

Change to FIT Increased CRC Screening Rates: Evaluation of a US Screening Outreach Program

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Objectives: To compare completion rates of colorectal cancer screening tests within a health maintenance organization before and after widespread adoption of the fecal immunochemical test (FIT).

Study Design: Retrospective cohort study.

Methods: Using electronic medical records of 113,901 patients eligible for colorectal cancer screening, we examined test completion during 2 successive time periods among those who received an automated screening outreach call. The time periods were: 1) the “guaiac fecal occult blood test (gFOBT) era,” a 15-month period during which only gFOBT was routinely offered, and 2) a 9-month “FIT era,” when only a new FIT was routinely offered. In addition to analyzing completion rates, we analyzed the impact of practice-level variables and patient-level variables on overall screening completion during the 2 different observation periods.

Results: The change from gFOBT to FIT in an integrated care delivery system increased the likelihood of screening completion by 7.7% overall, and the likelihood of screening with a fecal test by 8.9%. The greatest gains in screening completion using FIT were among women and elderly patients. Completion of FIT was not as strongly associated with medical office visits or with having a primary care provider as was screening with gFOBT.

Conclusions: Adoption of FIT within an integrated care system increased completion of colon cancer screening tests within a 9-month assessment period, compared with a previous 15-month gFOBT era. Higher completion rates of the FIT may allow for more effective dissemination of programs to increase colorectal cancer screening through centralized outreach programs.

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For author information and disclosures,
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Colorectal cancer (CRC) is the second-leading cause of cancer death in the United States, and affects men and women almost equally.¹⁻³ The US Preventive Services Task Force (USPSTF) recommends screening with any of 3 options, including fecal testing, flexible sigmoidoscopy, or colonoscopy. Screening for CRC with fecal occult blood testing done annually or biennially has been shown to decrease mortality from colorectal cancer by 15% to 33%, primarily through detection of early-stage cancers.⁴⁻⁹ The guaiac fecal occult blood test (gFOBT) has a known positive balance of benefit and risk in screening populations, is the least expensive screening method, and is preferred over endoscopy in 30% to 55% of patients.¹⁰⁻¹² However, gFOBT has limitations in the areas of test adherence and test performance because testing requires dietary and medication restrictions during the 3 days that 3 separate stool samples are collected—a cumbersome protocol that can interfere with test completion.¹³

While adherence to test completion in the initial round of screening with gFOBT in 3 large randomized trials was 59% to 67%,⁵⁻⁷ smaller-scale studies have demonstrated lower 1-time screening completion rates using gFOBT by 25% to 30%.^{14,15} Retaining patients in annual or biennial gFOBT screening programs has proved challenging, with observed rescreen rates of approximately 50% on a second round.^{9,16} The fecal immunochemical test (FIT) may improve upon these rates. Previous randomized studies have shown that adherence to 1-time completion of a 1-sample or 2-sample FIT is 10% to 12% greater than adherence to gFOBT, and that the sensitivity of FIT is equal to or greater than FOBT.^{14,15,17-19} A single (3-sample) gFOBT detects about 12% to 38% of cancers,²⁰⁻²² whereas a 1-sample FIT detects 25% to 69% of cancers,²²⁻²⁴ and a 3-sample FIT detects 66% to 92% of cancers.^{22,24-27} As a result, in 2008, multiple professional societies endorsed the use of 4 types of FITs for colorectal cancer screening as a replacement for gFOBT in the United States.^{1,28} However, it remains unclear to what extent a transition from gFOBT to FIT will improve screening test completion in large community-based populations and which specific populations may benefit the most. We capitalized on a natural experiment by analyzing completion rates before and after the change from gFOBT to FIT.

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METHODS

The protocol for this study was approved by the institutional review board within the study health maintenance organization (HMO).

Study Site and Data Sources

The study was conducted at Kaiser Permanente Northwest (KPNW), a not-for-profit HMO in the Pacific Northwest with about 485,000 members. The membership of KPNW is similar to the local insured community.²⁹ Electronic records and a patient survey described below provided clinician and patient data.

KPNW maintains a CRC screening clinical practice guideline based upon the recommendations of the USPSTF. Each of the USPSTF-recommended CRC screening modalities (ie, fecal testing, flexible sigmoidoscopy, or colonoscopy) is a covered benefit and available to patients, although fecal testing is encouraged through systemwide outreach efforts in lower-risk individuals. The study site has had an automated call CRC reminder program in place since January 2008; details of the patient selection process for outreach and of the automated call system have been published. The system targets average-risk individuals who are not being actively treated for major diseases (eg, cancer), or receiving nursing home or hospice care.³⁰ Each month, approximately 5000 eligible HMO members receive a telephone call with an offer for a fecal test to be sent to their home. Included in the mailed packets are the test, instructions, and a card stock envelope addressed to the KPNW laboratory for return. Those who request the test but do not complete it within 6 weeks receive up to 2 reminder phone calls, 6 weeks apart.

In April 2009, KPNW switched from sending the 3-sample gFOBT to sending a single-sample FIT that required no dietary or medication restrictions—the OC-Micro FIT (Polymedco, Cortland Manor, New York).

Study Design Overview

The retrospective cohort study examined colorectal cancer screening test completion among those receiving an automated telephone call (ATC) during 2 successive time periods: 1) The “gFOBT era,” a 15-month period during which the gFOBT was routinely offered through ATC outreach, and 2) a 9-month “FIT era.” We also analyzed the impact of practice-level variables (eg, primary care provider [PCP] assignment, primary care utilization, and specialty care utilization) and patient-level variables (eg, age, gender, number of medications, body mass index [BMI], and length of HMO member-

Take-Away Points

Dissemination of the fecal immunochemical test (FIT) resulted in higher colorectal cancer screening completion rates than were observed using the guaiac fecal occult blood test (gFOBT).

- Visiting a healthcare provider may be less important for completion of screening with the use of FIT than with the use of gFOBT.
- The FIT may enable broader adoption of centralized outreach programs for CRC screening.
- Populations less inclined to screen with fecal tests, including women, the elderly, and those taking more medications may more readily complete screening when offered FIT than when offered gFOBT.

ship) on overall screening completion during the 2 different observation periods.

Additionally, we mailed a survey to 2000 patients who received an ATC during 1 or both time periods. This survey was designed to understand the barriers and facilitators that patients encountered in their efforts to complete colorectal cancer screening. For the purposes of this analysis, we discuss the specific answers among only those respondents who answered questions about *both* tests, because they had had prior experience with each type of fecal test.

Study Populations

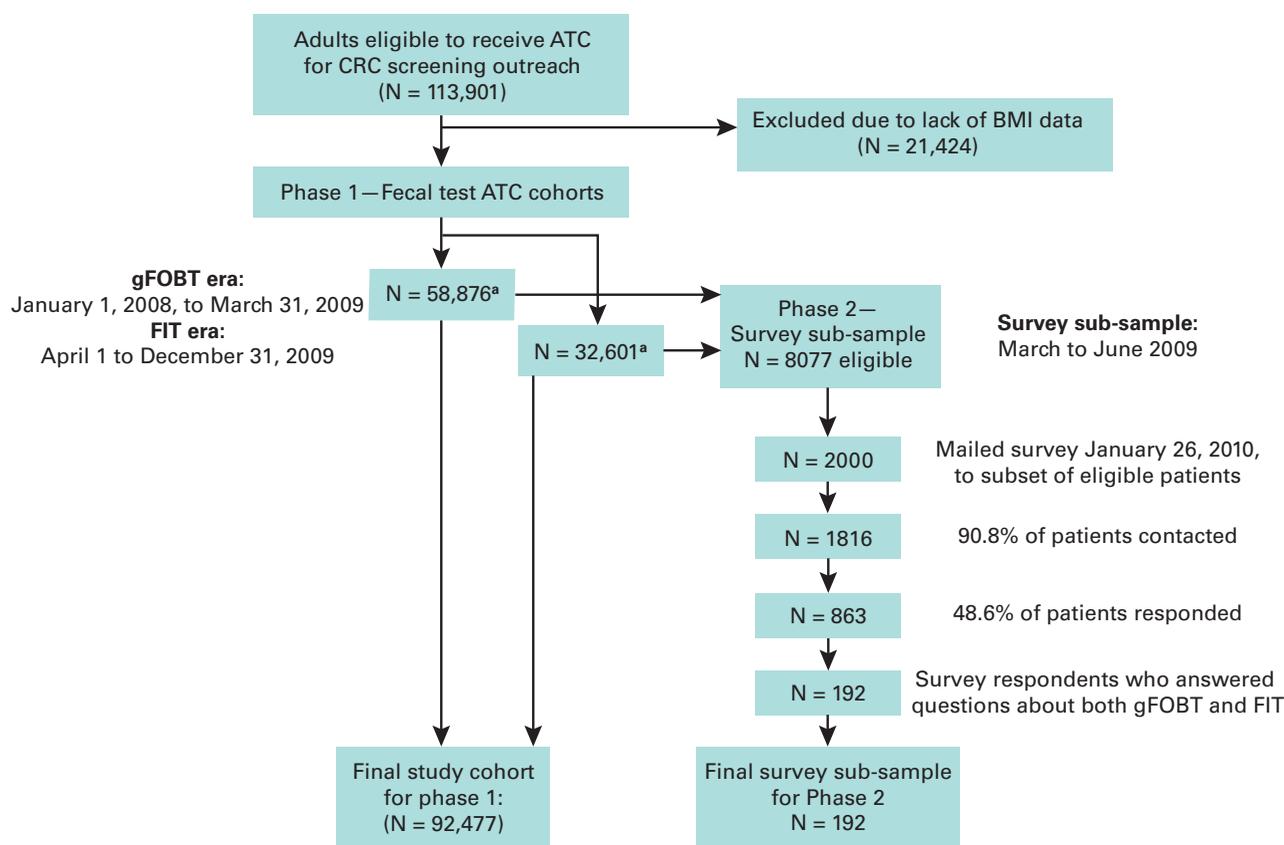
This retrospective cohort study was conducted in 2 phases. The **Figure** outlines the study population flow.

Cohort Population: The cohort consisted of HMO members aged 50 to 80 years who were overdue for CRC screening at the beginning of each month of an observation period, and who received an ATC from the CRC screening outreach program at KPNW.

We utilized 2 observation periods: 1) The “gFOBT era”—a 15-month period during which the gFOBT was routinely offered through ATC outreach from January 1, 2008, through March 31, 2009 (n = 59,876); and 2) a corresponding “FIT era” from April 1, 2009, through December 31, 2009 (n = 32,601), excluding a single month (September 2009) in which KPNW was piloting a different type of ATC vendor.

Survey Sample: Patients eligible to receive the survey about their experiences with both gFOBT and FIT included HMO members who had received an ATC for CRC screening between March and June 2009, had a PCP, and had no diagnosis of dementia in their electronic medical record (EMR). Of a total eligible population of 8077, we mailed the survey to 2000 randomly selected adults; of this population, 1816 (90.8%) were contacted. Reasons for non-contact included incorrect phone numbers and/or addresses; 48.6% (N = 883) responded. We analyzed responses from 192 patients who had previously received both types of fecal tests and answered questions about barriers and facilitators of fecal test completion.

■ **Figure.** Study Population Flow: Cohorts Receiving ATC Reminder Program and Survey Subsample



ATC indicates automated telephone call; BMI, body mass index; CRC, colorectal cancer; gFOBT, guaiac fecal occult blood test; FIT, fecal immunochemical test.

^a20% of patients (N = 18,508) were in both eras.

Survey Design. We included questions both from known validated prior questionnaires and questions that we designed in order to improve understanding of issues that emerged from 4 individual patient interviews. Interviewed patients were selected from lists of patients of PCPs at KPNW who had either the highest screening rates or the lowest screening rates. All 4 patients who agreed to be interviewed had completed screening. Two had higher screening rate PCPs and 2 had lower screening rate PCPs. Interviewees shared their beliefs about and knowledge of colorectal cancer and their perceived individual risk for cancer. Domains of the questionnaire included validated questions about beliefs, worries, and knowledge about CRC screening,³¹⁻³⁶ experiences with specific CRC-screening tests, experiences with healthcare providers and members of the healthcare team,^{37,38} and perceived barriers and facilitators to CRC screening completion.^{13,39-42}

The subset of survey respondents (N = 192) who answered specific questions about both gFOBT and FIT used a Likert scale (1 indicating strong agreement and 5 indicating strong

disagreement) to answer questions about specific test perceptions and experiences of gFOBT and FIT (Table 1).

Study Variables for Cox Proportional Hazards Regression. We extracted the following variables from the EMR: The primary outcome of CRC screening completion (any of gFOBT, FIT, flexible sigmoidoscopy, colonoscopy, or dual contrast barium enema) within 9 months of an ATC, demographic variables (age at the time the ATC was received, gender, race/ethnicity—derived from electronic databases, with missing data geocoded using the census tract block corresponding to each patient’s mailing address), health characteristics (BMI, number of active medications at the time of ATC receipt), “era” (whether they received the gFOBT or FIT as part of the ATC outreach program), and, lastly, the variables describing encounters with the healthcare system. These latter variables included length of KP membership (by 3 years), whether the participant had a PCP (vs none), and whether they had visited their PCP (vs no PCP visit) or a different PCP (vs no “other” PCP visit) within 9 months of the ATC. Healthcare encounters also included visits with medical spe-

Table 1. Proportions of Respondents Answering “Agree” or “Strongly Agree” to Questions About gFOBT and FIT, Respectively, N = 192

Question	gFOBT	FIT	P ^a
a. The instructions are easy to follow	64.6	80.7	<.0001
b. The stool test is unpleasant to complete	52.1	38.5	.0001
c. I believe the test cards are accurate	40.6	41.7	.7237
d. The stool test is convenient	38.0	57.8	<.0001

FIT indicates fecal immunochemical; gFOBT, guaiac fecal occult blood test.
^aBased on McNemar’s tests.

cialists (vs no visit) or with “other” specialists (eg, orthopedic surgery, neurosurgery, optometry) within 9 months of the ATC (vs no “other” specialty visit).

Analysis Approach—Cohort Analysis. Cox proportional hazard models were used to assess the association between factors that may be predictive of completing screening, and to assess whether those factors were associated with FIT or FOBT. Factors related to screening completion (using any screening method) were first tested with bivariate models and significant factors were carried forward into the multivariable model. We entered variables into the multivariable model in steps in the following order: 1) “Screening era” was the first variable examined (FIT vs gFOBT, with the latter as the reference level); 2) Next, we added demographic and health characteristics of the patient (eg, age, gender, number of medications—as a measure of disease burden) and patient healthcare utilization factors

(eg, recent visit to PCP); and 3) significant interaction terms (screening era by patient characteristic/utilization). To aid in interpretation of the interactions, we stratified the data by screening era, and estimated separate multivariable Cox proportional hazard models for the FIT and gFOBT eras (data not shown).

Analysis Approach—Survey Analysis. We assessed the proportions of patients answering either “agree” or “strongly agree” to each question of the 4-part questions about gFOBT and FIT (Table 1). We compared the proportions within each question between the answers for gFOBT and for FIT using a χ^2 test. In all analyses we considered a $P < .05$ to be statistically significant.

RESULTS

Table 2 compares patient demographic and utilization characteristics between those in the gFOBT era and the

Table 2. Patient Characteristics and Healthcare Utilization Measures

	gFOBT Era ^a (N = 59,876)	FIT Era ^a (N = 32,601)
Age, y ^b	60.7 ± 7.5	59.9 ± 6.8
Female, N (%)	32,422 (54.2)	17,682 (54.2)
Length of HMO membership, y ^b	12.1 ± 11.1	12.3 ± 10.9
No. of medications at baseline ^b	3.8 ± 4.1	3.6 ± 3.9
BMI ^b	30.4 ± 6.9	30.4 ± 6.9
Race: White ^c	37,837 (93.6)	19,435 (93.4)
Race: Black ^c	877 (2.2)	452 (2.2)
Ethnicity: Hispanic ^c	956 (3.0)	503 (3.1)
Race: Individual and geo-coded ^c	55,825 (94.0)	30,362 (93.9)
Assigned to a PCP, N (%)	57,166 (95.5)	31,045 (95.2)
≥1 PCP visits, N (%)	27,136 (45.3)	14,286 (43.8)
≥1 Non-PCP visits, N (%)	24,907(41.6)	13,819 (42.4)
≥1 Specialty visits—medical, N (%)	14,734 (24.6)	7481 (23.0)
≥1 Specialty visits—other, N (%)	37,095 (62.0)	18,817 (57.7)

BMI, body mass index; FIT, fecal immunochemical test; gFOBT, guaiac fecal occult blood test; HMO, health maintenance organization; PCP, primary care provider.
^aThere are 18,508 (20.0%) common patients in both eras.
^bMean and standard deviation values are reported.
^cIncomplete data—Percentage of data for individual race: FOBT (68%) and FIT (64%); ethnicity: FOBT (54%) and FIT (49%); individual and geo-coded race: 99% in both eras.

■ **Table 3.** Cox Proportional Hazards Regression Comparing the Association of Fecal Test (FIT vs gFOBT) With CRC Screening Completion Within 9 Months of an ATC

Variable	HR	95% HR Confidence Limits		P
Step 1: Era—FIT (unadjusted)	1.33	1.30	1.36	<.0001
Step 2: Era—FIT (adjusted for all characteristics below)	1.40	1.37	1.43	<.0001
Patient characteristics				
Age by 10 y	1.25	1.23	1.27	<.0001
Female	0.95	0.93	0.98	<.0001
Membership by 3 y	1.01	1.01	1.02	<.0001
No. of medications	0.999	0.996	1.002	.4162
BMI by 5 units	0.976	0.968	0.984	<.0001
Utilization measures				
Has a PCP	1.11	1.05	1.18	.0002
≥1 Other PCP visits	1.43	1.39	1.46	<.0001
≥1 Medical specialty visits	1.25	1.22	1.28	<.0001
≥1 Surgical and other specialty visits	1.70	1.65	1.74	<.0001

ATC indicates automated telephone call; BMI, body mass index; CRC, colorectal cancer; FIT, fecal immunochemical test; gFOBT, guaiac fecal occult blood test; HR, hazard ratio; PCP, primary care provider.

FIT era. The mean values and standard deviations in the table demonstrate the cohorts to be similar. In the gFOBT era, 28.3% completed stool testing, 4.1% flexible sigmoidoscopy, and 4.9% colonoscopy. In the FIT era, 37.2% completed stool testing, 1.9% flexible sigmoidoscopy, and 5.9% colonoscopy.

Table 3 displays the results of the Cox proportional hazards regression, comparing the association of fecal test (FIT vs gFOBT) with CRC screening completion within 9 months of an ATC. First, we considered only the association of fecal test era with screening completion; those in the FIT era were more likely to complete screening than those in the gFOBT era (hazard ratio [HR] = 1.33; 95% confidence interval [CI] 1.30-1.36, $P < .0001$). Results of step 2 of the regression model demonstrate that offering FIT was associated with increased screening completion, even after adjusting for any differences in patient characteristics and utilization variables (HR = 1.40; 95% CI 1.37-1.43, $P < .0001$). Patient age, gender, length of KP membership, number of medications, and BMI were each bivariately associated with screening completion using a fecal test; however, race was not significantly related to screening completion and thus race was not included in the multivariable model. Being older, male, having a lower BMI, having longer length of KP membership, having an assigned PCP, visiting a PCP other than one's assigned PCP, or having a medical specialty visit or any other type of specialty visit within 9 months following the call were all associated with increased screening completion.

In step 3 of the analysis, we found significant interactions with “screening era” for certain variables: age, gender,

number of medications, and having a PCP visit within the prior 9 months. **Table 4** presents the final model, including significant interaction terms. Older age, female gender, and increased number of medications were each more strongly associated with completion of screening in the FIT era than in the gFOBT era. However, visiting a PCP or other non-medical specialist was more strongly associated with screening completion in the gFOBT era than in the FIT era. In stratified models (not shown), the HR (controlling for the other variables in the model) for age in the gFOBT era was 1.20; that is, every additional 10 years of age increased the likelihood of completing screening by 20% during the gFOBT era. In the FIT era, the HR for age was 1.35 years; for every additional 10 years of age a person was 35% more likely to complete screening during the FIT era. Therefore, the change from gFOBT to FIT improved screening likelihood in older compared with younger patients. Females were 7.2% less likely to complete screening compared with males during the gFOBT era (31.7% vs 39.1%) and only 0.6% less likely (32.4% vs 37.9%) in the FIT era; controlling for other variables in the model and screening rates were no longer significantly different between men and women in the FIT era ($P = .756$). Having a PCP increased the likelihood of screening by 22.4% in the gFOBT era, but decreased this likelihood by 2.6% in the FIT era. However, having a PCP was no longer significant in the FIT era. Lastly, having at least 1 “other specialty” visit improved screening completion rates during both eras, but was more strongly associated with completion in the gFOBT era (increasing likelihood of screening by 85.6% in the gFOBT era and by 49.5% in the FIT era).

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Table 4. Cox Proportional Hazards Regression Comparing the Association of Multiple Variables, Including Interactions With Type of Fecal Test (“Era”), With CRC Screening Completion Within 9 Months of an ATC

Variable	HR	95% HR Confidence Limits		P
Era-FIT	0.89	0.70	1.13	.3449
Patient characteristics				
Age by 10 y	1.20	1.18	1.22	<.0001
Era × age	1.12	1.09	1.16	<.0001
Female	0.93	0.90	0.96	<.0001
Era × gender	1.07	1.03	1.12	.0002
Membership by 3 y	1.01	1.009	1.02	<.0001
No. of medications	0.996	0.992	0.999	.0202
Era × no. of medications	1.01	1.00	1.01	.0087
BMI by 5 units	0.97	0.96	0.98	<.0001
Era × BMI by 5 units	1.01	1.00	1.03	.1575
Utilization measures				
Has a PCP	1.23	1.14	1.33	<.0001
Era × has a PCP	0.79	0.70	0.88	<.0001
Other PCP visits	1.43	1.39	1.46	<.0001
Medical specialty visits	1.25	1.22	1.29	<.0001
Surgical and other specialty visits	1.86	1.79	1.92	<.0001
Era × surgical and other specialty visits	0.81	0.77	0.85	<.0001

ATC indicates automated telephone call; BMI, body mass index; CRC, colorectal cancer; HR, hazard ratio; PCP, primary care provider.

The survey subset of respondents was similar in age (mean 59.1 ± 4.9 years) and length of membership (mean 13.6 ± 10.6 years) to those in both of the larger cohorts, but had a greater proportion of women (68.2% compared with 54.2%). Table 1 shows the proportion of respondents answering “agree” or “strongly agree” to each of the 4 survey questions. The percent of respondents (80.7%) agreed that the instructions for FIT were easy to follow, whereas 64.6% agreed that the instructions for gFOBT were easy to follow ($P < .0001$). Also, a significantly greater proportion of respondents agreed that the stool test was unpleasant to complete for gFOBT (52.1%) compared with FIT (38.5%) ($P < .0001$). A significantly greater proportion of respondents agreed that the stool test was convenient for FIT (57.8%) compared with gFOBT (38.0%) ($P < .0001$). There was no difference in the perceived accuracy of the stool test between gFOBT (40.6%) and FIT (41.7%) ($P = .7237$).

DISCUSSION

We found that changing from gFOBT to FIT in an integrated care delivery system improved the likelihood of screening by 8.9% overall. Although our study could not show causality, and the screening improvement was modest, based on other literature and our findings, we concluded that systemwide adoption of FIT results likely was responsible for the observed increase. The patients’ survey responses—indicating

that FIT was less unpleasant, more convenient, and easier to complete than gFOBT—bolster this conclusion.

Our retrospective analysis of screening completion rates within a large ($N = 92,477$) cohort illustrates that older age was associated with increased screening utilization after the switch from gFOBT to FIT. Survey results may explain the greater uptake of FIT in this population, as prior studies indicate that adults aged 65 years and over report unpleasantness and discomfort as barriers to test completion.⁴³ Also, as lower educational attainment is also known to be associated with decreased screening in this age group,^{40,41,44-52} the increased usability of FIT may also have facilitated screening completion.

Although women tended to complete fewer fecal screening tests than men in both time periods, there was a relative increase in female participation in screening when FIT was offered. This is an important finding because women historically are less inclined to complete endoscopy than men, citing embarrassment,⁵³ and often request a female endoscopist.⁵⁴⁻⁵⁹ Also, enthusiasm for gFOBT in women seems to be waning. In earlier studies, more women reported completing gFOBT than men,⁶⁰ whereas in later studies, women reported completing gFOBT and colonoscopy equally⁶¹ or less often^{62,63} than did men. The advent of a more accurate stool test that is easier to complete may help raise CRC screening rates in women.

Perhaps the most significant finding of our study relates to the decreased association between FIT screening and an of-

fice visit, compared with gFOBT. Even as screening completion increased with adoption of FIT, it became more weakly associated with having a PCP, or with visits to any type of healthcare provider. This finding contrasts with findings of numerous published studies demonstrating the influence of physician recommendation, and of having a usual care provider, on completion of screening.^{60,64-66}

Strengths of this study include robust data from our EMR, large cohort size, and the observation of screening rates in a natural setting. The main limitation of this study is that dissemination of fecal testing in communities where colonoscopy is clearly favored may not be as easy to implement, limiting generalizability. Also, we did not include measures of socioeconomic status in our analysis. Lastly, the outcome of interest was screening with any test, not fecal testing only. This notwithstanding, our analyses indicated that the increase in overall CRC screening was mainly a result of an increase in FIT testing, not an increase in other exams. Although our study showed only a modest increase in screening completion due to the switch from gFOBT to FIT, our results indicate that FIT may have acceptability in certain populations that may have been reluctant to screen, such as women. Campaigns targeting the ease of use of FIT may be successful in these populations.

CONCLUSIONS

This retrospective study of a large cohort in an integrated care system demonstrates that adoption of a 1-sample FIT to replace gFOBT was associated with modestly increased colorectal cancer screening rates. Survey results support the conclusion that this change actually led to higher completion rates because patients indicated that the FIT was easier to complete, more convenient, and less unpleasant than gFOBT testing. A centralized outreach program through the mail may be more feasible with FIT than with gFOBT, and may be particularly successful in certain populations, ie, women and the elderly, compared with gFOBT. Such programs may enable dissemination of fecal tests to rural and underserved populations, with follow-up colonoscopy reserved for those with a positive screening FIT.

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