Enrolling Community Physicians and Their Patients in a Study of Prevention in the Elderly

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Synopsis

Enrollment of senior citizens in a community Medicare demonstration project to explore the efficacy of preventive health screening and health education was accomplished by using a two-stage process. This process consisted of initial communication with community physicians through the University of California at Los Angeles Clinical Faculty Association to establish credibility for the program. Physicians who agreed to participate then selected potential participants to receive, by mail, a description of the study and an introductory letter from their own physician. Followup and actual enrollment of participants was then handled by the study team. A total of 57.6 percent of the elderly people approached agreed to participate in the study.

MEMBERS OF THE CLINICAL faculty at the University of California at Los Angeles (UCLA) School of Medicine are community-based physicians in private practice. They generally have few opportunities to be involved in research projects since their usual faculty role is to teach, a role with which they often express low satisfaction (*1–3*).

There are many obstacles to doing research in a private medical practice setting, however. Often it is simply too time consuming, especially since many physicians do not have suitable resources, the necessary facilities, or the personnel to conduct research projects. Even if they do have ample personnel, their staff members may be unfamiliar with research needs, procedures, and methodology. Further, a single practice may not have a sufficient number of patients that meet study criteria. Coordinating multiple practices for research purposes can be very difficult, especially for a practicing physician trying to fulfill the demands of a full-time office practice (*4–7*).

These considerations guided the overall development of the UCLA Medicare Screening and Health Promotion Trial (MSHPT), one of five demonstration projects mandated by Congress under the 1985 Consolidated Omnibus Budget Reconciliation Act. The trial offered clinical faculty members and their patients the opportunity to be involved in a community-based research project without requiring the expenditure of resources on the part of the physicians.

Enrolling senior participants from the community in prevention trials, however, is challenging at best and can be impossible at worst. According to a personal communication in 1990 from Ann Jackman of the University of North Carolina, physicians overestimated the number of Medicare patients that they cared for by 50 percent in one Medicare funded project. Instead of soliciting participants from 4 practices in 6 months as planned, 10 practices in 13 locations over 21 months were needed to reach the modified enrollment goal in the North Carolina project. In another Medicare demonstration project, at Brown University, sufficient numbers of elderly Medicare recipients to proceed with the study were never enlisted. Project managers were able to enroll less than 10 percent of eligible Medicare beneficiaries in their geographic

area. Investigators felt that potential participants who were contacted did not see the usefulness of the program or those offering it (personal communication from Linda La Liberty of Brown, 1990). The Rutgers Medical School Project had a similar experience when researchers wrote to more than 5,000 older Blue Cross subscribers. Only 7 percent agreed to participate, although there was no charge for the services that were not usually covered by third party benefits, including Medicare (*8*).

Previous experience has demonstrated that older people are especially likely to follow the advice of their fee-for-service private practitioner (*9–12*). In the 1981-85 UCLA Functional Assessment Study, community-based physicians encouraged their patients to participate in the study that provided the physicians with information about their patients' ability to perform everyday tasks. More than 80 percent of the 619 patients who agreed to participate completed the program, indicating a high degree of compliance with the recommendation of their physicians (*1*).

The objective of this paper is to discuss the successful enrollment of community based physicians and their Medicare patients in this prevention trial. A report on the overall project, which tests the utility of the MSHPT for providing preventive screening and health education to community dwelling seniors, is published elsewhere (*13*).

Methods

The UCLA Medicare demonstration project is a 4-year study that began in June 1988. Under the leadership of the UCLA School of Public Health, the School of Dentistry, the School of Medicine, and the School of Social Welfare worked together to create a multidisciplinary preventive screening and health education program for ambulatory, community-dwelling seniors under the care of primary care physicians in private practice. The objective of this health promotion program is to determine whether the functional status and psychosocial, medical, and dental health of patients can be improved by a community-based intervention conducted by geriatric nurse practitioners and other allied health professionals. The intervention was administered three times in the form of an annual Screening and Health Promotion Clinic (SHPC) with personalized screening and interventions for the risk factors listed in the accompanying box.

Risk factors were targeted for their prevalence and seriousness among seniors, especially in terms of their impact on everyday functioning. It was also imperative that the risk factors could be detected by inexpensive and noninvasive screening administered by questionnaire or by allied health professionals. Furthermore, these risks had to be amenable to change through a medical intervention or a lifestyle change (*14*).

Factors and Interventions in the UCLA Medicare Screening and Health Promotion Trial, 1988

Overweight, underweight—Exercise workshop, diet and nutrition workshop
Alcoholism—Social work assessment, physician or community resource referral or both
Polypharmacy, adverse drug reactions—Physician referral
Social isolation—Social work assessment, physician or community resource referral, or both
Depression, anxiety—Social work assessment, physician or community resource referral, or both
Functional impairment, rehabilitation needs—Physical or occupational therapy assessment, exercise workshop, physician referral
Smoking—Smoking cessation workshop, home safety workshop
Insomnia—Physician referral
Injury, accidents—Home safety workshop
Urinary incontinence—Health education materials, physician referral
Falling—Physical or occupational therapy assessment, exercise workshop, home safety workshop, physician referral
Hypertension—Hypertension workshop, exercise workshop, diet nutrition workshop, physician referral
Oral health—Oral health assessment, oral and dental disease workshop, dental referral, unacceptable dental prostheses
Hearing impairment—Hearing assessment, physician referral
Visual impairment—Vision assessment, physician referral
Immunization status—Physician referral
Mammogram status—Physician referral
Papanicolaou smear status—Physician referral
Prostate, rectal examination status—Physician referral

Enrollment process. Enrollment proceeded in two stages. First, community-based physicians were recruited through the UCLA Clinical Faculty Association (CFA), whose membership consists of medical faculty members in private practice who volunteer their time in a teaching capacity at UCLA or an affiliated hospital. During the second stage, patients who were selected by participating physicians as potential participants for the MSHPT

Program were contacted. Although this approach made enrollment longer and more complex than going directly to the patients, we hoped to avoid some of the enrollment problems experienced by earlier Medicare demonstration projects. It also gave us the opportunity to enlist the support of the physicians in encouraging their patients to participate in the program and to stimulate the physicians to follow through with the recommendations resulting from the preventive screening.

Physician enrollment. Each week the names of approximately 30 physicians were selected from the CFA roster, a document that listed physicians by age and sub-specialty as well as how to get in touch with them. Because our Medicare project was to target patients of community-based physicians in private practice, health maintenance organization physicians were ineligible. Physicians who listed specialties or sub-specialties that were unlikely to provide ongoing or primary care, such as dermatology, emergency medicine, and infectious disease, were excluded, as were physicians age 65 or older. It was felt that older physicians would not be as likely as younger physicians to remain in practice for another 3 years. Physicians were also excluded if they listed a nonbusiness address or the address of a location further than a 45-minute drive from UCLA. The consensus of the investigators was that most patients of primary care physicians live in the area where that physician practices, and the patients, who would be our participants, would not want to travel long distances to attend the annual SHPC at UCLA. Ultimately, all eligible CFA physicians on the roster were contacted.

Initially, physicians received a letter endorsing our study from the president of the CFA and the MSHPT physician investigator. In addition, the letter introduced our project physician who would be telephoning to discuss the study. The letter was accompanied by an outline that described the benefits and obligations of participation in the program for both physicians and patients. Within a week of the mailing, a staff member contacted the physician's office to target a time for calls and eliminate ineligible physicians whenever possible. Eligible physicians were then called by our project physician.

Our previous experience indicated that physicians are generally more likely to take or return a call to another physician than to a research assistant, and undoubtedly our physician could answer questions about our project with more technical expertise and authority than other project members. We decided, therefore, to use the project physician's limited time and special qualifications for soliciting the cooperation of community physicians. Her calls were made within a week of the mailing while it was still fresh in a recipient's mind. The calls took more time than originally scheduled, however, so a second physician was hired to assist with the telephoning.

Each participating physician was asked for a list of at least 50 potential subjects who met our criteria. The physician was informed that participants would be randomly assigned to intervention and control groups, and the intervention group would receive screening and health education, not typically reimbursed under Medicare, as well as recommendations for followup when appropriate. It was stressed that each physician would receive feedback on his or her intervention patients shortly after each SHPC. Physicians were assured that their patients would be referred back to them for all medical followup. We also promised to provide immediate feedback regarding any urgent dental, medical, or psychosocial problems detected.

Continuous physician and patient enrollment allowed us to monitor the number of physicians needed to attain our patient enrollment goal. Eligible physicians were contacted on a weekly basis until approximately 2,500 eligible patient participants agreed to participate. Enrollment of physicians and patients was completed during a 5-month period.

Patient enrollment. Once a physician agreed to participate, one of our research assistants scheduled an appointment with the physician and the office manager. Office managers are usually responsible for assembling or facilitating access to the information that we needed and would therefore be invaluable in enabling us to attain our patient enrollment objectives.

The primary objective of the research assistant's office visit was to have the physician select a minimum of 50 patients meeting our criteria. Potential participants had to be age 65 or older, be ongoing patients who had been seen in the last 6 months and would be seen in the coming year, not have a dementing disease or terminal illness, speak English, and have a telephone. In addition, the physicians provided us with signed cover letters, preferably on their letterhead, to their patients encouraging them to participate in our study. We provided a sample text that the physicians could edit.

Although our research assistants were directed to

work as unobtrusively as possible, and project procedures were adapted to the needs and resources available at each site, the perceived inconvenience varied tremendously and was often more dependent on the attitude of the office manager than the physician. In some practices, it was very difficult to get a minimum of 50 patients identified, while in other practices information was easily obtained for several hundred. Even in computerized practices, the birth date might not be on the data base with the address and Social Security number. Perceived inconvenience and data availability, comprehensiveness, and accuracy were unpredictable and unrelated to the degree of automation, the size of the practice, or the number of physicians in the practice.

Once the identification information had been gathered, our project staff completed the mailing to the patients. Previous experience indicated that asking the physician's office staff to do so would be perceived as a burden and would prolong the enrollment process.

The mailing to each potential participant contained the cover letter from the physician, an outline of the MSHPT project and a postage-paid response card. Followup calls were made to potential participants who did not respond. Up to six calls were made to each nonresponder, and at least 50 percent of those calls were made during evening and weekend hours. Calls were usually spread over several weeks, both by design and by the sheer volume of followup calls being made by the staff. A call could result in no contact, a message being left on a machine or with a household member, a contact with the potential participant unwilling or unable to make a decision about participation, or a contact with a decision about participation as the outcome.

During calls to the potential participants, staff members described the intervention in detail and answered questions. The description of the SHPC emphasized that there would be no disrobing, X-rays, invasive procedures, or fees. Potential participants were also told that there would be a small annual honorarium for participation.

Some potential enrollees responded favorably to the suggestion that their participation might eventually influence Medicare to extend coverage to include health promotion activities for seniors like themselves. Many questions were asked concerning the effect of MSHPT participation on the health insurance or Medicare coverage of the individual. As has been found elsewhere, the most important aspect of the calls may not have been the content but the enthusiasm and commitment that the staff members were able to communicate to the potential participants (*15*).

If subjects asked, they were told that there would be free parking at the SHPC and assistance with transportation arrangements, if possible. We knew our participants would be very geographically diverse, but we didn't know how many participants really needed transportation (ultimately about 15 percent did), nor did we have extensive resources for that purpose. Our staff members told potential participants that we planned some assistance but could not promise what it would be.

Participants agreed to be randomly assigned to one of two groups, with one undergoing the intervention annually for three years and the other group once at a later date. All participants were randomly assigned to the intervention or control group with the exception of spouses and roommates who were randomized as pairs.

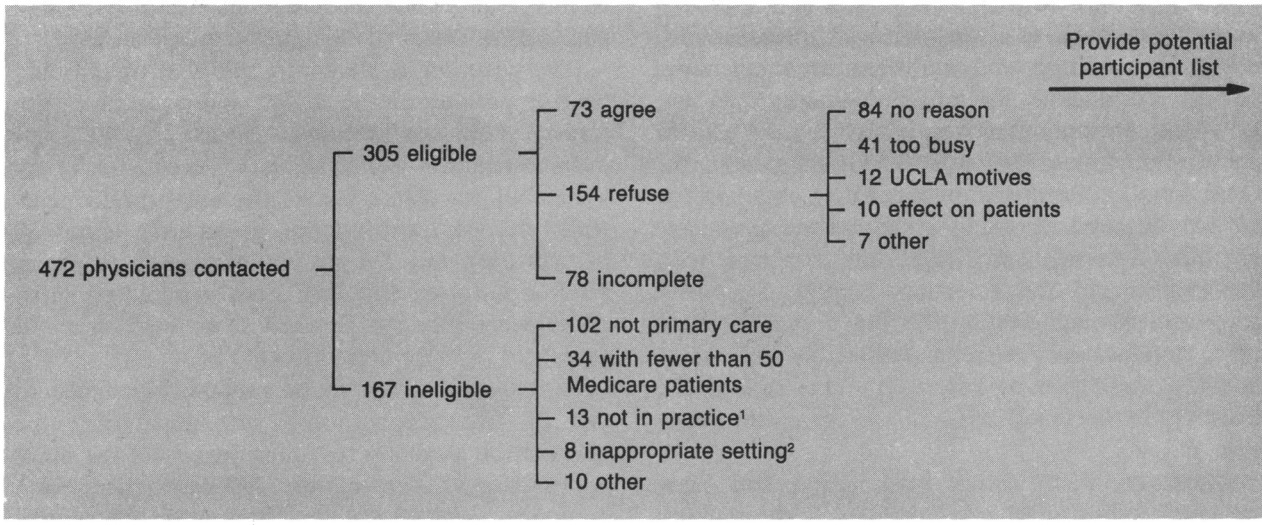
Results

Figure 1 examines the results of the physician enrollment process. A total of 472 physicians were contacted from the CFA roster. Of those, 167 were ineligible for the following reasons: 61.1 percent did not provide primary care; 20.4 percent had less than 50 Medicare patients; 7.8 percent had moved out of the area, were deceased, or retired; 4.8 percent practiced in an ineligible setting, such as an HMO, and 6.0 percent were ineligible for other reasons. That left 305 physicians who were eligible to have their Medicare patients age 65 or older participate. A total of 73, or 23.9 percent, agreed to participate. A total of 154, or 50.5 percent, refused. The remaining 78 contacts were not completed despite multiple attempts.

Of those who refused, more than half (54.5 percent) gave no reason, while nearly a quarter (26.6 percent) said their practice was too busy. Another 14.3 percent were concerned about the effect of the project on their patients. More than 40 percent (12 of 29) of the physicians who gave us a specific reason for refusing, believed that the underlying motive of the project was to divert their patients to UCLA. The remainder believed we might alarm patients or undermine their relationship with their primary care physician, or had other reasons, such as non-English speaking patients, to account for the final 4.6 percent of the physicians who declined to participate.

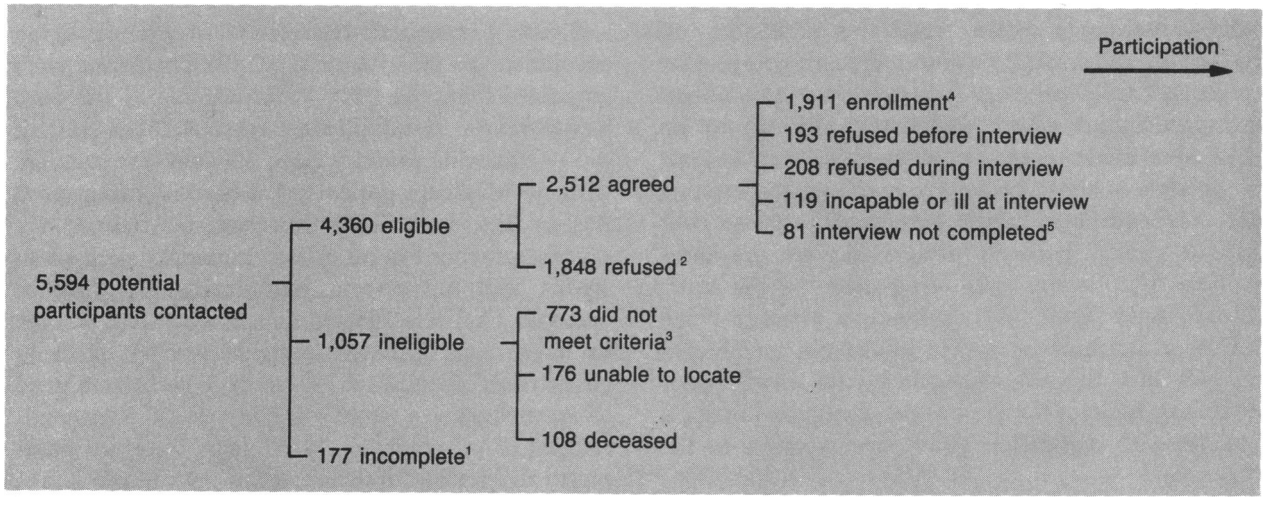
Participating physicians provided us with more than 7,000 names of potential participants. After

Figure 1. Physician enrollment in the UCLA Medicare Screening and Health Promotion Trial, 1988–92



[1]Deceased, retired, sabbatical, moved out of area.
[2]FHP, HMO, hospital based practice.

Figure 2. Participant enrollment in the UCLA Medicare Screening and Health Promotion Trial, 1988–92



[1]No contact and incomplete protocol.
[2]Refused by mail or telephone.
[3]Did not speak English, were not ambulatory, were not patients of participating physician, were confused, were younger than age 65.
[4]Consent form and complete baseline interview.
[5]Other reason for ineligibility determined at time of interview.

the lists were cleaned for duplications, incomplete information, people who lived outside of the greater Los Angeles area, and people who did not meet our criteria (such as Medicare recipients under the age of 65), 5,594 potential participants remained.

In figure 2, the results of the patient enrollment process are presented. Of the 5,594 persons contacted initially, a total of 1,057 candidates were ultimately determined to be ineligible. They included people who spoke little or no English, were not ambulatory, were not patients of physicians participating in the study, were younger than age 65, were too confused for meaningful communication regarding study participation, could not be located, or were deceased. Of the 4,360 who were contacted and remained eligible, 1,848 refused to participate. Thus, there were 2,512 eligible people who informally consented to participate, a preliminary rate of 57.6 percent.

Participants were randomly assigned to the experimental and control arms of the study at this

point. Spouses and other established partners were randomized as pairs. Official enrollment concluded with the return of 85.2 percent, or 2,139 of the signed consent forms that were mailed to the 2,512 people who had informally agreed to participate by mail and telephone.

Refusals totalled 1,848, or 42.4 percent of the initial list of eligible contacts. We counted those people who were contacted at least six times without reaching a decision about participating in the study as refusers. The remaining 177 nonparticipants were contacted five or fewer times.

Reasons for refusal were seldom given, especially by those who responded by mail. In a sample of 100 refusers, 75 gave no reason. Analysis on the entire sample, therefore, was not pursued. Poor health of either the potential participant or spouse was cited by 13 of the 25 who did give a reason for not participating. The remaining reasons were primarily due to lack of interest. Anecdotally, some people told us that they did not see the value of the prevention program. This corresponds with the Rutgers experience in which refusers often stated that they could not see the value of prevention for older persons (*8*). Either they didn't think health promotion was worthwhile for older persons or they felt that they were already doing everything possible to maintain their health. In addition, we were unable to assure some potential participants that enrolling in MSHPT would not have an impact on their insurance or Medicare coverage.

Discussion

We were able to enroll 23.9 percent of the eligible physicians that we contacted. Even with the endorsement of the UCLA Clinical Faculty Association and prior experience with similar research solicitations, almost 20 percent of the physicians who refused expressed concerns about having their patients participate. Mostly they were apprehensive that we intended to divert their patients to UCLA clinics, even though our letters and telephone calls emphasized that this was not the case. We repeatedly reminded the physicians that our protocol required that all recommendations for medical followup be referred back to the primary care physician. We stressed that our program was part of the UCLA School of Public Health and would be held in a multi-purpose center that was not a part of the medical center complex. In addition, the participants would be seen by allied health professionals, rather than physicians.

Other physicians expressed reluctance to have their patients participate because they thought we might undermine the established doctor-patient relationship by inferring that the physician was inadequate or was not providing sufficiently comprehensive care. Yet others responded that their practice already offered everything that we proposed to do for their patients. Notwithstanding, all of these reasons may arise from the physicians' perceived loss of autonomy (*16*). This supposition may be supported by the UCLA Functional Assessment Study, which used an analogous enrollment scheme and had a similar participation rate, but the intervention was in the form of feedback to physicians and the patients were never seen by the study team.

The physicians who participated in this study were self-selected, as were patient participants. This may help sustain interest in our preventive health project. It may also make it more difficult, however, to demonstrate a significant difference between our intervention and control groups.

We were able to meet our goal of attracting at least 2,500 ambulatory community senior citizens to our project in less than 6 months. Although more than half (57.6 percent) of those eligible for participation in our study chose to do so, that rate might have been greater if we had been able to offer more reimbursement for participation than the modest $5 annual honorarium. Although budgetary restrictions did preclude higher compensation, we wanted to demonstrate that people would choose to participate based on the merit of the program. We might have enhanced the desirability of our program also if we had marketed it by pointing out the equivalent monetary value of either the whole or individual components.

Our participation rate of 57.6 percent was very satisfactory, however, based on the experience of the previously mentioned Medicare demonstration projects and the UCLA Functional Assessment Study, in which 38.1 percent of the potential subjects chose to participate when solicited in a similar manner, according to Hirsch's unpublished data. Clearly our enrollment was more successful than the other Medicare projects, since we met our goals in terms of the number of participants enrolled using available personnel and did so within our projected 6-month time frame.

We believe the following factors were particularly important to the success of our enrollment:

1. The letter of endorsement from the CFA to the community physicians;
2. The written personal endorsement of our

'Semantics were very important in "selling" this study to our participants, and we would urge future researchers to pilot test their materials in the community, rather than on more convenient academic colleagues.'

project by the potential participant's primary care physician;

3. The project physician, rather than other staff members, telephoning the community physicians;

4. The followup of nonresponders that included evening and weekend calls;

5. The description of the SHPC;

6. The small honorarium, free parking, and some assistance with transportation for those who needed it; and

7. The enthusiasm that our project staff was able to communicate skillfully to potential participants.

The importance of the enthusiasm factor was also found by Kaye and colleagues when they studied the reasons that elderly persons participate in clinical studies (*17*). In addition, most participants liked the nonthreatening and noninvasive nature of our intervention, although a few refusers expressed concern that our project did not offer enough services to make participation worthwhile. Nearly three quarters of our participants, however, reported that their health was already good. Many expressed their perception of the benefits of the program for themselves, as well as the possible benefits to others in the future.

Our participants may be typical of those people who would be more interested in preventive health care programs. Cohen-Mansfield and coworkers found that the significance of the research, a clear presentation, and the absence of risk were the most important factors influencing participation of older people in clinical studies (*18*). The importance of perceived benefits was also substantiated by Kaye and colleagues (*17*).

Semantics were very important in "selling" this study to our participants, and we would urge future researchers to pilot test their materials in the community, rather than on more convenient academic colleagues. The project personnel worked to develop acceptable and comprehensible terminology for the physicians and the patients, both in our communication with them and in their communication with each other. For example, "intervention" replaced "experiment" which alarmed some of our patient participants. If our intervention sounded too medical, it ran the risk of unsettling the physicians, but it had to sound like more than a typical community health fair to interest our participants. Once terminology had been decided upon, staff members helped one another maintain consistency.

Everyone on the staff was capable of performing nearly all the tasks related to enrollment, and did so, but individual preferences were generally encouraged and honored. Consequently, each staff member tended to become the expert responsible for the coordination and control of a particular area. The consensus of the staff was that this helped maintain morale and was beneficial in reducing burnout during the enrollment period when staff members were working evenings, weekends, and many more hours than usual.

It is difficult to judge whether it would have been more efficient to have done additional prescreening of physicians and potential participants prior to our initial mailing. Physicians could have been called, prior to our initial mailing, to eliminate most of those who were ineligible. Nevertheless, the savings would have been negligible, since physician contact could generally be completed with one mailing and one phone call, and physicians only accounted for about 5 percent of our total contacts. Significant savings probably could have resulted if ineligible patient participants could have been screened out. Beyond the 1,500 that we removed from the original lists provided by the physicians' offices, many phone calls and multiple mailings were often required for more than 1,000 people who could not be located or did not meet the criteria presented to the physicians. The physicians were instructed to select potential participants based on the criteria we provided and screen the list for inappropriate candidates, yet we found that at least 108 of those recommended were dead, some for 3 or more years!

An example of a better procedure might be physicians choosing potential participants directly from their daily logs, as was done in the UCLA Functional Assessment Study (*12*). That resulted in a smaller proportion of inappropriate candidates. In that study, however, there were no age requirements stipulated and fewer participants per physician were requested. Our physicians were asked to screen the lists that were given to us, but obviously that was not done with great care.

Although our research assistants were directed to work as unobtrusively as possible and procedures were adapted to the needs and resources available at each site, the perceived inconvenience varied tremendously. In some practices it was very difficult to get the minimum information that was necessary for fewer than 50 patients, while in others it was easily obtained for several hundred. No discernible pattern emerged for the 73 practices we visited. Others have also found that the perceived inconvenience and data comprehensiveness and accuracy were unpredictable and unrelated to the degree of automation or the size of the practice (*19*).

Conclusions

Although only about a quarter of the community physicians that were eligible were willing to participate in a university-based preventive screening and health education research project involving their patients, a high percentage of older patients approached by their primary care physicians were willing to enroll in such a project. Further research on the merits of various methods for enrolling private practice physicians in clinical trials is needed.

Our enrollment design was not intended to be experimental, and thus it is impossible for us to differentiate the relative importance of the various factors that played a part in the success of our enrollment process. Our intent, however, was to examine the feasibility of enrolling elderly patients into preventive health care services trials and to begin to examine the dimensions of enrollment "enabling" factors. The importance of these dimensions have been confirmed by other investigators (*8,15,17,18*), but there are no published studies that simultaneously looked at systematic testing of factors such as the impact of the physician letter to the patient or the enthusiasm of the staff. Further controlled studies, examining the relative influences of each enabling factor are needed.

Conducting a research project using community based private physicians and their patients requires additional time, staff, and flexibility. The advantage, however, is that the results should be more acceptable to community practitioners and may be more rewarding and generalizable than findings from studies done in an academic, clinical setting. We urge university based researchers to conduct health services research studies with a community-based population by enlisting the support of physicians in private practice.

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