVPHO/EPICNet practices participating as either intervention or control practices in SATIS-PHI/CRC. In allocating practices to intervention or control study arms, we used five attributes:

- Size (number of clinicians dichotomized as small if three or fewer and large if more than three);
- Affiliation (affiliated with LVHN as either a hospital clinic or LVPG practice or not affiliated with LVHN and either part of MATLV or totally independent);
- Specialty (family medicine or general internal medicine);
- Location (urban, suburban, or rural); and
- EMR (having or not having an EMR system).

We used the same attributes in outcome analyses with the exception of EMR. The LVPHO central entity performed the SATIS-PHI/CRC function of identifying, contacting, and tracking eligible patients. Thus, the presence or absence of an EMR system in a practice should not have affected the rate at which its patients would be screened in response to the intervention. Still, our ability to access and use an EMR system for this function—as well as availability of other electronic data sources for this function—was likely to affect our how accurately we assessed

[xii] Some electronic records also contained fields for race and ethnicity; however, the data were incomplete and race and ethnicity categories were inconsistent across different record systems and with those used on the SEA form (which used OMB-approved categories). Thus, we decided not to use these data elements in any analyses.
[xiii] We were able to use electronic records to add marital status data for some patients not returning an SEA form.
[xiv] In addition to these three variables, the SEA form requested information on ethnicity, race, and primary language. We did not use these variables in any analyses because many SEA respondents did not provide the information. Of those who did, the overwhelming majority was non-Hispanic and spoke English. Thus, there was neither sufficient data nor sufficient variation for these variables to warrant their inclusion.

eligibility. It also could affect our ability to find evidence of screening and thus affect our ability to accurately measure screening rates. Therefore, we modified the EMR attribute variable to indicate the relative completeness of the electronic data available for a particular practice.

As shown in Table 3.1, for some practices we were able to use a combination of EMR and PHO insurance claims data. This combination provided the most complete data for patients identified as eligible in these practices. For other practices, we were only able to use PHO claims data. This single data source restricted us to patients who were insured through the PHO. The lack of EMR data restricted our ability to observe any clinical evidence of ineligibility; thus, we likely included a sizable proportion of ineligible patients in the denominator of screening rates for patients of these practices. However, the PHO claims were a good source of data for tracking screening. Accordingly, we coded these practices as having moderately complete data.

For the remaining practices, we were able to use a combination of billing records and PHO claims. The billing records allowed us to include more than PHO-insured patients but did not provide good tracking data for them. Therefore, we coded these practices as having the least complete data.

4. Assessment of the Intervention

In this section, we present our assessment of the SATIS-PHI/CRC intervention using the PRISM framework. We begin with the context domain element of evaluating the intervention from the perspective of the organizations implementing and delivering it (the LVPHO acting as the central entity) and serving as the setting for delivery (the participating practices). We also examine the intervention from the perspective of the patients.

We next examine the characteristics of the practices and patients participating in the intervention and assess how these characteristics may have affected its management, receipt, and outcome. We then assess the external environmental setting and how it also may have affected the intervention's management, receipt, and outcome. Finally, we assess the LVPHO central entity's implementation and sustainability infrastructure for evidence of how it may have affected the PHO's ability to implement and maintain the intervention.

We then turn to the outcome domain and assess the five RE-AIM outcome elements of Reach, Effectiveness, Adoption, Implementation, and Maintenance. We present our assessment in a somewhat different order, however. As Figure 3.1 suggests, adoption, implementation, and maintenance are most directly affected by the context domain elements and then, in turn, affect the reach and effectiveness outcome elements. For this reason, we present the outcome assessment by first considering the "AIM" elements and then turning to the "RE" elements.

PRISM Context Domain

Organizational Perspective

Before the central entity decided to implement the intervention, it already knew that this intervention had a strong evidence base. The intervention was based on an intervention previously tested in studies conducted by project staff at Thomas Jefferson University (Myers, 2007; Myers, 2001; Myers, 2004). Components of these prior studies showed that the intervention improved CRC screening rates in a large urban academic practice. The intervention also improved rates of diagnostic followup for positive screens in practices affiliated with a large, for-profit managed care organization. We designed this study to build on these prior studies. We examined how well the intervention could be transferred to a network of community-based practices and achieve similar rate improvements for both CRC screening and followup in a setting distinct from the previous studies.

The intervention also followed the most current (2008) clinical recommendations and guidelines (Leven, et al., 2008; U.S. Preventive Services Task Force, 2008). During the academic detailing sessions to the intervention practices, the central entity distributed and discussed information pertaining to these new guidelines to increase awareness among the clinicians and practice staff. This helped to further emphasize the evidence base of the recommended screening modalities and many of the key intervention elements.

Several factors affected the central entity's readiness to implement the SATIS-PHI/CRC intervention. This was the first time that it embarked on a study of this size. It had conducted prior studies and interventions but none with so many practices. The size increase resulted in a

greater time requirement for the central entity to manage and implement the intervention across the 15 practices than originally anticipated, especially in terms of the patient mailings.

This intervention also required a more standardized and systematized approach than the central entity had used previously. This problem was partially compounded by limitations with its health information technology (HIT) system. The HIT staff was more accustomed to conducting retrospective electronic record reviews of billings, claims, and EMR data than prospective queries to determine which patients were eligible and in need of colorectal cancer screening.

In addition, as the central entity's staff conducted subsequent electronic record reviews, they had problems using the electronic records to uncover evidence of screening. Clinicians could enter data on screening in either fixed-response fields or in progress notes or other text fields. Evidence of screening contained in fixed fields was relatively easy to extract. However, such evidence in text fields was more difficult to identify. Further, since specialists rather than the primary care providers in the SATIS-PHI/CRC intervention practices performed colonoscopies, there was only limited evidence of colonoscopy in the primary care EMR or billing records. On the other hand, evidence on FIT screening was provided directly by HNL, making it easy to identify who was screened by this modality.

The timing of OMB clearance also affected readiness. The central entity could not begin to review electronic records to identify eligible patients (Step 3 of the intervention) until OMB cleared the project's data collection. We received this clearance in early December 2008 in the midst of the open enrollment period for the central entity's insurance plan. This timing interfered with the central entity's HIT staff's ability to devote time, staff, and attention to the record review as opposed to updating enrollment records. Record review also had to be delayed until HIT staff finished updating the transition of patients into and out of insurance plans in order to ensure that they could produce an updated list of eligible patients for the intervention. The timing also overlapped with the winter holiday season, further delaying the record review.

Project staff at the central entity also reported that this intervention was ahead of the curve in terms of the readiness of the entity's leadership. At the time of implementation of the intervention, organization's leadership was generally supportive but did not fully appreciate it. The organization is now participating in efforts within Pennsylvania to transform affiliated practices into patient-centered medical homes and now sees how the SATIS-PHI/CRC intervention can be part of population-based screening efforts for a medical home.

To minimize the burden on practices participating in the intervention, the central entity played a coordinating role managing SATIS-PHI/CRC across the practices by working through the office manager of each practice. However, based on lessons learned from the study, the central entity found that it would have been helpful to have a clinical liaison at each practice to help facilitate the intervention's implementation. Whereas the office manger could distribute information and materials, a clinician acting as a liaison with and champion for the intervention may have allowed better and more direct communication with the full clinical staff at each practice.

There were a few aspects that the central entity could not manage, so these elements had to be managed by the individual practices. For example, because HNL required a physician order

form for each stool test kit, patients had to return stool test kits to the practice. The practice then attached the order form and sent the kit to the lab for processing, rather than having patients submit the test kits to the central entity for forwarding to the lab or having patients submit kits directly to the lab.

The central entity also did not coordinate directly with colonoscopy practitioners. However, the central entity did coordinate with each practice to compile a list of colonoscopy practitioners to whom a practice's clinicians referred. The central entity included this list in the invitation to screen mailing for that practice's patients.

Because the central entity managed and conducted most of the intervention itself, participating practices incurred no costs or only minimal costs. The central entity also worked with the individual practices to resolve any issues or problems as needed. The central entity learned from the pilot that the practices needed guidance in what they were expected to do to participate in the intervention. Therefore, for the full intervention, the central entity created a process guide for the practices that outlined what the practice and provider should do during each step of the process. It also included a detailed description of how to submit stool tests to the lab for processing and a shortened form for the practices to use when sending the kits to the lab.

Patient Perspective

We designed the intervention focusing on a patient-centered approach. One way we did this was to provide the patient with screening modality choices. The choices were an at-home stool test or a provider-delivered colonoscopy, as well as other screening modalities recommended by providers. Based on existing literature, we understand that some patients are not comfortable with certain screening modalities, so we worked to ensure that several options were available. Based on the patient focus groups, many patients noted that they liked the ease of the at-home stool test kits.

In addition, we wanted to provide patients with a way to ask questions about the intervention. We provided all eligible patients with a phone number for the central entity on the SEA mailing. Through this phone number, patients could ask questions and they could opt out of the study. Patients could also opt out by completing and returning the SEA form. We learned that the central entity phone number and SEA form also provided patients with an opportunity to raise concerns they had with the intervention.

At times, some patients were angry about receiving the mailings and clearly expressed their desire to no longer receive information. Once patients opted out, we removed them from our list of patients to receive subsequent mailings. However, due to timing, materials could have already been in the mail to the patient at the same time that the central entity received their request to opt out. To make this process transparent to patients, our mailing materials noted that there could be delays in updating our contact list, based on mailing time lags.

While the central entity managed and implemented the intervention to minimize the burden on the practices, the intervention mailing materials to the patients appeared to be coming from the patient's doctor and doctor's office. We designed the intervention this way to make it more patient centered. We believed that patients would be more encouraged to screen if the

recommendation came from their practice rather than an unknown central entity. Based on the patient focus groups, this was true. Patients reported that they had confidence in the source of the information, as it came from their providers. Some noted that their providers had previously noted the importance of CRC screening, but this intervention helped to encourage them to act.

To help address the seamlessness of transition between program elements and the feedback of results, the central entity provided feedback to clinicians about their patients' screening and followup results. We hoped that if we notified the clinicians, they in turn would notify patients. We also provided clinicians with forms to track the followup test results of their patients with positive screens. The central entity also provided each practice's office manager with a Screening Tracking Sheet to track all of the practice's patients. Based on the patient focus groups, however, we learned that many patients did not receive notification of their test results from their clinicians, which patients found frustrating.

From the perspective of the patients, the timing of the mailing of the intervention was likely not ideal. Due to receiving OMB clearance in December and needing several months for the initial electronic record review, mailing and review of SEA forms, and preparation of the Invitation to Screen mailing, we did not send the invitation and accompanying screening materials until the summer. By then, many patients were on vacation or planning a vacation. Had we been able to better time the intervention from the perspective of the patient, resulting screening rates may have been higher.

We designed the SATIS-PHI/CRC intervention to minimize burdens on patients and maximize accessibility. We supplied stool test kits free of charge to patients and provided information on colonoscopy providers to whom clinicians in their primary care practices referred. Still, from the patient's perspective, the method of obtaining stool test kits was not ideal.

Although we originally planned to have the central entity mail stool test kits directly to all intervention patients, the lab's financial constraints prevented us from being able to do so for all but a small subsample of patients. Most patients had to request a kit by mailing back a request card. This added burden on patients may have reduced screening rates. Uninsured or underinsured patients of LVHN practices were eligible to negotiate reduced pay options with the network, which helped increase their access to screening But this option required a patient to complete an eligibility form. This added burden may have acted as a barrier to their screening.

Recipient Characteristics

Organization

As noted, we conducted the intervention and its assessment in the Lehigh Valley of Pennsylvania through the Lehigh Valley Physician-Hospital Organization (LVPHO). LVPHO was formed by the Lehigh Valley Health Network (LVHN) and the Greater Lehigh Valley Independent Practice Association (GLVIPA) in 1993. LVHN is the region's largest hospital system and health network, primarily serving the two Pennsylvania counties that surround the Lehigh River Valley (Lehigh and Northampton) and that contain the urban centers of Allentown and Bethlehem.

The network of primary care practices affiliated with the LVPHO consists of a mix of primary care practice types and is supportive of practice-based research (as members of the EPICNet PBRN). These practices differ significantly from the sites where components of the CRC screening intervention were previously tested by TJU researchers. The LVPHO practices serve a smaller, less urban community and are members of a physician-hospital organization that offers a preferred provider organization insurance product to local employers.

Whereas many of the LVPHO practices are fully independent, others are members of either (1) Medical Associates of the Lehigh Valley (MATLV, an independent physician-owned professional corporation providing administrative and business services to solo and group practices in more than 25 separate locations throughout the Lehigh Valley); or (2) Lehigh Valley Physicians Group (LVPG, a distributed group of practices owned by the LVHN serving the general Lehigh Valley community). In addition, LVHN operates three hospital-based primary care clinics that help meet the needs of uninsured and underinsured patients in the region. These four entities (LVPHO, LVHN, LVPG, and MATLV) provided us with electronic data that we used for the initial and followup electronic record reviews and to track screenings and results.

Based on our baseline assessment of participating intervention practices through focus groups and surveys, we learned several new organizational characteristics. A complete summary of these findings are available in our Preliminary Report of Findings submitted to AHRQ in September 2009 (Harris and Borsky, 2009). With regard to management support and communication, we learned that when clinicians made screening recommendations they did not follow any specific screening guidelines; rather, they provided patients with screening options. A few indicated that they followed American Cancer Society/Multi-Society Task Force guidelines, and most were at least familiar with them. In addition, many tried to keep up to date with these changes.

We found that most of the larger practices held monthly staff meetings that provided an opportunity for practices to disseminate new information. Some of the smaller practices indicated that information was more often communicated as needed rather than through regularly scheduled meetings, due to staff and provider time limitations.

With regard to data and decision support and management support, overall none of the practices had formal policies for CRC screening; respondents felt it was up to the individual physician to discuss screening with the patient during an office visit. Some said there was a flowsheet in the paper records that recorded screenings, whereas others used an EMR. Some respondents said that they documented recommendations or results in the patient record; others reported using either a health maintenance flowsheet or an EMR. Some did not do any tracking. Many respondents reported following up with patients via the specialist who provided a followup colonoscopy; others reported that there was no followup.

Some of the larger practices said they also used their EMR to help identify who was eligible for screening. Practices without an EMR said they were eager to have an EMR, and they were especially excited to have one that provided popup reminders for screening. However, we also learned that several practices had an EMR but the central entity was unable to use their EMR for determining which patients were eligible for the intervention. The reasons these practices'

EMRs were not usable varied, but for some it related to the fact that they did not have the experience of using the EMR for population-based interventions.

Based on the preintervention practice surveys, we learned some additional information about the organizational culture. Some clinicians would recommend screening modalities that were not concordant with the current guidelines (e.g., digital rectal exam), and some clinicians would not recommend screening modalities that followed the guidelines (e.g., FIT). There were also clinicians who recommended screening modalities they did not believe to be effective.

In addition, we learned that clinicians and practice staff were more often aware of the screening process steps that occurred as part of an office visit rather than the steps that required tracking or outreach to patients. However, one strong positive finding was that most clinicians recommended the appropriate followup to positive stool tests. We designed our intervention to address many of these findings by educating clinicians and practice staff about the guideline-recommended screening modalities, appropriate screening followup, importance of tracking patient screening and followup, and all the required steps of the screening and tracking process.

Patients

The population served by LVHN includes 620,425 people, of whom 177,078 (28.5 percent) are ages 50-79, the target age population for this CRC screening intervention. Data provided by the LVPHO, based on Medstat Demographics expert, indicate that 3.6 percent of the area's population was non-Hispanic black or African American, 2.3 percent was Asian, and 11.0 percent was Hispanic or Latino. The fastest growing segments of the population are Hispanic and Asian according to figures cited by the Lehigh Valley Economic Development Corporation and supported the Medstat data. A recent cancer mortality report (Pennsylvania Department of Health, 2009) showed 1,824 new cases of invasive CRC in Lehigh and Northampton Counties in 2002-2006, with age-adjusted annual incidence rates per 100,000 as shown in Table 4.1.

Table 4.1. Number of Incident Cases and Average Annual Age-Adjusted Incidence Rates for Invasive Colorectal Cancer in Lehigh Valley, Pennsylvania, by County and Sex, 2002-2006

County	Males		Females	
	Number	Rate[a]	Number	Rate[a]
Lehigh	453	56.6	524	45.7
Northampton	409	59.8	438	45.0

[a.] Rate per 100,000 population.
Source: Pennsylvania Department of Health, 2009.

As noted, the central entity conducted an electronic record review to identify patients eligible for screening. After the subsequent SEA mailing, additional electronic record reviews, and chart audits, we obtained our final patient study population. Table 4.2 summarizes the demographics of the patient population. The table shows patients from the two intervention arms (kit and card) and from the control group.

As shown in the table, the control group patients are younger than the intervention group patients, but they have roughly the same proportion of males and females. We do not have insurance data for the control practices, but we assume that because the control group population is younger, they are more likely to be covered by commercial or Medicaid insurance or be self-insured rather than covered by Medicare. There is also significant variation between the intervention and control group patients for the practice characteristics. As there is such variation, we controlled for these factors when we conducted our statistical analyses.

We were able to gather information regarding the patient's knowledge and beliefs about CRC screening from our patient focus groups. Focus group participants clearly identified CRC screening with turning age 50 and with life milestones. Their knowledge sources were medical providers or family and friends. For family, this also related to the impact of having a family history of CRC or other cancer.

With regard to factors motivating people to get screened, respondents indicated that they sought to be proactive about their health. They also noted that family ties played a significant motivating role. However, fear can be a barrier to screening (e.g., colonoscopy prep). The focus groups also provided us with information about the patient's satisfaction with the intervention, which we describe later in this report.

Table 4.2. Distribution of Study Participant Population by Patient and Practice Characteristics

Characteristics	Card Intervention			Kit Intervention			Control		
	N	%*	Adj %†	N	%	Adj %	N	%	Adj %
Total population	7,495	100.0	—	470	100.0	—	2,662	100.0	—
Patient Characteristics									
Gender									
Male	3,194	42.6	44.3	201	42.8	49.4	1,191	44.7	44.7
Female	4,021	53.7	55.7	206	43.8	50.6	1,471	55.3	55.3
Unknown	280	3.7	—	63	13.4	—	0	0.0	—
Age									
50-54	1,945	26.0	26.0	154	32.8	32.8	927	34.8	35.1
55-64	3,190	42.6	42.6	179	38.1	38.1	1,067	40.1	40.4
65-69	947	12.6	12.6	52	11.1	11.1	286	10.7	10.8
70-79	1,411	18.8	18.8	85	18.1	18.1	363	13.6	13.7
Unknown	2	0.0	—	0	0.0	—	19	0.7	—
Insurance									
Commercial and other	4,346	58.0	62.8	266	56.6	74.3	—	—	—
Medicare	2,003	26.7	28.9	80	17.0	22.3	—	—	—
Self/Medicaid	575	7.7	8.3	12	2.6	3.4	—	—	—
Unknown	571	7.6	—	112	23.8	—	2,662	100.0	—
Practice Characteristics									
Practice affiliation									
Clinic	1,416	18.9	—	0	0.0	—	930	34.9	—
Independent	367	4.9	—	62	13.2	—	35	1.3	—
LVPG	5,645	75.3	—	408	86.8	—	1,646	61.8	—
MATLV	67	0.9	—	0	0.0	—	51	1.9	—

Characteristics	Card Intervention			Kit Intervention			Control		
	N	%	Adj %*	N	%	Adj %*	N	%	Adj %*
Specialty									
Family medicine	6,701	89.4	—	470	100.0	—	1,697	63.7	—
General internal medicine	794	10.6	—	0	0.0	—	965	36.3	—
Size									
Large	4,624	61.7	—	62	13.2	—	1,016	38.2	—
Small	2,871	38.3	—	408	86.8	—	1,646	61.8	—
Location									
Rural	3,057	40.8	—	408	86.8	—	898	33.7	—
Suburban	2,659	35.5	—	62	13.2	—	834	31.3	—
Urban	1,779	23.7	—	0	0.0	—	930	34.9	—

* Some percentages do not add to 100 due to rounding.
† Percentages adjusted for missing data.

External Environment

We implemented the SATIS-PHI/CRC intervention in Pennsylvania's Lehigh Valley. This setting primarily consists of two counties (Lehigh and Northampton) and contains the urban centers of Allentown and Bethlehem. LVHN is the region's largest hospital system and health network. Along with the GLVIPA, LVHN formed the LVPHO in 1993. The PHO offers a preferred provider organization health insurance plan to employers throughout the region.

Primary care practices in the PHO have varying degrees of affiliation with LVHN. The network owns and operates three hospital-based clinics that help meet the health care needs of uninsured and underinsured residents of the region. Two of these clinics are associated with residency programs. LVHN also owns and operates the practices of the Lehigh Valley Physician Group. Other practices are not owned by LVHN. Some, however, are members of Medical Associates of the Lehigh Valley, which is an independent, physician-owned professional corporation providing administrative and business services to solo and group practices throughout the Lehigh Valley. The remaining practices are neither owned nor operated by any larger entity.

Factors Affecting Implementation

Several notable conditions or occurrences in this environment affected the implementation of the SATIS-PHI/CRC intervention and perhaps its outcome as well. The downturn in the national and local economies that began in calendar year 2008 resulted in a narrowing of operating margins for many of the entities playing a role in the intervention effort. In particular, these economic conditions led to decisions and actions by LVHN and its affiliated PHO and clinical laboratory (HNL) that affected the intervention. The network was limited in its ability to provide in-kind funding and staff resources needed to supplement the funding available through the task order contract. This affected the ability of the LVHN/LVPHO study staff to meet deadlines for electronic record review, mailings, and screening tracking.

Perhaps more significantly, the economy affected the ability of HNL to supply stool blood test kits free of charge for mailing to all intervention patients, which necessitated changing our intervention implementation protocol. The laboratory needed a high enough response rate to the

invitation to be screened by stool test so that the revenue generated by charging patient insurance plans for processing the test kits would offset the cost of supplying the kit free of charge. Based on a lower than expected return rate in the intervention pilot, the laboratory informed the project's implementation team that it could not afford to provide stool test kits free to thousands of patients included in the full intervention. The laboratory required either that we substantially reduce the number of kits mailed out, that we assure them of a higher response rate, or both. To meet this requirement, the study team revised the intervention protocol for the invitation-to-be-screened mailing to enclose a card for patients to mail back to request a kit rather than to enclose the kit. In this way, the laboratory only had to provide kits for those requesting one and the response rate was likely to be higher among those requesting a kit than experienced in the pilot.

We were concerned that the change in protocol would add a burden from the patient's perspective and could significantly reduce the screening rate resulting from the intervention. We wanted to be able to estimate the effect of changing from enclosing the kit to enclosing the request card, so we negotiated with HNL to supply up to 500 kits for us to enclose with the invitation-to-be-screened mailing for a sample of patients. We had already mailed the invitation to Wave 1 patients by the time we reached this agreement with HNL, so we selected the two largest practices in Wave 2 to participate in this substudy. We randomly selected a subsample of each of these practice's patients to receive the kit rather than the card.

The economic environment also led to increased unemployment in the Lehigh Valley, with an accompanying loss of employer-based health insurance coverage. The regional unemployment rate rose to a 25-year high of 9.3 percent in August 2009, which was the second highest rate for a Pennsylvania metropolitan area. Anecdotally, we heard reports that even those who maintained their insurance coverage were experiencing higher copayments and deductibles. Loss of insurance or higher out-of-pocket costs for insured patients may have affected the rate at which patients targeted by the intervention were screened.

Another environmental condition likely affecting the intervention is the number and availability of local colonoscopy providers. To the extent that demand for colonoscopies put pressure on the supply of these providers as a result of the intervention, waiting times for screening colonoscopies likely increased. This situation may have led to some screens being delayed until after the intervention observation period was over, thus decreasing the observed effectiveness of the intervention.

Screening delays may have been most acute for those who are uninsured and underinsured. Local colonoscopy providers offer screening procedures to this population on a limited basis (again, the economic conditions may have worsened this situation). As discovered in key informant interviews and focus groups with hospital clinic personnel, the waiting list for screening colonoscopy for uninsured and underinsured patients may have been as long as 10 months, exceeding our 8-month observation period.

Possibly exacerbating this condition was the initiation of a CRC screening program sponsored by a local Blue Cross Blue Shield plan offering several insurance products (including a Medicare product) to residents of the Lehigh Valley. This program was launched just prior to

our SATIS-PHI/CRC intervention and likely increased demand for screening colonoscopies, which would have spilled over into the observation period for our intervention. Further, patients of practices participating in SATIS-PHI/CRC who had health insurance coverage through one of these Blue Cross Blue Shield products would have already received material from the other program before receiving our intervention material.

To avoid confounding our estimation of the effect of SATIS-PHI/CRC, we decided to exclude from the intervention all patients in participating practices who had insurance coverage through a Blue Cross Blue Shield products. This exclusion also reduced the potential of confusion among patients who would be receiving different screening invitations and protocols from both the Blue Cross Blue Shield program and our intervention.

The actions of the Blue Cross Blue Shield plan reflected findings of a study of commercial insurers throughout Pennsylvania conducted in 2006. This study found that they generally changed their policies and practices to be more supportive of increasing CRC screening rates after the National Committee for Quality Assurance included CRC screening as a measure in its Healthcare Effectiveness Data and Information Set in 2003 (Sarfaty and Myers, 2008). These changes included implementing or revising guidelines for screening, initiating measurement of screening rates, developing reminder systems for patients, and developing tracking systems. SATIS-PHI/CRC can be seen as an effort consistent with and complementary to these other efforts within Pennsylvania.

Changes in Primary Care Delivery

Two developments in the delivery of primary care throughout the Lehigh Valley also likely affected the SATIS-PHI/CRC intervention. Many primary care practices, including those participating in SATIS-PHI/CRC, were implementing, upgrading, or still learning how best to use various EMR systems. We found that we were unable to obtain needed patient eligibility information from several of these systems in a timely enough manner to include them in the intervention. Further, the delay in obtaining eligibility data from some practices necessitated our splitting the first mailout into two waves, placing the slower practices in Wave 2.

Elements of some EMR systems that would have facilitated our ability to differentiate between ineligible and eligible patients, as well as our ability to track screening and followup, were not being used at some practices. Two practices were transitioning to a new EMR system during the intervention period, requiring study staff to search both old and new systems at each practice. The fluid EMR situation at these practices also negatively affected their postintervention survey response rates. In general, the HIT environment in the Lehigh Valley was an issue for implementing SATIS-PHI/CRC.

The second primary care delivery development occurring in the Lehigh Valley at the time of the intervention was the transition to a patient-centered medical home model of care. There were statewide initiatives and regional initiatives in southeast Pennsylvania sponsored by both the Governor's office and insurance plans serving the region. The purpose of the initiatives was to transform primary care practices into patient-centered medical homes and to institute pay-for-performance programs tied to medical home status and performance on key quality indicators. These developments may have detracted from attention to or interest in SATIS-PHI/CRC among

LVPHO leadership since CRC screening was not a focus or key indicator of the medical home initiatives. Going forward, however, these initiatives are likely to facilitate dissemination and uptake of SATIS-PHI/CRC throughout the LVPHO practice network because CRC screening is becoming a focus.

The incidence of seasonal flu and H1N1 and concern over them led to higher than usual volume at primary care practices in the Lehigh Valley during the intervention period. This higher volume left little time for either providers or practice staff to devote to SATIS-PHI/CRC concerns, such as preparing returned stool test kits for submission to HNL for processing. In addition, staff did not have much time to respond to patient inquiries about the intervention or CRC screening.

Implementation and Sustainability Infrastructure

The LVHN/LVPHO central entity had a dedicated team of four people devoting part of their time to implementing and sustaining SATIS-PHI/CRC. This team recruited practices to participate in the project, extracted or arranged for extraction of electronic data, conducted all of the patient mailings, input data into the master patient database, and acted as liaison to the practices. Members of this team also participated with other project personnel from Thomas Jefferson University in conducting the academic detailing sessions and the practice and patient focus groups. This team also had in-kind assistance from the LVHN in preparing material for and carrying out the patient mailings. Nevertheless, the team was understaffed for what it was expected to do and frequently missed deadlines. The team was adaptable to changing situations (e.g., the change in protocol to use request cards instead of distributing stool test kits to all intervention patients, as well as adding an academic booster when the preintervention survey results indicated the need for one).

The central entity team had ongoing established relationships with each of the participating practices through EPICNet. Specific to this project, the team arranged to have a practice management staff person at each practice serve as the primary point of contact for the intervention. A number of issues that arose during the intervention implementation were clinical rather than administrative or required direct communication with the clinical staff. A clinical point of contact at each practice, such as a nurse or clinician, would have been advantageous.

The participating practices by and large did not have any population health infrastructure for an outreach screening program such as SATIS-PHI/CRC. To a large extent, the role of the SATIS-PHI/CRC central entity was to be that infrastructure for the practices: to take the place of having such an infrastructure at the practices. However, in addition to an implementation infrastructure, interventions such as SATIS-PHI/CRC benefit from a public health culture within the practices. The central entity could not compensate for the lack of such a culture in many of the participating practices.

Even though the central entity provided the infrastructure for screening outreach, the practices still needed to cooperate by providing clean and up-to-date patient population data to feed into that infrastructure (for record review, mailings to patients, and tracking screening) and to use the feedback and tracking tools and aids made available to them by the central entity. To do so, the practices would have needed to place a higher priority on these activities than they appeared

willing or able to do without a strong public health culture. As reported in our preliminary report (Harris and Borsky, 2009), the results of the preintervention survey indicated that the more public health-oriented steps in the screening process were not performed in many intervention practices. Academic detailing could perhaps be expanded in future implementation of SATIS-PHI/CRC to include inculcating a public health culture.

Health information technology personnel at LVPHO and at participating practices were not familiar with the types of queries required to identify eligibility for SATIS-PHI/CRC. They found it difficult to extract the required information from their electronic systems. The required queries were more prospective (who needs to be screened) than retrospective (who was screened) in nature, and they were more familiar and comfortable with retrospective queries. Those practices using billing data for eligibility found it difficult to extract population data for this purpose.

Several data analysis and programming personnel providing data for the electronic record review left their jobs shortly after the initial eligibility review. Their replacements chose not to use the data extraction programs written by them, resulting in the need for these programs to be rewritten. This task delayed our ability to obtain ongoing updated data (i.e., screening results).

PRISM Outcome Domain

Adoption

LVHN study staff recruited 25 primary care practices (20 intervention and 5 control), with a total of 100 providers (81 intervention and 19 control) to participate in the SATIS-PHI/CRC intervention. Subsequent to recruitment and allocation to study arm, but prior to the start of the intervention (during the time period of waiting for OMB clearance), 5 practices assigned to the intervention arm, with a total of 17 providers, dropped out. Thus, we had only 15 intervention practices with 64 providers to participate in SATIS-PHI/CRC; none of the control practices dropped out.

To recruit these practices, LVHN study staff needed to contact 43 practices, for a successful recruitment rate of 20/43 or 46.5 percent.[xv] Table 4.3 presents the number and distribution of the 25 intervention, dropout, and control practices and their providers, by affiliation, specialty, size, and location of the practice. These distributions by attribute for intervention and control practices are generally comparable without inclusion of the dropout practices.

To assess the representativeness of the practices participating in the SATIS-PHI/CRC intervention relative to the pool of practices in the LVPHO pool from which we recruited, we compared the distribution of practices in the pool and in the intervention. Table 4.4 presents this comparison for practices classified by affiliation (the only practice attribute for which we had comparison data). We recruited and included all three of the LVHN clinics in the pool to ensure inclusion of the urban core and a sufficient number of Medicaid and uninsured patients. LVPG

[xv] LVHN study staff actually contacted 44 practices and recruited 26 of them: 25 for allocation to a study arm and one to be the site of the pilot intervention.

practices are also overrepresented, and MATLV and independent practices are underrepresented, largely because LVPG practices were more willing to participate than were the others.

Based on information provided by LVHN study staff, we know that several practices approached during the recruitment process were reluctant to participate given the stringent economic environment and current transitions to EMR systems. They feared that participation would require too many resources, whether financial, information technology, or staff time. This fear was especially prominent among practices not owned or operated by LVHN. Similarly, the practices that initially agreed to participate but later dropped out said that they were too busy or too short staffed and they would need to be compensated for the time they spent participating. One dropout practice was sold to a competing network after agreeing to participate and thus no longer met the eligibility criteria for participation.

Table 4.3. Number and Percentage* Distribution of Intervention and Control Practices and Their Providers,† Recruited To Participate in the SATIS-PHI/CRC Intervention

	Intervention Group				Intervention Dropouts				Control Group			
	Practices		Providers		Practices		Providers		Practices		Providers	
Attribute	#	%	#	%	#	%	#	%	#	%	#	%
Total	15	100.0	64	100.0	5	100.0	17	100.0	5	100.0	19	100.0
Affiliation												
LVHN clinic	2	13.3	11	17.2	0	0.0	0	0.0	1	20.0	5	26.3
LVPG	7	46.7	34.5	53.9	3	60.0	10	58.8	2	40.0	4	21.1
MATLV	2	13.3	4.5	7.0	2	40.0	7	41.2	1	20.0	4	21.1
Independent	4	26.7	14	21.9	0	0.0	0	0.0	1	20.0	6	31.6
Specialty												
Family medicine	12	80.0	45	70.3	3	60.0	8	47.1	3	60.0	8	42.1
General internal medicine	3	20.0	19	29.7	2	40.0	9	52.9	2	40.0	11	57.9
Size												
Small	8	53.3	19.5	30.5	3	60.0	7	41.2	2	40.0	4	21.1
Large	7	46.7	44.5	69.5	2	40.0	10	58.8	3	60.0	15	78.9
Location												
Urban	3	20.0	12	18.8	1	20.0	4	23.5	1	20.0	5	26.3
Suburban	8	53.3	37.5	58.6	4	80.0	13	76.5	3	60.0	12	63.2
Rural	4	26.7	14.5	22.7	0	0.0	0	0.0	1	20.0	2	10.5

* Percentages may not add to 100 due to rounding.
† Providers can be physicians or nurse practitioners/advanced practice nurses and physician assistants who can see patients on their own during an office visit and who can maintain a panel of patients.

Table 4.4. Distribution of LVPHO Practices in Recruitment Pool and Practices Participating in the SATIS-PHI/CRC Intervention, by Practice Affiliation

	LVPHO Practices		Practices Participating in SATIS-PHI/CRC					
			Intervention		Control		All	
Practice Affiliation	#	%	#			%	#	%
LVHN clinic	3	2.7	2	13.3	1	20.0	3	15
LVPG	18	16.2	7	46.7	2	40.0	9	45
MATLV	26	23.4	2	13.3	1	20.0	3	15
Independent	64	57.7	4	26.7	1	20.0	5	25
All	111	100.0	15	100.0	5	100.0	20	100.0

Implementation

Overall, our intervention had high program fidelity, as we were able to implement most intervention elements as planned. We successfully recruited all 26 practices (1 for the pilot, 20 for the intervention, and 5 for the control). As previously noted, five intervention practices dropped out after recruitment but prior to the start of the intervention. We also were able to successfully recruit a stool test kit supplier for the intervention.

We were successful in conducting academic detailing in all of our intervention practices. We found it easier to schedule academic detailing sessions in some of the practices than others, but all were scheduled and completed as planned. We also had planned to conduct academic detailing sessions in the control practices at the end of the intervention period. Due to time and budget limitations, we were not able to roll out the intervention to all control practices. But the central entity still plans to distribute the intervention toolkit and other intervention materials to the control practices at the end of the study.

As noted, we needed to conduct an academic detailing booster to further emphasize guideline-recommended screening modalities. We disseminated this booster successfully. In addition, based on lessons learned from the pilot, we disseminated a packet of information to office managers explaining their role and what they needed to do, including what to do with the stool test kits. However, we learned that the office manager did not always distribute this information to others in the practice, so there was some lingering confusion.

We also were successful in conducting our electronic record reviews, although our experience varied by practice and by data source. The central entity had a more difficult time conducting the electronic record reviews in some practices than others. This problem caused us to send the patient mailings in several waves, depending on the patient mailing lists that were available.

In addition, the central entity could not retrieve complete lists of all age- and screening-eligible patients from each practice. Some practices could only provide a list of PHO-insured patients. One practice could not link its patient lists with its PHO insurance data, so it could not tell who was a PHO patient and who was not. Therefore, the final list of study participants was not a complete list of all age- and screening-eligible patients in these practices; it was a subset based on available data. As we have noted, the organization was not accustomed to population-based

public health interventions of this magnitude, which affected their ability to conduct the electronic record reviews.

We were able to mail all intervention materials to eligible patients, and we were able to mail stool test kits to all patients who requested one. However, there were times when patients responded to the SEA indicating they did not want to participate but the subsequent mailing was already on its way. We also experienced some delays in sending out the patient mailings, due to a greater than originally anticipated labor requirement to generate and disseminate the mailings. Finally, we found that the SEA was successful in identifying patients who were not eligible for the intervention.

For tracking patients and their screening results, we successfully implemented the intervention, but these elements of the intervention did not always produce the planned outcomes. For example, we provided a Screening Tracking Sheet to the office manager of each practice. However, we know that none of the practices used this tool to track their patients. Some practices used their own methods for tracking, but there were no practices that were able to share these methods with us. We were able to conduct nearly all the chart audits as planned. In a few cases, charts were not available for auditing.

For our final intervention step, providing feedback to practices, we successfully sent all Feedback Forms to the practices as intended. The stool test lab also sent all results directly to each practice. We reviewed the records and found that all patients with positive stool tests were notified of their results and followup was recommended or performed. However, the central entity performed these reviews manually, as there was no way to systematically search the electronic records for this information. For negative screening results, we could not determine if all patients were notified by their practice, becuase this information was not readily available in the data sources.

Maintenance

In terms of ongoing maintenance of the intervention, based on our informal conversation with LVHN, their organization's leadership is interested in adopting this intervention as part of its future patient-centered medical home efforts. Their leadership was originally focused on chronic disease registries, but they are now looking at screening, especially CRC. It is likely that this intervention will become part of the organization's wider medical home efforts.

Based on the postintervention practice focus groups, some of the practice respondents said the intervention had not changed the way in which they practiced. Others said that it had increased their awareness or convinced them to use the FIT and other new screening modalities. One respondent said that the intervention had stimulated more tracking of individual patients who began the screening process. Many of the focus group participants said they did not know the true impact of the intervention yet. However, most said they would participate in the intervention again if given the opportunity.

While we have minimal data in terms of patient maintenance, we did receive a response from the patient focus groups that indicated the patient was interested in continuing the intervention next year. The patient wanted to be able to receive another stool test kit request card without

having to go to the doctor. In the future, one way to accurately assess patient maintenance would be to see if patients who screened by stool test this year continue to rescreen annually.

Reach

A total of 10,627 patients participated in the SATIS-PHI/CRC intervention, 7,965 in either of the two intervention arms and 2,662 in the control arm (Figure 3.1 and Table 4.2). An initial pool of 12,808 patients was identified as potentially eligible based on an initial review of available electronic records. We deemed a total of 10,982 patients to be eligible for participation. From that group, we excluded 355 patients based on their opting out of the intervention or our inability to deliver intervention material to them by mail.

The 10,627 participants are 96.8 percent of deemed eligible patients and 83.0 percent of all initial potentially eligible patients. The initial pool of 12,808 patients may not be fully representative of the target population of all potentially eligible patients within LVPHO primary care practices. The practices participating in the intervention are not fully representative of all LVPHO primary care practices and several participating practices were not able to provide all of the electronic data required for identifying all of their potentially eligible patients (Table 3.1).

The flow diagram in Figure 3.2 illustrates the reasons for eliminating potentially eligible patients from the initial pool. Table 4.5 presents a more detailed look at eliminated patients. We eliminated some patients because we deemed them to be ineligible based on subsequent review of electronic records, charts audits, or responses to the SEA form. Others were eligible but excluded because they opted out or had undeliverable addresses (and thus could not participate in a mailed intervention).

We eliminated equivalent proportions of intervention and control group patients as ineligible based on electronic records and chart audits. We eliminated additional intervention group patients as ineligible based on responses to the SEA form, a source not available to control group patients to whom we did not mail SEA forms. Further, we excluded otherwise eligible intervention patients (but not control patients) based on sources not available to control patients. These additional sources of elimination may have caused the intervention and control groups to lose comparability.

Table 4.5. Elimination of Patients From Initial Pool of Potentially Eligible Intervention and Control Group Patients, by Source of Elimination

Source of Elimination	Intervention Group (10,063 Initially Eligible)		Control Group (2,745 Initially Eligible)	
	N	%	N	%
Ineligibility				
Electronic record	328	3.3	60	2.2
Chart audit	73	0.7	23	0.8
SEA form	1,342	13.3	—	—
All ineligible	1,743	17.3	83	3.0
Exclusion				
Opted out	300	3.0	—	—
Undeliverable	55	0.5	—	—
All excluded	355	3.5	—	—

Table 4.6 addresses the representativeness of intervention group patients who participated in SATIS-PHI/CRC by comparing their distribution on various attributes to intervention group patients whom we deemed to be ineligible or whom we excluded. Compared to participating patients, excluded patients were more likely to be female, older, and Medicare insured whereas deemed ineligible patients were largely comparable. All three groups were generally comparable on practice characteristics.

Table 4.6. Comparison of Percentage* Distribution of Intervention Group Patients Who Participated In, Were Deemed Ineligible For, or Were Excluded From SATIS-PHI/CRC on Selected Patient and Practice Attributes

Attribute	Participating		Deemed Ineligible		Excluded	
	%	Adj % [a]	%	Adj % [a]	%	Adj % [a]
Total Population	100.0	100.0	100.0	100.0	100.0	100.0
Patient Characteristics						
Gender						
Male	42.6	44.5	40.5	44.9	35.5	36.3
Female	53.1	55.5	49.7	55.1	62.3	63.7
Unknown	4.3	—	9.8		2.3	—
Age						
50-54	26.4	26.4	20.4	20.4	16.1	16.1
55-64	42.3	42.3	42.9	42.9	34.1	34.1
65-69	12.5	12.6	16.1	16.1	16.3	16.3
70-79	18.8	18.8	20.5	20.5	33.5	33.5
Unknown	0.0	—	0.0	—	0.0	—
Insurance						
Commercial and other	57.9	63.3	52.5	59.9	48.2	52.3
Medicare	26.2	28.6	28.6	32.7	41.7	45.3
Self/Medicaid	7.4	8.1	6.6	7.5	2.3	2.4
Unknown	8.6	—	12.3	—	7.9	—
Practice Characteristics						
Practice affiliation						
Clinic	17.8	—	19.3	—	5.4	—
LVPG	76.0	—	68.4	—	89.9	—
Independent+MATLV	6.2	—	12.3	—	4.8	—
Specialty						
Family medicine	90.0	—	82.0	—	93.0	—
General internal medicine	10.0	—	18.0	—	7.0	—
Size						
Large	58.8	—	60.4	—	54.1	—
Small	41.2	—	39.6	—	45.9	—

* Percentages adjusted for missing (unknown) data on patient characteristics. Some percentages may not add to 100 due to rounding.

Finally, Table 4.7 addresses representativeness by comparing the practice affiliation of all LVPHO patients ages 50-79 to intervention and control group patients included in the SATIS-PHI/CRC study. These distributions are not comparable for two reasons. First, we purposively sampled practices to ensure inclusion and a balanced proportion of each practice affiliation type in intervention and control arms of the study. Second, practices varied in their ability to provide electronic records data on their patients. In particular, patients from hospital clinics were overrepresented in the study. Especially in the control arm, patients of LVPG practices were also overrepresented in the study, and MATLV and other independent practices were underrepresented.

Table 4.7. Percentage* Distribution of LVPHO Patients (Ages 50-79) and Study Patients, by Practice Affiliation

Practice Affiliation	LVPHO Patients Ages 50-79	Study Patients	
		Intervention	Control
Hospital clinic	4.9	17.8	34.9
LVPG	32.3	76.0	61.8
MATLV	36.6	0.8	1.9
Independent	26.1	5.4	1.3
All	100.0	100.0	100.0

* Some percentages do not add exactly to 100 due to rounding.

Effectiveness

We assessed the effectiveness of the SATIS-PHI/CRC intervention by studying its effect on the screening rate for CRC, followup rate for positive screens, and provider and practice behavior.

CRC Screening Rates

Table 4.8 presents results comparing intervention group and control group CRC screening rates for stool test, colonoscopy, and any modality. It also includes results comparing screening rates for patients randomized to receive the stool test kit directly and those randomized to receive a mail-back card to request a kit. The table presents results separately for:

1. All participating practices,
2. Only the two intervention practices in which patients were randomized,
3. Only those practices with the most complete or moderately complete electronic data, and
4. Only those practices with EMR systems used for electronic record review.

We conducted the latter two analyses with only practices having more complete electronic data and EMR systems in order to exclude practices in which detecting colonoscopy screening was more problematic due to incomplete or less detailed data. We expected this data deficiency to affect our ability to detect colonoscopies, because we could only detect them through electronic records or chart audits. We did not expect it to affect our ability to detect stool test screens, because the participating clinical lab reported FIT results directly to us.

Results for all practices and for practices with more complete electronic data include a comparison of the intervention group to the control group using an "adjusted" control group denominator. We adjusted these denominators to account for lack of information from the SEA form, undeliverable mailings, and opt-outs that we had for intervention patients. The adjustment consisted of reducing the denominator (number of eligible participants) of control practices by a number proportionate to the number of SEA-ineligible, undeliverable, and opt-out patients in intervention practices. We then used this reduced denominator for purposes of this analysis only.

Results for the two practices with randomized patients only include a comparison of the kit intervention group to the card intervention group because neither is a control group practice. Results for practices with more complete electronic data and with EMR systems only include a comparison of the card intervention to the control because these practices do not include those with patients randomized to receive the kit intervention. We adjusted all odds ratio (OR) confidence intervals (CIs) and p values in Table 4.8 for possible clustering effects of assigning an entire practice's patients to intervention or control study groups. For all practices, both card intervention patients and kit intervention patients had significantly higher odds of having a stool test and of having any screening test compared to controls. This result persisted even after adjusting the control group denominator.

Although card intervention patients had somewhat higher odds than controls to be screened by colonoscopy, this result was not statistically significant. Our ability to detect colonoscopies in the practices with poorer data affected this result, as revealed in the results of the analyses restricted to practices with better data. For these better data practices, the ORs all improve in favor of the intervention group relative to the "all practices" ORs and in several instances are significant at the $p<0.10$ level.

Kit intervention patients, who all came from practices with poorer data for colonoscopy, had significantly lower odds of being screened by colonoscopy than did controls but this result is almost certainly a result of the poorer data. An alternative explanation could be that directly providing the test kit to patients increases the odds that stool test rather than colonoscopy will be the screening modality used.

In general, these OR results comparing intervention patients to controls are indicative of the intervention's effectiveness. The Table 4.8 ORs for any screening test are all statistically significant and compare favorably with the OR reported in the study on which we based the screening intervention portion of SATIS-PHI/CRC (Myers, et al., 2007). A comparison of the card intervention and the kit intervention with controls yields overall ORs for all practices for any screening test of 2.31 (CI=1.39-3.85) and 2.16 (CI=1.40-3.35), respectively.

The OR reported by the comparison study for the standard intervention[xvi] was 1.68 (CI=1.25-2.53). Our ORs decrease somewhat when we adjust the control group denominator (1.89 and 1.77 for the card and kit interventions, respectively) but remain significant and comparable to the OR reported by Myers, et al. (2007). Further, our ORs for practices with better data for detecting colonoscopies are somewhat higher than for all practices.

These effectiveness ORs presented in Table 4.8 would likely have been even higher if we had been able to send stool test kits directly to all intervention patients rather than having to use a card intervention for most of them. Within the two practices with randomized patients, those receiving the kit directly were 3 times more likely to be screened by stool test (OR=3.16; CI=2.40-4.16) compared to those having to mail back a card to request a kit. Kit intervention patients were also 2½ times more likely to be screened by any test (OR=2.53; CI=2.14-3.00). This result strongly suggests that had we used the kit intervention exclusively, the intervention would have been more effective overall.

Regardless of the OR results, the actual screening rates observed were substantially lower than we expected and substantially lower than those reported by Myers, et al. (2007). According to Table 4.8, screening rates by any test were 8.6 percent for card intervention patients and 8.1 percent for kit intervention patients (with a combined rate of 8.5 percent) and 4.7 percent for control patients using the adjusted denominator. By comparison, the Myers, et al., study reported screening rates of 46 percent for the standard intervention group and 33 percent for controls.

There are several potential reasons for our lower observed screening rates. Our measurement of screenings was not as robust as in the comparison study. We know that we have both numerator (detecting screenings) and denominator (detecting and eliminating ineligible subjects) errors involving both intervention and control patients. The original study was able to more closely review existing medical record and administrative data (and to conduct telephone interviews with patients) to identify truly eligible patients and to case find screenings. Further, to qualify for inclusion in that study, patients had to not only be eligible for screening but also had to complete a baseline survey and thus to have already indicated a willingness to participate.

Another reason is that our intervention and observation period was much shorter than in the original study. We implemented a single round of the SATIS-PHI/CRC intervention and observed subsequent screenings over an 8-month period. The original study implemented two successive rounds of intervention and observed subsequent screenings over a 24-month period.

A third potential reason is the nature of the study setting. The original study was based in a medical school-run teaching clinic that is very different than community practices. It is likely that offering screening to patients is taught as a recommended behavior in the medical school teaching clinic. The original study's control group screening rate was 33 percent compared with under 5 percent for the Lehigh Valley practices.

[xvi] The Myers, et al. (2007) study implemented a standard intervention and two more tailored interventions. They found that the more tailored interventions did not achieve higher screening rates than the standard intervention alone. We thus based SATIS-PHI/CRC on the standard intervention.

Table 4.8. Effect Size of SATIS-PHI/CRC Intervention on Screening Rates

Study Group	N	Stool Test					Colonoscopy					Any Screening Test[a]				
		% Screened	OR	95% CI		p	% Screened	OR	95% CI		p	% Screened	OR	95% CI		p
All Practices																
Control	2,662	0.56	—	—	—	—	3.31	—	—	—	—	3.91	—	—	—	—
Card intervention	7,495	4.16	7.66	1.68	35.04	0.009	4.52	1.39	0.61	3.17	0.439	8.59	2.31	1.39	3.85	0.001
Kit intervention	470	7.66	14.64	3.24	66.04	0.000	0.43	0.13	0.04	0.42	0.001	8.09	2.16	1.40	3.35	0.001
Adjusted Control Group Denominator[b]																
Control	2,199	0.68	—	—	—	—	4.00	—	—	—	—	4.73	—	—	—	—
Card intervention	7,495	4.16	6.32	1.36	29.31	0.018	4.52	1.14	0.50	2.58	0.760	8.59	1.89	1.14	3.13	0.013
Kit intervention	470	7.66	12.08	2.64	55.25	0.001	0.43	0.10	0.03	0.34	0.000	8.09	1.77	1.15	2.72	0.009
Practices With Patients Randomized to Card or Kit Intervention[c]																
Card intervention	1,877	2.56	—	—	—	—	0.80	—	—	—	—	3.36	—	—	—	—
Kit intervention	470	7.66	3.16	2.40	4.16	0.000	0.43	0.53	0.20	1.42	0.207	8.09	2.53	2.14	3.00	0.000
Practices With More Complete Electronic Data[d]																
Control	2,662	0.56	—	—	—	—	3.31	—	—	—	—	3.91	—	—	—	—
Intervention[e]	5,104	4.57	8.44	1.84	38.73	0.006	6.27	1.96	0.95	4.03	0.069	10.68	2.94	1.94	4.46	0.000
Adjusted Control Group Denominator[b]																
Control	2,199	0.68	—	—	—	—	4.00	—	—	—	—	4.73	—	—	—	—
Intervention[e]	5,104	4.57	6.96	1.50	32.40	0.013	6.27	1.60	0.78	3.28	0.195	10.68	2.41	1.60	3.62	0.000
Practices With EMR Systems Only[f]																
Control	2,576	0.54	—	—	—	—	3.18	—	—	—	—	3.77	—	—	—	—
Intervention[e]	4,950	4.57	8.75	1.66	46.23	0.011	6.06	1.96	0.90	4.27	0.090	10.46	2.99	1.93	4.61	0.000

[a] Includes stool test, colonoscopy, flexible sigmoidoscopy, or barium enema x ray. Persons with screens by multiple modalities are counted only once.
[b.] Control group denominator adjusted for information not obtained by SEA form or by mailings returned as undeliverable.
[c.] Includes only patients from the two intervention practices randomized to either receiving the kit directly or having to request it with a reply card.
[d.] Includes only those practices with most complete or moderately complete electronic data; excludes practices IAA, IHD, and ISA with least complete data.
[e.] Includes only patients receiving card intervention for stool test; patients receiving kit intervention excluded because of being from excluded practices.
[f.] Includes only those practices with EMR systems used for electronic record review.
Note: Odds ratio confidence intervals and p values have been adjusted using cluster variance estimators.

Even though our observed screening rates were substantially lower than those reported by the Myers, et al., study, the percentage increase, as reflected in the ORs, we observed exceeded that of the earlier study. The intervention group in the Myers, et al., study screened at a rate about 40 percent higher than controls (46 percent compared to 33 percent). Our intervention group screened at a rate 81 percent higher than controls (8.5 percent compared to 4.7 percent). In general, we conclude that our implementation of the SATIS-PHI/CRC intervention in Lehigh Valley primary care practices achieved screening rate outcomes that were comparable with those of the study used as the basis of our intervention.

We also calculated age-sex standardized screening rates to adjust for differences in age-sex distributions between intervention and control groups. Table 4.9 displays the results. Even after controlling for age and sex through standardization, the screening rates for both intervention groups significantly exceed those of the control group for screening by stool test and any test. The card intervention group colonoscopy screening rate also exceeds that of the control group. As was true for the unstandardized results in Table 4.8, the age-sex standardized colonoscopy screening rates for the kit intervention group is significantly lower than that of the control group for the same likely reasons as cited above for the Table 4.8 OR results.

Table 4.9. Age-Sex Standardized Screening Rates[a]

Study Group	N[c]	Stool Test		Colonoscopy		Any Screening Test[b]	
		% Screened	p[d]	% Screened	p[d]	% Screened	p[d]
Control	2,643	0.56	—	3.32	—	3.91	—
Card intervention	7,213	4.11	0.000	4.62	0.005	8.64	0.000
Kit intervention	407	6.92	0.000	0.20	0.000	7.13	0.003

[a] We standardized the age-sex distributions of each study group to that of the July 1, 2008, estimated U.S. resident population (U.S. Census Bureau, 2009).
[b] Includes stool test, colonoscopy, flexible sigmoidoscopy, or barium enema x ray. People with screens by multiple modalities are counted only once.
[c] The number of age-standardized patients in each study group is lower than the total number of patients in each group due to missing age and sex data. There were 19 control patients with missing age data, 2 card-intervention patients with missing age data and 280 with missing sex data, and 63 kit-intervention patients with missing sex data.
[d] We used a two-sample test of proportions to compare the control and card-intervention, and control and kit-intervention groups, respectively.

We investigated the effect of returning a completed SEA form on screening. Since only intervention patients received an SEA form, we could not include control patients in this analysis. Table 4.10 shows that the 1,131 intervention patients who returned a completed form (out of the 7,965 study-eligible patients to whom we sent one by mail) were significantly more likely to be screened by stool test (OR=5.90, CI=4.73-7.36), colonoscopy (OR=5.60, CI=4.48-7.01), or any test (OR=6.66, CI=5.63-7.87).

Returning an SEA form likely indicates an interest in or willingness to participate in a screening program. This result also suggests that capturing patient interest through a motivating introductory letter and getting them involved with the intervention effort early in the process with the simple SEA form could increase screening rates. Note that the screening rate for any screening test for patients responding to the SEA form (27.59 percent) more closely

approximates the rate reported by the Myers, et al., study that required patients to have completed a baseline survey in order to qualify for inclusion.

Table 4.10. Effect of Returning Completed SEA Form on Screening

Returned Completed SEA Form	N[a]	% Screened	OR	95% CI		p
Stool Test						
No	6,834	2.74	—	—	—	—
Yes	1,131	14.24	5.90	4.73	7.36	0.000
Colonoscopy						
No	6,834	2.74	—	—	—	—
Yes	1,131	13.62	5.60	4.48	7.01	0.000
Any Screening Test[b]						
No	6,834	5.41	—	—	—	—
Yes	1,131	27.59	6.66	5.63	7.87	0.000

[a.] This analysis only includes intervention patients; control patients did not receive an SEA form to complete and return.
[b.] Includes stool test, colonoscopy, flexible sigmoidoscopy, or barium enema x ray. People with screens by multiple modalities are counted only once.

We also investigated the variation in screening rates by practice. Table 4.11 presents the results. For this analysis, we excluded from the study the two control practices and five intervention practices that each had fewer than 60 patients because of the statistical instability of rates with small denominators. We also excluded the three intervention practices that had poor colonoscopy data from the analysis of colonoscopy screening rates. We separately calculated rates for control practices using unadjusted and adjusted denominators.

To help maintain comparability between intervention practice stool test screening rates, we kept the rates for card intervention patients separate from those for kit intervention patients in the two practices with patients randomized between interventions. We only compared the card rates in these practices to those in the other intervention practices. To assess variation within intervention practices and within control practices, we calculated group means and standard deviations for intervention practices and for control practices for each screening modality. We then computed a coefficient of variation (CV, equal to the standard deviation divided by the mean) for them. To assess variation between intervention and control practices, we calculated a comparison of means for them using an F test to estimate the statistical significance of any differences.

There is generally substantial variation between practices, with CVs ranging from 0.23 to over 1.4. The intervention group means are all considerably higher than the control group means for each modality and the difference between means in each case is statistically significant. On average, intervention group rates are significantly higher than control group rates.

Table 4.11. CRC Screening Rates by Practice[a]

Practice	Stool Test Screening Rate		Colonoscopy Screening Rate		Any Test Screening Rate[b]	
	Unadjusted	Adjusted	Unadjusted	Adjusted	Unadjusted	Adjusted
Control Practices						
CHA	0.00	0.00	4.14	5.01	4.28	5.17
CHB	0.00	0.00	4.57	5.53	4.57	5.53
CUA	1.51	1.82	1.08	1.30	2.58	3.12
Mean	0.50	0.61	3.26	3.95	3.81	4.61
Std dev	0.71	0.86	1.55	1.88	0.88	1.06
CV	1.42	1.41	0.48	0.48	0.23	0.23
Intervention Practices						
IAA[c, d]			—	—	—	—
Card	2.07	—				
Kit	6.86	—				
IHA	4.16	—	6.47	—	10.39	—
IHD[c]	6.03	—	—	—	—	—
IHE	3.44	—	8.52	—	11.89	—
IHF	4.68	—	6.34	—	11.02	—
IHH	7.53	—	5.77	—	12.82	—
IHI	3.83	—	10.69	—	14.52	—
ISA[c, d]			—	—	—	—
Card	5.36	—				
Kit	12.90	—				
IUA	3.40	—	1.70	—	5.10	—
IUB	5.03	—	4.70	—	9.40	—
Mean			6.31	—	10.73	—
Std dev			2.62		2.77	
CV			0.42		0.26	
Card mean	4.55					
Std dev	1.46					
CV	0.32					
Kit mean	9.88					
Comparison of Means[e]						
p value			0.132	0.242	0.005	0.010
Card	0.001	0.002				
Kit	0.028	0.030				

[a] We excluded practices with fewer than 60 study participants from this comparison of practice screening rates.
[b] Includes stool test, colonoscopy, flexible sigmoidoscopy, or barium enema x ray. Persons with screens by multiple modalities are counted only once.
[c.] Incomplete colonoscopy screening data were available for these practices, so we do not report their colonoscopy screening rates or include them in calculating an intervention group mean for colonoscopy or any test.
[d] We randomized patients in these practices to either the card or kit intervention arm. The card intervention stool test rates for these practices are averaged along with the stool test rates of the other intervention practices to produce the card intervention stool test mean. The kit intervention stool test rates for these practices are separately averaged by themselves to produce the kit intervention stool test mean.
[e] Reported p values are for F ratios associated with a comparison of unadjusted intervention group means with both unadjusted and SEA adjusted control group means, respectively, by screening modality and, for stool test rates, stool test intervention arm.

The next set of five tables (Tables 4.12-4.16) present bivariate and multivariate logistic regression analyses of CRC screening by stool test, colonoscopy, and any test. The first three tables present results for analyses of patients exposed to the SATIS-PHI/CRC intervention to indicate what types of patient and practice characteristics are associated with a greater or lesser likelihood of being screened by a given modality. Table 4.12 presents the bivariate results for six patient characteristics and five practice characteristics. For three of the patient characteristics (marital status, perceived health status, and education), we only had data for a limited subset of patients, so we excluded them from the multivariate analyses. All of the clinic practices were urban, making it inadvisable to include both practice affiliation and location in multivariate models. We decided to include location and exclude affiliation.

Table 4.13 presents the full multivariate model for each screening modality, incorporating the three patient characteristics for which we had data for more than just a subset of patients and the four remaining practice characteristics after we eliminated affiliation. Table 4.14 presents a reduced model incorporating only those characteristics found to be statistically significant at the $p<0.10$ level for a given modality in the full multivariate model. We included the data source characteristic for practices in the reduced model regardless of whether it was significant in the full model for a given modality because we wanted to be certain to control for data quality. Both of the multivariate tables present Hosmer-Lemeshow X^2 goodness of fit tests along with odds ratios for the screening tests.

The next two tables present similar multivariate analyses but also include study arm as a practice characteristic. These analyses allowed us to assess the effectiveness of the intervention by examining the ORs by each intervention arm relative to the control arm. As with the intervention practice analyses only, Table 4.15 presents the full multivariate model and Table 4.16 presents the reduced model. However, since we did not have insurance coverage data for control patients, we could not include that characteristic in these models. As with the previous multivariate model tables, these tables present Hosmer-Lemeshow X^2 goodness of fit tests along with odds ratios.

The bivariate results presented in Table 4.12 suggest that for stool tests, older patients and those insured through Medicare are more likely to be screened than younger patients or those insured through other health plans. Single patients are less likely to screen than married patients, and patients attending hospital clinic practices are less likely to screen than those attending independent practices.

For colonoscopy, the results show that women are somewhat more likely to be screened than men; Medicaid and uninsured/self-pay patients are less likely to screen than those with commercial insurance; single patients are less likely to screen than married patients; patients attending general internal medicine practices are more likely to screen than those attending family medicine practices; patients attending large practices are more likely to screen than those attending small practices, and patients attending suburban practices are somewhat more likely to screen than those attending urban practices. In addition, as expected, the completeness of colonoscopy data affects the likelihood of detecting screening by this modality.

Table 4.12. Screening Rate Bivariate Logistic Regression, Intervention Practices Only (page 1 of 3)

Characteristic	N	Stool Test				
		% Screened	OR	95% CI		p
Patient Characteristics						
Gender						
Male	3,395	4.12	—	—	—	—
Female	4,227	4.38	1.06	0.85	1.33	0.587
Age						
50-54	2,099	3.33	—	—	—	—
55-64	3,369	3.89	1.17	0.87	1.58	0.291
65-69	999	5.61	1.72	1.20	2.47	0.003
70-79	1,496	6.08	1.88	1.36	2.58	0.000
Insurance						
Commercial and other	4,612	4.08	—	—	—	—
Medicare	2,083	5.57	1.39	1.09	1.76	0.007
Self-insured/Medicaid	587	2.73	0.66	0.39	1.11	0.115
Marital status[a]						
Married	2,405	6.40	—	—	—	—
Divorced	813	7.26	1.14	0.84	1.56	0.398
Single	634	4.42	0.68	0.45	1.02	0.062
Health status[a]						
Fair/poor	203	10.84	—	—	—	—
Good	500	15.80	1.54	0.93	2.55	0.091
Excellent/very good	388	14.18	1.36	0.80	2.30	0.254
Education[a]						
High school/GED or less	508	15.94	—	—	—	—
Some college or higher	586	12.80	0.77	0.55	1.09	0.138
Practice Characteristics						
Practice affiliation						
Independent	429	6.06	—	—	—	—
Clinic	1,416	3.74	0.60	0.43	0.85	0.004
LVPG	6,053	4.38	0.71	0.45	1.11	0.134
MATLV	67	5.97	0.98	0.23	4.19	0.983
Specialty						
Family medicine	7,171	4.38	—	—	—	—
General internal medicine	794	4.28	0.98	0.67	1.42	0.902
Size						
Small	3,279	3.96	—	—	—	—
Large	4,686	4.65	1.18	0.71	1.96	0.517
Location						
Urban	1,779	3.93	—	—	—	—
Rural	3,465	4.50	1.15	0.62	2.14	0.658
Suburban	2,721	4.48	1.15	0.79	1.67	0.477
Data Source[b]						
Least complete	2,861	4.02	—	—	—	—
Moderately complete	154	4.55	1.14	0.42	3.11	0.802
Most complete	4,950	4.57	1.14	0.65	1.99	0.639

[a] Data for these characteristics based only on subset of the population. Marital status data come from responses to SEA form and, where available, from patient records. Education and health status data come from responses to SEA form.

[b] This variable reflects the amount of screening information available for patients of a given practice. It is not an indicator of predicting screening. Instead, this variable will be used in the multivariate analyses to control for the fact that some practices had more complete data than others.

Note: For practice characteristics, confidence intervals and p values have been adjusted using cluster variance estimators.

Table 4.12. Screening Rate Bivariate Logistic Regression, Intervention Practices Only (page 2 of 3)

Characteristic	N	Colonoscopy				
		% Screened	OR	95% CI		p
Patient Characteristics						
Gender						
Male	3,395	3.98	—	—	—	—
Female	4,227	4.76	1.21	0.96	1.51	0.100
Age						
50-54	2,099	4.53	—	—	—	—
55-64	3,369	4.10	0.90	0.69	1.18	0.444
65-69	999	4.20	0.93	0.64	1.34	0.684
70-79	1,496	4.34	0.96	0.69	1.32	0.795
Insurance						
Commercial and other	4,612	5.03	—	—	—	—
Medicare	2,083	4.32	0.85	0.66	1.09	0.209
Self-insured/Medicaid	587	2.39	0.46	0.27	0.80	0.006
Marital status[a]						
Married	2,405	6.61	—	—	—	—
Divorced	813	5.54	0.83	0.59	1.16	0.277
Single	634	3.79	0.56	0.36	0.86	0.009
Health status[a]						
Fair/poor	203	10.34	—	—	—	—
Good	500	13.40	1.34	0.80	2.26	0.269
Excellent/very good	388	14.43	1.46	0.86	2.49	0.163
Education[a]						
High school/GED or less	508	13.19	—	—	—	—
Some college or higher	586	13.48	1.03	0.72	1.45	0.887
Practice Characteristics						
Practice affiliation						
Independent	429	4.66	—	—	—	—
Clinic	1,416	2.33	0.49	0.10	2.35	0.371
LVPG	6,053	4.68	1.00	0.20	5.13	0.997
MATLV	67	7.46	1.65	0.12	23.28	0.711
Specialty						
Family medicine	7,171	3.82	—	—	—	—
General internal medicine	794	8.44	2.32	0.94	5.70	0.067
Size						
Small	3,279	1.92	—	—	—	—
Large	4,686	5.93	3.22	0.97	10.64	0.055
Location						
Urban	1,779	3.15	—	—	—	—
Rural	3,465	2.89	0.91	0.22	3.74	0.901
Suburban	2,721	6.80	2.24	0.88	5.75	0.092
Data Source[b]						
Least complete	2,861	0.73	—	—	—	—
Moderately complete	154	12.99	20.18	7.98	51.03	0.000
Most complete	4,950	6.06	8.73	4.92	15.47	0.000

[a] Data for these characteristics based only on subset of the population. Marital status data come from responses to SEA form and, where available, from patient records. Education and health status data come from responses to SEA form.

[b] This variable reflects the amount of screening information available for patients of a given practice. It is not an indicator of predicting screening. Instead, this variable will be used in the multivariate analyses to control for the fact that some practices had more complete data than others.

Note: For practice characteristics, confidence intervals and p values have been adjusted using cluster variance estimators.

Table 4.12. Screening Rate Bivariate Logistic Regression, Intervention Practices Only (page 3 of 3)

Characteristic	N	Any Screening Test				
		% Screened	OR	95% CI		p
Patient Characteristics						
Gender						
Male	3,395	7.98	—	—	—	—
Female	4,227	9.06	1.15	0.98	1.35	0.095
Age						
50-54	2,099	7.67	—	—	—	—
55-64	3,369	7.90	1.03	0.84	1.27	0.763
65-69	999	10.01	1.34	1.03	1.74	0.029
70-79	1,496	10.29	1.38	1.10	1.74	0.006
Insurance						
Commercial and other	4,612	8.98	—	—	—	—
Medicare	2,083	9.89	1.11	0.93	1.33	0.233
Self-insured/Medicaid	587	4.94	0.53	0.36	0.78	0.001
Marital status[a]						
Married	2,405	12.85	—	—	—	—
Divorced	813	12.67	0.98	0.78	1.25	0.895
Single	634	8.20	0.61	0.45	0.82	0.001
Health status[a]						
Fair/poor	203	21.18	—	—	—	—
Good	500	29.00	1.52	1.03	2.24	0.035
Excellent/very good	388	28.09	1.45	0.97	2.18	0.069
Education[a]						
High school/GED or less	508	28.94	—	—	—	—
Some college or higher	586	25.94	0.86	0.66	1.12	0.267
Practice Characteristics						
Practice affiliation						
Independent	429	10.72	—	—	—	—
Clinic	1,416	6.00	0.53	0.28	1.00	0.051
LVPG	6,053	8.95	0.82	0.40	1.69	0.590
MATLV	67	13.43	1.29	0.16	10.27	0.809
Specialty						
Family medicine	7,171	8.12	—	—	—	—
General internal medicine	794	12.59	1.63	0.94	2.82	0.079
Size						
Small	3,279	5.89	—	—	—	—
Large	4,686	10.44	1.86	0.97	3.59	0.063
Location						
Urban	1,779	7.03	—	—	—	—
Rural	3,465	7.22	1.03	0.40	2.63	0.952
Suburban	2,721	11.28	1.68	1.00	2.85	0.052
Data Source[b]						
Least complete	2,861	4.79	—	—	—	—
Moderately complete	154	17.53	4.23	1.67	10.68	0.002
Most complete	4,950	10.46	2.32	1.36	3.97	0.002

[a] Data for these characteristics based only on subset of the population. Marital status data come from responses to SEA form and, where available, from patient records. Education and health status data come from responses to SEA form.

[b] This variable reflects the amount of screening information available for patients of a given practice. It is not an indicator of predicting screening. Instead, this variable will be used in the multivariate analyses to control for the fact that some practices had more complete data than others.

Note: For practice characteristics, confidence intervals and p values have been adjusted using cluster variance estimators.

Patients more likely to be screened by any modality include women, older patients, those who perceive their health to be excellent/very good or good, and those attending general internal medicine practices, large practices, and suburban practices. Patients less likely to be screened by any modality include uninsured/self-pay patients, single patients, and patients attending hospital clinic practices. As with the results for colonoscopy, data completeness affects the likelihood of detecting screening by any means.

The multivariate results in Tables 4.13 and 4.14 reveal that gender is not significant for stool test screening but is for colonoscopy. Conversely, age is significant for stool testing but not for colonoscopy. Medicaid/self-pay patients are less likely to be screened by stool test. Patients of larger practices are less likely to be screened by any modality whereas those of general internal medicine practices are more likely to be screened by colonoscopy. Practice location is significant for colonoscopy, with patients of nonurban practices being more likely to screen. Neither the full or reduced model for stool tests is a good fit (by the Hosmer-Lemeshow test) whereas those for colonoscopy and any test are good fits.

Tables 4.15 and 4.16 reveal that even after statistically controlling for patient and practice characteristics, receiving the intervention significantly increases the odds of being screened for CRC. Both the full and reduced models were a good fit based on the Hosmer-Lemeshow test, with the reduced model being a better fit for stool test screening and screening by any test and the full model being a better fit for colonoscopy screening.

In particular, both the card and the kit intervention have significantly large ORs relative to controls for stool testing in both the full and reduced models, and the card but not the kit intervention also has significantly large ORs relative to controls for colonoscopy in both models. The kit intervention had no significant impact on colonoscopy screening in either model, although those receiving the kit intervention did have a nonsignificant 1.5 times higher odds of colonoscopy screening relative to controls in the reduced model. The inability of the kit intervention to increase the odds of colonoscopy screening is most likely the result of the poor quality of the colonoscopy detection data available in the two practices whose patients received this intervention. Both interventions had significant effects on being screened by any test in both models.

Based on all of the above results for the effectiveness of SATIS-PHI/CRC to increase the odds of being screened for colorectal cancer, and in particular on the results of Tables 4.15 and 4.16, we conclude that the intervention was effective.

Table 4.13. Screening Rate Multivariate Logistic Regression, Intervention Practices Only: Full Model

Characteristics	Stool Test[a]				Colonoscopy[b]				Any Screening Test[c]			
	OR	95% CI		p	OR	95% CI		p	OR	95% CI		p
Patient Characteristics												
Gender												
Male	—	—	—	—	—	—	—	—	—	—	—	—
Female	1.05	0.87	1.27	0.585	1.20	1.00	1.44	0.054	1.14	0.96	1.35	0.136
Age												
50-54	—	—	—	—	—	—	—	—	—	—	—	—
55-64	1.39	0.88	2.19	0.160	0.86	0.67	1.12	0.260	1.09	0.80	1.48	0.598
65-69	1.98	1.35	2.89	0.000	0.98	0.73	1.31	0.891	1.46	1.09	1.95	0.012
70-79	2.22	1.24	3.98	0.008	1.10	0.80	1.51	0.562	1.59	1.14	2.22	0.007
Insurance												
Commercial and other	—	—	—	—	—	—	—	—	—	—	—	—
Medicare	0.96	0.81	1.16	0.698	0.77	0.59	1.01	0.055	0.86	0.76	0.97	0.012
Self/Medicaid	0.72	0.51	1.01	0.058	0.63	0.29	1.36	0.237	0.63	0.40	0.99	0.046
Practice Characteristics												
Specialty												
Family medicine	—	—	—	—	—	—	—	—	—	—	—	—
General internal medicine	0.91	0.62	1.34	0.637	1.28	1.11	1.49	0.001	1.15	0.98	1.35	0.084
Size												
Small	—	—	—	—	—	—	—	—	—	—	—	—
Large	0.66	0.51	0.87	0.003	0.48	0.24	0.96	0.038	0.58	0.43	0.78	0.000
Location												
Urban	—	—	—	—	—	—	—	—	—	—	—	—
Rural	1.54	0.93	2.55	0.096	2.69	1.69	4.27	0.000	2.02	1.63	2.50	0.000
Suburban	1.21	0.74	1.97	0.450	3.82	2.42	6.02	0.000	2.25	1.81	2.80	0.000
Data sources used[d]												
Least complete	—	—	—	—	—	—	—	—	—	—	—	—
Moderately complete	1.90	0.58	6.20	0.287	17.90	5.95	53.82	0.000	4.86	1.71	13.81	0.003
Most complete	2.02	0.99	4.13	0.053	20.30	9.83	41.92	0.000	4.61	3.00	7.10	0.000

[a] Hosmer-Lemeshow $X^2 = 25.54$, $p = 0.001$.
[b] Hosmer-Lemeshow $X^2 = 9.84$, $p = 0.277$.
[c] Hosmer-Lemeshow $X^2 = 14.48$, $p = 0.07$. Includes stool test, colonoscopy, flexible sigmoidoscopy, or barium enema x ray. Persons with screens by multiple modalities are counted only once.
[d] The data sources used affects the amount of screening information available for patients of a given practice. It is not an indicator of predicting screening. Instead, this variable is used to control for the fact that some practices had more complete data than others.
Note: Confidence intervals and p values have been adjusted using cluster variance estimators.

Table 4.14. Screening Rate Multivariable Logistic Regression, Intervention Practices Only: Reduced Model

Characteristics	Stool Test[a]				Colonoscopy[b]				Any Screening Test[c]			
	OR	95% CI		p	OR	95% CI		p	OR	95% CI		p
Patient Characteristics												
Gender												
Male					—	—	—	—				
Female					1.20	1.01	1.44	0.043				
Age												
50-54	—	—	—	—					—	—	—	—
55-64	1.38	0.88	2.17	0.159					1.09	0.80	1.47	0.596
65-69	1.98	1.36	2.87	0.000					1.45	1.09	1.95	0.012
70-79	2.22	1.25	3.96	0.007					1.60	1.15	2.22	0.005
Insurance												
Commercial and other	—	—	—	—	—	—	—	—	—	—	—	—
Medicare	0.96	0.80	1.15	0.673	0.86	0.67	1.09	0.213	0.86	0.76	0.97	0.016
Self/Medicaid	0.71	0.52	0.96	0.028	0.63	0.29	1.39	0.255	0.64	0.40	1.01	0.055
Practice Characteristics												
Specialty												
Family medicine					—	—	—	—	—	—	—	—
General internal medicine					1.28	1.09	1.49	0.003	1.16	0.98	1.36	0.080
Size												
Small	—	—	—	—	—	—	—	—	—	—	—	—
Large	0.69	0.58	0.82	0.000	0.50	0.24	1.06	0.070	0.58	0.43	0.78	0.000
Location												
Urban	—	—	—	—	—	—	—	—	—	—	—	—
Rural	1.52	0.91	2.55	0.110	2.65	1.61	4.35	0.000	2.01	1.62	2.49	0.000
Suburban	1.18	0.80	1.73	0.410	3.74	2.29	6.13	0.000	2.23	1.79	2.78	0.000
Data sources used[d]												
Least complete	—	—	—	—	—	—	—	—	—	—	—	—
Moderately complete	1.91	0.58	6.29	0.287	18.56	6.11	56.31	0.000	4.88	1.71	13.92	0.003
Most complete	1.94	0.96	3.93	0.066	19.32	8.84	42.23	0.000	4.62	3.00	7.12	0.000

[a] Hosmer-Lemeshow $X^2 = 24.69$, $p = 0.002$.
[b] Hosmer-Lemeshow $X^2 = 14.33$, $p = 0.074$.
[c] Hosmer-Lemeshow $X^2 = 13.38$, $p = 0.099$. Includes stool test, colonoscopy, flexible sigmoidoscopy, or barium enema x ray. Persons with screens by multiple modalities are counted only once.
[d] The data sources used affects the amount of screening information available for patients of a given practice. It is not an indicator of predicting screening. Instead, this variable is used to control for the fact that some practices had more complete data than others.
Note: Confidence intervals and p values have been adjusted using cluster variance estimators.

Table 4.15. Screening Rate Multivarible Logistic Regression, Including Study Arm (Intervention and Control Practices): Full Model

Characteristics	Stool Test[a]				Colonoscopy[b]				Any Screening Test[c]			
	OR	95% CI		p	OR	95% CI		p	OR	95% CI		p
Patient Characteristics												
Gender												
Male	—	—	—	—	—	—	—	—	—	—	—	—
Female	1.07	0.89	1.28	0.470	1.14	0.94	1.40	0.191	1.12	0.95	1.32	0.162
Age												
50-54	—	—	—	—	—	—	—	—	—	—	—	—
55-64	1.41	0.92	2.17	0.115	0.89	0.73	1.10	0.284	1.09	0.85	1.39	0.499
65-69	2.00	1.43	2.79	0.000	0.85	0.68	1.07	0.166	1.30	1.03	1.65	0.028
70-79	2.16	1.33	3.52	0.002	0.94	0.74	1.19	0.612	1.39	1.07	1.80	0.012
Practice Characteristics												
Study arm												
Control	—	—	—	—	—	—	—	—	—	—	—	—
Intervention – Card	7.65	2.26	25.84	0.001	2.79	1.86	4.20	0.000	3.42	2.51	4.66	0.000
Intervention – Kit	17.66	4.16	74.97	0.000	1.02	0.68	1.55	0.910	6.96	3.80	12.75	0.000
Specialty												
Family Med	—	—	—	—	—	—	—	—	—	—	—	—
General Internal Med	1.33	0.74	2.36	0.340	1.31	1.07	1.60	0.008	1.21	1.01	1.45	0.043
Size												
Small	—	—	—	—	—	—	—	—	—	—	—	—
Large	1.35	0.70	2.61	0.377	0.59	0.38	0.91	0.018	0.76	0.54	1.05	0.098
Location												
Urban	—	—	—	—	—	—	—	—	—	—	—	—
Rural	1.07	0.47	2.46	0.874	2.85	1.85	4.37	0.000	1.86	1.30	2.65	0.001
Suburban	0.86	0.45	1.63	0.643	3.68	2.50	5.42	0.000	2.12	1.59	2.83	0.000
Data sources used[d]												
Least complete	—	—	—	—	—	—	—	—	—	—	—	—
Moderately complete	2.03	0.43	9.66	0.375	21.88	8.68	55.12	0.000	6.23	2.22	17.51	0.001
Most complete	1.19	0.36	3.93	0.779	17.19	11.11	26.59	0.000	4.33	2.25	8.33	0.000

[a] Hosmer-Lemeshow $X^2 = 8.28$, $p = 0.4068$.
[b] Hosmer-Lemeshow $X^2 = 10.9$, $p = 0.2074$.
[c] Hosmer-Lemeshow $X^2 = 12.25$, $p = 0.1404$. Includes stool test, colonoscopy, flexible sigmoidoscopy, or barium enema x ray. Persons with screens by multiple modalities are counted only once.
[d] The data sources used affects the amount of screening information available for patients of a given practice. It is not an indicator of predicting screening. Instead, this variable is used to control for the fact that some practices had more complete data than others.
Note: Confidence intervals and p values have been adjusted using cluster variance estimators.

Table 4.16. Screening Rate Multivariable Logistic Regression, Including Study Arm (Intervention and Control Practices): Reduced Model

Characteristics	Stool Test[a]				Colonoscopy[b]				Any Screening Test[c]			
	OR	95% CI		p	OR	95% CI		p	OR	95% CI		p
Patient Characteristics												
Age												
50-54	—	—	—	—					—	—	—	—
55-64	1.25	0.81	1.92	0.311					1.04	0.81	1.32	0.781
65-69	1.81	1.31	2.51	0.000					1.26	1.00	1.58	0.052
70-79	1.88	1.12	3.16	0.016					1.32	1.02	1.72	0.038
Practice Characteristics												
Study arm												
Control	—	—	—	—	—	—	—	—	—	—	—	—
Card intervention	8.00	1.71	37.43	0.008	2.62	1.72	3.99	0.000	3.09	2.26	4.22	0.000
Kit intervention	19.84	3.95	99.69	0.000	1.50	0.60	3.79	0.387	6.64	4.50	9.80	0.000
Specialty												
Family medicine					—	—	—	—	—	—	—	—
General internal medicine					1.27	1.03	1.57	0.025	1.16	0.93	1.45	0.182
Size												
Small					—	—	—	—	—	—	—	—
Large					0.64	0.41	1.01	0.054	0.89	0.60	1.34	0.588
Location												
Urban					—	—	—	—	—	—	—	—
Rural					2.70	1.70	4.29	0.000	1.69	1.10	2.60	0.016
Suburban					3.60	2.40	5.41	0.000	2.10	1.49	2.96	0.000
Data sources used[d]												
Least complete	—	—	—	—	—	—	—	—	—	—	—	—
Moderately complete	1.75	0.58	5.27	0.320	18.92	7.20	49.66	0.000	4.84	1.88	12.45	0.001
Most complete	1.38	0.65	2.92	0.395	13.85	8.05	23.83	0.000	3.31	1.79	6.12	0.000

[a] Hosmer-Lemeshow $X^2 = 1.96$, $p = 0.9619$.
[b] Hosmer-Lemeshow $X^2 = 10.2$, $p = 0.1163$.
[c] Hosmer-Lemeshow $X^2 = 10.49$, $p = 0.232$. Includes stool test, colonoscopy, flexible sigmoidoscopy, or barium enema x ray. Persons with screens by multiple modalities are counted only once.
[d] The data sources used affects the amount of screening information available for patients of a given practice. It is not an indicator of predicting screening. Instead, this variable is used to control for the fact that some practices had more complete data than others.
Note: Confidence intervals and p values have been adjusted using cluster variance estimators.

Followup of Positive Screens

In addition to increasing the odds of being screened for CRC, an intended effect of SATIS-PHI/CRC was to increase the likelihood that positive screens would be followed up with actions recommended by current screening guidelines. In particular for SATIS-PHI/CRC, which highlighted stool testing and colonoscopy, we expected that positive stool tests would be followed up with a complete diagnostic examination (CDE) using colonoscopy.

During the 8-month SATIS-PHI/CRC study observation period, we observed evidence of 363 stool test screens among intervention and control patients, 348 in the intervention group and 15 in the control group. Of those stool tests, 7 of the 348 (2.0 percent) intervention group screens had positive (abnormal) results and 18 (5.2 percent) had unknown results; the remainder (92.8 percent) were known to be negative (normal). Of the 15 control group stool tests, one (6.7 percent) was positive and none had unknown results; the remaining 14 (93.3 percent) were negative. Thus, during the observation period, we detected only 8 known abnormal stool tests and 18 with unknown results. These small numbers preclude a detailed analysis of effectiveness and especially preclude a comparison between intervention and control group experience.

We did, however, track this small number of positive and unknown stool tests to determine their outcome (without evaluating the comparative followup rate for intervention and control patients). Of the single control patient with a positive stool test, a chart audit revealed that the provider recommended a CDE colonoscopy but the patient refused it. Of the seven intervention patients with known positive stool tests, six (85.7 percent) received a CDE. We could not determine if the seventh patient received a recommendation for a CDE.

We also determined that 2 of the 18 intervention patients with unknown stool test results received CDE colonoscopies. Thus, eight intervention patients received a CDE. Of those eight patients, half had an abnormal finding. This finding does mean that these four patients were diagnosed with CRC but rather that an abnormality of some kind was detected. Of the remaining four CDEs, one was negative; we could not determine the results of the other three.

Provider Knowledge and Behavior

A third intended outcome of SATIS-PHI/CRC was to influence the CRC screening knowledge and behavior of providers receiving the academic detailing component of the intervention so that they were more consistent with current screening guidelines. To test the effectiveness of the intervention to achieve this outcome, we compared the responses of providers to the preintervention and postintervention survey of intervention practices. We focused in particular on responses to the first two sections of the survey.

Section A of the survey asked providers to indicate which CRC screening tests they frequently recommended to their screening-eligible patients and which tests they believed were effective. Section B asked providers to indicate their likely followup actions to a positive stool test and an abnormal flexible sigmoidoscopy finding. Tables 4.17 and 4.18 present the results of this analysis. We did not include comparisons with the survey of the control practices because the number of clinician respondents (N = 5) was too small for analysis.

Table 4.17. Comparison of Clinician Responses to the Pre- and Postintervention Survey Indicating That They Recommend Various CRC Screening Modalities or Believe They Are Effective

CRC Screening Modality[a]	Do You Recommend?			Is It Effective?		
	Pre % (N=53)	Post % (N=41)	p	Pre % (N=53)	Post % (N=41)	p
Colonoscopy	100.0	100.0	N/A	98.1	100.0	0.377
FOBT	46.2	39.0	0.491	71.7	82.5	0.225
FIT	15.7	36.6	0.021	41.5	80.5	0.000
Stool DNA	0.0	9.8	0.025	26.4	53.7	0.007
Flex Sig	3.8	2.4	0.715	75.5	85.4	0.236
Vrtual CX	0.0	2.4	0.253	52.9	61.0	0.440
Ba Enema	5.7	2.4	0.443	58.5	61.0	0.808
DRE	49.1	53.7	0.658	34.0	31.7	0.818

[a] FOBT = fecal occult blood test; FIT = fecal immunochemical test; Flex Sig = flexible sigmoidoscopy; Virtual CX = virtual colonoscopy (CT colonography); Ba Enema = barium enema x ray; DRE = digital rectal exam.

Table 4.17 indicates that a smaller percentage of postintervention respondents said they recommend fecal occult blood test (FOBT) screening compared to preintervention respondents. A larger percentage of postintervention respondents said they recommend fecal immunochemical test (FIT) screening.[xvii] This finding suggests that the academic detailing effort to increase FIT testing over FOBT was successful. There were no other statistically significant pre-post differences in response to the question on recommended tests.

We expected to see a decrease in the percentage of clinicians recommending digital rectal examination (DRE), which is not a guideline-recommended screening test for CRC, but that did not occur. On that criterion, the academic detailing was not effective. We did observe an increase in the percentage of respondents indicating that they believed a wide selection of tests are effective for CRC screening.

Although only two screening modalities had significant increases (FIT and stool DNA testing), all others with the exception of DRE increased somewhat, even if not significantly. However, given the small number of provider respondents to each of these surveys (54 to the preintervention survey and 41 to the postintervention survey), the surveys lack the statistical power to detect smaller differences. We also observed a small decrease in the percentage of respondents indicating that they believed DRE to be effective. This result is in the expected direction but is too small to be significant.

[xvii] Recall that the survey of practices was anonymous and that we have no way of knowing whether or to what extent the same or different respondents participated in the preintervention and postintervention administrations of the survey. We surveyed the same practices and distributed the survey to the same people within them for both administrations, but we cannot determine who responded to both or to one but not the other. Even though there may be sufficient background demographic information in survey results to allow us to match some pre and post respondents, our IRB protocol would preclude doing so.

Table 4.18. Comparison of Clinician Responses to the Pre- and Postintervention Survey Indicating That They Follow Up a Positive Stool Test or Abnormal Flexible Sigmoidoscopy With a Recommended or Not Recommended Action

	Stool Test			Flexible Sigmoidoscopy		
Followup Action	**Pre % (N-54)**	**Post % (N=41)**	**p**	**Pre % (N=54)**	**Post % (N=41)**	**p**
Recommended	87.0	97.6	0.067	94.4	97.6	0.561
Partly or Not Recommended	13.0	2.4		5.6	2.4	

Table 4.18 indicates that a higher percentage of postintervention provider respondents than preintervention provider respondents said they would follow up a positive stool test with a recommended action. This finding supports the effectiveness of the academic detailing. But there was no significant change in the percentage of respondents saying they would follow up an abnormal flexible sigmoidoscopy with a recommended action, although the observed difference was in the expected direction.

5. Dissemination

We developed our dissemination plan based largely on AHRQ's Dissemination Planning Tool (Carpenter, et al., 2005). The key components of this tool are:

- **Content:** What we intend to disseminate: the project findings and the redesign intervention tools that we have found to be useful or effective.
- **End users:** The intended targets of our dissemination efforts; those whom we will target to adopt and implement or otherwise use what we disseminate.
- **Dissemination partners:** Those with whom we will partner to help us disseminate our findings and encourage the spread and adoption of our redesign intervention.
- **Communication:** Our strategy for reaching our intended end users; the communication channels we will use to reach these end users.
- **Evaluation:** How we intend to assess the effectiveness of our dissemination effort.

We discuss below how we incorporated each of these components into our dissemination plan.

Content

Our dissemination efforts have two components: a SATIS-PHI/CRC intervention implementation toolkit and material and efforts beyond the toolkit. The primary component is the toolkit. Through it, we intend to inform potential new users and adopters about the SATIS-PHI/CRC intervention and our experiences implementing it. To facilitate the spread of the intervention, we will provide tools, guidelines, and tips for implementing SATIS-PHI/CRC based on the lessons learned reported here and on what we found effective and useful in our implementation efforts. To encourage the intervention's spread, the toolkit provides evidence of the intervention's effectiveness and reasons for its adoption. We describe the toolkit in greater detail below.

In addition to and beyond the toolkit, we will disseminate various elements of our project findings and various elements of the intervention. In particular, as part of our efforts beyond the toolkit, we will disseminate our analytical findings from the practice surveys and focus groups and report them at professional meetings and in professional publications. Similarly, we will report the full details of our intervention study (implementation process and outcomes) at professional meetings and in professional publications. We will also report summaries of our intervention and assessment in trade publications and to relevant professional associations and consortia of cancer care providers.

Topics for analysis and dissemination include:

- Overall effectiveness of the intervention to increase CRC screening rates,
- Evaluation of the intervention effort using the PRISM and RE-AIM frameworks,
- Assessment of clinician beliefs and behaviors related to CRC screening (based on the survey and focus groups),
- Assessment of patient attitudes regarding the CRC screening process (based on the focus groups), and

- Estimation of the extent of "ineligible eligibles"—patients whom the initial electronic record review identified as eligible but whom we deemed to be ineligible based on the SEA form, chart reviews, and subsequent electronic record review—in our data.

End Users

We envision two kinds of end users for our dissemination efforts. The first are potential adopters of our intervention. These primarily include integrated delivery systems, independent practice associations or foundations, insurers owned or operated by delivery systems, insurers not owned or operated by delivery systems, and State, county, or municipal public health agencies and related entities. They are the principal target of the toolkit.

The second group of users includes those who are not firstline new adopters but who may be able to inform and influence potential new users. It also includes people who may be interested in our intervention and findings for purposes of conducting followup research, incorporating our intervention elements into other CRC screening efforts, or developing next generation versions of the intervention. They are the principal target of our dissemination efforts beyond the toolkit.

Potential Adopters

These types of end users, the target of the toolkit, include the following in rough priority order of planned targets for our dissemination efforts:

- The remaining LVPHO/EPICNet primary care practices that did not participate as intervention practices in the SATIS-PHI/CRC intervention study.
- Delivery systems affiliated with Thomas Jefferson University (TJU) through Jefferson Health System or other collaborative arrangements.
- Delivery systems, insurers, and public health agencies throughout Pennsylvania.
- Delivery systems in the current CNA Health ACTION Team network.
- Delivery systems in other ACTION partnerships.

Influencers of Potential Adopters

These types of end users, the target of our efforts beyond the toolkit, include the following, in rough priority order:

- Pennsylvania Cancer Control Consortium (PAC3).
- Agency for Healthcare Research and Quality (AHRQ): staff members affiliated with the Prevention and Care Management research portfolio (and possibly the Health Information Technology research portfolio) and with the Center for Primary Care, Prevention, and Clinical Partnerships.
- Centers for Disease Control and Prevention (CDC): staff members affiliated with the Division of Cancer Prevention and Control of the National Center for Chronic Disease Prevention and Health Promotion in the Coordinating Center for Health Promotion, including the CDC State Cancer Control Plans.
- National Colorectal Cancer Roundtable (NCCRT).
- American Cancer Society (ACS).

- American Academy of Family Physicians (AAFP).
- American College of Physicians (ACP).
- America's Health Insurance Plans (AHIP).

Dissemination Partners

Our primary dissemination team consists of members of the CNA Health ACTION Team who participated on this Task Order: (1) CNA; (2) Thomas Jefferson University, including its School of Population Health, Department of Family and Community Medicine, and Department of Medical Oncology; and (3) LVHN, including the LVPHO and the Department of Family Medicine. In addition to our efforts, we will work with AHRQ and CDC to help package and disseminate information about our intervention and the availability of our intervention implementation toolkit.

We also plan to investigate the possibility of enlisting one or more of our type 2 end users (PAC3, NCCRT, ACS, AAFP, ACP, AHIP) to become a dissemination partner. We will work through contacts that team members already have established with PAC3, NCCRT, ACS, and AAFP. We will seek to make new contacts with ACP, AHIP, and other type 2 end users that we subsequently identify.

Communication

We will communicate our intervention implementation toolkit to potential new users and adopters through direct and mediated contact. We will directly disseminate it through the LVPHO to Lehigh Valley primary care practices, through TJU to members of the Jefferson Health System, and through CNA to other members of our ACTION partnership. We will work with AHRQ to disseminate it more broadly to other ACTION partnerships. In addition, we will work with both AHRQ and CDC, as well as our other targeted dissemination partners, to disseminate it beyond that. Our final toolkit will undergo remediation so that it can be compliant with Section 508 of the Rehabilitation Act and therefore made available on the AHRQ Web site. This posting will help disseminate the toolkit to both type 1 and 2 users.

We will also communicate information about the intervention and the findings of our assessment to type 1 and type 2 end users, as well as to the broader professional clinical and research communities. This communication will include writing articles for professional journals and trade publications, presenting papers and posters at professional and trade meetings, informing professional and trade associations, and using the dissemination capabilities of CNA and its partners on this ACTION Task Order.

Evaluation

Since the dissemination effort is being conducted at the end of this Task Order and will extend beyond it, we cannot evaluate its success within the scope of the Task Order. Such effort exceeds the Task Order's statement of work, period of performance, and funding. Still, we have an interest in evaluating our effort and plan to monitor response to it as best we can. One way we will gather data for our dissemination evaluation will be to seek feedback from our dissemination partners regarding their perception of the intervention and the toolkit and their experience

helping to disseminate information about it. We will also seek feedback from participants at the professional meetings where we present our study findings.

Dissemination Toolkit

Our Dissemination Toolkit includes the following three components: (1) introduction to the toolkit and its contents, (2) background information about the intervention and our study findings—including supporting evidence about the effectiveness of the intervention, and (3) intervention steps and tools. We delivered the toolkit to AHRQ and CDC as a companion deliverable document to this final report in satisfaction of our task order contract. Others wanting a copy may request one from CNA by e-mailing the CNA Health ACTION Partnership at CHAP@CNA.org.

Introduction

The introduction to the toolkit contains a brief statement of the purpose of the dissemination toolkit, its intended users, and ways the toolkit can help users. It include a brief overview of the need for CRC screening (including the prevalence and natural history of the disease) and a brief summary of the current research literature regarding screening programs and the need for the kind of intervention we developed and implemented. It also provides a general overview of the contents of the toolkit and its structure.

Background

In the background section, we briefly describe the Task Order project and the system redesign intervention that is the basis for this dissemination effort. We also provide descriptions of the intervention setting. We describe the applicability of this intervention to other users that are most conducive to successfully implementing the intervention or using the tools. Last, we briefly describe the assessment of the intervention, noting general evidence in support of its overall effectiveness and usefulness as well as that of various tools contained in the toolkit. We describe the assessment in the context of why a user would want to try to adopt our intervention and its components.

Intervention Steps and Tools

In the intervention protocol and steps section, we describe each of the six main intervention steps and then describe the optional assessment step. For each of the intervention and assessment steps, we describe what it entails, provide instructions for implementing it, and offer tips for implementing it based on lessons learned from our implementation experience, including pitfalls to avoid and how to avoid them. We also identify possible alternative ways of carrying out various steps and point out what would be required to make such alternatives practical. In addition, we point out 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 describing each intervention step, we include the appropriate corresponding intervention tools (forms, letters to patients, academic detailing material, etc.). The tools are based on the materials we used for our intervention. However, users can tailor and revise them as appropriate for their organizations and settings.

Table 5.1 presents a detailed list of the material in the intervention steps and tools section of the toolkit. Table 5.2 presents the same information for the optional assessment protocol.

Table 5.1. Intervention Steps and Implementation Tools

Intervention Protocol Steps	Intervention Implementation Tools
Step 1: Recruit Practices	
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
Step 2: Conduct Academic Detailing	
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
Step 3: Identify Eligible Patients	
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 ineligibles and opt-outs*	N/A
Step 4: Mail Screening Materials to Eligible Patients	
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†: *Version 1: Stool test kit enclosed* *Version 2: Request card for stool test kit enclosed*	4.b-1. Letter to patients *(Version 1)* 4.b-2. Letter to patients *(Version 2)* 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 *(Version 2)*
4.c. Respond to requests for stool test kits‡	4.c-1. Cover letter to patients
4.d. Mail reminder letter to unscreened patients	4.d-1. Reminder letter to patients *(who received a stool test kit)*† 4.d-2. Reminder letter to patients *(who received a stool test kit request card)*†
4.e. Mail subsequent reminder letter to unscreened patients*	N/A

Intervention Protocol Steps	Intervention Implementation Tools
Step 5: Track Screening	
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
Step 6: Provide Feedback to Practices/Clinicians	
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 and/or tools is/are 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 5.2. Assessment Protocol Step and Tools

Assessment Protocol Step	Assessment Tools
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.

Current Dissemination Activities

We are currently disseminating our intervention and its findings across multiple outlets, including research conferences, statewide clinical and policy working groups, peer-reviewed and trade manuscripts, and the World Wide Web.

Toolkit

Upon completion of this Task Order, AHRQ will post our final toolkit on their Web site, and it will also be linked from the CDC Web site. This posting will allow the toolkit to be accessible to both the clinical and research communities. The toolkit will undergo remediation to be accessible to all populations. In addition, we plan to disseminate the toolkit to our ACTION partners and throughout each primary care practice in the LVHN community. We also plan on posting it on the PAC3 Portal, a statewide network working to reduce cancer in Pennsylvania.

Clinical and Policy Working Groups

Steering Group members have become involved in various panels and working groups through which they will continue to spread and disseminate the findings from the intervention. Below is a summary of some of these activities:

- Pennsylvania Improving Performance in Practice (IPIP) Project. Steering Group members have been invited to participate as expert faculty in the Pennsylvania IPIP project. This 3-year effort was started by the Governor's Office of Healthcare Reform to move practices to the medical home concept and improve the management of chronic disease through participation in primary care collaboratives across the State. Starting in June 2010, Steering Group members planned to make statewide Web presentations to primary care practices throughout Pennsylvania. In some of the Web seminars, they included the content and findings from our study's intervention, such as lessons learned from the practice survey and focus groups in the Lehigh Valley, and tools to help increase CRC screening.
- Pennsylvania CRC screening Project. The Commonwealth of Pennsylvania has been selected by CDC to receive State grant funding to increase CRC screening in the low-income uninsured population. Steering Group members will also serve as expert faculty on this project, working with the 10 public health centers in the city and their points of referral.
- National Colorectal Cancer Roundtable. Steering Group members planned to attend the National Colorectal Cancer Roundtable meeting in November 2010 to report the findings of our intervention.
- Lehigh Valley Health Network Research Day. Steering Group members will present the intervention and study findings at the LVHN Research Day.
- Lehigh Valley Patient Centered Medical Home. LVHN is working toward implementing the patient-centered medical home concept in their practices, and they are looking at including CRC screening as one of the key elements of the medical home. Steering Group members are working with LVHN to incorporate elements of our CRC screening intervention in their medical home efforts.

Research Conferences

Study findings have and will be disseminated at several key research conferences. For example, some of our baseline study findings about primary care practice involvement with CRC screening activities and the utility of health information technology for population-based screening were disseminated at the North American Primary Care Research Group (NAPCRG) Conference in November 2009 and AcademyHealth Annual Research Meeting (ARM) in June 2010. We also planned to disseminate additional findings at the American Public Health Association (APHA) Annual Meeting in November 2010. This presentation focused on our baseline findings of clinician attitudes and behaviors associated with CRC screening.

The conference sessions included:

- "Colorectal Cancer Screening Responsibilities in Primary Care Practice," NAPCRG, November 2009, poster session.

- "Ineligible Eligibles: Incorrect Information in Electronic Health Data Affecting Intervention Implementation Research: A Report From the CNA Health ACTION Team," AcademyHealth, June 2010, poster session.
- "Primary Care and Colorectal Cancer (CRC): Attitudes and Behavior Associated With Performing Preventative Screening and Followup: A Report From the CNA Health ACTION Team," AcademyHealth, June 2010, poster session.
- "From AHRQ ACTION: Colorectal Cancer Screening Steps Reported by Primary Care Practices," APHA, November 2010, poster session.

Publications

We will draft and submit at least one peer-reviewed manuscript and one trade journal manuscript to the appropriate publications. The peer-reviewed manuscript will describe the intervention, research methods, and study results. The trade journal manuscript will focus on the process of implementing the intervention and will be geared more toward clinical entities that may be interested in implementing our intervention. In addition to these two publications, Steering Group members will be involved with publishing other elements of the results, such as how findings from our baseline practice survey align with the patient-centered medical home concept.

6. Conclusions

We successfully implemented the SATIS-PHI/CRC intervention, mostly as intended although not in all respects. The intervention was adopted by our targeted set of primary care providers and practices and it reached our targeted patient population. Overall, although the rate of CRC screening was lower than expected, the intervention increased the likelihood of those exposed to it being screened relative to unexposed control patients' odds of being screened. The effectiveness of the intervention persisted even after adjusting the control group denominator to compensate for having less information about true eligibility of controls and even after statistically controlling for a set of patient and practice characteristics.

Due to a small number of positive stool tests requiring CDE followup, we could not determine in detail the effectiveness of SATIS-PHI/CRC in improving followup rates or behaviors. Our comparison of preintervention and postintervention surveys of participating practices indicated that the academic detailing portion of SATIS-PHI/CRC was only moderately successful in decreasing behaviors and beliefs inconsistent with current CRC screening guidelines.

Lessons Learned

A key lesson learned from our experience with SATIS-PHI/CRC is that it is important for a central entity undertaking this intervention to understand its system's capacity for implementation. This understanding is needed so that the central entity can design the details of the intervention and possibly adapt it to its specific system or setting. For example, the ability of health systems to conduct a population-based electronic record review will likely vary widely. Knowing this ahead of time, and knowing its system's capabilities, will allow the central entity to design the intervention accordingly, including adding additional personnel and time for more manual reviews as needed.

Some elements of SATIS-PHI/CRC can be time and resource intensive (e.g., conducting the patient mailings, academic detailing, or chart audits), especially if the central entity is not organized and resourced to support these elements. The central entity should be aware of the time and resources required and be prepared to provide or have access to them.

Patients are more likely to screen by stool test if sent a test kit directly in the mail rather than having to request a kit through a mail-in card. Request cards may be needed due to budget limitations, as they were for our intervention. Still, we recommend approaching multiple stool test kit suppliers early to try to procure a supplier willing to provide a sufficient number of kits to support the intervention. Alternatively, the central entity may want to consider financially supporting the procurement of sufficient test kits.

The academic detailing sessions should be designed to address the prevailing knowledge base, awareness, and behavior of the local clinicians and practices. If possible, academic detailers who conduct a preintervention focus group session should listen to practice members' comments and try to add extra emphasis where needed in the detailing. Detailers should also try to gather information about prevailing conditions before finalizing the content of the detailing sessions.

It is important to make sure that the participating practices understand what is involved in SATIS-PHI/CRC participation and what is required of them. Maintaining communication with the practices is important. It is also important to have two primary points of contact at each practice, a clinician and an office manager. The clinician can be the "clinical champion" in the practice, and the office manager can facilitate and coordinate the logistical requirements.

Transferability to Other Systems/Settings

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

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

Environmental conditions most supportive of successful implementation include having a sufficient number of willing colonoscopy providers in the medical service areas participating in the intervention to accommodate any increased demand for colonoscopies resulting from the intervention. It is also key to avoid having 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.

Our 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 EMR systems. However, the central entity would need to have access to sufficient other electronic records (especially claims or other evidence of medical services provided to patents) for practices without fully functional EMR systems. Successful implementation would also be enhanced if participating practices have a dedication to population-based preventive health in general and strong leadership supportive of, and a clinical champion for, the SATIS-PHI/CRC intervention effort in particular.

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