Adaptation of the FLU-FOBT Program for a Primary Care Clinic Serving a Low-Income Chinese American Community: New Evidence of Effectiveness

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Abstract: Introduction. We sought to adapt and evaluate the FLU-FOBT Program for a primary care clinic serving a low-income Chinese American community. Methods. We compared colorectal cancer screening (CRCS) rate changes for patients who received flu shots *versus* those who did not receive flu shots during the FLU-FOBT Program. Analysis of data from the year prior to the intervention was used to validate the results. Results. Rates of CRCS increased by 18.0 percentage points for flu shot recipients during the FLU-FOBT Program *vs*. 1.7 percentage points for flu shot non-recipients ($p<.001$ for change difference). In the year prior to the FLU-FOBT Program, flu shot recipients had only a 3.3 percentage point increase in the CRCS rate *vs*. a 1.9 percentage point decline for flu shot non-recipients ($p=.08$ for change difference). Conclusions. The FLU-FOBT Program as adapted was effective at increasing CRCS rates for primary care patients in this low-income Chinese American community.

Key words: **NONE ????**

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Colorectal cancer mortality can be reduced with screening.[1] The U.S. Preventive Services Task Force (USPSTF) recommends routine colorectal cancer screening (CRCS) for adults aged 50 to 75 using home fecal occult blood tests (FOBT) annually, flexible sigmoidoscopy every five years with interval FOBT, or colonoscopy every 10 years.[2] However, recent results from the National Health Interview Survey indicate that only 55% of eligible adults were up-to-date with CRCS, with 11% completing FOBT; 2% flexible sigmoidoscopy; and 48% colonoscopy within recommended time intervals.[3] In resource-limited clinics where uninsured or underinsured patients often receive care, CRCS is typically limited to annual FOBT, with colonoscopy reserved for evaluation of abnormal FOBT or high-risk patients.[4]

Providing FOBT annually to patients who need it is challenging, and the obstacles may be magnified by educational, linguistic, social, and cultural factors.[5–9] Multiple strategies are required to address physician, patient or system level barriers.[10] Changes in staff responsibilities and office procedures are often the most important elements of successful primary care-based cancer screening interventions.[11] Office systems empowering nurses to offer FOBT to eligible patients has been suggested as an example of this approach.[12–13]

One opportunity for nursing staff to provide FOBT is at the time of annual influenza vaccinations (flu shots).[14] Providing FOBT with flu shots in a combined FLU-FOBT program (hereafter, the *FLU-FOBT Program*) has been shown effective in a hospital-based flu shot clinic and in community pharmacies serving diverse patient populations.[15–16] The FLU-FOBT Program has until now, however, not been tested as an intervention that could take place during primary care visits, a time when competing demands of clinical care may make the nurse-directed provision of colorectal cancer screening in addition to flu shots challenging. Our goal in this study was to adapt the FLU-FOBT Program as a nurse-driven primary care intervention and evaluate its effectiveness in preparation for a larger clinical trial in primary care clinics serving diverse, medically underserved communities.

Methods

Study setting. The Chinatown Public Health Center (CPHC) is one of nine community-based adult primary care clinics operated by the San Francisco Department of Public Health (SFDPH). The CPHC serves a population consisting mostly of monolingual Cantonese-speaking immigrants who live in San Francisco's Chinatown neighborhood. It employs eight primary care clinicians who each see patients 10 to 30 hours per week, collectively providing approximately 13,600 patient visits per year. Each autumn, the clinic's nursing staff is given standing orders to provide flu shots to eligible patients during primary care visits. Preventive services, including CRCS, are offered during primary care visits. The only available CRCS test for average-risk patients in this setting is Hemoccult II (Beckman Coulter), a home guaiac FOBT which requires the patient to collect two stool samples on each of three consecutive bowel movements after dietary and medication restrictions have been implemented for two to seven days.

Study population. The study population consisted of established primary care patients (defined as those with at least one primary care visit in the two years prior to

September 30, 2008), who came in for a primary care visit during the time when flu shots were available (September 30, 2008 to January 21, 2009) and who were eligible for CRCS (defined according to then current clinic guidelines as being age 50 to 80 years at the start of the intervention and having had no FOBT or colonoscopy within recommended time intervals or who would become due for them by January 1, 2009). Patients who completed flexible sigmoidoscopy within the last five years but had no FOBT or colonoscopy within recommended time intervals were considered eligible for FOBT because USPSTF Guidelines now recommend interval FOBT for patients receiving screening flexible sigmoidoscopy.[2]

Intervention preparation, tailoring, and training. The researchers met with the medical leaders of CPHC to discuss FLU-FOBT Program procedures and developed an implementation plan to maximize the potential success of the project. Key FLU-FOBT Program elements requested by the CPHC leadership included a flu shot log with a checkbox to remind nursing staff to assess FOBT eligibility using their electronic clinical data system and FOBT information sheets targeting individuals with low literacy, printed in Chinese and English. These materials provided information on the importance of CRCS, instructions for completing FOBT, and a clinic phone number for patient questions. The materials also included images of the clinic logo, clinic staff members, and a prominent advocate of CRCS from the local community. Nursing stations were equipped with a four-minute video in Cantonese on FOBT that could be played while nurses prepared the flu shots.[17] Kits for FOBT were packaged so that patients could mail completed kits directly to the clinical laboratory instead of bringing them back to the clinic in person, as had previously been the standard practice. Patients making primary care visits but not provided flu shots were not offered FOBT by the nursing staff unless ordered to do so by the primary care clinician during the visit. In those cases, the nursing staff offered FOBT using the resources and education materials provided by the FLU-FOBT Program.

Most of the nursing staff attended a one-hour group training session given by the medical director and principal investigator before the intervention began. A bicultural bilingual Cantonese co-investigator provided on-the-job training during the first few days of the intervention and made visits at least three days per week to record observations of the FLU-FOBT Program for evaluation purposes. The nursing staff was encouraged to suggest changes to the FLU-FOBT protocol and materials if these changes might improve their workflow or patient care. Culturally appropriate pictorial FOBT instructions were developed for low-literacy patients in response to feedback from nursing staff. Nursing staff were encouraged to follow the FLU-FOBT protocol whenever possible, but were also given the freedom to decide how to discuss FOBT with patients and which educational approaches or materials to use. They were allowed to bypass offering flu shots or FOBT when they were too busy.

Data analysis. We created a de-identified database with information on all eligible patients at the start of the intervention. Data elements included birth date; sex; ethnicity; primary language; income; insurance status; dates of primary care visits, emergency department visits, and hospitalizations; and dates of flu shots, CRCS tests (FOBT, flexible sigmoidoscopy, and colonoscopy), and other cancer screening (mammograms and prostate specific antigen [PSA] tests). Intervention participants were defined as

patients who had a primary care visit and a flu shot during the FLU-FOBT Program intervention period (September 30, 2008 to January 21, 2009), and comparison group participants were defined as those with at least one primary care visit during the intervention period but who did not receive a flu shot.

Data analyses were conducted using SAS version 9.2 software (SAS Institute, 2007). First, we compared baseline characteristics of the intervention and comparison participants, using two-sample t-tests for continuous variables and Pearson chi-squared tests for categorical variables. Next, to compare the changes in CRCS status between the two groups, a -1, 0, $+1$ score was created for the pre-intervention to post-intervention change in CRCS status for each patient during a measurement period beginning with the start of the intervention (September 30, 2008) and ending six months later (March 30, 2009). In this scoring system, a $+1$ indicates going from being due for CRCS at the beginning of the measurement period to being up-to-date with screening by the end of the study measurement period, a -1 means going from being up-to-date to being due for CRCS from the beginning to end of the measurement period, and 0 indicates no change in CRCS status during the measurement period. A two-sample Wilcoxon test was used to compare these change scores for the two groups. Within each group, McNemar's chi-squared test was used to compare pre-intervention to post-intervention percentage point changes in CRCS status. At each time point, differences in CRCS status between the intervention and comparison groups were assessed using the Pearson chi-squared test. Finally, we performed a similar analysis comparing changes in CRCS among patients in the database who were seen during an equivalent measurement period during the prior year (September 30, 2007 to March 30, 2008), when flu shots were provided with standing orders in the absence of the FLU-FOBT Program.

Using pre-selected variables associated with CRCS completion and available from the clinical database**,** we explored predictors of eligible patients becoming up-to-date for CRCS during the measurement period.[18] Retained covariates were intervention group (received flu shot *vs.* not); age (50–64 *vs.* 65–80 years); sex; primary language (Cantonese *vs.* other); insurance status (insured *vs.* uninsured); income (above *vs.* below the median); primary care visits in the prior year (above *vs.* below median number); hospital visits in the prior two years (none *vs.* $\geq$ 1); emergency department visits in the last two years (none *vs.* $\geq$ 1); and screening with mammography or PSA in the prior two years (no test *vs.* $\geq$ 1 test).

Clinic agreements and IRB approval. In return for participation in this research, CPHC was promised a $5,000 honorarium to be given at the end of the study regardless of the results achieved. The study was approved by the SFDPH Protocol Review Committee and the University of California, San Francisco, Committee on Human Research.

Results

Demographic characteristics. Characteristics of study participants are shown in Table 1. Most were low-income Cantonese-speaking Chinese Americans. The intervention group was slightly younger than the comparison group ($p=.044$) and included a slightly larger proportion of Asians ($p=.013$). Intervention group participants were more likely to be

uninsured (p=.037) and to have had a flu shot in the year prior to the study (p<.001). The intervention group was less likely to be up-to-date with any CRCS test at the start of the study (p=.032), primarily due to a lower colonoscopy rate (p=.006). However, the two groups started with similar FOBT rates, and they were similar with regard to health care utilization and other preventive health measures.

Flow diagram for study participants. Figure 1 provides an overview of the study groups. As of September 30, 2008, the clinic had 2,681 established primary care patients aged 50 to 80, and 1,499 of these patients (55.9%) had a primary care visit during the intervention period. Among these patients, 970 received flu shots (intervention group) and 529 did not (comparison group).

Main outcomes: Intervention effectiveness at increasing CRCS rates. Table 2 shows pre-post CRCS rate changes for the two groups of patients who had primary care visits while the FLU-FOBT Program was being run—those who received flu shots (intervention group) and those who did not (comparison group). Among those who

Table 1.

DEMOGRAPHIC CHARACTERISTICS OF 1499 ESTABLISHED PRIMARY CARE PATIENTS AGED 50 TO 80 WITH AT LEAST ONE PRIMARY CARE VISIT DURING THE INTERVENTION PERIOD (SEPTEMBER 30, 2008–JANUARY 21, 2009)

Characteristics	Intervention Group FLU Shot Given (n=970)	Comparison Group FLU Shot Not Given (n=529)	p-value
DEMOGRAPHICS			
Mean age, years (SD)	61.0 (6.2)	61.7 (6.7)	0.04[a]
Female Sex, (%)	71.7	71.1	0.81[b]
Ethnicity (%)			
Asian	96.1	93.4	0.01[b]
Caucasian	2.3	5.1	
Other	1.6	1.5	
Language (%)			
Cantonese	86.2	83.4	0.37[b]
Mandarin	3.3	4.1	
English	8.7	11.0	
Other	1.9	1.5	
ECONOMIC INDICATORS			
Health Insurance (%)			
Medicare	24.6	29.9	0.04[b]
Medicaid	15.7	17.9	
Commercial	32.5	29.7	
Uninsured	27.2	22.5	
Income, mean $ (SD)	14,670 (7,907)	14,699 (8,019)	0.95[a]
Income, median $ (min, max)	13,170 (1,308-55,692)	13,200 (1,200-47,616)	0.96[c]

(Continued on p. 288)

Table 1. *(continued)*

Characteristics	Intervention Group FLU Shot Given (n=970)	Comparison Group FLU Shot Not Given (n=529)	p-value
HEALTH CARE UTILIZATION			
Primary Care			
Number of visits in prior year,[d] mean, (SD)	4.7 (3.2)	4.8 (3.3)	0.53[a]
Emergency Care			
1 or more emergency room visits in prior 2 years[e] (%)	11.0	11.0	1.00[b]
Hospital Care			
1 or more hospitalizations in prior 2 years[e] (%)	7.0	4.9	0.12[b]
PREVENTIVE CARE			
Flu shot in prior year[d](%)	63.1	43.3	<0.001[b]
Mammography or Prostate Specific Antigen Test in prior 2 years[e] (%)	47.1	47.6	0.87[b]
CRCS STATUS			
FOBT in prior year[d] (%)	42.5	43.9	0.62[b]
Sigmoidoscopy in prior 5 years (%)	2.7	2.8	0.87[b]
Colonoscopy in prior 10 years (%)	17.9	24.0	0.006[b]
Any CRCS Test in recommended Time intervals (%)	57.3	63.1	0.03[b]

[a]2 sample t test
[b]Pearson chi-square test
[c]2 sample Wilcoxon test
[d]Year Prior to September 30, 2008.
[e]2 Years Prior to September 30, 2008.

got flu shots, the CRCS rate increased from 57.3% to 75.3% during the measurement period (September 30, 2008 to March 30, 2009) ($p<.001$), whereas among those who did not get flu shots, the CRCS rate did not change significantly ($p=.384$). The increase in CRCS among those receiving flu shots was 18.0 percentage points *vs.*1.7 percentage points among those not receiving flu shots ($p<.001$). A total of 372 out of 970 flu shot recipients (38.4%) completed FOBT during the measurement period, as did 90 of 529 primary care visitors (17.0%) who did not get flu shots ($p<.001$), showing that flu shot recipients were more likely than non-flu shot recipients to complete FOBT screening. Among patients making primary care visits during the intervention period, 12 individuals had abnormal FOBT test results (nine in the intervention group and three in the comparison group), and these results were reported to the clinic for follow-up by the clinical laboratory. From the beginning to end of the measurement period, the overall

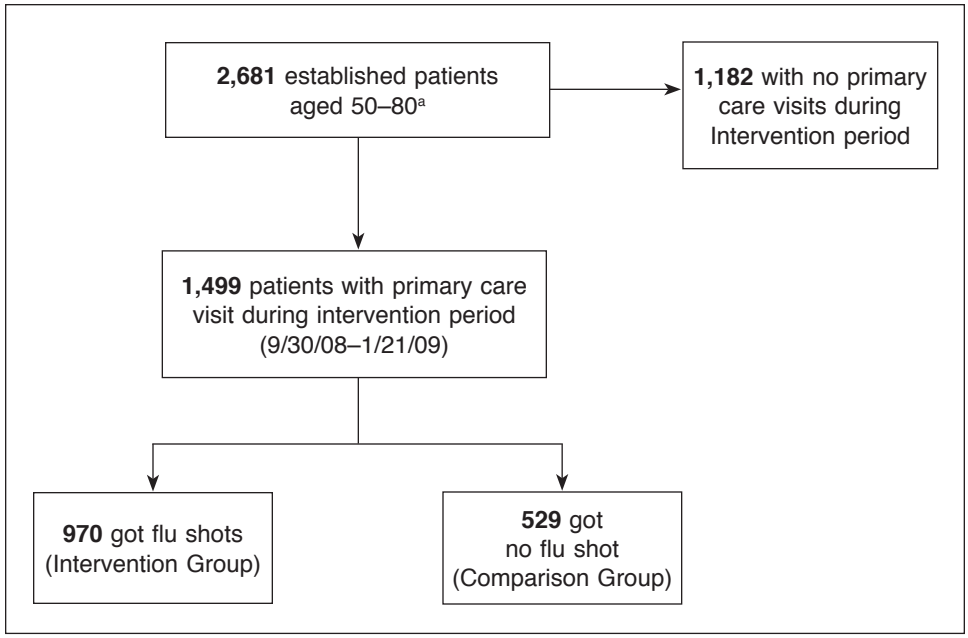

Figure 1. Study flow diagram.

[a]Established patients had at least one primary care visit in the 2 years prior to September 30, 2008 when the intervention began.

screening rate for all eligible primary care patients, whether or not they came in to the clinic at all during the FLU-FOBT Program, increased from 49.7% on September 30, 2008 to 56.7% by March 30, 2009.

Comparison data from the year prior to the intervention. Most of the patients in this study were seen for primary care during flu shot season in the year prior to the implementation of the FLU-FOBT Program, and those who got flu shots during that time period were similar demographically to those who did not get flu shots. Table 3 shows the changes in screening rates for the cohort of study participants who made primary care visits between September 30, 2007 and January 21, 2008, one year prior to the FLU-FOBT Program implementation. Among those who received flu shots during primary care visits during these dates, the CRCS rate increased from 59.0% to 62.3% between September 30, 2007 to March 30, 2008 (our "pre-intervention measurement period"), an increase of 3.3 percentage points. Among those who did not receive flu shots, the CRCS rate decreased from 53.1% to 51.2%, a decrease of 1.9 percentage points. This 5.2 percentage point change difference between the two groups did not reach statistical significance ($p=.078$). A total of 243 out of 992 flu shot recipients (24.3%) completed FOBT kits during this measurement period, as did 76 out of 375 primary care visitors (20.3%) who did not get flu shots ($p=.115$). These data indicate that, in a year when there was no FLU-FOBT intervention, primary care visitors who received flu shots were not significantly more likely than non-flu shot recipients to complete FOBT or to become up-to-date with CRCS.

Table 2.

CHANGE IN CRCS RATES FOR PATIENTS WITH PRIMARY CARE VISITS DURING THE FLU-FOBT INTERVENTION (SEPTEMBER 30, 2008 TO JANUARY 21, 2009), COMPARING CRCS RATES BETWEEN THOSE WHO GOT FLU SHOTS DURING THE INTERVENTION VS. THOSE WHO DID NOT

CRCS Status	Primary Care Visit with Flu Shot (n=970)	Primary Care Visit, no Flu Shot (n=529)	Between Group p-Value
CRCS up to date at start of measurement period (September 30, 2008) (%)	57.3	63.1	0.03[a]
CRCS up-to-date at end of measurement period (March 30, 2009) (%)	75.3	64.8	<0.001[a]
Percentage point change	+18.0	+1.7	<0.001[b]
Pre-intervention to post-intervention p-value	<0.001[a]	0.38[a]	

[a]Pearson chi-square test
[b]2-sample Wilcoxon rank-sum test on pre-post differences
[c]McNemar's test
CRCS = colorectal cancer screening

Multivariate logistic regression for becoming up-to-date with CRCS. Table 4 displays the multivariate model showing predictors for becoming up-to-date with CRCS among the subset of FOBT-eligible patients who made primary care visits and who were due for screening as of the September 30, 2008 start date for FLU-FOBT Program (n=609). The odds ratio of 3.46 (95% confidence interval [CI], 2.35–5.10) confirms the observation that primary care visitors who received flu shots were significantly more likely than those who did not receive flu shots to be up-to-date with CRCS by the end of the measurement period. Cantonese speakers (OR 1.92; 95% CI, 1.19–3.12) and those with a history of completing mammogram or PSA tests in the last two years (OR 1.60; 95% CI, 1.11–2.30) were also more likely to complete a CRCS test during the measurement period.

We used the same multivariate model and applied it to the group of participants who got primary care visits during the flu shot season in the year prior to the intervention. In this analysis, we found a small but non-significant association between getting a flu shot and becoming up to date with CRCS (OR=1.45 (95% CI 0.94–2.5).

Table 3.

CHANGE IN CRCS RATES FOR PATIENTS WITH PRIMARY CARE VISITS ONE YEAR PRIOR TO THE FLU-FOBT INTERVENTION (SEPTEMBER 30, 2007 TO JANUARY 21, 2008), COMPARING CRCS RATES BETWEEN THOSE WHO GOT FLU SHOTS DURING THESE DATES VS. THOSE WHO DID NOT

CRCS Status	Primary Care Visit with Flu Shot (n=992)	Primary Care Visit, no Flu Shot (n=375)	Between Group p-Value
CRCS up-to-date at start of measurement period (September 30, 2007) (%)	59.0	53.1	0.05[a]
CRCS up-to-date at end of measurement period (March 30, 2008) (%)	62.3	51.2	<0.001[a]
Percentage point change	3.3	−1.9	0.08[b]
Pre-intervention to post-intervention change difference p-value	0.03[c]	0.45[c]	

[a]Pearson chi-square test
[b]2-sample Wilcoxon rank-sum test on pre-post differences
[c]McNemar's test
CRCS = Colorectal cancer screening

Discussion

This study demonstrates that the FLU-FOBT Program can be implemented successfully in a primary care clinic serving a low-income, mostly monolingual Chinese American and limited English proficient patient population. During the intervention, the CRCS rate for those who made primary care visits and received flu shots increased by 18.0 percentage points, compared with only 1.7% for those who made primary care visits without flu shots ($p<.001$ for change difference). In contrast, during the pre-intervention year when there was no FLU-FOBT Program, patients who received flu shots during primary care visits increased their CRCS rate by just 3.3 percentage points, while those who made primary care visits but did not receive flu shots had their CRCS rate decline by 1.9 percentage points ($p=.078$ for change difference). These results strongly suggest that most of the increase in CRCS among flu shot recipients that took place during the intervention was due to the FLU-FOBT Program.

Other patient characteristics that were independent predictors of becoming up-to-date with CRCS were Cantonese as a primary language and history of having either a mammogram or PSA test in the two years prior to our intervention. The positive association between being Cantonese-speaking and becoming up-to-date with CRCS makes sense for patients in this clinic where nearly all the staff were native Cantonese

Table 4.

MULTIVARIATE LOGISTIC REGRESSION ANALYSIS OF PREDICTORS FOR PATIENTS DUE FOR CRCS ON SEP 30, 2008 BECOMING UP-TO-DATE WITH CRCS BY MARCH 30, 2009 (N=609)

Predictor Variable	OR (95% CI)
Primary care visit and flu shot (vs. primary care visit and no flu shot)	3.46 (2.35–5.10)
Age, 65–80 years (vs. 50–64 years)	1.01 (0.61–1.67)
Sex, male (vs. female)	0.84 (0.56–1.26)
Primary language, Cantonese (vs. other)	1.92 (1.19–3.12)
Income, above median (vs. below)	1.01 (0.71–1.45)
Health insurance, uninsured (vs. insured)	1.29 (0.83–1.98)
Number of primary care visits, above median in prior year (vs. below)	0.93 (0.58–1.48)
Mammogram or PSA testing in prior 2 years (vs. neither)	1.60 (1.11–2.30)
Emergency Room visit in prior 2 years (vs. none)	1.01 (0.57–1.79)
Hospitalization in prior 2 years (vs. none)	1.45 (0.67–3.11)

CRCS = Colorectal cancer screening
OR = Odds ratio
CI = Confidence interval

speakers; at CPHC, the language barriers between patients and providers that may decrease CRCS rates elsewhere[19] do not exist. In fact, language and cultural concordance between patients and nursing staff may have contributed higher uptake of screening among Cantonese-speaking patients. The positive association with CRCS for those with a prior history of being screened for other cancers is consistent with results reported by others.[18]

In this study, the FLU-FOBT Program was adapted to reach patients who received flu shots during a primary care visit. Overall, 36.2% of established clinic patients aged 50 to 80 came in for a primary care visit and received flu shots during the intervention period. Undoubtedly, a larger proportion of patients could have been screened if there was more outreach to encourage patients to come in for care during the flu shot season, or if FOBT were offered to all patients passing through the doors of the clinic regardless of whether or not flu shots were offered or given. Nonetheless, as designed and implemented, the FLU-FOBT Program required few clinic resources and contributed to a clinically significant improvement in overall clinic screening rates. The CRCS rate increased from 49.6% to 56.7% among all established patients, even though many patients were not seen at all in the clinic and most did not get flu shots during the intervention time period.

Implementation of the FLU-FOBT Program involved a partnership between the

research team and the clinic's leadership team and training for the nursing staff before and during the intervention. Procedures and educational materials for the FLU-FOBT Program were tailored according to the limited resources and needs of the clinic, its nursing staff, and its mostly non-English-speaking patients. After completing the research study, the clinic staff continued to employ systems for offering FOBT that were introduced by the research team, and the FLU-FOBT Program was implemented independently of the research study during the following autumn, providing preliminary evidence for sustainability of FLU-FOBT Program when developed and tailored to the needs of an individual clinic.

The absence of a randomly assigned control group is a limitation of this study. However, the comparison group selected was well-characterized and similar in many respects to the intervention group. Known baseline differences between the intervention and comparison groups were controlled for in our multivariate analysis. In the year prior to the intervention, provision of flu shots during primary care visits was not a significant predictor of increased CRCS rates, supporting our conclusion that it was the pairing of flu shots with FOBT that resulted in our intervention effect. Finally, our observational study design provided important insights into the intervention adaptation and implementation process that would have been impossible to capture with more intrusive or controlled research designs.

A second limitation is that our results may not be easily generalized, since the intervention took place in just one setting by a motivated clinical team and a unique patient population. Nonetheless, this intervention was tailored for a low-income, non-English-speaking population, many of whom had limited insurance coverage. It was also implemented during a period of significant public health department staffing and budget cuts. The success of the FLU-FOBT Program in this setting suggests that it could be robust enough for implementation in other primary care settings with low-income and underserved patient populations experiencing colorectal cancer screening disparities. A multisite trial is underway to evaluate the effectiveness of the FLU-FOBT Program in primary care settings with variable levels of staff motivation and more ethnically and linguistically diverse patients.

In summary, the FLU-FOBT Program is adaptable for primary care in a setting where low-income and historically medically underserved patients receive care, and it can increase screening CRCS rates for primary care patient participants. Further study will provide more information about the reach, effectiveness, acceptability, and sustainability of this approach in additional diverse practice settings.

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