

# Comparative effectiveness of two pharmacy-based colorectal cancer screening interventions during an annual influenza vaccination campaign

Michael B. Potter, Ginny Gildengorin, Yinan Wang, May Wu, and Lisa Kroon

## Abstract

**Objective:** To compare the effectiveness of two different pharmacy-based colorectal cancer screening (CRCS) interventions taking place during an annual influenza vaccination campaign.

**Design:** Time randomized clinical trial.

**Setting:** San Francisco, CA, in late 2008.

**Participants:** 133 adults aged 50 to 80 years visiting a pharmacy during an influenza vaccination campaign and also due for CRCS.

**Intervention:** On five dates, eligible patients were provided education and encouraged to obtain screening from their primary care clinician. On 17 dates, a home fecal immunochemical test (FIT) for CRCS was provided. A 16-item questionnaire was administered by phone 3 to 6 months after study enrollment.

**Main outcome measure:** Self-reported CRCS activity, comparing CRCS completion rates for participants provided with the FIT versus those provided with education and encouragement to obtain screening from patients' primary care clinician.

**Results:** 86 participants in the FIT arm and 28 the CRCS education arm were interviewed. Interviews revealed that 19.8% of the FIT group and 50% of the CRCS education group discussed CRCS with their primary care clinician ( $P = 0.002$ ). Of these participants, 59.3% in the FIT arm and 14.8% in the CRCS education arm reported completing screening ( $P < 0.001$ ). Of participants in the FIT group, 52.2% completed FIT dispensed to them by the investigators. Most participants in both groups reported interest in receiving CRCS education and home CRCS tests from pharmacists in the future.

**Conclusion:** Pharmacy patients are receptive to CRCS interventions delivered in community pharmacies. Providing FIT to eligible patients during a pharmacy-based influenza vaccination campaign increases screening rates more than CRCS education alone.

**Keywords:** Colorectal cancer, health screening, community pharmacists, fecal occult blood tests, influenza vaccine, patient education.

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Colorectal cancer screening (CRCS) can prevent most colorectal cancer deaths.<sup>1</sup> However, less than two-thirds of Americans are getting screened, and colorectal cancer remains the second leading cause of cancer mortality in the United States.<sup>2,3</sup> The U.S. Preventive Services Task Force (USPSTF) recommends CRCS for all individuals beginning at age 50 years and continuing at least until 75 years, as this is the population of average-risk individuals most likely to benefit from screening.<sup>4</sup> USPSTF recommends three different CRCS options: (1) fecal occult blood testing with high-sensitivity guaiac tests or fecal immunochemical tests (FITs) annually, (2) sigmoidoscopy every 5 years with guaiac test or FIT every 3 years, or (3) colonoscopy every 10 years. A decision analysis by USPSTF concludes that all three of these approaches to screening are equivalent in terms of their potential to reduce colorectal cancer mortality for average-risk individuals when done on time with appropriate follow-up.<sup>5</sup> Among these tests, annual high-sensitivity guaiac test and FIT are effective, noninvasive, inexpensive, and could be provided in U.S. pharmacies.

The principal of both types of home fecal occult blood tests (guaiac test and FIT) is that yearly testing can detect intermittent bleeding from slow-growing precancerous polyps or early

cancers that can be confirmed with colonoscopy and removed before they become life threatening.<sup>6</sup> Guaiac tests detect peroxidase activity of heme in stool using a hydrogen peroxide developer. The tests require dietary and medication restrictions to ensure accurate results. The most sensitive guaiac tests require taking a total of six samples of stool from three bowel movements. High-sensitivity guaiac tests have a reported sensitivity of 64% to 80% for colorectal cancer.<sup>4</sup> FITs use specific antibodies to human blood components such as the globin protein portion of human hemoglobin and therefore do not require dietary or medication restrictions. FITs have a reported sensitivity of 61% to 90% for colorectal cancer.<sup>4</sup> Lower-sensitivity, “throw-in-the-bowl” versions of the guaiac test have been sold in U.S. pharmacies but have not been evaluated or recommended for use by USPSTF. A variety of home fecal occult blood tests, including FIT, are sold in pharmacies in countries other than the United States, however.<sup>7</sup>

Every year, pharmacists administer hundreds of thousands of influenza vaccinations in the community pharmacy setting.<sup>8-12</sup> Many individuals who get influenza vaccinations in pharmacies are likely also due for CRCS. Based on evidence that a hospital-based influenza vaccine clinic can offer an opportunity to provide CRCS education and access to home fecal occult blood test kits to patients outside of the context of primary care, the investigators wished to explore the use of a similar intervention in community pharmacies.<sup>13</sup>

### At a Glance

**Synopsis:** The current study demonstrated that providing home colorectal cancer screening (CRCS) tests in the community pharmacy setting to eligible patients at the time of influenza vaccination can increase screening rates compared with providing CRCS education only. Patients were divided into two arms: a fecal immunochemical test and a CRCS education arm. Of participants interviewed 3 to 6 months after the intervention, 19.8% of the FIT group and 50% of the CRCS education group reported discussing CRCS with their primary care clinician. Completion of screening was reported by 59.3% in the FIT group and 14.8% in the CRCS education group. Participants in both groups expressed enthusiasm for CRCS interventions delivered in community pharmacies.

**Analysis:** *The current results indicate that pharmacy-based CRCS education can be successful in encouraging patients to discuss CRCS with their primary care clinicians but that offering FIT to patients in pharmacies may lead to greater increases in screening during a 3- to 6-month period compared with pharmacy-based education alone. The majority of participants indicated an intention to obtain influenza vaccinations at their community pharmacy again in the future, suggesting that annual pharmacy-based influenza vaccination clinics may provide good opportunities for pharmacists to reach specific groups of individuals with other important and personalized annual preventive health messages or interventions such as those relating to CRCS.*

### Objective

The goal of this pilot study was to assess the feasibility of providing a CRCS intervention to patients during influenza vaccination clinics held in community pharmacy settings. Specifically, the objective was to compare the effectiveness of providing eligible individuals with FIT versus an intervention consisting of CRCS education with encouragement to obtain CRCS from their primary care clinician. Outcomes were assessed by phone interviews with study participants 3 to 6 months after the intervention.

### Methods

The study took place at a large nationwide community chain pharmacy with stores in diverse San Francisco, CA, neighborhoods. These pharmacies provide an annual, in-store, pharmacist-administered influenza vaccination program by appointment and walk in. A total of 18 pharmacies located in different areas of the city were selected for participation based on recommendations of the regional pharmacy manager and factors such as available space to perform the intervention and potential volume of English-speaking patients in the targeted age group. All of the pharmacies contacted agreed to participate. The study was approved by the University of California at San Francisco Institutional Review Board.

The study used a time-randomized design. In consultation with the researchers, each of the 18 pharmacies selected one or two influenza vaccination sessions lasting 4 to 6 hours each, during which the researchers could visit and conduct the study. The researchers created a schedule consisting of 22 sessions

in October and November 2008, with one or two pharmacies participating on any given date. Each 4- to 6-hour session was randomized so that all patients in a given session were allocated to one of two interventions: FIT or CRCS education. Pharmacy customers were allowed to participate in the study regardless of whether they were in the pharmacy to get a vaccine.

Initially, a one-to-one randomization scheme was planned, but because of low pharmacy customer volume during the sessions selected in the first week, the allocation of the two interventions was changed to a four-to-one randomization. This change was made to maximize exposure to and experience with the FIT intervention. One to three members of the research team were present at each site on the day of the intervention. Potential study participants were approached by a member of the research team as they were waiting for their influenza vaccination, with eligibility determined by asking patients' age and the date and type of their last CRCS test. Patients were considered eligible for the intervention if they were both of average risk for colorectal cancer and due for screening, which was defined as age between 50 and 80 years with no colonoscopy in the previous 10 years, no home fecal occult blood test in the previous year, no personal or family history of colorectal cancer, and no history of inflammatory bowel disease. Consistent with USPSTF and other national guidelines, individuals who reported flexible sigmoidoscopy in the previous 5 years were not automatically excluded, and neither were older adults between 75 and 80 years of age who reported being in generally good health. Potential study participants who could not speak English or who had no primary care source to which test results could be sent or to which they could receive recommended follow-up were excluded. Informed consent was obtained from all eligible and interested participants. Eligibility and enrollment activities took place at a table located a few feet from the influenza vaccine station in the participating pharmacy. Sociodemographic data collected at enrollment included age, gender, ethnicity, educational level, health insurance status, history of receiving an influenza vaccination, and history of receiving a CRCS test.

In the FIT group, participants received a FIT kit (Enterix InSure—Quest Diagnostics) with brief counseling by a member of the research team on how to use the test and why screening is important. Participants were asked to complete the FIT and mail it to Quest Diagnostics. Test results were sent to the principal investigator, who then notified the patient and patient's designated primary care clinician of the results. Participants in the CRCS education group were provided with a two-page educational handout that was reviewed with the patient by a member of the research team. Patients in the CRCS education group were instructed to contact their primary care clinician to obtain CRCS. A reminder telephone call was made to each participant between 3 and 6 weeks after receiving the intervention, and each participant was encouraged to complete the FIT kit or contact their primary care clinician, depending on the study arm in which they were enrolled.

Approximately 3 to 6 months after the intervention, investigators interviewed participants by phone to complete a 16-item

survey assessing self-reported CRCS activity and attitudes toward the pharmacy-based CRCS service. The primary study outcome was self-reported CRCS activity (i.e., whether any type of CRCS test was completed). In the FIT group, completion of FIT was corroborated with results from the lab. Survey items for the CRCS education group included whether the participant remembered receiving written information about CRCS at the pharmacy during their influenza vaccination, whether the information was considered useful, whether the participant visited their primary care clinician and discussed CRCS since enrolling in the study, and whether CRCS was scheduled or completed. Survey items for the FIT group included whether the participant remembered receiving a home stool test at the pharmacy during their influenza vaccination, if the FIT was completed and reasons why or why not, their experience with using FIT, and whether the participant had seen their primary care provider and discussed CRCS since enrolling in the study. Both groups were asked whether they thought it was a good idea and helpful for community pharmacists to educate patients about CRCS and offer a CRCS test when indicated. Last, all participants were asked the amount of money they would be willing to pay out of pocket for such a test. The interview surveys are presented in Appendix 1 (electronic version of this manuscript, available online at [www.japha.org](http://www.japha.org)).

### Data analysis

Statistical analyses were performed using SAS (version 9.2; SAS, Cary, NC). Demographic and questionnaire data obtained from the enrollment form and the interview survey were analyzed. The frequency distributions and percentages were calculated for categorical data on each of the groups (CRCS education versus FIT). Continuous variables are reported as mean  $\pm$  SD. Chi-square or Fisher's exact test for categorical data and *t* test for continuous measures were used to determine any differences between groups. Potential differences in demographic data between participants not interviewed versus those interviewed were first examined. We then compared the FIT group with the CRCS education group for the participants who completed the interview survey. A significance level of 0.05 was used for all statistical tests.

### Results

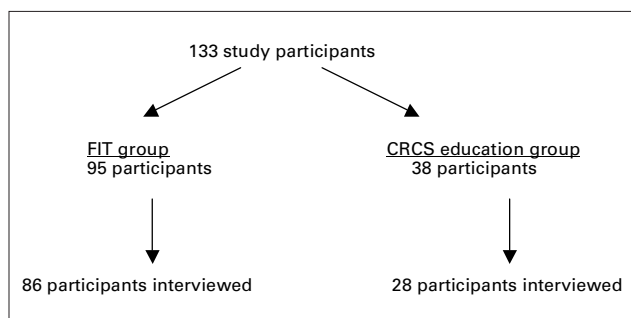
A flow diagram for study participants is presented in Figure 1. Overall, 967 individuals aged 50 to 80 years received influenza vaccines at the study locations during times when the study was being conducted. A total of 133 individuals, mostly drawn from this group but also from other pharmacy customers passing by who did not get influenza vaccines, were eligible and enrolled in the study. A total of 95 individuals were enrolled in the FIT group and 38 in the CRCS education group. Follow-up interviews were conducted with 86 (90%) of the FIT enrollees and 28 (74%) of the CRCS education enrollees. The 19 individuals who could not be reached were mostly nonwhite (14 of 19 [74%]), whereas a much smaller proportion of those interviewed identified themselves as nonwhite (33 of 114 [29%]). The FIT intervention participants were recruited on 17 dates

during which 700 influenza vaccinations were administered to patients between 50 and 80 years of age. A total of 73 FIT group participants were recruited from patients in the influenza vaccine line, with the remaining 22 FIT group participants recruited from customers passing by. A total of 28 CRCS education group participants were recruited from patients in the influenza vaccine line, with the remaining 5 CRCS education group participants recruited from customers passing by. Therefore, the FIT group included 10% of all influenza vaccination recipients aged 50 to 80 years on the dates allocated to the FIT group intervention, and the CRCS education group included 12% of all influenza vaccination recipients aged 50 to 80 years on the dates allocated to the CRCS education group.

Demographic characteristics of participants who completed the postintervention phone interviews are displayed in Table 1. Participants were mostly in their 50s and 60s, white, insured, and well educated. Most had received influenza vac-

inations in the past, but only about one-quarter had had CRCS in the past, with even fewer reporting having had a stool test for CRCS in the past. No significant demographic differences were found between the FIT group and the CRCS education group, although the overall sample sizes to make definitive comparisons are small.

Interviews were conducted  $108 \pm 26$  days after study enrollment for the FIT group and  $110 \pm 36$  days after enrollment for the CRCS education group. All participants remembered being enrolled in the study when they were contacted. Table 2 shows key comparisons between responses of participants in the CRCS education group and the FIT group. The CRCS education group was specifically asked to discuss CRCS with their "regular doctor or nurse," which was described to participants as the provider who handles their primary health care issues. By the time of the interview, 67.9% of these individuals had seen their provider, with one-half of this total cohort reporting a CRCS discussion with their primary care clinician since enrolling in the study and one-third reporting that they had scheduled or completed a CRCS test during the time between enrolling in the study and completing the interview. Only 1 of 14 participants who had not seen their provider stated that they had scheduled a test. In contrast, only 32.6% of FIT group participants reported seeing their primary care clinician, with only 19.8% having discussed CRCS with their clinician since enrolling in the study. However, 51 participants (59.3%) in the FIT group reported completing CRCS by any method by the time of their interview. Completion of FIT was independently confirmed for 52.2% of FIT group participants by receipt of results. Of results received, only one participant tested positive (abnormal) and that participant reported completing a diagnostic colonoscopy within 2 months of receiving the abnormal result from the principal investigator.



**Figure 1.** Study flow diagram for adults aged 50 to 80 years enrolled in the study  
Abbreviations used: CRCS, colorectal cancer screening; FIT, fecal immunochemical test.

**Table 1.** Demographics of study participants interviewed in the CRCS education and FIT groups

Characteristic	CRCS education <sup>a</sup> No. (%)	FIT <sup>a</sup> No. (%)	P <sup>b</sup>
n	28	86	
Age (years), mean $\pm$ SD (min, max)	61.1 $\pm$ 8.5 (49, 77)	59.2 $\pm$ 8.1 (49, 80)	0.277
Women	19 (67.9)	45 (52.3)	0.190
<b>Ethnicity</b>			
Asian	6 (21.4)	7 (8.2)	0.156
White	17 (60.7)	63 (74.1)	
Other/unknown	5 (17.9)	16 (18.6)	
<b>Education</b>			
High school or less	4 (14.3)	8 (10.0) (n = 80)	0.504
Some college or more	24 (85.7)	72 (90.0) (n = 80)	
Health insurance (yes)	24 (85.7)	82 (95.3)	0.100
Influenza vaccine on date of CRCS intervention (yes)	25 (89.3)	64 (74.4)	0.120
Any CRCS test in past (yes)	6 (21.4)	24 (27.9)	0.624
Stool test in past (yes)	3 (10.7)	17 (19.8)	0.394
Time from enrollment date to interview (days), mean $\pm$ SD (min, max)	107.8 $\pm$ 36.0 (76, 232)	110.0 $\pm$ 26.3 (66, 173) (n = 85)	0.725

Abbreviations used: CRCS, colorectal cancer screening; FIT, fecal immunochemical test.

<sup>a</sup>Items for which sample size varies as a result of missing responses are indicated.

<sup>b</sup>P values based on Fisher's exact or chi-square tests for categorical data and t tests for continuous data.

**Table 2.** Survey information from phone interviews

Questionnaire item	CRCS education <sup>a</sup> No. (%)	Intervention group <sup>a</sup> No. (%)	P <sup>b</sup>
n	28	86	
<b>Seen your regular doctor or nurse since enrolled in study and/or got influenza vaccine</b>			
Yes	19 (67.9)	28 (32.6)	0.002
No/uncertain	9 (32.1)	58 (67.4)	
<b>Discussed CRCS with provider since joined study and/or got influenza vaccine</b>			
Yes	14 (50.0)	17 (19.8)	0.003
No	14 (50.0)	69 (80.2)	
<b>Completed or scheduled a screening test since enrolled study and/or got influenza vaccine</b>			
Yes, completed	4 (14.8) (n = 27)	51 (59.3)	<0.0001
Yes, scheduled	5 (18.5) (n = 27)	0	
No	18 (66.7) (n = 27)	34 (39.5)	
<b>Think it is a good idea and helpful for community pharmacists to educate patients about CRCS when they come for influenza vaccine</b>			
Yes	24 (85.7)	81 (94.2)	0.220
No/uncertain/refused	4 (14.3)	5 (5.8)	
<b>Think it is a good idea and helpful for community pharmacists to offer patients home colon cancer screening tests when indicated</b>			
Yes	23 (82.1)	78 (90.7)	0.302
No/uncertain/refused	5 (17.9)	8 (9.3)	

Abbreviations used: CRCS, colorectal cancer screening.

<sup>a</sup>Items for which sample size varies as a result of missing responses are indicated.

<sup>b</sup>P values based on Fisher's exact or chi-square tests for categorical data and t tests for continuous data.

In the CRCS education group, 23 of 28 participants (82.1%) found the information they received to be useful, stating that it provided new information (11 of 23 [48%]) or served as a reminder to them to discuss the topic with their primary care clinician (12 of 23 [52%]). In the FIT group, 28 of the 51 individuals indicating that they completed CRCS (54.9%) stated that this was the first time they had ever completed a home CRCS test and 15 of the remaining 23 participants (65.2%) who had previous experience with home stool tests for CRCS indicated that FIT was easier to perform than previous versions of the test. Among the 35 FIT group participants who did not complete the test, only 2 of 35 (5.7%) said the reason for not completing it was that the instructions were too complicated. The most common reasons for not completing FIT were forgetting to complete the test and losing the kit, which was reported by 29% (10 of 35) and 20% (7 of 35) of these participants, respectively.

When asked to describe their perceptions regarding receiving CRCS education from pharmacists, participants in both groups were equally enthusiastic. Reasons cited for this enthusiasm by more than one-half of all participants were that pharmacies are a trustworthy and convenient source for obtaining health information, that colon cancer is a serious health issue to learn about, and that having such conversations with pharmacists would save them time with their primary care clinician. Participants were equally enthusiastic about the idea of obtaining FIT kits from pharmacies, but only 38.6% said that

they would be willing to pay \$20 or more for such tests.

## Discussion

To our knowledge, this is the first study to link the provision of CRCS screening activities to a pharmacy-based influenza vaccination program. The results indicate that pharmacy-based CRCS education can be successful in encouraging patients to discuss CRCS with their primary care clinicians but that offering FIT to patients may lead to greater increases in screening over a 3- to 6-month period than can be accomplished by education alone. The interviews with study participants indicated a high level of acceptance of pharmacy-based CRCS interventions.

The American Association of Colleges of Pharmacy has explicitly recognized the role of the pharmacist in public health in its educational policy statements, which state that pharmacists should promote "health improvement, wellness, and disease prevention."<sup>14</sup> Pharmacies are easily accessible in most communities, with increased hours of operation compared with primary care practices and drop-in services that are available to patients on a fee-for-service basis regardless of insurance status.<sup>15</sup> Participants in each arm of the study were equally interested in CRCS education and the option of getting home CRCS tests directly from their pharmacist, citing convenience and trust in pharmacists as primary reasons for their enthusiasm. In our study, the majority of participants indicated an intention to obtain influenza vaccinations at their community pharmacy

again in the future, suggesting that annual influenza vaccination clinics may provide good opportunities for pharmacists to reach a specific group of individuals with other important and personalized annual preventive health messages or interventions such as those relating to CRCS.

All 18 community pharmacies approached agreed to participate, and pharmacists at each site often helped with participant recruitment for the study. However, in this study, the intervention was delivered by researchers (usually a pharmacist or a student pharmacist), and more research is required to determine whether this intervention could be as effective when delivered outside the context of a research study by community pharmacists. In particular, more study is needed to understand the resources that U.S. pharmacies and pharmacists would require to develop and incorporate such programs into their busy clinical practices.

Reliance on patient self-report to determine screening status and eligibility for FIT was a drawback of our pharmacy-based CRCS interventions. Although concerns may exist about the ability of pharmacists to assess CRCS status without access to medical records, simple validated questions have proved reasonably accurate for identifying CRCS status.<sup>16–18</sup> As with other point-of-care tests available in pharmacies, follow-up of abnormal results may also be a concern. However, an increasing number of pharmacists communicate electronically with primary care offices regarding medications and provision of services such as influenza vaccinations, and it should be feasible for pharmacies to develop similar systems to communicate results of home CRCS tests to patients' primary care clinicians as well.

Finally, although the type of FIT used in this study is approved for sale in U.S. pharmacies, it is not currently available. Less studied and less sensitive "throw-in-the-bowl" CRCS tests are available in some U.S. community pharmacies. These tests are not endorsed by USPSTF or the researchers. However, the successful marketing of such products in some regions of the United States indicates that a market could exist for high-sensitivity home CRCS tests provided over the counter to patients in community pharmacies with adequate education and follow-up of results. To reach a large number of patients, the cost of these tests would likely have to be relatively low; most of participants in the current study indicated that they would not pay for a kit costing \$20 or more. However, Medicare currently reimburses \$22 for FIT; therefore, for example, pharmacies charging \$20 to \$35 for one of these tests could make arrangements to have all or enough of the costs of the test covered in a way that insured patients would not have to pay more than \$20 for them out of pocket. In the meantime, the cost of encouraging patients to speak with their primary care clinicians about CRCS is mostly measurable in time but appears from this pilot study to have some potential benefit in terms of encouraging patients to get screening when they need it.

### Limitations

The current study is limited mainly by its small sample size and scope. As a result of the lengthy consent process, only 1 in 10

age-eligible adults was assessed, determined to be eligible for the intervention according to study criteria, and enrolled in the study. Diversity of the participant pool was further limited by the exclusion of non-English-speaking patients and patients with no regular source of primary care. Despite completing interviews with 85.7% of enrolled participants, inability to retain a disproportionate subset of enrolled participants from ethnic minorities for the interviews may have also skewed the results. However, the study sample was recruited from 18 different sites in diverse neighborhoods and reflected a diversity of ages, ethnicities, and sociodemographic groups.

A second limitation is that the study design did not simulate usual care in the pharmacy, as community pharmacists were not responsible for providing the intervention or arranging follow-up of test results. Some patients were reluctant to talk with research team members not employed by the pharmacy. Patients may have been more accepting of the intervention if it was delivered by the pharmacist directly. More study will be needed to understand the clinical and financial incentives that could be put in place to encourage pharmacies and pharmacists to implement a program involving patient education and/or provision of FIT kits to patients in clinical practice. As in this study, this service could be coupled with influenza vaccination, with the screening questionnaire addressing both influenza vaccine and CRCS appropriateness simultaneously. Alternatively, a pharmacy computer system could be programmed to alert the pharmacist to counsel patients for whom CRCS may be indicated (e.g., age 50–75 years) at the time of prescription processing.

Finally, much of the information on screening eligibility and activity was obtained by self-report, which may not be reliable. However, among study participants contacted who discussed screening with their primary care clinician, very few reported being told by their physician or nurse that our assessment of screening eligibility was in error. In addition, the proportion of patients completing CRCS was roughly corroborated by FIT results received by the researchers from the laboratory.

### Conclusion

This pilot study demonstrated that providing home CRCS tests in the community pharmacy setting to eligible patients at the time of influenza vaccination can increase screening rates compared with providing CRCS education only. Study participants were receptive to the idea of pharmacists providing CRCS interventions consisting of CRCS education plus the provision of home CRCS tests at the time of their annual influenza vaccination activities, indicating that community pharmacies may be an ideal venue to increase access to CRCS and increase screening rates in diverse communities.

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