

# The FLU-FIT Program: An Effective Colorectal Cancer Screening Program for High Volume Flu Shot Clinics

Michael B. Potter, MD; Carol P. Somkin, PhD; Lynn M. Ackerson, PhD; Vicky Gomez, MPH;  
T. Teresa Dao, MD; Michael A. Horberg, MD; and Judith M. E. Walsh, MD, MPH

Colorectal cancer is the second leading cause of cancer death in the United States, and colorectal cancer mortality can be reduced with screening.<sup>1</sup> The American Cancer Society and US Preventive Services Task Force (USPSTF) recommend colorectal cancer screening (CRCS) for average-risk adults using high-sensitivity home fecal occult blood tests (FOBTs) such as fecal immunochemical tests (FITs), flexible sigmoidoscopy, or colonoscopy.<sup>2,3</sup> CRCS rates in the United States are gradually increasing. Among United States residents aged 50 to 75 years, the self-reported prevalence of having completed FOBT in the last year or lower endoscopy (sigmoidoscopy or colonoscopy) within the last 10 years increased from 51.9% in 2002 to 62.9% in 2008.<sup>4</sup> While these trends are encouraging, there is still much work needed to reach the American Cancer Society's goal of having 75% of Americans up-to-date with guideline-recommended screening by 2015.<sup>5</sup>

Achieving high rates of CRCS may require a variety of approaches. Some of the strongest interventions to increase CRCS include a structure for non-physician staff to interact directly with patients and offer CRCS when indicated.<sup>6</sup> One evidence-based intervention to increase CRCS rates is the FLU-FOBT (FLU indicates influenza vaccine) Program, a nurse-run program designed to allow hospital- or clinic-based nursing staff to offer FOBT to eligible patients at the time of influenza vaccination.<sup>7,8</sup> The FLU-FOBT Program was initially designed for use in safety net settings, but it may also be effective in health maintenance organizations where patients often attend influenza vaccination clinics by the thousands, and where the simpler-to-use high-sensitivity FIT has often taken the place of guaiac FOBT. In preparation for a randomized trial to test this hypothesis and to increase the potential for future dissemination and implementation of this program for diverse practice settings, the researchers developed a FLU-FIT Program for Kaiser Permanente Northern California's Santa Clara Medical Center. This is the first study to describe the development of this FLU-FIT Program and to evaluate its effectiveness in increasing screening rates for influenza vaccination clinic attendees in health maintenance organizations.

## METHODS

**Study Setting.** Kaiser Permanente Northern California (KPNC) is an integrated

**Objective:** To determine whether offering home fecal immunochemical tests (FITs) to eligible patients during a high volume influenza vaccination clinic could lead to increased colorectal cancer screening (CRCS) rates in a managed care setting.

**Study Design:** Observational study.

**Methods:** During influenza vaccination clinics in 2008, trained staff provided FITs to patients who were eligible for CRCS (FLU-FIT group) (FLU indicates influenza vaccine). Screening outcomes for this cohort of patients were compared with those of a similar group of influenza clinic attendees who were not exposed to the intervention (FLU-only group).

**Results:** Among eligible participants in the FLU-only group (N = 4653), 13.7% completed FIT within 90 days of their influenza vaccine, and in the FLU-FIT group (N = 2812), 30.3% completed FIT ( $P < .0001$ ). In the FLU-FIT group, 1447 (51.4%) were provided with a FIT kit, and 653 (45.1%) of these patients completed a FIT kit within 90 days. In multivariate analyses, FLU-FIT group participants were significantly more likely to complete FITs compared with FLU-only group participants (Odds Ratio = 2.76 [95% confidence interval, 2.45-3.11]). Overall, the CRCS rate for the FLU-only group increased from 51.5% to 56.3% (increase of 4.8 percentage points), compared with an increase from 49.2% to 63.2% (increase of 14.0 percentage points) in the FLU-FIT group ( $P < .0001$  for change difference).

**Conclusions:** The FLU-FIT Program is feasible to implement in a high volume influenza vaccination clinic conducted in a managed care setting and increases colorectal cancer screening activity among eligible influenza vaccination recipients who are reached with the intervention.

(*Am J Manag Care.* 2011;17(8):577-583)

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### Take-Away Points

- Many managed care organizations provide annual influenza vaccination clinics each autumn.
- Many influenza vaccination clinic attendees are over the age of 50 and due for colorectal cancer screening.
- Offering annual home fecal immunochemical test kits to influenza vaccination clinic attendees is a relatively simple and effective way to reach many patients who are due for colorectal cancer screening.

healthcare delivery system with over 3 million members. The study was conducted at KPNC's Santa Clara Medical Center (KPNC Santa Clara), which provides care to over 300,000 members. Each autumn, KPNC Santa Clara organizes drop-in influenza vaccination clinics in several different facility locations. These clinics, in 2008, were managed by facility nursing administrators and took place on weekends and evenings during the months of October and November. The study idea was presented by the principal investigator (MBP) to one of the co-authors (TTD), who introduced the idea to KPNC administrators, who in turn agreed to participate.

**Study Population.** The study population consisted of patients aged 50 to 80 years on the date of receiving influenza vaccination at KPNC Santa Clara's main campus location during the months of October and November in 2008, who also had neither had FIT in the current calendar year (since January 1, 2008) nor colonoscopy in the last 10 years (since January 1, 1999). January 1 was selected as the date from which to determine eligibility for screening to make it easy for clinic staff to quickly determine which patients were eligible for CRCS screening and to allow for a proactive approach to keep people up-to-date for screening who might otherwise become due by the end of the calendar year. Because recent USPSTF guidelines had recommended that patients receiving flexible sigmoidoscopy also receive periodic FIT, patients with flexible sigmoidoscopy in the last 5 years but neither FIT in the current year nor colonoscopy in the last 10 years were considered eligible for FIT.<sup>2</sup> The 50-to-80-year age group was selected as a compromise between USPSTF guidelines, which recommend age 75 as the upper limit for routine screening, and American Cancer Society Guidelines, which recommend no fixed upper age limit.<sup>2,3</sup>

**FLU-FIT Program Development and Training.** The FLU-FIT Program was pilot tested during the 2007 influenza vaccination season. The project team identified areas for improvement, including the need to: (1) provide pre-intervention staff training, including an opportunity to practice procedures before the intervention began, (2) establish eligibility for FIT with the assistance of the electronic medical record instead of reliance on self-report, and (3) provide FIT in a sequence immediately before influenza vaccinations were

offered, rather than after, in order to efficiently reach as many eligible patients as possible. These improvements were implemented for the study we conducted in the fall of 2008: a 90-minute staff training session was developed, participating medical assistants were each provided with a training manual and sample scripts for offering FIT to

patients waiting in line for their influenza vaccination, and patients aged 50 to 80 years were directed by a volunteer to a "FIT counter" where the medical assistants checked the electronic health records for eligibility for FIT before administering the influenza vaccination. Patients identified as eligible for FIT were provided with a FIT kit (the single-sample 100 ng OC-Micron test that is currently in use at all KPNC facilities). The FIT kit included multilingual written instructions (in English, Spanish, Chinese, and Vietnamese) with a pictorial demonstration of how to complete the kit, a lab slip, and an envelope for mailing the completed kit to the KPNC Regional Laboratory. Patients were also given a 1-page multilingual educational flyer explaining why annual FIT is important. Materials were written at the 8th grade reading level in English and at the 6th grade reading level in Spanish.<sup>9</sup> Chinese and Vietnamese versions were written at a similar level of simplicity. Staff recorded the medical record numbers of patients who were given FIT kits. These patients were sent a reminder postcard within 1 month of receiving their FIT kit. Results of completed tests were reported into the KPNC electronic health record and to patient primary care providers as usual or to the KP Santa Clara chief of medicine for the small number of patients without an assigned primary care provider.

Influenza vaccination clinics were run from October 12, 2008, until November 21, 2008. The FLU-FIT Program was implemented on weekday evenings and Saturdays during this time period (FLU-FIT group), and FLU-only clinics were run as usual during weekday hours, providing a comparison group (FLU-only group). A research associate (VG) was present on-site during part of most FLU-FIT dates to make observations and provide implementation support when needed.

**Data Analysis.** At the conclusion of the influenza season, medical record numbers for participants were collected and merged with other available electronic health record patient data held by KPNC to create a database including participant age, gender, race, language preference, CRCS history, and number of primary care visits in the prior year. To capture possible socioeconomic differences between the FLU-FIT and FLU-only groups, each study subject was also assigned a "neighborhood deprivation" index score and grouped into 1 of 4 quartiles, with the first quartile indicating residence in a

relatively less deprived neighborhood and the fourth quartile indicating residence in a relatively more deprived neighborhood. This score is based on 2000 US Census data including income, poverty, employment, education, and occupation by neighborhood.<sup>10</sup> The index has a mean of 0 and a standard deviation of 1, with scores below 0 indicating residence in a neighborhood with less social deprivation and scores above 0 indicating greater social deprivation. Baseline characteristics of the FLU-FIT and FLU-only groups were compared, using 2-sample *t*-tests for continuous variables and Pearson  $\chi^2$  tests for categorical variables.

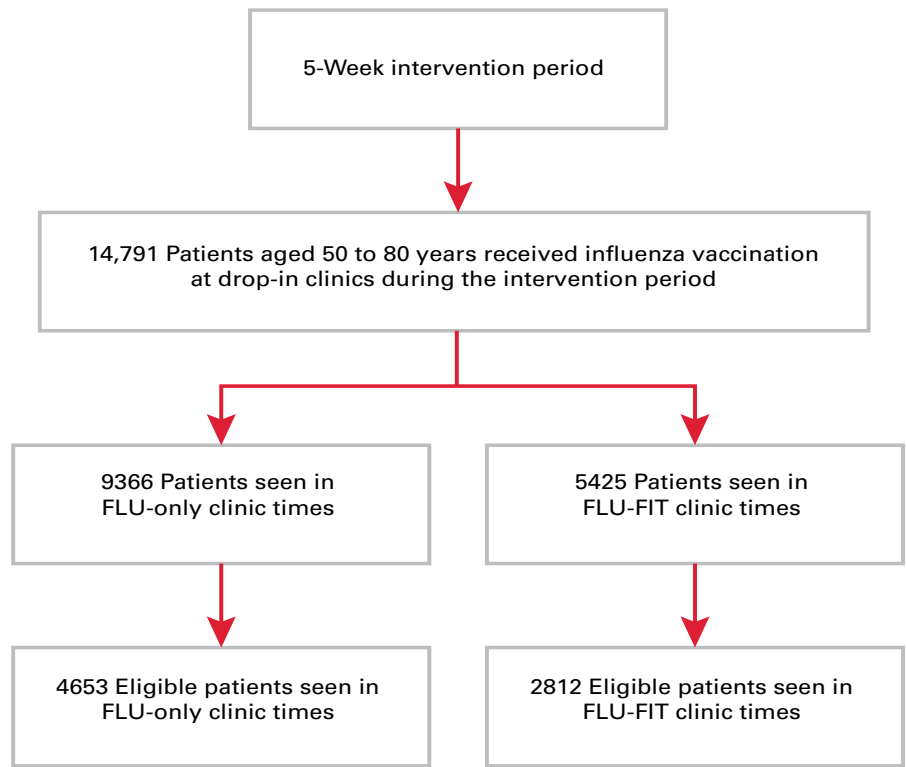
The primary outcome of this study was completion of FIT among eligible influenza vaccination clinic attendees. To estimate the impact of the FLU-FIT Program on CRCS rates for all influenza vaccination clinic participants between the ages of 50 and 80 years, we used a generalized estimating equation model to compare differences in CRCS rates from time of vaccination to 90 days later for the FLU-FIT and FLU-only groups among all influenza vaccination recipients. For this analysis, we defined up-to-date as having FIT within the 365 days prior or colonoscopy within the 10 years prior to the date on which screening status was assessed. We calculated *P* values for baseline differences in CRCS rates between groups for patients at the time of receiving their influenza vaccine, at a time 90 days after getting their influenza vaccination, and for the change difference observed in CRCS rates for each group during this 3 month time period.

Finally we examined the subgroup of influenza vaccination clinic attendees in the FLU-FIT and FLU-only cohorts who were eligible for FIT at the time of influenza vaccination to determine the relative benefit of the FLU-FIT Program compared with usual care in which FLU clinic participants receive FLU only. The proportions of eligible influenza vaccination clinic attendees in each group who completed CRCS within 90 days of their shot were compared using  $\chi^2$  tests. Using the data from patients who were not up-to-date with their CRCS at the time of their shot, we constructed a multivariate

logistic regression model incorporating demographic variables that could be confounders of the relationship between study group and FIT completion in less than 90 days after vaccination. These variables were age, gender, race, language preference, neighborhood deprivation index, and number of primary care visits in the prior year. Multiple imputation methods were used to handle the missing values of race, language preference, and neighborhood deprivation index score.

All data analyses were conducted using SAS version 9.2 software (SAS Institute, Cary, North Carolina). The study was approved by the KPNC Institutional Review Board and the UCSF Committee on Human Research, with a waiver of informed consent.

■ **Figure.** Study Flow Diagram



FIT indicates fecal immunochemical test; FLU, influenza vaccination.

## RESULTS

**Study Enrollment.** The **Figure** provides an overview of study enrollment. A total of 5425 patients aged 50 to 80 years received influenza vaccinations during FLU-FIT Program hours. Of these, 2812 (51.8%) were eligible to receive FIT according to study criteria. A total of 9366 patients aged 50 to 80 years received influenza vaccinations during FLU-

■ **Table 1.** Demographics and Clinical Characteristics by Group Among Those Who Were Eligible for FIT at Time of Influenza Vaccination

Variable	FLU-only group (n = 4653)	FLU-FIT group (n = 2812)	P
<b>Age (years)</b>			<.0001
Mean (SD)	64.1 (8.5)	62.2 (8.1)	
<b>Gender</b>			.09
Male, No. (%)	2039 (43.8%)	1288 (45.8%)	
<b>Race, No. (%)</b>			<.0001
Asian	840 (21.0%)	566 (24.9%)	
Black	94 (2.4%)	36 (1.6%)	
Hispanic	588 (14.7%)	257 (11.3%)	
White	2417 (60.5%)	1389 (61.0%)	
Other	58 (1.5%)	28 (1.2%)	
[Missing]	[656]	[536]	
<b>Language preference English, No. (%)</b>	4103 (89.7%)	2468 (89.4%)	.66
[Missing]	[78]	[50]	
<b>Neighborhood deprivation index score,<sup>a</sup> No. (%)</b>			.15
1st quartile	999 (22.9%)	607 (22.7%)	
2nd quartile	1069 (24.5%)	720 (26.9%)	
3rd quartile	1094 (25.1%)	652 (24.4%)	
4th quartile	1202 (27.5%)	699 (26.1%)	
[Missing]	[289]	[134]	
<b>Number of primary care visits in the prior year, No. (%)</b>			<.0001
0	889 (19.1%)	661 (23.5%)	
1	1134 (24.4%)	766 (27.2%)	
2-3	1453 (31.2%)	867 (30.8%)	
4-11	1035 (22.2%)	473 (16.8%)	
>11	142 (3.1%)	45 (1.6%)	

FIT indicates fecal immunochemical test; FLU, influenza vaccine.

<sup>a</sup>The quartiles for neighborhood deprivation index scores are arranged such that participants in the 1st quartile lived in relatively more deprived neighborhoods, whereas those in the 4th quartile lived in relatively less deprived neighborhoods.

only hours. Of these, 4653 (49.7%) were eligible to receive FIT according to study criteria. None of the patients in the FLU-only group were offered FIT during influenza vaccination clinic visits, but some may have received FIT kits on the day of influenza vaccination if they also had a primary care visit on that date. In addition, participants in either arm of the study may have had other opportunities to receive FIT before, during, or after the intervention as a result of other clinic visits or other outreach programs at KPNC Santa Clara.

**Demographics.** Characteristics of study participants who were eligible for FIT at the time of their influenza vaccination are shown in **Table 1**. The FLU-FIT and FLU-only groups were demographically similar. Compared with the FLU-only group, the FLU-FIT group was younger and had a higher proportion of men. The FLU-FIT group also had a greater proportion of Asian Americans and Whites, and a smaller proportion of Latinos and African Americans compared with the FLU-only group. The mean neighborhood deprivation index score for the population was -0.6 (standard deviation = 0.5), indicating that both groups resided in relatively affluent neighborhoods. Participants in each group were evenly

distributed within the 4 quartiles for this variable. The FLU-FIT group included a larger proportion of patients with 1 or fewer primary care visits in the last year compared with the FLU-only group.

**FIT Completion Rates in the FLU-FIT and FLU-Only Groups.** **Table 2** displays the number and proportion of eligible participants in each group that completed CRCS within 3 months of influenza vaccination. While 13.7% in the FLU-only group completed FIT, 30.3% in the FLU-FIT group completed FIT ( $P < .0001$ ), representing a 16.6 percentage point differential. This differential was similar when looking at any type of CRCS activity that took place within each group during this time period. Utilization of flexible sigmoidoscopy and colonoscopy was very low in both groups. After 6 months, the absolute differences between groups remained significant, with 37.5% of the FLU-only group having completed FIT, and 52.1% of the FLU-FIT group having completed FIT ( $P < .0001$ ), representing a 14.8 percentage point differential.

Within the FLU-FIT group, which included 2812 participants eligible for FIT, a total of 1447 (51.4%) were provid-

**Table 2.** Colorectal Cancer Screening Tests Completed by CRCS-Eligible Patients Within 90 Days of Receiving Influenza Vaccination

Variable	Eligible FLU-only group (n = 4653)	Eligible FLU-FIT group (n = 2812)	P
Completed FIT, No. (%)	635 (13.7%)	853 (30.3%)	<.0001
Completed sigmoidoscopy, No. (%)	71 (1.5%)	26 (0.9%)	.026
Completed colonoscopy, No. (%)	56 (1.2%)	32 (1.1%)	.80
Completed FIT or colonoscopy, No. (%)	670 (14.4%)	867 (30.8%)	<.0001
Completed FIT, flexible sigmoidoscopy, or colonoscopy, No. (%)	718 (15.4%)	884 (31.4%)	<.0001

CRCS indicates colorectal cancer screening test; FIT, fecal immunochemical test; FLU, influenza vaccine.  
Eligible patients = no FIT since January 1, 2008, and no colonoscopy since January 1, 1999. Patients were considered eligible for FIT if the only CRCS test they had in the past was flexible sigmoidoscopy.

**Table 3.** Change in CRCS Rates for All Influenza Vaccination Clinic Attendees

Variable	FLU-only group (n = 9366)	FLU-FIT group (n = 5425)	P
CRCS up-to-date <sup>a</sup> at time of shot, % (No.)	51.5% (4826)	49.2% (2668)	.0059
CRCS up-to-date 90 days after shot, % (No.)	56.3% (5270)	63.2% (3431)	<.0001
Percentage point change	4.8%	14.0%	<.0001

CRCS indicates colorectal cancer screening; FIT, fecal immunochemical test; FLU, influenza vaccine.  
<sup>a</sup>CRCS up-to-date defined as FIT in last 12 months or colonoscopy in last 10 years.

ed with a FIT kit and mailed a reminder postcard within 1 month. Of these participants, 653 (45.1%) completed a FIT kit within 90 days. Of the remaining 1365 participants in the FLU-FIT group who were not provided with a FIT kit with their influenza vaccination, 200 (14.7%) completed a FIT kit within 90 days.

**Change in CRCS Rates Among All FLU Clinic Participants.** To better understand the impact of the intervention on overall CRCS rates for patients aged 50 to 80 years who attended the influenza vaccination clinics, we used a generalized estimating equation model to calculate pre-post changes in CRCS rates in the FLU-FIT and FLU-only groups. These results are presented in **Table 3**. In the FLU-only group, the CRCS rate increased by 4.8 percentage points, from 51.5% to 56.3%, within 90 days of getting vaccinated. In the FLU-FIT group, the CRCS rate increased by 14.0 percentage points, from 49.2% to 63.2%, within 90 days of getting vaccinated. This change difference between the 2 groups was statistically significant ( $P < .0001$ ).

**Multivariate Logistic Regression Analysis of Predictors for FIT Completion by Eligible Patients Within 90 Days of Influenza Vaccination.** Unadjusted and adjusted models for completion of FIT by the target population of eligible patients in the FLU-FIT and FLU-only groups are displayed in **Table 4**. The unadjusted and adjusted models showed nearly identical odds ratios and confidence intervals, suggesting little or no influence of possible confounding variables on the comparison of outcomes in the FLU-FIT and FLU-only groups.

The adjusted odds ratio for completion of FIT in the FLU-FIT group was 2.76 (95% confidence interval, 2.45-3.11). The only other independent predictor of FIT completion within 90 days of getting an influenza vaccination in the unadjusted and adjusted models was female gender.

## DISCUSSION

This is the first evaluation of the FLU-FIT Program in an integrated managed care setting serving an ethnically diverse, insured patient population. More than half of the target population in the FLU-FIT group was provided with a FIT kit and sent a reminder postcard. Of patients in the FLU-FIT group who were provided with a FIT kit, nearly half completed a FIT kit within 90 days of their influenza vaccination. A greater increase in CRCS rates occurred in the FLU-FIT study arm than in the FLU-only arm. In multivariate analyses, the eligible patients in the FLU-FIT group (regardless of whether or not they were actually given a FIT kit) were 2.76 times more likely than the FLU-only group to complete FIT within 90 days of their influenza vaccination.

In a recent systematic review, several strategies to enhance the use of CRCS were identified.<sup>6</sup> Patient level interventions that eliminate structural barriers, that include one-to-one interactions between clinic staff and patients, and that include patient reminders were deemed highly effective, as were interventions that promote changes in the system of care.<sup>11-16</sup> The FLU-FIT Program as implemented at KPNC incorporates

**Table 4.** Multivariate Analysis of Predictors for Completing FIT Within 90 Days of Influenza Vaccination Among Patients Due for CRCS at Time of Vaccination

Variable	Unadjusted OR (95% CI) (n = 7465)	Adjusted OR (95% CI) (n = 7465)
<b>Treatment group</b>		
FLU-FIT group	2.76 (2.45, 3.09)	2.76 (2.45, 3.11)
FLU-only group	Reference	Reference
<b>Age (per year)</b>		
	0.996 (0.99, 1.003)	1.00 (0.99, 1.01)
<b>Gender</b>		
Female	1.19 (1.06, 1.33)	1.18 (1.05, 1.32)
Male	Reference	Reference
<b>Race</b>		
Asian	1.15 (0.99, 1.32)	1.07 (0.91, 1.26)
Hispanic	0.93 (0.76, 1.14)	0.99 (0.79, 1.25)
Other	1.01 (0.73, 1.41)	1.12 (0.80, 1.56)
White	Reference	Reference
<b>Language preference</b>		
Non-English	0.87 (0.73, 1.05)	0.88 (0.71, 1.08)
English	Reference	Reference
<b>Neighborhood Deprivation Index Score</b>		
1st quartile	1.11 (0.94, 1.30)	1.12 (0.94, 1.33)
2nd quartile	1.10 (0.94, 1.29)	1.09 (0.92, 1.28)
3rd quartile	1.08 (0.92, 1.27)	1.10 (0.93, 1.30)
4th quartile	Reference	Reference
<b>Number of primary care visits in the previous year</b>		
0	1.04 (0.91, 1.19)	1.17 (0.76, 1.81)
1	1.12 (0.99, 1.28)	1.30 (0.84, 2.00)
2-3	1.12 (1.00, 1.27)	1.34 (0.87, 2.06)
4-11	1.04 (0.91, 1.19)	1.33 (0.86, 2.06)
>11	Reference	Reference

CI indicates confidence interval; CRCS, colorectal cancer screening; FIT, fecal immunochemical test; FLU, influenza vaccine; OR, odds ratio.

many of these elements, which may account for the level of success achieved.

Only half of the eligible patients in the FLU-FIT group were provided with a FIT kit, suggesting opportunities to improve the implementation process adopted for the intervention. Very few patients declined to accept a FIT kit when offered by a medical assistant, and we observed only infrequent staff errors in the use of our algorithm for ascertainment of patient eligibility for FIT. However, the FIT counter was located several feet from the main influenza vaccination line, and volunteers were instructed to direct patients aged 50 to 80 years to the FIT counter for assessment of eligibility for FIT before their influenza vaccination. We believe that most patients missed by the intervention were not successfully directed to the FIT counter on the way to getting their influenza vaccinations. Addressing issues such as these in future itera-

tions of the FLU-FIT Program could substantially increase its reach and effectiveness.

This study tests just 1 of several possible strategies for increasing CRCS in an integrated managed care setting with several other CRCS outreach mechanisms already in place. At KPNC Santa Clara in 2008, most eligible patients received FIT kits during primary care office visits or were mailed FIT kits by the KPNC regional laboratory when they were overdue for screening. The fact that the FLU-FIT Program was effective at increasing screening activity for many participants in a short period of time demonstrates that it can add value to CRCS activities that are designed to maximize screening rates by the end of each calendar year. The positive impact of the FLU-FIT Program could still be observed 6 months after the intervention was completed, confirming the value of the FLU-FIT Program as an addition to a comprehensive, year-



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round, multilevel CRCS strategy in an integrated healthcare setting such as Kaiser Permanente.

A limitation of this study is that, for practical reasons, patients were not randomly assigned to the FLU-FIT and FLU-only groups. However, baseline characteristics of the 2 study groups were generally similar, and our multivariate analysis controlled for known baseline differences between groups that could have influenced outcomes. A second possible limitation of the study is the population-based approach. The simple algorithm used to identify eligible patients could lead to some individuals with comorbidities or limited life expectancy being offered FIT when they have little chance to benefit, or to patients with higher-than-average risk being offered FIT when in fact they should be offered colonoscopy instead. However, FIT is inexpensive, non-invasive, and presents little if any risk to patients. Physicians receiving the test results have the opportunity to assess the results and need for additional evaluation on a case-by-case basis. In settings with many unscreened average-risk patients, the benefits of this population-based approach are likely to outweigh the harms. Finally, the results obtained at KPNC Santa Clara may be difficult to generalize to other sites with different patient populations, baseline CRCS screening rates, or systems of organizing and implementing influenza vaccination clinics. A multisite randomized trial incorporating lessons learned from this study is currently under way.

In summary, the FLU-FIT Program is an effective intervention and deserves to be considered in managed care settings that rely on annual FIT as an option for CRCS. Even in settings that already have established effective CRCS programs, the FLU-FIT Program may find its place as an additional effective strategy to boost screening rates further. As the medical assistants who participated in this research were trained to tell patients, the FLU-FIT Program provides the important and reinforcing message to patients that “Just like a flu shot, you also need to get FIT every year.”

### Acknowledgments

The authors gratefully acknowledge the support of Kaiser Permanente clinical leaders, managers, and information technology and data analysis staff in the implementation of this study. These individuals include Bernadette Loftus, MD, Sheryl Sun, MD, Joanna Ready, MD, Deidra Staten, MS, RN, Sharon Brill, RN, Long Thai, MBA, Ben Nguyen, BA, Lisa Brill, MPH, MPP, Theodore R. Levin, MD, and Joan Schwalbe, MS.

**Author Affiliations:** From Department of Family and Community Medicine (MBP), University of California San Francisco School of Medicine; Kaiser Permanente Division of Research (CPS, LMA, VG), Oakland, CA; Kaiser Permanente Northern California (TTD), Santa Clara Medical Center; Mid-Atlantic Permanente Medical Group (MAH), Rockville, MD; Division of General Internal Medicine (JMEW), University of California San Francisco School of Medicine.

**Funding Source:** This project was supported with pilot funds from the HMO Cancer Research Network (Grant #5 U19 CA079689-10) and with a Research Scholar's Grant from the American Cancer Society (Grant #RSGPB-09-010).

**Author Disclosures:** The authors (MBP, CPS, LMA, VG, TTD, MAH, JMEW) report no relationship or financial interest with any entity that would pose a conflict of interest with the subject matter of this article.

**Authorship Information:** Concept and design (MBP, CPS, LMA, TTD, MAH, JMEW); acquisition of data (MBP, CPS, TTD); analysis and interpretation of data (MBP, CPS, LMA, MAH, JMEW); drafting of the manuscript (MBP, CPS, LMA); critical revision of the manuscript for important intellectual content (MBP, CPS, LMA, MAH, JMEW); statistical analysis (MBP, LMA); provision of study materials or patients (MBP, CPS); obtaining funding (MBP, MAH); administrative, technical, or logistic support (MBP, VG, TTD); and supervision (MBP, CPS).

**Address correspondence to:** Michael B. Potter, MD, Department of Family and Community Medicine, University of California San Francisco, 500 Parnassus Ave, MU3E-329, Box 0900, San Francisco, CA 94143. E-mail: pot-term@fcm.ucsf.edu.

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