Strategies and Opportunities to STOP Colon Cancer

In Priority Populations (STOP CRC)

Protocol 001

September 9, 2013

NIH Common Fund, National Cancer Institute (NCI)

UH2 AT007782-01

Kaiser Permanente Northwest

The Center for Health Research (CHR)

Group Health Cooperative (GHC)

OCHIN (OCHIN)

Protocol 001 Revision dates
September 27, 2013
Updated July 15, 2014
Updated January 13, 2015
Updated February 19, 2015
Updated March 24, 2015
Updated April 13, 2016
Updated April 26, 2016
Updated November 10, 2017

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1 Operational Plan for Implementation

1.1 Study Summary

This protocol describes Strategies and Opportunities to STOP Colorectal Cancer in Priority Populations, STOP CRC, a cluster-randomized pragmatic study designed to increase rates of colorectal cancer (CRC) screening in safety-net primary care practices. STOP CRC is a collaboration of The Center for Health Research at Kaiser Permanente Northwest (CHR), Group Health Cooperative Research Institute, and OCHIN, the nation's largest network of safety-net practices. OCHIN-member clinics are linked by the same electronic health record (EHR). Our overall goal is to increase CRC screening rates in large numbers of diverse patients by devising and testing an intervention that uses a low-cost fecal test. We plan do this in partnership with 24 OCHIN-member clinics. This project promotes the use of fecal immunochemical testing (FIT) for colorectal cancer screening, as it has been shown to be an effective population-based strategy for increasing CRC screening rates. While colonoscopy is recommended by some professional organizations, it may not be optimal for primary screening as serious adverse complications are not uncommon (1 in 250), endoscopic capacity is limited, procedure costs are high, access is limited, and many patients prefer alternative tests, particularly for some minority groups.(1,2) For these reasons, STOP emphasizes primary screening using fecal testing, with colonoscopy follow-up for positive tests.

The primary objectives in STOP CRC are the following:

Primary Aim 1. Assess the effectiveness of a large-scale, two-arm CRC screening program among diverse Federally Qualified Health Center (FQHC) patients and assess differences in CRC screening outcomes across patient subgroups – e.g. age, sex, insurance status, Hispanic ethnicity/race. The intervention will consist of:

- An automated data-driven, EHR-linked program for mailing FIT kits (with linguistically appropriate pictographic instructions and return postage) to patients due for CRC screening

Primary Aim 2. Assess the costs and long-term cost-effectiveness of the automated program.

The secondary objectives are to:

Secondary Aim 1. Assess adoption, implementation, reach and potential maintenance and spread of the program, using a mixed-method rapid assessment process, field notes, and other ethnographic data.

Secondary Aim 2. Adapt and pilot-test the adaptation of STOP CRC in an alternate EHR platform, *Allscripts*, and develop an implementation guide to assists sites in adopting the program.

1.2 Overall Phase 1 Trial Design

This two-phase project seeks to raise participation in CRC screening among patients who receive care at FQHCs. In Phase 1, we pilot-tested the STOP intervention in two clinics of the Virginia Garcia Memorial Health Center. In one clinic, we mailed an introductory letter, FIT kit, and reminder to about 100 patients. This intervention is called the Auto Intervention. In a second clinic, we mailed to about 100 patients all those items and conducted additional outreach designed by the clinic (i.e. live phone call outreach). This intervention is called the Auto Plus Intervention. We identified patients age-eligible for CRC screening, and used the electronic health record to code patients' receipt of CRC screening, test results, and related outcomes. **Figure 1** shows the three-aim trial design that was used in the pilot.

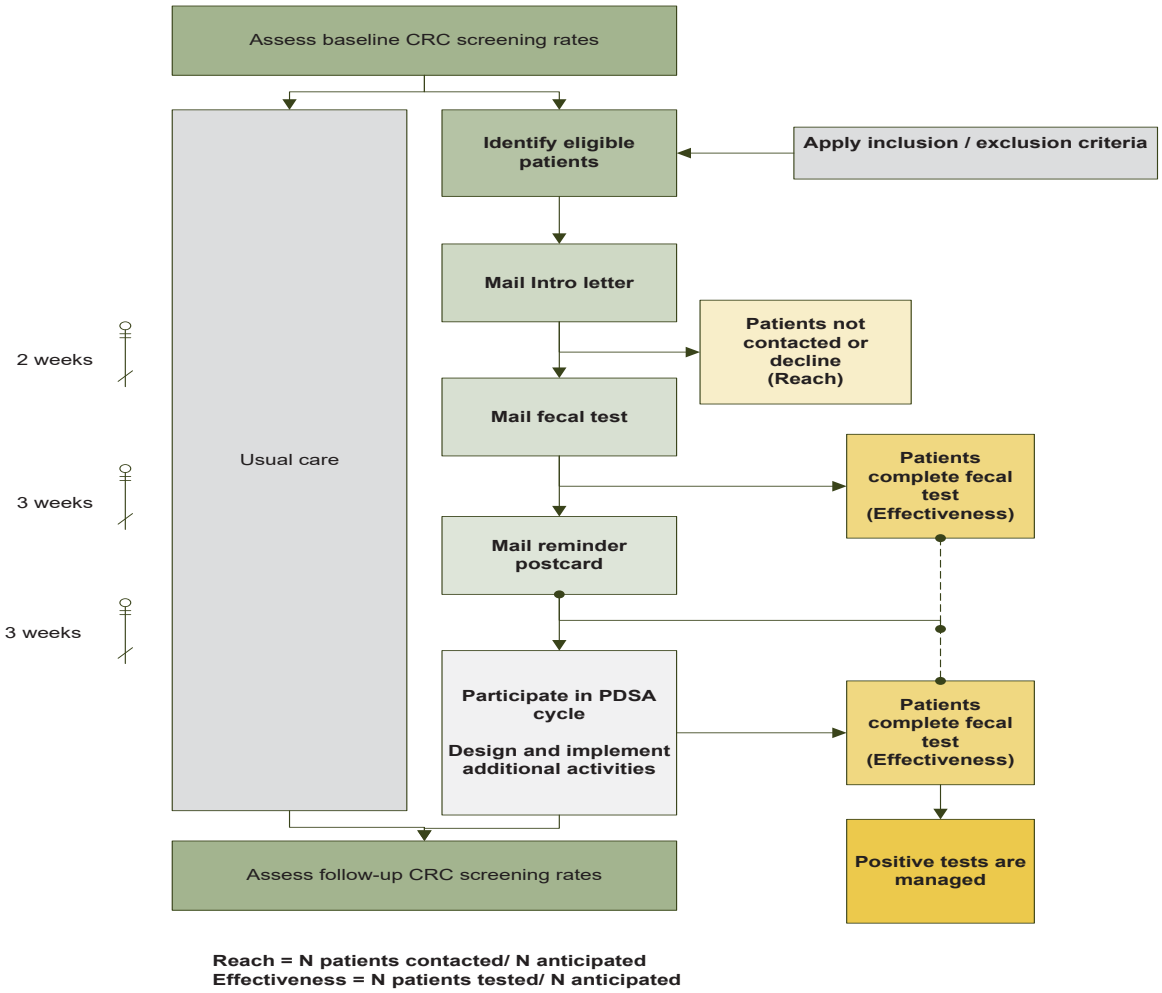
In Phase 2, we will expand our program to 26 FQHC clinics; 24 primary FQHC clinics and 2 that are affiliated with an academic medical center. The study will use existing clinic data and will impose few limits on who can and cannot participate. The STOP program is being designed collaboratively with our OCHIN partners

so that it can be implemented and maintained. We will evaluate FIT testing use (primary outcome), and any type of CRC screening (as recommended by the US Preventative Services Task Force, USPSTF; secondary aim), and whether the program was more or less effective for certain patient subgroups, such as those who do or do not have insurance.

1.3 Overall Phase 2 Project Design

The Phase 2 trial design has two arms (intervention vs. usual care), as shown in **Figure 1**. It also adds an Improvement step, where clinics evaluate small iterative improvements using a plan-do-study-act cycle approach.

Figure 1: STOP CRC Pragmatic Study Design



1.4 Clinic Activities

Because the goal of the STOP program is to transform the way that CRC screening is delivered, the program was designed to be sustained. Rather than building a stand-alone tracking system, we built a population management system directly into the EHR. The care that patients receive during in- clinic visit will therefore complement and reinforce this automated program. For example, a provider will know that a patient has been ordered and mailed a kit as part of the program and, during the clinic visit, can remind the patient to complete and return their kit. Similarly, if a provider encounters a patient who is a poor candidate for CRC

screening s/he can update the Health Maintenance tracking tool in the EHR, which will suspend fecal test mailings for that patient. The specific workflow that a clinic chooses will vary. In general, incorporating the STOP activities into established clinic workflows minimizes clinic disruption and training needs.

1.4.1. Identifying eligible patients – inclusion criteria:

We will use the following algorithm to identify eligible patients in our intervention and usual care sites – based on age and clinic location assignment.

Among patients who are age-eligible (aged 50-74) and have had a clinic visit in the past year:

- We will select patients whose primary location is an intervention clinic.
- If a patient has no assigned location, we will select patients whose assigned PCP's default location is an intervention clinic;
- If a patient has no assigned location and no assigned PCP, we will include patients if the provider of their last visit has a default location that is an intervention clinic;
- Patients who had no clinic visit in the past year will not be included;
- We will follow this same algorithm for selecting patients in our usual care sites.

1.4.2. Identifying eligible patients – exclusion criteria

We will use the following algorithm to identify eligible patients in our intervention and control sites – based on history of colorectal cancer screening, and other clinical factors.

Among patients who are age-eligible (aged 50-74) and have had a clinic visit in the past year and have a clinic assignment (See 1.4.1):

- We will select patients who are due for CRC screening, based on Health Maintenance and codes in other sections of the medical record. The codes that satisfy Health Maintenance for CRC screening are as follows:

- Codes for History of Colorectal Cancer

Code	Description
153	Malignant neoplasm of colon
153.0	Malignant neoplasm of hepatic flexure
153.1	Malignant neoplasm of traverse colon
153.2	Malignant neoplasm of descending colon
153.3	Malignant neoplasm of sigmoid colon
153.4	Malignant neoplasm of cecum
153.5	Malignant neoplasm of appendix vermi formis
153.6	Malignant neoplasm of ascending colom
153.7	Malignant neoplasm of splenic flexure
153.8	Malignant neoplasm of other specified sites of large intestine
153.9	Malignant neoplasm of colon unspecified site

154.0	Malignant neoplasm of recto-sigmoid junction
154.1	Malignant neoplasm of rectum
197.5	Secondary malignant neoplasm of large intestine and rectum
V10.05	Personal history of malignant neoplasm of large intestine

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Code	Description
44388	Colonoscopy through stoma; dx w/wo specimens, brushing/ washing (sep proc)
44389	Colonoscopy through stoma; w/bx single/multiple
44390	Colonoscopy through stoma; w/removal, fb
44391	Colonoscopy through stoma; w/control, bleeding
44392	Colonoscopy through stoma; w/removal lesion, hot forceps/cautery
44393	Colonoscopy through stoma; w/ablation, lesion, not removed by hot forceps/cautery/snare
44394	Colonoscopy through stoma; w/removal, lesion, snare
44397	Colonoscopy through stoma; w/transcendoscopic stent placed (w/predelation)
45355	Colonoscopy, rigid/flexible transabdominal via colostomy, single/multiple
45378	Colonoscopy, flexible, proximal to splenic flexure; dx, w/wo specimen/colon decomp (sep proc)
45379	Colonoscopy, flexible, proximal to splenic flexure; w/removal, fb
45380	Colonoscopy, flexible, proximal to splenic flexure; w/bx, single/multiple
45381	Colonoscopy, flexible, proximal to splenic flexure; w/directed submucosa injections, any substance
45382	Colonoscopy, flexible, proximal to splenic flexure; w/control, bleeding
45383	Colonoscopy, flexible, proximal to splenic flexure; w/ablatn lesn, not removed, hot forceps/cautery/snare
45384	Colonoscopy, flexible; w/removal, lesion, hot forceps/cautery
45385	Colonoscopy, flexible; w/removal, lesion, snare
45386	Colonoscopy, flexible, proximal to splenic flexure; w/dilation, balloon, 1-> strictures
45387	Colonoscopy, flexible, proximal to splenic flexure; w/transcendoscopic stent placed (w/predelation)
45391	Colonoscopy, flexible, proximal to splenic flexure; w/endoscopic US exam
45392	Colonoscopy, flexible, proximal tosplenic flexure; w/transcendoscopic US intr/transmural needle aspirate/bx
GO105	Colorectal cancer screening; colonoscopy on an individual at high risk
G0121	Colorectal cancer screening: colonoscopy on individual not meeting criteria for

	screening

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- Codes for FOBT/FIT

Code	Description
82270	Occult blood by perox activity, 1.3 spec (82270)
82271	Blood, occult, by perox activity (guaiac)
82272	Blood, occult, by perox activity (guaiac)
82274	Fecal globin by immunochemistry
G0328	Assay test for blood, fecal
G0394	Blood occult test (eg. Guaiac) feces, for single determination for colorectal neoplasm (i.e., patient was provided 3 cards or single triple care for consecutive collection)
LP1081	Fecal globin by immunochemistry (Medicare)
LP1398	Fecal occult blood x3 (ncnm lab)
LP926	Occult blood, stool, guaiac x3
LS652	Occult blood, fecal, immunoassay
LS885	Hemoccult/guaiac (colorectal) screen (82270)
LS900	Occult blood stool monoclonal 1
LS901	Occult blood stool monoclonal 2
LS 902	Occult blood stool monoclonal 3
LS912	Occult blood stool monoclonal x3
LS932	Guaiac heme in house (AHTMG)
LS944	Occult blood, series, first spec
LS945	Series occult blood third specimen
Ls990	Occult blood, series, second spec
LS992	Occult blood stool x1 (lab)
LV1433	FOBT waived, immunochemical
LV1542	Occult blood/hemoccult (88272)
LV1576	HP-lab-occult blood (Tahoe Forest)
LV1684	Fecal global by immunochemistry (POCT) 82274
LV1687	Occult blood, fecal, immunoassay, third spec
LV1737	Fecal occult by immunochemistry (82274) POCT
LV414	Fecal globin by immunochemistry (Medicare)
LV472	Occult blood (MTY in-house)
LV510	Stool occult blood, in-house (82270)

LV705	Hemoccult/iFOB test
LV877	Stool occult blood (CHC in –house)
LV908	Fecal globin- in house (Bend only)
LV919	Fecal occult blood x1 (NCNM lab)
LX063	Occult blood, stool (diagnostic)

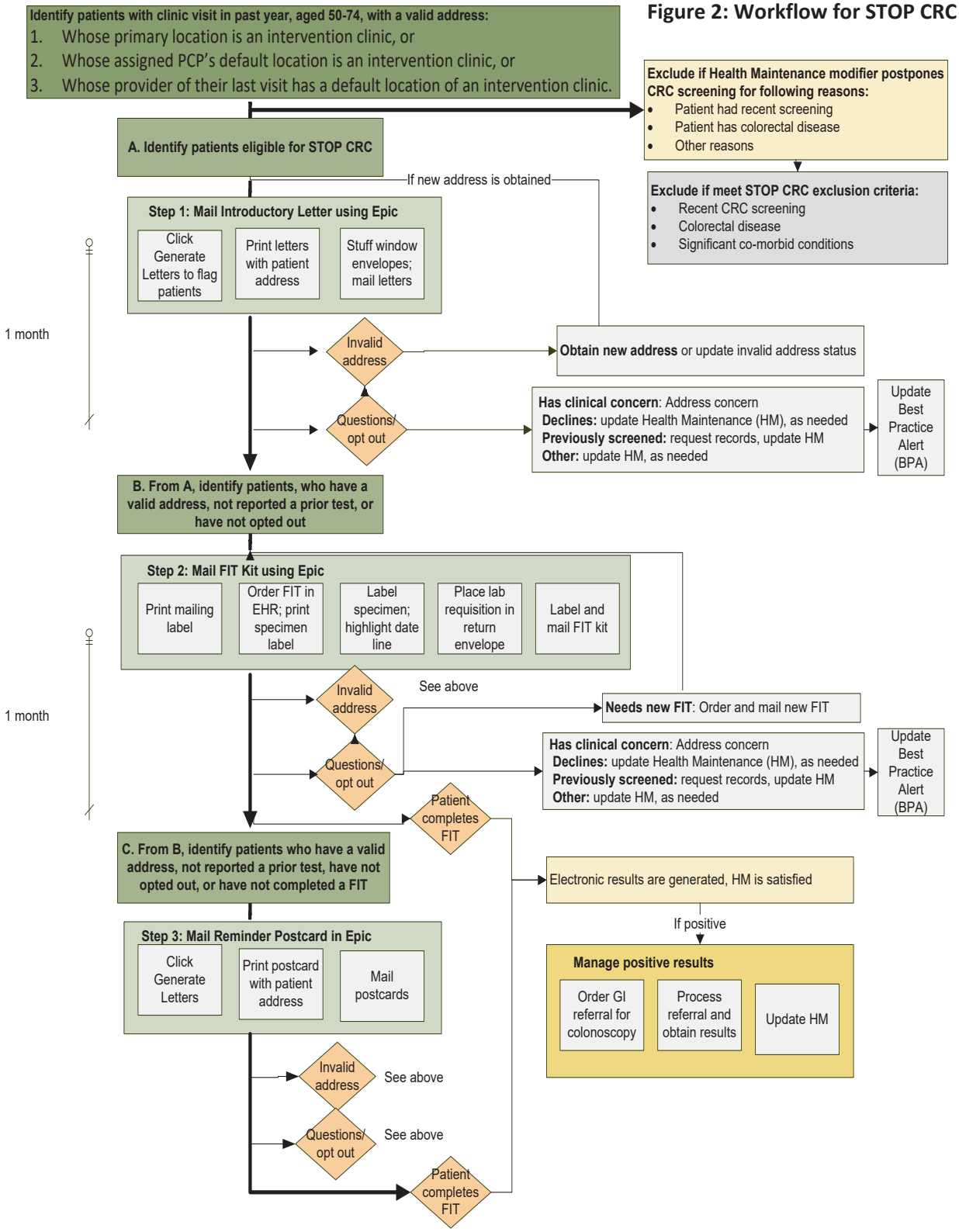
- Codes for Flexible Sigmoidoscopy

Code	Description
45330	Diagnostic sigmoidoscopy
45331	Sigmoidoscopy and biopsy
45332	Sigmoidoscopy, flexible; w/removal, fb
45333	Sigmoidoscopy, flexible; w/removal, lesion, hot forceps/cautery
45334	Sigmoidoscopy, flexible; w/control, bleeding
45335	Sigmoidoscopy, flexible; w/directed submucosal injections, any substance
45337	Sigmoidoscopy, flexible; w/decompression, volvulous, any method
45338	Sigmoidoscopy, flexible; w/removal, lesion, snare
45339	Sigmoidoscopy, flexible; w/ablation, lesion, not removed by hot forceps/cautery/snare
45340	Sigmoidoscopy, flexible; w/dilation, balloon, 1-> strictures
45341	Sigmoidoscopy, flexible; w/endoscopic ultrasound exam
45342	Sigmoidoscopy, flexible; w/transendoscopic ultrasound guided intra-transmural fine needle aspiration/bx
45345	Sigmoidoscopy, flexible; w/transendoscopic stent placed (w/predelation)
G0104	Colorectal cancer screening flexible sigmoidoscopy

1.5 Delivering the Intervention

A workflow for delivering the STOP intervention is provided in Figure 2.

Figure 2: Workflow for STOP CRC



1.5.1 Randomizing Clinics and Selecting Clinic Launch Dates

We will randomize clinics according to the randomization plan detailed in Section 2.2.

1. All clinics were able to start the intervention as early as February 2014. All clinics waited for the EPIC upgrade at the end of April, then started to work on testing the tools in May and June.
2. Usual care clinics will have access to the STOP CRC tools on a delayed roll-out beginning August 2015 (decision in Steering committee 2/12/15).

1.5.2 Pre-launch period [3-months prior to launch]:

a. We will conduct a clinic readiness assessment; we will interview key leadership at the clinics [medical director, operations director, QI lead, and EMR specialist] to learn about current CRC-related practices and clinic attributes. These interviews will be conducted in-person or over the phone.

b. We will train clinic staff in data validation activities and Best Practices to improve data quality. Data validation efforts will take place in both intervention and usual care sites. The training will address use of Health Maintenance (HM) to track patient use of preventive services, including CRC screening, and obtaining records from outside facilities.

   i. Updating HM using existing clinic data: At the beginning of YR01 and YR02, OCHIN will provide clinics with a list of patients in their clinic organization who have evidence of recent CRC screening [colonoscopy in the past 9 years, sigmoidoscopy in the past 4 years, fecal testing in the past 11 months]. Clinic will be encouraged to update HM for these patients and obtain outside records, where needed;

   ii. Updating HM using claims data: We will provide all clinics with Medicaid claims data for patients assigned to their clinic that have had a recent CRC screening. Clinics will be encouraged to update HM for these patients and obtain outside records, where needed.

   iii. Use of HM will be compared across intervention and usual care sites, as part of on-going validation activities [see Section 2.8.]

c. We will review a readiness checklist that will proactively prepare clinics to address early issues that can arise during launch.

   i. The readiness checklist will contain sections on 1) assuring lab interfaces are in place; 2) assessing needs for intervention materials; 3) establishing a site-specific training plan.

   ii. The checklist will be reviewed with each clinic during a pre-launch phone call with the project director, Mr. Josue Aguirre, the EMR specialist from Virginia Garcia, and Cindy Stergar from Lean HealthCare West.

d. Clinics will be trained to use the tools.

i. Training will be led by Ms. Coury, using job aides and training materials developed in Phase 1 (See Section 1.6).

ii. Training plans will be specific for each clinic; at a minimum a 4-hour training session will be held at each intervention site; each clinic will identify a contact person who will be responsible for training new staff in the use of the tools and providing elbow support for addressing questions as they arise.

1.6 Training Materials

Additional resources are available for implementation of the clinic workflow. **Clinic Implementation** guides will be provided to each clinic, which will outline steps in executing the intervention. Samples of clinic workflows used in the Phase I Clinic Implementation guide are available in the Appendix: Section 4.1 (Workflow Diagrams from Virginia Garcia). Clinic guides describe using Epic to support and document STOP CRC activities and mailing the patient materials:

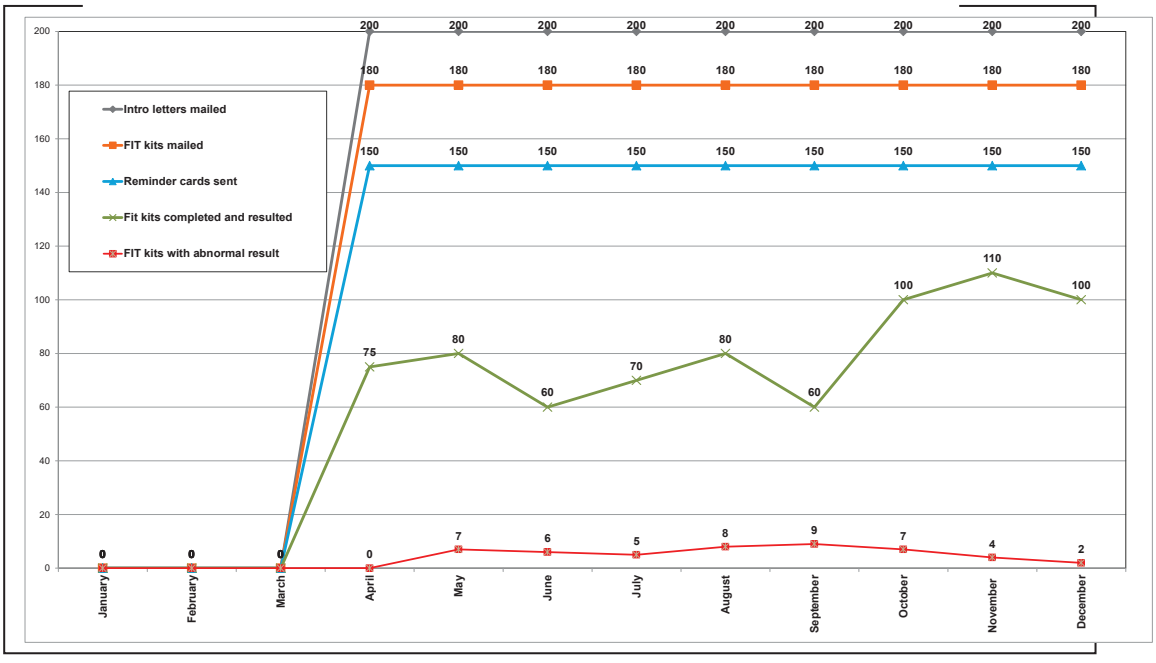
- Mailing the STOP CRC Letters and Reminders
- Mailing the FIT Kit
- Reporting Workbench and EHR Documentation

1.7 Launch

During the launch, we will hold monthly phone calls with representative from each clinic sites. We will also provide a clinic report showing current progress on CRC-related outcomes.

- The project director will facilitate a monthly phone call with the project EMR-specialist, Mr. Aguirre, Cindy Stergar of Lean HealthCare West, and EMR specialists and QI leads from each group of participating clinics. These meetings will address: 1) issues that arise with implementation; and 2) additional training needs.
- Clinic representatives will be emailed a clinic report monthly. An example of this report is provided below (Figure 3). An additional report will compare the progress of an individual site with the average for all participating sites.

Figure 3: Sample STOP CRC Clinic Run Chart



- The STOP CRC EHR tools will generate a real-time list of eligible patients in each intervention clinic, based on the clinic assignment, HM, and the STOP CRC eligibility criteria (See Section 1.12). Clinic staff will use the "Generate Letter" function in Reporting Workbench to print letters and document that they were printed. Clinics will prepare the mailing according to their preferred workflow. Clinic staff will affix postage and mail the Introductory Letter.
- Two-weeks to 1 month following the mailing of the introductory letter, clinic staff will run the list of patients who are due for Step 2: the mailing of the FIT. This list includes patients who are presumed to have a valid address (Introductory letter was not returned by the Post Office). Clinics will follow their standard procedure for updating patient addresses in cases where letters are returned (e.g. update account status); FIT kits will be prepared and mailed using the following steps:
    - FTI Kit orders will be placed for each patient (currently must be done one-by-one, but with new release of Epic, batch ordering will become available)
    - Lab requisition is printed and stuffed in the biohazard bag that is returned with the collected sample; (some clinics may opt to highlight the date line on the kit to prompt patient to complete this)
    - Wordless instructions for completing the kit will be stuffed in the kit;
    - Mailing labels and postage will be affixed to the kit.
    - FIT kits that are returned by the Post Office will be tracked, and the clinic will follow its standard procedures for obtaining updated address information for its patients (e.g. update account status). Patients whose address is updated will be re-sent the Introductory letter.
- Two weeks to 1 month following the mailing of the FIT kit, clinics will run a list of patients who are due for Step 3: the mailing of a Reminder Postcard. This list includes patients who are presumed to have a valid address (FIT kit not returned by the Post Office) and who have not returned their kit for processing. The procedure for mailing the Reminder Postcard is like that for the Introductory Letter: that is:
- Clinic staff will use the "Generate Letter" function in Reporting Workbench to print Postcards and document that they were printed. They will prepare the mailing using the clinic's preferred workflow. Clinic staff will affix postage and mail the Reminder Postcard.
- Clinic staff will follow the procedures in the workflow document to track incoming phone calls; specifically:
    - Record incoming phone calls in Best Practice Alert, using Reason for call: STOP CRC;
    - Patients who have clinical concerns will be directed to the Patient Care Coordinator;
    - Patients who request a new kit will be mailed a new kit;
    - Patients who report previous CRC screening will be directed to the Patient Care Coordinator, who will update HM and request records, as needed.

1.8 Improvement Cycles

In partnership with health center leadership teams and in consultation with Lean HealthCare West, we will conduct Improvement Cycles in all intervention clinics. Clinics will be assessed for their quality improvement resources and ability to perform an improvement cycle independently. Depending on the results assessment, the study will proceed one of two ways:

- Clinics whose staff are trained in conducting improvement cycles will be asked to do so independently. They will submit a report of their findings 6-months following the launch of the STOP CRC program at their site.
- Clinics that need additional assistance will be provided training and on-site support by consultants at Lean HealthCare West. This support will include on-line training modules and in-person training sessions that are customized to the structure of clinic teams.

The study team will collect all Improvement Cycle reports from clinic sites, 6 months after the launch of the STOP CRC program at a given site. Lean HealthCare West has experience working with most of our participating clinics.

Beginning three months before the end of YR01, clinic leaders will be asked to present the results of their Improvement Process during an on-going meeting of the STOP CRC advisory board. During the presentation, they will be provided with feedback from the Advisory Board. In some cases, the Improvement Process results will suggest an improvement that is internal to the clinic [strategies that improve efficiency of intervention delivery]; in other cases, clinics may be ready to expand the intervention to incorporate additional components [e.g. telephone reminders, etc.].

1.9 Maintenance

The second year of the intervention will be considered a maintenance year. Maintenance will comprise the following activities:

- Health Center leaders will choose whether to maintain the program in YR02 at the intervention sites;
- Those that maintain will document any adaptations that they make to the program, and we will capture this during the qualitative Rapid Assessment Process (See Section 2.8)
- Health Center leaders will also choose whether to roll-out the program in YR02 to usual care clinics within their health center.
- Health Center leaders may also opt to roll-out the program in YR02 to additional clinics in their health center that did not participate in the study (neither intervention or usual care).

The research team will document maintenance at the clinic- and patient-levels. Clinic-level maintenance will assess the number of clinics that maintained the program in Year 02, overall and by intervention status (including clinics that were neither assigned to intervention or usual care). Patient-level maintenance will assess the proportion of patients who completed fecal testing in both years of the program.

1.10 Advisory Board

The STOP project is guided by an advisory board of clinician, EMR experts, community organizations concerned with CRC and CRC screening, and patient advocates. Below is a list of advisory board members. The advisory board meets quarterly. The Advisory Board serves an important role on this project. We have relied on the Advisory Board to provide guidance and feedback on various activities of the project. The Advisory Board was asked to review project procedures, regularly review Phase 1 goals and milestones to ascertain progress and provide input on the design of the Auto Plus intervention. They also reviewed data from the pilot project and helped us select a high-impact, sustainable, and feasible program that could realistically be adopted by clinics. Finally, they reviewed criteria for inclusion and advised on clinics for the trial and the evaluation plan for pragmatic trial. We anticipate that this Advisory Board will also actively participate in Phase 2. The following are member of the Advisory Board:

- Marie Dahlstrom, MA, Executive Director, Familias en Acción (Latino Patient Navigator Organization)
- Olga Gerberg, Patient Navigator, Familias en Acción
- Janet Hamilton, MS, Executive Director, Project Access Now
- Elizabeth Steiner, MD, State Legislator, Oregon
- Mitch Greenlick, PhD, State Legislator, Oregon
- John Muench, MD, Director of Behavioral Medicine OHSU Richmond Clinic
  Co-Chair of OCHIN Center Operations Group
- Zoe O'Neill, MPA, Oregon Primary Care Association
- Joe Carroll, MD, Family Physician, Open Door CHC (FQHC)
- Steve Engle, MD, Mad River Community Hospital
- Meena Mital, MD, Medical Director (Interim), Multnomah County Health Department (FQHC)
- Ann Turner, MD, Co-Medical Director of Virginia Garcia Memorial HC (FQHC)
- Charles Gallia, Analysis & Research, Manager Division of Medical Assistance Programs
- Ricardo Jimenez, MD, Medical Director, Sea Mar
- Sara Barker, MPH, Health Home Director and Chronic Care Program Director, Sea Mar
- Jim Allison, MD, Gastroenterologist, Adjunct Investigator Kaiser Permanente Northern California Division of Research
- John Inadome, MD, Gastroenterologist, Cyrus E. Rubin Professor and Head, Division of Gastroenterology, University of Washington School of Medicine
- Ginger Scott, RN, BSN, Director of Nursing, CHC Medford
- Rob Unitan, MD, Director of Optimization and Innovation; Northwest Permanente, PC

During Phase 2, the Advisory Board will address the following topics:

- Guide the pre-launch and launch activities
- Review the status of all intervention sites, and suggest mid-course corrections
- Review results of data validation
- Review results from Improvement Cycles
- Serve as advocates for the project
- Review outcome data (both quantitative and qualitative), and assess strategies to improve Effectiveness, Reach, Implementation
- Provide guidance and strategies for program maintenance

1.11 Participating clinics

STOP CRC will work with several OCHIN-affiliated clinics in Oregon and California. In later years, we will adapt and pilot-test the program at Sea Mar Community Health Centers. Below is a list of participating clinics organizations, and the number of eligible and participating sites.

Clinic Organization	Number of clinic sites with 450+ active patients	Number of participating clinics
Health Center 1	2	2
Health Center 2	3	3
Health Center 3	3	3
Health Center 4	4	4
Health Center 5	6	6
Health Center 6	2	2
Health Center 7	6	4
Health Center 8	4	2

1.11.1 Clinic eligibility criteria

We selected these clinics by working with our advisory board to establish criteria for clinic participation. Below is a list of these criteria. These criteria are listed below.

Clinic Criteria	Description
Clinic site size	A clinic site must have 450+ patients aged 50 - 74
Number of clinic sites in organization	Clinic organization must have at least 2 sites that meet size requirement.
FOBT/FIT	Clinic organization must use the same screening method in its intervention and usual care clinics.
Colonoscopy capacity	Clinic must have sufficient capacity to perform colonoscopies for patients who screen positive on FOBT/FIT.
Lab interface/ capacity	Clinic sites must have direct electronic interface with lab that processes FOBT/FITs; lab must have sufficient capacity to process additional tests.
Randomization	Clinics must agree to randomize their clinics; each organization will be assigned at least one intervention and one usual care site.
Testing the uninsured	Clinic organization must have a plan for screening for uninsured patients.
Research requirements	Clinic organizations must consent to leadership requirements (clinic interviews, data validation, advisory board involvement, interpretation of findings)
Prioritization/ willingness	Clinic leadership must prioritize project and set improvement targets.
Human Subjects requirements	Clinic organization must agree to cede to KP NW IRB.
Federal Wide Assurance	Clinic organizations must maintain active FWAs

1.11.2 Clinic Recruitment Procedures

OCHIN and CHR staff reviewed lists of possible health centers and determined which were eligible. Health Center representatives were sent an email from OCHIN introducing the project and obtaining permission to provide contact information to CHR investigators. All health centers agreed. Health Center representatives were then contacted by Sally Retecki, Community Research Liaison, who organized in-person or WebEx meeting with leadership teams. These meetings lasted 1.5 hours. Ms. Retecki provided the following clinic recruitment materials to attendees during these meetings:

- Introduction to STOP CRC (document and PowerPoint)
- Scope of work
- Budget templates
- Draft letter of support
- Sample staffing plan

Health Center representatives were asked to respond with their interest in participating in the STOP CRC project by September 1, 2013.

1.12 Selection of Eligible Patients

The main eligibility criteria for STOP CRC are screening criteria as adopted by the National Quality Forum (NQF). Patients must be 50-74 years old, an active patient identified by a prior visit, without screening or conditions that would make them poor candidates for screening. Below is a list of the inclusion and exclusion criteria for the project.

Inclusion and Exclusion Criteria for STOP CRC Patient Participants	Time	Temporary/Permanent**
Inclusions		
Aged 50-74	Current	Temporary
Have at least 1 visit in past 12 months	Past 12 months	Temporary
Have viable address	Current	Temporary
Exclusions – CRC screening history		
Colonoscopy Complete	Past 9 years	Temporary
Colonoscopy Referral	Past 1 year	Temporary
Gastroenterology Referral	Past 1 year	Temporary
FIT (or FOBT) Orders	Past 11 months	Temporary
Flex sigmoidoscopy Referral	Past 1 year	Temporary
Flex sigmoidoscopy Complete	Past 4 years	Temporary
Exclusions – Colorectal disease		
Prior dx of colorectal cancer	Ever	Permanent
Prior dx of total colectomy	Ever	Permanent
Ulcerative colitis and Inflammatory Colitis	Ever	Permanent

History of high risk polyps –	Ever	Permanent
Exclusions: co-morbid conditions		
History of renal failure/ESRD	Ever	Permanent
Living in nursing home or assisted living	Past 1 year	Temporary
Hospice Program	Ever	Permanent

*Additional local codes should be included in procedures list if available.
**Temporary means that status can change during observation period.

The tables below list the codes that were used to identify colonoscopy orders, results and GI referrals, FIT/FOBT orders, flexible sigmoidoscopy referrals and completions, colorectal disease, and co-morbid conditions.

Codes to Identify Colonoscopy Orders or Results and GI Referral		
Description	**ICD9*/CPT Codes**	**HCPCS****
Colonoscopy Orders/Referral/Results	44388-44394, 44397, 45355, 45378-45387, 45391, 45392	G0105, G0121
Virtual Colonoscopy Referral	0066T, 0067T 74261-74263	
GI Referral		Referral Code indicating GI or colonoscopy referral or 9110 or 9140 for colonoscopy referral

*International Classification of Disease, Version 9
** Healthcare Common Procedure Coding System

Codes to Identify FIT/FOBT orders		
Description	**ICD9*/CPT Codes**	**HCPCS****
FIT/FOBT orders	82270, 82274	G0107, G0328, G0394

*International Classification of Disease, Version 9
** Healthcare Common Procedure Coding System

Codes to Identify Flexible Sigmoidoscopy Referral and Completion		
Description	**ICD9*/CPT Codes**	**HCPCS****
Flex sigmoidoscopy Referral	45330, 45331, 45332, 45333, 45334, 43335, 45337, 45338, 45339, 45340, 45341, 45342, 45345	G0104
Flex sigmoidoscopy completion		

*International Classification of Disease, Version 9
** Healthcare Common Procedure Coding System

Codes to Identify Colorectal Disease

Description	ICD9*/CPT Codes	HCPCS**
Prior dx of colorectal cancer	153, 154.0, 154.1, 197.5	V10.0
Prior dx of total colectomy	44150-44153, 44155-44158, 44210-44212	
Ulcerative colitis or inflammatory colitis	555, 556	
History of high risk polyps	211.3, 199.1	

*International Classification of Disease, Version 9
** Healthcare Common Procedure Coding System

Codes to Identify Co-morbid Conditions		
Description	**ICD9***	**HCPCS****
History of renal failure / ESRD	585.5, 585.6 and 586	Referral to dialysis
Living in nursing home / assisted living		Referral to nursing home
Under hospice care		Referral to hospice

*International Classification of Disease, Version 9
** Healthcare Common Procedure Coding System

1.13 Enrollment Procedures and Participant Identification

OCHIN programmers will develop an algorithm for using the EHR to automatically identify eligible patients, which will be updated regularly, so that the new data such as FOBT completion can be applied to those patients who are eligible to receive the automated intervention at each clinic. The electronic tools will automatically provide a list of eligible patients in the Reporting Workbench tool in EPIC. Clinics will review the patient list prior to mailing the introductory letter to assess whether the patient is appropriate for screening.

1.14 Intervention Delivery and Core Components

The intervention components are a mailed fecal test and an improvement cycle (e.g., a PDSA cycle). Each potential participant will be sent an introductory letter introducing the study, asking them to call if they have prior screening or clinical concerns. The letter will contain a toll-free telephone number that the participant can use to call the clinic if he or she does not want any further contact from the study. A patient can also choose another type of screening method, such as colonoscopy. Depending on the clinic's preference, the mailings may take place every month based on the birthday month of the patient, or less frequently depending on the clinic flow.

- Clinic staff will log whether a patient declines to participate in the study and declination rates will be monitored by the study team.
- One month after the mailing of the introductory letter, those patients not reporting being current for screening, who have a viable address and have not called to opt out of the program (because of prior screening or other reasons) will be mailed a FIT kit;
- One month after the mailing of the FIT kit, those not reported as completing the kit will be mailed a reminder postcard.

- Four to 6 months after the mailing of the FIT kit, an improvement cycle will be facilitated with the clinic; this will identify strategies to further enhance the reach or effectiveness of the program.

Phase 1 of the study developed the participant intervention materials, which consist of the following (see Appendix D for samples):

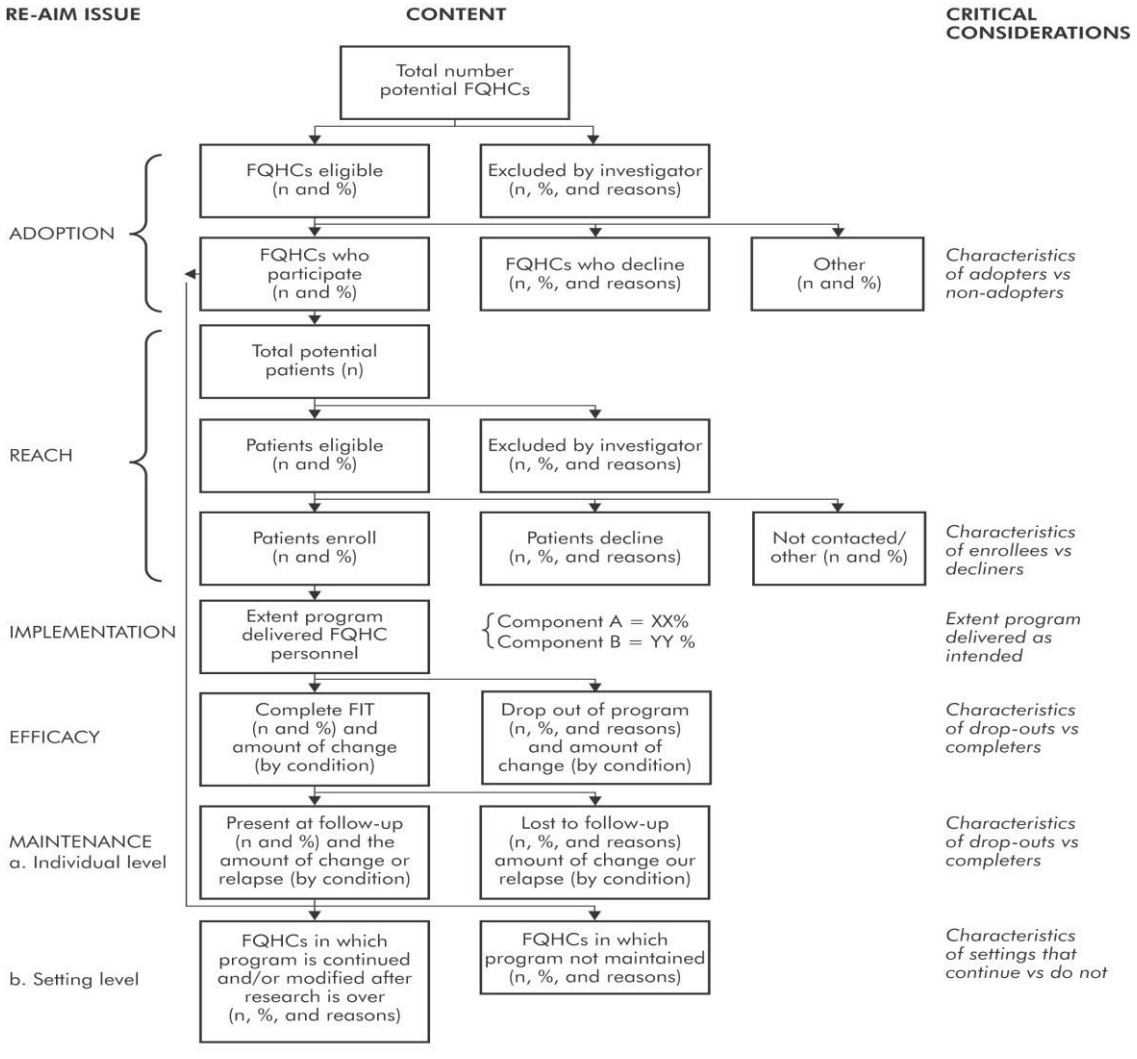
- STOP CRC introductory letter (in English and Spanish)
- STOP CRC wordless FIT kit instruction
- STOP CRC reminder postcard

2 Statistical Analysis Plan

2.1 Study Design

STOP CRC is a two-arm cluster randomized design with clinic as the unit of randomization and analysis. The analysis plan is based on an adapted consort diagram, see **Figure 4**:

Figure 4: Adapted Consort Diagram



*adapted from extended CONSORT diagram (Kessler 2011)

2.2. Randomization

Based on simulation work conducted by the Collaboratory's Biostatistics Core, we abandoned our original plans to conduct a constrained randomization and instead opted for a simple stratified randomization based on Health Center. Within each of these administrative units, the randomization was blocked to assure maximum possible balance of intervention and control clinics. Having created the basic randomization scheme with two groups (A and B), the assignment of the groups to intervention and control conditions was performed randomly on a conference call with all health center representatives on February 4th, 2014 to assure maximum transparency of the process to our participating sites. The randomization process relied on an electronic dice that was rolled by a member of the advisory board.

2.3 Study Outcomes

The original UH3 protocol stated that the study population would be accrued over the 12 months following randomization (February 4, 2014–February 3, 2015) and then be followed for 12 months after that to assess the study outcome. However due to the decision to roll out the intervention to control clinics in August of 2015, we truncated the follow up window for all individuals, intervention and control, as of this date. In addition, delays in intervention startup required us to reformulate some of our secondary outcomes. The revised is a statement of our current primary and secondary outcomes.

2.3.1 Primary Outcome Variable

Our primary outcome is the completion of fecal testing within the earlier of (a) 12 months from study accrual or (b) August 3, 2015 (when study tools were made available to usual care clinics). As our primary interest was on clinic level return rates, however, these individual responses were weighted by 1/(clinic size) so that each clinic's data was weighted equally (see section 2.4.1).

To assure maximum comparability of the intervention and control samples, all participants were accrued in the same manner. For control clinics we thus looked for the first date that a participant would have been eligible to receive the intervention had it been turned on for that site. It follows that both the distribution of accrual times as well as the distribution of follow up times should be comparable for participants in the two groups.

2.3.2 Secondary Outcomes

Our secondary outcomes are provided below:

- For participants who received a FIT kit, the probability of returning it within 3, 6, 9 and 12 months of its being sent as well as time to FIT/FOBT return
- Receipt of any CRC screening (fecal test, sigmoidoscopy or colonoscopy) during the follow-up window
- NQF score (proportion of those age 50-74 with a colonoscopy within 10 years, flexible sigmoidoscopy within 5 years, and FOBT/FIT within 1 year) as assessed relative to the one-year pre and each of the first two years post randomization
- Presence of a positive FIT/FOBT among those who return a FIT kit
- Referral for a colonoscopy among those with a positive FIT/FOBT
- Completion of a colonoscopy following a positive FIT/FOBT

2.3.3. Process Outcomes

Though not secondary outcomes per se, we will also record a number of process measures that describe the Reach, Adoption, and Implementation of the intervention among intervention clinics. These are

summarized below:

- Adoption: N clinics that participate/ N anticipated [characteristics of adopters]
- Reach: N participants who receive intervention components / N anticipated. We will record N invalid address, N decline, and N who report prior screening. We will also assess patient phenotype characteristics related to reach (e.g. such as race, language and invalid address)
- Implementation: N activities delivered by clinics / N anticipated.
- Maintenance: N clinics that implement STOP CRC in YR 02/ N implemented in YR 01.For those clinics who do adopt/maintain the intervention in year 2, we will describe similar intervention outcomes for year 2 (e.g., percent with FIT/FOBT returned within 12 months) and the proportion of eligible patients current for FOBT and any CRC screening for both years of the study.
- In addition to the measures above, we will gather qualitative data to assess the adoption and fidelity of implementation of the program in the clinics; including clinic-level barriers to ongoing maintenance and patient-level factors that influence program effectiveness.
- As this is a stepwise intervention, the reach and implementation for each component will be based on the number eligible for that step.
- The following variables will be captured in Reporting Workbench:
    - Intro letter mailed, date
    - Income phone call, date
    - Declined participation, date
    - Reported previous CRC screening, ineligible, date
    - Invalid address, date
    - FIT kit mailed, date
    - Requested new kit, date
    - Postcard mailed, date

Samples of project reports are available in Section 4: Research Reports.

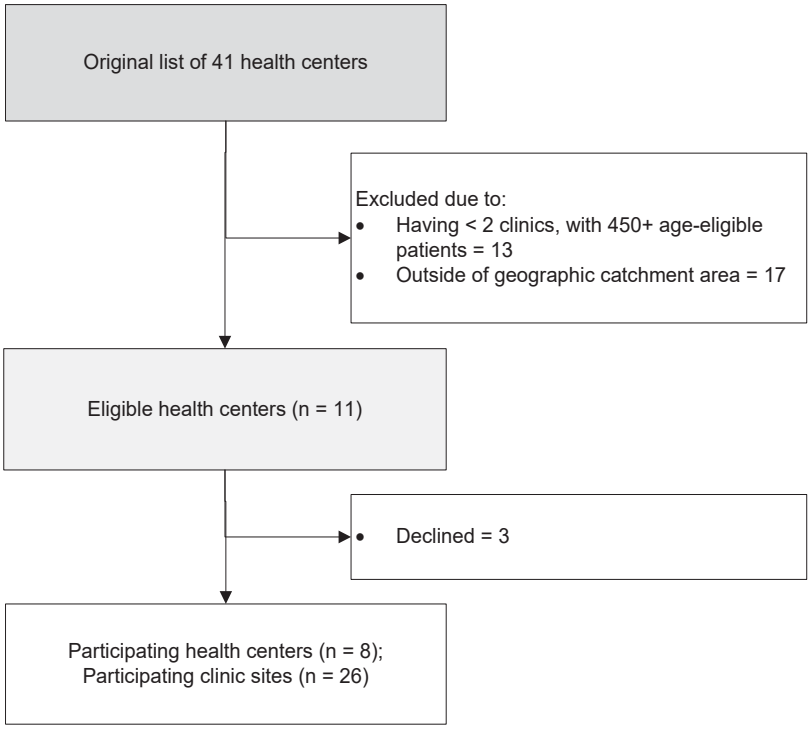
2.3.4. Assessment of adoption

From the original list of 41 Health Centers in Washington, Oregon and Northern California, 13 Health Centers had a single clinic or did not meet the size requirements of having at least 2 clinics with 450 patients aged 50-74, and 17 were outside of the geographic catchment area. The remaining 11 Health Centers were eligible and 3 declined participation. Among the recruited clinics, 24 were FQHCs with shared governance (a centralized leadership team, etc.) and 2 clinics were affiliated with an academic medical center (and operated independently of each other). To assess adoption, we will:

- Compare and report clinic characteristics of adopters and non-adopter; these include clinic size, location, % Hispanic, % uninsured, and baseline CRC screening rates, among others.
- For our assessment of maintenance, we will also track and report clinics that decline participation in YR02.

Figure 5, below, shows the CONSORT diagram of clinic recruitment.

Figure 5: Clinic-level CONSORT diagram for STOP CRC



2.3.5. Moderator Variables

Moderators include demographic characteristics, health status, and health care utilization variables. The following variables will be assessed as moderators of the intervention.

- Demographic characteristics will be assessed using the following variables:
  - Age, on date of first mailing [50-64, 65-75]
  - Gender [Female, Male]
  - Race, self-reported [Black, Asian, While, Native American, Unknown]
  - Ethnicity [Hispanic, non-Hispanic]
  - Language, primary self-declared [English, Spanish, other]
  - Tobacco use, at last visit [Current, Passive, Never, Unknown]
  - Socio-economic status [<100% FPL, 100-150 FPL, 151-200 FPL, 200+ FPL]
  - Insurance status [Uninsured, Medicaid, Medicare, Private, Other]
  - Community- and neighborhood-level variables obtained from linking EHR to Census and American Community Survey data.
- Health care utilization will be assessed using ACG or Charlson Risk Scores if possible, or the following variables:
  - History of FIT/FOBT, among aged 52-74 prior to exclusion period [Yes, No}]

- History of Pap screening, among women aged 50-64, in past 3 years [Yes, No]
- History of mammography screening, among women aged 50-74, in past 2 years [Yes, No]
- Flu shot in past year, both genders, all aged 50-74 [Yes, No]
- Number of office visits in past year [continuous N]
- Number of office visits during intervention year [continuous N]

- We will consider as moderators -- health status and co-morbid conditions -- using the following variables:
  - Congestive heart failure (CHF), ever
  - Peripheral vascular disease (PVD), ever
  - Cerebral vascular disease/ dementia, ever
  - Chronic obstructive pulmonary disease, ever
  - Diabetes mellitus (exclude gestational diabetes), ever
  - Metastatic solid tumor, ever
  - Hypertension diagnosis, ever
  - Depression diagnosis, ever
  - Currently using Warfarin
  - John Hopkins Adjusted Clinical Group (ACG) case-mix system comorbidity score

2.4 Analysis

The original analytic plan called for aggregating each clinic's data into 8 separate return rates (one each for subgroup defined by age (50-64 vs. 65+), gender and race (minority vs. non-minority). The resulting analytic dataset would thus consist of 208 observations (26 clinics X 8 observations per clinic). Treating the resulting proportions as approximately normally distributed, we planned to use mixed model ANCOVA to estimate the screening probabilities as a function of intervention, age, gender, race, and baseline clinic screening rate, with clinic specified as a cluster variable.

Once the analytic cohort was accrued, we discovered that some of the clinic subgroups were extremely small, which in turned threatened the validity of the planned analysis. In consultation with the NIH Collaboratory's Biostatistics Core, we therefore shifted to a patient level analysis. In order to maintain the initial focus on clinic-level differences, we weighted each individual by 1/(clinic size). This shift in analytic plan therefore maintained the spirit of the original analysis while providing a better fit to the nature of the data (i.e., a logistic model reflecting the binary nature of individual observations). An added bonus of this revised analytic framework is that it allowed for a finer adjustment for patient-level factors as part of secondary analyses.

In addition to the above change, we also added some sensitivity analyses to try to account for the startup delays that were experienced. Finally, we decided to adjust for Health Center in place of other clinic-level covariates since preliminary analyses indicated that this substantially reduced the intraclass correlation coefficient compared to other adjustment options.

2.4.1 Primary and Secondary Outcome Analysis

The data can be viewed as coming from a 2-level hierarchical model with patients clustered within clinics, and our primary interest is focused on clinic-level effects (to what extent did the intervention increase clinic-level FIT/FOBT completion rates).

Primary Analysis

To assess our primary outcome, we fit generalized estimating equations (GEE) models with a logistic link to model patient-level data. Patients are weighted by 1/(clinic size), so that each clinic's data will have an equal weight . The primary analytic model adjusted for age, gender and health center, used robust variance estimators, and specified clinic as a clustering variable to account for intra-clinic correlation. (The intra-class correlation coefficient for this adjusted model was 0.05.) We report the intervention effect as the absolute difference between intervention and usual care clinics in adjusted probabilities calculated using mean values for all covariates in the model since we felt this was the more relevant metric from a public health perspective. However, we report (two-sided) p-values based on the ln (odds ratio). A p-vlaue < 0.05 is considered statistically significant.

Secondary Analyses

We used the same analytic approach for the secondary outcome of any CRC screening. For both FIT completion and any CRC screening, additional models were fit using interaction terms to test the extent to which the intervention effect differed across Health Centers. The interactions were treated as fixed effects in these models.

The analysis of our other secondary outcomes will be more descriptive in nature. Regarding the proportion of returned FOBT/FIT kits that turn out positive, while we anticipate a sizeable number of returned FOBT/FIT kits for each of the intervention clinic (typically in excess of 150), the numbers will be much smaller for control clinics (for many of the smaller clinics less than 20) and hence much less precisely measured. The situation is only compounded for the secondary outcomes of referral for a positive FIT and completion of a colonoscopy following referral, since they are further limited to FOBT/FIT kits that are returned and are positive. Hence, for all these outcomes, the focus will be more on the experience of the intervention clinics than formal comparisons between intervention and control clinics, though we will look at this latter question to the extent we are able. Ultimately, we wish to know the extent to which the clinics are able to maintain the program and the impact it may have on their operations, and hope that this information will help to shed light on this issue.

For the NQF scores, the data can be interpreted as coming from a step wedge design. In the year prior to randomization all clinics were following usual care. In the first-year post randomization the intervention clinics were using the intervention and the control clinics still usual care. In the second-year post intervention all clinics were using the intervention. In each case we have a single observation per clinic. We will use a random effects model to assess intervention effects while adjusting for within clinic clustering. The model will allow for period effects and will also estimate separate effects for the first and second year of intervention rollout.

Sensitivity Analyses

Sensitivity analysis will include GEE models without weighting, GEE models that also adjust for insurance status, random effects models, and models excluding the two clinics (one intervention and one control)

affiliated with an academic medical center (these clinics did not have shared governance and did not use the same FIT kit throughout the intervention).

Finally, while our primary analysis will include all individuals accrued after EHR tools were provided to clinics on February 4, 2014, no clinic began printing letters until at least June of 2014; some did not begin until spring of 2015. To account for this implementation delay, we will repeat the above analyses for FIT completion and "any CRC screening" using a lagged dataset that only included individuals accrued between June 4, 2014 and February 3, 2015. As with the primary dataset, outcomes for this lagged dataset will be assessed through August 3, 2015, after which materials were made available to usual care clinics.

2.4.2 Analysis of Process Data

We will use proportions of clinics or patients to calculate adoption, reach, implementation and maintenance. Consistent with our adapted CONSORT, to the extent possible, we will report descriptive characteristics of adopters vs. non-adopters and maintainers vs. non-maintainers (at the clinic level) and completers vs. non-completers in YRS 01-02 (at the patient level).

2.4.3 Moderator analysis

In addition to the previously mentioned analysis looking at whether the intervention effect varied by service area network, we plan to conduct a detailed moderator analysis looking at the extent to which the intervention effects persisted within, and potentially differ across, subgroups defined by a variety of patient level factors. Since the focus of these analysis is on patient level effects, we will use random effects, rather than GEE models, for these analyses.

2.5. Power and Sample Size

For Phase 2, STOP effectiveness will be assessed using a two-arm, cluster randomized design with a total of 26 clinics. Our power calculations are based on the following assumptions:

- We have equal Ns per clinic and equal numbers of clinics per group. In practice, the sample sizes will not be equal, but since almost all clinics had at least 450 subjects who qualified for the intervention (most had at least 700 qualifying individuals), we conservatively use this figure for all sites.

- We compare two binomial proportions with a type I error rate of 5%. For each of a variety of design assumptions, we determined the design effect due to clustering and used this to calculate the effective sample size as if these were independent observations. We then used the formulas from Hulley et al., to estimate power.

- Finally, we assume an intention-to-treat approach in which we consider a treatment failure to be any individual who receives the initial intervention mailing (or for the UC clinics would have qualified to receive the mailing) and does not have a completed fecal test within their follow-up window. Although we expect to learn through the intervention process that many intervention participants do not require screening, we have no way to exclude comparable individuals from the control clinics and hence must ignore this information for the primary analysis.

We calculated power for Intra-class Correlation Coefficients (ICCs) of .03, .04, and .05, usual care FIT return probabilities of 5%, 10%, and 15%, and intervention effects (absolute differences) of 10 – 14 percentage

points. Based on analyses done by Dr. Green (STOP co-PI), we expected the ICC to be about .03, though as it turned out the ICC was closer to .05. Using this latter figure, we had >90% power for detecting effect sizes of at least 13 percentage points even with UC probabilities as high as 15%. Power was > 88% for detecting effect sizes of at least 11 percentage points if the UC probabilities were no higher than 10%. Power declines only slightly even for subgroups 1/6th of the full cohort (e.g., for 17% Hispanic patients). This reflects the fact that we have an overabundance of individuals within each clinic and that the main driver of power is thus the number of clinics.

Estimated Power with 26 clinics

Difference in probability between intervention and UC

ICC=.03

Prob in UC	.10	.11	.12	.13	.14
.05	99.2%	99.7%	99.9%	99.9%	100.0%
.10	96.2%	98.1%	99.1%	99.6%	99.8%
.15	91.7%	95.4%	97.6%	98.8%	99.4%

ICC=.04

Prob in UC	.10	.11	.12	.13	.14
.05	97.1%	98.5%	99.3%	99.7%	99.8%
.10	90.2%	94.2%	96.7%	98.2%	99.1%
.15	82.6%	88.7%	93.0%	95.8%	97.6%

ICC=.05

Prob in UC	.10	.11	.12	.13	.14
.05	93.2%	96.1%	97.8%	98.8%	99.4%
.10	82.6%	88.5%	92.7%	95.5%	97.3%
.15	73.2%	80.7%	86.7%	91.1%	94.3%

2.6. Cost Analysis

Our cost analysis will assess the costs and long-term cost-effectiveness of the Enhanced Auto Intervention, relative to usual care. The second primary outcome is an analysis of the cost, cost-effectiveness, and return on investment. The goal of cost-effectiveness analysis is to select the strategy that yields the greatest incremental health benefits per additional dollar spent.

Incremental cost-effectiveness: The measure of promotion success is how many members of the eligible population obtain screening. The difference in cost over the difference in effectiveness of a new intervention vs. standard care is the incremental cost-effectiveness of the new intervention, derived as:

$$\text{Incremental Cost-Effectiveness New} = (\text{CNew} - \text{CStd})/(\text{ENew} - \text{EStd})$$

where CNew and CStd refer to average total costs, and ENew and EStd refer to average total effectiveness for the new and standard arms, respectively. We denote the total cost of screening as Csceen. Screening promotion programs also have a per-person denoted as Cpromote. By reducing the incidence of advanced

cancers, screening can reduce the cost of treating cancer in those who were destined to develop the disease, denoted as Ccancer. Total costs for a particular screening + promotion program A are:

$$CA = [CsceenA + CpromoteA - CcancerA]$$

By reducing the incidence of advanced cancers, screening technologies increase the number of life years (LY) for a population, less any morbid or mortal side effects of the screening intervention. Thus, in comparing two screening promotion programs, the incremental cost-effectiveness of new program A versus the established program B is:

$$\text{Incremental Cost-Effectiveness Program A} = (CA - CB)/(LYA - LYB)$$

We will report cost-effectiveness as cost per additional screenee and cost per LY gained (note that cost per additional screenee does not include CsceenA or CcancerA and the denominator is total number of persons in each population obtaining screening rather than LY). Since realization of the benefits of screening promotion programs will take years or even decades, direct evaluation of the impact of promotion from the trial on LY is infeasible.

Costs associated with promotion (Cpromotion): We will document the non-research costs associated with implementing the CRC screening intervention. These include associated fixed costs (i.e., those unrelated to the size of the target group) and variable costs. Fixed costs include implementation costs (e.g., staff training), maintenance, office space used in the clinic, equipment and materials (e.g., computers), and telephone. Variable costs include labor costs associated with delivering the interventions as well as materials distributed to the participants (e.g., FITs). Accounting systems will be used as a source of data on the cost of equipment and supplies (e.g., printing). To estimate labor costs associated with delivering the intervention, clinic staff will record the time they spend delivering intervention components (e.g., for placing FIT orders) on staff logs. Fixed and variable costs will be amortized to determine the average expenditure associated with delivering an intervention (e.g., mailing costs) to the study population (Cpromotion).

Costs of colorectal cancer screening (Cscreen). Each individual who obtains screening will be assigned an associated cost, including the time-costs associated with screening, and costs for evaluation of true and false positives. Test and evaluation costs will be based on reimbursements from nationally standardized databases (e.g., Medicare reimbursements). As this is a home-based test, no time will be associated with transportation. Time spent in screening will be valued by national wage rates for individuals of the study population's age group and ethnicity. (This time is anticipated to be low.)

Estimating LY gained and quality-adjusted LY. Our trial is not designed to estimate differences in CRC rates or survival for the screened population. These will need to be estimated through modeling. We propose building a Markov state transition model to estimate years of life gained and quality-adjusted LY. Three states are accounted for: healthy, CRC, and death. The healthy and CRC states are assigned a utility weight for calculating quality-adjusted LY are calculated.

We start with simplifying assumptions that all individuals who start screening as a result of the program will continue and those who screen have no risk for developing invasive CRC. Risk of death in each year will be determined from life tables; risk of CRC in the unscreened population will be based on epidemiological data. Those who develop CRC face a risk of death (from other causes) or death from CRC. Disease-specific survival rates for CRC will be based on Surveillance Epidemiology and End Results (SEER) survival data.(3).

Consistent with previous research, we will use a three percent annual rate for discounting future costs and LY after conversion of all costs to a constant year's dollars. We will conduct one-way and multiway sensitivity analyses to explore the robustness of cost-effectiveness ratios to changes in assumptions.

Return on investment. Following the AHRQ Health Care Exchange recommendations, we will also present results in an ROI format. ROI can be measured prospectively or retrospectively and has historically been defined as the amount an organization expects to save (i.e., the difference in healthcare expenditures with and without a specified program), compared to expected program costs. Although results are sometimes reported as a ratio (e.g., ROI = savings/program costs, in current dollars), ratios are subject to misleading scale effects. The preferred financial metric is "net present value" (i.e., savings less program costs, in current dollars). In this sense, an ROI analysis is a restricted cost-benefit analysis.

Learning from Phase 1: Our Phase 1 experience will inform the Phase 2 economic evaluation, using the following analytic plan. One objective of the economic evaluation is to categorize program labor costs by both individual and by activity. In particular, we will refine our data collection methods, particularly as they can greatly influence our understanding of the multiple program tasks a given individual may perform. We will consult with the project team to appropriately categorize activities to be tracked and over what time frame. Below is the sample data capture sheet for ongoing intervention time, centralized outreach and management functions.

Mailing – work associated with mailing letters, FIT Kits and post cards
Prep time – work associated with planning and organizing the mailings
Clinic staff meetings, PDSA and training work – work associated with clinic meeting and training time to launch and improve the intervention
EMR changes – work associated with requesting, specifying, testing and implementing EMR changes associated with the intervention
Administration time – work associated with organizing meetings and logistics, preparing and distributing meeting materials and minutes associated with the intervention.
Project consultation meetings - work associated with meetings of clinic staff with research project staff and/or OCHIN staff
Other - other work related to ongoing delivery of the intervention but not associated with above categories

Ongoing Cost of STOP CRC Program							
DATA CAPTURE SHEET #2: ONGOING INTERVENTION TIME – CENTRALIZED OUTREACH AND MANAGEMENT FUNCTIONS							
Your Name: ***(each OCHIN, VG team member fills out own sheet)***					**Date:**		
Week of:	**Hours**						
	01	**10**	**11**	**41**	**45**	**40**	**Other**
What	**Mailing**	**Prep time**	**Clinic staff mtgs PDSA training**	**EMR changes**	**Admin Time**	**Project consult mtgs**	
1. Centralized activities							

Produce and deliver lists							
Prepare and mail introduction letter							
Prepare and mail FIT							
Prepare and mail reminder card							
Prepare and mail final reminder letter							
Produce tracking reports							
2. Clinic oversight and management							
Lab orders tracking							
BVtn results pool tracking							
Billing adjustments							
PDSA mtgs							
OTHER							

826
827 **2.6.1.1. Costs of Delivering the Intervention**

828 Clinic staff will incur ongoing costs as the program is implemented, including fielding incoming questions
829 from patients throughout the life of the study. They will incur costs associated with outgoing Motivational
830 Interview calls. We plan to calculate an estimate of the costs over two week-long time periods for incoming
831 and outgoing calls and multiply that estimate times the number of calls to assess total time expended.
832 Below are sample telephone tracking logs for incoming calls and Motivational Interviewing calls.

833 **a.** Incoming Calls
834 **i.** Sampling Period 1 – after the FIT Kits are mailed – (February 6-13th)
835 **ii.** Sampling Period 2 – after the reminder postcard is mailed
836 **b.** Outgoing MI Calls
837 **i.** Sampling Period 1 – Week 1 of MI calling
838 **ii.** Sampling Period 2 – Week 2 of MI calling
839

Sample Telephone Tracking Log for STOP CRC Incoming Calls					
STOP CRC PHONE TIME LOG - Sampling Period One – Incoming Calls					
Date:		**Your Name:**		**Duration of your work day:** ☐ **half day** ☐ **full day**	
Staff	**Enter tic mark for each call in appropriate call duration column**				
	Unable to Connect or <1	**1-3 Min**	**3-5 Min**	**5-10 Min**	**>10 Min**

	Min				
Client Initiated calls resolved real time or through call backs					
Centralized					
PCC					
RN					
MA					
PCP					
Other					

840
841

Sample Telephone Tracking Log for STOP CRC MI Calls					
STOP CRC PHONE TIME LOG - Sampling Period One – MI Calls					
Date:		**Your Name:**		**Duration of your work day: ☐ half day ☐ full day**	
Staff	**Enter tic mark for each call in appropriate call duration column**				
	Unable to Connect or <1 Min	**1-3 Min**	**3-5 Min**	**5-10 Min**	**>10 Min**
Clinic Initiated calls					
RN					
Other					

842
843 **2.7. Qualitative Data Collection**

844 The following table illustrates the qualitative work completed by the STOP CRC project.

Phase	Description	Method	Who	Timeline
Adoption	Organizational survey circulated to gain a readiness picture of the participating clinics.	Survey	1 survey per health center completed by a combination of project lead, medical director, operations director, EMR specialist, or QI.	Summer/Fall 2014
	Leadership Interview related to what health centers do regarding CRC screening and how they feel about implementing the	Phone Interview	3-5 completed per health center with a project lead, medical director, CFO, EMR specialist, QI, nurse manager,	Summer/Fall 2014

	upcoming STOP CRC program and related activities.		etc.	
	Provider Survey was circulated to gather provider attitudes and beliefs about crc screening.	Survey via Survey Monkey	Qualifying providers at all clinics were invited to complete a survey via Survey Monkey.	Winter 2014
Implementation	Observation of PDSA trainings.	Observation/documentation	Clinic teams	Winter 2014/ Spring 2015
	Observations of control clinic roll out trainings.	Observation/documentation	Clinic teams	Summer 2015
	Interview project leads to understand concerns and thoughts about sustainability.	Phone interview	All project leads at the intervention sites.	Summer 2015
Maintenance	Leadership meetings to discuss lessons learned and present intervention/ control activity data; discuss plans for sustainability.	In-person presentation by the Investigator and Project Coordinator.	Conducted at all intervention sites with project leads, QI specialists, Medical Director, etc.	Spring 2016
	Organizational Survey (follow-up) regarding STOP CRC implementation and roll out efforts.	Survey	1 survey per health center completed by a combination of project lead, medical director, operations director, EMR specialist, or QI.	Winter 2015
	Leadership Survey (follow-up) regarding STOP CRC implementation and roll out efforts.	Survey	3-5 per health center completed by a project lead, medical director, EMR specialist, or QI.	Winter 2015
	Provider Survey (follow-up) was circulated to gather provider attitudes and beliefs about CRC screening.	Survey via Survey Monkey	Qualifying providers at all clinics were invited to complete a survey via Survey Monkey.	Winter 2015/ Spring 2016
Patient interviews	Interview responders and non-responders. Understand persistent barriers and facilitators to CRC screening.	Phone Interview	40 Clinic patients (English and Spanish speakers)	Summer 2016

Other				
Non-participating health centers	Organizational surveys and interviews were used to understand the Health Center's decision to not participate in STOP CRC, and their activities to address CRC screening.	Survey and phone interviews	1 survey per health center to be completed by operations or medical director and 6 Interviews with clinic supervisors, operations director, medical director, QI, and office manager.	Spring 2015

Materials that support the qualitative process are provided in Appendix P; findings from the qualitative interviews and surveys conducted are provided in Appendix F.

2.8. Data Auditing and Validation

Data auditing will be conducted at OCHIN through a partnership between OCHIN and CHR. The process of validation and audits is as follows:

1. Identify CHR auditor to complete work (Note that CHR will ensure IRB approval for CHR audit personnel to access OCHIN data.) and determine potential schedule of auditor
2. Review OCHIN audit capabilities and finalize audit forms for use by CHR auditor
3. Train auditor
4. OCHIN will secure a workspace for CHR auditor at OCHIN
5. Have auditor complete OCHIN HIPAA training and sign confidentiality agreement
6. OCHIN will assist CHR auditor to be able to start validation activities:
    a. Create dataset for use by auditor (patient identifiers blinded)
    b. Instruct auditor on storage of electronic audit forms (where validation data should be stored)
    c. Compare OCHIN end-user data and EPIC chart data
    d. Prepare reports for data team and investigators

2.8.1. Validating Patient Selection using Inclusion/Exclusion Criteria (November 2014):

The intended purpose of this validation was to inform the accuracy and completeness of EMR codes and processes for selecting eligible patients for the study. Discrepancies in eligibility using codes vs. chart audit would identify systematic issues with codes or processes, determine if the codes list is complete to accurately select eligible patients for the intervention (and a similar group of patients for usual care), etc.

- Given the delay in rollout, the validation was not performed prior to roll-out, thus the original aim is no longer relevant. Instead, the validation serves as an assessment of our patient selection codes and processes at a snapshot in time; with that snapshot reflecting varying degrees of data cleanup per the work we've been doing with each site.

2.8.2. Chart Audits of Participating Clinic Organizations

For each participating clinic organization, we will apply our inclusion and exclusion criteria and select 20 patients for a chart audit. The audit will address the following variables:

- Date of Birth
- Date of most recent office visit

- FIT/FOBT order, result, code, date
- Flexible sigmoidoscopy order, result, code, data
- Recorded colonoscopy referral, order or result, date and field where found
- Interval for next colonoscopy
- GI referral date, reason and field where found
- History of colorectal disease
- History of ESRD
- History of hospice or SNF

Audit forms were created for the pilot and will be modified for use throughout the project. Below is a sample of the audit form used for validating clinic data.

	Sample	1
Reviewer	**Amanda**	
Date of audit	**7/15/2013**	
Clinic	**Hillsboro**	
Study ID	abcde	
Gender		
Date of Birth	1/23/1945	
Date of most recent office visit	1/15/2012	
Colonoscopy Ever or Flex Sig: ICD-9: 45.22, 45.23, 45.25, 45.42, 45.43		
CPT/Procedure Codes: 44388-44394, 44397, 45355, 45378-45387, 45391, 45392 G0105, G0121 - Virtual Colonoscopy: 0066T, 0067T 74261-74263		
Flex Sig: ICD-9 45.24 or CPT - 45330, 45331, 45332, 45333, 45334, 43335, 45337, 45338, 45339, 45340, 45341, 45342, 45345, G0104; OCHIN Codes - V15.29, V72.85, Imo0001		
yes/no (Flex or Colonoscopy)	yes	
Date of most recent colonoscopy (order or result)	6/15/2008	
Copy of procedure within the chart?	no	
Field where found	encounter	
Codes or text used	colonoscopy ordered at GI associates	
Interval for next colonoscopy; if yes, where recommendation was found.	no colonoscopy scan in chart	
yes/no	yes	
Date of most recent GI referral	5/1/2007	

Reason for referral (diagnosis associated if available)	none	
Field where found	encounter	
FIT/FOBT in January 13 2012-July 31, 2013 - CPT Codes: 45.22, 45.23, 45.25, 45.42, 45.43		
Yes/no	yes	
Lab order code	45.25	
Date of Most Recent Order	1/1/2007	
Resulted	yes	
Resulted date	2/15/2007	
Resulted Positive or Negative	positive	
Ordering Facility?	VG Hillsboro	
Facility where resulted?	Labcorp	
Associated Diagnosis/ (code?)	none	
Were any LOINC codes used?	na	
Comments		

The investigators will look at differences in findings in order to assess data quality and provide solutions for data recording. The table below illustrates findings from the pilot stage.

Summary of Chart Audit for Pilot Clinics, Eligibility (subjects included in the pilot)	**Proportion**	**95% CI (Fixed effects)**
Clinic A (n=40)		
% correctly included	90%	(75%, 97%)
% with colonoscopy (10 yrs)	10%	(3%, 25%)
% with sigmoidoscopy (5 yrs)	0%	(0%, 10%)
% with FIT/FOBT (1 yr)	0%	(0%, 10%)
Clinic B (n=40)		
% correctly included	87.5%	(72%, 95%)
% with colonoscopy (10 yrs)	12.5%	(5%, 28%)
% with sigmoidoscopy (5 yrs)	0%	(0%, 10%)
% with FIT/FOBT (1 yr)	0%	(0%, 10%)
All Clinics[1] (n=80)		
% correctly included	88.8%	(79%, 94%)
% with colonoscopy (10 yrs)	11.3%	(6%, 21%)
% with sigmoidoscopy (5 yrs)	0%	(0%, 6%)

% with FIT/FOBT (1 yr)	0%	(0%, 6%)

[1] proportions are simple average of individual clinic proportions; CIs calculated assuming a common proportion for each site (fixed effects) or allowing these proportions to vary across sites (random effects)

Summary of Chart Audit for Pilot Clinics, Exclusion (subjects excluded from pilot)	Proportion	95% CI (Fixed effects)
Clinic A[1] (n=10)		
% properly excluded, any reason	100%	
% properly excluded, indicated reason	90.0%	
Clinic B[1] (n=10)		
% properly excluded, any reason	70.0%	
% properly excluded, indicated reason	70.0%	
All Clinics[2] (n=20)		
% properly excluded, any reason	85.0%	(61%, 96%)
% properly excluded, indicated reason	80.0%	(61%, 96%)
-- colonoscopy/sigmoidoscopy exclusions (n=13)		
% properly excluded, any reason	92.3%	--
% properly excluded, indicated reason	76.9%	--
-- FIT/FOBT exclusions (n=8)		
% properly excluded, any reason	75.0%	--
% properly excluded, indicated reason	62.5%	--
-- Colorectal Disease exclusions (n=10)		
% properly excluded, any reason	90.0%	
% properly excluded, indicated reason	40.0%	

[1] weighted estimates across the three sampling strata

[2] proportions are simple average of individual clinic proportions

We will calculate sensitivity and specificity of the data, using the chart audit as the gold standard. An assessment of data quality in the moderator variables may result in additional chart audits.

2.8.3. Comparison of Claims Data and EHR Data for CRC Screening Outcomes

We will compare Medicaid claims data to clinic EHR data for colorectal screening (colonoscopy, fecal testing, sigmoidoscopy). To do this, we will obtain a list of patients from the participating organizations that have been screened in the relevant timeframe (colonoscopy past 9 years, fecal test past 11 months, sigmoidoscopy past 4 years). Medical records of patients with a claim will be abstracted. The chart auditor will verify evidence for the procedure in the medical record and will note where it was found (e.g. problem list, surgical history). We will report the concordance between claims data and EHR data for colonoscopy, fecal testing, and flexible sigmoidoscopy.

Summary of Chart Audit for Pilot Clinics, Outcome (subjects included in the pilot)	% with FIT/FOBT in chart	95% CI (Fixed effects)
Clinic A (n=30)		
Post intervention FIT/FOBT per EMR (n=14)	100%	(73%, 99%)
No post intervention FIT/FOBT per EMR (n=16)	0%	(0%, 16%)
Clinic B (n=30)		
Post intervention FIT/FOBT per EMR (n=14)	100%	(73%, 99%)
No post intervention FIT/FOBT per EMR (n=16)	0%	(0%, 16%)
All Clinics[1] (n=60)		
Post intervention FIT/FOBT per EMR (n=28)	100%	(85%, 100%)
No post intervention FIT/FOBT per EMR (n=32)	0%	(0%, 15%)

[1] proportions are simple average of individual clinic proportions; CIs calculated assuming a common proportion for each site (fixed effects) or allowing these proportions to vary across sites (random effects)

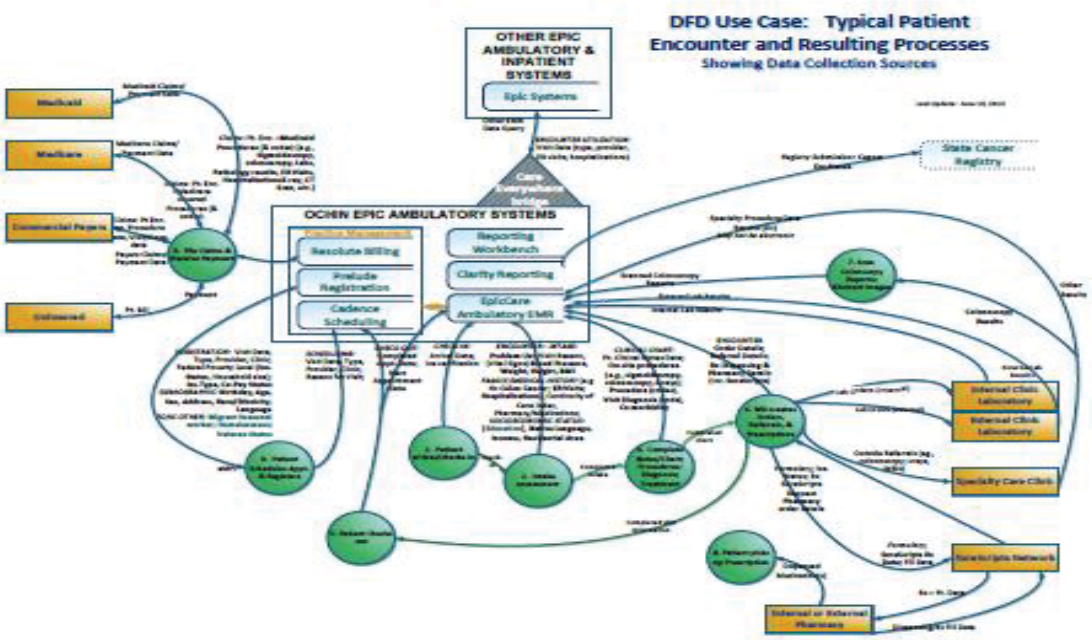
2.8.4. Capture of CRC screening in Health Maintenance

We plan to assess how completely CRC screening history is captured in the medical record. We will do this by comparing Health Maintenance with our list of patients excluded because of prior screening. We will do this at 4 time points: baseline, 6 months, 12 months, and 18 months.

We will do this in clinics selected for the intervention as well as the control clinics. This check will provide an independent assessment of whether data accuracy improvements are occurring relatively equally at intervention and usual care clinics.

2.9. Description of Data Sources

This section generally describes all data sources and data collection instruments to be used in STOP CRC. We worked with Dr. Meredith Nahm from the National Collaboratory Coordinating Center to develop a Data Flow Diagram and have included it here. As previously noted, STOP leverages data flow from these data sources and uses existing EPIC tools to deliver the interventions (e.g. Reporting Workbench, external and internal laboratory data feeds).



2.9.1. Electronic Data from OCHIN

OCHIN provides a common comprehensive information technology system to all its members. This includes an organization-wide single EHR, through an Organized Health Care Agreement, recognized by HIPAA's privacy rules to allow two or more entities participating in joint activities to share patient-protected health information. The Data Flow Diagram shows how information will be obtained for our primary outcome: receipt of FIT/FOBT. It also shows how data will be obtained for our secondary outcomes: any type of colorectal cancer screening. In the latter case, as colonoscopies ore obtained at outside facilities, we will work with both intervention and control sites to improve the data capture by 1) using Health Maintenance to postpone (pending records) for patients who report previous screening during a clinic encounter; 2) using claims Medicaid claims data to update medical records; and 3) improving clinic procedures to obtain records from patients who are referred to Gastroenterology. These data, once obtained by the clinics, will be extracted at OCHIN and analyzed at CHR under the direction of Dr. Bill Vollmer.

2.9.2. Data Transfer Procedures

OCHIN will transmit the participant data directly to CHR using a secure file transfer site. Standard Operating Procedures (SOPs) will be developed to describe in detail the specific steps necessary for encrypting the data files and for their secure transfer.

Although OCHIN has a Data Use Agreement with CHR, it covers only limited datasets. This agreement does not allow OCHIN to give protected health information (PHI) to CHR to use for patient interviews. Therefore, the following process must take place:

1. OCHIN will create a file containing the PHI and place it on OCHIN's Secure File Transfer Protocol (SFTP) website, to which all OCHIN member clinics have access.
2. The member clinic will download the file containing PHI from the SFTP

Limited personnel at the **clinics** have access to OCHIN's SFTP website. These include but are not limited to Electronic Health Record Specialist (IT Support/Site Specialist), IT Support, System Administrator, and Data Analysts. For CHR to receive the data, the following process must take place:

3. Upon notice that OCHIN has uploaded file to SFTP site designated clinic staff (most likely EHR Specialist) will log onto SFTP site and download the file.
4. An EHR Specialist will upload that file into CHR SFTP website.
5. The EHR specialist will notify CHR contact upon successful file upload.
6. The EHR Specialist will delete file from the saved location or save file in secure folder on the clinic's network.

Once OCHIN and the **clinics** have completed the above steps, **CHR** will complete the following process:

7. Upon notice that the **clinic** has uploaded file to SFTP site designated clinic staff will log onto SFTP site and download file
8. CHR staff will download the patient data to the file service under the appropriate folder.

Patient data cannot be forwarded on and must only be used as indicated in the IRB.

2.9.2.1. Safeguarding and Transfer of Data Abstracted from Medical Records

Data abstracted from medical records will be kept secure in all steps from the point of collection to storage at CHR.

3. Dissemination Plan

Our hope is that the intervention will continue well beyond the timeframe of the grant. Not only have we developed reusable materials, but we have embedded an adaptable intervention directly into the clinic process to facilitate easier adoption by other clinics. We have the following key dissemination efforts, detailed in the following sections:

- During the Phase 1 pilot, we developed several intervention materials, including an introductory letter (written in English and Spanish); wordless instructions for completing the FIT (OC Micro); wordless instruction for completing the FIT (Insure); reminder postcard (written in English and Spanish) and a clinic poster.
- With funding from Kaiser Permanente Community Benefit, we have developed a project video that showcases the STOP CRC project and the success in getting patients screened.
- We will create and maintain a project website for sharing project materials, videos, presentations, and manuscripts.
- We are hosting a webinar series, from October – December 2013 on CRC screening programs.
- We plan to develop and disseminate an implementation guide and web toolkit.
- We plan to present research findings at local and national conferences.

3.1. Intervention Materials

During the Phase 1 pilot, we developed several intervention materials: an introductory letter (written in Englsih and Spanish); wordless instructions for completing the FIT (OC Micro); reminder postcard (written in English and Spanish), and a clinic poster. We have already shared these with a variety of health systems, including Kaiser Permanente NW, the Salem Coordinated Care Organization, and Sea Mar Community Health Centers. Each of these sites is using our wordless instructions with their FIT kits. We have an in-press publication that describes the development of our wordless instructions and, once published, will allow for a broader dissemination of the materials. We plan to place these on a project website so that all participating sites can access these materials; we plan to make this website accessible to the public once our intervention period ends.

3.2. Implementation Guide and Web-based Toolkit

The Systems of Support Study to Increase CRC Screening and Follow-up (SOS), Green –PI on which STOP is based, protocols and materials, are being reviewed for publication on NCI's Research Tested Intervention Programs (RTIPs). STOP will also request a similar review and posting. Consistent with other studies, we will draft an implementation guide based on findings from Phases I and II. It will describe the program rationale and contain sections that orient a clinic to this program, including the following:

- target population with inclusion and exclusion criteria;
- minimum clinic capacity and resources (use of the EHR, use of Reporting Workbench and other similar population management tools; Practice Management; and direct interface with laboratory for processing FIT);
- program objectives and strategies;
- descriptions of CRC screening tests to help clinics select the right one;
- barriers and facilitators to patient reach and suggested solutions.

Other parts of the implementation guide will address the standard operating procedures; overall design and methods of the CRC screening program (e.g., data querying tools, training curriculum training clinical staff, suggested partnerships and collaborations); and other tools to support the implementation and achievement of results (e.g., evidence-based clinical practice guidelines, patient educational materials, and an outcome tracking plan).

We will also develop forms and procedures for conducting quality assurance activities and clinic reports to monitor compliance with the intervention protocol at each site. To assist other sites in adopting the program, the guide will contain data algorithms for selecting eligible patients, tracking relevant CRC outcomes and cost, and adjusting for relevant covariates (see software sharing plan). The guide will be developed with OCHIN and participating FQHCs through an iterative refinement process. The Advisory Board will also provide feedback on the implementation guide. We will develop a web-based toolkit to ensure broad dissemination of our research products and findings. The toolkit will contain individual components of the program, including materials translated into Spanish, and will be modeled after the successful PRIMER toolkit (www.researchtoolkit.org). During Phase 1, we worked with Lara Media Services to develop a video showcasing the success of our pilot project and its impact on patients lives.

We will disseminate the implementation guide and web-based toolkit through various channels, including (a) the leadership of other OCHIN-member clinics (presenting at monthly meetings of OCHIN organization medical directors, board meetings of individual FQHCs, and the OCHIN retreat planned for Year 5), (b) our

Advisory Group and other local stakeholders, and c) the national Collaboratory. We anticipate that the Coordinating Center will host a Collaboratory website where we post program products. Other possible websites include Research on Tested Intervention Programs (RTIPS), the Improving Chronic Illness Care Website (http://www.improvingchroniccare.org/), NCI's Cancer Planet, and AHRQ's Innovation Exchange. As colorectal cancer screening is an incentivized metric for a variety of health plans among our participating clinics. We will also distribute the guide and toolkit to state offices, such as the Oregon Health Authority and Washington State's Governor's Interagency Council on Health Disparities (of which Dr. Coronado is a member).

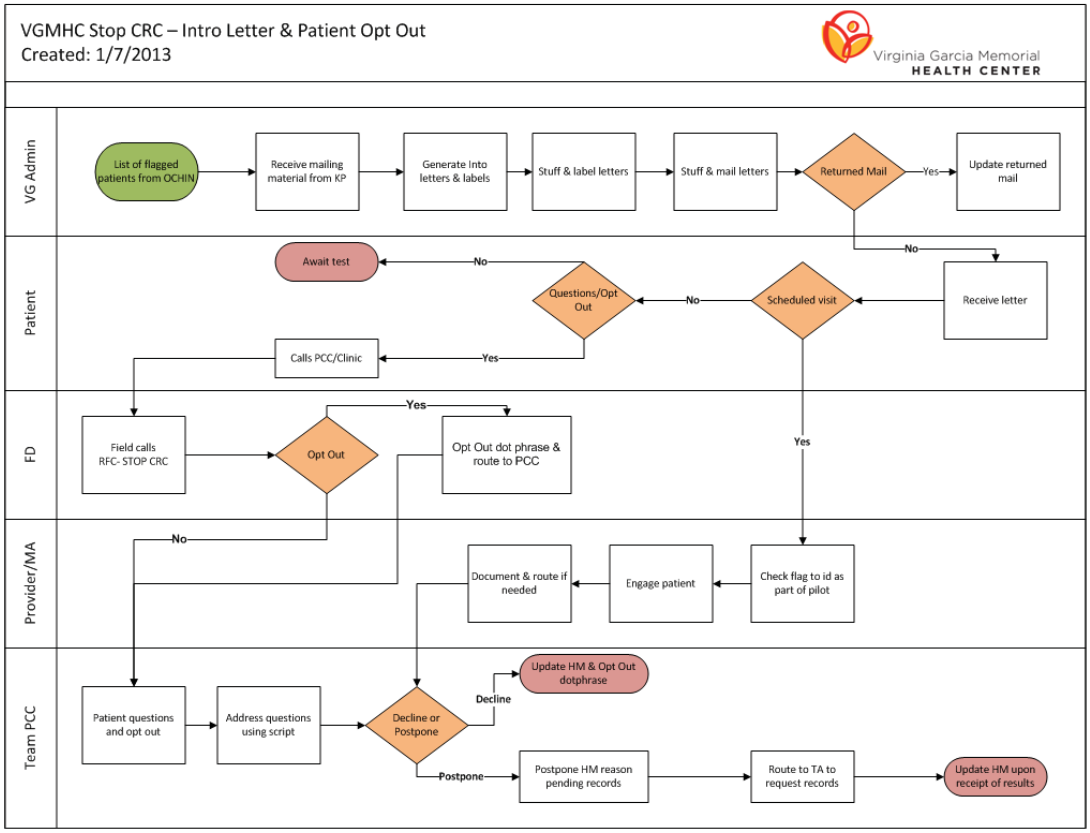
3.3. Dissemination of Research Findings

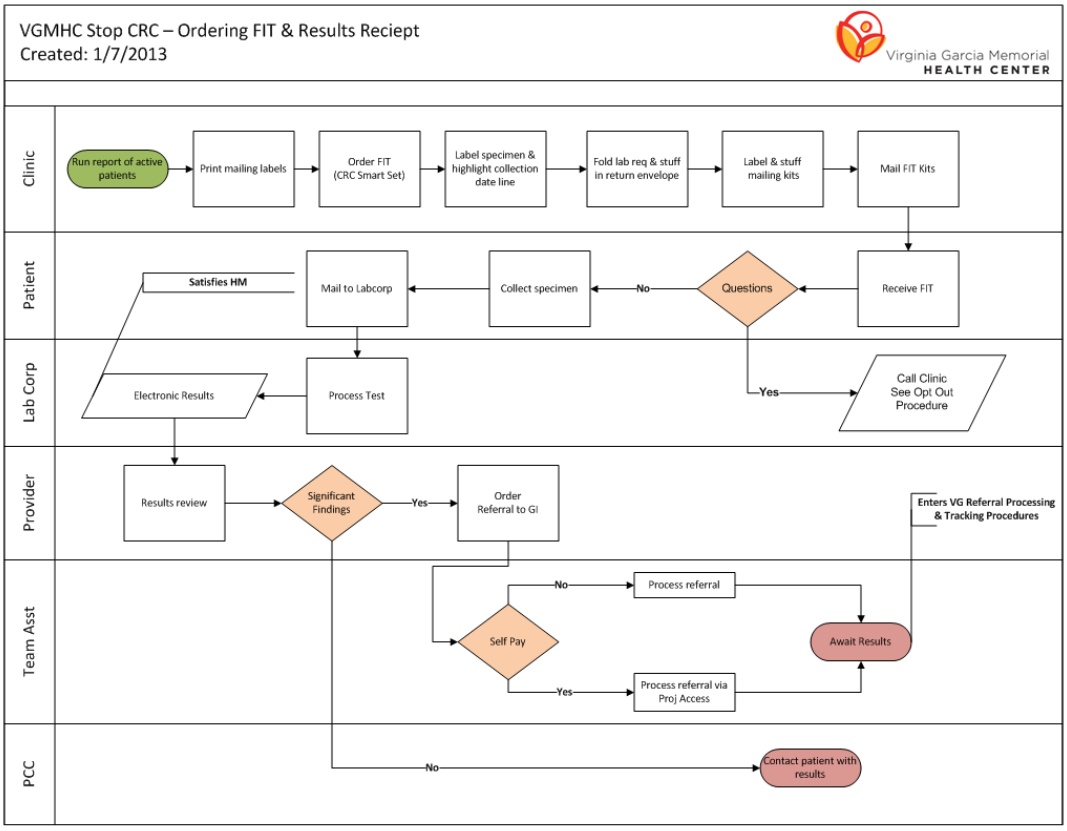
We will undertake specific dissemination efforts to reach the populations that receive care at FQHCs. We will present at national health disparities conferences and the Migrant Stream Forum Conference. Dissemination of our research findings to local audiences will likely include presentations at the annual Latino Health Equity Conference, organized by Familias en Accion (represented on our Advisory Group), and the Oregon State Health Equity Committee. We will write an article for the online magazine *eSalud* (Dr. Coronado is a member of the editorial board) for distribution to a lay audience. We will also present our findings to a variety of local audiences, including Spanish-language radio stations. Dr. Coronado has hosted several call-in radio programs on cancer prevention topics in the past. In addition, Dr. Coronado, and Dr. Green, will present our finding as several national research conferences, including the Health Maintenance Organization Research Network conference, and the American Association for Cancer Research.

	Dissemination Product	**Dissemination Plan**
UH2	Introductory letter Wordless instructions for FIT (OC Micro) Wordless instructions for FIT (Insure) Reminder postcard Video showcasing pilot	Publish wordless instructions in scientific literature Share wordless instructions to health systems and coordinated care organizations Post video on project website and share with clinics and state office of equity and inclusion.
UH3 – YR01	Findings from pilot	Publish in scientific literature Present at conferences Post on project website
UH3 – YR02	Findings from qualitative research	Publish in scientific literature Present at conferences Post on project website
UH3 – YR03	Findings from cost analysis	Publish in scientific literature Present at conferences Post on project website
UH3 – YR04	Findings from pragmatic study Expand program to non-Epic clinic; draft Implementation guide	Publish in scientific literature Distribute implementation guide Post on project website, RTIPS and Cancer PLANET

4. Appendix:

4.1. Workflow Diagrams from Virginia Garcia




VGMHC Stop CRC – Ordering FIT & Results Reciept
Created: 1/7/2013
Virginia Garcia Memorial
HEALTH CENTER
Clinic
Patient
Lab Corp
Provider
Team Asst
PCC
Run report of active patients
Print mailing labels
Order FIT (CRC Smart Set)
Label specimen & highlight collection date line
Fold lab req & stuff in return envelope
Label & stuff mailing kits
Mail FIT Kits
Receive FIT
Questions
No
Collect specimen
Mail to Labcorp
Satisfies HM
Yes
Call Clinic See Opt Out Procedure
Process Test
Electronic Results
Results review
Significant Findings
Yes
Order Referral to GI
Enters VG Referral Processing & Tracking Procedures
No
Process referral
Self Pay
Yes
Process referral via Proj Access
Await Results
No
Contact patient with results

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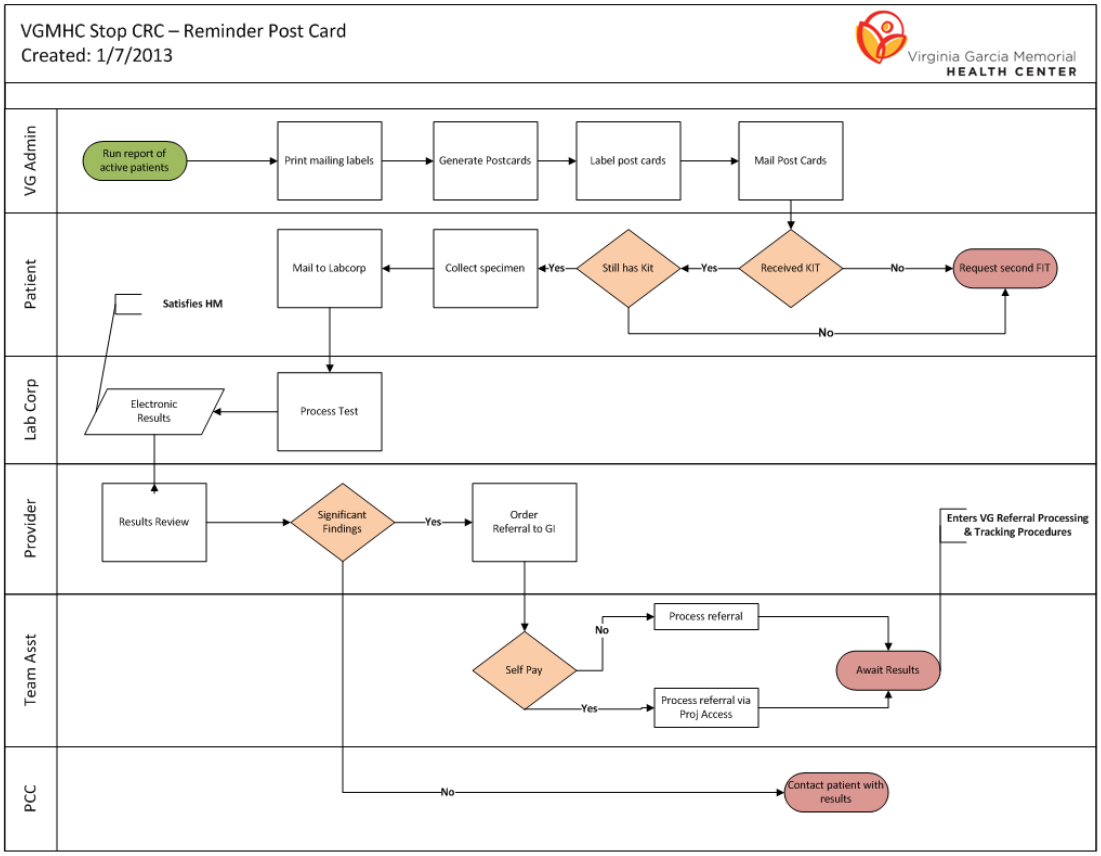
VGMHC Stop CRC – Reminder Post Card
Created: 1/7/2013
Virginia Garcia Memorial
HEALTH CENTER
VG Admin
Patient
Lab Corp
Provider
Team Asst
PCC
Run report of active patients
Print mailing labels
Generate Postcards
Label post cards
Mail Post Cards
Mail to Labcorp
Collect specimen
Yes
Still has Kit
Yes
Received KIT
No
Request second FIT
No
Satisfies HM
Electronic Results
Process Test
Results Review
Significant Findings
Yes
Order Referral to GI
Enters VG Referral Processing & Tracking Procedures
Process referral
No
Self Pay
Yes
Process referral via Proj Access
Await Results
No
Contact patient with results

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4.2. Research Reports

4.2.1. Patient Eligibility Table

Patient eligibility in Intervention Clinics 1-6	Clinic #1		Clinic #2		Clinic #3		Clinic #4		Clinic #5		Clinic #6		Total	
	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Patients 50-74 with clinic visit in past year	500	(100.0)	500	(100.0)	500	(100.0)	500	(100.0)	500	(100.0)	500	(100.0)	1000	(100.0)
Patients with valid address	226	(45.2)	188	(37.6)	188	(37.6)	188	(37.6)	188	(37.6)	188	(37.6)	414	(41.4)
Excluded due to:														
Prior CRC Screening	19	(8.4)	56	(24.8)	56	(24.8)	56	(24.8)	56	(24.8)	56	(24.8)	75	(33.2)
History colorectal disease	4	(1.8)	11	(5.9)	11	(5.9)	11	(5.9)	11	(5.9)	11	(5.9)	15	(3.6)
Co-morbid conditions	4	(1.8)	10	(5.3)	10	(5.3)	10	(5.3)	10	(5.3)	10	(5.3)	14	(3.4)
Patients Eligible after exclusions	199	(88.1)	111	(59.0)	111	(59.0)	111	(59.0)	111	(59.0)	111	(59.0)	310	(74.9)
Patient eligibility in Intervention Clinics 7-12	**Clinic #7**		**Clinic #8**		**Clinic #9**		**Clinic #10**		**Clinic #11**		**Clinic #12**		**Total**	
	N	**(%)**	**N**	**(%)**	**N**	**(%)**	**N**	**(%)**	**N**	**(%)**	**N**	**(%)**	**N**	**(%)**
Patients 50-74 with clinic visit in past year	500	(100.0)	500	(100.0)	500	(100.0)	500	(100.0)	500	(100.0)	500	(100.0)	1000	(100.0)
Patients with valid address	188	(37.6)	188	(37.6)	188	(37.6)	188	(37.6)	188	(37.6)	188	(37.6)	414	(41.4)
Excluded due to:														
Prior CRC Screening	56	(24.8)	56	(24.8)	56	(24.8)	56	(24.8)	56	(24.8)	56	(24.8)	75	(33.2)
History colorectal disease	11	(5.9)	11	(5.9)	11	(5.9)	11	(5.9)	11	(5.9)	11	(5.9)	15	(3.6)
Co-morbid conditions	10	(5.3)	10	(5.3)	10	(5.3)	10	(5.3)	10	(5.3)	10	(5.3)	14	(3.4)
Patients Eligible after exclusions	111	(59.0)	111	(59.0)	111	(59.0)	111	(59.0)	111	(59.0)	111	(59.0)	310	(74.9)

1068 **4.2.2. Monthly Activity Summary**

Month	Intro letter mailed	Incoming Encounter	Invalid address	Opt outs				FIT kits mailed	Reminder cards sent	Fit kits complete and results	FIT kits abnormal result	Total rate FIT/FOBT Screening at Clinic	Total rate Colonoscopy Screening at Clinic
				Med. Ineligible.	Prior Screen	Other	Decline						
		N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Jan													
Feb													
March													
April	200	7 (3.5)	20 (10.0)	0	0	0	1	180 (90.0)	150 (75.0)	75 (37.5)	0 (0.0)	75 (37.5)	75 (37.5)
May	200	8 (4.0)	20 (10.0)	0	0	0	0	180 (90.0)	150 (75.0)	80 (40.0)	7 (3.5)	80 (40.0)	80 (40.0)
June	200	0 (0.0)	20 (10.0)	1	2	1	1	180 (90.0)	150 (75.0)	60 (30.0)	6 (3.0)	60 (30.0)	60 (30.0)
July	200	0 (0.0)	20 (10.0)	0	0	1	0	180 (90.0)	150 (75.0)	70 (35.0)	5 (2.5)	70 (35.0)	70 (35.0)
Aug	200	0 (0.0)	20 (10.0)	0	2	0	0	180 (90.0)	150 (75.0)	80 (40.0)	8 (4.0)	80 (40.0)	80 (40.0)
Sept	200	0 (0.0)	20 (10.0)	1	4	1	1	180 (90.0)	150 (75.0)	60 (30.0)	9 (4.5)	60 (30.0)	60 (30.0)
Oct	200	0 (0.0)	20 (10.0)	0	2	0	1	180 (90.0)	150 (75.0)	100 (50.0)	7 (3.5)	100 (50.0)	100 (50.0)
Nov	200	0 (0.0)	20 (10.0)	0	2	0	0	180 (90.0)	150 (75.0)	110 (55.0)	4 (2.0)	110 (55.0)	110 (55.0)
Dec	200	0 (0.0)	20 (10.0)	0	0	0	0	180 (90.0)	150 (75.0)	100 (50.0)	2 (1.0)	100 (50.0)	100 (50.0)
Total:	1800	15 (0.8)	180 (10.0)	2	12	3	4	1620 (90.0)	1350 (75.0)	735 (40.8)	48 (2.7)	735 (40.8)	735 (40.8)

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1071 **4.2.3. Final Disposition Status**

	Clinic #1		Clinic #2		Clinic #3		Clinic #4		Clinic K		Total	
	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Patients eligible for Step 1	200		300		400		112		200		3307	
Step 1: Mailed Intro Letters	112	(56.0)	112	(37.3)	112	(28.0)	112	(100.0)	112	(56.0)	1344	(40.6)
Invalid Address	10	(8.9)	10	(8.9)	10	(8.9)	10	(8.9)	10	(8.9)	120	(8.9)
Medical ineligibility*	1	(0.9)	1	(0.9)	1	(0.9)	1	(0.9)	1	(0.9)	12	(0.9)
Prior Screening	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Other	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Declined	2	(1.8)	2	(1.8)	2	(1.8)	2	(1.8)	2	(1.8)	24	(20.0)
Patients eligible for Step 2	101	(90.2)	101	(90.2)	101	(90.2)	101	(90.2)	101	(90.2)	1212	(90.2)
Step 2: Mailed FIT Kits	101	(100.0)	101	(100.0)	101	(100.0)	101	(100.0)	101	(100.0)	1212	(100.0)
Invalid Address	10	(9.9)	10	(9.9)	10	(9.9)	10	(9.9)	10	(9.9)	120	(9.9)
Medical ineligibility*	1	(1.0)	1	(1.0)	1	(1.0)	1	(1.0)	1	(1.0)	12	(1.0)
Prior Screening	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Other	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Declined	2	(2.0)	2	(2.0)	2	(2.0)	2	(2.0)	2	(2.0)	24	(20.0)
Completed FIT Kit after mailing	17	(16.8)	17	(16.8)	17	(16.8)	17	(16.8)	17	(16.8)	204	(16.8)
Patients eligible for Step 3	71	(70.3)	71	(70.3)	71	(70.3)	71	(70.3)	71	(70.3)	852	(70.3)
Step 3: Mailed Reminder Postcard	70	(98.6)	70	(98.6)	70	(98.6)	70	(98.6)	70	(98.6)	840	(69.3)
Invalid Address	10	(14.1)	10	(14.1)	10	(14.1)	10	(14.1)	10	(14.1)	120	(14.3)
Medical ineligibility*	1	(1.4)	1	(1.4)	1	(1.4)	1	(1.4)	1	(1.4)	12	(1.4)
Prior Screening	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Other	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Declined	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)		

Completed FIT kits after reminder postcards*	21 (29.6)	21 (29.6)	21 (29.6)	21 (29.6)	21 (29.6)	252 (29.6)
FIT kits returned (within 3 months of FIT kit mailing)	38 (37.6)	38 (37.6)	38 (37.6)	38 (37.6)	38 (37.6)	456 (37.6)
FIT kits returned (more than 3 months after FIT kit mailing)	10 (9.9)	10 (9.9)	10 (9.9)	10 (9.9)	10 (9.9)	120 (100.0)
Total FIT kits returned within 10 months of mailing FIT kit	48 (47.5)	48 (47.5)	48 (47.5)	48 (47.5)	48 (47.5)	576 (47.5)
Test results (relative to kits returned)						
Positive	4 (10.5)	4 (10.5)	4 (10.5)	4 (10.5)	4 (10.5)	5(1.1)
Negative	34 (89.5)	34 (89.5)	34 (89.5)	34 (89.5)	34 (89.5)	34 (7.5)
Unusable kit	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Colonoscopy/ Flex Sig referrals as follow-up to positive FITS (within 6 months)						
Colonoscopies/ Flex Sig completed (within 6 months)						
TOTAL FIT/FOBT Return Rate in past 12 months						
TOTAL Colonoscopy Rate in past 12 months						

*Medically ineligible include conditions that prompt direct referral to GI, such as ulcerative colitis, Crohn's disease, and immediate family history of colorectal cancer; patient under hospice care, or otherwise medically ineligible for fecal testing.

*% reflected is of patients eligible after exclusions.

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4.2.4. Patient Eligibility and Outcomes in Usual Care Clinics

	Clinic #1		Clinic #2		Clinic #3		Clinic #4		Clinic K		Total	
	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Patients 50-74 with clinic visit in past year	500	(100)	500	(100)	500	(100)	500	(100)	500	(100)	6000	(100)
Patients with valid address	226	(45.2)	188	(37.6)	188	(37.6)	188	(37.6)	188	(37.6)	2294	(38.2)
Excluded due to:												
Prior CRC Screening	19	(8.4)	56	(24.8)	56	(24.8)	56	(24.8)	56	(24.8)	635	(28.1)
History of colorectal disease	4	(1.8)	11	(5.9)	11	(5.9)	11	(5.9)	11	(5.9)	125	(5.4)
Co-morbid conditions	4	(1.8)	10	(5.3)	10	(5.3)	10	(5.3)	10	(5.3)	114	(5.0)
Patients Eligible after exclusions	199	(88.1)	111	(59.0)	111	(59.0)	111	(59.0)	111	(59.0)	1420	(61.9)
TOTAL FIT/FOBT Return Rate in past 12 months	20	(10.1)	20	(18.0)	20	(18.0)	20	(18.0)	20	(18.0)	240	(16.9)
TOTAL Colonoscopy Rate in past 12 months	5	(2.5)	5	(4.5)	5	(4.5)	5	(4.5)	5	(4.5)	60	(4.2)

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