Comparative Effectiveness of a Multifaceted Intervention to Improve Adherence to Annual Colorectal Cancer Screening in Community Health Centers

A Randomized Clinical Trial

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**IMPORTANCE** Colorectal cancer (CRC) screening rates are lower among Latinos and people living in poverty. Fecal occult blood testing (FOBT) is one recommended screening modality that may overcome cost and access barriers. However, the ability of FOBT to reduce CRC mortality depends on high rates of adherence to annual screening.

**OBJECTIVE** To determine whether a multifaceted intervention increases adherence to annual FOBT compared with usual care.

**DESIGN, SETTING, AND PARTICIPANTS** Patient-level randomized controlled trial conducted in a network of community health centers. Included were 450 patients who had previously completed a home FOBT from March 2011 through February 2012 and had a negative test result: 72% of participants were women; 87% were Latino; 83% stated that Spanish was their preferred language; and 77% were uninsured.

**INTERVENTIONS** Usual care at participating health centers included computerized reminders, standing orders for medical assistants to give patients home fecal immunochemical tests (FIT), and clinician feedback on CRC screening rates. The intervention group also received (1) a mailed reminder letter, a free FIT with low-literacy instructions, and a postage-paid return envelope; (2) an automated telephone and text message reminding them that they were due for screening and that a FIT was being mailed to them; (3) an automated telephone and text reminder 2 weeks later for those who did not return the FIT; and (4) personal telephone outreach by a CRC screening navigator after 3 months.

**MAIN OUTCOMES AND MEASURES** Completion of FOBT within 6 months of the date the patient was due for annual screening.

**RESULTS** Intervention patients were much more likely than those in usual care to complete FOBT (82.2% vs 37.3%; \( P < .001 \)). Of the 185 intervention patients completing screening, 10.2% completed prior to their due date (intervention was not given), 39.6% within 2 weeks (after initial intervention), 24.0% within 2 to 13 weeks (after automated call/text reminder), and 8.4% between 13 and 26 weeks (after personal call).

**CONCLUSIONS AND RELEVANCE** This intervention greatly increased adherence to annual CRC screening; most screenings were achieved without personal calls. It is possible to improve annual CRC screening for vulnerable populations with relatively low-cost strategies that are facilitated by health information technologies.

**TRIAL REGISTRATION** clinicaltrials.gov Identifier: NCT01453894

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Only 60% of US adults aged 50 to 75 were up-to-date on colorectal cancer (CRC) screening in 2010, and disparities persist by income, education, race/ethnicity, language, and insurance coverage. The vast majority of CRC screening in the United States is by colonoscopy, even for individuals with low income and the uninsured. This is likely because US physicians believe that colonoscopy is the most effective screening strategy, although available studies suggest that FOBT, sigmoidoscopy, and colonoscopy can achieve similar reductions in CRC mortality. This heavy reliance on colonoscopy for CRC screening for populations that face barriers to completing colonoscopy may contribute to disparities.

Expanded use of fecal occult blood tests (FOBT) may help remediate disparities. New fecal immunochemical tests (FIT) have good sensitivity and specificity, can be completed at home, require only a single stool sample, and do not need dietary changes prior to specimen collection. A recent study conducted in an integrated health plan found that mailing patients FOBTs increased the proportion of people screened for CRC. In a study of uninsured patients cared for in a safety net health system, FIT outreach was completed by 40.7% of the target population, which was higher than for colonoscopy outreach (24.6%) and usual care (12.1%).

However, to reduce CRC mortality, high levels of adherence to annual or biennial FOBT are needed. In the study by Mandel and colleagues in which annual FOBT was found to decrease CRC mortality by 33%, 69% of participants completed 75% or more of all planned tests. It is unclear whether it is possible to achieve similarly high adherence rates among vulnerable populations that face multiple financial and non-financial barriers to CRC screening. Few studies have examined adherence to annual screening or strategies to increase adherence.

Our research group previously reported that at a community health center in Chicago, Illinois, only 22% of patients who completed a home FOBT in 2011 completed a second FOBT within 18 months of their first test. A study from Scotland reported that of the people who completed a FOBT after an initial outreach, only 54% completed FOBT during the second round. In a study of patients in an integrated health plan, adherence to annual FOBT was only 20.8% with usual care; however, outreach increased adherence to 70.4%

If screening by FOBT cannot be conducted annually with high reliability, endoscopy may be a more effective screening strategy for reducing CRC mortality in some populations. However, this would require a substantial increase in resources to make endoscopy available and affordable for underserved populations. Policy makers and clinicians need to understand the rate of adherence to annual FOBT to guide programs and policies to address CRC screening disparities. The goal of the present study was to determine the effectiveness of an intervention at a community health center (CHC) to maximize adherence to annual FOBT.

Methods
This study was approved by the Northwestern University institutional review board, which also waived informed consent from all eligible patients for inclusion in the study and randomization to intervention and usual care. The methods and patient outreach materials have been detailed previously. Briefly, this multimodal intervention involved mailing a FOBT kit to patients’ homes and following up with automated telephone and text reminders. If the FOBT was not completed in 3 months, a CRC screening navigator personally contacted the patient. The 2-stage design allowed us to determine the incremental benefits of the components of the intervention.

Study Site and Populations Served
The study was conducted at the Erie Family Health Center (EFHC), a federally qualified health center network in Chicago, Illinois. At the time of this study, EFHC had 4 CHCs serving adult patients. The EFHC serves an overwhelmingly Hispanic/Latino population; 66% are best served in Spanish; 36% are uninsured; and 91% have incomes below the federal poverty line. The EFHC’s electronic health record (EHR) includes clinical reminders for CRC screening. Prior to this study, the EFHC initiated a strategic plan to improve CRC screening, including (1) empowering medical assistants to identify patients due for screening, counsel them, and give them a home FOBT kit; (2) routine quality measurement and feedback to clinicians on their CRC screening rates; and (3) inclusion of CRC screening as one of the quality metrics used for clinicians’ incentive compensation formula. Following these improvements, the proportion of patients up-to-date on CRC screening increased from 17% in 2007 to 43% in 2009. These interventions were continued throughout the study for all patients.

Eligibility and Exclusion Criteria
The eligibility criteria were age 51 to 75 years; preferred language listed as English or Spanish; and a negative FOBT result obtained between March 1, 2011, and Feb 28, 2012. We focused on patients who had previously completed a FOBT because our goals were to improve adherence to annual FOBT and to see if it was possible to achieve the high rates of adherence needed to reduce CRC mortality. We excluded patients who (1) had undergone colonoscopy within the previous 10 years; (2) had undergone flexible sigmoidoscopy within the previous 5 years; or (3) had medical conditions that might render FOBT inappropriate for CRC screening (eg, chronic diarrhea, inflammatory bowel disease, or iron deficiency).

Identification of Eligible Patients and Randomization
We searched the EFHC’s EHR data to identify eligible patients and to document their demographic characteristics, chronic medical conditions, clinic visits, and contact information. All eligible patients were randomly assigned to the intervention or usual care groups; people living in the same household (n = 28) were randomized by household; all statistical analyses adjusted for this clustering.

Intervention
The intervention was designed to address reasons for failure to adhere to annual FOBT. The main components of the intervention are briefly summarized in the Box. All aspects of the intervention were implemented by clinic staff members (ie,
health informaticist and care manager) using existing resources in the clinic (health information technology, automated calling and texting system). Outreach and specimen processing were performed centrally for all sites.

We used the Polymedco OC-Light Fecal Occult Blood Test, a FIT that detects human hemoglobin in feces in concentrations as low as 0.05 μg/mL. It is a single-specimen test that does not require dietary modifications. The reported sensitivity and specificity of the OC-Light for detecting CRC are 91.0% and 93.8%, respectively. The OC-Light is a Clinical Laboratory Improvement Amendments (CLIA)-waived test; returned tests were developed by the EFHC central laboratory. At the start of the study, all EFHC sites had their previous guaiac-based FOBTs replaced by the OC-Light FIT, and the staff was trained in proper use of the test, so this became the new standard of care.

Each week, we mailed a FIT kit to all intervention patients due for repeat FOBT screening along with a letter from their primary care clinician and plain language FIT instructions. We then sent an automated telephone call and 2 days later a text message via a contracted commercial system (CallPointe). The system software allowed tracking of completed telephone and text messages and whether messages were answered in person or by voice mail. Two weeks later, we queried the EHR to identify patients who did not return the FIT, and we sent them another automated telephone call and text message.

Three months after the initial outreach, we identified those who still had not completed screening, and the CRC screening navigator attempted to contact them by telephone. If the patient was contacted and verbalized willingness to complete the test, we mailed another FIT kit. If the navigator only reached voice mail, a standard script was read and a contact number provided.

FIT kits were centrally processed. If the FIT result was negative, the navigator notified the patient by mail; the envelope included a letter reminding the patient that the test must be repeated in 1 year and a separate reminder card. If the FIT result was positive, the navigator worked with the patient’s physicians to arrange diagnostic colonoscopy. The EFHC provided free transportation for patients if necessary, and free colonoscopy was available through the Northwestern Medical Faculty Foundation and Northwestern Memorial Hospital.

We estimated intervention costs by summing the costs of all of the following: FITs; automated telephone and text message reminders; study mailings (materials and associated postage costs); and estimated labor costs (wages plus 25% fringe) for (1) outreach by the CRC screening navigator and (2) processing of completed FITs by a laboratory technician.

Outcome Assessment and Analysis
Analyses were performed using Stata 11.2 (StataCorp LP). The primary outcome for the study was completion of FOBT within 6 months of the date due for annual testing based on an EHR query. We exclusively used EHR date to assess completion of CRC screening.

Some study patients had a repeat FOBT performed at a clinical encounter before their due date. The intervention was not conducted for these patients, but they were included in analyses of the primary end point. Differences in outcomes between the intervention and control groups were compared using χ² tests. A predefined subgroup analysis was performed to determine how the effect of the intervention varied by the number of clinic visits patients had during the 6-month follow-up period.

The study was originally designed to assess annual adherence for 2 waves of outreach over 2.5 years. After observing a very high completion rate in the intervention group during the initial few months, we met with all members of the study team, the medical director from the EFHC, and a representative from another community health center to determine whether it would be ethical to continue if the difference between study groups was as large as expected, based on the historical rate of adherence to annual testing (we were blinded to the rate in the usual care group). The group decided to conduct an interim analysis after patients in the first 6 months of the study had all reached their primary end point. We developed pre-specified rules using the O’Brien-Fleming method to determine stopping criteria, setting a P < .006 as the cutoff for the interim analysis and a P < .044 for the final analysis. In the interim analysis (n = 137 in both groups), 78.8% of the intervention and 36.5% of the control patients reached the primary outcome (P < .001). Therefore, we completed the first year as planned, concluded the randomized clinical trial, and began outreach (mailing, automated baseline and 2-week telephone calls/texts) to the usual care group.

We also examined the fidelity of the intervention, including the proportion of patients for whom the mailed FIT was returned to sender, the proportions that received the text message and the

### Box. Intervention Components

- The electronic health record was searched to identify patients due for annual FOBT.
- Patients due for annual FOBT were mailed FOBT kits (a single-sample FIT) along with a postage-paid return envelope so they could perform the test conveniently at home without the time and expense of a clinic visit.
- Automated telephone calls and text messages were used to notify patients that they were due for repeat CRC screening and that they would be receiving a kit in the mail.
- To overcome literacy barriers, plain language information and instructions with explanatory graphics were developed for the study and included in the mailing to increase understanding of FOBT use and adherence.
- If the FOBT was not returned in 2 weeks, we repeated the automated call and text.
- After 3 months, the CRC screening navigator called patients who failed to complete the FOBT; a second FOBT was sent to patients who could be contacted and who said they would complete it if sent again.
- If a returned FOBT result was negative, we informed patients by mail and reminded them that they are not protected by a single test and that the test should be repeated in 1 year; if the FOBT result was positive, colonoscopy was arranged, and the patient was tracked until completion.

Abbreviations: CRC, colorectal cancer; FIT, fecal immunochemical test; FOBT, fecal occult blood test.
automated call, and the proportion of automated calls answered either in person or by voicemail. To analyze the associations between the components of the intervention that patients received and whether they completed the FIT, we first conducted bivariate analyses using χ² tests. Receipt of the automated call was classified as (1) answered in person, (2) answered by voicemail, or (3) not completed. Receipt of the text message was a dichotomous (yes/no) variable. We then used multivariate logistic regression to adjust for demographic characteristics and determine the independent association between receipt of the automated call, receipt of the text message, and completion of the FIT within 2 weeks of the initial outreach. We excluded 23 patients in the intervention group who did not receive the intervention. A 2-sided \( P = .05 \) was considered significant in these models.

**Results**

At the start of the study, 450 patients were identified as eligible based on a negative FOBT result in the prior year (Figure); 225 were randomized to each group. A total of 23 patients in the intervention group (10.2%) completed the FIT prior to their due date and were not given the outreach intervention. The average age of participants was 60 years; 72% were female; the vast majority identified their race/ethnicity as Latino/Hispanic and their preferred language as Spanish; over three-fourths were uninsured; and approximately two-thirds had 1 or more chronic conditions (Table 1).

The rate of completion of the FIT within 6 months of the due date was 82.2% in the intervention group and 37.3% in the usual care group (absolute increase, 44.9%; relative increase, 83.1%; number needed to perform outreach to achieve 1 additional completed FIT, 2.2; \( P < .001 \)) (Table 2). Among FIT completers, the median times to completion for the intervention and usual care groups were 13 and 83 days, respectively. In addition, 6 patients in each group (2.7%) underwent colonoscopy.

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**Table 1. Patient Characteristics for the Intervention and Usual Care Groups**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention (n = 225)</th>
<th>Usual Care (n = 225)</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>59.5 (6.1)</td>
<td>59.6 (5.7)</td>
<td>.60</td>
</tr>
<tr>
<td>Female</td>
<td>158 (70.2)</td>
<td>164 (72.9)</td>
<td>.60</td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Latino/Hispanic</td>
<td>197 (87.6)</td>
<td>205 (91.1)</td>
<td>.29</td>
</tr>
<tr>
<td>Other</td>
<td>28 (12.4)</td>
<td>20 (8.9)</td>
<td></td>
</tr>
<tr>
<td>Preferred language</td>
<td></td>
<td></td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Spanish</td>
<td>188 (83.6)</td>
<td>188 (83.6)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>37 (16.4)</td>
<td>37 (16.4)</td>
<td></td>
</tr>
<tr>
<td>Insurance status</td>
<td></td>
<td></td>
<td>.91</td>
</tr>
<tr>
<td>Uninsured</td>
<td>174 (77.3)</td>
<td>172 (76.4)</td>
<td></td>
</tr>
<tr>
<td>Insured</td>
<td>51 (22.7)</td>
<td>53 (23.6)</td>
<td></td>
</tr>
<tr>
<td>Chronic medical conditions</td>
<td></td>
<td></td>
<td>.11</td>
</tr>
<tr>
<td>0</td>
<td>81 (36.0)</td>
<td>61 (27.1)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>73 (32.4)</td>
<td>72 (32.0)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>58 (25.8)</td>
<td>71 (31.6)</td>
<td></td>
</tr>
<tr>
<td>≥3</td>
<td>13 (5.8)</td>
<td>21 (9.3)</td>
<td></td>
</tr>
</tbody>
</table>

*Unless otherwise indicated, data are reported as number (percentage) of patients.

**Table 2. Completion of CRC Screening Within 6 Months of Due Date Among Patients Who Completed a FOBT in the Previous Year**

<table>
<thead>
<tr>
<th>Test Completed</th>
<th>Patients, No. (%)</th>
<th>Intervention (n = 225)</th>
<th>Usual Care (n = 225)</th>
<th>( \chi^2 ) ( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>FOBT</td>
<td>185 (82.2)</td>
<td>84 (37.3)</td>
<td>&lt;.001</td>
<td></td>
</tr>
<tr>
<td>Colonoscopy*</td>
<td>6 (2.7)</td>
<td>6 (2.7)</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Either test</td>
<td>191 (84.9)</td>
<td>90 (40.0)</td>
<td>&lt;.001</td>
<td></td>
</tr>
</tbody>
</table>

* This result does not include patients who had a positive FOBT result and subsequently underwent diagnostic colonoscopy; most patients had a clinical condition for which a diagnostic colonoscopy was performed.

Abbreviations: CRC, colorectal cancer; FOBT, fecal occult blood test; NA, not applicable.
Thus, 84.9% of the intervention group and 40.0% of the usual care group completed some form of CRC screening within 6 months of their due date ($P < .001$). The estimated cost of the outreach intervention was $34.59 per patient. Of the 202 patients who received outreach, 162 (80.2%) completed the FIT. Thus, the estimated cost per completed test was $43.13.

The effect of the intervention varied by the number of visits patients had during follow-up ($P = .03$ for interaction). Among those with no visits, 2 of 60 usual care patients (3%) and 31 of 53 intervention patients (59%) completed the FIT ($P < .001$). In contrast, among patients with 3 or more visits, 29 of 50 usual care patients (58%) and 37 of 43 intervention patients (86%) completed the FIT ($P < .001$). The magnitude of the intervention’s effect did not differ by age, sex, race/ethnicity, preferred language, or insurance coverage.

Among the 185 patients in the intervention group who returned a completed FIT, 10 results (5.4%) were positive. After 6 months or more of follow-up after the positive FIT result, 6 (60%) had completed diagnostic colonoscopy. Of these, 3 were found to have an adenomatous polyp, and 1 had an inflammatory polyp. Among the 84 patients in the control group who completed a FIT, 19 results (23%) were positive ($P < .001$ vs intervention group). Of these, 11 (53%) completed diagnostic colonoscopy, and 4 (36%) had an adenomatous polyp detected.

The timing of completing FITs is detailed in Table 3. The FIT was completed prior to the due date by 10.2% of the intervention group. In the 2 weeks after the initial reminder and mailing of the FIT, 89 patients in the intervention group (39.6%) returned a completed test. After the 2-week reminder call and/or text, an additional 54 returned a completed test between 2 and 13 weeks (24.0% of all patients and 47.8% of the 113 intervention patients who had not been screened by 2 weeks). Another 19 (8.4%) completed a FIT after the 3-month reminder call (which is 32% of the 59 intervention patients who still had not been screened by 3 months). Among the usual care group, 25 (11.1%) completed the FIT prior to their due date; during the following 6 months, approximately 1% per week completed a FIT.

Table 4 details the proportions of intervention patients who received different components of the intervention and the association between this and completion of the FIT. Only 9 patients had the home FIT returned for invalid addresses. The vast majority of patients (n = 171) had an automated call completed; of those completed calls, 86 were answered in person, and 85 were answered by voicemail. Over half of eligible patients received a text message. Receipt rates for the automated call and text were similar for the 2-week reminders (data not shown). In bivariate analyses (Table 4), patients who answered the automated call in person were more likely to complete the FIT within 2 weeks of due date. Among patients who had a completed call, those answered in person were more likely to complete the FIT than those answered by machine ($P = .03$). Patients who had a completed text message were not more likely to complete the FIT than those who did not ($P > .99$).

The proportion of completed calls was similar for the 2-week and 3-month reminders ($P = .21$). Patients who had a completed call or text were more likely to complete the FIT than those who did not ($P < .001$). The proportion of completed calls was similar for the 2-week and 3-month reminders ($P = .21$). Patients who had a completed call or text were more likely to complete the FIT than those who did not ($P < .001$).
complete the FIT than those who did not have a completed automated call (51.2% vs 28.6%; \( P = .03 \)), but they were equally likely to complete the FIT compared with patients whose automated call was answered by voicemail (51.2% vs 42.4%; \( P = .22 \)). Whether a patient received a text message was not associated with FIT completion (44.3% vs 43.7%). Patients who spoke to the navigator on the 3-month call were much more likely to complete the FIT (50.0% vs 21.6%; \( P = .04 \)). The results were similar in multivariate analyses that adjusted for demographics.

### Discussion

Even among a vulnerable population with low socioeconomic status, high rates of no insurance, limited English proficiency, and low health literacy,24 our multifaceted intervention achieved a rate of adherence to annual FOBT screening (82.2%) far above the usual care group (37.3%). Moreover, the adherence rate in the intervention group was in the range achieved in randomized clinical trials in which FOBT was shown to reduce CRC mortality.6 The majority of FOBT completions were accomplished with mailing FITs and sending automated voice and text reminders, strategies that can be facilitated by health information technologies that are increasingly available at CHCs.22,23 All eligible patients (ie, those who received a negative FOBT result in the previous year) were included, so the high adherence rate was not owing to the selective enrollment of highly motivated patients. Although further follow-up is needed to understand long-term adherence rates, our study suggests that it is possible to achieve high annual FOBT adherence rates even among highly vulnerable patient populations.

The relatively low rate of adherence to annual FOBT testing among patients in the usual care group shows the limitations of relying on point-of-care methods to increase CRC screening. Although health care teams routinely try to identify patients presenting for care who needed CRC screening and offer them home FIT kits, the rate of adherence to FOBT within 6 months of the due date was only 37.3%. Even among those with 3 or more visits, the rate was only 58%. This outcome is not surprising in light of the high volume of patients cared for by this organization, the limited time for face-to-face visits, and patients’ complex medical and social needs. If CHCs and other organizations want to improve CRC screening, outreach should be part of their overall strategy in addition to point-of-care interventions (eg, automated reminders to clinicians and standing orders for team members to distribute FOBT kits to patients).

Despite the success of this intervention at increasing adherence to annual FOBT, the hope that this strategy might be used in the future to reduce disparities in CRC mortality must be tempered by the fact only 17 of 29 patients with a positive FOBT result completed diagnostic colonoscopy (59%), despite the fact that EFHC had a navigator, free transportation, and access to free colonoscopy. Our findings are consistent with other reports.25–28 The FOBT should not be used for CRC screening at CHCs unless organizations have sufficient access to affordable diagnostic colonoscopy and navigator programs to help those with positive results. Additional research is needed to identify optimal strategies to increase completion of diagnostic colonoscopy.

Our study has several limitations. First, it was conducted in a single organization with a relatively small number of clinical sites treating a somewhat homogenous patient population (ie, urban, low income, Latino/Hispanic, and female). The organization has a very positive reputation in the community, and patients may have a higher level of trust than patients at other CHCs. The population was also more stable than expected. Very few patients had incorrect addresses in the EHR, and 75% of all eligible patients had 1 or more visits during their 6-month follow-up period. Thus, our findings may not be generalizable to CHCs that have weaker ties with their community, lower level of trust in their clinicians, or less stable patient populations. Second, the patients who were eligible for this study because of a prior FOBT are probably different than patients who had never completed FOBT. Finally, we report data from only the first cycle of this intervention to increase adherence to annual FOBT; in subsequent years, the response to outreach may diminish.

This study has important policy implications. The Health Resources and Services Administration requires that CHCs report CRC screening rates, which are publicly available.29 Although this requirement will motivate efforts to improve CRC screening, most CHCs will need significant support to use their health information technology to improve both point-of-care and population-based interventions. The Office of the National Coordinator for Health Information Technology’s Regional Extension Centers could play an important role in accomplishing such improvements. More importantly, CHCs will need a stable source of funding for outreach and navigator programs for patients with positive FOBT results. Finally, the availability and affordability of diagnostic colonoscopy for patients with low income must be improved, including coverage of pathology reports if biopsies are performed. While our results show that it is possible to achieve high rates of adherence to annual FOBT for CRC screening at CHCs, achieving broad dissemination and implementation of this type of care will require a concerted effort across public and private organizations.

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