Background: Screening reduces colorectal cancer mortality, but effective screening tests remain underused. Systematic reminders to patients and physicians could increase screening rates.

Methods: We conducted a randomized controlled trial of patient and physician reminders in 11 ambulatory health care centers. Participants included 21,860 patients aged 50 to 80 years who were overdue for colorectal cancer screening and 110 primary care physicians. Patients were randomly assigned to receive mailings containing an educational pamphlet, fecal occult blood test kit, and instructions for direct scheduling of flexible sigmoidoscopy or colonoscopy. Physicians were randomly assigned to receive electronic reminders during office visits with patients overdue for screening. The primary outcome was receipt of fecal occult blood testing, flexible sigmoidoscopy, or colonoscopy over 15 months, and the secondary outcome was detection of colorectal adenomas.

Results: Screening rates were higher for patients who received mailings compared with those who did not get mailings compared with those who did not (44.0% vs 38.1%; P < .001). The effect increased with age: +3.7% for ages 50 to 59 years; +7.3% for ages 60 to 69 years; and +10.1% for ages 70 to 80 years (P = .01 for trend). Screening rates were similar among patients of physicians receiving electronic reminders and the control group (41.9% vs 40.2%; P = .47). However, electronic reminders tended to increase screening rates among patients with 3 or more primary care visits (59.5% vs 52.7%; P = .07). Detection of adenomas tended to increase with patient mailings (5.7% vs 5.2%; P = .10) and physician reminders (6.0% vs 4.9%; P = .09).

Conclusions: Mailed reminders to patients are an effective tool to promote colorectal cancer screening, and electronic reminders to physicians may increase screening among adults who have more frequent primary care visits.

Trial Registration: clinicaltrials.gov Identifier: NCT00355004


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PATIENT AND PHYSICIAN ELIGIBILITY

We identified 59,181 patients aged 50 to 80 years who had a visit with 1 of the 110 primary care physicians at 11 centers during the prior 18 months (Figure 1). From this cohort, we excluded 37,321 patients (63%) who had been screened for colorectal cancer in accordance with the HVMA clinical guideline, having received either flexible sigmoidoscopy within 5 years along with FOBT in the prior year or colonoscopy within 10 years. The remaining 21,860 patients (37%) and their 110 primary care physicians were eligible for our study.

Screening tests were ascertained via an automated electronic algorithm using laboratory results, diagnostic codes, procedure codes, and outpatient and hospital encounters from the electronic record. Compared with physician medical record review for a random sample of patients, this algorithm was 88% sensitive (95% confidence interval [CI], 79%-93%) and 96% specific (95% CI, 87%-100%) in identifying screening tests. Appropriate screening was typically undetected by the automated algorithm when colonoscopy occurred at outside hospitals, particularly before patients received care at HVMA.

The Harvard Medical School and HVMA Human Studies Committees approved the study protocol, including a waiver of informed consent for both patients and physicians because the study was promoting the HVMA standard of care for colorectal cancer screening.

PHYSICIAN INTERVENTION

Throughout the 15-month intervention period, physicians received electronic reminders during office visits with their patients overdue for colorectal cancer screening. Immediately prior to the intervention, we educated physicians in both the intervention and control groups regarding the use of these reminders via a 1-hour presentation and discussion at each center. The alerts were present in both a passive and active form within each patient’s electronic medical record. Physicians could view the passive alert at any point during an encounter within the elec-
tronic visit summary screen, while the active alert required acknowledgment from physicians attempting to place electronic orders (Figure 2). The alerts provided details regarding the most recent screening tests and facilitated “1-click” electronic ordering of screening examinations. Electronic orders for endoscopic procedures were automatically forwarded to the gastroenterology department for scheduling. Physicians did not receive similar alerts for other preventive services during the intervention period.

RANDOMIZATION PROCESS

The patient intervention was randomized at the level of individual patients within each physician’s patient panel. Among all 59,181 patients aged 50 to 80 years, we estimated a multivariable logistic regression model for their propensity to have been screened for colorectal cancer at baseline in accordance with the HVMA clinical guideline (Figure 1). Predictors included patient age, sex, race, insurance coverage, and socioeconomic characteristics based on linking patient 5-digit ZIP codes to the 2000 US Census data, including proportion of high school graduates, median household income, and proportion of households below the federal poverty level. Within each physician panel, we paired patients overdue for screening with similar values of this propensity and randomly assigned 1 patient in each pair to receive the intervention mailing, thus closely balancing treatment groups on characteristics related to their baseline screening propensity.

The physician intervention was randomized at the physician level. Within each health care center, we paired physicians with similar colorectal cancer screening rates and numbers of patients overdue for screening and then randomly assigned 1 physician in each pair to receive electronic reminders. We repeated the randomization 20 times and chose the assignment that provided the best overall balance on these 2 characteristics between the intervention and control groups.

STUDY OUTCOMES

All data were collected from the electronic record, and study outcomes were assessed 15 months following the start of the intervention for all randomized patients. The primary study outcome was completion of 1 of the following 3 options during the 15-month study period: FOBT, flexible sigmoidoscopy, or colonoscopy.1,9 We did not include barium enema examination because it is rarely used for screening purposes at HVMA. Because the detection and removal of precancerous adenomas is a major objective of colorectal cancer screening,2 the secondary study outcome was detection of adenomas based on diagnostic codes. A visual review of electronic records found that these codes had a positive predictive value of 94% (95% CI, 84%-99%) and negative predictive value of 96% (95% CI, 86%-100%) for identifying colorectal adenomas. For a random 10% sample of patients who had colorectal adenomas removed during the study, we conducted medical record reviews to identify the following high-risk findings: (1) 3 or more adenomas, (2) adenoma 10 mm or greater in diameter, or (3) adenoma with villous histologic features. We also ascertained new diagnoses of colorectal cancer via the presence of a new International Classification of Diseases, Ninth Revision, Clinical Modification code of 153.0 to 153.9 or 154.0 to 154.1. We then conducted medical record reviews to verify the diagnosis of colorectal cancer and collect staging data.10

PHYSICIAN SURVEY

We surveyed all 43 of the original 55 physicians in the electronic reminder intervention group who were still practicing at HVMA 4 months after the study ended. The survey instrument assessed perceived effectiveness of colorectal cancer screening modalities and of the electronic reminders using a 3-point Likert scale of “very effective,” “somewhat effective,” or “not effective.” Physicians also identified which screening test they most commonly recommended, as well as the perceived proportion of electronic reminders that accurately reflected patients’ screening status. The surveys were administered in a 3-stage process that involved an initial paper mailing, followed by a reminder e-mail and a final paper mailing.

DATA ANALYSIS

All analyses were conducted on an intention-to-treat basis. Baseline characteristics for patients in the intervention and control groups were compared using the Pearson χ² test for dichotomous variables and an unpaired t test for continuous variables. We analyzed the impact of the interventions by fitting a single linear regression model to predict performance of an appropriate screening examination after adjusting standard errors for clustering of patients by physician. Independent variables included patient intervention status, physician intervention status, and physician baseline screening rate, and we also tested the interaction of patient and physician intervention status. We fit separate models for prespecified subgroup analyses according to characteristics known to affect rates of colorectal cancer screening, including age (50-59, 60-69, or 70-80 years), sex, and number of primary care visits (0, 1-2, or ≥3).12-13 All analyses were performed using SAS version 9.1 statistical software (SAS Institute Inc, Cary, North Carolina), and we report 2-tailed P values or 95% CIs for all comparisons.

RESULTS

STUDY SUBJECTS

We studied 110 primary care physicians and their 21,860 patients who were overdue for colorectal cancer screening. Patients in the intervention and control group were similar for both the patient-level and physician-level randomizations, except for a nonsignificant trend (P = .08) toward more office visits in the control group for the physician intervention (Table 1). The mean (SD) age of physicians was 48 (9.7) years, and 57% were female. Their mean (SD) number of eligible patients aged 50 to 80 was 199 (95), with no differences according to intervention status.

SCREENING RATES

Among this group of patients who were overdue for screening with usual care, patients who received the mailing were significantly more likely to complete colorec-
tal cancer screening than those who did not (44.0% vs 38.1%; \( P < .001 \)). The patient mailing was more effective among older patients, with the absolute increase in screening rates ranging from 3.7% among patients aged 50 to 59 years to 10.1% among patients aged 70 to 80 \( (P = .01 \) for trend) \( (\text{Table 2}) \). Among patients whose physicians received electronic reminders compared with the respective control \( (\text{Table 3}) \). Among patients of physicians receiving electronic reminders and whose physicians received electronic reminders was 0.6% less than the sum of their effects when applied individually.

**DETECTION OF ADENOMAS AND CANCERS**

Detection of colorectal adenomas tended to be greater among patients who received mailed reminders and whose physicians received electronic reminders compared with the respective control groups \( (6.0\% \) vs \( 4.9\% ; \ P = .09 \) \( (\text{Table 3}) \). Among patients with adenomas, 15% had 3 or more adenomas removed, 8% had an adenoma 10 mm or greater in diameter, 1% had villous histologic features, and 23% had at least 1 of these high-risk features. Overall, 34 patients (0.2%) were newly diagnosed as having colorectal cancer, with no significant differences between intervention groups \( (\text{Table 3}) \). Among these 34 incident colorectal cancers, 56% were diagnosed at an early stage (stage
0, 1, or 2), 35% were diagnosed at a later stage (stages 3 or 4), and 9% lacked definitive stage data.

PHYSICIAN SURVEY

Of 43 eligible physicians, 33 (77%) in the intervention group completed the survey. Nearly all (97%) physicians considered colonoscopy every 10 years to be “very effective” at reducing colorectal cancer mortality, while only 3% perceived an annual FOBT as similarly effective. Accordingly, all respondents (100%) reported colonoscopy as the screening test they most often recommended to patients. Physicians reported that electronic reminders accurately reflected their patients’ screening status for a median of 50% of the reminders (interquartile range, 30%-80%). Most physicians in the intervention group reported that the electronic reminders were “very effective” (9%) or “somewhat effective” (47%) in increasing the colorectal screening rate among their patients.

In a large cohort of patients who were overdue for screening, we demonstrated that personalized mailings to individual patients produced a modest increase in colorectal cancer screening, particularly by FOBT and among patients in the oldest age group, suggesting that patients represent an untapped resource for improving quality of care. Patients frequently report that they have not received effective counseling regarding the importance of colorectal cancer screening.11,34 However, once eligible patients are appropriately informed, most opt to be screened for colorectal cancer.35,36 Our findings underscore that informed patients can play an active role in completing effective preventive services.37

Electronic reminders to physicians did not significantly increase overall screening rates, in part because over one-third of patients had no visits with their primary care physicians during the 15-month study period. However,
physician reminders exhibited a trend toward increased overall screening rates among patients with at least 3 primary care visits over this period. Orders for colonoscopy were modestly increased with reminders to physicians but without a corresponding increase in completed procedures, as nearly half of the patients for whom a colonoscopy was ordered did not complete this procedure. This finding underscores the need for more effective communication with patients to encourage them to complete colonoscopy procedures that are scheduled.

The limited effectiveness of our electronic physician reminders may reflect the challenges primary care physicians face in providing adequate preventive counseling amid competing demands during brief office visits. We provided “active” alerts that required physicians to respond, but some physicians may have disregarded the alerts if they disrupted their work flow or were deemed inaccurate. Although we validated the accuracy of our algorithm for detecting whether patients were up-to-date with screening, many physicians considered the electronic reminders as substantially less accurate, and nearly half of the physicians considered the reminders as ineffective. This suggests that further collaboration with the practicing physicians who receive reminders via electronic health records may be required to achieve a greater impact on screening rates.

Our study highlights an important contrast between the screening strategy pursued by patients and the preferences of their physicians. The patient mailings produced a modest increase in the use of FOBT, but all physicians considered colonoscopy as the preferred screening test for their patients. This finding is consistent with recent studies indicating a preference for FOBT over colonoscopy among patients who were provided information to make an informed choice, whereas physicians report a strong preference to recommend colonoscopy. This contrast highlights 1 potential challenge to engaging patients in quality-improvement programs. For services such as colorectal cancer screening for which multiple reasonable options exist, quality-improvement programs will need to address the possibly differing preferences of patients and their physicians and develop methods to reconcile such differences.

Increased screening is essential to reduce the incidence, morbidity, and mortality of colorectal cancer. One recent study estimated that US mortality from this disease could be reduced 23% by 2020 if screening rates rose to 70%. The importance of colorectal cancer screening has been recognized through expanded Medicare coverage for this service in 2001 and the endorsement of colorectal cancer screening as a health plan performance measure by the National Committee for Quality Assurance in 2005. Published studies of interventions to improve rates of colorectal cancer screening have targeted patients, physicians, or both groups. Physician-directed interventions such as reminders, videotaped decision aids, educational mailings, and nurse counseling may also increase screening rates. Our randomized trial builds on these studies in several important ways. First, these prior studies typically occurred in settings where baseline screening rates were much lower than the screening rate of 63% in our population, often produced larger absolute increases in screening rates, and focused on increasing use of FOBT or flexible sigmoidoscopy. These studies may not apply to the current era in which screening rates are higher and colonoscopy has become a preferred screening strategy among physicians and is therefore increasingly used. In fact, more recent interventions that have included use of colonoscopy in their recommendations have not successfully increased overall screening rates.

Our study provides important insights into the effect of interventions focused on patients who remain unscreened as screening rates rise through usual care. First, the modest effect of patient reminders in our study suggests the need to develop more effective strategies to actively engage these remaining patients and encourage them to be screened for colorectal cancer. However, the clear advantage of patient involvement over physician reminders in our study suggests that future strategies should increasingly involve patient-based activity. Promising alternatives include the use of the Internet to facilitate patient-provider communication and promote increased patient involvement in their preventive health issues. Patient navigators have also been used with success in promoting cancer screening, particularly among low-income and minority groups.

Second, our intervention simultaneously evaluated the use of personalized mailings to patients and electronic reminders to physicians. We found that patient mailings were more effective than physician reminders in raising overall screening rates, and nonsignificant trends in detection of colorectal adenomas were evident with each approach. Involving patients in decisions about colorectal cancer screening fits well with models that promote informed patients, moving them through the “stages of decision,” from awareness of screening options through the decision to be screened.

Fourth, the use of data from electronic medical records provided relatively complete clinical information on this large patient population, including data on clinical processes and outcomes. Approximately three-quarters of the positive FOBT results in our study population were followed by a colonoscopy. Although closing this loop is essential to realizing the benefits of a screening program, many studies demonstrate a similar gap in care. Physicians may not recommend appropriate follow-up testing to patients, patients may refuse further testing, or appropriate systems may not be in place to help clinicians identify abnormal test results and ensure appropriate follow-up.

The generalizability of our study must also be considered. We implemented our intervention within a single group practice using an advanced electronic health record, so our findings may not apply to less structured settings. In particular, integrated medical groups generally provide higher-quality care for screening services. However, our patient mailing intervention could be implemented across a wide range of health care settings, and the adoption of electronic health records is being ac-
tively promoted to improve ambulatory care. Our study demonstrated how electronic data can be used to create clinical registries for outreach to patients, and it assessed the utility of decision support that is directly integrated with computerized order entry for physicians providing ambulatory care. After our study found that the patient mailings were effective, the integrated group practice instituted a routine protocol to identify patients overdue for colorectal cancer screening (including patients in our control group) and send them mailings regarding their need for screening.

In conclusion, this randomized trial of personalized patient mailings and electronic reminders to physicians in a large integrated group practice found that patient mailings produced modest increases in rates of colorectal cancer screening, whereas electronic physician reminders tended to promote screening only among patients who have more frequent primary care visits. These complementary approaches have the potential to promote the overarching goal of widespread screening to reduce the incidence, morbidity, and mortality of colorectal cancer.

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