TIMELINESS OF FOLLOW-UP TO A POSITIVE FECAL IMMUNOCHEMICAL TEST AMONG COMMUNITY HEALTH CENTER PATIENTS

by

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CERTIFICATE OF APPROVAL

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Abstract

Timeliness of follow-up to a positive fecal immunochemical test result among community health center patients

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Background:
Colorectal cancer (CRC) is the fourth most common cancer and the fourth leading cause of cancer death in the United States. Fecal testing, including fecal immunochemical testing (FIT), has been proven to reduce mortality from colorectal cancer. Such mortality reductions can only be achieved, however, if those with an abnormal test result receive follow-up colonoscopy. Rates of completion of follow-up colonoscopy are low, especially in community health centers, where many Latinos receive care. As part of the Strategies and Opportunities to STOP Colon Cancer in Priority Populations (STOP CRC) project, we examined rates of adherence to follow-up colonoscopy, time to colonoscopy completion, and characteristics of patients who complete a colonoscopy after an abnormal FIT result compared to those who do not.

Methods: Virginia Garcia Memorial Health Center served as a clinic partner for the project. Project staff reviewed charts from patients who had an abnormal FIT result, following the STOP CRC mailed outreach program. Reviews of electronic medical charts ascertained patient demographic characteristics; referral to colonoscopy (yes/no), date of referral and reason (if not made); colonoscopy completion (yes/no), date of colonoscopy and reason (if not completed). Bivariate analyses and regression analyses were used to examine associations and complete mediator analysis.

Results: A total of 56 patients had an abnormal FIT result, 29 (52%) were Latino and 31(55%) were female. Forty-five (80%) patients received referral for colonoscopy, with a median time to referral of 2 days. Of the 56 patients, 32(57%) had evidence of a completed colonoscopy in their medical chart. The median time to colonoscopy completion was 62 days. Females were less likely than males to complete their colonoscopy within 60 days of a positive FIT result (OR = 0.23, 95% CI: 0.05, 0.96). Mediation analysis indicated that time to referral was not a mediator between patient-level factors and

completion of follow-up colonoscopy. Finally, qualitative results show that there are differences in the CRC screening process between English and Spanish speakers.

Conclusion:
For fecal testing to reduce mortality from CRC, patients with a positive test result must obtain a follow-up colonoscopy. Our findings suggest improvements are needed to increase rates of follow-up colonoscopy completion, especially among females and Latino patients. Future research might explore the role that clinic-level factors (colonoscopy capacity) and patient-level factors (patient declined) play in colonoscopy completion.

Introduction

Colorectal cancer in the US

In the United States, colorectal cancer (CRC) is the fourth most common type of cancer and the fourth leading cause of cancer death among both males and females. The 2011 age-adjusted incidence of CRC for Blacks, Whites, Hispanics, Asian/Pacific Islander, and American Indian/Alaska Natives were 46.7, 38.9, 35.4, 32.4, and 29.1 per 100,000 persons, respectively. Age-adjusted mortality was 21.1, 14.6, 12.3, 11.9, and 10.7 per 100,000 persons for Blacks, Whites, American Indian/Alaska Natives, Hispanics, and Asian/Pacific Islanders, respectively (US Cancer Statistics Working Group, 2014).

Currently, the United States Services Preventive Task Force (USPTF) recommends that individuals between the ages of 50 and 75 undergo CRC screening using either high-sensitivity guaiac fecal occult blood testing (FOBT) annually, sigmoidoscopy every 5 years with high-sensitivity FOBT every 3 years, or colonoscopy every 10 years (USPTF, 2008). The 2012 Behavioral Risk Factor Surveillance System survey (BRFSS) indicates that approximately 65% of the US adult population is up-to-date with USPTF CRC screening recommendations, with colonoscopy being the primary method utilized (Centers for Disease Control and Prevention, 2013).

Although a large portion of the US population is up to date with CRC screening recommendations, disparities in screening exist, especially among minority and

underserved populations. In addition, the US has fallen short in meeting the Healthy People 2020 goal to drop CRC related mortality from 17.1 deaths to 14.5 deaths per 100,000. In the 2012 BRFSS survey, 66.4% of Non-Hispanics versus 53.1% of Hispanics were up to date with CRC screening. Forty-one percent of Hispanic respondents reported never being screened for CRC versus only 26.3% of Non-Hispanic respondents (CDC, 2013). Wang et al. (2012) attribute lower CRC screening rates in minority populations to low literacy, influence of social groups, fatalism, and decreased confidence in healthcare providers. Cross-sectional studies also indicate that reduced language barriers, older age, discussion of CRC risk factors with a physician, not smoking, and encouraging family members or friends to be tested for CRC increase CRC screening rates in minority populations such as Hispanics (Otiniano et al., 2013 and Johnson-Kozlow et al., 2009).

Alternative approaches to colorectal cancer screening

Fecal immunochemical tests (FIT) are a type of FOBT that use labeled antibodies to detect the globin protein of hemoglobin in stool. Unlike traditional guaiac FOBTs (gFOBT) that detect peroxidase-like activity in stool, the FIT is considered a more superior test than the gFOBT. The FIT is able to detect more advanced neoplasms and proximal colon lesions than the gFOBT. Some FITs only require one stool sample with no dietary and medication restrictions, whereas the gFOBT requires three samples plus dietary and medication restrictions. In addition, the FIT is more specific for detecting

lower GI bleeds than the gFOBT (Day et al., 2013). In a systematic review and meta-analysis conducted by Hernandez et al. (2014), the calculated pooled sensitivity and specificity of FITs across 19 studies was 0.79 (95% CI: 0.69, 0.86) and 0.94 (95% CI: 0.92, 0.95), respectively. Compared to other CRC screening modalities like colonoscopy or sigmoidoscopy, FITs are cheap, non-invasive, and convenient to use (Day et al., 2013). However, unlike colonoscopy or sigmoidoscopy, a FIT must be repeated yearly.

Colonoscopy adherence rates after a positive FOBT

For the FIT to be a truly effective screening method, individuals with positive results must undergo timely follow-up colonoscopies. Research has yet to focus on understanding colonoscopy adherence following positive FITs. Research results indicate that there is wide variability in both adherence rates and in timeliness of follow-up colonoscopy completion across different populations and health systems (Table 2).

Migloretti et al. (2008) found that among 8,291 identified enrollees aged 50-79 years between 1993 and 1996 at Group Health Cooperative, a non-profit health care system in Washington State, colonoscopy adherence rates following a positive FOBT ranged between 57-64% within 1 year of a positive FOBT. With an intervention that consisted of a tracking system, the health care system saw a drastic increase in colonoscopy adherence rates, which ranged from 82-86% within 1 year of positive FOBT between 2000 and 2005.

Other studies, such as those conducted at Veteran Affairs (VA) medical centers, support the notion of suboptimal colonoscopy adherence following positive FOBTs. In a nationwide-survey of 132 VA medical centers, the median-facility reported 60-day follow-up rate for positive FOBTs in 2007 was 24.5% (interquarterile range = 13.8% to 40.7%). In a different study conducted by Fisher et al. (2006) of the Durham VA Medical Center in North Carolina, approximately 44% of the 538 patients adhered to follow-up colonoscopy within 12 months of a positive FOBT. Meanwhile, a prospective study examining the relationship between age, comorbidity, and other factors with colonoscopy evaluation after a positive FOBT in older individuals conducted by Carlson et al. (2011) involving 4 VA medical centers in 2001 found only 42% of the study's 2,410 veterans aged > 70 years received a complete colon evaluation within 1 year of a positive FOBT.

Factors associated with adherence to follow-up colonoscopy

The preceding paragraphs highlight the wide variability in both adherence and timeliness of follow-up colonoscopy after a positive FOBT. Several studies have tried to characterize factors that affect receipt of follow-up colonoscopy after a positive FOBT.

In the study conducted by Carlson et al. (2011) among veterans aged > 70 years at 4 different VA sites, VA site, number of positive FOBT cards, and number of VA outpatient visits were significantly associated with completion of a colon evaluation after a positive

FOBT. Interestingly, in the same study, age and comorbidity were not associated with completion of follow-up colon evaluations.

Contrary to the findings in the study by Carlson et al., Choi et al. (2012) found a significant association between younger age and adherence to follow-up colonoscopy in the Korean National Cancer Screening Program (NCSP) for Medical Aid recipients and National Health Insurance (NHI) beneficiaries. Individuals in the Korean NCSP between the ages of 50 -69 years were more likely to complete either colonoscopy or double-contrast barium enema than those aged > 70 years (for those 50 -59 years: OR = 1.90, 95% CI: 1.81, 1.99; for those 60 – 69 years: OR = 1.47, 95% CI: 1.40, 1.54). Insurance type, specifically National Health Insurance beneficiaries, and history of screening were also significantly associated with adherence to follow-up colonoscopy.

Socioeconomic conditions have also been associated with adherence to follow-up colonoscopy. Morris et al.(2012) investigated the relationship between deprivation and follow-up colonoscopy among those with positive FOBT results in England's NHS Bowel Cancer Screening Programme between Oct. 2006 and Jan. 2009 (n = 24,180). In this study, deprivation was defined using the Index of Multiple Deprivation, which combines the domains of income, employment, health deprivation and disability, education training and skills, barriers to housing and services, crime, and living environment. Small but significant associations between uptake of follow-up colonoscopy and deprivation in

both unadjusted and adjusted models (confounders included age, sex, area self-assessed health, ethnic diversity, rurality, and region) were noted in the study.

Apart from individual level factors, characteristics of health systems have been shown to be associated with adherence to colonoscopy among those with positive FOBTs. Across 98 VA medical centers, Partin et al. (2013) reported in adjusted multivariable regression models that the odds of having a follow-up colonoscopy within 60 days was 1.82 times greater (95% CI: 1.17, 2.83, $p< 0.05$) when gastroenterologists were notified of positive FOBTs from gastroenterology staff relative to being notified by primary care providers. Adjusted multivariable models also showed that organizational structures, such as colonoscopy appointment availability are significantly associated with follow-up colonoscopy within 60 days of a positive FOBT test result (OR = 1.48, 95% CI: 1.14, 1.92, $p < 0.05$). Unadjusted multivariable models indicated that frequent, individual feedback to primary care providers about timeliness of colonoscopy referrals is significantly associated with follow-up colonoscopy within 60 days (OR = 1.79, 95% CI: 1.02, 3.16, $p < 0.05$) , but these findings were not retained in adjusted models. In regards to patient-centered processes, adjusted regression models showed that the odds of having a follow-up colonoscopy within 6 months was 1.50 times greater (95% CI: 1.16, 1.95, $p < 0.05$) among those who had a verbal group appointment or other combined verbal/written method than among those who received a verbal phone or individual appointment.

Furthermore, Singh et al. (2010) investigated the association between referral characteristics and timeliness of colonoscopy among a cohort of 367 electronic VA medical records with a confirmed CRC diagnosis between June 2001 and June 2007. Over the six-year time interval, the median wait time from referral to colonoscopy was 57 days. Multivariable quantile regression showed that the number of indications (e.g. symptoms, signs, test results) for a referral, inpatient referrals, referrals with an urgency of < 1 week or < 30 days, referrals marked with 'next available', and outpatient referrals with documented verbal consultation were significantly associated with shorter wait times from referral to colonoscopy. Overall, the results suggest that in resource poor environments (e.g. decreased colonoscopy capacity) the quality and quantity of information contained within a referral is important for timeliness of follow-up colonoscopy.

Research questions

Adherence and timeliness of follow-up colonoscopy is critical if FITs are to become a mainstay of CRC screening in the US. Currently, a large portion of research has focused on understanding adherence and timeliness of follow-up colonoscopy in the VA population or in national CRC screening programs. However, because of the disparity in CRC screening, morbidity, and mortality among underserved and minority populations, it is important that research focus on understanding factors associated with follow-up

colonoscopy among community health center populations. Therefore, the aims of this research project are as stated:

Aims:

Aim 1: To gain a quantitative understanding of colonoscopy adherence after a positive FIT among patients of a community health center

- Patient Factors
    - What is the rate of follow-up colonoscopy adherence after a positive FIT?
    - Among those with positive FIT results, what patient characteristics are significantly associated with timely adherence (defined as being within 60 days of a positive FIT result) to follow-up colonoscopy?
    - Among those with positive FIT results, what patient characteristics are significantly associated with overall adherence to follow-up colonoscopy?

- Clinical Factors
    - What is the average and median time to referral?
    - Does time to referral serve as a mediator between our predictor variable set of interest and time to colonoscopy? We define a mediator as a variable that is associated with both the independent and dependent variables but is also part of the causal chain between the independent and dependent variables.

Aim 2: To explore the CRC screening experience of patients (both English and Spanish speakers) who have an abnormal FIT result and need a follow-up colonoscopy

- Phone interviews will be conducted with 10 patients (goal: 5 English speaking participants, 5 Spanish speaking participants) who received FIT kits. Phone interviews will be recorded, transcribed, coded, and themes analyzed.

Hypothesis

We hypothesize the following:

- There will be statistically significant differences in patient characteristics between those who adhere to follow-up colonoscopy versus those who do not. Patient characteristics of interest include: age, gender, ethnicity, race, language, insurance status, and co-morbidities (e.g. diabetes, hypertension, and smoking status (former/current vs. never)).
- There will be statistically significant differences in time to referral between Hispanic and Non-Hispanics
- Time to referral will be a mediator between predictor variables and time to colonoscopy (Figure 1).

Methods

Study Population

The cohort for this mixed methods study was obtained from the Virginia Garcia Memorial Health Center (VGMHC), specifically the Cornelius and Hillsboro clinics. VGMHC is a federally qualified health center that serves approximately 36,000 patients annually in the Washington and Yamhill counties of Oregon. The majority of VGMHC patients are Hispanic (60%). A high percentage of VGMHC patients live in poverty (57%), and 80% of patients live below 200% of the federal poverty level. Uninsured patients comprise about 25% of patients. While Medicare, Oregon Health Plan/Medicaid, individual/private subscribers represent about 5%, 62%, and 7% of patients, respectively (Virginia Garcia Memorial Health center, 2014).

Participant Recruitment

Recruitment involved the identification of VGMHC patients at both the Cornelius and Hillsboro clinics, who had a FIT kit (InSure FIT ®) ordered between September 2013 and October 2014.There were two main recruitment phases. The first phase occurred as part of an evidenced-based pilot program called STOP CRC, which is described in detail elsewhere (Coronado et al., 2015). Briefly, FIT kits were mailed to eligible participants between the ages of 50-74 years, who were identified through an electronic health record registry. Eligible participants then mailed their completed FITs to a laboratory in pre-paid envelops for analysis. The second phase occurred when additional grant

funding was attained by VGMHC and in conjunction with VGMHC's desire to increase CRC screening. As part of usual care, medical assistants reviewed medical charts and identified patients who had gaps in their preventive care. Through morning meetings, both medical assistants and providers worked together to decide which of the patients were eligible for FIT kits. Eligible patients were offered FIT kits in clinic and counseled on the importance of CRC screening by either a medical assistant or provider. Interested patients were then given the FIT kit along with instructions on how to complete kit and how to submit their stool sample for analysis.

Data Collection

Retrospective chart reviews were conducted to ascertain demographic information, status of FIT results and colonoscopy adherence, date of colonoscopy, referral information, and pathology results. Chart reviews were conducted by three different individuals. A senior data analyst at VGMHC completed chart abstractions for participants that received FIT kits as part of the STOP CRC program. A research intern, completed chart reviews for individuals that received FIT kits in clinic. The author of this thesis verified information collected by other study staff members and completed further chart abstractions to obtain additional information (e.g. pathology reports and referral information) when necessary.

A FIT was considered positive/abnormal based on the manufacture's guidelines for the detection of hemoglobin in stool using antibodies. Time to colonoscopy (TTC) was

calculated as the time elapsed between the date of a resulted FIT kit to the date of the follow-up colonoscopy procedure. Likewise, time to referral (TTR) was calculated as the time elapsed between the date of a resulted FIT kit to the date the referral was made. Complete colonoscopy adherence was defined as having received a colonoscopy within our study period of 18 months. We also considered colonoscopy adherence within 60 days. Sixty days was chosen as a marker of timely adherence to follow-up colonoscopy for two reasons – 1: Several previous studies, especially those involving the VA medical system, have indicated that 60 days is adequate time to complete follow-up colonoscopy. Therefore, by keeping the standard 60 days as our marker for timeliness to colonoscopy, in the future, it may permit easier comparison of the results in this study with other studies. 2: The median time to follow-up colonoscopy in our study centered around 62 days. Therefore, 60 days (2 months) was a natural cut point.

The author of this thesis worked with an experienced clinician to risk stratifies patients in terms of colorectal malignancy based on colonoscopy findings and pathological diagnoses. We used a modified pathological classification scheme presented by Liebermann et al. (2012) to create the risk categories. Briefly, Liebermann's classification scheme is based on the presence/absence of polyps, type of polyps (hyperplastic, tubular adenomas, villous adenomas, sessile serrated), and size of polyps.

Interviews

Interview guides

Interview questions (Appendix) were developed by a lead qualitative researcher on the team and the author of this thesis. Questions were modified from prior STOP CRC qualitative interviews (Coronado et al., 2014). Briefly, the STOP CRC interview guide consists of questions based on previous qualitative interviews conducted with Federally Qualified Health Center patients (Coronado et al., 2015 and Coronado et al., 2006). The goal of the STOP CRC semi-structured, open-ended interview guide is to explore the awareness of CRC and CRC screening, prior screening history, general barriers and facilitators to CRC screening, and reasons for not completing or returning FIT kits. In our study, input was received from the lead investigator, research staff members, and the author of this thesis and any necessary changes to the interview questions were made. The goal of our interview guide was to elicit participants experience with completion of the FIT kit and follow-up colonoscopy.

Recruitment of interview participants

We sent interview invites by mail to all participants who had both received a FIT kit as part of the STOP CRC program and had a positive FIT result. However, only three participants responded to the mail invite. Therefore, JR called all remaining participants to elicit participation in the interviews. Our goal was to interview 10 patients, half who self-identified as primarily English speaking individuals and half who self-identified as primarily Spanish speaking individuals.

The interview

For the interview, participants were verbally consented and mailed a $10 gift card to Fred Meyer stores in appreciation of their time. Interviews were conducted by phone, audio recorded, and lasted about 30-45 min each. All 10 interviews were conducted by JR, who is a fluent Spanish speaker, with six interviews being conducted in English and four in Spanish.

Coding and transcribing the interviews

A coding dictionary was created using a qualitative content analysis approach (Lofland, 1995; Wolcott, 1994; Coffey, 1996; Riessman, 1993; Bernard, 1994; Patton, 2002) with grounded theory coding techniques (Elo, 2008; Graneheim and Lundman, 2004; Denzin and Lincoln, 2011; Strauss, 2008). The recorded interviews were transcribed verbatim and coded by a research staff member and the lead investigator. The author of this thesis worked with two lead qualitative researchers on the team to analyze themes within the coded transcripts. Coded reports were reviewed and collapsed into summary themes through a process of re-reading and interpreting.

Statistical Analysis

All analyses were done using STATA version 13 for Windows (StataCorp, College Station, TX). The two primary patient outcomes of interest were: 1. overall adherence to follow-up colonoscopy after a positive FIT result and 2. adherence to follow-up colonoscopy

within 60 days of a positive FIT result. Our secondary outcome of interest was time to referral in relation to its potential mediation effects.

Descriptive statistics were computed for age, gender, ethnicity, race, language, insurance type, clinic, and comorbidities. We collapsed age into three ordinal categories. We also calculated time to referral (TTR) and time to colonoscopy (TTC) with units as days.

To understand what patient factors might be associated with adherence to follow-up colonoscopy, we assessed the association between each predictor variable and each primary dichotomous outcome using Fisher's exact test. Fisher's exact test was used because of small sample size and because some cells contained counts less than five. Furthermore, we used logistic regression models to assess the association between patient characteristics and adherence to colonoscopy. Unadjusted and adjusted analyses were done in which the former included each variable individually and the latter included potential confounders. Through an extensive review of the literature, known confounders include age, race, ethnicity, sex, and insurance; therefore, we adjusted for these variables. All associations with $p < 0.05$ or a 95% confidence interval that did not include the value 1 was considered statistically significant.

Furthermore, we tested TTR as a potential mediator (predictor variable → TTR → TTC) using methods developed by Baron and Kenny (1986) (Appendix Table 2A). This approach requires the following steps for each predictor variable:

Step 1	Simple linear regression analysis with X predicting Y
Step 2	Simple linear regression analysis with X predicting M
Step 3	Simple regression analysis with M predicting Y
Step 4	Multiple linear regression analysis with X and M predicting Y
where X = predictor variable; M = potential mediator, Y = outcome of interest significance level = 0.05	

We followed the procedures by Kleinbaum et al. (2009) to complete simple linear regression using the least-squares method. Because TTC and TTR were not normally distributed, which led to violation of linear regression assumptions, we log transformed these variables. After transformation, all assumptions of linear regression were met.

IRB Approval

This study was approved by the Kaiser Permanente Northwest Institutional Review Board expedited review procedure.

Results

Quantitative Results

Patient Characteristics

Between September 2013 and October 2014, there were a total of 56 positive FIT results among patients 50 – 70 years old at VGMHC's Beaverton and Hillsboro clinics (Figure 1). Over half of these patients were female (55%) or White (91%) and 52% of the patients self-identified as being of Hispanic origin (Table 2). A significant proportion of patients received Medicaid or Medicare benefits (38% for Medicaid; 32% for Medicare) while the remaining patients were either uninsured (23%) or had employer sponsored insurance (7%).

Association of patient characteristics with adherence to follow-up colonoscopy within 60 days of a positive FIT result

Because timeliness of colonoscopy after a positive FIT result is important in any CRC screening process that utilizes FITs, we assessed and measured the association between patient characteristics and adherence to follow-up colonoscopy within 60 days (Table 3). Of the 32 patients that completed colonoscopy, only 14 (44%) adhered to follow-up colonoscopy within 60 days. In unadjusted and adjusted calculations, age, race, language, insurance status, primary VGMHC clinic site, and presence of co-morbidities were not significantly associated with completion of follow-up colonoscopy within 60 days. However, in unadjusted associations, there was a statistically significant

association between adherence to follow-up colonoscopy within 60 days and gender. The odds of adhering to follow-up colonoscopy within 60 days of a positive FIT result was 77% lower among females than among males (unadjusted OR = 0.23 with 95% CI: 0.05, 0.96). This statistically significant association was lost when confounders were included in the logistic regression model.

Association of patient characteristics with ever vs never adhering to follow-up colonoscopy after a positive FIT result

Of the 56 individuals with positive FIT results, only 32 (57%) ever adhered to follow-up colonoscopy, with a median time to colonoscopy of 62 days. In unadjusted and adjusted calculations, age, gender, race, language, insurance status, primary VGMHC clinic site, and presence of co-morbidities (e.g. diabetes, hypertension, and smoking status) were not significantly associated with completion of follow-up colonoscopy (Table 4). Interestingly, in both unadjusted and adjusted calculations, Hispanics were less likely than non-Hispanics to complete follow-up colonoscopy (unadjusted OR = 0.34 with 95% CI: 0.11, 1.03 vs adjusted OR = 0.31 with 95% CI 0.09, 1.10). Although these association were statistically non-significant at the 0.05 alpha-significance level, in unadjusted calculations the association trended (p = 0.057) around an alpha-significance level of 0.05.

Because of the trend around a p-value < 0.05 and because CRC screening disparities often occur in minority communities, we examined patient characteristics with respect

to ethnicity (Hispanic vs. Non-Hispanic) (Table 5). Calculations indicate that there were no statistically significant differences in age, gender, language, insurance status, primary VGMHC clinic, and presence of comorbidities between Hispanics and Non-Hispanics.

Documented reasons for non-adherence to follow-up colonoscopy

There are a variety of reasons, as documented in VGMHC medical records, why 24 (48%) of the 56 FIT positive individuals did not adhere to follow-up colonoscopy (Table 5). Twenty-five percent of these patients either refused colonoscopy or cancelled their colonoscopy appointment. For 4 (17%) of the 24 individuals that did not adhere to follow-up colonoscopy, colonoscopy was not indicated because the procedure had been performed within 10 years of their FIT positive result. For 38% of non-adherers, their charts indicated miscellaneous reasons to why colonoscopy was not performed. For example, several patients were leaving the country for an extended period of time and therefore would not be available to complete a colonoscopy. Finally, for 5 (21%) of the 24 non-adhering patients, there were no documented reasons in the medical records for non-adherence.

Timeliness of referral and colonoscopy

As indicated in the literature, clinical factors, like gastroenterologist capacity, are important to consider when investigating timeliness of colonoscopy after positive FIT results. Timeliness of referral may also be considered a clinical factor because referrals are created and submitted by the clinic and involve several clinical processes. In this

study, we sought to: 1. describe the timeliness of referrals with respect to patient factors and 2. determine if timeliness to referral is a mediator between our predictor variables of interest and time to colonoscopy.

Of those who did not complete a follow-up colonoscopy (n = 24), only 54% received a referral. There was a statistically significant difference (p = 0.05) in the average time to referral among those who completed a follow-up colonoscopy (n = 32) and among those who received a referral but did not complete a follow-up colonoscopy (Table 7). To note, the average time to referral among colonoscopy adherers was 27 days (SD ± 84.5) while the average time to referral among non-colonoscopy adheres that received a referral was 4.3 days (SD ± 3.2 days). However, there was no statistically significant difference (p = 0.24) in the median time to referral among those who adhered to follow-up colonoscopy (median TTR = 2.5 days) versus those who received a referral but did not adhere to follow up colonoscopy (median TTR = 0 days).

Furthermore, when comparing referral characteristics between Hispanics and Non-Hispanics, 85% of Non-Hispanics (n = 27) and 75% of Hispanics (n = 29) received a referral (Table 8). This difference was not statistically significant (p = 0.51). Among patients who received a referral, the median time to referral for Hispanics was 3 days and for Non-Hispanics it was 1 day (p = 0.18).

Finally, in mediation analysis, we log transformed TTC and TTR in order to meet the assumptions of simple linear regression. LogTTR was not found to be a mediator with respect to the outcome Log(TTC) and several predictor variables (age, gender, race, ethnicity, and insurance status).

Qualitative Results

A total of 10 individuals, with 80% of the participants receiving FIT kits through the STOP CRC mail out program, were interviewed. Six participants self-identified as primarily Spanish speaking, and 50% of participants indicated that they have been receiving care at VGMHC for 11 years or more. Three out of 4 English speaking participants and 4 out of 6 Spanish speaking participants never had a colonoscopy prior to receiving the FIT kit.

Evaluation of the qualitative data revealed several themes. The major themes expressed during the interviews included the following (Table 9):

1. There was positive reaction to the CRC screening program
2. English speaking participants and Spanish speaking participants have different experiences with the FIT kit and other related material that was mailed
3. In general, patients expressed concerns and worries about their positive FIT results
4. Some participants were okay with the need to complete follow-up colonoscopy
5. English speaking participants faced fewer barriers to follow-up colonoscopy than did Spanish speaking participants

6. Spanish speaking participants and English speaking participants share similar experiences with completing follow-up colonoscopy
7. Participants believe that the CRC screening program should continue but believe that the program can be improved with patient education

Theme 1: Reaction to CRC screening program

We elicited participants' general feelings, both positive and negative, about the CRC screening program. In general, participants were appreciative of the screening program and found the program to be a good reminder of the need to complete CRC screening. However, Spanish speaking participants tended to express more concerns about the CRC screening program than did English speaking participants. For example, at least one Spanish speaking participant was confused as to why they had received the kit, another thought they had cancer, and one stated that they never received their results.

Theme 2: English and Spanish speaking participants have different experiences with the FIT kit and other related mailed materials

In addition to expressing positive reactions towards the CRC screening program, many positive comments were made about the patients' experiences with the FIT kits. English speaking participants also commented on what they believed to be the "weirdness" of using stool samples to screen for CRC but no Spanish speaking participants made such comments. Furthermore, Spanish speaking participants stated that they had to either call or take the FIT kit to the clinic for further explanation. While, the English speaking

participants found the FIT kit instructions easy to understand and did not need further explanation.

Theme 3. Patients expressed concerns and worries about their positive FIT results

Both Spanish and English participants expressed concerns and worries about having a positive FIT result. Spanish speaking participants also tended to express that they had difficulty understanding the FIT results and several Spanish speaking participants stated that they did not even realize that they had positive FIT results.

Theme 4: Some participants were okay with the need to complete follow-up colonoscopy

For the most part, interviewees were comfortable with the need to complete a follow-up colonoscopy. One English speaking participant but no Spanish speaking participants stated that they were scared of having to complete a follow-up colonoscopy. One Spanish speaking participant indicated that he did not understand what a colonoscopy was and was not told he needed to complete a follow-up colonoscopy; therefore, he did not complete a colonoscopy. Another Spanish speaking participant stated that she was told that she needed to complete a follow-up colonoscopy but did not receive her FIT test results or any explanation of why a colonoscopy was indicated.

Theme 5: English speaking participants faced fewer barriers to follow-up colonoscopy than did Spanish speaking participants

More barriers to follow-up colonoscopy were noted by Spanish speaking participants than English speaking participants. There were a variety of barriers mentioned such as those related to transportation, understanding both the screening process and importance of screening, and costs.

Theme 6: T*he majority of participants completed follow up colonoscopy*

Seventy-percent of the participants (75% English speaking; 67% Spanish speaking) completed follow-up colonoscopy and believed that the colonoscopy procedure went well. Fifty percent of English speaking and 50% of Spanish speaking participants stated that they had to wait less than 1 month from the date of their test result to complete their colonoscopy. Three out of 4 English speaking participants and 4 out of 6 Spanish speaking participants stated that they received their results. However, 1 out of the 4 Spanish speaking participants who did receive their colonoscopy results stated that they needed additional explanation from family members about their colonoscopy results because they did not understand the results.

Theme 7: Majority of participants believe that the CRC screening program should continue and offered suggestions for improving the screening program.

All participants believed that the CRC screening program should continue. Participants also provided a wide variety of suggestions for improving the CRC screening program. The most frequently mentioned advice for improving the program related to more patient education on the importance of CRC screening, test procedures, and testing

options. For example, several participants commented that they believed that providers should explain what a FIT and colonoscopy were in basic terms during appointments.

Discussion

This mixed method study examined the timeliness to follow-up colonoscopy after a positive FIT result among a cohort of 56 community health center patients. Only 57% of the cohort eventually completed a follow-up colonoscopy, with 44% of these individuals completing the colonoscopy within 60 days of a positive FIT result. When compared to other CRC screening programs that utilized either FOBT or FIT as a primary CRC screening tool, the follow-up colonoscopy adherence rate in this study is of an intermediate rate (Table 1).

When specifically compared to community health centers that have utilized FITs, our colonoscopy adherence rate was lower than that found by Hillyer et al. (2013) (adherence of 84.2% over 2 years in Northern Manhattan) and Loconte et al. (2013) (adherence of 91% over 2 years in Wisconsin). However, similar adherence rate were found in a study by Levy et al. (2010) (adherence of 61% in Iowa but time frame not stated). Such comparisons might suggest that CRC screening programs with longer durations have higher rates of adherence to follow-up colonoscopy. Longer-running programs may be able to create more efficient systems and processes that transition patients from positive FIT results to follow-up colonoscopy. For example, in the Loconte

et al. study, adjustments like increasing the number of interpreters were made after evaluating the program at the end of each intervention phase.

Furthermore, in this study, patient-level factors like age, ethnicity, race, language, insurance status, and comorbidities were not associated with adherence to follow-up colonoscopy within 60 days or with overall completion of colonoscopy after a positive FIT result. It is important to note, however, that an association between ethnicity and overall colonoscopy adherence did trend around an alpha significance level of 0.05. Similar studies have found no association between patient-level factors like age, race, or comorbidity and follow-up colonoscopy completion (Dupont-Lucas et al. , 2011; Ferrat et al., 2013; Mansouri et al.,2013; Fisher et al., 2006; Carlson et al., 2011). However, in studies by Choi et al. (2012) and Morris et al (2012) in Korea and England, respectively, insurance status and socioeconomic factors were associated with follow-up colonoscopy among those with positive FOBT results. One potential reason why we did not see an association between insurance status and colonoscopy adherence may be due to implementation of the Affordable Care Act, which has increased access to health insurance and care for many underserved individuals within Oregon. In addition, VGMHC is able to make referrals to specialist providers through a program called Project Access NOW, which connects low-income and uninsured individuals in the Portland metropolitan area with donated health care services.

Moreover, in our study, men were more likely than females to complete a follow-up colonoscopy within 60 days of a positive FIT result, but this association was lost with overall colonoscopy completion. In the study by Ferrat et al., male gender was not associated ($p = 0.41$) with colonoscopy completion within 58 days of a positive FOBT result relative to completion of colonoscopy ≥ 58 days of appositive FOBT result. Both Fisher et al. and Dupont-Lucas et al. also found no association between gender and colonoscopy completion within 1 year and 2 years of a positive FOBT, respectively. However, Miglorietti et al. (2008) did find an association between gender and follow-up colonoscopy within 1 year of a positive FOBT. In our study, it is unclear why gender is associated with follow-up colonoscopy completion within 60 days of a positive FIT result but not with overall colonoscopy adherence. Using the Health Belief Model, some potential explanations to describe the association found in our study include the following: 1. Women may be initially more concerned with other forms of cancer like breast cancer but overtime their concern spans all types of cancers. and 2. Women may be more concerned and have more responsibilities in the well-being of other household members (e.g. children); therefore, they prioritize colonoscopy as less important. Also, because the incidence of CRC and CRC-related mortality is highest in men, health care providers may encourage males more often than females to complete follow-up colonoscopy.

Another important point to note is that in 4 out of the 24 patients that did not adhere to colonoscopy, colonoscopy was contraindicated because the patients had received a

colonoscopy at least 10 years prior to completing their FIT kit. Exclusion of these individuals from this study might have allowed us to see some effects or associations that are currently not apparent. Additionally, because these individuals received FIT kits, it suggest that we need to re-examine the processes that determine who will be offered a FIT kit.

In addition to examining the association between patient-level factors and adherence to colonoscopy, we also examined the relationship between time to referral, a clinical factor, and time to colonoscopy. Through mediation analysis, our results indicate that time to referral is not a mediator in the pathway from patient-level factors to timeliness of colonoscopy. A potential explanation for this observation is that VGMHC uses an electronic health system that allows providers to easily input information and submit referrals in a timely fashion.

Finally, in our qualitative study, both English speaking and Spanish speaking participants were receptive to CRC screening and to the use of FIT kits. However, there were differences in the experience of English and Spanish speaking participants in the screening program. Of note was the fact that Spanish speakers made more comments about barriers and adversities in completing the entire screening process than did English speaking participants. For example, Spanish speaking participants found it more difficult to understand screening instructions, results, or any 'next steps' needed. Some Spanish speakers even commented that they turned to clinic staff or family members for

help in understanding how to complete the FIT kit or what to do or with interpreting their results. Reducing barriers is important because it may decrease the time to colonoscopy and also increase CRC screening rates. These results provide a starting point for addressing barriers that arise during any step of the CRC screening process.

There are several limitations to this study. First, we had a small sample size, which led to a non-normal distribution of data thus requiring the data to be transformed for linear regression analysis. Secondly, this study focused on two community health centers; therefore, generalizability in this study is limited. In addition, interview participants may have 'self-selected' to be interviewed. This could lead to our qualitative results overly representing patients who are more proactive with their health care thus not reflecting the broader study population's experience. Recall bias is of concern as interviewees were asked to recall their CRC screening experience. We tried to overcome any shortcomings in this study by using objective markers to verify information (e.g. completion of colonoscopy) obtained within interviews. Interviewer bias was avoided by having a semi-structured interview format. Finally, reliability of the data is not of concern as the collected data from medical charts were reviewed by a second individual.

Implications for Public Health

Findings from this study have several implications for public health. First, underserved communities are receptive to using FIT kits as a CRC screening method. However,

patients should be educated at the onset that CRC screening via FIT kits is a process that will involve several subsequent steps if the FIT result is positive. One evidence-based approach to improving patient education in vulnerable populations is through the use of culturally-tailored patient navigation programs (Percac-Lima et al., 2009 and Percac-Lima et al., 2013). Patient navigators can explain the screening process to patients, answer patient questions throughout the process, and encourage patients to complete follow-up colonoscopy. Furthermore, specific public health interventions should focus on reducing barriers associated with follow-up colonoscopy. For example, in our study population, Spanish speaking participants had more difficulty than did English speaking participants in understanding written instructions and test results. Interventions can overcome this barrier by combining written instructions with pictorial or wordless instructions because the Hispanic population has an oral and pictorial tradition (Coronado et al., 2014).

Moreover, in terms of clinical factors, public health interventions should focus on improving clinical information systems like electronic medical records. Clinical information systems in community health settings can be improved by designing reminder systems that alert providers about patients that have yet to complete a follow-up colonoscopy within a defined amount of time after a positive FIT. Clinical information systems should also be designed to generate automatic phone calls and/or reminder emails and letters that can be sent to patients that have not completed a follow-up colonoscopy within a specified timeframe. Together, the preceding

suggestions provide ways in which public health efforts can increase adherence to follow-up colonoscopy in a timely manner.

Limitations

There are several limitations associated with this study. First, the generalizability of our results has limitations, and extrapolation of the results is best suited to health care settings that share similar characteristics as VGMHC. Secondly, we had a small sample size which might have made it difficult to capture some effects. Approximately 190 patients are required to have an 80% chance of detecting, as significant at the 5% level, a decrease in colonoscopy adherence from 60% in those who completed a follow-up colonoscopy to 40% in those who did not complete a follow-up colonoscopy. Furthermore, 'self-selection' of interviewees is of concern as interviewees may represent a sub-population in the study cohort that is more involved with their health care.

We enlisted several steps to avoid any bias that may have arisen in our study. Medical records were reviewed by more than one person to ensure validity. Objective markers were used whenever possible and also to verify information provided by interviewees. Finally, we used semi-structured interviews to prevent interviewer bias.

Future Directions

Based on this study, there are several different directions that future research can take. First, research should examine adherence to follow-up colonoscopy over a longer length of time and with a larger cohort. In addition, research should also examine other associations between patient level factors, like immigration status, and adherence to follow-up colonoscopy. Future research should also include qualitative studies that elicit health care providers perceptions about what they believe to be the patient-level and clinic-level factors associated with adherence to follow-up colonoscopy. Moreover, mediation analysis should consider referral status, as a binary variable (yes/no), rather than time to referral. Finally, because timely colonoscopy is defined differently across different studies, future research should look at and define what is truly meant by "timely colonoscopy" among community health center populations.

Tables and Figures

Table 1. Colonoscopy adherence among individuals with positive FOBT/FIT results

Author (Publication Yr.)	**Setting**	**FOBT/FIT**	**% of study population that adhered to follow-up colonoscopy**	**Time**
Bobridge (2013)	Australia	FIT	23%	30 days
Powell (2009)	132 different VA medical centers	FOBT	24.5%	60 days
Fisher (2006)	Durham VA Medical center	FOBT	44%	1 year
Ferrat (2013)	France (Val-de-Marne)	FOBT	45.2%	≤ 58 days (early)
			44.8%	> 58 days (late)
Baig (2003)	Several Managed Care Organizations in Philadelphia	FOBT	51%	1 year
Levy (2010)	University of Iowa Clinic and the Iowa City Free Medical Clinic	FIT	61%	Not stated
Van Kleek (2010)	Single urban VA medical center	FOBT	66%	1 year
Hillyer (2014)	Community health clinic in Northern Manhattan	FOBT	77%	2 years
		FIT	84.2%	
Steele (2013)	US Center for Disease Control and Prevention	FOBT	82%	4 years
Miglioretti (2008)	Group Health Cooperative in the Puget Sound Region of Washington State	FOBT	82%	1 year
Dupont-Lucas (2011)	France (Calvados, Normandy, Cote-d'Or, Burgundy)	FOBT	83.8%	2 years
LoConte (2013)	Community-clinics in Wisconsin	FIT	91%	2 years

Figure 1. Time to referral as a potential mediator between patient-level factors and time to follow-up colonoscopy

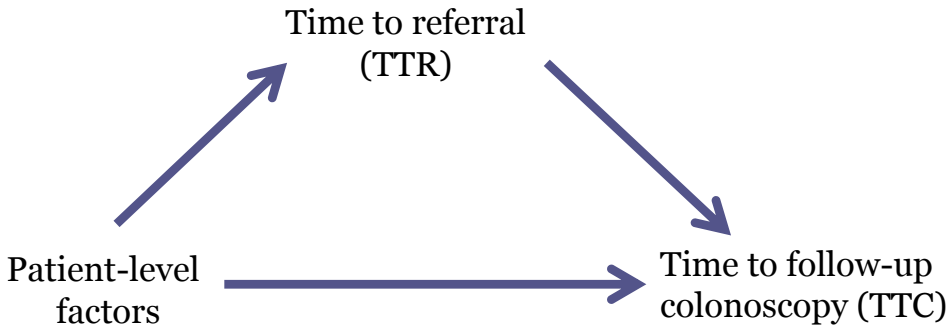

Figure 2. Flow chart of CRC screening using FIT kits at a local community health center

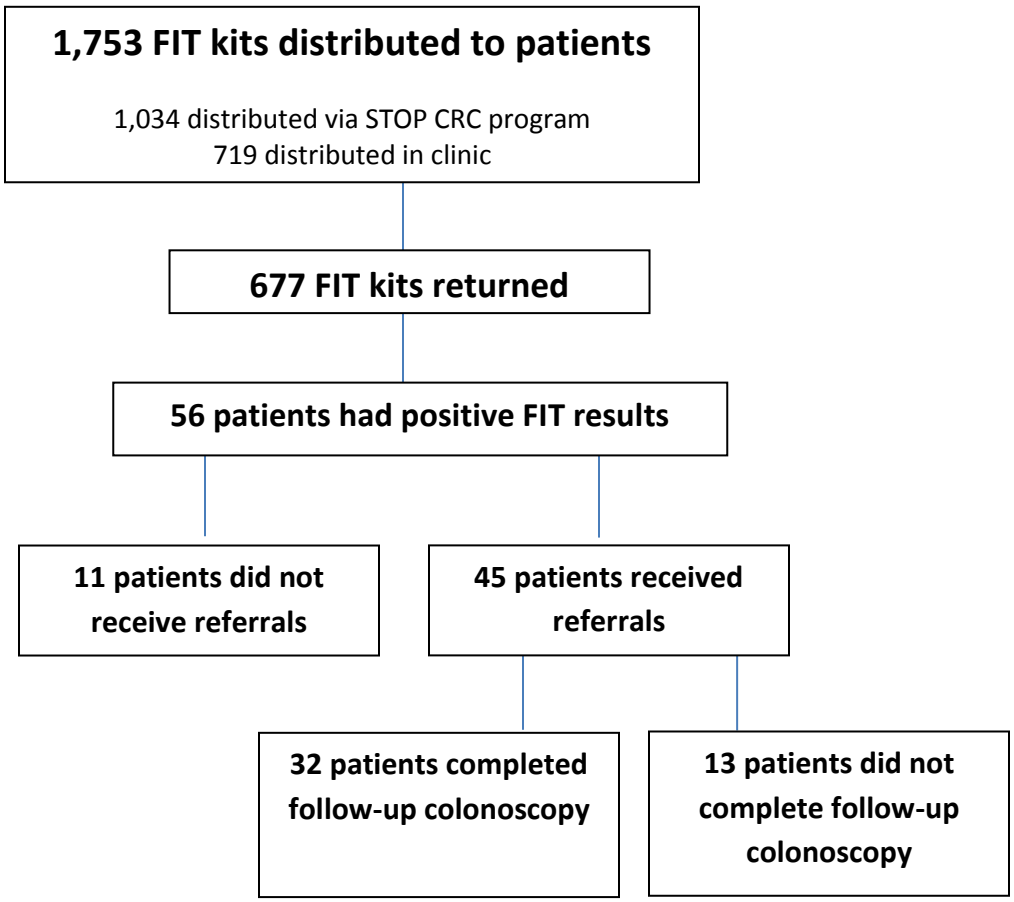

Table 2. Characteristics of the analytic cohort of 56 patients aged 50 years and older

Characteristic	N	%
Age (years)		
< 60	32 (57)	57
60-69	16 (29)	29
> 70	8 (14)	14
Gender		
Female	31 (55)	55
Male	25 (45)	45
Ethnicity		
Non-Hispanic	27 (48)	48
Hispanic	29 (52)	52
Race		
White	51 (91)	91
Non-White	5 (9)	9
Language		
English	28 (48)	48
Spanish	28 (50)	50
Other	1 (2)	2
Insurance Status		
Medicaid	12 (21)	21
Medicare	19 (34)	34
Uninsured	17 (30)	30
Other	8 (17)	17
Primary VGMHC clinic		
Cornelius	28 (50)	50
Hillsboro	28 (50)	50
Co-morbidities		
Diabetes	21 (38)	38
Hypertension	33 (59)	59
Smoker (former or current)	19 (34)	34

Table 3. Analyses of variables associated with adherence to follow-up colonoscopy within 60 days of a positive FIT result

Characteristic	Number of Patients (n = 32), N (%)	Completed Colonoscopy (n = 14), N (%)	Unadjusted OR (95% CI)	Adjusted OR[a] (95% CI)
Age (years)				
< 60	18 (56)	7 (50)	1.00	1.00
60-69	9 (28)	5 (36)	1.96 (0.39 – 9.93)	2.26 (0.18 -28.51)
> 70	5 (16)	2 (14)	1.05 (0.14 – 7.93)	0.74 (0.06 – 9.30)
Gender				
Male	14 (44)	9 (64)	1.00	1.00
Female	18 (56)	5 (28)	0.23 (0.05 – 1.96)[b]	0.21 (0.03 – 1.44)
Ethnicity				
Non-Hispanic	19 (59)	10 (71)	1.00	1.00
Hispanic	13 (41)	4 (29)	0.40 (0.09 – 1.76)	0.21 (0.03 – 1.76)
Race				
Non-White	4 (13)	1 (7)	1.00	1.00
White	28 (88)	13 (93)	2.60 (0.24 -28.15)	3.67 (0.14 – 93.1)
Language				
English/Other	18 (56)	10 (71)	1.00	1.00
Spanish	14 (44)	4 (29)	3.13 (0.71 - 14.3)	2.56 (0.05 -100)
Insurance				
No	10 (31)	2 (14)	1.00	1.00
Yes	22 (69)	12 (86)	4.80 (0.82 – 28.0)	5.33 (0.65 – 43.7)
Co-morbidities				
Diabetes				
No	20 (63)	11 (79)	1.00	1.00
Yes	12 (32)	3 (21)	0.27 (0.06 – 1.32)	0.26 (0.01 – 10.8)
Hypertension				
No	11 (34)	6 (43)	1.00	1.00
Yes	21 (66)	8 (57)	0.51 (0.12 – 2.25)	0.48 (0.08 – 3.01)
Smoker				
No	21 (66)	8 (57)	1.00	1.00
Yes	11 (34)	6(43)	1.95 (0.44 – 8.55)	1.58 (0.21 – 12.1)

[a] Adjusted for age, sex, race, ethnicity, insurance status; [b] Significant at $p < 0.05$; OR: completers vs. non-completer

Table 4. Analyses of variables associated with adherence to follow-up colonoscopy among those with a positive FIT result

Characteristic	Number of Patients (n = 56), N (%)	Completed Colonoscopy (n = 32), N (%)	Unadjusted OR (95% CI)	Adjusted OR[a] (95% CI)
Age (years)				
< 60	32 (57)	18 (56)	1.00	1.00
60-69	16 (50)	9 (28)	1.00 (0.30 – 3.35)	1.22 (0.32 – 4.68)
> 70	8 (11)	5 (16)	1.30 (0.26 – 6.37)	1.95 (0.32 – 11.8)
Gender				
Male	25 (45)	14 (44)	1.00	1.00
Female	31 (55)	18 (56)	1.08 (0.38 – 3.15)	0.88 (0.27 – 2.81)
Ethnicity				
Non-Hispanic	27 (48)	19 (59)	1.00	1.00
Hispanic	29 (52)	13 (41)	0.34 (0.11 – 1.03)[b]	0.31 (0.09 – 1.10)
Race				
Non-White	5 (9)	4 (13)	1.00	1.00
White	51 (91)	28 (88)	0.30 (0.03 – 2.92)	0.64 (0.05 – 7.43)
Language				
English/Other	28 (50)	18 (56)	1.00	1.00
Spanish	28 (50)	14 (44)	0.55 (0.19 – 1.62)	2.18 (0.19 -25.25)
Insurance				
No	17 (30)	10 (31)	1.00	1.00
Yes	39 (70)	22 (69)	0.91 (0.29 -2.87)	0.63 (0.17 – 2.35)
Co-morbidities				
Diabetes				
No	35 (63)	20 (63)	1.00	1.00
Yes	21 (38)	12 (38)	1.00 (0.36 – 2.98)	0.99 (0.29 – 3.32)
Hypertension				
No	23 (41)	11 (34)	1.00	1.00
Yes	33 (59)	21 (66)	1.91 (0.65 – 5.63)	2.10 (0.66 – 6.67)
Smoker				
No	37 (66)	11 (34)	1.00	1.00
Yes	19 (34)	21 (66)	1.05 (0.34 – 3.21)	0.67 (0.17 – 2.67)

[a] Adjusted for age, sex, race, ethnicity, insurance status; [b] Significance at $p < 0.05$; OR: completers vs non-completers

Table 5. Comparison of Non-Hispanic and Hispanic patients with positive FIT results

Characteristic	Non-Hispanic (n = 27), N (%)	Hispanic (n = 29), N (%)
Age (years)		
< 60	18 (67)	14 (48)
60-69	6 (22)	10 (34)
> 70	3 (11)	5 (17)
Gender		
Male	10 (37)	15 (52)
Female	17 (63)	14 (48)
Language*		
English/Other	25 (93)	3 (10)
Spanish	2 (7)	26 (90)
Insurance Status		
No	6 (22)	11 (34)
Yes	21 (78)	18 (62)
Co-morbidities		
Diabetes		
No	17 (63)	18 (63)
Yes	10 (37)	11 (38)
Hypertension		
No	11 (41)	12 (41)
Yes	16 (59)	17 (59)
Smoker		
No	14 (52)	23 (79)
Yes	13 (48)	6 (21)

*significant at $p < 0.05$

Table 6. Reasons documented in VGMHC medical record for lack of follow-up colonoscopy after a positive FIT result (N = 24)

Reason	Incidence No. (%)
Patient refused or cancelled colonoscopy	6 (25)
Clinician documented miscellaneous reasons for why complete colon evaluation was not pursued	9 (38)
Colonoscopy not indicated because patient had recent colonoscopy (within 10 years)	4 (17)
Unknown	5 (21)

Table 7. Analyses of timeliness of referrals and colonoscopy among patients with positive FIT results

Characteristic	Completed colonoscopy (N = 32)	Did not complete colonoscopy (N = 24)	p-value
Received Referral			
Yes	32 (100%)	13 (54%)	
No	0 (0%)	11 (46%)	_____
Time to referral among those who received a referral (days)			
Average (SD)	27 (84.5)	4.3 (8.2)	0.05[a,b]
Median (min – max)	2.5	0	0.24[c]
Time to colonoscopy among those with colonoscopy (days)			
Average (SD)	110 (114)	_____	_____
Median (min – max)	62 (10 – 493)		

[a] Wilcoxon rank-sum; [b] Significant at $p < 0.05$; [c] Mood's median test

Table 8. Comparison of timeliness of referrals and colonoscopy among Non-Hispanic and Hispanic patients

Characteristic	Non- Hispanics (n = 27)	Hispanics (n = 29)	p-value
Received Referral			
Yes	23 (85%)	22 (75%)	0.51[a]
No	4 (15%)	7 (25%)	
Time to referral among those who received a referral (days)			
Mean (SD)	31.4 (99.4)	9 (13.6)	0.83[b]
Median (min – max)	1 (0 - 417)	3 (0 -48)	0.18
Completed colonoscopy			
Yes	19 (70%)	13 (45%)	
No	8 (30%)	16 (36%)	0.06[a]
Time to colonoscopy among those with colonoscopy (days)			
Average (SD)	105.9 (121)	117 (104.9)	0.38[b]
Median	60	62	0.95

[a] Fisher's Exact ; [b]Wilcoxon rank-sum; [C] Mood's median test

Table 9. Qualitative results of English (n = 4) and Spanish (n=6) speakers with positive FIT results

Theme	Number of times a given comment was coded			Sampling of illustrative quotes
	English (ELP)	Spanish (SLP)	Total	
1. Reaction to CRC screening program				
Positive, appreciative reaction	3	5	8	Oh, yes, I felt fine about it [CRC screening program]. I don't have any problem with that at all. In fact, I think it's wonderful. They're getting more and more inventive. - ELP Oh, it was great because otherwise I wouldn't have completed the test. - ELP [When I received the kit] I did not understand and I went to the clinic to ask what I needed to do … and a woman explained to me what to do. - SLP I did not know if they give you the result at the clinic… because I was not given my results. - SLP
Negative, thought he/she had cancer		1	1	
Made sense given patient's age (e.g. "had to come in because I'm over 50")	1	1	2	
Fine, but patient didn't receive results		1	1	
Confused as to why they were receiving kit		1	1	
2. Experience with FIT kit and other mailed material				
General reaction to FIT kit				Yeah, I set it [FIT kit] aside. I had so many things going on in my life that finding time to do things that I know need to be done, sometimes it gets a little bit difficult. But, I do finally get them done. - ELP I was really, well, at first I was really freaked out by sending the sample through the mail, but it worked out really well. - ELP The little samples and the instructions were very accurate.
Positive, appreciative	2	6	8	
Thought it was "kind of strange"	1		1	
Felt weird sending fecal matter through the mail	1		1	
Action with kit				
Opened kit, read instructions, and completed it	3	2	5	
Set it aside for a couple of weeks	1		1	

Called or took it to the clinic for further explanation		3	3	The instructions on the packet were very well clear and, you know, to the point on how to take the test. - ELP
3. Reaction to FIT results				
A little scared	1		1	Well…it was a little scary at first, makes you wonder. You know. - ELP Well, just…Oh, gee…Well, I better get this taken care of before it gets out of hand. Nip it in the bud, so to speak. And it was just those reasons. Well, I had to setup an appointment with my gastroenterologist, which I did. And I was seen, and then we scheduled a colonoscopy. So it was all just boom, boom, boom. - ELP I was a little worried about it but then I talked to the doctor and after the colonoscopy I was fine. - ELP … I did not understand when they told me [that I had an abnormal result] and then I called to speak to the doctor's assistant and that was when I asked her am I dying or do I have cancer or what is it that I have? She told me not to worry. She told me there are various reasons [why someone has an abnormal result], not just cancer … she told me hemorrhoids, and various things… - SLP At first, I was surprised because one doesn't know whether it is something bad or not. They told me that it could be that I have something or that I have nothing because [the abnormal result] can be something else. – SLP
Patient thought FIT results were normal and was not sure why a follow-up colonoscopy was needed but did it anyways		1	1	
Didn't know FIT results were abnormal and needed a colonoscopy		2	2	
4. Reaction to the need to complete follow up colonoscopy				

Fine with completing follow-up colonoscopy	3	3	6	Actually, yeah, because I was a little scared. I was a little leery about going under and everything. And the doctor was real good because they saying it's something I should do. Yeah. - ELP It was just one of those things that I had to deal with. Just something that needs to be done and dealt with and, you know, get it off your checklist…your bucket list, or whatever they call it. - ELP
Patient didn't understand what a follow-up colonoscopy was and therefore didn't complete one		1	1	
5. Barriers to follow-up colonoscopy				
Travel/transportation	1		1	I've been so sick, we've had to keep on rescheduling it [follow-up colonoscopy] and rescheduling it because I'd be coming down with the flu and the cold I've got now…They [clinic staff] were right on it. But I had to keep on calling to cancel because I was being sick all the time. - ELP My only thing was transportation. Yeah, they gave me a paper with some places I could call to get medical transportation. And it worked out good. – ELP (Reference to time off work) Now, well no, I cannot go [for a colonoscopy]. I have a small child that I care for and they bring her early and they return late and I cannot go now. - SLP
Doesn't understand the process or what a colonoscopy is		2	2	
Multiple health issues take priority	1	1	2	
Doesn't have time because of work schedule		1	1	
Transfer to a specialist took > 1 year		1	1	
No barriers expressed	2	1	3	
6. Experience with completing follow-up colonoscopy				
Experience				It was a pretty smooth process. - ELP It [gastroenterology consult appointment] went really well and the doctor explained everything and I just made the appointment [colonoscopy appointment]. -ELP
Completed colonoscopy and it went well	3	4	7	
Wait time				
Waited < 1 mo. to complete colonoscopy	3	3	6	
Waited 1 yr. to complete colonoscopy		1	1	
Understanding results				

Received colonoscopy results	3	3	6	It was a much better experience than I expected. - ELP [In the hospital after the procedure] the nurse told me [the results] but I did not understand and I went and asked the doctor… I also asked my niece… They told me that I had a mole… but they removed it… like a wart. - SLP
Received colonoscopy results but needed additional explanation from family		1	1	
Colonoscopy results				
Normal		2	2	
Non-cancerous polyps	3	1	4	
Hemorrhoids		2	2	
7. Reaction to continuation of the CRC screening program and ways to improve program				
Believes the program should continue	4	6	10	Make sure that it's explained in basic terms so that the person understands what they need to do.- ELP I do know that language can be a barrier at times. And then it can also be a bridge as well. So if you can get over the big hurdles that most American's…or most people, as they get older, think that they know about the procedures, that in itself is huge. You're halfway there. - ELP Ask them what their…Well, how can I say this? Ask them if they have any concerns or any questions when people are going in for a colonoscopy. You know, a lot questions that you should know before you ever go into the doctor…in to have it. – ELP … that they [the doctors] explain what [the colonoscopy] is for and what it prevents. - SLP … there needs to be more education about the exams, which are required, and the differences among the various exams, something like that. - SLP
Letter and instructions need to be more clear especially for first time completers		1	1	
More patient education on importance, test procedures, testing options	2	5	7	
Have providers explain FIT & colonoscopy in basic terms during appointment	2	2	4	
More clarity about the follow up process		1	1	
Marketing- stickers, fliers, reminders, etc. around the clinic	1	1	2	
Patient advocates		3	3	
Timely FIT results		1	1	
Timely follow-up care		1	1	

				… I think that for this program it would be improved if patients have more information from people who have had these experiences [done the exam] and to speak with friends or someone that you know that has done it … because it is simple. - SLP

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Appendix

Table 1A . Risk of colorectal malignancy based on colonoscopy and pathology reports among the 32 patients that completed a follow-up colonoscopy

Risk Category	Number of Subjects	%
Minimal	17	53
Low	6	18
Moderate	2	6
High	2	6
Missing data	5	16

Interview Guide for English speakers

Introduction

Hello, my name is _____ and I am from the Kaiser Permanente Northwest Center for Health Research.

Thanks for agreeing to schedule this interview with me. [If over the phone, ask: Is this still a good time to talk?]

As we mentioned in the letter you received, during the 30 to 45 minute telephone interview we would like to hear your experience with the STOP CRC program and any follow up care you may have received. During the telephone interview we would ask questions about:

- your overall reaction to and experience with the colon cancer screening;
- your experience receiving the letter, kit, and reminder in the mail;
- your experience in receiving abnormal fecal test results;
- your experience obtaining a colonoscopy;
- your reasons for why you may or may not have completed a follow up colonoscopy;

We will use input from these interviews to guide future improvements to the colon cancer screening program. Your name and other personal information will be kept confidential.

Since we are not able to write fast enough to record everything, we will be record our discussion today. The recorded information will be transcribed into a written format; however, it will not include your name or any other information that might let people guess who you are. Quotes for the discussion may be used at presentations of the study

results, but they will not identify who the speaker was. The recordings will then be destroyed at the end of the study.
Any questions before we start?

Background Information

1) Please share with me how long you've have been getting medical care from [insert name of clinic]? *probe:* Do you have a regular doctor or medical team (nurse, medical assistant, case manager, etc.) that you see at [clinic] How long have you been with this provider (s)?

Experience with/Reaction
The program, called Screen to Prevent Colon Cancer, included a letter sent to your home explaining the importance of colon cancer screening, followed a week or so later with sending a FIT kit to you in the mail to complete and mail back to the clinic. You may have also received a reminder postcard and a phone call from the clinic encouraging you to complete the test and return it.

Broad Recall/Reaction Questions

1) Overall, how did receiving this type of outreach make you feel?
    a. What have you liked about it and why is that?
    b. What have you disliked about it and why is that?

Specific Components
Initial Letter

1) Did you open up and read the letter? Why or why not?

FIT Kit

1) What do you remember about receiving the FIT kit – do you recall getting it in the mail?
    c. What did you do when you got the FIT kit in the mail? [Open it, set it aside, ask someone else to look at it, threw it away etc.] Why did you do this?

Reminder Postcard

1) Do you recall receiving the reminder post card encouraging you to complete and return the FIT kit?
    d. Did you find it helpful in reminding you to complete the FIT kit?

Overall Facilitator Questions

1) What are some things that other people have said or done that have influenced your decision to do something for your health like get screening for colon

cancer? [probe: have you received encouragement from family, friends, your medical providers, others]

2) Who do you go to for health advice? Who would you trust when seeking information about colon cancer screening like using a FIT test or getting a follow up colonoscopy?

Follow up care Questions

1) What was your reaction to the positive FIT kit results? How did you receive these results (by mail, by phone, by email, etc.)? Did the results make sense to you?
2) What, if anything, had you heard about a colonoscopy? Had you had one before?
3) Where were you told you needed to go to get one?
4) What were some of your concerns or questions about getting the follow up colonoscopy?
5) Did you speak to your PCP or anyone else about your concerns/questions regarding the follow up colonoscopy? Why or why not? If so, was this helpful?
6) Did anyone tell you not to get a colonoscopy? If so, what did they say?
7) Did you decide to complete the follow up colonoscopy? Probe: Why or why not?

IF RESPONDENT DID NOT OBTAIN A COLONOSCOPY:

If not, what got in the way of completing the follow up colonoscopy?

1) Do you plan on getting the follow up colonoscopy sometime in the future? Please explain.
2) What might motivate you to get the follow-up colonoscopy?

IF RESPONDENT OBTAINED A COLONOSCOPY:

1) How long did you have to wait to get a colonoscopy?
2) What, if any, obstacles did you face?
3) What was your experience getting a colonoscopy? Did anything surprise you?
4) What could someone have said to make you more prepared for the colonoscopy?
5) What were you told about the results of your colonoscopy?
6) Do you plan to get another colonoscopy in the future?

Improvement / Continuation Questions

1) What suggestions do you have for how the Screen to Prevent Colon Cancer program could be improved for you or other individuals?
2) Any other thoughts on how we could help someone screen for colon cancer by completing a FIT kit?
3) Any other thoughts on how we could help someone who had an abnormal screening result complete a follow up colonoscopy?

4) How do you feel about this program being continued at [clinic name]? Any concerns about this?

Closure Question

1) That completes the formal questions we have. Is there anything else you would like to share?
   Thank you!

Interview guide for Spanish speakers

Introduction:

Hola, mi nombre es _____ y yo soy de El Centro de Investigaciones de la Salud de Kaiser Permanente la Permanente Center Northwest Kaiser de Investigación en Salud.

Gracias por hacer esta entrevista conmigo. [Si por teléfono, pregunte: ¿Sigue siendo un buen momento para hablar?]

Como hemos mencionado en la carta que recibió, durante la entrevista telefónica de 30 a 45 minutos quisiéramos oír su experiencia con el programa STOP CRC y cualquier atención de seguimiento que pueda haber recibido. Durante la entrevista telefónica hacíamos preguntas sobre:

¬ Su reacción general a la experiencia y con la detección del cáncer de colon;
¬ su experiencia de recibir la carta, kit, y un recordatorio en el correo;
¬ su experiencia en la recepción de los resultados de pruebas de heces anormales;
¬ su experiencia de obtener una colonoscopia;
¬ sus razones por las cuales usted puede o no ha completado una colonoscopia de seguimiento;

Vamos a utilizar las contribuciones de estas entrevistas para mejorar el programa de cáncer de colon. Su nombre y otra información personal serán confidenciales.

Puesto que no somos capaces de escribir lo suficientemente rápido para grabar todo, estaremos grabando nuestra entrevista de hoy. La información registrada se transcribe en un formato escrito; sin embargo, no va a incluir su nombre o cualquier otra información que pueda permitir que la gente adivine quién es usted. Presupuestos para la discusión se pueden utilizar en las presentaciones de los resultados del estudio, pero no van a identificar quién fue el orador. Las grabaciones entonces serán destruidas al

final del estudio.

¿Cualquier pregunta antes de empezar?

Background information

1) ¿Por favor comparta conmigo el tiempo que ha estado recibiendo atención médica de [inserte el nombre de la clínica]? sonda: ¿Tiene usted un médico de cabecera o equipo médico (enfermera, asistente médico, administrador de casos, etc.) que ve en la [clínica] ¿Cuánto tiempo ha estado con ese proveedor(s)?

Experience with/Reaction

El programa, pruebas para evitar el cáncer de colon, incluía una carta enviada a su casa para explicar la importancia de la detección del cáncer de colon, una semana más tarde con el envío de una prueba de FIT para usted en el correo para completar y enviar de vuelta a la clínica o al laboratorio. Es posible que también haya recibido un recordatorio por correo.

Broad Recall/Reaction Questions

1) En general, ¿cómo se siento haber recibido este tipo de alcance?

a. ¿Qué le ha gustado del programa y por qué?

b. ¿Qué le disgustado al respecto y por qué?

Specific Components

Initial Letter

2) ¿Abrió y leo la carta? ¿Por qué o por qué no?

FIT Kit

1) ¿Qué recuerda acerca de recibir la prueba de FIT - ¿Recuerda haber recibido la prueba en el correo?

a. ¿Qué hiciste cuando recibiste la prueba de FIT en el correo? [Abrirlo, dejarlo a un lado, pedirle a otra persona que lo vea, lo tiró etc] ¿Por qué hizo esto?

Reminder Postcard

1) ¿Te acuerdas de la recepción de la tarjeta postal/recordatorio que la animaba a completar y devolver la prueba de FIT?

a. ¿Te resulto útil para recordar de que completar la prueba de FIT?

Overall Facilitator Questions

1) ¿Cuáles son algunas cosas que otras personas han dicho o hecho que han influido en su decisión de hacer algo por su salud como conseguir la detección del cáncer de colon? [sonda: ¿ha recibido el apoyo de la familia, los amigos, a sus proveedores médicos, otros]

2) ¿Con quién se puede ir en busca de consejos de salud? En quién confía en la búsqueda de información sobre la detección del cáncer de colon como el uso de una prueba o conseguir una colonoscopia de seguimiento?

Follow up care Questions

1) ¿Cuál fue su reacción a los resultados positivos de la prueba de FIT? ¿Cómo recibió estos resultados (por correo, por teléfono, por correo electrónico, etc)? ¿Los resultados tienen sentido para usted?

2) ¿Que, si algo, había escuchado acerca de una colonoscopia? ¿Has tenido una antes?

3) ¿Dónde te dijeron que necesitabas una colonoscopia?

4) ¿Cuáles fueron algunas de sus preocupaciones o preguntas acerca de cómo obtener la colonoscopia de seguimiento?

5) ¿Habló con su proveedor o cualquier otra persona acerca de sus preocupaciones / preguntas con respecto a la colonoscopia de seguimiento? ¿Por qué o por qué no? ¿Si es así, fue útil esta información?

6) ¿Alguien te dijo que no conseguirás una colonoscopia? Si es así, ¿qué dijeron?

7) ¿Decidió usted completar la colonoscopia de seguimiento? ¿Por qué o por qué no?

IF RESPONDENT DID NOT OBTAIN A COLONOSCOPY:

Si no, que se puso en el camino de completar la colonoscopia de seguimiento?

1) ¿Usted planea en conseguir la colonoscopia en algún momento en el futuro? Por favor, explique.

2) ¿Qué podría motivar a usted para obtener la colonoscopia de seguimiento?

IF RESPONDENT OBTAINED A COLONOSCOPY:

1) ¿Cuánto tiempo tuvo que esperar para conseguir una colonoscopia?

2) ¿Cuál, en su caso, fueron los obstáculos que tuvo que enfrentar?

3) ¿Cuál fue su experiencia en conseguir una colonoscopia? ¿Hubo algo que te sorprendió?

4) ¿Qué podría alguien haber dicho para hacerte más preparado para la colonoscopia?

5) Qué le dijeron sobre los resultados de la colonoscopia?

6) ¿Tiene planes para conseguir otra colonoscopia en el futuro?

Improvement / Continuation Questions

1) ¿Qué sugerencias tiene para cómo el programa de cáncer de colon se puede mejorar para usted u otras personas?

2) ¿Cualesquiera otras ideas sobre cómo podríamos ayudar a alguien completar la prueba de FIT?

3) ¿Alguna otra idea sobre cómo podríamos ayudar a alguien que tuvo un resultado anormal en completar una colonoscopia de seguimiento?

4) ¿Cómo te sientes acerca de este programa que se continúe en [nombre de la clínica]? ¿Cualquier duda acerca de esto?

Closure Question

1) Esto completa las cuestiones formales que tenemos. ¿Hay algo más que te gustaría compartir?

¡Gracias!

Table 2A. An example of testing for mediation

Step 1. Conduction of simple linear regression with Ethnicity predicting Log(TTC),
Log(TTC) = β_0+ β_1(Ethnicity)) + ε

Variation source	SS	Df	MS	F-value
Regression	0.3654	1	0.3654	0.45
Error	24.315	30	0.8105	
Total	24.68	31		

Variable	Coefficient	Standard Error	P-value from Wald test	95% CI for Coefficient
Ethnicity	0.217	0.3240	0.507	-0.44 – 0.88
Intercept	4.21	0.207	< 0.01	3.79 – 4.64

Step 2. Conduction of simple linear regression with Ethnicity predicting Log(TTR),
Log(TTR) = β_0+ β1(Ethnicity) + ε

Variation source	SS	Df	MS	F-value
Regression	6.037	1	6.038	0.128
Error	71.439	29	2.463	
Total	77.477	30		

Variable	Coefficient	Standard Error	P-value from Wald test	95% CI for Coefficient
Ethnicity	0.894	0.571	0.128	-0.274 – 2.06
Intercept	1.306	0.370	0.001	0.549 – 2.06

Step 3. Conduction of simple regression analysis with Log(TTR) predicting Log(TTC), Log(TTC) = β_0+ β_1(Log(TTR)) + ε

Variation source	SS	Df	MS	F-value
Regression	8.7011	1	8.7011	0.0003
Error	11.7232	24	0.4885	
Total	20.4243	25		

Variable	Coefficient	Standard Error	P-value from Wald test	95% CI for Coefficient
Log(Time to referral)	0.35	0.08	< 0.01	0.18 – 0.52
Intercept	3.79	0.19	< 0.01	3.39 – 4.19

Step 4. Conduction of multiple regression analysis with Ethnicity and Log(TTR) predicting Log(TTC) = β_0+ β_1(Log(TTR)) + β_2(Ethnicity)+ ε

Variation source	SS	Df	MS	F-value
Regression	9.086	2	4.543	9.22
Error	11.338	23	0.493	
Total	20.424	25		

Variable	Coefficient	Standard Error	P-value from Wald test	95% CI for Coefficient
Log(Time to referral)	0.338	0.0853	< 0.01	0.161 – 0.514
Ethnicity	0.255	0.288	0.386	-0.341 – 0.850
Intercept	3.717	0.212	<0.01	3.28 – 4.16