Randomized, Controlled Trial of a Multimodal Intervention to Improve Cancer Screening Rates in a Safety-Net Primary Care Practice

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BACKGROUND: Cancer screening rates are suboptimal for low-income patients.

OBJECTIVE: To assess an intervention to increase cancer screening among patients in a safety-net primary care practice.

DESIGN: Patients at an inner-city family practice who were overdue for cancer screening were randomized to intervention or usual care. Screening rates at 1 year were compared using the chi-square test, and multivariable analysis was performed to adjust for patient factors.

SUBJECTS: All average-risk patients at an inner-city family practice overdue for mammography or colorectal cancer (CRC) screening. Patients' ages were 40 to 74 years (mean 53.9, SD 8.7) including 40.8 % African Americans, 4.2 % Latinos, 23.2 % with Medicaid and 10.9 % without any form of insurance.

INTERVENTION: The 6-month intervention to promote cancer screening included letters, automated phone calls, prompts and a mailed Fecal Immunochemical Testing (FIT) Kit.

MAIN MEASURES: Rates of cancer screening at 1 year.

KEY RESULTS: Three hundred sixty-six patients overdue for screening were randomly assigned to intervention ($n=185$) or usual care ($n=181$). Primary analysis revealed significantly higher rates of cancer screening in intervention subjects: 29.7 % vs. 16.7 % for mammography ($p=0.034$) and 37.7 % vs. 16.7 % for CRC screening ($p=0.0002$). In the intervention group, 20 % of mammography screenings and 9.3 % of CRC screenings occurred at the early assessment, while the remainder occurred after repeated interventions. Within the CRC intervention group 44 % of screened patients used the mailed FIT kit. On multivariable analysis the CRC screening rates remained significantly higher in

the intervention group, while the breast cancer screening rates were not statistically different.

CONCLUSIONS: A multimodal intervention significantly increased CRC screening rates among patients in a safety-net primary care practice. These results suggest that relatively inexpensive letters and automated calls can be combined for a larger effect. Results also suggest that mailed screening kits may be a promising way to increase average-risk CRC screening.

KEY WORDS: breast neoplasms; colorectal neoplasms; cancer screening; healthcare disparities.

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BACKGROUND

In the US, patients from racial minority groups and low income patients are less likely to receive cancer screening tests than other patients.^{1,2} Differential access to healthcare services, cultural and communication barriers, and competing health and economic priorities partially explain this disparity.³ Low rates of breast and colorectal cancer screening result in later stage at diagnosis and disparities in cancer survival.⁴

Effective interventions to improve cancer screening rates are needed, particularly those that are effective for low-income populations. Systematic review of the evidence for interventions to promote breast and colorectal cancer screening reveals that the most effective local interventions for increasing screening are those performed in the healthcare setting, as opposed to the community at large.^{5,6} Furthermore, patient navigation programs and other forms of tailored patient counseling that remove access barriers such as cost, transportation and appointment-scheduling have been proven successful.^{7–10} Unfortunately, expensive or complex strategies such as patient navigator programs may not be feasible in the under-

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resourced primary care practices in which many poor and minority patients receive care.^{10–12}

By contrast, electronic physician reminders have little effect on screening rates, and solitary, lower-cost interventions (mailed patient reminders, automated phone calls) increase screening rates, but only modestly.^{6,13–17} However, several low-cost interventions might be combined to improve effect sizes. Stone et al. reviewed interventions to improve preventive healthcare services and showed an additive effect of combined interventions.¹⁸ Providing empirical support for this concept, several recent studies have reported on combined interventions to increase cancer screening.^{19,20}

In this context, we sought to combine lower cost, feasible interventions into a multimodal cancer screening promotion for mammography and colorectal cancer screening for low income patients past due for screening.²¹ Using the Health Belief Model “cues to action” as a guiding framework, we employed repeated reminders and prompts at different times and through different modalities to prompt action.²² We selected the bundle of interventions to target the patient (based on the work of Stone *et al*) and to include both reminders (patient letters, phone calls to patients, provider prompts) and organizational change (mailed testing kits rather than opportunistic screening), because these have the greatest evidence supporting them, among lower-cost options.¹⁸

To avoid the selection bias often introduced by formally enrolling patients via an informed consent process, the current trial randomized all patients in the practice who were overdue for screening; waiver of informed consent was provided by the IRB. This design was employed to increase the generalizability of findings.

METHODS

Practice Setting

A large primary care practice in Rochester, New York, serving a large proportion of low-income and minority patients was recruited to participate. An electronic listing of all active patients was obtained, and eligibility criteria for patient inclusion were reviewed in the practice’s electronic health record (EHR). The study was approved by the Institutional Review Board of the University of Rochester.

Eligibility Criteria

Patients were eligible for randomization if they were overdue for the targeted cancer screening and average-risk for the cancer by EHR review. Age criteria were age 40–74 years for mammography (females) or 50–74 years for colorectal cancer (males and females) on the date of randomization. Patients were defined as overdue for mammography screening if more than 18 months from the last mammogram or past due for the follow-

up interval specified at the prior mammogram. For colorectal cancer screening, patients were defined as overdue if >12 months from the last fecal occult blood testing or >5 or 10 years since last sigmoidoscopy or colonoscopy, respectively, or past the time recommended at last screening. Female patients could be eligible for both interventions. Patients were excluded if they did not have a visit to the practice during the past 2 years (in order to be considered an “active patient”). High-risk patients for breast or colorectal cancer were not randomized or included in the analysis, but received the intervention.

Patient data [race/ethnicity, zip code (mapped to median income), insurance status and type, name of the primary care physician and contact information] were imported into a secure, customized registry (Microsoft AccessTM). Most recent dates of screening were determined through manual review of the EHR by trained research assistants using data abstraction instruments. An offsite study statistician randomized participants to intervention or control groups using a random number algorithm stratified by the type of screening required (breast cancer, CRC or both). Healthcare and data abstraction personnel were blinded to group assignment.

Multimodal Intervention

The multimodal intervention was delivered between April and September 2010, consisting of letters, automated telephone calls, a point-of-care prompt and mailing of a home testing kit to CRC screening patients. The timeline of the intervention is summarized in Table 1.

Letters. An outreach worker mailed a personalized letter to each intervention patient. The letter was addressed from the patient’s primary care office and indicated the patient was overdue for mammography, CRC or both. The letter also indicated why screening was important and included information on how uninsured patients could obtain free cancer screening [i.e., through a local program supported by the National Breast and Cervical Cancer Early Detection Program (NBCCEDP)²³ and the Colorectal Cancer Control

Table 1. Intervention Timeline

Timeline	Intervention group	Control group
Week 1	Letter 1	Usual care
Week 2	Automated telephone message 1	
Week 6	Automated telephone message 2	Blinded chart review
Week 11	Blinded chart review (if patient screened, stop intervention)	
Week 12	Letter 2 and FIT kit	
Week 14	Automated telephone message 3	
Week 25	Automated telephone message 4	
Week 1–25	Point-of-care prompt (if a primary care appointment occurred)	Blinded chart review-final
Week 26	Stop intervention/usual care	
Week 52	Blinded chart review-final	

Program (CRCCP)²¹. The letter also gave the patient the opportunity to call the outreach worker with questions or for assistance, although only a small minority of patients did so.

A second letter was sent at week 12 of the intervention to patients who remained unscreened. Patients in need of CRC screening were mailed kits for stool testing [Fecal Immunochemical Test (FIT) kit] with the second letter.²⁴ Interventions and screening were tracked in the database.

Automated Telephone Calls. An automated telephone reminder system (Televox® system) was utilized to deliver automated calls to the telephone number in the practice database for each intervention patient. The automated phone calls contained similar information to the letters, but in a brief form (approximately 25 s), with a phone number to call to arrange for screening. The automated calls were made on weeks 2 and 6 of the intervention period and repeated on weeks 14 and 25 for patients remaining unscreened on EHR review performed on week 11. Each call cost \$0.09 to the program, which represents an institutional rate.

Point-of-Care Prompts. Written prompt sheets for providers and patients were developed as previously described.²⁵ These were delivered to the practice each week for medical assistants to distribute at the time of an intervention-randomized patient appointment. The study team did not attempt to confirm that the prompts were actually given to the patient and/or clinician. The prompt sheets reminded both the clinician and patient that the patient was past due for mammography and/or CRC screening. The back of each CRC prompt sheet briefly summarized the advantages and limitations for CRC screening modalities as a way of facilitating clinician-patient discussion. Because the research team hypothesized that the complex decision-making for CRC screening was a barrier to screening, the decision-making summarized in the prompt was *dichotomized* to colonoscopy versus high-sensitivity home stool testing. This is because preliminary interviews of primary care providers revealed that these were the predominant modes of testing utilized in the practice.

Medical Record Reviews. At week 12 of the intervention period, a review of the EHR was performed to determine whether each patient had undergone screening; if so, the intervention was stopped. To avoid bias in outcome ascertainment, these reviews were performed on both intervention and control group patients by research personnel unaware of the randomization group (the randomization group and intervention information were made electronically inaccessible to the personnel performing chart reviews).

Cost of Intervention. The cost per letter mailed was approximately \$1.90, including material and labor costs. The total cost for the automated calls was about \$0.92, including the preparation of each list of call recipients from the database

and the monitoring of post-call status. The FIT kits cost about \$25.12, including the Medicare reimbursement rate for the kit and the preparation for mailing/mailling costs. Finally, a small labor cost was incurred for using the point-of-care prompts. Medical assistant wages are about \$14.48 per hour (<http://www.bls.gov/oes/current/oes319092.htm>). Using the prompts is estimated to take about 15 min per day of a medical assistant's time, so for a practice about \$3.62 per day in staff time would be needed to distribute the written prompts.

Outcome Measures

The primary outcome was documented mammography or colorectal cancer screening during the 52 weeks after randomization. This was measured using EHR review; a research assistant blinded to treatment assignment abstracted data from the EHR. A patient was considered 'screened' based on the EHR documentation of screening for breast cancer (mammography report) or colorectal cancer (fecal occult blood testing, colonoscopy, flexible sigmoidoscopy or double contrast barium enema reports).

Statistical Analysis

Rates of screening were compared using a chi-square test and also using a logistic regression model that included age, sex, race/ethnicity, insurance and median household income by zip code from the 2000 US Census. An intention-to-treat analysis was performed; that is, all patient originally assigned to a group were analyzed. SAS 9.2 for Windows was used for analysis.

RESULTS

Figure 1 outlines patient flow through the clinical trial protocol. Among 520 patient medical records reviewed, 366 patients met the inclusion criteria. The characteristics of the randomized patients are shown in Table 2. The overall sample was middle aged and predominantly female. Approximately half were minority, one quarter had Medicaid and 11 % were uninsured. Despite randomization, there was a statistically significant difference in age and income between the intervention and control groups for the mammography intervention; the control group was older and of lower income. There were no significant differences in participants at baseline between those in the intervention and control groups in the CRC group.

The fidelity of the interventions was informally tracked by the research team. Overall, the automated phone calls were answered in most cases; out of 670 calls to 183 subjects, 86 % of calls were "successful" and 96 % of subjects received at least one "successful" call. For the prompts delivered to the practice

Figure 1. Patient randomization flow chart.

by research staff, the proportion that were actually given to the provider and/or patient was not formally tracked; anecdotally, there was a minority of instances in which the prompts were discovered “undelivered” at the end of the day.

Unadjusted rates of cancer screening were significantly higher in the intervention compared to the control group for

both mammography and CRC screening (Fig. 2). Specifically, at the end of the study, screening rates for mammography were 29.7 % in the intervention group vs. 16.7 % in the control group ($p=0.034$). The CRC screening rate was 37.7 % in the intervention group vs. 16.7 % in the control group ($p=0.0002$). In Figure 3, these results are stratified by race/

Table 2. Baseline Characteristics of Mammography (a) and Colorectal Cancer Screening (b) Participants by Intervention Group

a. Mammography proportion by group	Intervention (n=101)	Control (n=90)	p-value*
Age (years)			0.0244
40–49	59.4	45.6	
50–59	25.7	23.3	
60+	14.9	31.1	
Race/Ethnicity			0.6292
Non-Hispanic black	41.1	45.8	
Other race—including Hispanic	11.1	7.2	
Non-Hispanic white	47.8	47.0	
Household income			0.0296
>\$40,000	48.0	27.0	
\$30,000–\$39,000	31.0	43.8	
<\$30,000	21.0	29.2	
Insurance			0.2280
Private	46.5	37.8	
Medicare	21.8	28.9	
Medicaid	14.9	22.2	
None	16.8	11.1	
b. Colorectal cancer screening proportion by group	Intervention (n=114)	Control (n=126)	p-value*
Age (years)			0.8524
50–59	62.3	61.1	
60+	37.7	38.9	
Race/Ethnicity			0.4056
Non-Hispanic black	43.0	36.3	
Other race—including Hispanic	5.0	8.8	
Non-Hispanic white	52.0	54.9	
Household income			0.7611
>\$40,000	33.9	32.8	
\$30,000–\$39,000	43.8	40.8	
<\$30,000	22.3	26.4	
Insurance			0.5866
Private	36.8	34.1	
Medicare	31.6	34.1	
Medicaid	18.4	23.0	
None	13.2	8.7	

*Chi-square test; column percentages reported. Note: patients eligible for both breast cancer and colorectal cancer screening are counted twice in the table under both (a) mammography and (b) colorectal cancer screening

ethnicity. African American subjects have a pronounced increase in screening rates in the intervention groups.

These screening rates were assessed 1 year after randomization; however, an early assessment was also performed at 11 weeks after randomization. In the intervention group, 20 % of breast cancer screenings and 9.3 % of colorectal screenings were performed at the 11-week early assessment, while the remainder occurred after repeated interventions.

Within the CRC intervention group, 44 % of screened patients used a FIT kit, 44 % used colonoscopy and 12 % used a traditional fecal occult blood testing (FOBT) kit. By contrast, in the control group, 14 % used a FIT kit, 52 % used colonoscopy, and 33 % used a traditional FOBT kit. These results suggest that the mailed FIT kit portion of the intervention may have been particularly effective. Overall, of 92 FIT kits mailed, 19 were successfully used.

We reassessed these findings with logistic regression models that controlled for participant characteristics, given

that the randomized groups were not equal in their baseline characteristics. The adjusted odds ratio for mammography screening (Table 3) was not significant in this secondary analysis [1.96 (95 % CI 0.87–4.39)]. Medicare insurance and Hispanic/other race were each independently associated with higher screening rates. The adjusted odds ratio for CRC screening remained significant [3.22 (95 % CI 1.65–6.30)] (Table 3). Intervention (versus control group) and age (50–59 versus 60+) were independently associated with screening in the CRC screening multivariable model.

We analyzed those subjects in the intervention group that remained unscreened (the “failed intervention” group) to determine whether particular characteristics were associated with lack of response to the intervention (Table 4). There were no statistically significant differences between screened and unscreened intervention patients, but there was a trend toward the failed intervention group having a greater proportion of white patients, more low income patients, more uninsured patients and fewer Medicare patients.

DISCUSSION

This randomized trial tested a relatively low-cost, multimodal intervention to improve cancer screening rates for primary

Figure 2. Breast (a) and colorectal cancer (b) screening rates at 12 months: intervention vs. control groups (notes: All patients were overdue for screening at the time of randomization; p-values are not adjusted for differences in patient characteristics).

Figure 3. Breast (a) and colorectal cancer (b) screening rates stratified by race/ethnicity: intervention vs. control groups.

Table 3. Adjusted Logistic Regression Model for Mammography (a) and Colorectal Cancer Screening (b)

	Odds ratio	Lower 95 % CI	Upper 95 % CI
a. Mammography effect			
Groups			
Intervention	1.96	0.87	4.39
Control (ref.)	1.00	1.00	1.00
Age			
40–49	1.41	0.48	4.14
50–59	2.05	0.61	6.98
60+ (ref.)	1.00	1.00	1.00
Race/ethnicity			
Non-Hispanic black	1.23	0.49	3.10
Other race—including Hispanic*	5.64	1.57	20.29
Non-Hispanic white (ref.)	1.00	1.00	1.00
Household income			
>\$40,000	2.65	0.84	8.43
\$30,000–\$39,000	1.44	0.49	4.29
<\$30,000 (ref.)	1.00	1.00	1.00
Insurance			
Private	1.50	0.36	6.19
Medicare*	6.24	1.23	31.61
Medicaid	2.57	0.57	11.59
None (ref.)	1.00	1.00	1.00
b. Colorectal cancer screening effect			
Groups			
Intervention*	3.22	1.65	6.30
Control (ref.)	1.00	1.00	1.00
Sex			
Male	1.80	0.91	3.56
Female	1.00	1.00	1.00
Age			
50–59*	2.17	1.01	4.70
60+ (ref.)	1.00	1.00	1.00
Race/ethnicity			
Non-Hispanic black	1.68	0.80	3.50
Other race—including Hispanic	1.78	0.45	6.98
Non-Hispanic white	1.00	1.00	1.00
Household income			
>\$40,000	1.88	0.69	5.09
\$30,000–\$39,000	1.98	0.83	4.76
<\$30,000 (ref.)	1.00	1.00	1.00
Insurance			
Private	1.58	0.38	6.53
Medicare	3.61	0.83	15.55
Medicaid	2.53	0.57	11.21
None (ref.)	1.00	1.00	1.00

*Statistically significant ($p < 0.05$)

care patients at average risk for breast and colorectal cancer who were past due. The intervention was associated with an increase in screening rates (to almost 30 % for mammography and almost 37 % for CRC) against a background of very low screening rates among patients not current with screening who received usual care (16.7 %), though the improvement in breast cancer screening did not quite reach statistical significance after adjustment [(OR 1.96 (95 % CI 0.87–4.39)]. This study is a significant contribution to the existing literature in two main ways: (1) it shows a larger effect size than most studies among patients past due, and (2) it highlights the potential for a mailed CRC screening kit, building on several recent studies.^{19,26}

Decreasing healthcare disparities is a major public health goal in the US.²⁷ For several reasons, cancer screening is an obvious target for addressing disparities. First, it has been shown that socioeconomically disadvantaged patients are disproportionately unscreened, and a lack of screening is

one mechanism for decreased survival from breast and colorectal cancer.^{2,28} Second, financial barriers may be less prohibitive for cancer screening compared to other healthcare services, because cancer screening is generally covered by governmental and other healthcare insurers, and cancer screening programs for the uninsured are available.²⁹

Nevertheless, improving rates of cancer screening for patients in safety-net primary care practices has proven difficult due in part to the stressed environment of the under-resourced primary care practices in which many disadvantaged patients receive care.^{11,30,31} These practices often lack adequate staffing and information systems to support tracking, reminders and counseling for preventive services. Furthermore, low socioeconomic status is associated with a higher burden of comorbid illnesses, leading to further difficulty in allocating time to preventive care within a rushed primary care visit.^{31,32}

Other intervention trials have suggested that organizational change is a successful way to increase screening rates, such as designating non-physician providers to discuss screening, holding specific clinics for this purpose or employing patient navigators.^{10,33} However, dissemination of these resource-intensive interventions may not always be feasible in the

Table 4. Baseline Characteristics of Mammography (a) and Colorectal (b) Participants by Screening Status for Intervention Group

	Screened (n=30)	Not screened (n=71)	p-value*
a. Mammography proportion by group			
Age (years)			0.6865
40–49	63.3	57.7	
50–59	20.0	28.2	
60+	16.7	14.1	
Race/ethnicity			0.0889
Non-Hispanic black	37.0	42.9	
Other race—including Hispanic	22.2	6.3	
Non-Hispanic white	40.8	50.8	
Household income			0.3898
>\$40,000	56.7	44.3	
\$30,000–\$39,000	30.0	31.4	
<\$30,000	13.3	24.3	
Insurance			0.0823
Private	46.7	46.5	
Medicare	26.7	9.9	
Medicaid	20.0	22.5	
None	6.6	21.1	
b. Colorectal screening proportion by group			
Age (years)			0.6269
50–59	65.1	60.6	
60+	34.9	39.4	
Race/ethnicity			0.4407
Non-Hispanic black	50.0	38.7	
Other race—including Hispanic	2.6	6.5	
Non-Hispanic white	47.4	54.8	
Household income			0.1540
>\$40,000	32.6	34.8	
\$30,000–\$39,000	53.5	37.7	
<\$30,000	13.9	27.5	
Insurance			0.6261
Private	34.9	38.0	
Medicare	32.6	31.0	
Medicaid	23.2	15.5	
None	9.3	15.5	

*Chi-square test; column percentages reported

safety-net primary care setting, in which personnel are often working at peak capacity and cannot take on additional tasks. Low-intensity interventions may be successful in practices with high baseline screening rates, but may not be successful among practices with low socioeconomic status and low screening rates.^{33,34} This trial was specifically designed for use in safety-net practices: a relatively low-cost intervention with low-literacy materials and a minimum of provider time required to implement it. Another unique feature of the trial was that *all* patients behind on screening were randomized, instead of approaching patients and obtaining informed consent, which in other studies has created selection bias in the study population.

These findings suggest a multiple-pronged strategy for reducing disparities in cancer screening. The first step is to target practices serving lower income and minority patients. The second step is to focus on those past due, and the third step is to use increasingly intensive interventions for non-responders, as this study did. We found that less than 20 % of patients who eventually were screened in the intervention group had completed screening at the early time-point assessment. Most of those eventually screened were screened only after multiple interventions, emphasizing the importance of repeated contacts. Finally, this study suggests a multimodal intervention may be superior to single interventions in practices serving patients of low socioeconomic status. Furthermore, we feel this intervention has potential for real-world implementation. As EHR systems become more functional in response to meaningful use criteria, it will become increasingly feasible to implement multimodal outreach to patients. Also, our low-literacy prompts could be implemented in any practice regardless of the presence of an EHR system.

The primary limitation of this trial is that these results may not be generalizable, as it was conducted in a single practice. The extremely low screening rates among usual care patients in the study reflect a primary care setting predominantly serving patients of low socioeconomic status, previously shown to be at risk for omission of cancer screening.³⁵ As such, these results are most applicable to practices with low baseline rates of cancer screening. Also, the non-statistically significant result of the breast cancer intervention on multi-variable analysis may reflect limited power, since the odds ratio approached two. Finally, a weakness of this study is that it did not incorporate a formal “implementation assessment” to allow the investigators to understand the details of which aspects of the intervention were implemented successfully, barriers to implementation and which aspects of the multimodal intervention actually “worked.” We hypothesize that “what works” varies by patient; that is, different patients respond to different processes, explaining why this multimodal intervention had a bigger effect than single interventions. This is consistent with the underlying Health Belief Model (specifically “cues to action”). In future research, we will seek to better understand the implementation and differentiate the effects of different components of the intervention.

In summary, a combination of letters, automated phone calls, patient prompts and home testing kit mailing resulted in increased cancer screening for patients in a safety net practice. We believe that implementing a combination of low-cost interventions such as these is feasible in safety-net practices, and this multimodal intervention does show a larger effect size compared to individual interventions. These results particularly highlight the promise of mailing a test kit directly to unscreened patients. Additional studies will be required to determine the “ideal” low-intensity intervention and to streamline the process for dissemination to primary care practices with low cancer screening rates.

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