ORIGINAL RESEARCH

Recruitment of Private Practices for Primary Care Research: Experience in a Preventive Services Clinical Trial

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BACKGROUND. Recruitment of community primary care practices for studies to improve health service delivery is important to many health care organizations. Prior studies have focused on individual physician recruitment or academic settings.

METHODS. This descriptive study evaluated the efficiency and utility of three different recruitment methods to encourage community practice participation in a preventive services research trial. Primary care practices in four midwestern states were recruited using different sources for initial mailings (physician lists, practice lists, and a managed care organization's primary care network) and different recruiting methods. Outcome measures included response rates, participation rates, and comparative costs of each method.

RESULTS. Of the 86 eligible practices contacted, 52 (60%) consented to participate. Mailing to individual physicians was the most cumbersome and expensive method and had the lowest response rate. Initial contacts with practice medical directors increased the participation rate substantially, and practice recruitment meetings improved both study participation and practice–project communication.

CONCLUSIONS. Experience with these three methods suggests that the most efficient way to recruit practices for participation in a preventive services research trial involves targeted mailings and phone calls to medical directors, followed by on-site practice meetings.

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Recruitment of participants is a critical element in any type of human research. Recruitment of patients and physicians for primary care research has been described,[1-3] but these reports do not address the recruitment of practices for research studies. Practice research networks have been used to recruit physicians and practices for research,[4-6] but these physicians and practices may not be representative of the general population of community practices or practitioners because of their academic affiliations or special research interests.[4]

Health care organizations and researchers are increasingly interested in research to evaluate and improve the quality of clinical service delivery in primary care. This type of research usually requires recruitment of the majority or all members of a practice, rather than individual physicians, as the consensus of the physicians and office staff is essential to facilitate system change.[7,8] The generalizability of health services research may be enhanced by recruitment of community practices, and successful methods to encourage practice participation are important for obtaining a representative sample of practices. As few clinical trials of health services have been conducted with community practices, efficient methods to recruit practices need further description.

This paper describes the methods used to recruit practices for the Health Education and Research Trial (HEART), a randomized, controlled trial encouraging development of office prevention systems to improve the screening, managing, and moni-

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toring of heart disease risk factors. The yearlong interventions that practices were randomized to, using a 2 × 2 factorial design, included (1) a series of practice consultations to promote practice policies and procedures for improving preventive services, and/or (2) provision of monetary support and training for a practice prevention coordinator to assist in organizing and providing heart disease prevention services.

Since this trial used the practice as the unit of randomization and intervention, we evaluated practice recruitment strategies and present here the design, response, and utility of the three methods used to recruit practices for HEART. These methods included (1) recruiting through direct mailings to individual physicians; (2) recruiting practices affiliated with a large managed care organization through mailings and phone calls to medical directors of those practices; and (3) recruiting directly through mailings and phone calls to practice medical directors. While not a randomized trial of recruiting methods, the description of the methods developed to encourage practice participation could be useful for future primary care field research.

METHODS

Target Population. Practices in this multicenter trial were sequentially recruited from four geographical regions of the Midwest. Included were primary care practices within a 100-mile radius around Madison, Wisconsin (Region 1); Minneapolis, Minnesota (Region 2); Iowa City, Iowa (Region 3); and Eau Claire, Wisconsin (Region 4). The goal was to recruit 11 practices in each region, with two additional practices in Region 1 in case of dropouts.

Practice Commitment. In addition to intervention randomization, practices recruited for HEART agreed to pre- and postintervention medical record reviews; patient, staff, and physician surveys; periodic staff interviews by phone; and attendance at a 1-day conference for physicians and staff. The outcome measures (not part of this report) included changes in preventive services delivery, practice organization, and patient outcomes, data that will be available in 1997. Several aspects of the design were developed to encourage practice participation, including intervention pretesting, a primary care advisory board, state-of-the-art conferences and educational materials, and reimbursement for study work by practice staff. A more complete trial description is available elsewhere.[7,8]

Eligibility Criteria. For the purposes of the trial, a practice was defined as a group in which a majority of the established, adult primary care physicians had practiced 50% for a year or more at that location and planned to stay there for at least 1 more year. The specific eligibility criteria for practice participation were: (1) not a residency or university practice; (2) no prior participation in prevention studies; (3) a discrete unit consisting of two to eight primary care physicians (family physicians, internists, or general practitioners) who serve mainly adult patients; (4) ablility to make changes regarding their practice preventive services, staffing, and medical records; (5) if a multispecialty group, the majority are primary care physicians; and (6) willingness on the part of a majority of the eligible primary care physicians to sign a participation agreement. Practices could be affiliated with larger health care organizations such as hospitals and health management organizations (HMOs).

Practice List Development. Identification of potential practices was a three-step process. First, practice and/or physician names and addresses within each geographic target area were obtained using databases from the American Medical Association, state licensing boards, HMOs, telephone directories, physician and clinic directories, and regional primary care research networks. Second, regional databases were prescreened where possible for practice size, location, and specialty. Third, a mailing list was developed for the physicians or practices that passed the prescreening.

Recruitment Strategies. The actual recruitment methods used in each region are summarized in terms of both their common and different components in Table 1. Each method included list prescreening, an initial mailing, follow-up phone contacts, detailed eligibility screening, and a recruitment meeting about the study. All methods initiated contact by mailing a cover letter, brochure, and fact sheet describing the project. The letterhead of the sponsoring organization for that region (the HMO or a university) was used, and the letter was signed by a study physician at the HMO or at the university in

TABLE 1

Components of Recruitment Methods

	Method I Direct to Primary Care Physicians	Method II Through HMO to Practice Leaders	Method III Direct to Practice Leaders
Prescreen source lists	■	■	■
Mailings			
To all physicians (with reply card)	■		
To practice leaders		■	■
Follow-up calls			
Physician-to-physician	■	■	■
Detailed eligibility screening	■	■	■
Presentations and closure			
Recruitment meeting (pre-consent)	■		■
Consent/closure post-meeting	■		■
Consent/closure over telephone		■	
Orientation meeting (post-consent)		■	

that region. This mailing provided an introduction to physician-to-physician follow-up calls approximately 2 weeks after the mailing.

All methods employed follow-up calls to the medical directors by the study physicians to personalize the recruitment effort, reinforce the content of the mailing, answer questions, and assess initial practice interest. Next, interested practices were screened in detail for eligibility criteria by the HEART practice coordinator who gathered data from the clinic contact, usually a practice manager. Final eligibility review and approval was completed by a HEART committee. The practice coordinator facilitated, scheduled, monitored, and documented the entire recruitment process for each practice in all regions to provide consistency in data collection and communication.

Each of the three recruitment methods included an informational meeting with the practice. The meetings were held at the practice site to maximize staff participation and reflect the project's premise that this study was a collaborative effort with the practices. All staff and physicians were asked to attend. Meetings were scheduled at the practices' convenience, with HEART providing food to encourage attendance. The purposes of the meetings were to introduce study details and encourage participation (Methods I and II); introduce the practice to the project personnel; model and encourage physician and staff collaboration; and assess the practice environment.

THE THREE RECRUITMENT METHODS

Method I. Direct to Physicians (Region 1). Mailings (with return postcards) from a study physician at a regional academic institution to all primary care specialists in the target area, and medical journal advertisements were used to identify physician contacts in potential practices. Follow-up and screening phone calls were made to responders only. Pre-consent recruitment meetings were offered to eligible practices.

Method II. Through HMO to Affiliated Practice Leaders (Region 2). An HMO practice roster, excluding practices in another preventive services trial, was used for the recruitment. It was supplemented with a few practices randomly selected from the database of the American Medical Association when it appeared that the recruitment goal might not be met with the roster alone. The mailing contents were the same, but they were sent from a study physician at the HMO using the HMO letterhead. Recruitment meetings were omitted in an effort to reduce the time and costs. This meant that recruitment of a practice was dependent on each practice leader's understanding and explanation of the study to the other practice physicians and staff rather than on a HEART faculty presentation. After consultation with practice colleagues, this leader notified the study personnel of a willingness to participate, and confirmed this with written consents from each participating physician. An informational meeting was scheduled after consents were received to orient staff at each site to the study details.

TABLE 2

Recruitment Results by Method

	Method I Direct to Primary Care Physicians	Method II Through HMO to Practice Leaders	Method III Direct to Practice Leaders
Initial mailings, no.	2485	46	112
Practices contacted, no.	84	43	104
Known eligibles, no. (%)	26 (31)	16 (37)	44 (42)
Meetings, no. (%)	17 (65)	11 (69)	31 (70)
Signed,* no.(%)	14 (54)	11 (69)	27 (61)

*These differences are not statistically significant

Method III. Direct to Practice Leaders (Regions 3 and 4). This approach used a wider variety of lists to prescreen practices to ensure that those on the mailing list met the two criteria of size and specialty. These lists were then randomly ordered for staggered mailings from study physicians at an academic institution to 10 different practices every 2 weeks. The staggered approach allowed for more timely follow-up calls to medical directors, while giving all practices an equal opportunity to be among the early contacts. Eligible practices were offered pre-consent recruitment meetings.

Evaluation of Methods

With variation in regions, rural/urban character, health care organization structures, and mailing databases, the evaluation of these methods must, for the most part, be descriptive and qualitative in nature. A strict statistical comparison of approaches is not the intent of this report. Any of these approaches could be the preferred strategy for another study, depending on the purpose and unit of analysis.

RESULTS

Overall, 86 practices were eligible, and 52 (60%) consented to participate. Only 45 (52%) were accepted and entered into the trial, as this was the required number of practices called for in the study design. Practices were accepted in the order in which they signed up. The accepted practices included 13 urban/suburban and 32 rural locations. Of the accepted practices, 87% were made up totally or mainly of family physicians, 11% of the practices were mainly internists, and 2% an equal mix of the two. In 44% of practices all physicians participated, while 38% had at least one ineligible physician, and 24% had eligible physicians who declined to participate (note some overlap here). The specific results of each recruitment method are described in Table 2 and detailed below.

Method I. Direct to Physicians

The response to the 2485 letters and the advertisements included 84 returned postcards and 6 phone calls (total response rate, 3.6%). A large, detailed advertisement in a state medical society journal generated only one response. The 90 responding physicians represented 84 practices, of which 26 (31%) were found to be eligible. Most of the ineligible were solo practices.

Of the 26 eligible practices, 14 wanted to participate in the trial, 7 declined, and 5 practices on the outer perimeter were held in reserve. Of the 14 signing practices, 12 had a pre-consent recruitment meeting. The last two vied for the one remaining slot and signed up without a meeting. The accepted practice was given a post-consent meeting. It took 8 months (November through June) to complete recruitment from mailing to closure, including 4 months for scheduling and completing meetings. This was also the development phase for many of the forms, protocols, and databases used in subsequent recruitment efforts, so more time was spent on recruitment in this region.

Method II. Through HMO to Affiliated Practice Leaders

Of the 43 practices contacted, 19 declined without being screened. The remaining 24 clinics were screened, and 16 were determined to be eligible.

Five practices later declined, leaving 11 that agreed to participate. Recruitment in this region took 8 months (May through December). Despite fewer practices and their closer proximity in this urban setting, coordinating recruitment in a different region took longer than anticipated, partly because of summer vacations and the long-distance coordination involved.

Method III. Direct to Practice Leaders

Mailings were targeted to 59 practice leaders in Iowa (Region 3) and 53 in northern Wisconsin (Region 4). Follow-up phone calls to 104 medical directors yielded 44 eligible practices, 31 ineligible practices, and 29 (28%) who declined without being screened for eligibility. Of the 44 eligible practices, 12 declined, 31 had recruitment meetings, and 27 signed participation agreements; the first 21 eligible consenting practices were accepted. Region 3 benefited from team experience in the first two regions, and recruitment took just over 5 months despite the winter weather (October to March). While Region 4 also had the benefit of team experience, vacation schedules again proved a bigger barrier to scheduling recruitment meetings than the winter weather, and recruitment took 7 months (April to November).

Other Findings

Meetings. The pre-consent recruitment meetings fulfilled their purpose; over 90% of these meetings included practice staff in addition to physicians and administrators. Most practices that had a pre-consent meeting took a few days to a few weeks to consider and discuss the study before making their participation decision.

Ineligible Practices. Of the 97 practices known to be ineligible, practice size was the leading reason for 66% of them, meaning that a practice had fewer than 1.5 full-time-equivalent physicians (48%), or exceeded the limit of more than eight adult primary care physicians (18%). The direct mailing to physicians (Method I) used a database that did not identify the practice size, and consequently 28 solo physicians responded. Other common reasons for practice ineligibility were having been an active participant in a recent prevention study (9%), not practicing adult primary care (6%), and not having a majority of primary care providers (6%). The eligibility status of those who promply declined to take part was not determined.

Declining Practices. Of the 72 practices that declined to participate, the most common reasons given were: "we are too busy" (24%), "not enough doctors interested" (24%), "we are interested, but bad time for us" (8%), "understaffed" (4%), "doing prevention well enough already" (4%), and "participation in another study" (4%). There were 18 practices (25%) where no reason for declining was given.

Costs. Personnel costs were the largest cost factor in recruitment (Table 3). As salaries varied between organizations, we defined personnel costs in terms of the time commitment of the project's personnel. Direct costs to recruit these practices included mailing costs, study personnel time, food, mileage, and phone calls. Because recruitment Method II was conducted in a large metropolitan area, direct costs were different owing to much lower mileage and travel time. A modest practice reimbursement ($250 per physician team) to help cover practice time given over to medical record filing, surveys, and phone interviews was an additional cost built into this study.

DISCUSSION

This study demonstrates that nonacademic community practices can be successfully recruited for a preventive services trial. We found that 60% of eligible practices consented to participate in this trial, which is similar to prior trials that recruited only individual physicians.[13] The trial interventions have been completed with no practice dropouts. Practices were cooperative with all phases of data collection, including the medical record reviews, physician, staff, and patient surveys, and selected phone interviews.

The three methods used to recruit practices were different as a result of regional characteristics and lessons learned during recruiting, but they demonstrated that the most successful strategies to obtain well-informed consent included careful prescreening of practice databases, recruitment letters and follow-up phone calls from study physicians to practice medical directors, and practice-site recruitment visits. The use of a practice coordinator to direct prac-

TABLE 3

Cost Summary for Recruitment Methods

	Method I Direct to Primary Care Physicians	Method II Through HMO to Practice Leaders (in urban area)	Method III Direct to Practice Leaders (2 region average)
Physician recruiter phone hours (total)	7.5	5.75	7
Average minutes/clinic contacted	9	8	8
Grant staff hours for meetings (physician/staff)	66/80	3.5/25	60/78
Practice coordinators hours	201	198	194
Average minutes/clinic contacted	8.7	16.5	10.2
Clerical hours	52*	39	57
Total mailings during recruitment	2815	233	312
Number of meetings	17	11	16
Miles traveled	2268	374	2121
Direct costs,† $	3834	1424	2068

*Initial mailing was contracted out, so this time is not included in the table.
†Printing, mileage, food, mailing, database, and equipment costs (not personnel or overhead).

tice recruitment, communication, and data collection was also very helpful. The coordinator performed the essential tasks of (1) developing mailing and recruitment databases; (2) building and maintaining rapport as a supportive liaison between the research team and the clinic through all study phases; and (3) consistently and reliably documenting all practice communications.

A direct mailing to all or selected physicians in a target region (Method I) is a traditional recruitment method, but proved the least appropriate for this type of trial. It was inefficient in time and money spent on follow-up calls and mailings to so many ineligible practices and physicians who were not opinion leaders within the practice. While the overall response was low (3.6%), the pool of eligible practices (n=26) identified was similar to the other regions, and responding eligible practices were likely to participate.

The direct mailing to practice medical directors, followed by study-initiated phone calls (Methods II and III), was more successful in targeting practices' organizational leadership. The phone calls provided the opportunity to market the study and clarify details that could not be covered in a letter. This experience is consistent with a similar study that recruited physicians.[3]

The organizational approach used in Method II had the advantage of shortening the time needed to build or locate a database of practices, which reduced the physician recruiter's calls and meeting time. At the time of recruitment for this study, the Minneapolis metropolitan area, with its strong HMO environment, was the only region where this organizational approach could be utilized. With increases in managed health care practice networks, this method of recruiting may soon be feasible in nonurban areas as well.

With Method II, the practice medical directors, rather than the project recruiters, were put into the role of interpreting and selling the study to the rest of the practice. Without a pre-consent meeting, there was little or no assurance that the practice was getting an accurate view of involvement in the study. Few practices in this region included their staff in the participation decision, which created minor dissonance in some practices. Nevertheless, staff participation in the study was similar to the other three regions. It is also possible that if Method II had included pre-consent recruitment meetings, more practices might have been interested in participating.

The use of prescreened practice lists, random ordering, targeting leaders, and pre-consent recruitment meetings in Method III ensured (1) a target population with a higher likelihood of meeting study criteria; (2) an equal opportunity for each practice to be among the early contacts; (3) direct access to influential practice leaders; and (4) an opportunity for staff involvement in the decision-making. This

method generated, for a reasonable cost, a more than adequate pool of eligible, interested, and diverse practices whose members were well informed about the study.

Recruitment of representative primary care practices for research purposes is important to the potential generalizability of these results. Practices that allow research teams to review medical records, survey patients and staff, introduce new patient care or organizational methods, and intrude in other ways into practice routine, may be different from practices that have declined to participate. The high percentage of eligible practices recruited, however, improves the likelihood that participating practices are representative of other practices in those regions. With final data collection still underway, it is too soon to determine whether regional or practice differences may affect study outcomes.

The reasons practices declined or were ineligible to participate are also important to the potential generalizability of these findings. Nearly 100 interested practices were ineligible on the basis of study criteria and might have participated if eligible. Many of the interested but ineligible practices were solo practices and could be recruited for other studies. Dietrich et al[1] found that physicians who declined participation in a preventive services trial stated that they were too busy, uninterested, or anticipating a major practice transition. This is consistent with the reasons noted by the declining practices in this trial. Since many of the participating practices could also be characterized this way, we suspect that these may not be differentiating characteristics. In retrospect, a follow-up interview of those practices that declined to take part, so that eligibility, general practice characteristics, and reasons for declining could be documented, would have been useful for comparison with participating practices.

The description of our recruitment experience could help future trials save time and resources while optimizing practice participation rates. The methods used encouraged participation by a variety of practices that included rural and urban locations, differing organizational structures, and a balanced distribution of primary care specialties. We recommend that future trials include the following elements: a project practice coordinator; prescreening practice databases for readily identifiable eligibility criteria; phone calls from study physicians to the practice medical directors; and pre-consent recruitment meetings at the practice site that include all patient care staff.

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