Colorectal Cancer Screening Among Ethnically Diverse, Low-Income Patients

A Randomized Controlled Trial

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Background: Patient navigators may increase colorectal cancer (CRC) screening rates among adults in underserved communities, but prior randomized trials have been small or conducted at single sites and have not included substantial numbers of Haitian Creole–speaking or Portuguese-speaking patients.

Methods: We identified 465 primary care patients from 4 community health centers and 2 public hospital–based clinics who were not up-to-date with CRC screening and spoke English, Haitian Creole, Portuguese, or Spanish as their primary language. We enrolled participants from September 1, 2008, through March 31, 2009, and followed them up for 1 year after enrollment. We randomly allocated patients to receive a patient navigation–based intervention or usual care. Intervention patients received an introductory letter from their primary care provider with educational material, followed by telephone calls from a language-concordant navigator. The navigators offered patients the option of being screened by fecal occult blood testing or colonoscopy. The primary outcome was completion of any CRC screening within 1 year. Secondary outcomes included the proportions of patients screened by colonoscopy who had adenomas or cancer detected.

Results: During a 1-year period, intervention patients were more likely to undergo CRC screening than control patients (33.6% vs 20.0%; P < .001), to be screened by colonoscopy (26.4% vs 13.0%; P < .001), and to have adenomas detected (8.1% vs 3.9%; P = .06). In prespecified subgroup analyses, the navigator intervention was particularly beneficial for patients whose primary language was other than English (39.8% vs 18.6%; P < .001) and black patients (39.7% vs 16.7%; P = .004).

Conclusions: Patient navigation increased completion of CRC screening among ethnically diverse patients. Targeting patient navigation to black and non–English-speaking patients may be a useful approach to reducing disparities in CRC screening.

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screening among urban, racial minority patients. One prior randomized study of patient navigation for CRC screening was conducted at a single health center serving mostly patients who speak English or Spanish as their primary language. To build on this limited research, we conducted a randomized controlled trial of patient navigation that included immigrants from the Azores, Brazil, Haiti, and Portugal receiving care at 4 different health centers and 2 public hospital–based clinics in the safety-net health care system (ie, a health care system that provides a significant level of care to low-income, uninsured, and vulnerable populations).

STUDY DESIGN

We performed a randomized controlled trial of patient navigation to promote CRC screening. We included a sample of patients aged 52 to 74 years who had not completed CRC screening according to US Preventive Services Task Force guidelines (defined as colonoscopy in the past 10 years, sigmoidoscopy or double-contrast barium enema in the past 5 years, or fecal occult blood testing [FOBT] in the past year) and who spoke English, Haitian Creole, Portuguese, or Spanish as their primary language. We randomly assigned patients to receive a maximum of 6 hours of patient navigation in 6 months or usual care. The intervention encouraged FOBT or colonoscopy, the most frequently used screening tests at the study sites. The Cambridge Health Alliance Institutional Review Board approved the study protocol. The board provided a waiver of informed consent because the study was promoting an established screening standard.

SETTING AND PARTICIPANTS

We conducted the study at Cambridge Health Alliance, a primary care practice–based research network composed of 15 community health centers. The health centers serve a multicultural, low-income population in Cambridge, Somerville, and Everett, Massachusetts. After pilot testing our intervention at 1 health center, we selected 6 primary care sites (4 health centers and 2 hospital-based clinics) that were not part of a Massachusetts Department of Public Health Patient Navigation Program to participate in the study. At the time of the study, all study sites used a common electronic health record (Epic Systems Corporation, Verona, Wisconsin) that supports computerized ordering of laboratory tests and referrals. Gastroenterologists perform colonoscopies at 1 of 3 hospital-based endoscopy centers.

We used the electronic clinical data system to identify patients at the primary care sites who were not up-to-date with CRC screening. We recruited patients aged 52 to 74 years who had had 1 visit to a primary care provider (PCP), ie, a physician or nurse practitioner, in each of the 2 previous years at 1 of the study sites. We limited the sample to patients who identified English, Haitian Creole, Portuguese, or Spanish, the most frequently spoken languages at Cambridge Health Alliance, as their primary language. Using explicitly predefined exclusion criteria, 1 of the study investigators (K.E.L.) performed manual medical record reviews, excluding patients if they had acute illness, an end-stage medical disease, severe psychiatric conditions (such as psychosis, bipolar disorder, paranoia, or schizophrenia), active substance abuse, or cognitive impairment. The figure shows the number of patients accrued, randomized, and assessed for the primary outcome. Of the 823 potentially eligible patients, 465 (56.5%) met study entry criteria.

INTERVENTION

We randomly assigned patients to usual care or a maximum of 6 hours of patient navigation during a 6-month period. Some patients required little or no navigation. For example, those who had a previously scheduled colonoscopy appointment and reported that they understood the preparation instructions did not require navigation. For other patients, the maximum of 6 hours was spent contacting patients, educating them regarding CRC and CRC screening tests (FOBT and colonoscopy), motivating them to get screened, helping them decide which test to undergo, helping them obtain health insurance coverage, educating them regarding the correct way to complete FOBT cards, helping them make colonoscopy appointments and finding someone to accompany them home after the procedure, educating them regarding the required bowel preparation, and meeting them on the day of their colonoscopy.

We randomized individual patients, stratified by health center and primary language, using a computer-generated random number table. We enrolled participants from September 1, 2008, through March 31, 2009, and followed them up for 1 year after enrollment. In the intervention group, we sent letters by first-class mail, signed by the PCP of each patient, notifying patients that they were overdue for CRC screening and that a patient navigator would call them. The mailing also included a CRC screening brochure designed by the Harvard Center for Cancer Prevention and the Massachusetts Colorectal Cancer Working Group (Take Control: Get Tested for Colorectal Cancer). The brochure, written at a sixth-grade reading level, offered information regarding reasons for screening and different screening modalities. We sent brochures to patients in English, French (for Haitian patients because the brochure was not available in Haitian Creole), Portuguese, or Spanish.

Intervention patients were also eligible to receive navigation from 3 trained navigators who were fluent in English and Spanish, Portuguese, or Haitian Creole. The navigators were based centrally in the Departments of Medicine and Community Affairs. The navigator who worked with Spanish-speaking patients was from Nicaragua, had completed some college-level education, had extensive experience performing community health outreach, and was also a certified nurse assistant. The Portuguese-speaking navigator had a bachelor’s degree in clinical psychol-
ogy from Brazil and was an experienced community health worker. The Haitian Creole-speaking navigator was also an experienced community health worker who had completed some college-level education. The navigators were aged 48, 43, and 25 years, respectively. We did not encounter problems matching female navigators with male patients.

The navigators attended a 2-day training program October 4 and 5, 2007, and received additional training on August 22, 2008. The training program included lectures and role-play scenarios concerning the principles of motivational interviewing; CRC and how patients can be screened for it; logistics (eg, how-tos, pros, and cons) of FOBT cards and colonoscopy; CRC prevention (including removal of adenomas); use of open-ended questions, reflective listening, and summarizing; assessment of the readiness of a patient for screening; and approaches for patients who refuse screening (precontemplation), are willing to consider it (contemplation), or are ready to act (action).23 We based the intervention on a “stages of change” model because other cancer prevention studies24 have successfully used this model.

During study implementation, the project manager (who also attended the training sessions) audited at least 5 patient calls by each navigator for adherence to a calling script and for motivational interviewing techniques. The project manager and the project manager also met on a weekly basis to discuss challenges arising during the outreach calls and to review the use of motivational interviewing techniques.

After randomization, the navigators contacted intervention patients during a 6-month period using a staged rollout procedure by site. Because of financial difficulties, 1 health center closed during the study period (with some patients transferring care to another study health center), and 2 study health centers each merged with other sites that were not part of the study. The navigators continued the intervention with patients at affected sites. Some patients in 2 of the study health centers received mailed outreach material from health center staff regarding CRC screening in early 2009, when planned care outreach became the community standard of care.

During a 3-week period, the patient navigators made as many as 11 attempts to call each patient on different days and times (including evenings and weekends). The navigators also left at least 2 messages for the patient on voice mail or with a family member. If the navigators were unable to contact patients initially, they sent a follow-up letter and made periodic attempts to contact patients during the remainder of the intervention period.

During the initial telephone contact, the navigators educated patients regarding CRC screening, explored barriers to screening, and addressed patients’ barriers and their stage of change. For those who were contemplating screening, navigators discussed the screening options of colonoscopy and FOBT cards and the advantages and disadvantages of each test. The navigators presented the screening options in a neutral fashion and did not emphasize the superiority of any test compared with another. The navigators used flexible problem-solving techniques. For example, an elderly patient resisted the idea of colonoscopy because she was concerned that the preparation would make her weak and at risk for a fall. The navigator elicited this concern and suggested the alternative option of FOBT cards.

For patients who chose to complete FOBT cards, the navigators reviewed instructions and mailed FOBT cards and illustrated instructions via first-class mail. If a patient did not return the FOBT cards within 4 weeks, the navigator called the patient to provide support and address barriers to completion. For patients who opted for colonoscopy, the navigators described the test in detail, and the lead navigator contacted the PCP of the patient via the electronic medical record to arrange a colonoscopy referral. Patients with few comorbid medical conditions were referred directly for colonoscopy (also known as open-access colonoscopy); the patient did not require an initial visit with a gastroenterologist but met him or her on the day of the procedure. Patients with conditions such as sleep apnea or a history of problems with anesthesia were referred to a gastroenterologist to discuss colonoscopy. For patients referred directly to colonoscopy, a registered nurse or the lead navigator educated them regarding the procedure and the required bowel preparation, mailed instructions for bowel preparation, and scheduled the procedure.

The navigator worked with the nurse to schedule colonoscopies because the nurse oversaw the colonoscopy schedule. Gastroenterology staff placed reminder calls to all patients 1 day before their colonoscopy. If the navigators were unable to help patients identify someone to escort them home after the colonoscopy, the navigators advised them to complete FOBT cards instead. For medicolegal reasons, the navigators did not accompany patients home. In some instances, the navigators met patients in the colonoscopy suite to offer emotional support. Some patients were having the first colonoscopy of their life and were fearful about the procedure.

For patients who were not contemplating performing any CRC screening test, the navigators assessed and addressed barriers. For example, for patients who did not have health insurance coverage, the navigators referred them to insurance counselors and worked closely with the insurance department to ensure that eligible patients received coverage. For other patients, the navigators would establish rapport by learning more about the lives of the patients (eg, whether patients were caring for grandchildren or an elderly parent). The navigators motivated some patients to undergo screening by pointing out that by taking care of their own health, patients would be able to continue caring for their family members.

OUTCOME MEASURES

Using a predefined algorithm, 1 study investigator (K.E.L.) performed medical record reviews masked to the intervention assignments to determine CRC screening rates within 1 year of the start of the intervention for all randomized patients. Medical records were reviewed twice to minimize error. We chose to analyze the data at 1 year because the average wait for a screening colonoscopy at the time of the study was approximately 4 months and we assumed that patients would have had sufficient time to complete their colonoscopy during the 1-year period. The primary outcome was completion of CRC screening (colonoscopy, FOBT, flexible sigmoidoscopy, or double-contrast barium enema) within 1 year. Although the navigators focused on helping patients choose between FOBT cards and colonoscopy, PCPs may have chosen to use other accepted screening modalities, namely, flexible sigmoidoscopy or double-contrast barium enema. Secondary outcomes included the proportion of patients screened by colonoscopy and the proportion in whom the screening detected adenomas or cancer. Another secondary outcome was the proportion of patients with high-risk lesions (classified as a dichotomous yes/no variable), defined as 3 or more adenomas of any type, adenomas 1 cm or larger, or adenomas with any villous features.

STATISTICAL ANALYSIS

We calculated that a sample size of at least 197 patients in each group would be required to show a minimum clinically important improvement in CRC screening of 10.0% (10.0% vs 20.0%), with a power of 80.0% and a 2-sided significance level of 0.05. We conducted all analyses on an intention-to-treat basis. Using χ² and Fisher exact tests for dichotomous variables, we performed prespecified subgroup analyses according to the
primary language, age, race, and health insurance coverage status of the patient because these factors are known to affect CRC screening rates. All analyses were performed using SAS statistical software, version 9.1 (SAS Institute Inc, Cary, North Carolina), and we report 2-tailed $P$ values or 95% confidence intervals for all comparisons.

### RESULTS

#### PATIENT CHARACTERISTICS

The navigators contacted 181 of the 235 intervention patients (77.0%). The navigators made a median of 8.5 telephone calls (interquartile range, 7.0) to these patients, spending an average of 107 minutes (range, 4-335 minutes) on the telephone with each patient during the 6-month study period. The patient navigators were unable to contact the remaining 54 patients (22.9%) after a median of 10 attempted telephone calls (interquartile range, 7.0), including 34 patients whose telephone service had been intermittently disconnected and 8 patients whose initial outreach letters were returned to sender. Among patients who were and were not contacted, no statistically significant differences were observed in age, sex, race, primary language, or health insurance coverage status.

**Table 1** lists the baseline demographic characteristics of the intervention and usual care groups; randomization resulted in groups with similar baseline characteristics. The mean age of the patients was 61.3 years. Most patients were women because women are more likely than men to seek primary care. A substantial proportion of patients were racial minorities and did not have private health insurance coverage. Almost half of patients in both groups spoke English as their primary language (48.2%), with the remainder speaking Portuguese (20.0%), Spanish (13.8%), or Haitian Creole (18.1%).

#### OUTCOME MEASURES

A total of 33.6% of intervention patients had been screened by 1 year after study entry vs 20.0% of control patients ($P < .001$). Intervention patients whom the navigators were able to contact were significantly more likely to be screened than those whom the navigators were unable to contact (39.8% vs 18.6%; $P < .001$). A larger proportion of intervention patients were screened by colonoscopy relative to controls (26.4% vs 13.0%; $P < .001$); similar numbers of intervention and control patients completed FOBT cards (7.2% vs 6.5%; $P = .76$). One control patient had a positive FOBT result that was not followed up with a colonoscopy; the remaining FOBT results were negative. Stratified analyses demonstrated that patient navigation was particularly beneficial for individuals whose primary language was other than English and for patients older than 60 years (Table 2). The intervention was more effective in white and black individuals relative to those of other or unknown race, and a somewhat smaller effect was observed in those with non- vs private health insurance coverage. Because of the small numbers in some race categories, differences between individual race categories should be interpreted with caution.

#### COMMENT

Patient navigation increased CRC screening rates substantially among racially and linguistically diverse patients served by urban community health centers and public hospital–based clinics. Our study confirms the findings of smaller trials and of a recent study of culturally tailored telephone counseling by community health advisers and demonstrates that patient navigation is also effective among patients who speak Haitian Creole or Portuguese as their primary language. Because the Cambridge Health Alliance was undergoing serious financial problems, which led to health center closures and the departure of PCPs, we speculate that our intervention might have had an even stronger effect in a more stable health care system. The fact that our intervention was effective may reflect the inclusion of several evidence-based components recommended by the Task Force on Community Preventive Services of the Centers for Disease Control and Prevention. These components include client reminders through outreach letters, one-on-one education by the navigators, reduction of structural barriers...
related to linguistic and cultural factors, and the inclusion of a mailed educational pamphlet. Although some of the patients in our study may not have been able to read the educational brochure, patients often showed the brochure to their PCP or to a more educated family member. Our intervention also included tailoring to the preferences of patients and informed decision making, elements that may have increased the willingness of patients to be screened. Other possibly beneficial features of the intervention included the lead navigators working closely with the nurse in the gastroenterology center who scheduled colonoscopies; navigators communicating with PCPs via the electronic medical record, enabling the PCP to place orders for a screening test as soon as a patient chose one; and navigators working evenings and weekends for greater flexibility in contacting patients. At the time of the intervention, the overall screening rate at the Cambridge Health Alliance was higher than the national average (61% in calendar year 2009) because it reflects patients who are engaged in primary care and who mostly have health insurance coverage. Despite the high baseline screening rate, our intervention was effective.

Strengths of our study are its inclusion of a racially diverse sample of patients from multiple health centers and public hospital–based clinics and its real-world setting. Our study has several limitations. Patients were from 1 geographic area, and some may have obtained CRC screening outside the Cambridge Health Alliance. The navigators were unable to contact 23.0% of intervention patients, which is not surprising given the mobile nature of urban immigrants with low socioeconomic status. In the future, contact rates might be improved by using technology such as text messaging. Patients at some of the intervention health centers began to receive mailed outreach materials regarding CRC screening in early 2009; this may have diminished our intervention effect. We did not have access to data regarding country of birth, citizenship status, length of time in the United States, or level of acculturation for participants. We were also unable to determine which individual components of the intervention were most effective. Prior studies have shown that letters have only a limited effect, suggesting that the navigation efforts may have largely accounted for the effectiveness of the intervention. Finally, we excluded patients with active substance use and mental illness documented on the problem list (18.1% of eligible patients); thus, our results may not be generalizable to these patients.

Patient navigation appears to be effective in increasing receipt of colorectal and cervical cancer screening. Yet, clearly, hiring individual navigators for each type of screening would not be feasible. In Massachusetts, as part of a Department of Public Health Program, patient navigators now handle a variety of cancer screenings (breast, cervical, and colorectal) and also provide navigation to link patients to smoking cessation services. Future studies will need to determine whether such dissemination of patient navigation activities, in which an individual patient may receive far less than 1 to 2 hours of patient navigation regarding CRC screening, for example, still results in increased cancer screening. Finally, a need exists to examine the relative efficacy and cost-effectiveness of navigation compared with other viable alternatives (or complements), such as computerized tailored interventions offered in simple and easy-to-understand formats and in the primary language of the user.

As primary care practices are redesigned as medical homes, nonphysician members of the health care team will increasingly take on tasks previously performed by PCPs (eg, counseling and connecting to services). Although the medical home concept is being adopted throughout the United States, its promise requires effective interventions that can be implemented within this new model. Patient navigation is 1 potential intervention that can be integrated into the medical home model. Again, future studies will need to explore whether patient navigation is effective within the context of the medical home.
In conclusion, our findings suggest that patient navigation may represent a powerful tool for increasing CRC screening rates among racially diverse patients. Focusing patient navigation on populations of patients who are black and whose primary language is other than English may be a particularly effective approach to reducing CRC screening disparities for these patients. Future research should assess how health care systems can sustain this benefit when patient navigation is implemented as a routine component of primary care.

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REFERENCES

Building Blocks of the Patient-Centered Medical/Health Home

The search for the patient-centered medical home resembles the quest for the Holy Grail. Yet no one is sure what this sacred vessel actually looks like. Elements of the patient-centered medical home have been identified by the National Committee on Quality Assurance requirements and meaningful use components from the US federal government (Table). Three articles in this issue of the Archives provoke thoughts regarding what primary care transformation—the Holy Grail—is all about.

In the study by Lasser et al,1 patient navigators, who also could be called health care coaches, are community health care workers trained to guide patients through the health care system. Lasser et al found that patients contacted by language-concordant patient navigators are more likely than patients undergoing usual care to be screened for colorectal cancer.

See also pages 897 and 903

Romano and Stafford2 analyzed 2 ambulatory care databases to examine the association between the use of the electronic health record (EHR)—with or without decision support tools—and clinical quality measures. Decision support tools are reminders to order medications or screening tests recommended by practice guidelines. The study found virtually no difference in 20 quality indicators among visits with no EHR, with an EHR, and with EHR plus decision support.

Commenting on the article by Romano and Stafford, McDonald and Abhyankar3 suggest that for computerization to improve quality, EHRs need to include clinical decision tools. However, even without decision tools, an EHR combined with a clinical registry can be used to improve clinical care. The EHR-registry component can be used to generate a list of all patients in a medical practice with particular conditions (eg, diabetes mellitus), along with accompanying data (eg, hemoglobin A1c [HbA1c] levels). This information enables practices to identify patients who are overdue for needed interventions (eg, ocular examinations) or who have not achieved consistent disease control (eg, elevated HbA1c levels). Also, registries can generate lists of patients who are overdue for preventive care (eg, mammograms).

How do these 3 articles assist us in understanding the building blocks of transformed primary care, which include the EHR, patient registry, and team-based care? The study by Romano and Stafford and the response by McDonald and Abhyankar demonstrate that the EHR is necessary but not sufficient for improved quality of care. Decision support reminders failed to improve quality of care because physicians must implement the actions that reminders prompt them to perform, for which physicians often do not have adequate time. Treating a typical panel

Table. Elements of the Patient-Centered Medical Home

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