

# Physicians Encouraging Colorectal Screening

## *A Randomized Controlled Trial of Enhanced Office and Patient Management on Compliance With Colorectal Cancer Screening*

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**Background:** Colorectal cancer screening is underused. Our objective was to evaluate methods for promoting colorectal cancer screening in primary care practice.

**Methods:** A 2 × 2 factorial randomized clinical trial measured the effects of a tailored vs nontailored physician recommendation letter and an enhanced vs nonenhanced physician office and patient management intervention on colorectal cancer screening adherence. The enhanced and nonenhanced physician office and patient management interventions varied the amount of external support to help physician offices develop and implement colorectal cancer screening programs. The study included 10 primary care physician office practices and 599 screen-eligible patients aged 50 to 79 years. The primary end point was medical-record-verified flexible sigmoidoscopy or colonoscopy. Statistical end-point analysis (according to randomization intent) used generalized estimating equations to account for correlated outcomes according to physician group.

**Results:** During a 1-year period, endoscopy in the lower gastrointestinal tract (lower endoscopy) occurred in 289 of 599 patients (48.2%). This finding included the following rates of lower endoscopy: 81 of 152 patients (53.3%)

in the group that received the tailored letter and enhanced management; 103 of 190 (54.2%) in the group that received the nontailored letter and enhanced management; 58 of 133 (43.6%) in the group that received the tailored letter and nonenhanced management; and 47 of 124 (37.9%) in the group that received the nontailored letter and nonenhanced management. Enhanced office and patient management increased the odds of completing a colonoscopy or flexible sigmoidoscopy by 1.63-fold (95% confidence interval, 1.11-2.41;  $P = .01$ ). However, the tailored letter increased the odds of completion by only 1.08-fold (95% confidence interval, 0.72-1.62;  $P = .71$ ).

**Conclusions:** Approximately one-half of the screen-eligible primary medical care patients aged 50 to 79 years obtained lower endoscopic colorectal cancer screening within 1 year of recommendation. An enhanced office and patient management system significantly improved colorectal cancer screening adherence.

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**C**OLORECTAL CANCER IS THE second leading cause of cancer death in the United States. Despite recent declines in colorectal cancer incidence and mortality, it is estimated that 148 810 new cases will be diagnosed and that 49 960 individuals will die of this disease in 2008.<sup>1</sup> Screening by a variety of methods has been shown to reduce colorectal cancer mortality through early detection.<sup>2-6</sup> Screening has also been shown to decrease incidence by identifying and removing premalignant adenomatous polyps.<sup>2-5</sup> Consequently, groups such as the US Preventive Services Task Force, the American Cancer Society, and the US Multisociety Task Force on Colo-

rectal Cancer recommend colorectal cancer screening for average and high-risk individuals,<sup>2-8</sup> with screening beginning at 50 years of age for average-risk persons. Despite proven effectiveness, colorectal cancer screening rates have been poor, with approximately 50% of age-eligible persons undergoing recent screening.<sup>9</sup>

Put Prevention Into Practice (PIIP), an initiative developed by the US Department of Health and Human Services to help primary care providers deliver clinical preventive services, is a multilevel programmatic approach that targets office systems, health care providers, and patients.<sup>10</sup> Although comprehensive and promising, interventions using PIIP as a framework have not consistently increased use of pre-

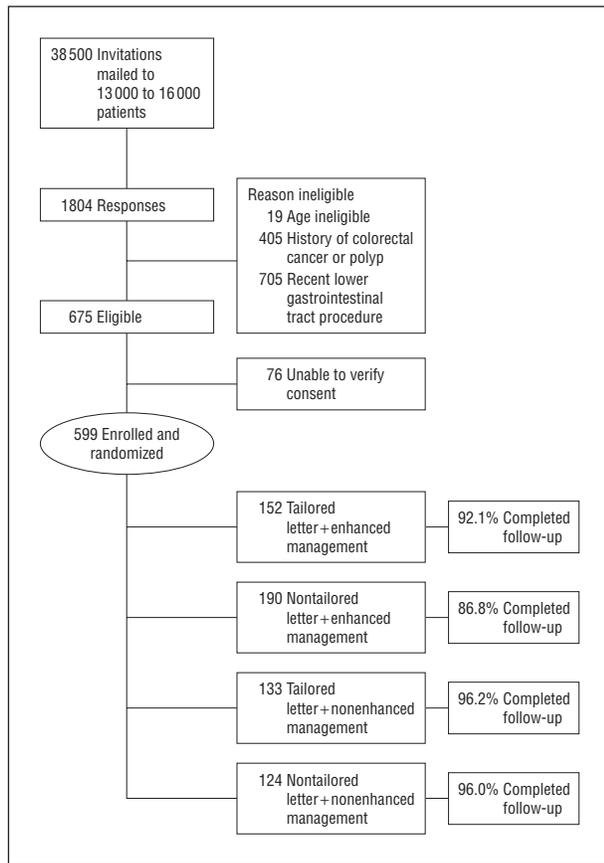
## DESIGN

A 2 × 2 factorial randomized clinical trial design measured the effects of separate interventions targeting written physician communications recommending endoscopic colorectal cancer screening and associated office and patient management systems designed to encourage patient compliance with this recommendation. We first paired the physician group practices according to the number of physicians, specialty (family practice vs internal medicine), location (urban vs suburban), and clientele (nonminority vs minority race) and then randomized one member of each pair to enhanced office and patient management and the second member of each pair to a nonenhanced office and patient management. Within each physician group practice, eligible patients were randomized individually to receive a personalized (tailored) or nonpersonalized (nontailored) letter that recommended endoscopic colorectal cancer screening. We used flips of a coin, witnessed by a person not involved in the research, to allocate physician group practices and computer-generated random numbers to allocate individuals between interventions. This design created the following 4 distinct intervention groups for comparison: (1) enhanced management with a tailored letter, (2) enhanced management with a nontailored letter, (3) nonenhanced management with a tailored letter, and (4) nonenhanced management with a nontailored letter.

## STUDY SUBJECTS

The randomized clinical trial enrolled consenting PRONET patients aged 50 to 79 years who completed a questionnaire from June 1, 2002, through April 30, 2004. Eligibility required no personal history of colorectal cancer or polyp and no recent lower gastrointestinal tract procedures (flexible sigmoidoscopy or barium enema within 5 years or colonoscopy within 10 years). We used electronic billing records to identify age-eligible PRONET patients who had had an office visit in the preceding fiscal year. Patients were mailed a packet that included an invitation letter, printed on physician practice letterhead, requesting voluntary participation in a special project “to develop better ways to prevent cancer of the colon and rectum” and “to standardize procedures in doctors’ offices and to improve information given to patients.” The packet also contained an informed consent document and a 34-item questionnaire asking about past lower gastrointestinal tract medical procedures (FOBT, barium enema, rigid proctoscopy, flexible sigmoidoscopy, and colonoscopy; 16 items), personal history of colorectal cancer or polyp (2 items), family history of colorectal cancer (4 items), interest and intentions related to colorectal cancer screening (3 items), sociodemographic characteristics in addition to sex and age (3 items), general health status and preventive health care practices (2 items), and opinions regarding colorectal cancer screening (4 items). We mailed packets in batches balanced across physician group pairs. Patients received up to 3 invitations to participate. Before enrolling patients, study personnel telephoned responders to verify informed consent.

**Figure 1** contains a diagram of patient recruitment, randomization, and follow-up using the recommendations of the Consolidated Standards of Reporting Trials (CONSORT).<sup>16</sup> Recruitment procedures entailed the preparation of 38 500 invitations mailed to an estimated 13 000 to 16 000 patients aged 50 to 79 years from the 10 participating PRONET practices (3 mailings per PRONET practice). The number of unique patients included in the 38 500 mailings could not be determined exactly because a third party (PRONET) updated lists when preparing subsequent mailings. To protect the identity



**Figure 1.** The Consolidated Standards of Reporting Trials (CONSORT) diagram of patient recruitment, randomization, and follow-up. Completed follow-up is reported as the percentage of randomized patients with a documented lower gastrointestinal tract endoscopy (lower endoscopy) or as a telephone contact occurring no more than 30 days before the anniversary of the recommendation letter in which the patient communicates no intent or plans to obtain lower endoscopy.

ventive clinical services in general or fecal occult blood testing (FOBT) in particular.<sup>11-15</sup> In a controlled study of primary care patients eligible for colorectal cancer screening, we sought to compare 2 PPIP-based physician office and patient management interventions for their effect on completion of endoscopic screening. Conceptually, the 2 interventions varied the amount of external support provided by the investigators to help physician offices develop and implement colorectal cancer screening quality improvement plans.

## METHODS

### SETTING

We identified and recruited 10 primary cancer physician group practices participating in the Physician Research in Office Network (PRONET), organized and supported by the University of Pittsburgh School of Medicine. The 10 PRONET practices included 38 physicians (range, 1-13 physicians per practice; 26 men and 12 women; 21 family practice and 17 internal medicine physicians) under contract with the University of Pittsburgh Medical Center Health System. Physician group practices that expressed interest in patient-care research and permitted access to billing records for research purposes were chosen for PRONET.

of nonparticipating patients (described in the “Human Use Considerations” subsection of the “Methods” section), the investigators were not permitted to link personal identifying information across the separate mailings to distinguish unique patients from patients who received a second or third mailing. This effort yielded 1804 responses, representing 11.3% to 13.9% of the estimated age-eligible population. Eligibility criteria excluded 19 age-ineligible persons, 405 patients with a personal history of colorectal cancer or polyp, and 705 with a recent lower gastrointestinal tract procedure. Seventy-six of 675 eligible patients (11.3%) could not be reached by telephone to verify consent, resulting in 599 study subjects. We randomized 152 to the enhanced-management–tailored-letter group, 133 to the nonenhanced-management–tailored-letter group, 190 to the enhanced-management–nontailored-letter group, and 124 to the nonenhanced-management–nontailored-letter group.

### Recommendation Letters

Letters recommended endoscopic colorectal cancer screening and asked recipients to telephone for an appointment (**Table 1**). The nontailored letter lacked a personalized salutation or patient-specific content. The computer-generated tailored letter inserted a personalized salutation, named the patient’s personal physician, commented on the patient’s age, family cancer history, and history of colorectal testing, and responded to a negative opinion expressed about endoscopic screening (sample letters available on request from the authors). Both letter formats used patient-appropriate physician practice letterhead and the signatures of the 2 physician investigators (J.L.W. and R.E.S.), who signed on behalf of each physician practice.

### Nonenhanced Office and Patient Management Interventions

The office and patient management interventions used research staff and a PPIP paradigm to help physician group practices promote and arrange patient referrals for endoscopic screening. In the nonenhanced office and patient management intervention, we educated physicians and office staff members about colorectal cancer screening guidelines and common barriers and misperceptions related to colorectal cancer screening. Working with office managers, we also helped offices write protocols to guide patient referrals for endoscopic screening of the lower gastrointestinal tract (hereinafter referred to as lower endoscopic screening). A sample physician office and patient management protocol is available on request from the authors.

For each physician group practice, we held 1 informal 30-minute educational meeting with physicians and another informal 60-minute meeting with office staff members. Meetings covered screening guidelines, barriers and misperceptions related to screening, and the study aims, objectives, and procedures. Using handouts and a semistructured interactive format, educational sessions actively solicited information about current colorectal cancer screening practices and related attitudes, opinions, values, and beliefs. Working with office managers, we helped offices write protocols to accomplish patient referrals for lower endoscopic screening. We alerted physicians about patients discovered to be eligible for lower endoscopic screening. Physician alerts arrived in several formats, including a standardized patient-specific summary report placed into the patient’s office record. In brief, the office-based intervention aimed to help physician groups standardize and systematize operating procedures pertaining to screening and to help physicians identify appropriate candidates for screening. However, physicians and physician office staff were solely re-

**Table 1. Major Features of the Physician Recommendation Letter and the Office and Patient Management Interventions**

Physician Letter Recommending Endoscopic Colorectal Cancer Screening	
Nontailored letter	
On practice letterhead	
Signed by physician investigators	
Used impersonal salutation	
Tailored letter	
On practice letterhead	
Signed by physician investigators	
Used personalized salutation	
Acknowledged personal physician by name	
Contained patient-specific information (age, family history of cancer, history of colorectal cancer screening, and opinions about colorectal screening) based on questionnaire responses	
Office and Patient Management Interventions	
Nonenhanced intervention	
Conduct informal, interactive, 30-min small-group educational meeting and discussion with physicians	
Conduct informal, interactive, 60-min small-group educational meeting and discussion with office staff	
Write office protocols implementing screening	
Enhanced intervention	
Conduct informal, interactive, 30-min small-group educational meeting and discussion with physicians	
Conduct informal, interactive, 60-min small-group educational meeting and discussion with office staff	
Write office protocols implementing screening	
Help implement office protocols	
Track short-term (3-mo) patient acceptance of referral for endoscopic screening	
Use motivational interview method to counsel patients	
Help patients overcome medical care and administrative barriers to screening (eg, scheduling appointment, transportation, insurance)	

sponsible for implementing patient referral protocols. The nonenhanced intervention represented a current standard of care in which providers use published tools (eg, PPIP<sup>10</sup>) and existing resources to initiate and sustain office procedures for promoting preventive clinical services.

### Enhanced Office and Patient Management Interventions

The enhanced office and patient management intervention used research staff to help office staff (1) adapt office-based protocols for endoscopic screening referral, (2) track patient outcomes, and (3) resolve patient-specific barriers to screening. To provide more help, research staff stayed in continual communication with physician office managers and worked to troubleshoot office procedures developed to standardize and facilitate referrals for screening colonoscopy or flexible sigmoidoscopy. Three months after sending the physician recommendation letter, research staff examined office records to determine compliance with the physician recommendation. To simulate an office management strategy that includes continual and systematic postreferral follow-up, a research staff member telephoned presumed noncompliant study patients. Guided by a standardized data collection form with closed and open-ended questions, the research staff member completed a telephone interview to determine behavioral stage (according to the principles of the transtheoretical model<sup>17</sup>) and to elicit factors motivating or hindering endoscopic screening (according to the methods of motivational interviewing<sup>18,19</sup>). The motivational interviewing technique used a patient-centered, em-

pathetic approach to determine a patient's assessment of the importance or value of colorectal screening and his or her readiness to undergo colorectal cancer screening. The interviewer identified discrepancies between stated values and apparent readiness to change behavior and then used probing questions to elicit explanations for discrepancies or barriers to behavior change. The motivational interview concluded with a discussion of possible ways and, where appropriate, an offer of assistance to overcome personal barriers to colorectal cancer screening.

The primary motivational interviewer (T.E.) had a Bachelor of Science degree in community health education and was a Certified Health Education Specialist. The primary interviewer supervised a nurse practitioner, who also conducted motivational interviews. The training of the primary motivational interviewer included (1) a review of published<sup>20,21</sup> and electronic materials<sup>22</sup> and (2) personal and telephone sessions (total training time, 5 hours) with an investigator (J.M.T.) whose credentials included a certificate of completion in Motivational Interviewing Change Planning for Health Behaviors (basic and advanced courses).

The median duration of the motivational interviews was 15 (interquartile range, 10-20) minutes. Study personnel used results from the motivational interview to counsel patients about colorectal cancer screening. Communicating with physician offices, study personnel also worked to rectify any medical care-related or administrative barriers uncovered during the motivational interview. For example, during the motivational interview, a patient might report difficulty making an appointment as a barrier to successful lower endoscopy follow-up. In this case, the motivational interviewer, serving as an intermediary between the patient and the physician's office, could contact the office directly and communicate the patient's difficulties making an appointment.

### STUDY END POINT

The primary study end point was medical record-verified flexible sigmoidoscopy or colonoscopy occurring between the date of completion of the study questionnaire and the 1-year anniversary of mailing the physician recommendation letter. We chose to focus on this end point because (1) our participating primary care physicians strongly favored screening sigmoidoscopy and colonoscopy over FOBT and (2) ascertaining and documenting FOBT is difficult.<sup>23,24</sup> To ascertain procedures missed by medical record reviews, we telephoned patients in the enhanced and nonenhanced management interventions to ask about completed or planned procedures. The enhanced office and patient management intervention included periodic telephone contacts. We attempted to contact patients in the nonenhanced management intervention after the anniversary of the recommendation letter if preliminary medical record reviews failed to document occurrence of the study end point. The remainder of this article uses the phrase *end-point telephone contact* to refer to the last patient telephone contact that provided information about sigmoidoscopy and colonoscopy status.

### STATISTICAL ANALYSIS

Because we realized that the outcome from 2 individuals belonging to the same matched pair of physician practices will be correlated, statistical analysis of the clinical trial end point (analyzed according to randomization intent) used generalized estimating equation (GEE) methods<sup>25</sup> to model the association of interventions with the outcome. This approach consists of 2 models fitted simultaneously. The main model specifies the logistic regression of the outcome on the independent vari-

ables and the other model accounts for the correlations between patients arising from their belonging to the same physician group practice (within practice) and to the same matched pair (between practice). We used alternate logistic regression<sup>26</sup> models to specify within- and between-practice associations in terms of pairwise odds ratios. These odds ratios enter into the main GEE model as nuisance parameters allowing unbiased estimation of the parameters of interest. The procedure provides valid tests of statistical significance related to the physician group practice-level intervention, the patient-level intervention, and the interaction between the practice- and patient-level interventions. We used commercially available software (the PROC GENMOD procedure in the SAS System for Windows, Release 8.02, with NEST1 and SUBCLUST options in REPEATED statement; SAS Institute Inc, Cary, North Carolina) to fit the alternate logistic regression and GEE.

### HUMAN USE CONSIDERATIONS

To protect the identity of nonparticipating patients, the PRONET organization prepared mailing lists used to invite study patients. The institutional review board for the University of Pittsburgh approved the methods, consent form, and questionnaires.

## RESULTS

The study group included 599 patients, consisting of 44.9% men, 28.7% who were 65 years or older, 12.4% Hispanic or nonwhite race, 77.5% educated past high school, and 16.4% in fair or poor health. The mix of study patients according to race, education, and general health status varied across the 10 physician practices (data not shown). However, matching and randomization procedures eliminated statistically significant differences according to the office and patient management (**Table 2**) and physician letter interventions (data not shown). A median 71 (interquartile range, 55-97) days elapsed between the study questionnaire completion date and the recommendation letter mailing date. The intervals between study questionnaire completion and recommendation letter mailing were similar between intervention groups (tailored vs nontailored physician recommendation letter and enhanced vs nonenhanced physician office and patient management).

Follow-up documented a flexible sigmoidoscopy or colonoscopy end-point procedure in 289 of 599 patients (48.2%), including 81 of 152 patients (53.3%) in the tailored-letter-enhanced-management group, 103 of 190 (54.2%) in the nontailored-letter-enhanced-management group, 58 of 133 (43.6%) in the tailored-letter-nonenhanced-management group, and 47 of 124 (37.9%) in the nontailored-letter-nonenhanced-management group (**Table 3**). In 241 of the 289 procedures (83.4%), the end-point procedure represented patients' first lifetime flexible sigmoidoscopy or colonoscopy procedure. In a main-effect GEE model, enhanced management increased the odds of an end-point procedure by 1.63-fold (95% confidence interval, 1.11-2.41;  $P = .01$ ). The tailored letter increased the odds of an end-point procedure by only 1.08-fold (95% confidence interval, 0.72-1.62;  $P = .71$ ). Although the tailored letter intervention was associated with a 5.7-percentage point

**Table 2. Patient Characteristics According to Physician-Office-Practice Intervention**

Characteristic	No. (%) of Patients		P Value <sup>c</sup>
	Enhanced Office and Patient Management (n = 342) <sup>a</sup>	Nonenhanced Office and Patient Management (n = 257) <sup>b</sup>	
Sex			.22
Men	148 (43.3)	121 (47.1)	
Women	194 (56.7)	136 (52.9)	
Age, y			.33
50-54	124 (36.3)	80 (31.1)	
55-59	84 (24.6)	57 (22.2)	
60-64	49 (14.3)	33 (12.8)	
65-69	37 (10.8)	35 (13.6)	
70-74	27 (7.9)	32 (12.5)	
≥75	21 (6.1)	20 (7.8)	
Race			.37
White, not Hispanic	307 (90.0)	217 (84.4)	
Other	34 (10.0)	40 (15.6)	
Education			.26
<High school	11 (3.2)	9 (3.5)	
High school graduate	64 (18.7)	50 (19.5)	
>High school	38 (11.1)	21 (8.2)	
Some college	74 (21.6)	50 (19.5)	
College graduate	79 (23.1)	48 (18.8)	
Graduate or postbaccalaureate school	76 (22.2)	78 (30.5)	
Marital status			.82
Married or living as married	250 (73.1)	179 (70.8)	
Other	92 (26.9)	74 (29.2)	
General health status <sup>d</sup>			.32
Excellent	92 (27.1)	63 (24.6)	
Good	188 (55.3)	155 (60.5)	
Fair	56 (16.5)	34 (13.3)	
Poor	4 (1.2)	4 (1.6)	

<sup>a</sup>One patient was missing information for race and 2 patients were missing information for general health status.

<sup>b</sup>One patient was missing information for education, 4 patients were missing information for marital status, and 1 patient was missing information for general health status.

<sup>c</sup>Indicates statistical significance of the difference between the enhanced vs nonenhanced office and patient management, controlling for physician group pairings.

<sup>d</sup>Indicates response to entry questionnaire item "In general, would you say your health is excellent, good, fair, or poor?"

higher completion rate in the nonenhanced management setting and a 0.9–percentage point lower completion rate in the enhanced management setting, a formal test of the interaction between the office- and letter-based interventions was not statistically significant ( $P = .38$ ).

Thirty patients (5.0%) received flexible sigmoidoscopy only, 252 (42.1%) received colonoscopy only, and 7 (1.2%) received both procedures. Thirty-three received an end-point procedure after completing the study questionnaire but before receiving the physician recommendation letter.

**Table 4** summarizes the effects of enhanced office and patient management in patient subgroups defined according to sex, age, race, education, marital status, and general health status. Enhanced management was more effective among patients aged 50 to 64 years, college gradu-

**Table 3. Number of Study Patients and Frequency of End-Point Colonoscopy or Flexible Sigmoidoscopy According to Intervention Grouping**

Office Intervention, Letter Type	No. of Patients	Occurrence of Colonoscopy or Flexible Sigmoidoscopy	
		No. (%) of Patients	95% CI
Enhanced			
Tailored	152	81 (53.3)	45.4-61.2
Nontailored	190	103 (54.2)	47.1-61.3
Nonenhanced			
Tailored	133	58 (43.6)	35.2-52.0
Nontailored	124	47 (37.9)	29.4-46.4

Abbreviation: CI, confidence interval.

ates, married individuals, and patients reporting excellent health. In a GEE model, the effects from enhanced management differed statistically in patients aged 50 to 64 and 65 to 79 years ( $P = .052$ , based on generalized score statistic), with intervention increasing lower endoscopy by 18.4 and 2.4 percentage points among patients aged 50 to 64 and 65 to 79 years, respectively. A history of flexible sigmoidoscopy or colonoscopy did not modify the association between the management group and completion of an end-point lower endoscopy procedure ( $P = .96$ ).

Among the 342 patients from enhanced management practices, 235 (**Figure 2**) were not yet compliant when first reached for the motivational interview. Eighty-nine of 235 (37.9%) subsequently completed an end-point colonoscopy or flexible sigmoidoscopy (**Figure 2**). The motivational interview uncovered patient concerns about screening costs or insurance coverage in 29 instances (12.3%). An end-point flexible sigmoidoscopy or colonoscopy occurred in only 7 of these 29 patients (24.1%), compared with 82 of the remaining 206 patients (39.8%) who stood to benefit from the motivational interview ( $P = .10$ ).

We examined end-point procedure dates in relation to the date of the physician recommendation letter and motivational interview (**Figure 3**). These analyses excluded patients with an end-point procedure before the mailing of the physician recommendation letter (18 and 21 patients from the enhanced and nonenhanced management offices, respectively; **Table 5**) and patients without any subsequent telephone contact (8 patients each from the enhanced and nonenhanced management offices). For the remaining 316 and 228 patients from the enhanced and nonenhanced management offices, respectively, **Figure 3** shows the proportion who had not undergone endoscopy according to days since the mailing of the physician recommendation letter. Curves appear to diverge during a time frame corresponding to the timing of the motivational interviews, suggesting a specific effect from the motivational interviews.

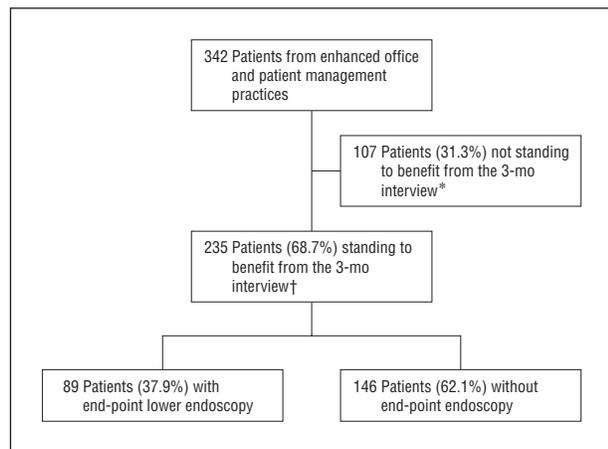
Because the office-based intervention manipulated the amount of contact between study personnel and medical providers and because study personnel who collected end-point information were not blind to subjects' membership in enhanced or nonenhanced management

**Table 4. Colonoscopy or Flexible Sigmoidoscopy Outcome According to Patient Subgroup and Physician-Office-Practice Intervention**

Subgroup	% of Patients (N) With Primary Study End Point <sup>a</sup>		Difference, %	P Value <sup>b</sup>
	Nonenhanced Management	Enhanced Management		
Sex				.76
Men	43.0 (121)	56.8 (148)	13.8	
Women	39.0 (136)	51.5 (194)	12.6	
Age, y				.052
50-64	35.3 (170)	53.7 (257)	18.4	
65-79	51.7 (87)	54.1 (85)	2.4	
Race				.69
White, not Hispanic	41.0 (217)	53.7 (307)	12.7	
Other	40.0 (40)	55.9 (34)	15.9	
Education				.30
≤High school	35.6 (59)	49.3 (75)	13.7	
Technical or some college	40.8 (71)	48.2 (112)	7.4	
College graduate	43.7 (126)	60.0 (155)	16.3	
Marital status				.30
Married or living as married	41.3 (179)	57.2 (250)	15.9	
Other	40.5 (74)	44.6 (92)	4.0	
General health status				.48
Excellent	38.1 (63)	54.3 (92)	16.3	
Good	41.3 (155)	55.9 (188)	14.6	
Fair/poor	44.7 (38)	48.3 (60)	3.6	

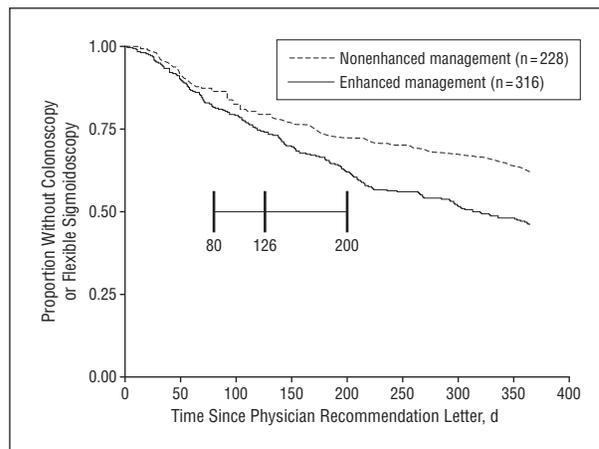
<sup>a</sup>Primary study end point was defined as the medical record–verified sigmoidoscopy or colonoscopy occurring between the date of completion of the study questionnaire and the 1-year anniversary of mailing the physician recommendation letter.

<sup>b</sup>Indicates statistical test of the null hypothesis: the physician-office-practice intervention (enhanced vs nonenhanced) does not depend on patient subgroup characteristic in a generalized estimating equation model that also includes the main effect due to physician recommendation letter type (tailored vs nontailored letter).



**Figure 2.** Outcomes after delivery of the 3-month motivational interview.

\*This category includes 2 patients found to have had recent lower gastrointestinal tract endoscopy (lower endoscopy) before completing the baseline questionnaire, 38 patients never contacted for the motivational interview, and 67 patients found to have already had an end-point lower endoscopy when first contacted for the motivational interview. This category also includes 95 of 107 patients (88.8%) with an end-point lower endoscopy. †This category includes patients who had not had an end-point lower endoscopy when first reached for the motivational interview.



**Figure 3.** Kaplan-Meier plot of the proportion of patients in enhanced and nonenhanced office and patient management practices without colonoscopy or flexible sigmoidoscopy according to timing of the motivational interview, expressed as the number of days since the mailing of the physician recommendation letter. The bracket (day 80, 5th percentile; day 126, median; and day 200, 95th percentile) indicates the timing of motivational interviews with patients from enhanced office and patient management practices (n=235) who stood to benefit from the motivational interview (see Figure 2).

offices, incomplete or dissimilar end-point information threatens the internal validity of the study. To assess this threat, Table 5 supplies a complete accounting of study patients classified according to study end points, timing of the end-point telephone contact, and physician office group assignment. The top half of Table 5 classifies patients with an end-point procedure according to the following 3 important dates: (1) the dates patients com-

pleted the study questionnaires used to assess candidacy for endoscopic screening; (2) the dates the investigators mailed the physician letters that recommended endoscopic screening; and (3) the 1-year anniversaries of mailing the physician recommendation letters. Table 5 illustrates that the better outcome observed under the enhanced management intervention results from patients who received end-point endoscopy after the mail-

ing of the physician recommendation letter (49.7% vs 33.5% of patients in enhanced and nonenhanced management offices). Table 5 also identifies patients with a prior procedure not reported on the study questionnaire (1.2% and 0.8% of patients in the enhanced and nonenhanced management offices, respectively) and patients with late procedures occurring after the anniversary of the recommendation letter (3.5% and 5.1% of patients in the enhanced and nonenhanced management offices, respectively). To respect the intent of the randomization and to maintain comparable follow-up information according to the intervention, these patients were included as intervention failures in the analyses of the primary study end point.

The bottom half of Table 5 classifies patients without an end-point procedure according to the timing of the end-point telephone contact. The enhanced management group included higher proportions without an end-point procedure and with a missing or premature (more than 30 days before the anniversary of the recommendation letter) end-point telephone contact (10.8% vs 3.9%). Therefore, the higher frequency of sigmoidoscopy and colonoscopy observed under enhanced management cannot be attributed to fewer patients with missing or premature end-point telephone contacts. Final reviews of electronic medical records occurred after the letter anniversary date in all instances of missing or premature end-point telephone contact.

#### COMMENT

We developed a multipart intervention to increase lower endoscopic colorectal cancer screening in the primary care setting. One part targeted office and patient management procedures relating to the referral for endoscopic screening, and another part targeted the written communication used to recommend endoscopic screening. Patients in enhanced office and patient management practices had higher rates of lower endoscopy after 1 year (approximately 54%) than did patients in nonenhanced practices (approximately 40%). This 14-percentage point difference corresponds to a number needed to treat of 7, indicating 1 additional patient undergoing screening for every 7 patients exposed to enhanced management. Although the tailored letter appeared to increase lower endoscopy in the nonenhanced management setting (43.6% vs 37.9%), this difference was not statistically significant ( $P = .37$ ). Moreover, modeling did not show a statistically significant interaction between the recommendation letter and the office and patient management intervention ( $P = .38$ ).

We used information collected on study entry questionnaires to create individualized (tailored) physician recommendation letters.<sup>27,28</sup> Tailored print communications are better remembered, read, and received.<sup>27</sup> However, controlled studies generally show only small effects of tailored print communications on health behavior change.<sup>29</sup> Effect sizes observed in comparative studies of tailored print communications depend on the comparison group, with studies that use no-treatment control groups showing larger effect sizes than studies that use

**Table 5. Timing of Colonoscopy or Flexible Sigmoidoscopy Procedures and of End-Point Telephone Contacts, According to Office and Patient Management Intervention**

Timing	No. (%) of Patients	
	Enhanced Management (n=342)	Nonenhanced Management (n=257)
Colonoscopy or flexible sigmoidoscopy procedure <sup>a</sup>		
Before questionnaire <sup>b</sup>	4 (1.2)	2 (0.8)
Between questionnaire and recommendation letter	14 (4.1)	19 (7.4)
Between recommendation letter and anniversary of recommendation	170 (49.7)	86 (33.5)
After anniversary of recommendation letter <sup>b,c</sup>	12 (3.5)	13 (5.1)
End-point telephone contact, in patients without colonoscopy or flexible sigmoidoscopy procedure <sup>a,d</sup>		
After anniversary of recommendation letter	72 (21.1)	111 (43.2)
≤30-d interval before anniversary of recommendation letter	33 (9.6)	16 (6.2)
Missing end-point telephone contact or end-point telephone contact more than 30 d before anniversary of recommendation letter	37 (10.8)	10 (3.9)

<sup>a</sup> *Questionnaire* refers to the date the patient completed the study questionnaire used to assess candidacy for screening colonoscopy or flexible sigmoidoscopy. *Recommendation letter* refers to the date the investigators mailed the physician letter that recommended screening colonoscopy or flexible sigmoidoscopy.

<sup>b</sup> Patients in these categories were counted in the intention-to-treat analysis as not having completed an end-point lower gastrointestinal tract endoscopic procedure.

<sup>c</sup> This category includes some colonoscopy or flexible sigmoidoscopy patient self-reports that the research did not try to verify through examinations of medical records.

<sup>d</sup> *End-point telephone contact* refers to the telephone contact used to help ascertain occurrences of colonoscopy and flexible sigmoidoscopy.

nontailored message control groups.<sup>29</sup> A recently published randomized study<sup>30</sup> definitively showed no effect of tailored vs nontailored print communications on mammography screening behavior in US women veterans. Therefore, our null results agree with other studies. Unfortunately, with 150 subjects per group, our study had limited power to detect clinically meaningful effects from tailoring.

The nonenhanced and enhanced physician office and patient management interventions followed a PPIP model,<sup>10</sup> an approach that encourages the development of systems for delivering preventive clinical services. Empirical research demonstrates the value of organizational changes or systematic approaches that use, for example, specialized prevention clinics, planned preventive care visits, or nonphysician staff to perform specific prevention activities.<sup>31-35</sup> However, large-scale efforts to disseminate organizational change to the level of small provider groups have been difficult.<sup>36</sup> Our enhanced physician office and patient management intervention used exter-

nal research-supported resources in an effort to assist and sustain organizational change in small primary care physician group practices.

The enhanced physician office and patient management intervention used a standardized approach and brief motivational interviews to promote adherence to colorectal cancer screening recommendations. This conceptually simple intervention could, in principle, be absorbed easily into clinical practice by assigning the task of systematic patient follow-up to existing office personnel. With training, we believe that primary medical care nonprofessionals and professionals are capable of delivering the motivational interview intervention. Motivational interviewing has been shown to encourage behaviors leading to improved health outcomes in body mass index, cholesterol levels, blood pressure control, and alcohol intake.<sup>18,19</sup> More recently, Dietrich et al<sup>37</sup> showed increased breast, cervical, and colorectal cancer screening among low-income women exposed to a motivational support intervention delivered by telephone. Although the timing of colorectal cancer screening end points suggested a specific contribution from the motivational interviews (Figure 3), our study was not designed to determine the relative value of the separate components (eg, organized patient follow-up vs motivational interviewing) within the enhanced management intervention.

Although retraining existing office personnel and changing physician office and patient management procedures may improve colorectal cancer screening rates, widespread organizational change of this nature is difficult. Organizational change, particularly change that adds new employees or reduces productivity, may create expenses not feasible for small organizations with limited resources.<sup>38</sup> Organizations also vary with respect to readiness to adopt new procedures or to change existing structures,<sup>39</sup> and the very complexity of clinical practice often inhibits organizational change.<sup>38</sup> Crabtree et al<sup>38</sup> identified as many as 30 factors (eg, office efficiency, patient volume, medical and socioeconomic needs of patients, and cognitive framework of providers [ie, problem- or patient-focus]) affecting organizational change in primary care settings. It is likely that the success of our office and patient management resulted from the infusion of resources to help with patient follow-up.

Because lack of blinding could have biased determinations of colorectal cancer screening outcomes, we used several information sources (patient telephone contacts, paper medical records, and electronic medical records) to ascertain occurrences of lower endoscopy, but we analyzed clinical trial results according to intention to treat and accepted only screening end points verified by the medical record. In fact, a complete and detailed accounting of clinical trial end points in relation to patient follow-up (Table 5) suggested that follow-up may have been more complete for patients from nonenhanced management practices. For these reasons, we believe that the improved screening outcomes observed with enhanced management are not artifacts of biased self-reports or better follow-up.

A study limitation included uncertainty regarding the rate of response (estimated 11.3%-13.9%) to mailed invitations to join the study. Our relatively low patient par-

ticipation rate also raises a concern that patient recruitment may have selected a group more inclined to accept endoscopic screening. However, it is not known whether subject recruitment procedures selected patients more or less inclined to respond to our particular study interventions. To facilitate access to medical records and to enable the motivational interviews, we chose to restrict the study group to patients who completed formal informed consent procedures. We attribute the low response rate to our recruitment method, which required signed written consent for participation in research. To participate, patients had to (1) receive and open a mailing, (2) read and react favorably to its contents, and (3) sign and return an unfamiliar consent form. Response rates may be higher with recruitment methods that use face-to-face contacts in clinical settings. Most likely, more patients could be exposed to the interventions described in this report in settings not requiring informed consent. Our intervention study occurred at a time when study participants may have been exposed to public messages that encouraged or promoted colorectal cancer screening. However, we encountered no reason to believe that a single comparison group was more or less exposed to these external messages. Finally, we defined colorectal cancer screening compliance solely in terms of endoscopic screening. We asked patients who had not undergone lower endoscopy screening to report FOBT since study entry. Based on the responses to this question, we estimate that 15.4% of patients who did not undergo lower endoscopy underwent FOBT instead. Statistically, the frequency of FOBT in patients who do not undergo lower endoscopy was similar between patients in the nontailored vs tailored letter groups (12.0% vs 18.9%;  $P=.15$ ) and between patients in the nonenhanced vs enhanced office and patient management groups (17.9% vs 12.6%;  $P=.26$ ). We did not attempt to use medical record reviews to validate FOBT self-reports or to ascertain FOBT occurrences, owing to the literature that shows patient self-report of FOBT to be inaccurate.<sup>23,24</sup>

In conclusion, approximately one-half of screen-eligible primary medical care patients aged 50 to 79 years obtained endoscopic colorectal cancer screening within 1 year of recommendation. These results underscore not only the opportunities to enhance endoscopic screening through primary care but also the difficulty of near universal screening. An enhanced office and patient management system significantly improved screening adherence.

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