

A System-Based Intervention to Improve Colorectal Cancer Screening Uptake

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Colorectal cancer is the fourth most frequently diagnosed cancer and the second leading cause of cancer death in the United States.¹ Randomized controlled trials of guaiac-based fecal occult blood tests (gFOBTs) have shown that screening significantly reduces colorectal cancer incidence and mortality.²⁻⁵ Although mortality trends for colorectal cancer are decreasing,⁶ there is considerable room for improvement because only about half of eligible adults are current with colorectal cancer screening.⁷ Consequently, most cancers are being detected at regional or distant stages, for which treatment is less effective and more expensive.⁶ Barriers to achieving colorectal cancer screening are numerous and include health system, provider, patient, and test factors.⁸

One system barrier arises from relying on routine physician office visits to implement screening. Interventions involving health system organizational changes, including the use of separate prevention clinics, direct patient reminders, and designation of nonphysician staff to perform prevention activities, are effective in increasing screening uptake.⁹ A “new model of primary care delivery” based on the chronic care model¹⁰ has been proposed to guide system changes to improve colorectal cancer screening rates.¹¹ Important components of this model are an emphasis on using information systems to identify and remind patients who are due for screening, to track results, and to drive a team approach that allows for non-visit-based delivery of care.

The New Mexico Veterans Affairs (VA) Health Care System relies on patient visits to trigger screening alerts to implement screening, usually with gFOBT. Our group conducted a randomized controlled trial to compare testing adherence between fecal immunochemical tests (FITs) and gFOBTs; results showed greater adherence with FITs and are described elsewhere.¹² To enroll patients for the intervention trial, we used the VA electronic health record system, the Veterans Health Information Systems and Technology Architecture (VistA), which allowed us to identify the entire cohort of New Mexico VA Health Care System patients who were eligible for colorectal cancer screening. We randomly selected a sample of 50.0% of these patients to be invited for the intervention study. However,

this strategy also allowed us to identify several control groups who would require clinic visits to initiate screening (Figure). Therefore, we performed a secondary analysis of our study

Objective: To determine whether mailing guaiac-based fecal occult blood tests (gFOBTs) directly to patients who are due for colorectal cancer screening would achieve higher screening uptake than using visit-based screening.

Study Design: Comparative effectiveness analysis.

Methods: We used an electronic medical record to identify 7053 New Mexico Veterans Affairs Health Care System patients aged 50 to 80 years who were due for screening in 2008. We invited 3869 randomly selected patients to participate in a randomized controlled trial comparing adherence with different fecal blood tests; 202 intervention patients were assigned to receive mailed gFOBTs. We identified the following 3 control groups who could receive only visit-based colorectal cancer screening: 3184 individuals who were not invited for the randomized controlled trial (control group 1), 2525 individuals who did not respond to invitations to participate in the randomized controlled trial (control group 2), and 255 individuals who could not be contacted (control group 3). We measured gFOBT screening within 3 months after enrollment in the intervention group, as well as gFOBT or colonoscopy screening within 6 months of identification as a control subject. We compared screening across groups using multivariate logistic regression analysis to adjust for sex, race/ethnicity, clinic site, previous gFOBT, and comorbidities.

Results: Colorectal screening occurred less often in each of the control groups (in 18.6% of control group 1, in 14.3% of control group 2, and in 18.8% of control group 3) than among patients mailed a gFOBT (48.5%). Adjusted odds ratios for screening among the control groups were all less than in the intervention group (adjusted odds ratios, 0.25, 0.19, and 0.23, respectively; all, $P < .001$).

Conclusion: Using an electronic medical record to identify screening-eligible patients and mailing them gFOBT cards achieved higher colorectal screening uptake than performing visit-based screening.

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Take-Away Points

Visit-based approaches to implementing cancer screening are inefficient.

- Visit-based approaches may not coincide with due dates for providing preventive services, and they overselect for sicker patients, who are more frequently seen in clinic but are less likely to benefit from preventive services.
- An electronic health record enables a healthcare system to identify the entire population of patients who are due for screening and facilitates screening efforts that directly reach these patients whether or not they are being routinely seen in clinic.

Raymond G. Murphy VA Medical Center in Albuquerque, New Mexico, and community-based outpatient clinics (CBOCs) in Artesia, Gallup, Raton, Santa Fe, and Farmington, New Mexico. These primary care clinics were staffed by 36 healthcare providers, including 8 working in the CBOCs. The study was approved by the Raymond G. Murphy

data to evaluate whether using the electronic health record to identify eligible patients and then to directly mail gFOBT kits to enrolled patients would increase screening uptake compared with usual care screening that is based on clinic visits.

VA Medical Center Research and Development Committee and the University of New Mexico Human Research Review Committee, Albuquerque. The clinicaltrials.gov identifier is NCT00692211.

METHODS

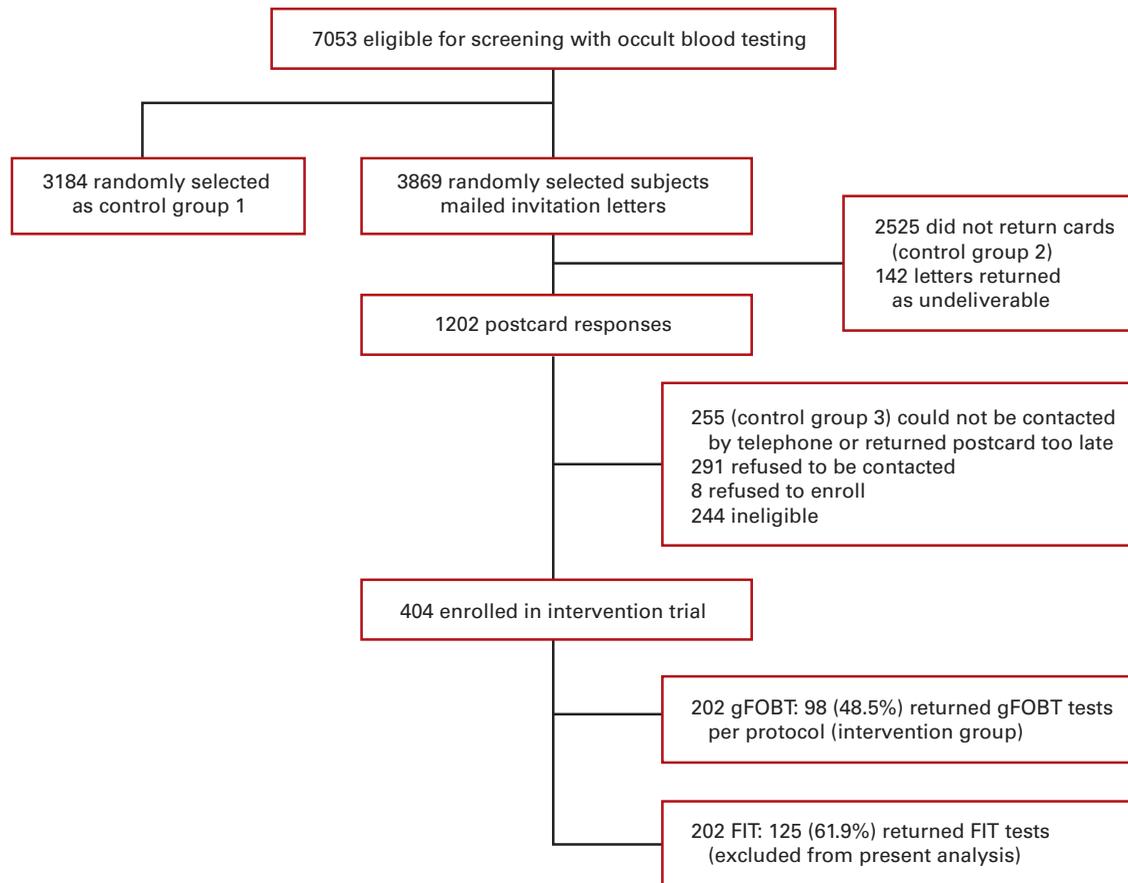
Setting

The study setting was the New Mexico VA Health Care System, including primary care clinics and laboratory at the

Participants

We used VistA files, including demographics, problem lists, procedure codes, pathology records, and screening reminders, to identify eligible patients. Inclusion criteria were active enrollment in a VA primary care clinic, age 50

■ **Figure.** Consolidated Standards of Reporting Trials diagram of study enrollment, New Mexico Veterans Affairs Health Care System, 2008



gFOBT indicates guaiac-based fecal occult blood test; FIT, fecal immunochemical test.

to 80 years, and status of being due for colorectal cancer screening, for which gFOBT was appropriate. We used *Current Procedural Terminology* codes to exclude patients who had undergone colonoscopy in the past 10 years, flexible sigmoidoscopy in the past 5 years, or barium enema in the past 5 years. We used a laboratory results file to exclude patients who had undergone gFOBT in the past year and *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* and *Systematized Nomenclature of Medicine* codes to exclude patients with any history of adenomatous polyps, colorectal cancer, inflammatory bowel disease, or terminal illness.

Recruitment. Recruitment was conducted in 2 phases. We initially identified 6405 patients who were eligible for screening on May 19, 2008, and did not have an upcoming primary care appointment in the next 2 months. This exclusion was to allow sufficient time to contact and enroll patients. We randomly selected 3221 patients for the intervention study and 3184 patients as control subjects using a random number generator.

We asked primary care providers to identify any patients for whom fecal blood test screening would be inappropriate. We then mailed cover letters to 3100 potential patients from their primary care providers describing the study and asking them to return a postcard if they were interested in participating. We called interested patients, confirmed their eligibility, and enrolled those wishing to participate.

Unexpected delays in enrolling patients prompted a second phase of recruitment in August 2008, when we identified another 5029 eligible patients. We randomly selected 1226 to be contacted. After obtaining approval from the primary care providers, we mailed invitation letters to 1088 patients. Overall, for the 2 phases we identified 7053 unique patients who were eligible for colorectal cancer screening and mailed 4188 letters to 3869 of these patients (Figure). We ended enrollment on December 15, 2008.

Intervention Patients. We used a Web-based random number generator (<http://www.randomizer.org/>) to randomly assign patients ($n = 404$) in groups of 8 to FIT kits (2 sample collectors) or to gFOBTs (3 cards). Assignments were based on consecutively returned postcards that contained only unique study identification numbers. We sent consent forms and Health Insurance Portability and Accountability Act of 1996 forms with the test kits along with an envelope addressed to the laboratory with prepaid postage for returning the test kits and regulatory forms. Herein, we evaluate screening uptake only in the gFOBT arm of the study because this was the only fecal blood test available to patients in the control groups. In addition, because screening adherence was higher among patients receiving FITs,¹² we would

bias results in favor of the intervention by including them in the analyses.

Control Subjects. We created 3 usual care control groups. Patients in these groups would be offered colorectal cancer screening when they were seen in clinic and the electronic health record indicated that they were due for screening. The screening reminder is based on the date of the most recent fecal blood test, lower endoscopic procedure, or barium enema; the screening reminder excludes patients who require surveillance testing based on previously diagnosed colorectal neoplasia. The first control group was composed of 3184 patients who were not randomly selected to be contacted for the intervention study. A second control group was composed of 2525 patients who were contacted for the intervention study but did not return a postcard regarding their interest in participating in the study (and did not live out of state [$n = 29$] or have their invitation letter returned as undeliverable [$n = 113$]). Overall, 1202 patients (31.1%) responded to an invitation letter by returning a postcard, including 291 who refused to participate. The third control group was composed of 255 patients who returned a postcard indicating interest in participating in the study but could not be enrolled because we could not reach them by telephone ($n = 246$) or their postcard was returned after enrollment ended ($n = 9$).

Study Procedures

Baseline Data Collection. We used VistA to collect data for all intervention and control subjects, including age when identified as eligible for screening, sex, race/ethnicity (which is not routinely collected from patients), clinic site, gFOBTs during the previous 3 years, and the number of comorbidities based on ICD-9-CM problem list counts.

Stool Testing. Patients received gFOBT cards (Hemoccult II; Beckman Coulter, Fullerton, California). Patients were instructed to avoid aspirin (acetylsalicylic acid) and other nonsteroidal anti-inflammatory drugs, as well as rare meat, vitamin C, and foods containing peroxidase during the 3-stool collection period. All gFOBT cards were interpreted visually for positivity after adding developer.

Outcome Measurements. We used the VA electronic health record laboratory file to track gFOBT completion among patients in the gFOBT arm of the intervention trial and among control subjects. We also used *Current Procedural Terminology* codes to capture data on colonoscopies performed among control subjects. The New Mexico VA Health Care System does not perform flexible sigmoidoscopy or barium enemas for colorectal cancer screening. We collected testing data for control groups 1 and 2 for 6 months after identification as due for screening. For control group

Table 1. Baseline Characteristics of Guaiac-Based Fecal Occult Blood Test (gFOBT) Intervention Group and Control Groups, New Mexico Veterans Affairs Health Care System, 2008^a

Variable	gFOBT				P
	Intervention Group (n = 202)	Control Group 1 (n = 3184)	Control Group 2 (n = 2525)	Control Group 3 (n = 255)	
Age, mean (SD), y	63.9 (7.3)	63.0 (7.9)	62.7 (7.9)	62.8 (7.2)	.10 ^b
Male sex, No. (%)	199 (98.5)	3069 (96.4)	2425 (96.0)	250 (98.0)	.14 ^c
Race/ethnicity, No. (%)					.001 ^c
Non-Hispanic white	42 (20.8)	539 (16.9)	474 (18.8)	36 (14.1)	
Hispanic	15 (7.4)	500 (15.7)	403 (16.0)	42 (16.5)	
Other	11 (5.4)	191 (6.0)	178 (7.0)	27 (10.6)	
Unknown	134 (66.3)	1954 (61.4)	1470 (58.2)	150 (58.8)	
CBOC, No. (%)	57 (28.2)	1108 (34.8)	748 (29.6)	95 (37.3)	<.001 ^c
Previous gFOBT, No. (%)	119 (58.9)	1311 (41.2)	962 (38.1)	124 (48.6)	<.001 ^c
Comorbidities, median (interquartile range)	9.0 (6.0-13.0)	9.0 (6.0-13.0)	9.0 (6.0-14.0)	9.0 (6.0-13.0)	.20 ^d

CBOC indicates community-based outpatient clinic.
^aControl group 1 was not invited for the randomized controlled trial (RCT), control group 2 did not respond to the invitation for the RCT, and control group 3 could not be contacted.
^bOne-way analysis of variance.
^c χ^2 Test.
^dKruskal-Wallis test.

3, we collected testing data for 6 months after receipt of the postcard indicating interest in participating in the study. We referred patients in the intervention study with positive gFOBT results for colonoscopy.

Statistical Analysis

Baseline Statistics. We used descriptive statistics with 95% confidence intervals to characterize patients in the gFOBT arm of the intervention study versus the usual care control groups. Differences across groups were evaluated using analysis of variance for normally distributed continuous variables, Kruskal-Wallis test for skewed data, and χ^2 test for categorical variables.

Outcomes. We used multivariate logistic regression analysis to compare the proportion of intervention patients completing protocol gFOBTs within 3 months after enrollment in the intervention group (excluding 13 gFOBTs ordered by primary care providers) versus control subjects completing gFOBT or colonoscopy screening within 6 months of identification as a control subject. We adjusted for demographics (age, sex, and race/ethnicity), clinic site, previous gFOBT, and ICD-9-CM comorbidities. We modeled the square root of the comorbidity counts because of the skewed distribution. *P* <.05 was considered statistically significant.

RESULTS

Baseline characteristics of the cohort are given in **Table 1**.

Most patients were middle-aged men with multiple comorbidities. Compared with intervention patients, control subjects were less likely to have had previous gFOBTs, more likely to receive care in a CBOC, and less likely to be identified as being of non-Hispanic white race/ethnicity.

The proportion of patients assigned to receive gFOBTs in the intervention trial who completed tests within 3 months was 48.5% (98 of 202). By comparison, 18.6% (591 of 3184) in control group 1 completed testing within 6 months, including 490 tested with gFOBT alone, 66 with colonoscopy alone, and 35 with both tests. In control group 2, the proportion was 14.3% (361 of 2525) who underwent testing, including 313 tested with gFOBT alone, 45 with colonoscopy alone, and 3 with both tests. In control group 3, the proportion was 18.8% (48 of 255) who underwent testing, including 43 tested with gFOBT alone and 5 with colonoscopy alone. Colorectal cancer testing uptake was significantly lower in each of the control groups compared with the intervention group (*P* <.001 for all comparisons). Depending on the control group, the number needed to mail a gFOBT to achieve 1 additional completed colorectal cancer screening ranged from 2.9 to 3.3. Multivariate logistic regression analysis showed that the odds for completing a screening test were significantly lower for all 3 control groups compared with the referent gFOBT arm of the intervention (**Table 2**). Other significant predictors included receiving primary care at a CBOC, completing previous gFOBTs, and having more comorbidities.

DISCUSSION

We found that using an electronic health record to identify patients who were eligible for colorectal cancer screening and mailing them gFOBT cards achieved significantly higher screening uptake than a usual care approach to screening based on clinic visits. Our screening intervention adopted important elements of the new model of primary care delivery,¹⁰ particularly the use of information systems to identify eligible patients to initiate screening, monitor results of screening tests, and refer patients with abnormal test results for diagnostic procedures.¹¹ Klabunde and colleagues noted the critical role for electronic health records in the care delivery model: “[T]hey improve the practice’s ability to systematically identify and track patients for various risks and services....

Such systems can identify those eligible for colorectal cancer (CRC) screening, facilitate the use of reminder and recall systems, and enable monitoring of screening utilization, delivery, and outcomes for purposes of performance measurement and quality improvement.”^{11(p1197)}

Using the electronic health record to create a colorectal cancer screening registry represents an important departure from a hospital’s usual care model of using the electronic health record just to provide screening reminders at the time of a clinic appointment.¹³ By dissociating screening from visits, we are better able to offer timely screening to a population of patients. Given the increasing demands for providing preventive services in primary care, our study also demonstrated the success of shifting responsibility for preventive services away from the primary care provider. We effectively modeled a team approach to care delivery because the study nurse and physician implemented screening, while keeping the primary care providers fully apprised of test results and referrals.

The benefits of mailing stool tests directly to patients have been demonstrated in other studies, although not in VA settings. Baron and colleagues¹⁴ conducted a meta-analysis of client-directed interventions to increase community access to colorectal cancer screening. Mailing gFOBT kits was cat-

■ **Table 2.** Multivariate Logistic Regression Models to Evaluate the Primary Care Model

Variable	Adjusted Odds Ratio (95% Confidence Interval) for Being Screened	P
Study group^a		<.001
gFOBT intervention group	1 [Reference]	
Control group 1	0.25 (0.19-0.34)	
Control group 2	0.19 (0.14-0.26)	
Control group 3	0.23 (0.15-0.36)	
Age, per 10 y	1.03 (0.95-1.13)	.45
Sex, female vs male	1.27 (0.88-1.85)	.20
Race/ethnicity		.37
Unknown	1 [Reference]	
Non-Hispanic white	1.10 (0.92-1.33)	
Hispanic	1.18 (0.97-1.42)	
Other	0.99 (0.74-1.33)	
Hospital, clinic site, CBOC vs VA	1.50 (1.30-1.73)	<.001
Comorbidities, square root	1.21 (1.12-1.30)	<.001
Previous gFOBT	3.33 (2.88-3.83)	<.001
CBOC indicates community-based outpatient clinic; gFOBT, guaiac-based fecal occult blood test; VA, Veterans Affairs.		
^a Control group 1 was not invited for the randomized controlled trial (RCT), control group 2 did not respond to the invitation for the RCT, and control group 3 could not be contacted. .		

egorized as an intervention to reduce structural barriers. All studies reported increased gFOBT completion, with a median change of 16.1 percentage points (interquartile range, 12.1%-22.9%) compared with control subjects requiring clinic visits to implement screening or who received letters asking them to request tests. Mailings were more successful if they provided a return mailer and postage. The meta-analysis did not find benefit for interventions designed to reduce out-of-pocket costs for colorectal cancer screening.

Other mailed interventions to increase screening have also been effective. Lewis and colleagues¹⁵ increased overall screening rates by mailing a package to randomly selected patients who were due for screening that included a letter from their primary care provider, a decision aid, and instructions for obtaining a screening test without an office visit (either gFOBT or lower endoscopy). Within 5 months of mailing the intervention, 14.6% (20 of 137) of the intervention group had undergone screening compared with only 4.0% (4 of 100) of a wait-listed control group ($P = .01$). Denberg and colleagues¹⁶ conducted a randomized controlled trial to evaluate the added benefit of mailing information brochures to patients referred for screening colonoscopy. The intervention increased adherence by 11.7 percentage points (95% confidence interval,

5.1%-18.4%), from 59.0% to 70.7%, compared with a usual care control group.

As predictive factors for screening adherence, we also identified undergoing previous gFOBT, receiving care at a rural clinic, and having higher comorbidity counts. Our findings are consistent with previous studies in the literature. Myers and colleagues¹⁷ showed that completing a first round of gFOBT was the strongest predictor for adherence with continuous testing, particularly for patients older than 65 years. Many patients seen at the CBOCs have dual sources of care, so the VA visit often focuses on preventive services. A meta-analysis⁹ showed that having a prevention visit is associated with increased rates of cancer screening. Finally, Walter and colleagues¹⁸ noted that sicker patients with more frequent clinic visits undergo more screening than patients with fewer visits. More visits provide more opportunities to be offered screening, especially in the VA system, where colorectal cancer screening is a quality indicator.

An important issue for a healthcare organization that is considering a population approach to screening is cost-efficient use of resources. We estimated that the incremental cost for achieving an additional completed screening test was approximately \$240. This is based on 5% of a physician's time, 15% of a nurse's time, a \$5 cost per screening (test kit and postage), and the mailing of 202 test kits, resulting in a mean cost per providing a screening test of \$79. The \$240 estimate is based on needing to mail a test kit to 3 patients to achieve 1 additional completed colorectal cancer screening compared with usual care. Part of the personnel time was dedicated to research regulatory issues that would not be required in routine clinical care. However, the electronic health record was already established, and the programming and laboratory support were part of routine operations. This is a crude estimate because the study was not designed to measure costs, which could differ for other healthcare systems. Clearly, these results would need to be confirmed in a randomized controlled trial of a population-based screening approach versus usual care that systematically captures the costs needed to achieve additional screening uptake, as well as detection of advanced colorectal neoplasia.

Our study had some potential limitations. The intervention group that received mailed gFOBTs was highly selected; patients had to respond to a postcard expressing their interest in the study, be reachable by telephone, be eligible for screening, and be willing to participate. This is why we chose 3 separate control groups, including control group 1 who were eligible for screening at the study inception but were not randomly selected to be invited to participate, control group 2 who did not return postcards regarding their interest in the study, and control group 3 who returned postcards express-

ing interest but could not be contacted. We tracked screening for 6 months following the selection of patients for control groups 1 and 2 or following the date of postcard receipt expressing interest for control group 3, but we tracked screening for only 3 months in the intervention study. Finally, we counted colonoscopies toward screening uptake in the control groups. We chose the 3-month cutoff to isolate the effect of mailing the gFOBT cards; after 3 months, some patients subsequently received gFOBTs from their providers. Even during the 3-month follow-up period, we counted only gFOBTs completed as part of the study protocol. Regardless, we were able to demonstrate significantly higher screening uptake in the intervention group even after adjusting for demographic and clinical data. However, results may not be applicable to non-veterans or to women, and we could not determine whether our strategy would be effective for repeated screening.

CONCLUSIONS

We showed that a primary care delivery model based on using an electronic health record to identify eligible patients and then directly mailing them gFOBT kits might be a more efficient method for achieving colorectal cancer screening than a usual care model that relied on an office visit to implement screening. The delivery model supports a population-based approach to implementing screening and then monitoring utilization and outcomes. Further research is required to determine the cost-effectiveness of this care model, particularly for systems that largely use annual fecal blood tests for colorectal cancer screening. Cost analyses will need to account for the increased use of FITs, which are more expensive than the gFOBTs used in our study but are also associated with increased adherence¹² and greater diagnostic yield for advanced colorectal neoplasia.¹⁹

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