Randomized Controlled Trial of the Impact of Intensive Patient Education on Compliance with Fecal Occult Blood Testing

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BACKGROUND: Randomized controlled trials have demonstrated that fecal occult blood testing (FOBT) reduces colorectal cancer (CRC) mortality. However, patient compliance with FOBT is low and this is one of the major barriers to CRC screening.

OBJECTIVE: To determine whether intensive patient education increases FOBT card return rates.

DESIGN: Randomized controlled trial.

SETTING: Department of Veterans Affairs primary care clinic.

PARTICIPANTS: Seven hundred eighty-eight patients who were referred for FOBT.

INTERVENTIONS: Patients were randomly allocated to receive either intensive ($n=396$) or standard ($n=392$) patient education. Patients in the intensive education group received a one-on-one educational session by primary care nurses on the importance of CRC screening, were instructed on how to properly collect stool specimens for FOBT, and were given a 2-page handout on CRC screening. Patients in the standard education group only received the FOBT cards and written instructions from the manufacturer on how to properly collect stool specimens for FOBT.

RESULTS: Patients in the intensive education group were more likely to return the FOBT cards (65.9% vs 51.3%; $P<.001$) and called the clinic with additional questions less often (1.5% vs 5.9%; $P=.001$) than the standard education group. The median time to return the FOBT cards was significantly shorter in the intensive education group (36 vs 143 days; $P<.001$ by log-rank test). However, the proportion of patients who had a positive FOBT did not differ in the two groups (4.6% vs 6.0%; $P=.51$).

CONCLUSIONS: Intensive patient education significantly improved patient compliance with FOBT. Future studies to evaluate additional educational strategies to further improve patient compliance with CRC screening are warranted.

KEY WORDS: randomized controlled trial; colon cancer screening; fecal occult blood testing; primary care; patient education.

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Colorectal cancer (CRC) is the second leading cause of cancer-related death in the United States and a common cause of morbidity and mortality worldwide.¹ In 2004, there were approximately 150,000 newly diagnosed cases of CRC and over 57,000 deaths in the United States alone.¹ Based on compelling evidence that population-based screening can reduce the mortality from CRC,²⁻⁴ the U.S. Preventive Services Task Force,⁵ the American Cancer Society,⁶ the Gastrointesti-

nal Consortium,⁷ and others^{8,9} recommend that all persons 50 years of age and older who are at average risk for CRC receive CRC screening. There are several acceptable approaches to CRC screening, including annual fecal occult blood testing (FOBT), flexible sigmoidoscopy every 5 years, annual FOBT in combination with flexible sigmoidoscopy every 5 years, colonoscopy every 10 years, or barium enema every 5 years.

Despite these recommendations, CRC screening is underutilized. In an analysis of data from the 2001 Behavioral Risk Factor Surveillance System, the Centers for Disease Control and Prevention reported that only 44.6% of adults 50 years of age and older ever had FOBT while an even lower proportion (23.5%) had FOBT within the past year.¹⁰ In a national attempt to improve CRC screening, one of the goals of the Healthy People 2010 objectives is to increase the percentage of adults 50 years of age and older who have received an FOBT within the preceding 2 years to at least 50%.¹¹

The success of any FOBT screening program requires that patients agree to participate in the testing, that they comply with the instructions provided, and that patients with a positive FOBT are willing to undergo more definitive testing for CRC.¹² Collection of stool samples for FOBT is an unpleasant chore and poor patient compliance with this task is one of the major barriers to CRC screening.¹³ In clinical practice, patients often do not receive appropriate CRC education or instructions on how to perform FOBT and are usually given the FOBT cards and told to return them at the next visit or to mail them back to the clinic or laboratory.^{14,15} However, previous studies have shown that educating patients about proper stool sampling is important because sample collection technique can influence results.¹³ To date, few studies have evaluated whether patient education can improve compliance with CRC screening. The purpose of this randomized controlled trial was to determine whether intensive patient education would increase FOBT card return rates and, therefore, improve patient compliance with CRC screening.

METHODS

Study Population

Participants were recruited between August 1 and November 30, 2002 from the primary care clinics at the VA New York Harbor Healthcare System in New York City. Patients were eligible for this study if they were 50 years of age and older, were outpatients seen in the primary care clinic, had an FOBT ordered by their health care provider, and were referred to primary care nursing for patient education and distribution of FOBT kits. At our medical center, all ambulatory patients who have an FOBT ordered by their health care provider are referred to primary care nursing for education on how to properly collect the stool specimens and for distribution of the test kits.

Patients were excluded from this study if they were less than 50 years of age, were inpatients, or refused to participate

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in this study. The Institutional Review Board at our medical center reviewed and approved the research protocol, and all participants consented to study participation.

Study Design

Eligible patients were randomly allocated to receive either intensive or standard patient education. Randomization was performed using sequentially numbered, sealed, opaque envelopes. The primary care nurses were given the sealed opaque envelopes containing the assigned teaching methods, as well as educational materials and standardized data collection sheets. The primary care nurses opened sequential envelopes after eligible patients provided informed consent to participate in the study.

The 12 primary care nurses who participated in this study were trained as a group to provide consistent teaching in intensive and standard FOBT patient education. Prior to the start of the study, a group of primary care nurses and a health education specialist developed a 2-page informational handout on CRC and FOBT for the intensive education group. The educational handout gave specific information on dietary and medication restrictions prior to and during stool collection, how to collect the stool samples, how to complete the FOBT cards, and what to do with the cards after stool testing. In addition, the handout provided a daily schedule for patients to help them properly complete the FOBT cards. This handout was pretested in a group of primary care patients to ensure that it was informative and easy to understand.

In the intensive education group, the patients also received a one-on-one 10- to 15-minute educational session on the importance of CRC screening and FOBT. Patients were instructed how to properly collect stool specimens, prepare the cards for FOBT, and return them to the clinic. The nurses explained how the fecal occult blood test works and what a positive or negative result means. In addition, they explained to patients what would happen if the test was positive (colonoscopy) as well as what would happen if the test was negative (annual FOBT and flexible sigmoidoscopy every 5 years). The patients were given the 2-page informational handout on CRC screening and the nurses answered the patients' questions. All participants were instructed to return the FOBT cards within 2 weeks and to call the clinic if they had any additional questions.

In the standard education group, patients were given the FOBT cards and written instructions on how to properly collect stool specimens, prepare the cards for FOBT, and return them to the clinic. The written instructions consisted of an enlarged version of the manufacturer's instructions that come with the Hemoccult II FOBT kits (Beckman Coulter, Fullerton, CA). Similar to the intensive education group, patients in the standard education group were instructed to return the FOBT cards within 2 weeks and to call the clinic if they had any additional questions. No patient reminders of any type were used in either the intensive or standard education groups.

Baseline data collected on each patient included age, gender, race/ethnicity, current warfarin use, family history of CRC in a first-degree relative, and the number of times that the patient had FOBT in the past. We included data on warfarin use, family history of CRC, and prior FOBT because warfarin may influence FOBT test results and the other factors may affect patient compliance with testing. For each participant, the primary care nurses recorded the group to which the

patient was randomly allocated (intensive vs standard education), the date of enrollment, and the amount of time spent on patient education.

Study Outcomes

The primary outcome of this study was the proportion of patients who returned the FOBT cards within 6 months. A period of 6 months was chosen to allow adequate time for patients to return the FOBT cards to the clinic. All analyses were based on the intention-to-treat principle. Therefore, if a patient did not return the FOBT cards within 6 months, they were censored and considered not returned. In addition, we determined factors associated with successfully returning the FOBT cards.

Secondary outcomes of this study included the amount of time nurses spent on FOBT teaching, the number of telephone calls from patients who had additional questions about how to do the FOBT cards during follow-up, the median time it took for patients to return the FOBT cards, the cost per FOBT card returned, and the frequency of positive FOBT results. An FOBT was considered positive if a positive test was noted on at least one slide on any of the 3 cards in the set.

Nursing costs were calculated by multiplying the amount of time that the nurses spent teaching the patient about CRC screening and FOBT by the average hourly primary care nursing salary, which is \$48.98 (\$37.68 base salary+\$11.30 fringe benefits) per hour at our medical center. In addition, our cost analysis included the cost of the FOBT kits (\$1.98 per patient) and the cost of making the copies of the handouts (\$0.10 per patient). For patients in the intensive education group, we also included the nursing costs for the design and pretesting of the educational materials (8 hours) and for training the nurses (1 hour per nurse). The cost per FOBT card returned was calculated by adding up the total cost for each group and dividing this amount by the number of patients who returned the FOBT cards.

Statistical Analysis

Based on published reports¹⁶ as well as unpublished data from our medical center, we estimated that the FOBT card return rate would be approximately 50.0% in the standard education group. We determined that 388 subjects per group would be required to detect an absolute difference of 10% (assuming FOBT card return rates of 60.0% in the intensive education group and 50.0% in the standard education group) at a power of 80% and a two-tailed α of .05.

Continuous variables were compared using the Student *t* test or the Mann-Whitney U test as appropriate. Data are expressed as means $\pm$ standard deviation (SD) for those variables that were normally distributed, and medians and interquartile range (25th percentile to 75th percentile) for those with a non-Gaussian distribution. Categorical variables were compared using the χ^2 test or Fisher's exact test.

The time taken to return the FOBT cards was estimated using Kaplan-Meier analysis.¹⁷ If the patient did not return the FOBT card by 6 months, that individual was censored at 180 days. The difference in time to return the FOBT cards between the intensive and standard education groups was compared using the log-rank test. Statistical analysis was performed using SPSS software version 12.0 for Windows (SPSS, Chicago, IL) and a two-tailed *P* value of $< .05$ was considered statistically significant.

FIGURE 1. Flow of participants through the study.

RESULTS

Study Participants

Of the 794 participants referred for FOBT, 788 (99.2%) were randomly allocated to receive either intensive or standard patient education (Fig. 1). The baseline characteristics of the subjects were similar in the 396 patients in the intensive education group and the 392 individuals in the standard education group (Table 1). The majority of study participants were male, and the patients were racially/ethnically diverse. Despite a median age of 67 years, more than half of the patients in both groups never had FOBT performed or only had FOBT once in the past.

Primary Outcome

Overall, 462 of the 788 participants (58.6%; 95% confidence interval [CI], 55.1% to 62.1%) returned the FOBT cards within 6 months and the proportion of patients who returned the FOBT cards was significantly higher in the intensive education group than with those who received standard education (65.9% vs 51.3%; $P < .001$).

The proportion of patients who returned the FOBT cards according to demographic and clinical characteristics is shown

in Table 2. Patients between the ages of 60 and 79 years were more likely to return the FOBT cards compared with those 50 to 59 years of age and individuals 80 years of age and older. In addition, the proportion of patients who returned the FOBT cards increased as the number of prior times that the patients had FOBT performed in the past increased.

Secondary Outcomes

The mean amount of time that the nurses spent on FOBT teaching was significantly longer in the intensive education group than in the standard education group (13.2 ± 4.5 vs 8.6 ± 3.8 minutes; $P < .001$), a difference of 4.6 minutes (95% CI, 4.0 to 5.2 minutes). After the initial teaching session, patients in the intensive education group were significantly less likely to call the clinic with additional questions than those in the standard education group (1.5% vs 5.9%; $P = .001$).

Kaplan-Meier analysis of the time to return the FOBT cards is shown in Figure 2. The median time to return the FOBT cards was 36 days in the intensive education group compared with 143 days in the standard education group ($P < .001$ by log-rank test).

Although the mean nursing cost was \$6.33 higher in the intensive education group compared to the standard education group ($\$15.43 \pm \3.66 vs $\$9.10 \pm \3.08 ; $P < .001$), the cost per FOBT card returned was only \$5.67 more costly in the intensive education group ($\$23.41$ vs $\$17.74$).

Among the 462 patients who returned the FOBT cards, 1 or more cards were positive for occult blood in 5.2% (95% CI, 3.4% to 7.6%) of patients. The FOBT was positive in 4.6% of the patients in the intensive education group compared with 6.0% of those in the standard education group ($P = .51$).

DISCUSSION

Screening for CRC presents a unique set of barriers that reduces the number of individuals who participate in FOBT screening programs. The Health Belief Model and social cognitive theories state that patient health prevention behaviors are largely determined by perceived susceptibility and seriousness of a health threat or personal risk.¹⁸ Other tenets of the model are the patients' consideration of benefits and barriers

Table 1. Baseline Demographic and Clinical Characteristics

	Intensive Education (n=396)	Standard Education (n=392)	P Value
Age,* y	67.0 (58.0–75.0)	67.0 (58.0–74.0)	.694
Male gender, n (%)	377 (95.2)	377 (96.2)	.502
Race/ethnicity, n (%)			
Non-Hispanic white	185 (46.7)	190 (48.5)	.584
Non-Hispanic black	147 (37.1)	129 (32.9)	
Hispanic	59 (14.9)	66 (16.8)	
Other	5 (1.3)	7 (1.8)	
Currently taking warfarin, n (%)	29 (7.3)	33 (8.4)	.568
Family history of colorectal cancer, n (%)	28 (7.1)	24 (6.1)	.592
Number of prior FOBTs, n (%)			
None	133 (33.6)	113 (28.8)	.594
1	105 (26.5)	118 (30.1)	
2	78 (19.7)	82 (20.9)	
3	41 (10.4)	44 (11.2)	
4+	39 (9.8)	35 (8.9)	

*Data are expressed as median (25th–75th percentile).

FOBT, fecal occult blood test.

Table 2. Proportion of Patients Returning the FOBT Cards Within 6 Months According to Demographic and Clinical Characteristics

	Proportion Returning the FOBT Cards	P Value
Age, %		.002
50–59 years	50.0	
60–69	63.9	
70–79	64.3	
80+	50.0	
Female gender, %	61.8	.704
Male gender, %	58.5	
Race/ethnicity, %		.655
Non-Hispanic white	59.2	
Non-Hispanic black	58.0	
Hispanic	60.0	
Other	41.7	
Currently taking warfarin, %	64.5	.327
Not taking warfarin, %	58.1	
Family history of CRC, %	63.5	.464
No family history of CRC, %	58.3	
Number of prior FOBTs, %		.002
None	49.6	
1	57.8	
2	63.1	
3	68.2	
4+	70.3	
Intensive education group, %	65.9	<.001
Standard education group, %	51.3	

FOBT, fecal occult blood test; CRC, colorectal cancer.

to action, including interactions with the health care system, adequacy of information to cue action, and self-efficacy or confidence in the ability to successfully take action.¹⁸ Major patient barriers to FOBT testing are consistent with this model and include limited knowledge of CRC and screening tests for CRC, low perception of personal risk for CRC, inconvenience, the perception that FOBT is time consuming, lack of confidence in the ability to do FOBT, aversion to stool testing, and fear of the consequences of screening (cancer fatalism).^{14,16,19–22}

Numerous studies have evaluated patient participation in CRC screening programs and FOBT card return rates and all of these showed that patient adherence was suboptimal.^{16,23–25} Overall, the median compliance rate with FOBT is between 40.0% and 50.0%, depending on the population studied.¹⁶ The compliance rates with FOBT were 59.6% to 75.2% in randomized trials for CRC screening,^{2–4} but were lower in community-based mass screening programs (26.0% to 48.0%).^{24–27} Studies of relatively impersonal or minimal interventions where patients were asked to pick up a test kit or to mail in a reply card in order to receive a test kit reported even lower compliance rates of 10.0% to 30.0%.¹⁶ The 51.3% compliance rate with return of the FOBT cards in the standard education arm in our study was similar to what has been reported in other studies and was nearly identical to the guaiac-based FOBT card return rate of 47.1% in the primary care clinics at the VA Puget Sound Healthcare System.^{16,28}

An important challenge for CRC screening programs is to improve screening participation rates and compliance with FOBT. To date, attempts to promote CRC screening have used both a public health model that targets communities and a medical model that targets individuals, and these studies have been summarized by Vernon.¹⁶ Various patient interventions have been evaluated to increase compliance with FOBT, including telephone reminders and instructional telephone calls, postal re-

FIGURE 2. Kaplan-Meier analysis of time to return FOBT cards. The median time to return the FOBT cards was 36 days in the intensive education group (solid line) compared with 143 days in the standard education group (dashed line), and this difference was statistically significant ($P < .001$ by log-rank test).

mindings, letters signed by personal physicians, interventions based on theories or models of behavior change, and other education strategies.¹⁶ More recently, Pignone et al.²⁹ conducted a randomized, controlled trial to examine whether a strategy to reduce a combination of barriers would increase adherence rates. The investigators evaluated an educational videotape, a brochure for patients, and chart reminders for physicians and found that these additional tools increased FOBT completion rates to 28.5% compared with 20.2% among controls.

Overall, the most intensive patient-directed interventions delivered to a well-defined population of eligible persons rarely increased adherence to FOBT above 50.0%.¹⁶ However, patient education and educational brochures about CRC and the importance of screening can be effective in improving patient knowledge and compliance with FOBT.^{30–32} Our randomized study demonstrated that intensive patient education significantly increased patient compliance with FOBT to 65.9% compared with 51.3% in the control group. Our study expands on previously published data and shows that one-on-one patient education can significantly improve patient compliance with FOBT. The intensive teaching emphasized the importance of the test and may have increased the patients' confidence in their ability to complete the FOBT. Our study showed that teaching patients exactly how to do the test and giving them the time to ask questions while they were at the clinic enabled them to perform FOBT at home and return the cards as requested.

Although our intervention was effective in improving FOBT return rates, one-on-one patient education by registered nurses is costly and time consuming. A substantial proportion of the cost of our intervention was due to the use of registered nurses to individually educate each patient. It may be more cost-effective to utilize less costly health care personnel, such as certified medical assistants. Another alternative is to educate patients in a group setting as opposed to the one-on-one approach used in the present study. Future studies to evaluate the cost and effectiveness of these educational strategies are needed.

Previous studies have shown that patient adherence to repeat annual FOBT is low.³³ Therefore, the long-term success of a CRC screening program will require policy-, institution-,

and system-level changes. Public health programs to increase awareness of CRC screening, as well as a patient educational intervention similar to our intervention combined with clinician education, patient and clinician reminders, and a strong clinician-patient partnership are needed in order to deliver an effective annual FOBT screening program.

The strengths of this study include the large sample size, randomized design with concealed allocation, inclusion of a control group, and long-term follow-up to allow adequate time for participants to return the FOBT cards. However, some limitations also need to be considered in the interpretation of our findings. First, our population included predominantly male subjects who were enrolled at a single VA medical center and compliance rates may differ with females, in other primary care clinics, or in non-VA settings. Second, our study utilized 12 primary care nurses to teach patients and different teaching styles may have impacted patient compliance. Third, health care providers, staff, and patients were not blinded and this may have influenced the effect size of our intervention. Finally, we did not evaluate the reasons for noncompliance in those who did not return the FOBT cards. Therefore, our results may not be fully generalizable to other clinic settings.

In conclusion, patients in the intensive education group were significantly more likely to return the FOBT cards and called the clinic with additional questions less often than those in the standard education group. The question of whether our educational intervention can further increase patient compliance with FOBT when added to patient and clinician reminder systems is an important topic for future investigation. Screening for CRC requires ongoing adherence to be effective and, therefore, further studies are needed to determine whether these behaviors can be sustained over time. In addition, research is needed to identify novel means of reaching persons at risk for CRC who currently are not served or are underserved by the existing health care system.

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