

## Short Communication

# Barriers to Full Colon Evaluation for a Positive Fecal Occult Blood Test

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### Abstract

**Background:** Failure to appropriately evaluate a positive cancer screening test may negate the value of doing that test. The primary aim of this study was to explore the factors associated with undergoing a full colon evaluation for a positive fecal occult blood test (FOBT) in a single Veterans Affairs center.

**Methods:** Medical records of consecutive patients ages  $\geq 50$  years, who had a positive screening FOBT from March 2000 to February 2001, were abstracted. Patient demographics, dates of ordering and doing follow-up test(s), and adherence with scheduled procedures were collected. The primary outcome, full colon evaluation, was defined as having a colonoscopy or double-contrast barium enema plus flexible sigmoidoscopy completed within 12 months.

**Results:** The sample ( $N = 538$ ) was 98% men (58% Caucasian, 29% African-American, and 13% unknown race). Approxi-

mately 77% of the patients were referred to gastroenterology. Ultimately, only 44% underwent full colon evaluation within 12 months. Approximately 20% of the patients failed to attend a scheduled procedure. Referral to gastroenterology and adherence to follow-up appointments were associated with full colon evaluation. There was no association between African-American versus Caucasian race and full colon evaluation.

**Conclusions:** Less than half of the patients with a positive FOBT had a full colon evaluation within 12 months. Multiple failures were identified, including lack of referral for further testing and patient nonadherence. Although the overall performance in evaluating a positive colorectal cancer screening test was poor, no racial disparity was observed. (Cancer Epidemiol Biomarkers Prev 2006;15(6):1232-5)

### Introduction

Colorectal cancer screening is recommended because of the high burden of disease and the proven efficacy of screening to reduce cancer deaths (1, 2). A national survey suggests that only half of the individuals eligible for colorectal cancer screening have had a test within the recommended time interval (3). Among the Veterans Affairs primary care population, the proportion of patients screened has been higher in recent years: 67% to 72% in fiscal years 2004 and 2005 (4). Although increased screening among eligible people is encouraged, the initial screening is only part of the story. The primary benefit of cancer screening is in the early detection of cancer and reduction in mortality from cancer in those patients with a positive screening test. The mortality benefit of screening with fecal occult blood testing (FOBT) was shown in the context of subjects with a positive FOBT undergoing a full colon examination (FCE; refs. 5-7). Guidelines published in 1997 recommended colonoscopy or double-contrast barium enema (DCBE) plus flexible sigmoidoscopy for evaluation of a positive FOBT (1). Revised guidelines published in 2003 emphasized that colonoscopy is the preferred follow-up test for a positive FOBT (8). However, studies in a variety of health care settings suggest that only 25% to 59% (9-12) of positive

FOBTs are followed with appropriate diagnostic tests. One published Veterans Affairs study found 59% follow-up after a positive FOBT at 7 months, suggesting that evaluation following a positive FOBT is suboptimal (13). Details of why FCE does not occur, such as a failure to note positive test, failure to make referral for further testing, or patient nonadherence to recommended procedures, are generally lacking.

We hypothesized that follow-up rates at our Veterans Affairs facility would also be low. Because our data included a time when published guidelines supported either colonoscopy or DCBE plus flexible sigmoidoscopy, we accepted both strategies as FCE. As a secondary analysis, we defined colonoscopy or DCBE alone as FCE. We also sought to explore any racial disparity associated with FCE. It has been reported that the mortality for African-American patients with colorectal cancer is higher than for Caucasian patients with colorectal cancer (14). This racial disparity may be attenuated in the Veterans Affairs system, but it is not eliminated (15). The reasons for this difference in mortality are unknown but, at least in the Veterans Affairs, do not seem to be related to differences in colorectal cancer care, such as surgery, chemotherapy, or radiation therapy (15). As receipt of cancer treatment seems equivalent, differences in colon cancer detection (in the present study via follow-up of positive FOBT) may contribute to the mortality difference if such disparities resulted in diagnosis at a more advanced stage.

### Materials and Methods

**Setting.** This study was a retrospective medical record review conducted at the Durham Veterans Affairs Medical Center (Durham, NC). As with all Veterans Affairs facilities,

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the medical record is electronic. The electronic medical record also allows viewing of clinical data at a Durham Veterans Affairs patient received at any other Veterans Affairs facility. In addition, we have local laboratory and endoscopy electronic databases. The primary care clinics have a standard protocol for FOBT, in which a nurse gives patients the three stool cards and instructions. The patients collect the stool at home and return the stool cards to the Veterans Affairs facility by mail. All FOBTs are processed and interpreted in the central clinical laboratory. A positive test will trigger an electronic laboratory result alert to the ordering provider. A colonoscopy or flexible sigmoidoscopy requires a gastroenterology consult request to be scheduled. A DCBE requires a radiology order.

**Sample Size.** Our sample size requirements were based on testing for a racial difference in receiving a FCE. We assumed that the racial distribution for patients with a positive FOBT would be similar to that of the clinical population (approximately 70% Caucasian, 24% African-American, and 6% other). We estimated the proportion of FCE to be between 40% and 70% for Caucasians. Based on tests for a difference in proportions between the racial groups, we estimated that between 404 and 726 subjects would provide 80% power to detect an 11% to 15% difference in FCE between African-American and Caucasian patients. To avoid bias resulting from potential seasonal variation in patient evaluation (such as housestaff turnover), we evaluated the medical records of all patients over a 12-month consecutive period (March 1, 2000 and February 28, 2001) who met our inclusion criteria. Subjects were included if they had a positive FOBT that was ordered from a primary care clinic between March 1, 2000 and February 28, 2001 and if they were  $\geq 50$  years of age (recommended age of colorectal cancer screening).

**Variables.** If any of the three cards were positive for occult blood, then the FOBT result was "positive." The medical records were reviewed for up to 18 months following the positive FOBT result date and abstracted for the following: subject race, age, gender, and marital status; primary care clinic (usually a single provider) from which FOBT was ordered; whether referral to gastroenterology occurred; any "no shows" (patient failed to appear) for a procedure or "cancellations" (patient contacted clinic to cancel the appoint-

**Table 1. Characteristics of Durham Veterans Affairs Medical Center patients with a positive FOBT and associations with full colon evaluation within 12 months**

Variable*	Overall (N = 538)	FCE <sup>†</sup>	P <sup>‡</sup>
Race			
White	312	143 (45.8%)	0.0006
Black	154	77 (50%)	
Missing	72	17 (23.6%)	
Gender			
Male	528	232 (43.9%)	0.7
Female	10	5 (50%)	
Married			
Yes	340	152 (44.7%)	0.88
No	190	82 (43.1%)	
Unknown	8	2 (25%)	
Referral for GI Consult			
Yes	415	237 (57.1%)	<0.0001
No	123	0 (0%)	
No show/cancel			
Yes	108	7 (6.5%)	<0.0001
No	430	230 (53.5%)	
Age, mean (SD)	67.2 (9.1)	67 (9)	0.58

\*Data sources medical record (1995-2003), laboratory database (2000-2001).

<sup>†</sup>Percentage of each category that had undergone FCE within 12 months.

<sup>‡</sup>P<sub>s</sub> reflect testing for differences between those with and without a FCE within 12 months.

**Table 2. Adjusted analysis of predictors of full colon evaluation within 12 months following a positive FOBT**

Variable	Adjusted odds ratio	95% Confidence interval	P
Race			
White	Reference		
Black	1.14	0.75, 1.75	0.54
Missing	0.33	0.18, 0.6	0.0003
No show/cancel			
No (reference)			
Yes	0.06	0.03, 0.13	<0.0001
Age	0.99	0.97, 1.01	0.48

NOTE: GI referral not in logistic model because of empty cell, 0 of 123 without a referral had FCE.

ment) that occurred; and whether colonoscopy, flexible sigmoidoscopy, or DCBE was done. Predictor variables were chosen either because they reflected part of the process in receiving a FCE (gastroenterology referral and procedure cancellation) or because they were patient-level data available from the medical record that could potentially define subsets at particular risk for not undergoing a FCE (race, age, gender, and marital status). Other potential predictor variables, such as education, were not available in the medical record. Primary care clinic from which FOBT was ordered was collected to evaluate potential cluster effects of clinic. The medical record was also examined for up to 5 years before the positive FOBT result for documentation of any colonoscopy or DCBE. Patients who had undergone colonoscopy or DCBE within the prior 5 years were excluded from analysis because they were not due for screening. Patients who died within 12 months of the FOBT result date were also excluded from analysis.

Our primary outcome was defined as either a FCE with a colonoscopy or a DCBE plus flexible sigmoidoscopy within 12 months of the positive FOBT. As a secondary outcome, FCE was defined as colonoscopy or DCBE alone.

**Analysis.** All analyses were done using SAS version 9.1 for Windows (SAS Institute, Cary, NC). The primary outcome, FCE within 12 months, is a dichotomous variable. Thirteen percent of the sample was missing data for the race variable. Descriptive statistics were computed for age, gender, race, marital status, appointment adherence, and referral to gastroenterology. We conducted bivariate analyses of predictor variable (Table 1) with our primary outcome of FCE (Table 1). For these unadjusted analyses, we used  $\chi^2$  tests (or exact tests) to examine differences by race, adherence, and referral to gastroenterology in the proportion of patients with FCE within 12 months. A two-sample *t* test was used to examine differences in age between those who had a FCE and those that did not.

For the adjusted analysis (Table 2), we used logistic regression models (16) to evaluate factors associated with FCE within 12 months. Factors were included in the logistic regression model if the bivariate association with FCE was significant ( $P < 0.05$ ). Based on the bivariate analyses, gender and marital status were not included in the logistic regression model. Referral for gastroenterology consult was not included in the logistic regression model as there were no subjects who had a FCE within 12 months that were not referred for a gastroenterology consult. We examined clinical clustering effects in the adjusted analysis using generalized estimating equations (17).

## Results

We identified 676 subjects who had a positive FOBT screening test result. Subjects were excluded from the analysis who had a nonscreening indication for the FOBT ( $n = 22$ ), were <50 years

of age ( $n = 31$ ), had race listed as other than African-American or Caucasian ( $n = 4$ ), died within 12 months of follow-up ( $n = 19$ ), had undergone colonoscopy and/or DCBE within the previous 5 years ( $n = 59$ ), or had a combination of these exclusion criteria ( $n = 3$ ). Therefore, our final sample size used in the analysis was 538 patients (see Table 1 for sample characteristics). Approximately 44% of the study sample underwent a colonoscopy or DCBE plus flexible sigmoidoscopy within 12 months of the positive FOBT. If we increased the window of follow-up from 12 to 18 months, then an additional 34 subjects (6%) had undergone FCE. Using the less stringent end point of colonoscopy or DCBE alone within 12 months of the positive FOBT minimally increased the follow-up rate to 46%.

In the unadjusted analysis, referral to gastroenterology consult was strongly associated with FCE ( $P < 0.001$ ). Overall, 77% (415 of 538) of subjects had a referral for gastroenterology consult. Fifty-seven percent (237 of 415) of the subjects referred for gastroenterology consult underwent FCE within 12 months compared with 0% (0 of 123) of the subjects who were not referred for gastroenterology consult. (Table 1). In both the unadjusted and adjusted analyses, adherence to follow-up appointments was associated with FCE (Tables 1 and 2). Although the subjects with missing race seemed less likely to undergo FCE than those with a recorded race data, we found no association between African-American versus Caucasian race and performance of FCE (Table 2). We found no evidence of clustering by clinic. The average (median) time to colonoscopy, DCBE plus flexible sigmoidoscopy, or either FCE strategy following a positive FOBT was 267 days (204), 253 days (240), and 262 days (210), respectively.

## Discussion

Previous studies have measured performance of a "complete diagnostic evaluation" for a positive FOBT during a follow-up of 3 to 36 months, but only one study has been in the Veterans Affairs setting. Where reported, patient nonadherence occurred between 4% and 23% of the time (9, 11, 12) and referral for evaluation occurred 54% to 66% of the time (10, 11, 13). The Veterans Affairs system already has performance measures for colorectal cancer screening, an electronic medical record and automatic laboratory alerts. Therefore, one might expect that the evaluation of positive FOBT would be better in a Veterans Affairs setting than in other settings. Our study and the prior one (13), however, do not support this idea. Based on the previous data, we hypothesized that an important breakdown in screening follow-up would be failure to refer a patient with positive FOBT to gastroenterology. Although a 77% referral rate is not ideal, it is better than in prior studies. Instead of a single predominant problem, we identified multiple potential barriers, including failure of referral and patient nonadherence to appointments. We also noted that the average time from FOBT result to FCE (for those who underwent a procedure) was well over 200 days. The implications for intervention are that no single change, such as automatic gastroenterology referral for positive FOBT, will solve the problem.

There are limitations inherent to any single-center retrospective review. The validity of the data collected is limited by the accuracy of the medical record and clinical databases (laboratory and endoscopy). Our Veterans Affairs may not be representative of other Veterans Affairs facilities. Although, we think it is quite likely that both patient and system failures are also present at other Veterans Affairs medical centers. In addition, a shortage of endoscopists, which may contribute to the prolonged average time from FOBT result to follow-up procedure, is a common problem in the Veterans Affairs system. Although patient factors, such as burden of comorbid illness, may not vary significantly among Veterans Affairs

centers, other factors contributing to nonadherence could. For example, differences in the cancellation and "no show" rates among Veterans Affairs facilities could be related to system differences, such as scheduling procedures (patient choice versus clinic choice) and local notification and reminders systems already in place. Finally, chart review does not allow examination of why referrals are not made or appointments attended and may miss procedures done outside of the Veterans Affairs system and not documented in the Veterans Affairs record.

There are no published guidelines for when the FCE after positive FOBT should occur. The 12-month cutoff was clinical judgment. One could argue that a shorter interval, such as 6 months or even 2 months, is more appropriate.

Finally, one of our covariates of interest, patient race, was missing for 13% of the study sample. Race data are not recorded with every clinical encounter. Therefore, we suspect that missing race is a surrogate marker for reduced contact with the Veterans Affairs system and, as a result, decreased opportunity for further evaluation.

Although Veterans Affairs data may not be generalizable to non-Veterans Affairs settings, our data have implications for the Veterans Affairs system, the largest integrated healthcare system in the United States. Approximately 1 million veterans ages  $\geq 50$  years will develop colorectal cancer over the remainder of their lives and  $\sim 433,000$  will die from it (18). The existing infrastructure has great potential for interventions to improve FOBT follow-up, but our data suggest that multiple simultaneous interventions will ultimately be needed.

Interventions with shown efficacy to improve the evaluation of abnormal cancer screening tests have been primarily patient based and focused on cervical cancer screening. These include telephone and mailed reminders and educational interventions to address fear of cancer diagnosis (19). Myers et al. (20) showed that a physician-based intervention of reminder-feedback and educational outreach improved the evaluation of positive FOBT. It is difficult to extrapolate these data to the Veterans Affairs setting. For example, our standard of care includes patient reminder letters and phone calls for colonoscopy appointments. Our electronic medical record already alerts the ordering provider to the positive FOBT result. Future directions may include improving the current provider reminder system with additional information, such as the guidelines for evaluation of FOBT, or considering automatic, or at least streamlined, gastroenterology referral. In addition to reminding patients of their appointments, we could make the scheduling process more patient centered. In addition, the lag time between FOBT result and colonoscopy scheduling may suggest to patients that the test is unimportant and therefore contributes to nonadherence. Increasing the capacity to do colon evaluations in a timely manner will be difficult, however.

Ultimately, a colorectal cancer screening program depends on primary care providers adhering to screening guidelines, on the system level coordination of subspecialty clinics, such as gastroenterology, radiology, and surgery to provide care in a timely manner, and on patient adherence to tests or procedures recommended by their healthcare providers. Problems at the system, provider, or patient level will decrease the effectiveness of colorectal cancer screening and could lead to diagnostic delay and presentation at a later and less curable stage of disease.

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