Published in final edited form as:
Cancer. 2013 November 1; 119(21): 3879–3886. doi:10.1002/cncr.28272.

Improving Colon Cancer Screening in Community Clinics

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Abstract

Background—We evaluated the effectiveness and cost-effectiveness of two interventions designed to promote colorectal cancer (CRC) screening in safety-net settings.

Methods—A three-arm, quasi-experimental evaluation was conducted among 8 clinics in Louisiana. Screening efforts included: 1) enhanced usual care, 2) literacy-informed education of patients, and 3) education plus nurse support. Overall, 961 average-risk patients, ages 50–85 were eligible for routine CRC screening and recruited. Outcomes included CRC screening completion and incremental cost-effectiveness the latter two approaches versus enhanced usual care.

Results—Baseline screening rates were < 3%. After the interventions, screening rates were 38.6% with enhanced usual care, 57.1% with education and 60.6% with additional nurse support. After adjusting for age, race, gender, and literacy, patients receiving education were not more likely to complete screening than those receiving enhanced usual care; those additionally receiving nurse support were 1.60 fold more likely to complete screening than those receiving enhanced usual care (95% CI 1.06 – 2.42, p=0.024). The incremental cost per additional person screened was $1,337 for nurse over enhanced usual care.

Conclusions—FOBT rates were increased beyond enhanced usual care by providing brief education and nurse support but not education alone. More cost effective alternatives to nurse support need to be investigated.

INTRODUCTION

Of all cancer screening initiatives, colorectal cancer (CRC) screening rates are the lowest.[1] While CRC screening rates have improved in the general population, disparities persist among adults who have lower socioeconomic status, limited health literacy, are members of racial/ethnic minority groups, and/or live in rural locations.[1–5] Reducing these disparities is a primary public health objective.[6]

Numerous studies have examined barriers and facilitators to CRC screening among vulnerable populations.[2,7–17] Limited health literacy, specifically, has been linked to less

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CRC knowledge, negative attitudes towards screening, lower self-efficacy and less likelihood of screening completion.[7,18–23] As evidence clearly demonstrates an association between limited health literacy and poor health outcomes, the Department of Health and Human Services has called for the dissemination of health information that is accessible, understandable and actionable.[24] Despite this, few low literacy initiatives have been specifically developed to promote CRC screening.[20, 25, 26] Even fewer are suitable for use in rural and urban community clinics. The Colorectal Cancer Roundtable recently recommended focusing future initiatives on Federally Qualified Health Centers (FQHCs) to address national screening challenges.[27]

In response, our team designed, implemented and evaluated a multifaceted intervention to increase CRC screening rates among low-income, uninsured patients receiving care from FQHCs. FQHCs provide primary care to over 20 million individuals in the United States.[28] Our study was designed to test two strategies to promote CRC screening: 1) the use of literacy-informed educational materials with accompanying 'teach back' to confirm comprehension[29] or 2) the utilization of this educational strategy with support and follow-up by a nurse manager. These strategies promoted the use of fecal occult blood tests (FOBT), the most feasible, cost-effective screening option for low-income and uninsured patients.[30–31] The intervention arms were each compared to an enhanced usual care arm. Given the resource-constrained, FQHC environment, we evaluated not only the effectiveness of our two interventions, but also their cost-effectiveness.

METHODS

Study Design

This study took place between May 2008 and August 2011 in North Louisiana. Two intervention strategies were tested in a three arm study: 1) enhanced usual care, where patients were given a recommendation for CRC screening and an FOBT kit, 2) an educational strategy, where patients were given enhanced usual care plus brief education that included pamphlet, video and simplified FOBT instructions; or 3) the nurse support arm, where patients received enhanced usual care, the educational strategy and additional nurse support and follow-up to encourage completion of CRC screening.

The target population was the five FQHCs in predominantly rural Louisiana. Three FQHCs participated in this study; the other two were involved in cancer screening programs at the time. As part of this three-arm, quasi-experimental evaluation, each FQHC was randomly assigned to one of the three study arms. Each study FQHC was affiliated with multiple clinics which were assigned to the same arm as their parent FQHC. At the time of randomization, there were a total of seven clinics associated with the three FQHCs: two in enhanced usual care, two in the educational strategy arm, and three in the nurse support arm. After the first year of the study, one additional clinic was enrolled in the enhanced usual care arm due to limited patient recruitment in this arm. The eight participating clinics were located in eight towns in seven parishes across the state. Six clinics were located in rural towns, with populations ranging from 450–13,000. Two were located in low-income areas of cities with populations of 63,000 and 199,000 respectively. Baseline rates of CRC screening at each of the eight study clinics ranged from 1 to 2 percent.

Participants

Patients were recruited through a multi-step process. First, while taking patients' vital signs, a medical assistant at each clinic identified potentially eligible participants by the age listed in their chart (between 50–85 years of age). Medical assistants were trained to ask patients age 50 to 85 if they would be willing to talk to an onsite research assistant (RA) about

participating in a CRC screening study prior to their physician encounter. Those who were interested met with the RA, who screened them for further eligibility: 1) English-speaking, 2) current clinic patient, 3) not requiring screening at an earlier age according to American Cancer Society (ACS) guidelines,[1] 4) not up-to-date with United States Preventives Services Task Force[32] CRC screening recommendations (i.e., a FOBT annually, flexible sigmoidoscopy every 5 years or colonoscopy every 10 years), 5) not having an acute medical concern.

The Louisiana State University Health Sciences Center – Shreveport Institutional Review Board approved the study. Each patient received $10 for their participation in the baseline survey.

Structured Survey

The study interview included demographic and CRC screening items from validated questionnaires used previously by the authors.[11, 33–34] A detailed description of the survey, which was written on a 4th grade level and administered orally has been reported previously.[35] Literacy was assessed using the Rapid Estimate of Adult Literacy in Medicine (REALM).[36] Raw REALM scores (0–66) can be converted into reading grade levels that correlate with literacy skills.

Theoretical Framework

The intervention components were designed following health literacy best practices and the theory of health learning capacity to simplify the complexity of independently completing an FOBT. [29,37] Health Belief Model and Social Cognitive theories guided the framing of intervention content to address the salience of CRC screening and the need to take action.[38–39] The educational strategy and nurse support arms were designed to overcome key patient barriers to CRC screening, such as access to tests, limited knowledge, negative beliefs, poor self-efficacy and lack of motivation. The education materials were developed and pilot-tested using focus groups and cognitive interviews with FQHC patients, providers and our community advisory boards to help insure they were useful, understandable, appealing and cultural appropriate. The nurse support arm was included as an intervention strategy to determine the added benefit of more in-depth counseling and telephone follow up support to encourage FOBT completion.

Clinic in-service and Training of RAs and Nurse Managers

All staff and providers in each clinic attended a two hour in-service on CRC screening and an orientation to the study during a quarterly clinic meeting.

RA training in the enhanced usual care arm included practice interviewing patients and administrating the survey and literacy test. RAs were given a script for recommending CRC screening and introducing the FOBT kit. For the educational strategy arm, RAs were given additional training in using health literacy techniques.[29] For the nurse support arm, the nurse manager training additionally included motivational interviewing techniques, [40] use of a tracking system and a protocol for contacting patients and assisting them with navigation if a test was positive.

Three Study Arms

Enhanced Usual Care Arm—At enrollment, after completing the structured interview, the clinic-based RA gave patients a recommendation to complete CRC screening, the FOBT kit, and a suggestion to talk with their primary care provider about screening during their visit that day. Patients returned FOBTs to the clinic by mail using a pre-addressed stamped

envelope. Regular clinic protocol was followed for positive test results and if diagnostic testing was needed.

Educational Arm—At enrollment, after completing the structured interview, the clinic RA gave patients the same FOBT kit and recommendation as those in the enhanced usual care arm, but simplified FOBT instructions were provided. In addition, the RA gave a brief literacy-informed educational intervention that included a colorful, illustrated CRC pamphlet written on a 5th grade level that provided actionable information organized from a patient's perspective as well as a short video developed by the authors that captured FQHC patients discussing barriers and facilitators to screening, and a physician making a recommendation while showing key steps in FOBT completion. The education also included the RA giving a concrete demonstration of FOBT instructions. The RA employed techniques such as 'teach back' to confirm the accuracy and completeness of patients' understanding.[29] Patients returned FOBTs to the clinic by mail. Tracking and follow-up was done the same manner as the EUC arm.

Nurse Support Arm—At enrollment, after the structured interview, the nurse manager provided the same materials and FOBT instructions as those in the education arm prior to patient's physician visit. The nurses used motivational interviewing techniques[40] to identify and problem-solve barriers and motivate patients to complete FOBTs. To promote comprehension and confidence, the nurses often showed patents how to complete the FOBTs and called within a week to ask if they had questions and, if necessary, to review the instructions. If patients did not return their FOBT, the nurses followed up by phone within two weeks and again in one month. If results were positive, the nurse manager called patients to discuss results, facilitate appointments with their primary care provider and if indicated, schedule patients for a diagnostic colonoscopy at the appropriate treatment center.

Outcomes

EZ Detect™ was the FOBT chosen based on the simplicity of the test from a patient perspective and recommendations from FQHC patients, providers, CEOs, and our community advisory board. The test requires three separate bowel movements but no stool handling. The sensitivity and specificity has been reported previously.[41] Previous research also found patients overwhelmingly preferred the EZ Detect™ to other hemoccult cards (92% vs. 8%).[41]

Eligible patient FOBT completion at three months post-enrollment was the primary outcome measure as documented by the clinic nurse (enhanced usual care and educational **s**trategy arms) or nurse manager (nurse support arm).

Statistical Analysis

FOBT completion rates were defined as the percentage of FOBT cards returned to the clinic. A barrier scale was calculated using four questions concerning confusion, embarrassment, trouble and messiness related to the FOBT test. This scale ranged from 4 to 20; high values indicating the participant thought these were barriers. To examine whether patients in the study arms differed on continuous baseline characteristics of age and the barrier index, analysis of variance was used. Chi-square tests were performed for categorical factors, including literacy level. Screening ratios were defined as the ratio of FOBT completion rates between two groups. Both screening ratios and pairwise tests for FOBT completion were calculated using logistic regression which accounted for clustering by clinic. Multivariate analyses adjusted for age, race, gender, and literacy level. Tests for interaction between literacy level and study arm were assessed.

Cost Effectiveness Analysis

Cost data was collected from purchase orders, receipts, and questioning research staff. Total incremental costs and additional number of persons screened were calculated for the education arm and the nurse case manager arm (comparison arms) over the enhanced usual care arm (reference arm). Incremental costs for the education arm were writing, producing and editing a DVD ($10,000), brochures ($2,000) and research assistant ($1,036). Costs for the nurse arm were postcards ($60) and 40% of two nurses for one year ($106,280). Comparison arm costs and number screened were normalized to the reference arm to account for differences in sample size. The incremental cost effectiveness was calculated as the total incremental cost of a comparison arm relative to the reference arm divided by the total number of additional person screened.[42]

RESULTS

In all, 1055 patients were identified as meeting age criteria, of these 33 (3.1%) refused to participate and 61 (5.8%) were ineligible because they were up to date on CRC screening. A total of 961 patients were consented and enrolled, with a determined cooperation rate of 91.1%. Baseline characteristics are compared among groups in Table 1. Participants ranged in age from 50–85, 77% were female. The majority (67%) were African American. Over half (56%) had limited literacy (i.e. < 9th grade level). There were significant differences across groups for age, race/ethnicity, marital status, literacy, prior recommendation, previous FOBT, wanting to know if they had CRC and positive beliefs concerning FOBT efficacy.

The FOBT return rate was 38.6% in the enhanced usual care arm, 57.1% in the education arm and 60.6% in the nurse arm (Table 2). Adjusting for age, race, gender and literacy, there was a significant difference in screening ratio across arms (p=0.012). Participants in the nurse support arm were 1.60 times more likely to be screened (95% CI 1.06 – 2.42 p=0.024) compared to those in the enhanced usual care, but no more likely to be screened than those in the educational arm (p=0.09). Those in the educational arm were not more likely to be screened compared to those in the enhanced usual care arm (p=0.20).

Table 3 indicates there were significant differences across study arms in FOBT completion among patients with limited literacy (p=0.006) but not among those with adequate literacy (p=0.064). The interaction term for study arm and literacy level was not statistically significant (p=0.80) indicating that the screening ratios were not significantly different between literacy groups.

Table 4 presents the incremental cost effectiveness ratio of the educational arm relative to the enhanced usual care arm and for the nurse support arm relative to the educational arm. The incremental cost of the educational intervention per additional person screened was $250 over enhanced usual care while the incremental cost of the nurse intervention per additional person screened was $1,337 over enhanced usual care.

DISCUSSION

Among urban and rural southern FQHCs patients, our study documented extremely low baseline CRC screening rates. Sizable gains over baseline were detected in screening completion in our enhanced usual care arm and literacy informed education arm; further benefit of our educational strategy combined with the support of a nurse manager was substantial. FOBT completion rates in our education with nurse support strategy are among the most successful reported in CRC screening interventions among lower income populations that have ranged from 43–70%.[30, 43–46]

Prior studies in safety net clinics cite low rates of physician recommendation and inadequate insurance as causes of low CRC screening rates.[12, 28] Overcoming this barrier may be a reason for substantial improvement in the enhanced usual care arm, where non-medical staff gave patients an FOBT kit, a CRC recommendation and suggestion to talk with their provider during their routine office visit. Recent studies show some of the strongest interventions include use of non-physician staff to communicate with patients and offer FOBT kits.[30, 43]

Patients receiving nursing support were most likely to complete screening. When the nurses called patients, the most common barrier for not returning FOBTs was confusion about instructions or losing the kit, rather than additional decision-making or cancer-related anxiety. Given the cost of the nurse, other strategies to prompt patients such as letters, texting, automated calls or personal calls by a less-costly medical assistant should be investigated. If a less expensive clinic staff was used, estimates could fall to $389 per additional patient completing screening; a third of the cost of the nurse. However this still might be cost prohibitive among FQHC clinics. With the increasing presence of electronic health records (EHRs) especially among community health centers, the amount of staff time dedicated to identifying and tracking patients might also be substantially reduced. None of the FQHCs in this study had an integrated EHR system at the time this study. Future studies that aim to evaluate other low cost interventions also need to use currently recommended FOBTs such as the FIT. [27]

Our study has limitations. Differences were noted between arms in sociodemographic characteristics, perceived barriers, wanting to know if they had CRC, and belief that FOBTs would decrease chances of dying of CRC, but not for the primary outcome of screening rates. Adjustments for key variables were therefore made in statistical analyses. Other limitations relate to the generalizability of our results; we included predominantly African American and female patients receiving care from FQHCs in one state. However, this is generally representative of FQHC populations in the southern United States.

Of note, our choice of EZ Detect™ was determined both by currently available and USPSTF recommended options at the time of the study onset as well as the perceived simplicity of the test from a patient's perspective. The EZ Detect™ kit demonstrated comparable sensitivity and specificity as Hemoccult II FOBT. Yet USPSTF and ACS recommendations changed and now both recommend immunochemical tests that have superior sensitivity and no longer recommend tests with less sensitivity such as Hemoccult II or EZ Detect™.[32] By the time we were aware of this change, patient screening had been completed. Based on ACS and USPSTF guidelines, tests such as EZ Detect™ and Hemoccult II should no longer be used for screening or research. Future efforts should consider how similar strategies as those we studied, might incorporate the newer, recommended FOBTs among similar vulnerable populations.

Achieving the Healthy People 2020 goal of having >70% of eligible adults up-to-date with CRC screening guidelines may require a variety of approaches.[5, 30] Since the menu of screening options in FQHCs is often limited to annual FOBT, strategies are needed to overcome challenges of limited resources for patient education and continued outreach.[30] Given highly constrained resources, decision-makers require information on cost effectiveness of interventions.[47] Future studies should use currently recommended tests that have superior sensitivity and employ strategies to make annual FOBT completion easier for patients to access and understand, as well as offer community clinics an effective, low cost, and potentially sustainable means for screening.

Acknowledgments

Funding for this project was supported by the National Cancer Institute (R01CA115869)

We would like to thank Ivory Davis, MSN and Cara Pugh, BSN, for their commitment to helping patients completed screening.

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Table 1

Characteristics of Study Sample at Baseline, Stratified by Study Arm

Characteristic	All Patients (n=961)	Study Arm			p-value
		Enhanced Usual Care (n=275)	Education (n=282)	Nurse (n=404)	
Age, Mean (sd)	58.4 (7.3)	57.7 (7.5)	57.8 (6.5)	59.2 (7.5)	0.014
	N (%)	N (%)	N (%)	N (%)	
Age Categories					
50–59	611 (64)	190 (69)	181 (64)	240 (59)	0.11
60–69	265 (28)	63 (23)	80 (28)	122 (30)	
70–85	85 (9)	22 (8)	21 (7)	42 (10)	
Female	740 (77)	207 (75)	224 (79)	309 (77)	0.50
Years of Education					
Less than high school	313 (33)	98 (36)	92 (33)	123 (31)	0.26
High school grad	435 (45)	109 (40)	139 (49)	187 (47)	
Some College	157 (16)	50 (18)	40 (14)	67 (17)	
≥ College Graduate	53 (6)	18 (7)	11 (4)	24 (6)	
Race					
African-American	645 (67)	199 (72)	114 (40)	332 (83)	<0.0001
Caucasian/Hispanic	313 (33)	76 (28)	168 (60)	69 (17)	
Marital Status					
Single	276 (29)	62 (23)	55 (20)	159 (40)	<0.0001
Married	330 (34)	101 (37)	142 (50)	87 (22)	
Separated	66 (7)	22 (8)	14 (5)	30 (7)	
Divorced	155 (16)	47 (17)	38 (13)	70 (17)	
Widowed	131 (14)	43 (16)	33 (12)	55 (14)	
Literacy Level					
Limited (0–60)	537 (56)	188 (68)	98 (35)	251 (62)	<0.0001
Adequate (61–66)	424 (44)	87 (32)	184 (65)	153 (38)	
Seen Doctor in Past 12 months	849 (89)	236 (86)	258 (91)	355 (89)	0.09
Prior Recommendation	357 (39)	96 (35)	83 (29)	178 (48)	<0.0001
Ever Completed an FOBT	262 (28)	62 (23)	26 (9)	174 (47)	<0.0001
Would want to know if have CRC?					

Characteristic	All Patients (n=961)	Study Arm			p-value
		Enhanced Usual Care (n=275)	Education (n=282)	Nurse (n=404)	
Yes	837 (90)	242 (90)	261 (93)	334 (89)	0.03
No	56 (6)	12 (4)	15 (5)	29 (8)	
Don't know	34 (4)	17 (6)	6 (2)	11 (3)	
FOBT finds CRC early					
Strongly Agree/Agree	889 (96)	255 (94)	276 (98)	358 (96)	0.24
Disagree/Strongly Disagree	9 (1)	3 (1)	2 (1)	4 (1)	
Don't know	29 (3)	13 (5)	4 (1)	12 (3)	
FOBT decreases chances of dying from CRC					
Strongly Agree/Agree	742 (80)	194 (72)	243 (86)	305 (82)	0.0001
Disagree/Strongly Disagree	109 (12)	43 (16)	29 (10)	37 (10)	
Don't know	76 (8)	34 (13)	10 (4)	32 (9)	
Barrier Index, Mean (sd)	8.98 (2.29)	9.42 (2.24)	8.04 (2.11)	9.38 (2.26)	<0.0001

Table 2

Primary outcome measure - return of initial FOBT (Screened) within 12 months.*

	All Patients (n=961)	Study Arm			p-value
		Enhanced Usual Care (n=275)	Education (n=282)	Nurse (n=404)	
	N (%)	N (%)	N (%)	N (%)	
FOBT returned (Screened)	512 (53)	106 (38.6)	161 (57.1)	245 (60.6)	<0.0001
FOBT not returned	449 (47)	169 (61.4)	121 (42.9)	159 (39.4)	
Screening Ratio 95% Confidence Interval		1.00	1.39 (0.86– 2.22)	1.52 (1.00 – 2.31)	0.11
p-value			0.18	0.049	
Screening Ratio 95% Confidence Interval			1.00	1.10 (0.86 – 1.40)	
p-value				0.44	
Adjusted Screening Ratio 95% Confidence Interval		**1.00**	**1.36 (0.85– 2.18)**	**1.60 (1.06 – 2.42)**	**0.012**
p-value			**0.20**	**0.024**	
Adjusted Screening Ratio 95% Confidence Interval			**1.00**	**1.18 (0.97 – 1.42)**	
p-value				**0.09**	

*Adjusted p-values control for age (in years), race (African American vs Caucasian and Hispanic), gender, and literacy (2 categories).

Table 3

Primary outcome measure – return of initial FOBT (Screened) within 3months, by literacy level.*

	All Patients	Study Arm			p-value
		Enhanced Usual Care	Education	Nurse	
	N (%)	N (%)	N (%)	N (%)	
Limited Literacy	N=537	N=188	N=98	N=251	
FOBT returned (Screened)	264 (49)	69 (36.7)	51 (52.0)	144 (57.4)	0.0006
FOBT not returned	273 (51)	119 (63.3)	47 (48.0)	107 (42.6)	
Screening Ratio 95% Confidence Interval		1.00	1.39 (0.97– 1.98)	1.60 (1.19 – 2.16)	
p-value			0.07	0.002	
Screening Ratio 95% Confidence Interval			1.00	1.15 (0.99 – 1.34)	
p-value				0.07	
Adequate Literacy	N=424	N=87	N=184	N=153	
FOBT returned (Screened)	248 (58)	37 (42.5)	110 (59.8)	101 (66.0)	0.064
FOBT not returned	176 (42)	53 (57.5)	74 (40.2)	52 (34.0)	
Screening Ratio 95% Confidence Interval		1.00	1.27 (0.74– 2.20)	1.58 (0.99 – 2.54)	
p-value			0.39	0.057	
			1.00	1.24 (0.92 – 1.67)	
				0.15	

*p-values control for age (in years) and race (African American vs Caucasian and Hispanic).

Table 4

Cost-effectiveness analysis

		Education (comparison arm) vs EUC (reference arm)	Nurse (comparison arm) vs EUC (reference arm)
	Additional persons screened in comparison arm		
A	Sample size in reference arm	275	275
B	Number screened in reference arm	106	106
C	Sample size in comparison arm	282	404
D	Number screened in comparison arm	161	245
E	Number screened in comparison arm normalized to size of reference arm	157	167
F	Additional number screened in comparison arm normalized to size of reference arm = row E - row B	51	61
	Incremental costs of comparison arm		
G	Personnel	$731	$106,280
H	Non-personnel	$12,000	$13,096
I	Total Incremental Costs	$12,731	$119,376
J	Total incremental costs normalized to size of reference arm	$12,415	$81,258
	Incremental cost-effectiveness ratio = row J/row F	$250	$1,337