Practice of Epidemiology

Issues in Conducting Epidemiologic Research Among Elders: Lessons From The MOBILIZE Boston Study

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Conducting research in elderly populations is important, but challenging. In this paper, the authors describe specific challenges that have arisen and solutions that have been used in carrying out The MOBILIZE Boston Study, a community-based, prospective cohort study in Massachusetts focusing on falls among 765 participants aged 70 years or older enrolled during 2005–2007. To recruit older individuals, face-to-face interactions are more effective than less personal approaches. Use of a board of community leaders facilitated community acceptance of the research. Establishing eligibility for potential participants required several interactions, so resources must be anticipated in advance. Assuring a safe and warm environment for elderly participants and offering a positive experience are a vital priority. Adequate funding, planning, and monitoring are required to provide transportation and a fully accessible environment in which to conduct study procedures as well as to select personnel highly skilled in interacting with elders. It is hoped that this paper will encourage and inform future epidemiologic research in this important segment of the population.

accidental falls; aged; aging; cohort studies; epidemiologic methods; patient selection; prospective studies

Abbreviation: MOBILIZE, Maintenance of Balance, Independent Living, Intellect, and Zest in the Elderly of Boston.

Epidemiologic studies of community-dwelling, elderly persons are beset by many challenges encountered to a more limited extent in clinic-based patient research or in community-based studies of younger adults. Nevertheless, population-based studies of elders are necessary to learn about disease etiology as well as to enable valid generalizations of research findings for this growing and important segment of our population.

While the previous 2 decades have seen a marked increase in the study of older adults’ health (1), information on practical problems and possible solutions in conducting population-based research among elders are limited. Although a major review was published nearly 20 years ago (2), current analysis of issues involved in carrying out epidemiologic research of older individuals is lacking.

In this paper, we present specific challenges that have arisen and solutions we have used in carrying out The MOBILIZE Boston Study (Maintenance of Balance, Independent Living, Intellect, and Zest in the Elderly of Boston), a community-based prospective cohort study of 765 participants aged 70 years or older. Our intent is to provide researchers with information to encourage and inform future epidemiologic research among elders.

DESCRIPTION OF THE MOBILIZE BOSTON STUDY

Initiated in 2005, The MOBILIZE Boston Study is a prospective cohort study to identify risk factors and underlying mechanisms of falls for Massachusetts elders, including the roles of cerebral hypoperfusion, peripheral sensory deficits, musculoskeletal pain, and foot disorders (3). Conducted by the Institute for Aging Research at Hebrew SeniorLife (Boston) and funded by the US National Institute on Aging, The MOBILIZE Boston Study has enrolled 765 individuals.
aged 70 years or older and is following them for the occurrence of falls over a 2-year period. Participants were randomly selected for recruitment by using town lists and were required to complete a 3-stage eligibility screening procedure including 1) an initial “doorstep visit” at the randomly selected household, 2) a telephone interview, and 3) an interviewer-administered questionnaire at the home of the respondent.

Participants underwent comprehensive assessments, including a home visit and a clinic examination. At the home visit, trained interviewers administered a standardized questionnaire that covers demographic characteristics, medical history (4), medications (5), falls history, self-efficacy regarding avoidance of falls (6), fracture history, pain assessments (7, 8), vision and hearing, footwear (9, 10), physical activity (11), cigarette smoking (12), social supports (13), bladder and bowel function, sleep and energy, depression (14), syncope, restricted-activity days, activities of daily living (15, 16), and neuropsychological and mental status assessments (17, 18). During the home visit, study interviewers instructed participants on how to use a “falls calendar” to record whether or not a fall occurred each day (“F” to denote a fall and “N” for no fall) (19). The 12-month falls calendars were affixed to a magnetized backing for placement in a highly visible location in the home, such as a refrigerator door. Each month of the falls calendar was located on a detachable prepaid postcard that respondents mailed to the study office upon completion.

During the clinic visit, a research nurse administered a standardized examination including measurements of height, weight, postural blood pressure, visual acuity, static balance (20), and lower limb strength. In addition, the participant underwent venipuncture and transcranial Doppler measurements of cerebral blood flow (21). The clinical examination included the Short Physical Performance Battery (22), a foot disorder evaluation (23, 24), a musculoskeletal examination (25–27), a manual tender point survey (28), and somatosensory function tests (29).

Although we used previously validated instruments for data collection whenever possible (3), it was not feasible to test reliability of screening procedures such as the Mini-Mental State Examination. However, very few individuals (n = 8) were excluded because of cognitive impairment. We did conduct reliability testing for carbon dioxide vasoreactivity. The intraclass correlation coefficient was 0.92 for 2 transcranial Doppler measurements performed 6 months apart in 21 elderly volunteers.

Follow-up examinations were originally planned for 12 and 24 months after baseline assessments. Because of an unanticipated high rate of ineligibility because of language barriers that necessitated unexpectedly large amounts of time and resources to recruit and conduct study procedures, we were advised by our scientific advisory board to change the number of follow-up examinations to 1 assessment at follow-up visits but by monthly calendars for the 5-year duration of the study, the change in follow-up frequency did not limit our ability to achieve our primary aims.

ELIGIBILITY

To make our study as inclusive (and therefore as generalizable) as possible, we used the least restrictive eligibility criteria that still enabled us to carry out the study procedures. A minimum age of 70 years was required for participation, but we placed no upper age limit on eligibility. In many studies, upper limits on age are imposed, even in geriatric research (30–36), so that findings may not be applicable to very elderly individuals. However, older age groups are likely to benefit greatly from research, given the universal association between aging and morbidity. In addition, since seniors represent the fastest growing segment of the population (37, 38), their exclusion from participation in research is particularly problematic from a public health perspective.
Although we planned to use the least restrictive inclusion criteria, participation did require English-language skills, hearing, cognition, and ambulation. We therefore elected to use the lowest level of ability in each of these areas in order to be as inclusive as possible. For example, exclusion criteria regarding cognitive ability were limited to moderate-to-severe impairments (39) that prohibited participating in the informed consent process or other study procedures such as recording falls on monthly calendars. Although a Mini-Mental State Examination (40) score of 24 points or lower (of 30 possible) is the definition of cognitive impairment used by clinicians (41), we allowed a minimum score of 18 points, similar to that used in the Women’s Health and Aging Study (42).

Investigators must carefully evaluate language proficiency as a criterion for exclusion because the benefits with respect to generalizability must be weighed against the high costs of performing research in multiple languages. We required our study participants to be able to speak and understand English well enough to read and comprehend the informed consent documents, schedule appointments, and complete study procedures. However, since little information is available on differences in the frequency of falls in different ethnic groups (43, 44), research among elders for whom English is not the primary language is certainly warranted. If just 1 predominant language other than English is spoken, such as Spanish in many parts of the country, it may be highly worthwhile to include Spanish-speaking personnel.

Finally, we required individuals to be able to ambulate 20 feet (6 m) without the assistance of another person. This definition of ambulation was the least restrictive we could use because participants are required to travel to the study clinic for examinations. This requirement excluded elders who were confined to a wheelchair but included those who could ambulate with a cane or walker.

Eligibility was evaluated by using a 3-stage screening procedure (Figure 1). The first stage involved a recruiter administering a brief interview at the home (“doorstep”) of a potential participant. Second, a research assistant conducted a similar interview by telephone. Finally, an interviewer administered a questionnaire at the home of the respondent, including the Mini-Mental State Examination. The results of this process are discussed below.

RECRUITMENT METHODS AND PRACTICAL CONCERNS

Community support

Obtaining the acceptance and support of community leaders prior to the recruitment phase of population-based geriatric research is also critical to the success of the study (45–48). Older adults who are isolated by limited English proficiency or who have strong cultural ties often obtain care through community-based organizations that provide native-language and culturally sensitive services. Elders often look to these individuals and organizations to help them decide whether to participate in a research study.

In The MOBILIZE Boston Study, we faced an additional challenge because elder fraud and abuse prevention programs were prevalent in our target population. Consequently, we worked with local public safety agencies sponsoring these programs to learn how best to distinguish our recruitment efforts from inappropriate solicitations of community-dwelling elders. This step included visits to local police and fire departments, elder services, and other community agencies throughout our target area to introduce our research team, distribute materials describing the study, and learn about issues facing seniors in the area that might help inform recruitment efforts. We also placed informational advertisements in local print media and on radio as well as with local cable television stations to educate local communities about the study. Using large print and easy-to-understand language, we provided information to community leaders and elder service organizations describing participation in our study, recruitment methods, researchers’ credentials, affiliated institutions, and how to obtain further information using a toll-free telephone number.

We believe that elders were more likely to participate in the study as a result of these efforts. Although it was not possible for us to quantify the extent to which these efforts improved participation, recruiters frequently provided feedback to the study team that elders “checked us out” before agreeing to participate. In addition, if potential participants were to contact local officials regarding concerns or fears about the solicitations, these leaders were able to reassure these individuals and encourage participation in the research.

In conjunction with direct outreach in the local communities, we also established a community advisory board that consisted of representatives from elder service agencies and housing sites in our target area. This board met with study investigators and recruiters to form a partnership before recruitment began. Members of the board advised the research team regarding all phases of study conduct, including guidelines for publicity and recruitment efforts, transportation services, study materials and procedures, and protocols for dealing with suspected elder abuse.

A community advisory board can also conduct critical “damage control” regarding unanticipated challenges throughout a study. For example, after a series of violent events inside particular senior housing projects, residents were fearful and security was increased. A member of the community advisory board responded by sending letters to housing site managers explaining the research study and allowing field staff to enter the housing facilities.

Recruitment method

Our experience indicates that few elders are likely to participate in research if the method of recruitment relies on contact via telephone or mail rather than face-to-face communication (49, 50). Telephone calls and letters of invitation require potential participants to be able to see, hear, and read. However, problems with oral and written communication are highly prevalent (51, 52). In addition, older people are more likely than younger adults to refuse participation for reasons that include poor health (53), a general suspicion of studies, and concern about signing consent forms and safety (2).
We addressed these barriers by using door-to-door recruitment. First, a letter of introduction was sent to selected households announcing the study. Written in easily understood language and large print, the letter provided a 2-sentence description of the study’s purpose and introduced the participating organizations. The letter explained that an interviewer wearing an identification card would visit the home in about 1 week to speak to the recipient about participating in the study. To help ease security concerns for the elder, a picture of the identification card was included in the letter. Finally, the letter provided a local telephone number for individuals to call for further information or to indicate they did not want to be visited by an interviewer.

Subsequently, unless the person had indicated that she or he did not want to talk to the interviewer, the recruiter made an unscheduled visit to the household to briefly introduce the study, conduct the initial screening interview to determine eligibility status, and obtain permission for the study team to contact the individual by telephone to conduct the next phase of eligibility screening. If necessary, the recruiter arranged to return at a more convenient time.

The recruiter conducted the screening interview either inside the home or at the door, whichever made the elder feel more comfortable. All attempts were made by the recruiter to ensure that the elders were fully informed and comfortable (54). For example, if the elder preferred the presence of family members or caregivers during the interview (or at any point in the study), the request was honored.

To help ensure the safety of recruiters in neighborhoods known to be unsafe, recruiters either visited in teams of 2 or were accompanied by an escort (such as a retired police officer). Escorts would never go to the door, but they remained a safe distance away.

Although door-to-door recruitment is highly recommended for elderly populations (55), it is also more labor intensive than using mailings or random digit dialing techniques (56, 57). Approximately half of the households (53%) were visited 1 time to determine initial eligibility status, but 20% needed to be visited twice, 11% had to be visited 3 times, and 16% required 4 or more visits. However, a total of 11,305 household visits yielded 1,616 eligible individuals who agreed to participate in the next stage of recruitment. To successfully enroll 1 participant in The
MOBILIZE Boston cohort, recruitment staff required an average of 7 doorstep visits.

In contrast to a door-to-door approach, less-personal methods of recruitment do not easily accommodate the frequent and multiple impairments among elders or enable the study team to communicate effectively the nature of the study and the benefits and risks of participation (58). In addition, some evidence suggests that participation bias is minimized by face-to-face interviews with elders compared with other methods of recruitment (56, 59–65). Another important benefit of the door-to-door approach is that it enabled us to know in advance the specific needs or concerns of a participant. Consequently, the staff was able to meet those needs in order to facilitate recruitment as well as negotiate future interactions with the elder throughout the study. For example, knowing about a sensory deficit or anxiety about a specific study component such as phlebotomy is helpful so that study personnel can address and allay concerns. Comments regarding interference of study visits with work or family commitments, fears about having a research assistant in the home, or requests for including a family member at study visits were common and were easily addressed with this advance knowledge. Even though we were unable to measure the cost-effectiveness of the door-to-door approach, the study team reported that the connection made between the elder and the recruiter at the doorstep was a critical first step in achieving high participation and retention rates (66).

The personnel involved in our recruitment effort were all highly experienced interviewers, and additional training was provided to sensitize them to specific needs of the elderly population. This training included how to communicate effectively with individuals with hearing loss, address privacy and safety concerns of elderly people, and conduct brief assessments of English-language proficiency; another topic covered cognitive and physical impairments.

In general, the individual characteristics of interviewers have not been considered major factors in enlisting cooperation (67). In our experience, use of older women recruiters was most successful. Elderly people are necessarily wary of strangers coming to their door, particularly teenagers, young adults, and males. Older women generally appear much less threatening to older individuals and, from our experience, have a better chance of being able to initiate the critical initial conversation. All of our 11 recruiters were older than age 55 years, and 3 were aged 70 years or older.

RECRUITMENT RESULTS

Over a period of 24 months, recruitment staff completed stage 1 eligibility screening of 4,319 residents aged 70 years or older from 5,655 randomly selected households in the target area (Figure 1). Eighty-nine percent of residents (n = 3,822) completed the doorstep visit, while 11% either refused or could not be contacted. One-third were ineligible (n = 1,440) primarily because of non-English-speaking backgrounds.

Within 2 days of the doorstep visit, a research assistant telephoned the potential participant to conduct stage 2 of eligibility screening (as well as schedule the third and final screening at the home of the respondent). Research assistants used a standardized script that included a friendly greeting and reference, by name, to the recruiter who had recently visited the home to talk about the study. Although “best times to contact” were noted by the recruiters, multiple calls were required to contact an elder. For example, a mean of 5 telephone calls was required to reach each of the 1,616 respondents and complete the screening interview, and 25% of respondents required more than 7 calls. It is important to track the effort required to conduct eligibility screening (and other components of study conduct) to budget time and resources and to evaluate the efficacy of study methods.

At the final eligibility assessment in the respondent’s home, a research assistant administered a questionnaire that included a Mini-Mental State Examination. Of 817 potential participants who successfully met requirements at the doorstep and completed telephone screenings, 95% (n = 765) were eligible and agreed to participate in The MOBILIZE Boston Study, 5% (n = 44) refused, and <1% (n = 8) were excluded, primarily because of cognitive impairment (Figure 1). Thus, a population-based study of elders may require multiple interactions and assessments to determine eligibility and enroll qualified participants (50).

MINIMIZING SUBJECT BURDEN

We recognized that our study assessments could be burdensome for our target population. As a result, we decided to break baseline data collection into 2 visits, with 1 visit conducted in the home of the participant and the other at the clinic site. We developed the following strategies to help reduce subject burden and fatigue during study visits. In planning the examinations, we arranged for specific breaks during which participants were provided with a relaxing place to rest, eat a snack and drink, and use nearby restrooms. Study personnel were trained to identify signs of fatigue, such as changes in responsiveness or mood and increased restlessness. Staff was instructed to take a break if participants exhibited any of these behaviors or verbalized feeling tired or uncomfortable. Interviewers carried refreshments, including bottles of water, for participants during the home visits. We provided privacy during interviews or assessments that included questions on issues sensitive to elders, such as hearing or memory loss and symptoms of depression. Bathrooms and examination tables, in addition to any other equipment used for the study, were made accessible and safe for use by elderly participants. Transportation to and from clinic visits was provided at no cost to the participants (50), and we also arranged for parking spaces near the entrance of the facility. Study personnel monitored the transportation service closely throughout the study by interacting regularly with drivers and asking participants about their experience with the service.

CONCLUSION

Epidemiologic studies in elderly populations are very rewarding but are also difficult, expensive, and time-consuming
to conduct (2). As a result, resources to meet these challenges must be anticipated by investigators and supported by funding agencies. To recruit individuals from older age groups, methods that rely on face-to-face interactions are more effective than less personal approaches. Similarly, it is important for study personnel to meet directly with community leaders to gain local acceptance of and enthusiasm for the research. Establishing eligibility for potential participants may require several interactions, and the criteria for exclusion must be weighed against the generalizability of the study findings.

Assuring the safety of the elder, as well as providing a positive and meaningful experience for him or her, is the first priority to be considered in planning and carrying out a study. Transportation and a readily accessible physical environment must be provided so that older individuals can feel comfortable and welcome to participate fully in the research. Research with the elderly requires particularly sensitive, patient personnel who are able to connect with elders, gain their trust, and express appreciation for their participation. Although there are significant challenges in carrying out epidemiologic research in elderly populations, there are many rewards, including the opportunity for the population most burdened by disease to benefit from the research.

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REFERENCES


