Joint breast and colorectal cancer screenings in medically underserved women

Terry C Davis, PhD,[a] Connie L Arnold, PhD,[a] Michael S Wolf, PhD, MPH,[b] Charles L Bennett, MD, PhD, MPH,[c] Dachao Liu, MS,[d] and Alfred Rademaker, PhD[d]

[a]Department of Medicine, Louisiana State University Health Sciences Center, Shreveport, Louisiana; [b]Division of General Internal Medicine, Northwestern University, Chicago, Illinois; [c]South Carolina College of Pharmacy, Hollings Cancer Center of the Medical University of South Carolina, Arnold School of Public Health, and the William Jennings Bryan Veterans Administration Medical Center, Charleston and Columbia, South Carolina; and [d]Department of Preventive Medicine and The Robert H Lurie Comprehensive Cancer Center, Northwestern University

Background Breast and colon cancer screening in rural community clinics is underused.

Objective To evaluate the effectiveness and cost-effectiveness of alternative interventions designed to promote simultaneous screening for breast and colon cancer in community clinics.

Methods A 3-arm, quasi-experimental evaluation was conducted during May 2008-August 2011 in 8 federally qualified health clinics in predominately rural Louisiana. Baseline screening rates reported by the clinics was <10% for breast cancer (using mammography) and 1%-2% for colon cancer (using the fecal occult blood test [FOBT]). 744 women aged 50 years or older who were eligible for routine mammography and an FOBT were recruited. The combined screening efforts included: enhanced care; health literacy-informed education (education alone), or health literacy-informed education with nurse support (nurse support).

Results Postintervention screening rates for completing both tests were 28.1% with enhanced care, 23.7% with education alone, and 38.7% with nurse support. After adjusting for age, race, and literacy, patients who received nurse support were 2.21 times more likely to complete both screenings than were those who received the education alone (95% confidence interval [CI], 1.12-4.38; $P = .023$). The incremental cost per additional woman completing both screenings was $3,987 for education with nurse support over education alone, and $5,987 over enhanced care.

Limitations There were differences between the 3 arms in sociodemographic characteristics, literacy, and previous screening history. Not all variables that were significantly different between arms were adjusted for, therefore adjustments for key variables (age, race, literacy) were made in statistical analyses. Other limitations related generalizability of results.

Conclusions Although joint breast and colon cancer screening rates were increased substantially over existing baseline rates in all 3 arms, the completion rate for both tests was modest. Nurse support and telephone follow-up were most effective. However, it is not likely to be cost effective or affordable in clinics with limited resources.

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Breast and colorectal cancer (CRC) screening in safety-net settings is underused.[1-3] Screening rates for these cancers remain persistently lower among disadvantaged populations including low-income women, those with no health insurance, those with lower health literacy and fewer years of education, racial and ethnic minorities, and those who live in rural areas.[4-14] The reduction of these screening disparities is a national public health priority.[15] The Community Preventive Service Task Force's systematic review on the effectiveness of joint interventions to increase the rates of breast, cervical, and CRC screening found that one-on-one education, patient reminders, and enhancing access to screening services were effective.[16] Another systematic review looking at multiple cancer screening also found that provider audits and culturally appropriate mail and telephone outreach improved breast and CRC screening rates.[17] Few initiatives have been specifically developed to improve multiple-cancer screening rates in safety-net primary care clinics. In community clinics that participate in a county-funded health plan in Florida, a cancer screening office reminder system using chart stickers was effective in increasing joint rates of mammograms and fecal occult blood tests (FOBTs).[18] Mammogram and FOBT screening rates among inner-city patients in Rochester, New York, increased

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with the use of a multimodal intervention of repeated letters and automated phone calls and a mailed FOBT kit with a point-of-care prompt if the patient had an appointment.[19] An expansion of that study found that personal patient reminder calls and provider and patient prompts delivered at a patient-initiated visit were more effective in improving screening rates among poor and minority inner-city patients than were reminder letters alone or letters with automated calls.[20] Although all of those interventions targeted 2 or more cancers, none targeted rural areas.

Our team developed and evaluated a health literacy-informed intervention designed to promote mammogram and FOBT screening in rural and inner-city populations that were at higher risk for not undergoing cancer screening: low-income and uninsured women who were cared for in Federally Qualified Health Centers (FQHCs) in Louisiana that were not participating in state or national screening programs. FQHCs are located in areas designated as medically underserved and provide care nationally to 20 million individuals regardless of their insurance status.[21]

The objective of this study was to test 3 strategies to promote joint breast and CRC screening: enhanced care, which ensured that women received screening recommendations and access to both tests; health literacy-informed educational materials with accompanying "teach back" to confirm comprehension; [22, 23] or use of the health literacy-informed education strategy with telephone follow-up by a nurse. All of the strategies promoted use of mammography at a rural community hospital or the nearest public hospital and of the FOBT, the most feasible, cost-effective screening option for CRC in low-income and uninsured patients.[24-25] This report looks at whether women completed both tests. Given the resource-constrained FQHCs environment, we also evaluated the cost effectiveness of the interventions targeting breast and CRC. Cancer screening interventions are a priority in Louisiana because the state has high rates of cancer mortality, ranking third among states in breast cancer deaths and fourth in colon cancer deaths.[26]

Methods

Study design and sample

A 3-arm, quasi-experimental (ie, based on randomization of sites, but not of patients within those sites), comparative-effectiveness evaluation was conducted among 3 Louisiana FQHC networks during May 2008-August 2011. The target population was from the 5 FQHC networks in predominantly rural north Louisiana. Three networks participated in this study; the other 2 were involved in a year-long, state-funded colon cancer screening program. The study statistician used computer-generated random numbers to allocate each network to an arm. Each participating FQHC parent network was affiliated with multiple clinics that were assigned to the same study arm as their parent network. This resulted in 2 clinics in the enhanced-care arm (enhanced care), 2 in the literacy-informed education arm (education alone), and 3 in the education with nurse support arm (nurse support). After the first year of the study, 1 additional clinic was enrolled in the enhanced-care arm because of limited patient recruitment in that arm. The 3 parent networks each served between 1,162-2,386 female patients aged 50 years or over.

The 8 study clinics were located in 8 towns in 7 parishes across the state. Six clinics were located in rural towns, with populations ranging from 450-13,000 people; and 2 clinics were in low-income areas of cities with populations of 63,000 and 199,000, respectively. Baseline screening rates reported by each clinic ranged from 5%-9% for mammography and 1%-2% for CRC. Due to ethical concerns and to ensure that all patients had access to the tests, all of the women were given an FOBT kit and the grant provided no-cost mammograms to those without insurance.

Participants

The patients were recruited through a multistep process. First, a medical assistant would identify potentially eligible female patients by age (≥50 years) while taking patient vital signs. The assistant would ask the woman if she'd be willing to talk to a research assistant (RA) about participation in the cancer screening study before she met with the physician. Women who were interested met with the RA, who screened them for further eligibility based on whether they could speak English, were a current patient at the clinic, had not needed a cancer screening at an earlier age based on American Cancer Society guidelines,[7] were not up-to-date with United States Preventive Services Task Force[27] screening recommendations (ie, a mammogram every other year, an FOBT annually, flexible sigmoidoscopy every 5 years, or colonoscopy every 10 years), and did not having an acute medical concern.

In all, 783 patients were identified as being eligible for both mammography and colon cancer screening. Of those, 27 (3%) refused to participate and 12 (2%) were ineligible, leaving 744 patients who were enrolled. All of the patients were consented before data collection. The Louisiana State University Health Sciences Center-Shreveport's Institutional Review Board approved the study. Each patient received $10 for participation in the baseline survey.

Structured survey

The study interview included demographic and breast and colon cancer screening items from validated questionnaires[29-32] that had been used previously by the authors and conceptually guided by the Health Belief Model (HBM)[33-34] and Social Cognitive Theory (SCT).[35-36] A detailed description of the survey, which was written on a 4th grade

level and administered orally has been reported previously.[37-38] Literacy was assessed using the Rapid Estimate of Adult Literacy in Medicine (REALM).[39] Raw REALM scores (0-66) can be converted into reading grade levels that correlate with literacy skills. Raw scores of ≤60 indicated a reading grade level of 8th grade or lower or limited literacy, and scores >61 indicated at least a 9th grade reading level, or adequate literacy.

Clinic in-service and training of RAs and nurses

Staff and providers in each clinic attended a 2-hour in-service training session on mammography and FOBT screening guidelines and an orientation to the study during a quarterly clinic meeting. RA training for the enhanced care arm included interviewing patients and administrating the survey and literacy test. Each clinic RA (who was a part-time clinic staff member) was given a script for recommending screening. For the education-alone arm, RAs were given additional training in using health-literacy techniques and materials.[22,23] For the nurse support arm, nurse training also included motivational interviewing techniques,[40] uses of a tracking system, and a protocol for contacting patients and assisting them with navigation if a test was positive.

Study arms

Enhanced care. At enrollment, after completing the structured interview, the RAs gave patients a recommendation to complete both tests and suggested they talk with their primary care provider about the screening tests during their visit that day. They also gave patients the FOBT kit and told them the clinic nurse would schedule a mammogram before they left the clinic. Regular clinic protocol was followed in scheduling mammograms at the community hospital with which the clinic had a contract or with the closest state public hospital. Mammography was provided at no cost to those who did not have adequate insurance, and the FOBT kits were given at no cost to patients or clinics. Regular clinic protocol was followed for tracking; contacting patients; and, if appropriate, scheduling diagnostic testing.

Health literacy-informed education arm (education alone). The RA followed the enhanced care protocol and also provided brief education for both screening tests using health literacy best practices, such as using plain language and "teach back" (asking to teach back key information and directions) to confirm understanding.[22-23] The education included the RA using a brief video, 2 colorful pamphlets, and simplified FOBT instructions as teaching tools. The materials were created by the authors, a video production team, and input from focus groups of FQHC patients and providers. The video featured FQHC patients discussing positives and negatives of completing both screening tests. It showed a physician recommending both tests and demonstrating the steps in completing an FOBT; it also showed a woman getting a mammogram and encouraging her friends to complete both tests. The pamphlets, written at a 5th grade level, highlighted the risk factors for breast and colon cancers, the benefits of regular screening for them, a brief explanation and illustration of the tests, and empowering messages to encourage screening completion.

All of the materials incorporated evidence-based practices for the design of multimedia tools, guided by the theory of health learning capacity.[41] The Health Belief Model and Social Cognitive Theory guided the inclusion and framing of content to address the salience of screening; patient barriers such as limited knowledge of disease risk and screening benefits, negative beliefs about screening, poor self-efficacy, lack of motivation;[10, 42-49] and the need to take action.[23] As in the enhanced-care arm, regular clinic protocol was followed for scheduling mammograms, recording results, and following up with patients.

Nurse-support arm. The RA followed the enhanced care protocol and the registered nurse gave participants the educational intervention, which included the FOBT kit with simplified instructions, a brief counseling session, and a suggestion to talk to their primary care provider about both tests. The nurse worked with each patient to schedule a mammogram at her convenience and followed up by phone within 2 weeks to remind the patient of the mammogram appointment and ensure that she knew where the clinic was. The nurse also encouraged the patient to complete the FOBT if the patient had not mailed it back to the clinic and if necessary, reviewed instructions with the patient on how to use the FOBT. This strategy was designed to extend the educational intervention by adding supportive follow-up calls to help identify and problem-solve barriers and to motivate patients to complete both tests. If the patient missed her appointment and/or failed to return her FOBT, the nurse called again in 2 weeks and 1 month to reschedule the mammogram and/or problem solve completion of the FOBT. When the patient had completed both screenings, the nurse entered the results in the tracking system and clinic chart. If the screening results were negative, then the nurse sent a letter informing the patient that their results were normal. If results were positive, the nurse called the patient to discuss the results and to schedule an appointment for a diagnostic test.

Outcomes

The primary outcome measure was the completion by eligible patients of both tests at 6 months after enrollment, as documented by the clinic nurse (enhanced-care and education-alone arms) or the nurse (nurse-support arm) when the mammography and FOBT results were returned to

the clinic. Screening completion rates were defined as the percentage of patients for whom mammogram results and FOBT cards were returned to the clinic.

Statistical analysis

Generalized linear models accounting for clustering by clinic were used to examine whether patients in the 3 study arms differed on baseline characteristics (age, age categories, education, race, marital status, literacy level, and screening items). Screening ratios were defined as the ratio of screening completion rates between 2 arms. Both screening ratios and pairwise tests for screening completion were calculated using generalized linear models, accounting for clustering by clinic and adjusting for age, race, and literacy level.

Cost and cost-effectiveness analysis

Cost data were collected from purchase orders, receipts, and questioning research staff. Incremental costs and additional number of persons screened were calculated for the education-alone arm over the enhanced-care arm. Costs included a video ($5,000), pamphlets ($4,000), and research assistant ($2,009). Each site had a part-time research assistant. Costs for the nurse-support arm over the education-alone arm included 70% of 2 registered nurses ($185,990) (each of the nurse-support sites had a full time nurse). Comparison arm costs and number screened were normalized to the reference arm to account for differences in sample size. The incremental cost-effectiveness ratio was calculated as the total incremental cost of a comparison arm relative to the reference arm divided by the total number of additional persons screened as was done in our prior studies of cost-effectiveness of cancer screening interventions.[49]

Results

Baseline participant characteristics stratified by study arm are shown in Table 1. There were significant differences across groups for age categories, race, marital status, literacy, previous recommendation for both tests, and ever having completed both tests. The overall joint screening rate for mammogram and FOBT was 31.2%; 28.1% in the enhanced-care arm, 23.7% in the education-alone arm, and 38.7% in the nurse-support arm (P =.028). Adjusting for age, race, and literacy, those in the nurse-support arm were 2.21 times more likely to be screened (95% confidence interval compared with those in the education-alone arm [CI], 1.12-4.38, P =.023), and 1.45 times more likely to be screened compared with those in the enhanced-care arm (95% CI, 0.86 – 2.46, P =.16). Participants in the education-alone arm were 0.66 times more likely to be screened compared with those in the enhanced-care arm (95% CI 0.28 – 1.56, P =.34; Table 2).

The differences in screening completion rates among the study arms for the 2 literacy groups are shown in Table 3. There were significant differences across arms for the adequate literacy group, but not for the limited literacy group – among those with adequate literacy, screening completion rates were highest in the nurse-support arm (49.6%). An interaction term for study arm and literacy level was entered into the final model and was statistically significant (P =.0002), indicating significantly different levels of effectiveness for the 2 literacy categories.

The incremental cost effectiveness of the most effective arm, nurse-support, relative to the enhanced-care and education-alone arms are shown in Table 4. The incremental cost of the nurse-support arm compared with the education-alone arm was $3,987 per additional women screened. The incremental cost of the nurse-support arm compared with enhanced-care arm was $5,987 per additional woman screened.

Discussion

Our study documented extremely low baseline mammogram and FOBT screening rates among urban and rural southern FQHC patients. Although the results indicate that 3 different interventions improved the joint rates of mammography and FOBT screening, the nurse-support arm with education and ongoing support was superior. In a post hoc analysis, the nurse-support arm was particularly effective among women with adequate literacy skills, with half of the women completing both screens in a timely manner.

It is noteworthy that a third of the study women (all of whom were not up to date with cancer screening) indicated they had never received a physician recommendation for both tests, and 1 in 4 reported ever having completed both tests. Almost all of the women had seen a physician within the previous year and indicated they would want to know if they had breast and or colon cancer. Our findings indicate that reducing the barriers to getting these screenings by ensuring that women receive recommendations for screening and could then have the screenings at no cost resulted in almost a third of them (28%) completing both tests. Our literacy and culturally appropriate education, developed with the target audience, was not more effective than enhanced care for increasing completion of both tests. The nurse-supported education with telephone follow-up had the greatest impact in increasing screening completion of the mammogram and FOBT. That finding supports previous studies in safety-net settings that focused jointly on breast, colon, and cervical cancers and that found mailed reminders and personal telephone outreach to prompt patients were most effective in encouraging screening completion for the 3 cancers. [20]

Although recent cancer screening interventions focus on more than one cancer, it is difficult to compare screening completion studies because of different study designs,

TABLE 1 Characteristics of study sample at baseline, stratified by study arm

Characteristic	All patients (n = 744)	Study arm			P
		Enhanced-care (n = 210)	Education-alone (n = 224)	Nurse-support (n = 310)	
Mean age, y (SD)	58.4 (7.3)	57.8 (7.6)	57.7 (6.2)	59.3 (7.7)	.29
Age category, y					
50-59	475 (64)	143 (68)	146 (65)	186 (60)	.006
60-69	203 (27)	50 (25)	65 (29)	88 (28)	
70+	66 (9)	17 (8)	13 (6)	36 (12)	
Education, n (%)					
<High school	228 (31)	72 (34)	66 (29)	90 (29)	.27
High school grad	340 (46)	84 (40)	113 (50)	143 (46)	
Some college	132 (18)	41 (20)	35 (16)	556 (18)	
College graduate	44 (6)	13 (6)	10 (4)	21 (7)	
Race, n (%)					
Black	495 (67)	145 (69)	94 (42)	256 (83)	<.0001
White/Hispanic	249 (33)	65 (31)	130 (58)	54 (17)	
Marital status, n (%)					
Single	206 (28)	47 (22)	47 (21)	112 (36)	.009
Married	235 (32)	66 (31)	102 (46)	67 (22)	
Separated	50 (7)	15 (7)	12 (5)	23 (7)	
Divorced	128 (17)	38 (18)	34 (15)	56 (18)	
Widowed	125 (17)	44 (21)	29 (13)	52 (17)	
Literacy level, n (%)					
Limited, <9th grade	355 (48)	123 (59)	61 (27)	171 (55)	.0005
Adequate, ≥9th grade	389 (52)	87 (41)	163 (73)	139 (45)	
Health related, n (%)					
Seen doctor in past 12 mo.	676 (91)	191 (91)	207 (92)	278 (90)	.19
Prior mammogram, FOBT recommendation[a]	217 (33)	57 (29.5)	57 (25.5)	103 (43.3)	<.0001
Prior mammogram, FOBT[a]	160 (24)	39 (20.2)	23 (10.3)	98 (41.2)	.003
Want to know if have breast or colon cancer[a]	577 (88)	166 (86)	201 (90)	210 (88)	.72

[a]n = 655

baseline screening rates, and incomplete information on dates of screening completion.[16-20, 51-52] Our findings support a dual approach to cancer screening in safety-net clinics using personal telephone calls to improve completion rates of mammography and FOBT. In our study, the telephone call not only served as a touch point to connect with the patient and remind her about the screening tests, but helped patients overcome barriers encountered after the clinic visit. The most common barrier to mammography completion was being unable to make the appointment, lack of skills or confidence in rescheduling, and/or uncertainty about finding the public hospital in a distant city. The most common barrier to FOBT completion was losing the kit, forgetting to do the test, needing additional step-by-step instructions on completing the FOBT, and/or mailing the specimen back to the clinic. Providing personal follow-up calls and, if needed, assistance for arranging for another test or problem solving completion may reduce completion barriers for vulnerable patients. Given the cost of the nurse, other strategies such as using less costly medical assistants should be investigated. Even though use of a medical assistant would reduce cost by 45%-50%, this may still be cost prohibitive among FQHCs.

With the recent federal requirement for community

TABLE 2 Primary outcome measure – mammogram and/or FOBT completion within 12 months

Measure	All patients (n = 744)	Study arm, n (%) Enhanced-care (n = 210)	Education-alone (n = 224)	Nurse-support (n = 310)	P[a]
Mamm + FOBT	232 (31.2)	59 (28.1)	53 (23.7)	120 (38.7)	.028
Mamm only	184 (24.7)	57 (27.1)	54 (24.1)	73 (23.6)	
FOBT only	156 (21.0)	29 (13.8)	65 (29.0)	62 (20.0)	
None	172 (23.1)	65 (31.0)	52 (23.2)	55 (17.7)	
		Screening ratio (95% CI), P			
—	—	1.00	0.66 (0.28-1.56), .34	1.45 (0.86-2.46), .16	—
—	—		1.00	2.21 (1.12-4.38), .023	—

[a]All *P* values are from multivariate analyses controlling for age (in years), race (black vs white and Hispanic) and literacy (limited, adequate).

TABLE 3 Primary outcome measure by literacy – both mammogram and FOBT completed within 12 months

Literacy level[a]	All patients, n (%)	Study arm, n (%) Enhanced-care	Education-alone	Nurse-support	P[a]
Limited[b]	355	123	61	171	
Both completed	101 (28)	36 (29.3)	14 (23.0)	51 (29.8)	.60
Adequate[c]	389	87	163	139	
Both completed	131 (34)	23 (26.4)	39 (23.9)	69 (49.6)	.03[d]

Assessed with the Rapid Estimate of Adult Literacy in Medicine (REALM, 0-66; ≤60 = limited, 61-66 = adequate). [b]Reading level at 8th grade or lower. [c]Reading level at 9th grade or higher. [d]*P* = .024, nurse-support vs education-alone.

[a]All P values are from multivariate analyses controlling for age (in years) and race (black vs white and Hispanic).

TABLE 4 Cost-effectiveness analysis

Additional people screened in comparison arm, n	Nurse-support (comparison) vs enhanced-care (reference)	Nurse-support (comparison) vs education-alone (reference)
A Sample size in reference arm	210	224
B No. screened in reference arm	59	53
C Sample size in comparison arm	310	310
D No. screened in comparison arm	120	120
E No. screened in comparison arm normalized to size of reference arm	81.3	86.7
F Additional no. screened in comparison arm normalized to size of reference arm = E – B	22.3	33.7
	Incremental costs of comparison arm, US$	
G Personnel	$185,990	$185,990
H Nonpersonnel	$11,009	$0
I Total incremental costs	$196,999	$185,990
J Total incremental costs normalized to size of reference arm	$133,451	$134,393
Incremental cost-effectiveness ratio = row J/row F	$5,987/person	$3,987/person

health centers to have electronic health records (EHRs), the amount of staff time dedicated to identifying and tracking patients could be substantially reduced. None of the FQHCs in this study had an integrated EHR system at the time of this study. Future studies in FQHCS networks should consider a collaborative outreach program coupling reminder letters generated from the EHR with outreach calls using a designated medical assistant to provide follow-up reminder calls for patients from multiple clinics.

Our study has limitations. Differences were noted between arms in sociodemographic characteristics, literacy, and previous screening history. Due to sample size considerations, not all variables significantly different between arms in Table 1 were adjusted for. Adjustments for key variables (age, race, literacy) were therefore made in statistical analyses. Other limitations relate to 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.

Strategies are needed to overcome limited resources supporting joint cancer screenings for women patients in FQHCs. Future research should explore leveraging less expensive clinic staff, distributing the workload over multiple clinics, and using EHR technology. The foundation seems to be education and nurse support for these interventions.

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