

Results of a Randomized Controlled Trial to Increase Colorectal Cancer Screening in a Managed Care Health Plan

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BACKGROUND. Colorectal cancer (CRC) is the third most common cause of cancer deaths; however, rates of regular screening for this cancer are low. A quality improvement (QI) program to increase CRC screening was developed for use in a managed care health plan.

METHODS. Thirty-six provider organizations (POs) contracting with the health plan were recruited for a randomized controlled effectiveness trial testing the QI program. The intervention was delivered over a 2-year period, and its effectiveness was assessed by chart review of a random sample of patients from each PO.

RESULTS. Thirty-two of the 36 POs were evaluable for outcome assessment. During the 2-year intervention period, only 26% of the eligible patients received any CRC screening test. Twenty-nine percent of patients had any CRC screening test within guidelines, with no differences between the intervention or control POs. Significant predictors of having received CRC screening within guidelines were older age ($P = 0.0004$), receiving care in an integrated medical group ($P < 0.0001$) and having had a physical examination within the past 2 years ($P < 0.0001$).

CONCLUSIONS. A facilitated QI intervention program for CRC screening that focused on the PO did not increase rates of CRC screening. Overall CRC screening rates are low and are in need of improvement. *Cancer* 2005;104:2072-83.

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In 2005, it is estimated that 56,290 men and women will die from colorectal cancer (CRC), making it the third leading cause of cancer mortality.¹ Although there have been multiple strategies proposed to screen for CRC, by 1996 there was sufficient evidence for the efficacy of stool occult blood testing and flexible sigmoidoscopy, leading the US Preventive Services Task Force to recommend screening for all average risk individuals 50 years of age and older,² with other health-care organizations supporting these recommendations.³ There has also been increasing support for the use of colonoscopy as a CRC screening test,^{4,5} with the Centers for Medicare and Medicaid Services approving the reimbursement of all CRC screening tests (including colonoscopy) for those insured by Medicare in July 2001.^{6,7} Despite growing recognition of the efficacy and importance of CRC screening, rates of screening are extremely low^{8,9} with a critical need to find strategies to increase CRC screening in healthcare settings where adults receive their care.

Historically, uptake and utilization of cancer screening tests has required prolonged campaigns targeted at healthcare providers and

patients, as well as financial or evaluative incentives at the organization and health plan level (e.g. Papanicolaou smears and mammograms). Randomized clinical efficacy trials have been conducted to demonstrate which types of interventions work to increase screening rates and to understand the barriers or facilitators of screening. Once the efficacy of an intervention is established in Phase III trials, then the effectiveness of the intervention must be examined in a real world settings (e.g., a Phase IV cancer control study); however, as noted recently by Glasgow et al.,¹⁰ this is seldom done. During the 1990s, several research teams conducted Phase III cancer control studies testing strategies directed at increasing cancer screening rates (including for CRC) among patients and providers in various practice settings.¹¹⁻¹⁹ Dietrich and colleagues²⁰ had even exported a successful office practice intervention in community health centers as part of an effectiveness trial.

Given this background and the importance of increasing CRC screening, in 1998 we initiated a research program designed to conduct a randomized effectiveness trial within the setting of a large managed care health plan,²¹ with our target being the healthcare delivery setting (administrative structure of provider organizations, physicians and other professional staff working within the organization). We selected the managed care setting for an effectiveness trial, as it had several organizational features and past history suggesting better performance in the conduct of some cancer screening tests.²²⁻²⁴ This report describes the results of the effectiveness trial, which used a facilitated quality improvement intervention program to enhance CRC screening at the provider organization (PO) level. The principal goal of the study was to increase rates of CRC screening within guidelines using either take home fecal occult blood testing (FOBT) and/or endoscopy (flexible sigmoidoscopy or colonoscopy) in age eligible enrollees of the health plan.

MATERIALS AND METHODS

Setting for the Effectiveness Trial

We conducted this study within a large network model health maintenance organization (HMO)²¹ that contracted with POs throughout California. This HMO is responsible for the healthcare of approximately 1.5 million individuals, representing about 22% of those covered by commercial HMO insurance. (In California, about 6 million additional individuals are insured by a large, nonprofit group model HMO.) In the network model HMO, physicians join POs to facilitate contracting with health insurance plans,²⁵⁻²⁸ which delegate most responsibility for utilization review,

coverage decisions, and quality assurance activities to these POs.²⁹ As part of these contracts, the POs are required to have quality assurance or improvement structures that are responsible for promoting adherence to evidence-based guidelines and recommendations. This study planned to capitalize on this existing structure for implementation of the intervention program.

There are two main types of POs within the network model HMO.³⁰ The independent practice association (IPA) is formed by a loose association of individual providers and offices that join together primarily for contracting purposes. The IPAs have a limited administrative structure and providers often belong to more than one IPA. In contrast, the integrated medical groups (IMG) are usually well organized multispecialty groups, with a more developed administrative structure, with shared offices and facilities, and a higher level of practice integration. For this health plan, and California in general, roughly 66% of POs were IPAs.^{21,30,31}

During the time of this study, the health plan members (patients) included about 260,413 individuals 50 years of age and older (16.8% of the total health plan members), with 74% 50-59 years, 19% 60-64 years, and 7% 65 years or older. There was an equal gender distribution for those aged 50-64 years, with slightly more men among those older than 65 years of age. Ethnicity and marital status are not available from the health plan.

Recruitment and Randomization of the Provider Organizations

The details of the study design and the collaboration with the health plan, as well as the process of recruitment of the POs have been reported elsewhere.²¹ The sampling frame for the trial consisted of all the POs contracting with the health plan, with PO as the unit of randomization. To be eligible, a PO had to have a sufficient number of patients age 50 years and older for the intervention to be relevant (i.e., at least 1100 members). Therefore, POs were eligible if they either 1) had more than 10,000 members enrolled in the health plan, or 2) had between 1100 and 10,000 members and had a minimum of 500 members who were age 50 years or older. Between April and December 1999, we recruited 36 to the study, representing 71% of the eligible organizations. The 36 POs were distributed throughout California and reflected the overall geographic distribution of POs contracted with the health plan.³⁰ The University of California Los Angeles (UCLA) institutional review board approved all of the research and procedures used in this study.

Randomization occurred in June 2000, after com-

pletion of a baseline provider and patient survey,^{31,32} which was conducted to refine the intervention providing information on perceived barriers and facilitators of CRC screening. This limited patient survey at baseline also provided assurance that there were no imbalances in CRC screening rates between the intervention and control POs viewed as a group, but it was not intended to provide a baseline rate of CRC screening before intervention. Randomization used stratification to account for organizational structure: IPA versus IMG; number of providers in each PO (small ≤ 35 providers, medium 36–99 providers, large ≥ 100 providers); and potential provider crossover between POs (in one region there was overlapping provider membership in an IPA and MG). Ultimately, 19 POs were assigned to the intervention, and 17 to the control condition. After randomization, there was no further contact with the control POs.

Description of the Intervention and its Delivery

The intervention program drew heavily on the work of Dietrich and colleagues,^{15,16} who had developed a cyclical model for practice change that included goal setting, assessment, planning and starting and maintaining practice changes, including the testing of this model through randomized efficacy and effectiveness trials.^{15–17,20} This QI approach informed the strategies, content, approach, and delivery of the intervention program for the effectiveness trial. The research team developed a QI program that focused on CRC screening, thus taking the problem identification and intervention development processes from the purview of the PO, providing the PO with a set of comprehensive tools and strategies to address CRC screening. Instead of targeting individual practitioners or offices,^{16,19,33} this intervention program took advantage of existing PO structure and the QI staff employed by the PO. The QI program reflected an awareness of the literature on intervention effectiveness and physician behavior change,^{34–37} with a focus on implementing a multiplicity of simultaneous strategies including the identification of organizational opinion leaders, the enhancement of provider self-efficacy and adherence to CRC screening recommendations.³⁸ Supporting materials were included for office staff and patients.

The intervention began with a 2-hour workshop that introduced the program to the PO leadership and staff (see Table 1), including a scientific presentation on the importance of CRC as a disease and the data supporting the efficacy of screening. The workshop was conducted by the research team leader (PAG), the project director (MMF), and the intervention coordinator (CAG), who traveled to the PO site to present the workshop information. PO-specific results from the

TABLE 1
Description of the Facilitated Quality Improvement Program Activities

Intervention start-up activities

- 1) Workshop for Providers, Administrative Staff, Nursing and others-onsite at the PO with CME and CEU offered.
- 2) Provision of a Resource Guides (multiple copies) and Facilitator's Manual at the time of the Workshop.
- 3) Selection of a PO Facilitator to champion the QI program.
- 4) Assistance with a chart audit to understand current screening rates and quality of chart documentation within the PO.
- 5) Assistance with an organizational strategy/goal meeting to review audit findings and select strategies
- 6) Organizational meeting to present plan and start the intervention

External supportive activities by the research team over the course of the intervention

- 1) Assistance with initial chart audit to establish baseline screening rates.
- 2) Help in setting organizational goals.
- 3) Minigrants (up to \$400) to support organizational innovation, development of local resources or office systems.
- 4) Booster activities: quarterly newsletters to providers highlighting intervention activities, interviews with opinion leaders, updates on CRC screening literature.
- 5) Instructions on follow-up chart reviews and provision of feedback.
- 6) Ongoing consultation and organizational "academic detailing" focusing on the facilitator and the medical director.

primary care provider survey³¹ were presented, as well as results from a statewide telephone survey of the health plan patients sampled from the participating POs.³² The presentation included a discussion of the QI process and an introduction to the intervention materials. Workshop participants received a Resource Guide that included scientific reference materials, a detailed discussion of the QI process, materials on how to do chart audits to assess practice patterns of CRC screening, as well as examples and instructions for a variety of tools and strategies for enhancing provider, nurse and office staff education, office systems, and patient education. A Facilitator's Manual described how to launch and perform the QI intervention. Office posters and brochures for patients were displayed and left with the PO at the time of the workshop.

The medical director of the PO was asked to identify an intervention facilitator to spearhead intervention activities within the organization. After identification of the facilitator, each PO was asked to schedule an internal chart audit and goal meeting. The research team intervention coordinator (CAG) was available to help with the chart audit and participate in the goal meeting. The specific activities recommended as part of the intervention are described in Table 2; these were introduced at the workshop but discussed in more detail at the goal meeting and through ongoing interactions with the research team intervention coordinator. We encouraged implementation of at least

one strategy from each of three domains (professional staff education, office systems, patient education). The research team intervention coordinator provided ongoing external support for the QI intervention, through regular monthly telephone or electronic contact with PO facilitator, monitoring progress of intervention activities, and providing assistance in implementing the tools and strategies. The intervention coordinator also sent monthly faxes to the medical director and facilitator to provide updates on CRC screening activities (e.g., news notes, scientific papers), as a form of academic detailing. Quarterly newsletters focusing on CRC screening were also mailed to the primary care providers at the intervention POs. However, unlike previous efficacy trials, we did not provide on-site assistance with implementation of the intervention activities, as the goal was to test a model that could be maintained with limited external supports, for example, through a centralized coordinator at the health plan.

During the time of the study, this health plan provided coverage for all of the CRC screening tests, although the extent of patient copayment for the endoscopic procedures varied by individual insurance policy. FOBT was fully covered. From the perspective of the PO, there was variability in the extent of capitation and whether or not the PO had providers trained to perform sigmoidoscopy or colonoscopy. However, the intervention was flexible and did not mandate which CRC screening test to use, letting the PO have discretion in adopting a policy that could advocate one CRC screening test over another.

Sample Size and Outcome Assessment

Sample size calculations and power estimates required only 32 POs for the trial. However, given the volatility of the healthcare environment, we chose to recruit a larger number of provider organizations to have a sufficient sample at the end of the trial. We calculated the required sample size based on a 10% background sigmoidoscopy adherence rate and a 15% FOBT adherence rate.³⁹ We hypothesized that the intervention would increase sigmoidoscopy screening rates to 25% and FOBT to 35–40% based on interventions reported in the literature;⁴⁰ however, we also took into account a range of other scenarios with smaller or larger increases in screening rates. Taking into account a plausible Hawthorne effect in both arms, secular trends in screening rates over the course of the study, and stratification by PO size and organization type (LMG or IPA), we required a final sample of 1600 eligible patients (50 patients from each PO). This assumed that all tests were two-tailed in a logistic model relating screening rate to intervention or con-

TABLE 2
Domains and Tools for Action

Domain of action	Tools for action
Provider, nurse and office staff education	A practice policy for CRC screening, to be developed at the organizational level and distributed to all providers, nurses and office staff. Academic Detailing or Grand Rounds on CRC screening, to be prepared for providers, nurses and office staff.
Office systems (Inreach)	Identification and implementation <ul style="list-style-type: none"> ● Health maintenance flow sheet ● Periodic Health Examination form ● Pre-printed prevention note ● Routinized patient queries for providers, nurses and office staff ● External chart identifiers ● Screening history form Monitoring <ul style="list-style-type: none"> ● Health maintenance flow sheet ● Develop a code to be used on flowsheet to distinguish if test was recommended, scheduled, or done ● Tickler file ● Patient follow-up binder
Patient education	Inreach <i>Passive</i> <ul style="list-style-type: none"> ● Brochures in waiting room or exam room ● Posters in waiting room or exam room ● Bulletin board with screening information in office <i>Active</i> <ul style="list-style-type: none"> ● Provider, nurse or staff member hands brochure to patient and discusses ● Nurses wear pins which prompt the patient to ask about screening ● Patient health maintenance diary Outreach <i>Active</i> <ul style="list-style-type: none"> ● Office sends cards or letters with screening information to patients on 50th birthday ● Provider organization hosts patient information sessions on CRC screening

trol status and multiple potential covariates, corrections for clustering within PO, to maintain a significance level of 0.005 with an overall error rate of 0.05 in the presence of 3 outcome variables (FOBT, endoscopy, or any test within guidelines) with at least 80% power to detect the postulated intervention effect.

Outcome assessment for the trial was accomplished through medical record review at the completion of 2 years of intervention. The chart review instrument was designed to determine 1) the date of the most recent CRC screening tests (take home FOBT, flexible sigmoidoscopy, or colonoscopy) for at least the past 10 years if the chart was available during that time period, 2) why the test was recommended (screening, symptoms, no documentation), 3) if or when the test was completed, 4) the results of the

completed tests, and 5) whether a follow-up test was recommended and completed for an abnormality. FOBT performed as part of a digital rectal examination was not considered a screening test and was not recorded, nor was double-contrast barium enema unless in follow-up for an abnormal screening test. Other data abstracted included comorbid conditions, date of most recent physical examination, and documentation of other cancer screening tests (e.g., mammogram, Papanicolaou [Pap] smear, prostate-specific antigen [PSA]), as well as qualitative information about the chart organization (i.e., flow sheet that included CRC screening).

Our sample size calculations required 50 eligible patients from each PO. Some eligibility exclusions could only be determined after chart review (e.g., history of CRC, polyps, inflammatory bowel disease, or serious comorbid conditions). Therefore, to achieve this final sample goal, and to account for eligibility exclusions required after data collection was completed, we set as a goal the abstraction of 60 patient charts from each PO. This was implemented by selecting a random sample of 90 patients from the health plan enrollees for each PO (45 males, 45 females) and preparing this list for the abstractors. The charts of the first 30 patients from each gender list were reviewed if possible, with a reserve of 15 patients of each gender in case charts were missing or unavailable. To be eligible for random selection for the chart review sample, a patient had to be at least 52 years old and had to have been a member of the PO for 2 years or more (determined from health plan database), and alive at final chart review.

The chart review was fielded between November 2002 and June 2003 on site at the PO by the health plan's centralized quality assurance staff registered nurses (RNs) and contractors trained specifically for this study. An in-depth training program was provided for each reviewer including a training manual with background information on CRC (e.g., time for cancer to develop, types of screening tests available), screening recommendations, instructions for reviewing records, frequently encountered clinical scenarios, and instructions on how to enter information on the chart review form. Hands-on training was also provided by the research project staff by doing chart over-reads with immediate feedback in the training sessions and in the field. Over-reads were done for each reviewer until there was a 100% match between reviewer and research staff chart review forms. For most of the POs, a research staff member was available on site to answer questions, address concerns, and perform random checks to ensure reliability.

Data Management

Chart abstraction forms were reviewed by one of the research staff and cleaned before data entry. Charts from all of the primary care providers available for each patient in our sample were reviewed; therefore, some patients had multiple charts (e.g., 3 patients had 3 charts, 105 patients had 2 charts). In the case of multiple charts for a single patient, the chart review forms were reviewed and merged based on systematic rules to create one patient file reflecting a patient history told by all charts. With the exception of race or ethnicity, missing data was not a problem. In the few cases where dates were missing or partially complete, imputations were done. If day of screening was missing, the 15th of the month was used, and if the month of screening was missing, July 1st was used.

Outcome Variables and Analytic Strategy

We hypothesized that POs randomly assigned to receive the intervention would, over the course of 2-years observation, have higher rates of CRC screening among their eligible patients than POs assigned to the control condition. The primary outcome variable used to assess the effectiveness of the randomized intervention was the *rate of CRC screening with any test* (a composite variable that gave credit for FOBT, flexible sigmoidoscopy, or colonoscopy) during the time period of the intervention (from randomization to chart review in both intervention and control conditions). Because having had a prior CRC screening test with either flexible sigmoidoscopy or colonoscopy could have made it unnecessary to perform a CRC screening test during the period of the intervention, we also examined whether patients had ever had a CRC screening test and whether they had a CRC screening test within guidelines (FOBT within the last year, flexible sigmoidoscopy within the last 5 years and/or colonoscopy within the last 10 years). Measures for *ever had* and *had within guidelines* were created for FOBT, flexible sigmoidoscopy, colonoscopy, and for any test. Other variables included patient characteristics (e.g., age, gender, comorbidity, physical examination in past 2 years), and PO characteristics, (e.g., geographic region, PO structure: IPA vs. IMG).

For the chart review data, frequencies, *t*-tests, and chi-square analyses were used for descriptive comparisons of patient and PO characteristics by intervention and control group and by the outcome variables. At the bivariate level, we compared *ever had any test* and *had any test within guidelines* by intervention or control group. Finally, a logistic regression model was fit to predict screening by *any test within guidelines*. All

TABLE 3
Characteristics of the Provider Organizations Enrolled in the Randomized Trial

	Total PO	Intervention	Control
	36	19	17
PO Type			
IMG	12	6	6
IPA	24	13	11
Size			
Small PO (≤ 35 PCPs)	7	4	3
Medium PO (36–99 PCPs)	15	8	7
Large PO (≥ 100 PCPs)	14	7	7
Geographic region of California ^a			
Northern	6	4	2
Central	8	3	5
Southern	22	12	10
No. of PCPs in PO	Mean (range)	Mean (range)	Mean (range)
Small PO	21 (15–29)	23 (17–29)	19 (15–23)
Medium PO	65 (39–99)	70 (39–99)	60 (39–77)
Large PO	220 (106–482)	270 (114–482)	170 (106–290)

^a Of the POs that were not evaluable for study outcomes, 1 control was from Central California, 2 interventions were from Southern California, and 1 intervention was from Northern California.

analyses were performed using SAS software, version 8 (SAS Institute, Cary, NC).

RESULTS

Characteristics of the POs Participating in the Randomized Trial

The organizational features of the POs participating in this trial are presented in Table 3. As described previously,²¹ all of these POs had demonstrated a commitment to the study by allowing us to perform a pre-intervention patient and provider survey. During the course of the trial, three IPAs dissolved (two assigned to intervention and one to control), making them unavailable for further intervention activities or outcome assessment. At the time of final chart review outcome assessment, one of the POs (an IPA assigned to intervention) did not permit a chart review. Thus, our final number of evaluable POs was 32, which provided adequate sample and power to test the effectiveness of the intervention.

Chart review sample derivation and patient characteristics

Chart reviews were conducted at the 32 evaluable POs. Figure 1 provides an overview of the study design and sample derivation. The patient sampling scheme resulted in completed chart reviews for 1997 individuals, with equal numbers from the intervention and control groups (1001 from intervention POs and 996 from control POs). This represented an average of 31 men (range, 23–41) and 32 women (range, 23–42) from

each PO. From this sample, 147 patients were excluded from the analytic sample because of ineligibility for CRC screening that was determined by protocol design (e.g., colorectal cancer, colon polyps, comorbid conditions). A total of 1850 patients comprised the analytic sample. As noted in our procedures, charts were reviewed to examine retrospectively at least 10 years of data if available, to determine whether colonoscopy had been completed in that time period. The median number of years captured in the chart review was 5.75 (intervention 5.3 yrs; control 6.3 yrs).

Demographic and medical characteristics of patients in the chart review analytic sample are shown in Table 4. There were no significant differences in age, gender, or ethnicity between the intervention and control samples; however, the intervention and control samples differed in regional distribution within the state, with southern region POs more likely to be in the control group ($P < 0.01$) (see also Table 3). The intervention sample included significantly more patients from IPAs than IMGs ($P = 0.01$), and patients in the control sample were more likely to have had a complete physical in the last 2 years ($P = 0.01$). Compared with the health plan distribution of age and gender for enrollees 50 years or older, the study sample had more individuals who were 60 years and older and had slightly more women.

CRC Screening Rates by Intervention and Control Condition

Table 5 presents the unadjusted chart review results for CRC screening outcomes. During the time of this randomized trial (2.2 yrs; mean, 0.2 standard deviation [SD], between randomization and chart review) only 26% of eligible average-risk men and women received any CRC screening test, and there was no difference according to intervention or control group. FOBT was the most frequently used screening test (19%), with 7.7% of patients receiving sigmoidoscopy and 5% receiving colonoscopy. Overall, 43% of the sample had received any CRC screening test ever, with the most common test recorded being an FOBT (30%). For within guidelines testing, 29% of the total sample were up-to-date on CRC screening, with the most frequently used test being sigmoidoscopy (15.4%). Colonoscopy was infrequently used in this sample of patients. Comparison of patients from the intervention and control POs showed no significant difference for any test within guidelines (28% vs. 30.6%; $P = 0.22$), although sigmoidoscopy was used significantly more often among patients in the control POs ($P = 0.04$).

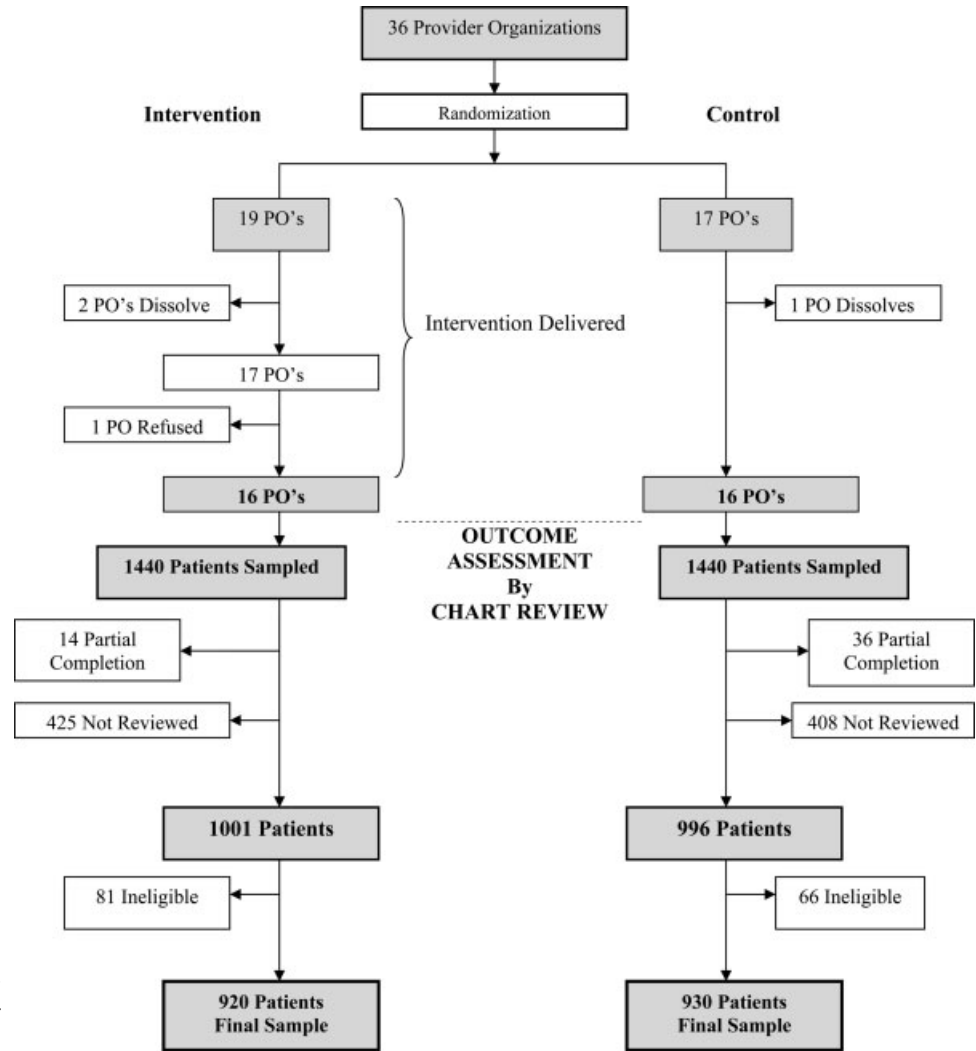


FIGURE 1. Overview of the study design and derivation of patient sample for the chart review outcome assessment.

Relation of CRC Screening to Demographic and Medical Variables

We next examined the relation of CRC screening to key demographic and medical variables for the entire study sample (Table 6). As expected, being age 60 years or older, being enrolled in an IMG, and having a physical examination in the past 2 years were significantly associated with a greater likelihood of ever having been screened for CRC. Logistic regression was performed to examine the role of these variables, along with assignment to intervention or control, in influencing CRC screening with any test within guidelines (Table 7). No significant intervention effect was noted; however, being older and having had a physical examination in the past 2 years significantly increased the odds of having a CRC screening test within guidelines, whereas being a patient in an IPA reduced the odds of having had CRC screening within guidelines by 39% ($P < 0.0001$). The same analysis was performed

taking into account clustering of patients within POs, and there was no significant difference in the model results (data not shown).

Uptake of the Intervention

Although a workshop was conducted at all 19 intervention POs, the level of subsequent intervention uptake varied substantially across the POs. Only 10 (53%) POs completed the recommended in-house baseline chart review to collect CRC screening data before starting intervention activities, with 3 choosing to use administrative claims data for flexible sigmoidoscopy and colonoscopy, which meant that the reason for the tests (screening vs. diagnostic) was unknown. FOBT was not available from claims data for these POs. Only 4 (21%) POs, followed all of the steps suggested in the Facilitator’s Manual to launch the intervention including naming a facilitator, conducting the preintervention chart audit and organizational strat-

TABLE 4
Distribution and Characteristics of Patients Sampled by Total Sample, Intervention, and Control

	Total N = 1850 no. (%)	Intervention n = 920 no. (%)	Control n = 930 no. (%)	P value ^a
Mean age in yrs	60.9	61.0	60.7	0.36
Range	52.9–83.6	53–83.6	52.9–80.2	
52–59	1012 (55)	485 (53)	527 (57)	0.16
60–64	454 (25)	242 (26)	212 (23)	
≥ 65	384 (21)	193 (21)	191 (21)	
Gender				
Male	889 (48)	440 (48)	449 (48)	0.85
Female	961 (52)	480 (52)	481 (52)	
Race or ethnicity ^b				
White	455 (64)	246 (66)	209 (63)	0.10
Black	31 (4)	14 (4)	17 (5)	
Hispanic	113 (16)	65 (17)	48 (14)	
Asian	84 (12)	34 (9)	50 (15)	
Other	25 (4)	15 (4)	10 (3)	
Region of chart abstraction				
Southern	1274 (69)	519 (56)	755 (81)	< 0.01
Central	236 (13)	175 (19)	61 (7)	
Northern	340 (18)	226 (25)	114 (12)	
% in IPA vs. IMG	66.3	69.0	63.5	0.01
% with chronic condition	8.8	10.0	7.5	0.06
% with complete physical	72.8	72.1	73.5	0.47
% with complete physical past 2 yrs	45.9	42.8	48.9	0.01
Time since last physical, mos ^c				
Mean	24.88	26.02	23.78	0.12
Range	0.03–248	16–248	0.03–181	
Other cancer screening				
Women				
% with mammogram ^d	79.5	80.7	78.3	0.36
% with Pap smear ^e	65.0	68.0	62.1	0.06
Men				
% with PSA ^f	83.5	84.3	82.7	0.53

^a P values are based on chi-square comparisons, *t*-tests for means.

^b Missing data on 546 intervention patients and 596 control patients.

^c Missing data on 257 intervention patients and 246 control patients.

^d Missing data on 3 intervention patients and 1 control patient.

^e Missing data on 8 intervention patients and 6 control patients.

^f Missing data on 3 control patients.

egy meeting, the orientation meeting to present the strategies to PO members, and designating a start date for the intervention.

As part of the intervention, we recommended implementation of at least one strategy from each of three domains (Table 2). By the end of the intervention period, only five POs had implemented at least one strategy in each domain (one PO dissolved before the final chart review). Four POs had implemented strategies in two domains, and four had implemented strategies in one domain over the study period. At the close of the study, six POs had not implemented any

strategies (including one PO that dissolved before the chart review). All but 1 PO identified a facilitator at some point during the 2-year intervention period; however, in half of the POs there was turnover in the facilitator position (3 times at 1 PO), which meant that the program had to be reintroduced and activities had to be reinitiated with each new staff person. Seven of the 16 POs had nonphysician facilitators, who were usually nurses or administrative staff involved in quality improvement or assurance activities. The remaining POs had physician facilitators who were either the medical director or another physician responsible for quality improvement activities. The physician facilitators, in general, had the lowest participation rate in intervention activities because of their other competing commitments. In addition, at 5 of the 16 POs the medical directors also changed during the course of the randomized trial, which challenged our ability to maintain ongoing relationships with facilitators and other staff.

DISCUSSION

The need to increase rates of CRC screening among older adults is a recognized cancer control priority. CRC screening lags behind other recommended examinations, and there have been only modest improvements in recent years. The barriers and facilitators to CRC screening are many, including lack of provider knowledge about the efficacy of screening, lack of time to discuss the various tests, lack of capacity to perform screening, and patient reluctance to be screened. Research efforts to increase CRC screening have largely focused on the patient, sometimes on the provider, and rarely on the healthcare system.³⁸ This is one of the few studies to focus on the healthcare delivery system directly. We were especially interested in the potential effectiveness of a QI intervention conducted within the setting of a managed care health plan, whose contracted POs are mandated to coordinate QI activities.

Zapka and colleagues^{38,41} recently described a Framework for Improving the Quality of Cancer Care, and our study fits well within this broader framework. In their commentary,⁴¹ they remind us that provider-patient interactions take place in a multilevel environment in which several factors influence the processes of care, including factors at the level of the practice or provider organization (e.g., leadership, resources, structure, procedures, systems, culture), at the health plan or medical group level (e.g., leadership, resources, culture, risk distribution, policies, covered benefits, contractual relationships, care delivery or management policies, financial features, structure, products), as well as at the community level (e.g.,

TABLE 5
Unadjusted CRC Screening Rates by Intervention or Control Group

	Distribution of patients by total, intervention, and control group			<i>P</i> value ^a
	Total <i>N</i> = 1850 no. (%)	Intervention <i>n</i> = 920 no. (%)	Control <i>n</i> = 930 no. (%)	
During time of intervention ^b				
Any	488 (26.4)	243 (26.4)	245 (26.3)	0.97
Flexible sigmoidoscopy	142 (7.7)	58 (6.3)	84 (9.3)	< 0.03
FOBT	342 (18.5)	172 (18.7)	170 (18.3)	0.81
Colonoscopy	93 (5.0)	50 (5.4)	43 (4.6)	0.42
Ever				
Any	788 (42.6)	389 (42.3)	399 (42.9)	0.79
Flexible sigmoidoscopy	341 (18.4)	144 (15.6)	197 (21.2)	< 0.01
FOBT	548 (29.6)	265 (28.8)	283 (30.4)	0.44
Colonoscopy	155 (8.4)	78 (8.5)	77 (8.3)	0.88
Within guidelines				
Any	543 (29.4)	258 (28)	285 (30.6)	0.22
Flexible sigmoidoscopy	284 (15.4)	125 (13.6)	159 (17.1)	0.04
FOBT	194 (10.5)	96 (10.4)	98 (10.5)	0.94
Colonoscopy	153 (8.3)	78 (8.5)	75 (8.1)	0.75

FOBT: fecal occult blood test.

^a *P*-values are based on chi-square comparisons.

^b Individuals having an endoscopy procedure before this 2-year interval (sigmoidoscopy within 2–5 yrs or colonoscopy within 2–10 yrs) were excluded from the denominator.

public policy or regulations, professional group standards or accreditation, purchaser requirements, market pressures, reimbursements). Many of these factors may have to be aligned to improve on a complex outcome such as CRC screening. A limitation of our intervention was that it primarily focused on only one level—the practice environment. As we described here and elsewhere,²¹ the volatility of the healthcare market in California during the study at the practice level (e.g., frequent changes in PO medical directors, mergers and dissolution of POs) seriously challenged our ability to encourage the adoption and implementation of the intervention we were testing. Furthermore, we believe that without substantial external efforts to require CRC screening (e.g., health plan and community level), it is unlikely that major changes will occur in CRC screening rates in the near future, as these incentives are likely to be necessary, as was the case for Pap smears and mammography.

Although we failed to demonstrate an intervention effect in this study, we learned much about this healthcare setting,^{21,30,31} which will inform future research and practice. For example, despite having health insurance and access to a primary care physician, this sample of patients had low rates of CRC screening in 2000–2003—a time that was marked by intensive public educational campaigns to increase awareness about the importance of CRC screening,⁴²

the approval of reimbursement for CRC screening for Medicare recipients, the promotion of CRC screening by a media celebrity (Katie Couric from the Today Show), and the intention of a major quality assurance organization to include CRC screening as a performance measure.⁴³ Although the mean rates of screening were low for all tests evaluated, there was substantial range among the various POs from a low of 2% to a high of 33% for FOBT within guidelines (1 yr) and for flexible sigmoidoscopy there were ranges from a low of 0% to a high of 46% within guidelines (5 yrs). These disparities in test-specific screening rates were also reflected in the proportion of patients having any CRC test within guidelines, which ranged from a low of 13% to a high of 70%. Clearly, there were some POs that were able to address the need for CRC screening, and anecdotally this seemed to have been associated with having stable organizational leadership, as has been noted in another study.²⁰

Limitations of this study include the fact that the intervention only targeted the organizational structure of the PO, with patients being targeted secondarily as a result. Perhaps direct activation of patients would have enhanced the overall screening rate; however, our telephone interviews with patients before embarking on the intervention documented the importance of provider recommendation.³² Also, the chart review could possibly have underestimated the rates of CRC

TABLE 6
CRC Screening by Selected Medical and Demographic Variables

	Ever had any test			P value ^a	Had any test within guidelines		P value ^a
	Total no.	Yes no. (%)	No no. (%)		Yes no. (%)	No no. (%)	
Total	1850	788 (42.6)	1062 (57.4)		543 (29.4)	1307 (70.6)	
Age group in yrs							
52–59	1012	385 (38.0)	627 (62.0)	0.0001	264 (26.1)	748 (73.9)	0.0006
60–64	454	221 (48.7)	233 (51.3)		163 (35.9)	291 (64.1)	
≥ 65	384	182 (47.4)	202 (52.6)		116 (30.2)	268 (69.8)	
Gender							
Male	889	381 (42.9)	508 (57.1)	0.8261	255 (28.7)	634 (71.3)	0.5443
Female	961	407 (42.4)	554 (57.6)		288 (30)	673 (70)	
Ethnicity ^b							
White	455	228 (50.1)	227 (49.9)	0.3889	162 (35.6)	293 (64.4)	0.5400
Black	31	16 (51.6)	15 (48.4)		12 (38.7)	19 (61.3)	
Hispanic	113	46 (40.7)	67 (59.3)		31 (27.4)	82 (72.6)	
Asian/PI	84	42 (50)	42 (50)		30 (35.7)	54 (64.3)	
Other	25	10 (40)	15 (60)		8 (32)	17 (68)	
Geographic region							
Southern	1274	562 (44.1)	712 (55.9)	0.1201	383 (30.1)	891 (69.9)	0.4876
Central	236	89 (37.7)	147 (62.3)		62 (26.3)	174 (73.7)	
Northern	340	137 (40.3)	203 (59.7)		98 (28.8)	242 (71.2)	
Provider organization							
IPA	1226	439 (35.8)	787 (64.2)	<0.0001	303 (24.7)	923 (75.3)	< 0.0001
IMG	624	349 (55.9)	275 (44.1)		240 (38.5)	384 (61.5)	
Chronic condition							
Yes	162	65 (40.1)	97 (59.9)	0.5055	44 (27.2)	118 (72.8)	0.5215
No	1688	723 (42.8)	965 (57.2)		499 (29.6)	1189 (70.4)	
Physical in past 2 years							
Yes	849	468 (55.1)	381 (44.9)	< 0.0001	349 (41.1)	500 (58.9)	< 0.0001
No	1001	320 (32)	681 (68)		194 (19.4)	807 (80.6)	

^a P values are based on chi-square comparisons.

^b Missing 1142 in total.

^c Missing 446 in Ever Had Any Test Group.

^d Missing 696 in Never Had Any Test Group.

^e Missing 300 in Ever Had Any Test Group.

^f Missing 842 in Never Had Any Test Group.

TABLE 7
Logistic Regression Predicting CRC Screening Using Any Test Within Guidelines for N = 1850^a

Parameter	Estimate	Standard error	P value	Odds ratio (CI)
Intercept	-2.549	0.545	< 0.0001	—
Age	0.025	0.009	0.004	1.03 (1.01–1.04)
Male gender	-0.019	0.106	0.857	0.98 (0.80–1.21)
IPA	-0.499	0.115	< 0.0001	0.61 (0.49–0.76)
Southern region	-0.009	0.143	0.952	0.99 (0.75–1.31)
Central region	0.127	0.205	0.533	1.14 (0.76–1.70)
Comorbid condition	-0.088	0.193	0.649	0.92 (0.63–1.34)
Physical exam in past 2 yrs	0.994	0.109	< 0.0001	2.70 (2.19–3.34)
Intervention group	-0.065	0.110	0.557	0.94 (0.76–1.16)

^a Adjusted for age, gender (male vs. female), type of provider organization (IPA vs. Integrated Medical Group), geographic region (Southern and Central vs. Northern California), presence or absence of comorbid conditions, having a physical examination documented in the chart in the past 2 years, assignment to the study intervention vs. Control condition. Significant findings are noted in bold type.

screening if the patients sampled had obtained care outside of the PO, if our retrieval of charts had not been complete, or if there had been inaccuracies in the chart abstraction procedures; however, all of these factors had equal potential for affecting the intervention and control POs and, thus, should not have biased the results of the randomized trial. Nevertheless, our results are very similar to another report that used claims data to determine rates CRC screening tests in a managed care health plan operating in the southeastern United States during 2000 and 2001.⁴⁴

In retrospect, our efforts to increase CRC screening within the setting of this large network model HMO may have been premature and hampered by an underestimation of the limited QI resources and structures available within the POs. The previously successful efficacy trials had all included staff paid from the research study to implement the office systems and staff interventions. During the dissemination of our intervention program, we became acutely aware of the limited PO resources that were available to implement and sustain the QI activities, which had not been anticipated. Although well intentioned, the medical directors, facilitators, and providers with whom we worked were unable to galvanize their organizations to make the changes necessary to have an impact on CRC screening rates. Providers we talked to were waiting for electronic medical record systems to remind them to screen or more time to be able to discuss these issues with their patients.⁴⁵ One medical director in an IPA decided to organize the gastroenterologists to provide colonoscopy for all patients in an endoscopy center; however, by the time we completed our study this had not been accomplished, and he was no longer the medical director for the organization. It is clear that additional resources will be necessary to facilitate change.

We found higher rates of screening in IMGs and among individuals who had a physical examination within the past 2 years, suggesting that the IMG structure may be more conducive to promotion of CRC screening. Also, patients who have regular physical examinations are more likely to have these services discussed or offered. Whereas the role of the regular physical examination has been questioned,^{46,47} it may provide the only scheduled opportunity for providers to discuss important life style and health protective services with their patients. Interestingly, the predictors of screening from the chart review, with regard to IMG and regular health maintenance examinations, echo the findings from our previously reported provider survey. Future interventions should capitalize on efforts to enhance these opportunities, as well as di-

rectly target providers to ensure they address CRC screening with their patients.

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