

Improving Colorectal Cancer Screening Rates in a Managed Care Health Plan: Recruitment of Provider Organizations for a Randomized Effectiveness Trial¹

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Abstract

Evidence-based guidelines recommend regular colorectal cancer (CRC) screening for adults 50 years and older, yet screening rates remain very low. In this paper we describe the challenges associated with recruitment and retention of provider organizations (POs) for a group randomized, controlled effectiveness trial to increase CRC screening, among patients in a managed care health insurance plan. Using the health plan as the sampling frame, we recruited POs to test a facilitated quality improvement program to increase CRC screening. Defined eligibility and recruitment procedures were used as part of this process. We successfully recruited 36 POs over the course of 9 months; however, there were many challenges associated with the recruitment and retention process, including difficulties in (a) identifying the PO medical director and the individual authorized to agree to study participation, (b) making contact with the medical director, and (c) obtaining the materials necessary to initiate the study. All of these factors delayed the research substantially. Retention activities were also a major challenge in that one-third of the medical directors changed during the course of the intervention. This study benefited from a strong partnership between the health plan and the research group. Although many challenges exist, there are tremendous opportunities that result from the design and conduct of effectiveness research in existing POs. Successful implementation of programs that are feasible and take advantage of existing quality

improvement mechanisms within the PO has potential to improve CRC screening rates and can have a major public health impact.

Introduction

CRC³ is the third leading cause of cancer mortality in men and women (1), accounting for an estimated 57,100 deaths in 2003. Screening rates for CRC are extremely low and have shown limited improvement in the past decade (2). By 1996, there was sufficient evidence for the efficacy of two screening tests for CRC that the United States Preventive Services Task Force recommended CRC screening for all average-risk individuals 50 years and older (3). These recommendations have since been echoed by other health care organizations (4). Our research group has had a long-term scientific interest in increasing adherence to cancer screening (5) and thus seized on the opportunity to initiate research on CRC screening.

We chose the setting of a managed care health plan in California for this study for several reasons. This type of health plan was the fastest growing model in California in the 1990s, providing coverage for most insured Californians, including a sizable proportion of Medicare beneficiaries (6). Although CRC screening was not yet included in the quality of care evaluation program for managed care health plans, *i.e.*, Health Employer Data Information Set (HEDIS) (7), it was being considered for inclusion. Furthermore, in California, the network model of managed care, in which physicians join POs to facilitate contracting with health insurance plans (6, 8–10), was dominant. In this model, the health plan delegates most responsibility for utilization review, coverage decisions, and quality assurance activities to these POs (11), and PO level quality assurance/improvement structures are in place to address adherence to evidence-based guidelines and recommendations, thereby providing a potential mechanism for influencing medical practice. Finally, given the evidence of increased use of other cancer-preventive services in the managed care setting (12–14), we hypothesized that providers in these settings might be more receptive to an intervention to increase CRC screening. In this paper we provide a brief overview of the study design, followed by a detailed description of challenges associated with the recruitment and retention of the POs that were the target of our intervention. We also discuss the opportunities associated with conducting research in collaboration with a major health plan. This study fits within the Framework for Improving the Quality of Cancer Care recently described by Zapka *et al.* (15) in this journal.

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³ The abbreviations used are: CRC, colorectal cancer; PO, provider organization; QI, quality improvement.

Overview of the Research Program. The University of California Los Angeles-Blue Cross Colorectal Cancer Screening Study was designed to evaluate the effectiveness of a facilitated QI program, using the organizational structure of the PO to intervene on the practice environment of POs that contracted with the health plan to provide primary care services. The goal of the intervention was to increase CRC screening rates with either Fecal Occult Blood Test (FOBT) and/or flexible sigmoidoscopy in men and women 50 years and older. The sampling frame consisted of all of the POs that contracted with the health plan, and the unit of randomization was the PO. This provided an efficient strategy for recruitment of a large number of representative POs throughout a large geographic area and had many advantages including direct access to the Pos and complete databases of enrolled patients, as well as the ability of the health plan to do chart review without requiring individual patient consent. Working through the health plan was also an important consideration for future implementation of the intervention because most QI efforts are initially instituted at the health plan level, which is accountable for outcomes and performance measures (rather than the PO).

The study used a health services utilization framework to understand the influence of PO and patient characteristics on adherence to screening. This framework integrates the Adherence Model (5, 16, 17) with Andersen's Behavioral Model of Health Services Use (18–20). The study also includes a comprehensive evaluation of all costs associated with the research and the intervention delivery to analyze the marginal cost-effectiveness of increasing adherence to CRC screening. This research program contrasts with the evaluation of centralized CRC screening efforts used by some managed care health plans (e.g., Aetna US Healthcare) that have mailed FOBT screening materials directly to the patient, rather than working through the PO and the provider as part of the process (21–23).

Phases of the Research. In phase one, we surveyed medical directors of the POs that contracted with the health plan to learn about their organizational structure, implementation of guidelines, quality assurance programs, and beliefs about the efficacy and feasibility of CRC screening (24). Other developmental activities included focus groups (physicians, nurses, office staff, and patients) and development and pilot testing of intervention materials. In phase two, we recruited POs for the randomized trial. Each participating PO was asked to allow us to conduct baseline surveys with a sample of primary care providers from their organization and a sample of the patients who were insured by the health plan and had been a member of the PO for at least 2 years. Both tasks were performed at baseline before initiation of the randomized trial.

In phase three, each participating PO was randomly assigned to either an intervention or a control condition (see Fig. 1). The intervention was delivered over the course of 2 years, after which time (phase four), a medical record review of a random sample of patients from each group is being done (an independent sample from baseline) to assess the rates of CRC screening. Patient interviews are also being completed in parallel to understand the barriers and facilitators of screening. Rates of CRC screening in the intervention versus control POs will be used to evaluate the success of the intervention. A second provider survey (longitudinal panel) is being conducted to assess the intervention program's impact on provider attitudes, beliefs, and behaviors.

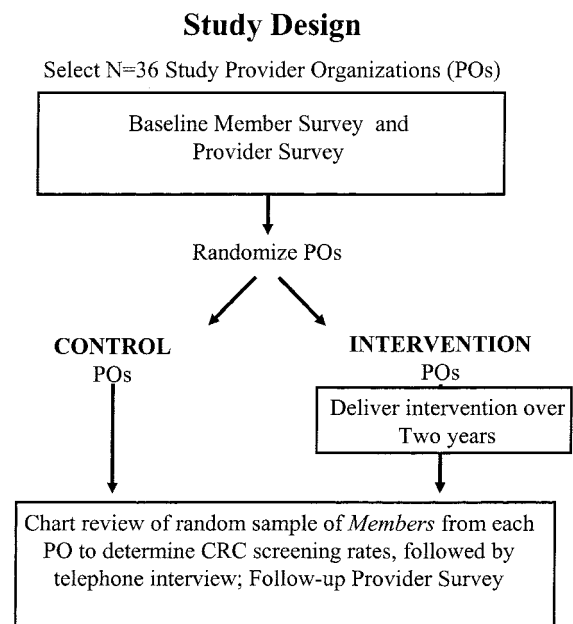


Fig. 1. Study design of the randomized trial.

Materials and Methods

Study Eligibility. Only those POs that participated in the Medical Director Survey were eligible (24). To be eligible for the intervention, the PO had to have a substantial number of patients age 50 years and older to make the intervention a relevant issue to consider for QI. Therefore, POs were eligible for phase two if they either (a) had more than 10,000 members or (b) had between 1,100 and 10,000 members and had a minimum of 500 members age 50 years or older. POs with fewer than 1,100 members were not eligible.

Recruitment. The medical director of each eligible PO was mailed a letter describing the full study and requesting participation in phase two of the study, which included the provider and patient survey. The letter was signed by the health plan medical director of quality management and by the principal investigator of the research study. In follow-up to the letter, each PO medical director was contacted personally by telephone, first by the health plan director of quality management to introduce the study, and then by a senior member of the research team (either an M.D. or Ph.D.) to verbally explain the study and obtain agreement to participate. PO medical directors who agreed to participate were required to supply (a) a listing of all primary care providers, along with their addresses; (b) PO stationery, and (c) the medical director's approval and electronic signature to be used in the recruitment letter to patients invited to participate in the baseline telephone survey. Provision of these materials was used to indicate successful recruitment of the PO for the study. The University of California Los Angeles institutional review board approved all of the research and procedures used in this study.

Results

Recruitment of POs. Between April and December 1999, we recruited a total of 36 POs into the study (see Fig. 2). A total of 124 medical directors had completed the initial survey for a 76% response rate (24); however, 6 medical directors had indicated on the survey that they did not want to participate in

Provider Organization (PO) Recruitment

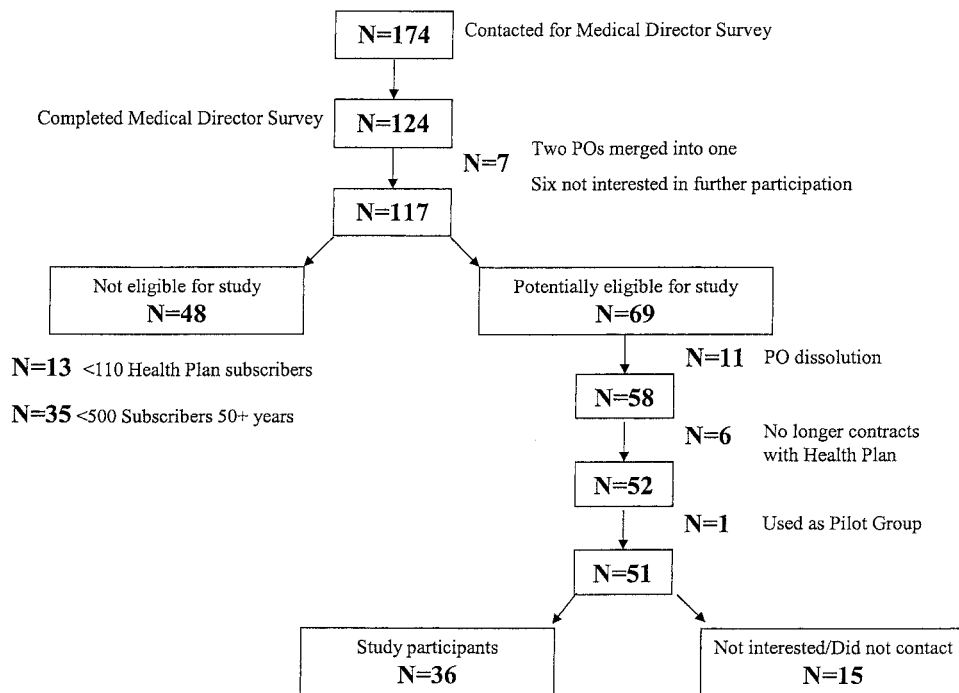


Fig. 2. Recruitment results for the POs.

future studies, and 2 POs had merged in the interval, leaving total of 117 POs to approach. For these 117 POs, the health plan provided contact information for the medical director to update our database, the number of subscribers enrolled, the approximate number of individuals aged 50 years and older, and whether the PO had a Medicare contract. This information was critical to determine PO eligibility. Of the 117 potentially eligible POs, 48 (41%) were ineligible based on an insufficient number of patients age 50 years and older. Of the remaining 69 potentially eligible POs, 11 (16%) were excluded because of organizational failure (dissolution of group, bankruptcy, or lack of current medical director), and 6 (9%) were eliminated because they no longer contracted with the collaborating health plan. Of the remaining 52 POs, we excluded a pilot test organization. We successfully recruited 36 of 51 POs (71%), 4 more than our planned target of 32 POs. We chose to include these additional POs because of our concern for attrition over the course of the study. The 36 participating POs were distributed throughout California, with about two-thirds in southern California, and the remaining third in central and northern California. This reflected the overall distribution of POs from our original survey (24).

Barriers to Recruitment of POs. The principal barrier to recruitment was difficulty in identifying the correct person to approach (*i.e.*, who had the authority to make a commitment to the research) and then in actually making contact with that person to discuss the research study. A series of mailed recruitment materials, phone calls, and faxes were required to finally reach the person in authority to decide whether or not to participate. The number of calls made before obtaining agreement to participate ranged from 1–12 calls, with an average of 5 calls. The length of time between first phone contact with a PO medical director and agreement to participate was even more varied, with an average of 37 days (range, 1–172 days).

Even after the PO medical director agreed to participate, there were further delays related to achieving buy-in from the other organization leaders and obtaining information needed for the research, such as provider listings. Therefore, continued contact with the medical director through phone calls, faxes, e-mail, and regular mail was required to answer questions, provide documentation needed for organizational approval, and simply to serve as a reminder to keep our project on their list of activities. Data systems varied considerably among the POs, requiring flexibility in how and when we received the required data for the surveys. Although our recruitment was very successful, the cost was a delay in the project timeline by 6 months (Fig. 3).

The PO leaders were cautious about adding one more activity to their already hectic schedules (25, 26). Frequent barriers were: the medical director was too busy to discuss the project; concerns about overburdening providers and staff; and lack of financial resources needed to start a new QI initiative. We also had to respond to queries relating to patient privacy and confidentiality, with particular concerns about the new privacy regulations and implementation of the Health Insurance Portability and Accountability Act. Common concerns were the release of any patient information to the research institution, as well as review of medical records by an outside organization without individual patient consent. Other concerns related to the evaluation of PO performance and whether individual PO data would be available as part of the study process or results reporting. Another issue was PO dissatisfaction with the health plan contract negotiations, which were unrelated to the research study but nevertheless led to delay in recruitment (or a break in project activities) until the conflict was resolved. Although most medical directors were enthusiastic about participating in a research project, there were a few who expressed negative feelings about research in general. In one case, recruitment

Timeline

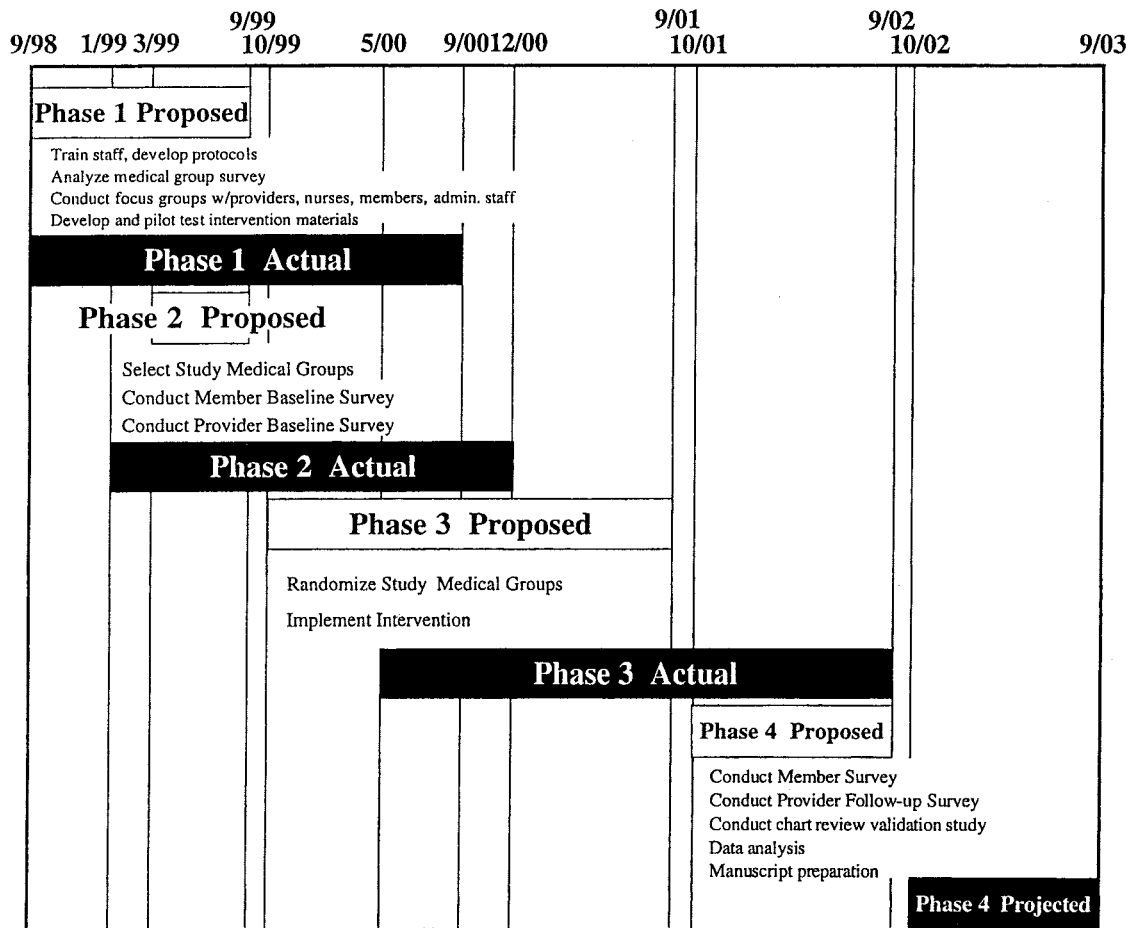


Fig. 3. This timeline describes the four phases of the research and the substantial delays that occurred in initiating the research due to the challenges of working in the real world environment.

efforts had to address specific negative views of the academic research institution. These situations required careful intervention by the principal investigator and the coinvestigator from the health plan to assure the medical director about the intent and purposes of this research program.

Retention Activities Required throughout the Project. Retention of the POs in this study required substantial effort as well. Between phase two (the baseline provider and patient surveys) and phase three (the intervention), each medical director had to be recontacted to ensure willingness to proceed with the randomized trial. Some POs were concerned that the intervention would require extra resources, whereas others worried that their own CRC screening activities might contaminate the research design. Nevertheless, all of the 36 POs involved in phase two agreed to participate in the randomized trial.

After randomization and during the intervention, retention efforts had to be maintained in the intervention group POs, because each change in management of a PO required re-recruitment to ensure that the new management was committed to the project. During this time, many POs experienced changes in leadership and even in their overall structure, including dissolution, changed names, and mergers with other POs. Three

of the 36 POs disbanded during the course of the study. Changes in the medical director were more common than we expected, with about one-third having had a medical director change during the first 3 years of the project. One PO changed medical directors four times between recruitment and the completion of the baseline surveys. By maintaining contact with the PO medical director and/or administrative staff on a regular basis, as well as working closely with the health plan's medical director of quality management, we were able to promptly identify changes in leadership and obtain the contact information for the new director. In only one case did the medical director contact us to inform us of a change in leadership.

Collaboration with the Health Plan. The research partnership with the health insurance plan was critical for the implementation of this research study; in particular, the active involvement of the health plan's medical director for quality management, who was a coinvestigator on the project, was also critical. He facilitated introductions to each PO, made us aware of their idiosyncrasies, helped us reach the hard-to-reach, and provided critical data (listing of insurance plan members with contact information, which was not available at the PO level). Furthermore, with the heightened concerns of privacy and con-

fidentiality raised by Health Insurance Portability and Accountability Act, we would have been unable to conduct this research without the health plan's partnership. Specifically, it is the health plan that has authority for quality assurance activities associated with the care provided to its members. The health plan also has the authority to audit and evaluate medical charts as part of these activities. Because the health plan was our research partner, they could provide us with the information to determine PO eligibility, as well as the names and contact information of the health plan members for our patient survey, making institutional review board approval possible. This was particularly important because of limitations in information technology at the PO level. Most of the POs did not know how many patients were enrolled in their organization or their ages, addresses, or telephone numbers. Our final collection of outcome data for the intervention relies on sampling a group of age and enrollment eligible patients to evaluate CRC screening rates through chart review and telephone interviews. The health plan, funded through the research, is conducting the chart reviews without need for individual patient consent for medical record review.

Discussion

This report describes some of the practical obstacles to conducting effectiveness research in a diverse group of POs in a managed care health plan. This study differs substantially from other effectiveness trials of preventive services (27–29), in that we chose not to work within a specific health care organization but used the health plan as a means of sampling representative POs within California. Our approach provided both challenges and important opportunities and gave us substantial insight into the efforts that are necessary to translate evidence-based guidelines for CRC screening into community practice.

A major challenge for our recruitment and retention efforts was the extremely volatile health care market. Consistent with what we learned in our earlier survey (24), the POs are very diverse in their settings and structures, but they do follow several patterns. Throughout California, the integrated medical groups have more structural and administrative organization, thus making it somewhat easier to recruit and retain them. In southern California, the independent practice associations were much more loosely organized and, as a group, were more difficult to obtain interest and commitment for the research. In contrast, the northern California independent practice associations tended to be more structured and often had more characteristics of an integrated medical group, with more central administrative structures. This organizational heterogeneity represents an important challenge for recruitment and retention.

Another challenge was that the POs felt overburdened financially and organizationally, and their incentive to participate in the research was limited (30). Although financial incentives are often used to promote organizational and provider behavior change, the results of research studies addressing use of incentives for preventive services has been mixed (31–36). Our health plan research collaborators did not believe that this approach would be financially viable in the long run, and thus such incentives were not used as part of the research study. In concert with recent research findings (37), our intervention focused on organizational and structural strategies that could enhance adherence to CRC screening guidelines within the POs. Among the PO medical directors there was awareness that CRC screening was on the test set for new Health Employer Data Information Set (HEDIS) measures, and for some organizations, this was a modest incentive to participate in the

study. The only tangible incentive we could provide to the POs assigned to the control condition was to make our intervention materials available to them at the end of the study.

As noted earlier, our collaboration with the health plan was critical for the implementation and conduct of the research program. However, there were also some limitations in using a health plan as the sampling frame for the study. The participating POs have a very large patient population who are insured by other health plans. At the PO level, the intervention has the potential to impact a larger number of patients than those we can sample from the insurance plan. If the intervention is also affecting patients who have other insurance, we may not capture their improvements in CRC screening rates. Although we would have liked to sample from all age-eligible patients within the PO, independent of health plan insurance status, the burdens associated with consent and confidentiality issues precluded that possibility for this study.

In conclusion, there are tremendous opportunities in conducting effectiveness research in this setting where developing programs that are feasible might improve CRC screening rates and have a major public health impact. Our intervention program, if successful, can be assumed by the health insurance plan as a centralized QI effort. Whereas the model of health care delivery that exists in California (POs assuming the QI responsibilities for their insured population) may be overrepresented on the West Coast, millions of Medicare and non-Medicare patients now receive care under this system. Facilitated QI initiatives may make it easier for POs to attack important health care issues by having an outside organization develop the resources and tools for them to adapt to their organization.

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