Soliciting Defined Populations To Recruit Samples of High-Risk Older Adults

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Background. Generalizable research on high-risk older persons requires samples that are both large enough for adequate statistical power and similar enough to community populations that its results can be generalized to them. We tested the effectiveness and efficiency of mixed-mode (mail-telephone) solicitation of a defined population as a method for recruiting a large, representative sample for a randomized trial of outpatient geriatric evaluation and management (GEM).

Methods. Fee-for-service, community-dwelling older Medicare beneficiaries were mailed a short self-administered screening questionnaire. Eligible respondents were called to assess eligibility and willingness to give consent; consenters were called again for baseline data. Information about nonrespondents, ineligiblees, and refusers was obtained from the Health Care Financing Administration.

Results. The response rate to the screening questionnaire was 61.1%. Of the respondents, 13.2% were eligible for the study and, of those, 34.4% agreed to participate. Response rates appeared to be influenced by small financial incentives and by subjects' age, sex, race, location of residence, and use of hospitals in the previous year. Consent rates were influenced by age and sex. The final sample (N = 322) was representative of community high-risk respondents in racial composition, previous use of hospitals, and probability of repeated admission (P_r) in the future, but it was slightly younger and contained a higher percentage of men. Recruitment costs averaged $286.92 per consenting person.

Conclusions. Mixed-mode solicitation of defined populations can produce, at reasonable cost, large samples whose representativeness of community high-risk populations can be determined. Procedures that may enhance the success of this approach include: advance communication with members of the target population and their families and physicians; provision of medical and small financial incentives; continuous monitoring of recruitment results; and attention to subjects' needs for convenience, time, transportation, and reassurance.

Generalizable research on high-risk older persons requires the recruitment of samples that are both large enough for adequate statistical power and similar enough to community populations that findings can be generalized to them. Large samples of older populations can be recruited through the media, at social gathering places, from medical records, and from lists of voters, Medicare beneficiaries, and members of associations and health care organizations (1–5). Recruitment is difficult, however, often taking 25% longer than planned (3,6–8) and costing $363 (5) to $949 (9) [or 31 staff hours (10)] per participant. Of the elders who are initially identified as potential participants, fewer than 10% usually enroll (8) [1–11% in large clinical trials (2,3,5)]. The vast majority meet an exclusion criterion, refuse to give consent, or drop out.

Recruiting by mail can be successful when certain principles are followed (1,3,4). Response rates are higher when potential participants are reassured by television stories or newspaper articles (preferably with pictures) that the project is reputable (4,11); they are more likely to respond to questionnaires mailed with university and government letterheads (12). To accommodate some individuals' impairments in vision and writing ability, questionnaires should be brief, simple, and easy to complete (2,11,12). Sending surveys by first class mail (13), sending a second mailing to initial nonrespondents (12,14), and including financial incentives (12) usually increase response rates.

Willingness to participate has been reported as inversely related to age (2,4,11,15–17), but not in all cases (3,10). Although additional research is needed, poor response rates in older populations appear to be linked also to female sex (2,4), unmarried state (2,4,8), low educational level (2,4,8,15), non-White race (4,8,15), poor health (2,4,10), and cognitive impairment (18). Some older persons with health problems are more willing to respond to an invitation that includes medical care (19,20).

Even after elders have been identified as interested and eligible candidates, obtaining their informed consent can be difficult. They may fear signing legal documents and, if pressured, may refuse outright. They may want to have the forms reviewed by their relatives or primary physicians (8,11). In the Systolic Hypertension in the Elderly Program (SHEP) pilot study, the most common reason for eligible elders' nonparticipation was reluctance of families or private physicians (10,15). Other reasons include lack of convenient transportation (4,11,21), family members' medical problems (10,15), and personal inconvenience.

Publicizing the study to the local lay and medical com-
munities before recruitment begins usually leads to higher rates of consent (3,4,8,11). It is helpful if the study site is conveniently located, accommodates family members, and has accessible, friendly staff and elderly volunteers (4). Free transportation and, for some, respite care can make participation feasible (4). Older persons’ decisions to consent are often based on the possibility of improved health for themselves or others (8,21). Once enrolled, elders usually follow study protocols at rates comparable to those of younger age groups (3,10,15,22).

Some recruitment techniques may yield samples that are large but highly selected. If the characteristics of the final sample differ significantly from those of the original target population, the generalizability of the study’s findings may be limited. A follow-up survey showed that the participants in a randomized trial of exercise to prevent falls were significantly more likely to be male, married, educated, healthy, active and functionally independent than the nonrespondents (2). A review of death certificates showed that, compared to the nonparticipants, the participants in a cohort study had lower rates of mortality from smoking-related causes such as heart disease and lung cancer (23).

Selection bias is particularly difficult to detect and manage when recruitment is conducted through the media and in public places because the number and characteristics of the nonrespondents are not known. In contrast, when recruitment is conducted by soliciting individual members of defined populations about whom information is available, investigators can monitor the characteristics of participants and nonparticipants, increase their sampling of groups that are participating at low rates, and take selection biases into account when interpreting their results and making recommendations.

In attempting to recruit a large representative sample of the community-dwelling older population at high risk for repeated hospital admission but not seriously ill, we used direct mixed-mode solicitation of Medicare beneficiaries. Those ultimately enrolled in the study were randomly assigned to receive either usual care or outpatient geriatric evaluation and management (GEM) for 6 months. Enrollment of 227 participants in each group was projected to provide 90% power to detect a clinically and statistically significant difference (α = .05) between the groups’ hypothesized 18-month hospital admission rates (30% vs 45%). In a pilot study (24), similar recruiting methods were used to enroll 154 participants.

In this article, we describe a series of modifications that were made to the recruitment process in order to improve the rate of response to the solicitation and the representativeness of the sample. In order to assess the results of these techniques, we compare the characteristics of the respondents to those of the nonrespondents, the consenters to the nonconsenters, and the enrolled participants to the eligible nonparticipants.

**METHODS**

To be eligible for this study, participants had to be at least 70 years old, community-dwelling, and have a high probability of repeated hospital admission, \(P_a\) (25). \(P_a\) is calculated by inserting a person’s answers to eight questions into a logistic equation. Persons classified as high risk have been shown to use hospital and other health-related services at twice the rate of persons classified as low risk (26-29).

Exclusion criteria for the study were: serious current illness (e.g., receiving hospice, dialysis or active care for unstable health), inability of the subject or proxy to provide information by telephone (e.g., because of deafness, cognitive impairment, nonfluency in English, or anticipated travel), refusal to give consent (by the subject or established primary physician), and ineligible insurance status (e.g., membership in a Medicare “risk” or “cost” plan; lack of Medicare supplemental insurance coupled with income exceeding 200% of the federal poverty threshold—in the latter case, offering “free” care might have violated the federal “antikickback” statute).

The first step in recruitment was a direct mailing to Medicare beneficiaries in order to identify those at high risk for hospitalization. Approximately every 2 months from May 1994 through July 1995, the Health Care Financing Administration (HCFA) provided an electronic list of the name, address, race, sex, and birth date of all fee-for-service Medicare beneficiaries at least 70 years old living in a previously unscreened part of Ramsey County, Minnesota, or adjoining ZIP codes. This region includes urban, inner-city (low-income, high population density), suburban, and rural areas. HCFA was able to supply current addresses without delay because the study protocol, which had been approved by the National Institute on Aging, conformed to the requirements specified by HCFA policies regarding the release of information about Medicare beneficiaries.

The University of Minnesota’s Data Collection and Support Services (DCSS) deleted from each list all persons whose addresses were obviously those of nursing homes or financial trustees. It surveyed at 2- to 3-week intervals by first class mail 33 geographically defined groups of beneficiaries, sending an introductory letter on HCFA letterhead, followed 1 or 2 weeks later by a packet containing a cover letter, questionnaire, self-addressed, stamped return envelope, and enclosures intended to encourage participation. The cover letter, on University of Minnesota letterhead, explained the nature and goals of the study and stated that participation would be voluntary, free, and (if the subject was assigned to the experimental group) coordinated with and approved by his or her established primary physician. It also provided the name and telephone number of a person who could answer questions about the study. Potential participants who did not respond within 2 to 3 weeks were sent a second packet.

Responses were scored weekly by computer, and DCSS staff members called all high-risk respondents \((P_a \geq .40)\) to explain the study and to assess their ability to follow the study protocols. Ten dollars were promised for each of four 15-minute follow-up telephone interviews during the 18-month course of the study. Depending on the participant’s preference, consent was recorded by audiotaped telephone conversation or by mail.

Data about consenters were transferred electronically every week from DCSS to the GEM research center. There a research assistant promptly called all consenters to obtain
more information about eligibility and, from those who were eligible, to obtain baseline data (a 15-minute interview). Any consent who had difficulty communicating by telephone or who failed a brief test of cognitive ability (30) was asked to name a proxy for most components of the baseline interviews.

Consenters assigned to the control group—and their primary physicians—were notified of their high-risk status and assignment to receive usual care. Subjects assigned to the experimental group entered a four-step enrollment process. The principal investigator called the subject's established primary physician to explain the intervention, to promise collaboration of the GEM team's temporary primary care of his or her patient, to pledge that the University would not "steal the patient" when the study ended, and to request permission for the subject to participate. If permission was granted, the assigned GEM social worker then visited the subject's home to describe GEM care, to build rapport, and to gather evaluative data. Next, the subject visited the GEM clinic for a physical evaluation by a geriatrician, a social worker, and a nurse. The study protocol was approved by the University of Minnesota's Institutional Review Board.

Awareness of the study and of its easily accessible, barrier-free clinical site with free parking was promoted through articles in the local newspapers and postings at senior housing units. An article from the major local newspaper accompanied the screening questionnaires, which were printed in large (15-point) type. The cover letters and telephone interviews were informative, friendly, and polite; they encouraged subjects' friends and family to become involved. Free transportation to and from the clinic was offered. Primary physicians learned about the study through a program advisory board (composed of leaders of the medical community), articles in local professional newsletters, and presentations at meetings of local medical societies, hospital staffs, and practice groups.

During the early phases of recruitment, when consenters were not yet being randomized, the response rates (number of scorable questionnaires returned / number of questionnaires mailed) were monitored closely. Because the initial rates were lower than projected, complex questions about insurance coverage were simplified or eliminated (see Table 1). Then, potentially sensitive questions about income, Social Security number, present medical care, and marital status were deleted, shortening the questionnaire from seven to four pages. When response rates remained low, the newspaper article was omitted from one batch of mailings to test for a possible negative effect. Seeing no change, the investigators inserted new one-dollar bills (and copies of the article) in the next batch of mailings. This combination was used in all subsequent mailings, ultimately to 94% of the persons eventually enrolled in the study.

Monitoring also detected that, at each step of the recruitment process, men were choosing to participate at significantly higher rates than women and that about 16% of the subjects randomized to the experimental group were dropping out before completing the enrollment process, primarily because they were reluctant to complete the required home and clinic visits. To address the first problem, the investigators screened only women during the final recruitment mailings; to address the second, they changed the ratio of random assignments (experimental:control) from 4:4 to 5:3.

HCFA provided data about the solicited persons' demographic characteristics and use of hospitals during the year before the study. To help judge the degree to which the enrolled sample resembled the target population in the community, we estimated the size of the target population by dividing the number of high-risk, non-seriously ill respondents by the overall response rate. Differences in means and frequencies between groups were compared using the chi-square and single-sample and independent-sample two-tailed $t$ statistics, as appropriate.

**Results**

As shown in Table 1, decreasing the complexity and length of the screening questionnaire boosted the response rate from 38.7% to 41.6% among the residents of St. Paul's inner city. Residents of non-inner-city urban areas (groups 7–9) responded at higher rates (46.5–47.4%) regardless of whether a newspaper article about GEM was included. Enclosing a new dollar bill in the mailings led to significantly higher response rates in the remaining urban areas (60.3%, $p < .0001$) and in the combined urban, suburban, and rural areas (62.0%, $p < .0001$) during the following 12 months.

Older persons in groups 7–33 ($n = 23,801$) were recruited for participation in the randomized phase of the study. Initial mailings to these groups produced 10,498 scorable forms, and follow-up mailings to nonrespondents produced an additional 4,038, bringing the cumulative re-

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Table 1. Response Rates Among Solicited Groups of Medicare Beneficiaries
sponse rate to 61.1%. Response rates varied significantly by race: 88.2% of 85 Hispanic/Mexican Americans, 83.3% of 18 Native American Indians, 73.0% of 178 Asian Americans, 60.5% of 21,916 Whites, and 46.5% of 402 African Americans responded (p < .001).

Attrition and selection bias.—In Figure 1, we show the results of the recruitment process. In the following discussion, we compare at each significant point of attrition (and, therefore, of possible selection bias) the characteristics of the persons lost from and retained in the recruitment process. Respondents were younger (77.7 vs 80.2 years, p < .001), had fewer mean hospital admissions in the previous year (.26 vs .34, p < .001), and were more likely to be male (29.4 vs 23.8%, p < .001) than nonrespondents.

Of the 14,536 respondents, 852 (5.9%) were living in nursing homes and were excluded. Of the remaining 13,684 community-dwelling respondents, 11,398 (83.3%) were excluded by low Pra values (< 0.4). Among the 2,119 five high-risk respondents (Pra ≥ 0.4) who were not seriously ill, 313 were unable to adhere to the data collection protocols, leaving 1,806 (13.2% of the community-dwelling respondents) eligible for participation in the study.

About one third (621) of the eligible subjects gave informed consent to participate, either by telephone (143) or by mail (478). The mean hospital admissions, P_r, and the racial composition of consenters were similar to those of refusers (admissions = .86 vs .89, P_r = .4934 vs .4978, % White = 96.5 vs 97.8), but the consenters were younger (79.2 vs 80.9 years, p < .001) and more likely to be male (54.6% vs 38.0%, p < .001).

Of the consenters, 568 (91.5%) completed the baseline interview and were randomized, 274 to the control group and 294 to the experimental group. Of those assigned to the experimental group, 248 (84.4%) completed the enrollment process: 10 were eliminated because their physicians refused to give permission, and 36 withdrew. Permission for experimental subjects to participate was granted by 92.4% of the physicians (98.1% of family physicians, 87.6% of internists).

Representativeness and cost of final sample.—The enrolled participants (N = 522) constituted 24.6% of the high-risk, non-seriously ill respondents to the mailed solicitation (n = 2,119) and about 15% of the whole target population. (2,119 / 0.611 = 3,468). The participants were similar to the eligible respondents in mean hospital admissions in the previous year (.83 vs .87), mean probability of repeated admission (P_a = .4937 vs .4960), and racial composition (96.6% vs 96.2% White), but they were younger (79.1 vs 80.5 years, p < .01) and more likely to be male (56.9% vs 44.4%, p < .01). The cost of designing, testing, revising, and conducting the recruitment program was $178,176—$7.02 per name received from HCFA and $286.92 per consent.

DISCUSSION

These findings demonstrate that mixed-mode solicitation of a defined population can be an effective and efficient method for recruiting large representative samples of high-risk, community-dwelling older persons, even when participation requires acceptance of an intensive clinical intervention. The observed racial differences in response rates, although statistically significant, were based on mailings to small numbers of urban Minnesotans and may not represent differences elsewhere. The final sample exceeded the size needed for adequate statistical power and had characteristics that were similar to the high-risk, non-seriously ill respondents, which were the closest possible approximation to the target population. The unknown health and risk status of the nonrespondents precludes direct comparisons of the final sample and the actual target population. This estimate of the degree to which the final sample resembled the target population will inform the parent study’s analyses, interpretations, and recommendations.

The success of this recruitment resulted from the simultaneous use of several techniques. The largest improvement in the response rate to the screening questionnaire (from 46.5% to 60.3%) occurred with the addition of a new one-dollar bill. This was consistent with a previously reported 6% increase for each 25 cents enclosed (12). Shortening and simplifying the questionnaire increased the response rate by only about 3%; including a newspaper article about the study had very little effect. Among people who did not receive dollar bills in their mailings, response rates in inner-city areas were 6.1% lower than in non-inner-city urban
areas (40.4% vs 46.5%), perhaps because of differences in education, socioeconomic status, and previous experience with government-related organizations.

Difficulties in recruitment for this project's pilot phase, in which care was provided at a busy university medical center, corroborated that eligible subjects sometimes decline to participate in clinical studies because of perceived difficulties in travel and access to the study site. The recruitment for the randomized trial was designed to minimize such difficulties. Telephone and postal services were used to obtain as much data as possible. Subjects knew in advance that, if they were assigned to the control group, they could complete the study protocols at home and that, if they were assigned to the experimental group, they would receive care at a small, physically accessible clinic with free transportation available. The amount of the payment for each semiannual telephone interview ($10) was chosen to represent a token of appreciation rather than a significant financial incentive to participate.

The pilot phase had also revealed that some community physicians opposed their patients' participation in clinical programs sponsored by the University of Minnesota, in which many cases was their competitor. Efforts to inform these physicians about the program in advance, to ask their permission for their patients to participate, to communicate and collaborate with them, and to return their patients after the study may have contributed to the unexpectedly high level of cooperation (92.4%).

Prompt detection and correction of deviations from the projected rates of recruitment were made possible by the program's data management systems. The response rate to each mailing determined the size of the subsequent mailing (and the next request for names from HCFA). The suboptimal rate of participation by women was addressed by increasing the proportion of mailings to women, boosting the percentage of women enrolled in the study from 25% of the early consenters to 43% of the final sample. Similarly, the revised randomization ratio (5:3:controls:3 controls) compensated for early suboptimal rates of completed enrollment into the experimental group, resulting in a controlled stream of participants flowing into the experimental clinic, a larger experimental group, and greater statistical power for the study's analyses.

Recruitment of a large representative sample of high-risk older populations is complex, lengthy, and expensive, requiring detailed advance planning, vigilance, and careful execution. Direct solicitation of a population about which data are available allows the monitoring and avoidance of many types of selection bias. Until more information about the effects of specific recruitment techniques is available, it is recommended that programs of direct solicitation include:

- dissemination of information in advance to elders, their families, and physicians;
- small financial incentives;
- processes that provide the information, reassurance, time, convenience, and transportation desired by many seniors; and
- continuous monitoring of recruitment results.

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