The Effectiveness of the FLU–FOBT Program in Primary Care
A Randomized Trial

Michael B. Potter, MD, Judith M. E. Walsh, MD, MPH, Tina M. Yu, Ginny Gildengorin, PhD, Lawrence W. Green, DrPH, Stephen J. McPhee, MD

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Background: The FLU–FOBT Program is an intervention in which nurses provide home fecal occult blood tests (FOBTs) to eligible patients during annual influenza vaccination (FLU) campaigns. The effectiveness of the FLU–FOBT Program when implemented during primary care visits has not been extensively studied.

Purpose: The effectiveness of the FLU–FOBT Program was tested as adapted for use during primary care visits in community clinics serving multiethnic patients with low baseline colorectal cancer (CRC) screening rates.

Design: Randomized clinical trial. During intervention weeks, nurses routinely initiated the offering of FOBT to eligible patients who were given FLU (FLU–FOBT group). During control weeks, nurses provided FOBT with FLU only when ordered by the primary care clinician during usual care (FLU-only group).

Setting/participants: The study was conducted in six community clinics in San Francisco. Participants were patients aged 50–75 years who received FLU during primary care visits during an 18-week intervention beginning on September 28, 2009.

Main outcome measures: The primary outcome was the change in CRC screening rates in the FLU–FOBT group compared to the FLU-only group at the end of the study period, on March 30, 2010. Multivariate logistic regression analysis was used to determine predictors of becoming up-to-date with CRC screening.

Results: Data were analyzed in 2010. A total of 695 participants received FLU on FLU–FOBT dates, and 677 received FLU on FLU-only dates. The CRC screening rate increased from 32.5% to 45.5% (+13.0 percentage points) in the FLU–FOBT group, and from 31.3% to 35.6% (+4.3 percentage points) in the FLU-only group ($p=0.018$ for change difference). For those due for CRC screening, the OR for completing CRC screening by the end of the measurement period was 2.22 (95% CI=1.24, 3.95) for the FLU–FOBT group compared to the FLU-only group.

Conclusions: FLU–FOBT Program participants were twice as likely to complete CRC screening as those receiving usual care. The FLU–FOBT Program is a practical strategy to increase CRC screening in community clinics.

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From the Department of Family and Community Medicine (Potter, Yu, Gildengorin), Division of General Internal Medicine, Department of Medicine (Walsh, McPhee), Helen Diller Comprehensive Cancer Center and Department of Epidemiology and Biostatistics (Green), University of California San Francisco School of Medicine, San Francisco, California

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

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Background

Colorectal cancer is the second-leading cause of cancer death in the U.S., and colorectal cancer mortality can be reduced with screening.[1] The U.S. Preventive Services Task Force (USPSTF) recommends colorectal cancer (CRC) screening for average-risk adults aged 50–75 years using home fecal occult blood tests (FOBT) every year, flexible sigmoidoscopy every 5 years with interval FOBT, or colonoscopy every 10 years.[2,3]

Screening rates for CRC in the U.S. are gradually increasing, but disparities in CRC screening rates persist among socioeconomically disadvantaged populations.[4,5] In primary care sites serving these patients, the menu of CRC screening options is often limited to FOBT, a test that must be repeated yearly.[6] Relying on an annual home test to achieve high CRC screening rates may be particularly challenging in clinical settings with limited staff and resources for patient outreach by telephone or mail and where even standing orders to carry out multiple tasks at every office visit can be challenging to implement. Successful and sustainable approaches to achieve high rates of FOBT in these settings may require multiple strategies, including systems that enable members of the healthcare team to share in the responsibility for providing FOBT using time-efficient methods.[7–9]

One potentially efficient opportunity to involve clinic nursing staff in providing FOBT while limiting the potential interference with other high-priority activities that must be performed at every office visit is at the time of annual influenza vaccinations (FLU). Offering FOBT with FLU in a "FLU–FOBT Program" has been shown to be effective as a stand-alone intervention delivered by nonphysicians apart from routine primary care visits.[10,11] Adapting the FLU–FOBT Program for implementation during routine primary care visits has the potential to reach many more patients,[12,13] but it also may be challenging because of competing clinical demands and other logistic constraints.[14] The current study, conducted in six community clinics in San Francisco, evaluated the effectiveness of the FLU–FOBT Program when integrated with primary care visits in resource-limited settings relying on FOBT as the primary method of CRC screening.

Methods

Theoretic Framework

The General Model of the Determinants of Behavioral Change is a synthesis of behavioral theories and asserts that the performance of a desired health behavior is influenced most by a person's attitudes toward the behavior in question; perceived norms relating to the behavior; self-efficacy, skills, and abilities related to performing the behavior; and other environmental conditions, such as time-efficient systems of care to support, simplify, and reinforce the desired behavior.[15] The FLU–FOBT intervention was designed to address these issues by creating an annual opportunity and structure for busy nursing staff to focus on FOBT, with a clear message to patients that "just like a flu shot, you need FOBT every year."

Study Setting

The San Francisco Department of Public Health operates nine community-based adult primary care clinics. One of these nine sites participated in a pilot study of the intervention,[12] and the remaining eight were invited to participate in this clinical trial. Six of these eight sites chose to participate; one site declined to participate because of clinic leadership transitions and another because of other competing quality improvement activities. The six participating clinics vary in size and patient mix, with one clinic serving marginally housed adults aged >55 years, one clinic serving homeless patients, one serving primarily Latinos, one serving primarily African Americans, and two serving multiethnic neighborhoods. Each autumn, these six clinics provide FLU to eligible patients during primary care visits, often with standing orders (nurses providing FLU proactively without waiting for a doctor's order). Preventive services, including CRC screening, may also be offered during primary care visits. In participating clinics at the start of the study, CRC screening typically was offered only if the physician ordered it. In addition, the only available CRC screening test for average-risk patients was FOBT; colonoscopy was not an option for average-risk individuals. The FOBT used in these clinic sites is Hemoccult II (Beckman Coulter), a guaiac FOBT used in many resource-limited settings where it is challenging to obtain reimbursement for more sensitive and slightly more expensive immunochemical FOBTs. Hemoccult II requires patients to collect two stool samples from each of three separate bowel movements at home after dietary and medication restrictions have been implemented for 2–7 days. Before the study began, the role of nurses in facilitating CRC screening generally was limited to providing patients with FOBT kits when ordered by primary care clinicians on a case-by-case basis.

Study Population

The study population included patients aged 50–75 years as of the beginning of the intervention (September 28, 2009) who received FLU during any primary care visit that took place at any of the six participating sites during the 18-week study period. Patients aged 50–75 years were selected as participants because the USPSTF recommends CRC screening testing for average-risk adults in this age group.[2]

Study Design

Using 1-week blocks, each site was assigned randomly to groups in which nursing staff would perform the FLU–FOBT intervention protocol or in which they would provide the FLU-only protocol. The blocks were arranged so that three clinics performed the FLU–FOBT protocol and three clinics performed the FLU-only protocol on any given week, thereby balancing exposure to the intervention and control arms over the 18-week study period. During FLU–FOBT weeks, the nurses were given standing orders to provide FLU to patients aged 50–75 years during primary care visits, and, for patients given FLU, also to provide FOBT if due. To simplify the process of determining who was eligible for screening, nurses were

asked to consider patients due for FOBT if they had had no FOBT since the beginning of 2009 and no colonoscopy since January 1, 2000. Nurses were instructed to determine dates of CRC screening tests by consulting either electronic or paper-based medical records. During FLU-only weeks, nurses had standing orders to provide FLU to patients aged 50–75 years but were instructed to provide FOBT to patients only if ordered to do so by the patient's primary care clinician as part of usual care. The nursing staff was informed at the end of each week whether the following week would be a FLU–FOBT week or a FLU-only week.

Intervention Preparation, Training, and Implementation

The medical director of each clinic provided standing orders to nurses (including licensed vocational nurses and medical assistants) to provide FLU to primary care patients between the ages of 50 and 75 years during all dates of the study. Before the study began, the research team provided a 1-hour training session for nursing staff. During the week before the beginning of FLU season, one research assistant visited each site to observe baseline clinic processes and patient flow and to review study procedures individually with each nurse. During the study period, three research assistants made frequent visits to each of the six study sites to ensure that clinic nurses were aware of that week's study procedures and to make observations of the implementation process. Research assistants were available on a daily basis to answer nurse questions regarding study implementation.

The study was designed to determine the effectiveness of the intervention under circumstances simulating real-world conditions. For example, nursing staff could decline to offer FOBT during FLU–FOBT days if they judged a patient to be too ill to accept it or if the clinic was too short staffed or if they were too burdened with other orders to allow time for this intervention. The nurses at each clinic were provided a variety of tools to assist with the offering of FOBT to eligible patients during FLU–FOBT days, including a FLU–FOBT Log Sheet to remind them to check FOBT eligibility at the time of FLU, visual aids for explaining FOBT to patients (including a diversity of common ethnic foods to avoid to prevent false positive results), simple multilingual written instructions, video instructions, and stamped envelopes for completing and returning the FOBT kits to the laboratory. These materials were provided in English, Cantonese, Mandarin, Russian, Spanish, and Vietnamese. Nurses were encouraged to use whichever materials they found most useful to encourage patients to complete FOBT.

In 2009, there were intermittent FLU shortages, and some clinics decided to ration FLU during days when supplies were limited. In these situations, the nurses were instructed to continue providing FOBT to patients for whom FLU was provided, according to the study protocol. Also in 2009, there was an H1N1 influenza epidemic, and each clinic provided a limited number of H1N1 vaccines to patients, in addition to FLU, the seasonal influenza vaccination. To adhere to the original study design, H1N1 vaccination in the clinics was not a trigger for nurses to provide FOBT to patients during the FLU–FOBT weeks of the study.

Data Analysis

All data analyses were conducted in 2010. A de-identified database was created from electronic medical records and patient registration data, including records of participants aged 50–75 years who had a primary care visit and FLU shot during the study period. Data elements for each participant in the database included age; gender; ethnicity; primary language; insurance status; annual income; number of primary care, emergency care, and hospital visits; and dates of FLU, CRC screening tests (FOBT, flexible sigmoidoscopy, and colonoscopy), and other cancer screening (mammograms and prostate-specific antigen [PSA] tests) commonly recommended in this age group. The FLU–FOBT intervention group was defined as those who had a primary care visit and FLU on a FLU–FOBT date, and the FLU-only comparison group was defined as those who had a primary care visit and FLU during a FLU-only week.

Data analyses were conducted using SAS, version 9.2. Baseline characteristics of the FLU–FOBT and FLU-only groups were compared, using two-sample *t*-tests for continuous variables and Pearson chi-square tests for categoric variables. Next, the effect of the intervention was evaluated by comparing changes in FOBT status (defined as FOBT within the past 12 months) and CRC screening status (defined as having had FOBT, flexible sigmoidoscopy, or colonoscopy within the recommended time interval) between the two groups during the study period, defined as the period of time beginning on September 28, 2009 (the first date of the intervention), and ending on March 30, 2010 (2 months after the completion of the 18-week intervention). The end date for the study period was selected to allow sufficient time for participants to complete screening tests provided during the intervention. Within each participant group, McNemar's chi-square test was used to compare pre-intervention to post-intervention percentage point changes in FOBT and CRC screening status. A linear model was used to compare differences between the FLU–FOBT and FLU-only groups in the pre–post percentage changes. At each of these two time points, differences in FOBT and CRC screening status between the FLU–FOBT and FLU-only groups were assessed using the Pearson chi-square test.

Using pre-selected variables associated with CRC screening completion in prior studies of the FLU–FOBT Program and in general,[10,12] an exploration was made of predictors of eligible participants completing FOBT and CRC screening during the study period. A logistic regression model was built for each outcome excluding patients up-to-date with CRC screening at the start of the study. Retained covariates were intervention group (FLU–FOBT group versus FLU-only group); age; gender; ethnicity; primary language (non-English versus English); insurance status (Medicare or Medicaid vs other programs for the uninsured); income (above versus below the median); primary care visits in the prior year (above versus below median number); hospital visits in the prior 2 years (none versus ≥1); emergency department visits in the prior 2 years (none versus ≥1); mammography in the prior 2 years for women (no test versus ≥1 test); or PSA testing in the prior year for men (no test versus ≥1 test). Adjustments were made for the potential presence of a clinic site as a fixed effect in the models. The significance level was set at $p \leq 0.05$ for all tests.

Clinic agreements, institutional review board approval, and clinical trial registration. In return for participation in this research, each site was promised a $5000 honorarium for participation in the study that was not dependent on successful study implementation or results achieved. The study was approved by the San Francisco Department of Public Health Protocol Review Committee and the University of California, San Francisco, Committee on Human Research, with a waiver of informed consent. This study is registered on www.clinicaltrials.gov (NCT01211379).

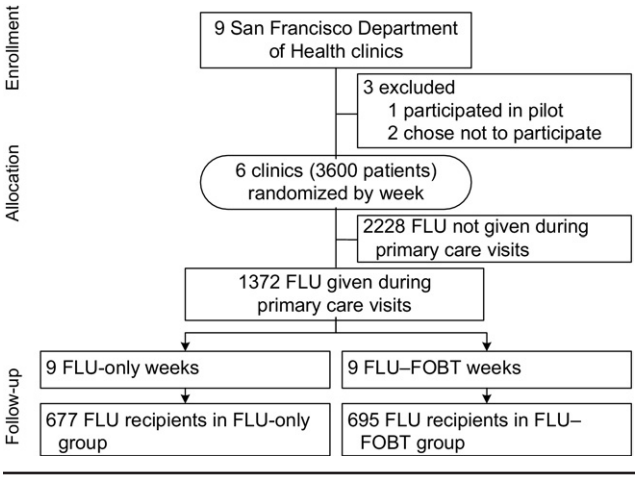

Figure 1. Study flow diagram
FLU, influenza vaccination; FOBT, fecal occult blood test

Results

Study Enrollment

Figure 1 provides an overview of the study. The intervention began on September 28, 2009, and continued for 18 weeks. Each clinic was assigned randomly to have 9 FLU–FOBT weeks and 9 FLU-only weeks, distributed throughout the FLU season, with a different pattern of randomization for each clinic. A total of 3600 patients aged 50–75 years came in for at least one primary care visit during the 18-week study period. Of these, 1372 patients were documented in the electronic medical record as having FLU during one of these primary care visits. A total of 695 of these patients came in for primary care on a FLU–FOBT date, and the remaining 677 came in for primary care on a FLU-only date. Patients in each group had an average of about two primary care visits during the 18-week study period.

Demographics

Characteristics of study participants are shown in Table 1. There were no significant demographic differences measured between participants in the FLU-only and FLU–FOBT groups. The study population was ethnically diverse, with African Americans representing more than one third of participants, and substantial representation of Latinos, non-Latino whites, and Asian Americans. Slightly more than half of the study cohort was male and most identified English as their primary language. According to the electronic database used to establish eligibility for care in these clinics, nearly all patients had an annual reported income well below $20,000, and health insurance coverage for these patients was divided relatively evenly among Medicare, Medicaid, and other city-sponsored programs for the uninsured, all of which cover the costs of FLU and FOBT for patients. Patients were frequent clinic visitors, with a mean of more than eight clinic visits in the year prior to the study. In addition, more than a quarter of patients had an emergency department visit in the past 2 years, and more than one in seven had been hospitalized during that time. Despite all of this clinical care, less than one third had completed a CRC screening test and only about one in five participants had completed FOBT within recommended time intervals at the beginning of the study. Only a little more than half of women in the cohort had completed a mammogram in the past 2 years, and only about one in ten of the men had received a prostate-specific antigen test in the prior year. Even though there were interruptions of FLU supply during the time of the study, a similar number of patients were enrolled in each study arm at each clinic, with the exception of one site where there were somewhat more participants in the FLU–FOBT arm than in the FLU arm.

Fecal Occult Blood Test Completion Rates

Table 2 displays the changes in completion rates for FOBT in the two study arms. FOBT completion rates increased in both study groups during the study period. In the FLU–FOBT group, the proportion of patients with FOBT in the past 12 months increased from 21.4% to 33.8%, and in the FLU-only group from 17.6% to 21.7%. This represents a 12.4–percentage point increase in the FLU-only group versus a 4.1–percentage point increase in the FLU–FOBT group ($p=0.010$ for change difference). A total of 21.6% of the FLU–FOBT group completed FOBT during the study measurement period, versus 11.8% of the FLU-only group.

Colorectal Cancer Screening Completion Rates

Table 3 displays the overall change in completion rates for any CRC screening test within the two groups. CRC screening rates increased in both study groups during the study measurement period. In the FLU–FOBT group, the proportion of patients with any CRC screening test in the past 12 months increased from 32.3% to 45.5%, and in the FLU-only group from 31.3% to 35.6%. This represents a 13.0–percentage point increase in the FLU–FOBT group versus a 4.3–percentage point increase in the FLU-only group (p value 0.018 for change difference). As can be seen by comparing Table 2 and Table 3, nearly all of the increase in CRC screening that took place during the study can be attributed to increased completion of FOBT.

Multivariate Logistic Regression Analysis for Patients Eligible for Colorectal Cancer Screening Completing Fecal Occult Blood Test and Colorectal Cancer Screening

Table 4 displays the multivariate model showing predictors of the subset of patients who were due for CRC

Table 1. Demographic characteristics of patients aged 50–75 years in the FLU-only and FLU–FOBT study arms, % unless otherwise indicated

Characteristics	FLU-only (*n*=677)	FLU–FOBT (*n*=695)	*p*-value
DEMOGRAPHICS			
Age (years; M [SD])	60.1 (6.6)	59.9 (6.4)	0.594[a]
Male	53.4	56.3	0.303[b]
Ethnicity			
African-American	36.5	37.7	0.845[b]
Asian-American	10.6	11.5	
Latino	21.1	19.7	
Non-Latino white	30.1	28.9	
Other	1.6	2.2	
Language			
English	80.7	83.3	0.430[b]
Spanish	13.4	11.8	
Other	5.9	4.9	
ECONOMIC INDICATORS			
Annual income ($; M [SD])	9747 (7239)	10,011 (7,047)	0.494[a]
Health insurance			
Medicare	36.2	33.1	0.075[b]
Medicaid	32.9	30.2	
Other programs for the uninsured	30.9	36.7	
HEALTHCARE UTILIZATION			
Primary care			
Number of visits in prior year (M [SD])	8.6 (6.3)	8.4 (6.0)	0.490[a]
Emergency care			
1 or more emergency department visits in prior 2 years	28.4	27.9	0.857[b]
Hospital care			
1 or more hospitalizations in prior 2 years	16.1	15.5	0.824[b]
PREVENTIVE CARE			
Flu shot in prior year	56.6	54.4	0.447[b]
Mammography in prior 2 years (% of women)	57.5	52.6	0.258[b]
Prostate-specific antigen test in prior 1 year (% of men)	11.1	11.5	0.908[b]
CRC SCREENING STATUS			
FOBT in prior year	17.6	21.4	0.077[b]
Sigmoidoscopy in prior 5 years	1.8	1.6	0.836[b]
Colonoscopy in prior 10 years	15.5	12.7	0.140[b]
Any CRC screening test in recommended time intervals	31.3	32.5	0.644[b]

Note: prior year = year prior to September 28, 2009; prior 2 years = 2 years prior to September 28, 2009
[a]Two-sample *t*-test
[b]Pearson χ^2 test
CRC, colorectal cancer; FLU, influenza vaccination; FOBT, fecal occult blood test

screening at the beginning of the intervention and who completed FOBT or any CRC screening test during the study measurement period. Participants with primary care visits and FLU on dates assigned to the FLU–FOBT group were more than twice as likely to complete FOBT and become up-to-date with CRC screening compared to patients in the FLU-only group, with ORs of 2.25 (95% CI=1.56, 3.24) and 2.22 (95% CI= 1.24, 3.95), respectively.

Other predictors of FOBT and CRC screening completion for eligible participants during the intervention included male gender and having a primary language other than English. Eligible participants with annual incomes below the median were less likely to complete FOBT and CRC screening. Asian Americans were the ethnic group most likely to complete FOBT. Participants with at least one emergency department visit in the past 2 years were less likely to complete CRC screening, but other healthcare utilization indicators did not appear to influence completion of FOBT and CRC screening.

Discussion

The FLU–FOBT Program is an effective approach to increase access to CRC screening during routine primary care office visits in clinics that rely on FOBT as the primary method of CRC screening. The CRC scr-

eening rate increased by 13 percentage points in the FLU–FOBT group compared to an increase of 4.3 percentage points in the FLU-only group (p= 0.010). In multivariate analyses focusing on patients due for screening at the beginning of FLU season, the OR for completing CRC screening within 6 months was 2.22 (95% CI=1.24, 3.95) for FLU–FOBT participants, compared to FLU-only participants. Other predictors for completing CRC screening were similar to predictors for completing CRC screening observed in other studies by the authors in similar clinical settings.[10,12] Men, Asian Americans, non-English speakers, and individuals with higher incomes were more likely than others to complete FOBT during the 6-month study period. This is the first randomized trial to determine the effectiveness of a nurse-run program to offer FLU and FOBT together during routine primary care visits.

Table 2. Changes in fecal occult blood test completion rates during the study period, % unless otherwise indicated

	FLU-only (n=677)	FLU–FOBT (n=695)	Between-group p-value
Pre-intervention: FOBT in past year	17.6	21.4	0.077[a]
FOBT completed during study period	11.8	21.6	**<0.001**[a]
Post-intervention: FOBT in past year	21.7	33.8	**<0.001**[a]
Pre–post change in FOBT completion in past year	≥4.1	≥12.4	**0.010**[b]
p-value for pre–post change in FOBT completion in last year	0.006[c]	<0.001[c]	

Note: Boldface indicates significance. Study period = September 28, 2009, to March 30, 2010.
[a]Pearson χ^2 test
[b]Two-sample Wilcoxon rank-sum test on pre–post differences
[c]McNemar's test
FLU, influenza vaccination; FOBT, fecal occult blood test

The population served by participating clinics was ethnically diverse and poor, with low baseline CRC screening rates despite frequent primary care visits in the year prior to the intervention. Most study participants came in for more than one primary care visit during the study period and had opportunities to be offered FOBT by their primary care clinicians outside of the FLU–FOBT intervention. The study results demonstrate that the nurse-run FLU–FOBT Program made a positive contribution to CRC screening rates as an addition to usual primary care.

This study intervention was designed as a practical clinical trial that would produce results that would be relevant and replicable in routine clinical practice.[16] Primary care clinicians were not asked to alter their usual behavior, and nurses were given autonomy in terms of how to offer FOBT. Patient participants were from diverse neighborhoods and ethnic groups. These design elements should allow clinical decision makers to understand what the FLU–FOBT Program can add to usual care in diverse clinical settings with low baseline CRC screening rates.

The study was implemented during a FLU season that posed unusual logistic challenges because of FLU shortages and the introduction of the H1N1 vaccine. Nonetheless, all six participating clinics were able to offer the FLU–FOBT Program on study dates when FLU was available. Nursing staff recorded dispensing 243 FOBT kits to 382 eligible FLU–FOBT group patients (64%) on their FLU log sheets during intervention weeks, although observations by the research team during weekly visits sug-

Table 3. Changes in colorectal cancer screening completion rates during the study period, % unless otherwise indicated

	FLU-only (n=677)	FLU–FOBT (n=695)	Between-group p-value
Pre-intervention: CRC screening rate	31.3	32.5	0.644[a]
CRC screening completed during study period	13.4	24.2	**<0.001**[a]
Post-intervention: CRC screening rate	35.6	45.5	**<0.001**[a]
Pre–post change in CRC screening rate	≥4.3	≥13.0	**0.018**[b]
p-value for pre–post change in CRC screening rate	0.004[c]	<0.001[c]	

Note: Boldface indicates significance. Study period = September 28, 2009, to March 30, 2010.
[a]Pearson χ^2 test
[b]Two-sample Wilcoxon rank-sum test on pre–post differences
[c]McNemar's test
CRC, colorectal cancer with fecal occult blood testing in the past year, flexible sigmoidoscopy in the past 5 years, or colonoscopy in the past 10 years; FLU, influenza vaccination; FOBT, fecal occult blood test

Table 4. Predictors for completing colorectal cancer screening tests for eligible participants (n=933), OR (95% CI)

Predictor variable	Completion of FOBT	Completion of CRC screening
FLU–FOBT group (vs FLU-only)	**2.25 (1.56, 3.24)**	**2.22 (1.24, 3.95)**
Age	0.99 (0.96, 1.02)	0.99 (0.95, 1.02)
Gender, male (vs female)	**1.73 (1.14, 2.63)**	**1.69 (1.18, 2.41)**
Ethnicity (vs non-Latino white)		
African-American	1.32 (0.81, 2.14)	1.24 (0.79, 1.94)
Asian-American	**2.25 (1.15, 4.38)**	2.15 (0.83, 5.12)
Hispanic	0.71 (0.36, 4.41)	0.76 (0.41, 1.41)
Other	1.38 (0.42, 4.53)	1.27 (0.33, 4.85)
Primary language, non-English (vs English)	**2.24 (1.25, 4.00)**	**2.14 (1.35, 3.43)**
Income, below median (vs above)	0.56 (0.39, 0.80)	0.58 (0.42, 0.80)
Health insurance, uninsured program (vs Medicare or Medicaid)	0.83 (0.55, 1.27)	0.87 (0.48, 1.61)
Number of primary care visits in prior year, above median (vs below)	0.93 (0.63, 1.37)	0.99 (0.81, 1.20)
Mammogram in past 2 years or prostate-specific antigen testing in prior year (vs neither)	1.24 (0.79, 1.94)	1.16 (0.67, 2.00)
Emergency department visit in prior 2 years (vs none)	0.69 (0.45, 1.07)	**0.65 (0.43, 0.96)**
Hospitalization in prior 2 years (vs none)	0.80 (0.47, 1.37)	0.88 (0.56, 1.39)

Note: Boldface indicates significance. Prior year = year prior to September 28, 2009; prior 2 years = 2 years prior to September 28, 2009.
CRC, colorectal cancer with fecal occult blood testing in the last year, flexible sigmoidoscopy in the last 5 years, or colonoscopy in the last 10 years; FLU, influenza vaccination; FOBT, fecal occult blood test

gest that these FLU logs underestimate the number of patients given FOBT with FLU during the intervention. Among those patients logged by nurses as having been given a kit, 91 (37.5%) completed FOBT by March 30, 2010. The increase in CRC screening rates for FLU–FOBT participants in each clinic during the study varied from 10.0 to 19.6 percentage points. The increase in CRC screening rates for FLU-only participants in each clinic varied from 0.4 to 10.1 percentage points. All six clinics experienced success, and most decided to implement their own FLU–FOBT Programs for the following FLU season, with one clinic adding smoking cessation activities to the FLU–FOBT Program and another implementing year-round standing orders for FOBT. Additional study is underway to evaluate and continue to document the processes of adoption, implementation, and maintenance of the FLU–FOBT Program in these six clinics and to develop a toolkit for dissemination of the FLU–FOBT Program nationally.

The within-clinics design of the study (i.e., with both intervention and control subjects enrolled within each participating clinic) ensured that the intervention and control arms would be delivered by comparable clinical personnel and that the patient populations in each arm of the study would be similar. This level of similarity between intervention and control group participants could not have been achieved with a cluster-randomized design in which some clinics participated only in the intervention arm and others participated only in the control arm. A limitation of the within-clinics design was the risk of contamination between the FLU–FOBT and FLU-only groups. For example, clinic staff could have begun to implement intervention procedures during control dates. However, the research team did observe some nurses implementing FLU–FOBT procedures during FLU-only dates, although infrequently. Contamination between groups would diminish the difference in outcomes measured between the intervention and control groups and suggest that the true impact of the FLU–FOBT Program on CRC screening rates might well be greater than what was observed.

In summary, the FLU–FOBT Program is a theory-based intervention that is feasible to implement during primary care visits and is an effective method to increase CRC screening rates in settings that rely on FOBT as the primary method of CRC screening. If its key elements are shown to be sustainable over time, the FLU–FOBT Program could serve as new paradigm to engage primary care nursing staff in activities that increase awareness of and access to CRC screening in settings where resources are limited and CRC screening disparities persist.

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The six authors (Michael B. Potter, Judith M.E. Walsh, Tina M. Yu, Ginny Gildengorin, Lawrence W. Green, and Stephen J. McPhee) have no commercial associations currently or within the last 5 years that could constitute a conflict of interest.

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References

1. Jemal A, Siegel R, Xu J, Ward E. Cancer statistics, 2010. CA Cancer J Clin 2010;60:277–300.
2. U.S. Preventive Services Task Force. Screening for colorectal cancer: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med 2008;149:627–37.
3. Zauber AG, Lansdorp-Vogelaar I, Knudsen AB, Wilschut J, van Ballegooijen M, Kuntz KM. Evaluating test strategies for colorectal cancer screening: a decision analysis for the U.S. Preventive Services Task Force. Ann Intern Med 2008:149;659–69.
4. Edwards BK, Ward E, Kohler BA, et al. Annual report to the nation on the status of cancer, 1975–2006, featuring colorectal cancer trends and impact of interventions (risk factors, screening, and treatment) to reduce future rates. Cancer 2010;116:544–73.
5. Centers for Disease Control and Prevention. Vital signs: colorectal cancer screening among adults aged 50–75 years—U.S., 2008. MMWR Morb Mortal Wkly Rep 2010;59:808–12.
6. Fisher JA, Fikry C, Troxel AB. Cutting cost and increasing access to colorectal cancer screening: another approach to following guidelines. Cancer Epidemiol Biomarkers Prev 2006;15:108–13.
7. Sarfaty M, Wender R. How to increase colorectal cancer screening rates in practice. CA Cancer J Clin 2007;57:354–66.
8. Klabunde CN, Lanier D, Breslau ES, et al. Improving colorectal cancer screening in primary care practice: innovative strategies and future directions. J Gen Intern Med 2007;22:1195–205.
9. Holden DJ, Jonas DE, Porterfield DS, Reuland D, Harris R. Systematic review: enhancing the use and quality of colorectal cancer screening. Ann Intern Med 2010;152:668–76.
10. Potter MB, Phengrasamy L, Hudes ES, McPhee SJ, Walsh JM. Offering annual fecal occult blood tests at annual flu shot clinics increases colorectal cancer screening rates. Ann Fam Med 2009;7:17–23.
11. Potter MB, Gildengorin G, Wang Y, Wu M, Kroon L. Comparative effectiveness of two pharmacy-based colorectal cancer screening interventions during an annual influenza vaccination campaign. J Am Pharm Assoc 2010:50;181–7.
12. Potter MB, Yu TM, Gildengorin G, et al. Adaptation of the FLU–FOBT Program for a primary care clinic serving a poor Chinese–American community: new evidence of effectiveness. J Health Care Poor Underserved 2011;22(1):284–95.
13. Singleton JA, Poel AJ, Lu PJ, Nichol KL, Iwane MK. Where adults reported receiving influenza vaccination in the U.S. Am J Infect Control 2005;33:563–70.
14. Yarnall KS, Pollack KI, Ostbye T, Krause KM, Michener L. Primary care: is there enough time for prevention? Am J Public Health 2003;93(4):635–41.
15. IOM. Committee on Communication and Behavior Change in the 21st Century: Improving the Health of Diverse Populations, Board on Neuroscience and Behavioral Health. Speaking of health: assessing health communication strategies for diverse populations. Washington DC: National Academies Press, 2002.
16. Tunis SR, Stryer DB, Clancy CM. Practical clinical trials: increasing the value of clinica research for decision making in clinical and health policy. JAMA 2003;290:1624–32.

Supplementary data

A pubcast created by the authors of this paper can be viewed at http://www.ajpm-online.net/content/video_pubcasts_collection.