Recruitment and Retention of Older Adults in Aging Research

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Older adults continue to be underrepresented in clinical research despite their burgeoning population in the United States and worldwide. Physicians often propose treatment plans for older adults based on data from studies involving primarily younger, more-functional, healthier participants. Major barriers to recruitment of older adults in aging research relate to their substantial health problems, social and cultural barriers, and potentially impaired capacity to provide informed consent. Institutionalized older adults offer another layer of complexity that requires cooperation from the institutions to participate in research activities. This paper provides study recruitment and retention techniques and strategies to address concerns and overcome barriers to older adult participation in clinical research. Key approaches include early in-depth planning; minimizing exclusion criteria; securing cooperation from all interested parties; using advisory boards, timely screening, identification, and approach of eligible patients; carefully reviewing the benefit:risk ratio to be sure it is appropriate; and employing strategies to ensure successful retention across the continuum of care. Targeting specific strategies to the condition, site, and population of interest and anticipating potential problems and promptly employing predeveloped contingency plans are keys to effective recruitment and retention. **J Am Geriatr Soc 56:2340–2348, 2008.**

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If research is to inform clinical practice, the study participants should represent the target population. Thus, it is a serious problem that older adults are underrepresented in virtually all health-related research.[1–6] Researchers limit the participation of older adults in ways that are intentional and unintentional. Researchers may have concerns about safety, risks of study procedures, and capacity to consent.[7–11] Coexisting medical conditions may confound treatment outcomes and lead to heterogeneity in treatment response. Heterogeneity of treatment occurs when the same treatment produces different results in different patients and should be considered when evaluating outcomes.[12] In addition, there are often numerous unintentional exclusions resulting from lack of attention to the practical barriers formed by study activities, demands, and operations.

Because recruitment and retention of older adults in clinical research are critical to inform practice, concerns about safety, science, and barriers must be addressed. The population of older adults is large and potentially available for clinical research studies. Evidence shows that when approached, older adults are often willing to participate in clinical research.[13,14] Experienced investigators within the field of aging research have developed numerous strategies and techniques to address concerns and overcome barriers to elder participation in clinical research. The purpose of this article is to disseminate information on these practical approaches.

A set of general concepts and principles with examples of applications to all aging studies is first presented. These principles are then applied to special aging populations, including older adults with health and functional limitations, those from underrepresented social and cultural groups, and those in institutional settings.

GENERAL PRINCIPLES

Clinical research should be considered a respectful partnership of investigators, participants, families and caregivers, funding agencies, regulators, institutions, providers, and communities. Success is based on a balanced solution to the needs and concerns of every party. Although the science must be rigorous, there are numerous ways to adapt it to the

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priorities of the other partners. Inattention to this partnership affects not only aging research, but also most areas of clinical research. Failure to recruit targeted numbers of participants, not just of underrepresented groups but also of all willing participants, is widespread.[15,16] Attention to all interested parties can lead not only to an adequate population sample and better representation, but also to greater willingness to participate in further studies.

Strategies to promote recruitment and retention that incorporate the interests of all parties can be organized in two dimensions (Table 1). The first dimension represents general research goals, including achieving a representative sample of adequate size, promoting participation, considering feasibility, and retaining participants. The second dimension involves various phases of research, including initial information gathering, study design, pilot studies, and study implementation. Specific strategies and actions to achieve goals can be articulated for each research phase. There are numerous examples in Table 1. A few deserve special attention: adapting the research question to be as inclusive as possible, using advisory boards, maximizing the benefit:burden ratio, and monitoring throughout the study.

Table 1. General Principles for Recruitment and Retention of Older Adults in Research Studies

Recruitment and Retention Goals	Information Gathering	Study Design	Pilot Studies	Implementation
Achieve a representative sample	Characterize target population. Identify sources of participants and gatekeepers. Develop HIPAA-compatible contact plan.	Make inclusion criteria as liberal as possible. Minimize exclusions based on acceptable benefit:risk ratio.	Assess characteristics of those who consent. If study sample differs from target sample, modify study; add strata to target underrepresented groups	Track accrual according to a preplanned rate. Implement backup plans for recruitment early if rate is falling behind
Promote participation	Develop advisory boards of key informants. Develop long-term relationships with communities of interest for mutual benefit.	Plan for benefit and rewards for all participants. Minimize respondent burden, including participants, gatekeepers, and significant others. Consider travel support or data collection in the home and community. Involve members of the target population or gatekeepers in the recruiting process. Design study activities that accommodate common health and functional limitations of older adults. Incorporate plans for diverse populations of interest based on ethnicity, races, and languages.	Develop and test attractive and easy-to-read promotional materials. Measure time, convenience, and discomfort of all study procedures. Survey satisfaction and concerns of participants, caregivers, and gatekeepers. Track promotion and recruitment strategies for yield. Make communication with study staff simple and convenient.	Train staff in courtesy and accommodation of participant concerns. Maintain communication with the communities of interest and advisory boards.
Consider feasibility	Estimate screen-to-recruit ratio.	Develop efficient screening process with high-cost steps later in the process. Consider convenience and accessibility to research sites.	Measure time and cost of screening and screen-to-recruit ratio (include travel costs, if planned). Assess acceptability of sites to participants and gatekeepers.	Track screen-to-recruit ratio. Implement backup plans for recruitment sites early if rate is falling behind.
Retain participants in the study	Develop an understanding of motives to participate by subjects and gatekeepers.	Incorporate continued attention, feedback, and rewards into study plan. Plan for costs of retention activities.	Assess perceptions of rewards and modify if needed. Use trained participant informants to assess all study aspects from participant perspective.	Implement attention, feedback, and reward systems and modify if needed. Develop an early detection system for risk of dropout. Monitor satisfaction with the study. Promote a stable research staff.

HIPAA = Health Insurance Portbility and Accountability Act.

When designing inclusion and exclusion criteria, one goal should be to align the criteria closely with the aims of the study and to assess whether the final enrolled population represents the target population. If the aim is to generalize results to older adults with complex health problems, then the criteria should allow their participation. Many research questions are designed to determine a main or most important effect. Although the specificity of the effect might be most precise by excluding the high proportion of older adults with potentially effect-modifying coexisting conditions, important main effects should be present despite the coexistence of modifying factors. Thus an intervention for heart failure or arthritis should have a detectable effect in the presence of other common coexisting conditions, such as coronary heart disease or anemia.

Advisory boards are an invaluable resource for investigators. They should consist of representatives of all interested parties and be reflective of the target population. Gatekeepers, who can influence access to participants, identify appropriate recruitment sites, and provide a general atmosphere of support for the study, should be included. These gatekeepers may vary with each study and include family, community leaders, and institutional leadership. Advisory boards can inform investigators about the nature and sources of potential participants. They can help anticipate the needs and concerns of providers, significant others, and institutions. They can also promote early awareness and feedback in larger community groups and frontline providers. Advisory boards can review study materials to identify user-friendly practices and help develop alternative recruitment and retention plans. Some advisory groups include representative participants who provide direct experience with the study and help identify key areas for monitoring and change.

One of the most important keys to successful recruitment and retention of older adults is to maximize the benefit:burden ratio. Benefits to participants include access to helpful treatments, services, or diagnostic tests; social interactions with staff or other participants; recognition of one's contribution; or even general altruism. Burdens include risks and costs. Risks, typically enumerated in consent forms, include health complications or discomforts from treatments or tests and loss of privacy. Costs, both direct and indirect, include the financial and time costs of participation to the participant and caregivers, travel requirements, and interference with competing obligations.

The benefit:burden ratio varies from study to study. The potential for benefit may be perceived as greater in a trial with an intervention that is thought to be potentially useful than it would be in an observational study. Burden is generally higher in studies involving sick or disabled persons who are more vulnerable to complications of study activities and who have more difficulty with travel, fatigue, and need for caregiver assistance with participation. Thus, during study design, the relationship between benefit: burden ratio and the degree of vulnerability in the target population must be carefully considered. For example, to include or retain older adults with physical or cognitive deficits in an observational study that lacks any potentially helpful treatment, benefits such as access to test results and socialization should be incorporated, and burdens such as discomfort, time, and travel should be limited. In contrast, older adults with physical or cognitive deficits might participate in an intervention study with a higher probability of personal benefit even if burdens from testing or travel are somewhat higher.

The best way to determine whether the benefit:burden ratio is appropriate is to explicitly enumerate all possible benefits and burdens, to seek feedback from advisory committees, and to perform pilot tests of recruitment that include brief interviews about perceived benefits and burdens. Ways to make study participation rewarding should be considered. This is especially important in unblinded clinical trials with no-treatment control groups, where failure to be assigned to a potentially useful intervention can lead to disappointment and dropout. To reduce burden, invasive or uncomfortable procedures might be secondary rather than primary outcomes and needed only in a subset of participants. Be especially aware of hidden participant barriers, including travel costs, need for assistance to participate, discomfort, and fatigue.[17] Also consider burdens to care providers and participating institutions. The research budget should include the costs of activities that maximize benefit and reduce burden. For example, the research protocol can call for home assessments by research staff to increase research participation by older adults unable to travel. This can reduce burden to older adults and reduce attrition and volunteer bias. The costs of home visits can be substantial and must include staff time for data collection and travel, as well as gasoline and vehicle use, portable equipment and supplies, and sometimes additional data and personnel security measures. Thus the additional costs of participant retention must be weighed in the context of the magnitude of the risk of bias in the study.

Finally, all aspects of recruitment, retention, and satisfaction with study procedures should be tracked. The investigator should estimate screening costs and the screen-to-recruit yield and have a backup plan in case of slow accrual. Participant concerns should be documented and addressed. Early-detection systems can identify subjects at a high risk of dropout, such as persons who repeatedly reschedule or who have had a recent serious illness. For these individuals, adaptation of study procedures that might make continued participation more attractive should be considered.

RECRUITMENT AND RETENTION OF OLDER ADULTS WITH HEALTH CONCERNS

Older subjects in representative samples typically have multiple health concerns that challenge successful recruitment and retention. Well-designed preplanned protocols can minimize exclusions and make the study sample as representative as possible. Commonly encountered health concerns in older adults, their effect on effective recruitment, and retention strategies are outlined in Table 2.

The effects from commonly encountered hearing and vision deficits can be limited with hearing amplifiers and written materials designed for the vision-impaired. Severe emotional problems such as major depression complicate recruitment and retention. The study design may include such persons after appropriate management of such conditions. Manual dexterity difficulties can usually be

Table 2. Specific Health Problems in Older Adults Affecting Recruitment and Retention

Health Problem	Problems	Potential Strategies
Hearing deficit	Difficulty hearing study descriptions and informed consent; unwillingness to do interviews	Use handheld hearing augmenters (in-person), provide telephone amplifiers (telephone), and use written materials liberally.
Visual dysfunction	Discomfort in being approached by a stranger for enrollment; difficulty reading study materials and performing written portions of assessment (including some cognitive tests)	Use large, bold name tags, prominent display of the sponsoring organization(s). Use large, bold fonts. Adapt interpretation of cognitive tests to adjust for visual problems.
Cognitive slowing	Enrollment, assessment, and other research tasks are more difficult, take longer, and cause frustration for the subject	Encourage and reassure subjects during enrollment and data acquisition; let them take the time they need. Enlist caregivers' assistance, as appropriate.
Frank dementia or delirium	Difficulty (or inability) understanding study procedures. Generally, such persons do not provide sole consent	Conduct communication and informed consent process through knowledgeable caregiver; consider whether formal guardian is required. Consider assent from primary subjects (at enrollment and over time) or consent from both (mildly) demented subjects and caregivers.
Major emotional decline	Apathetic, low motivation, inability to concentrate (anxiety and/or depression)	Notify PCP and facilitate treatment; if no PCP, facilitate referral. Have protocol for suicidal ideation. Consider recontact for enrollment after (successful) treatment. May enroll early using the above approach for persons with dementia or delirium.
Manual dexterity	Difficulty or inability signing name and completing cognitive screening tests or other written portions of protocols	Allow subjects to respond verbally and have someone record responses, if appropriate.
Multiple comorbidities or frequent hospitalizations	Difficulty catching subject at scheduled appointments for recruitment Follow-up data collection often difficult May complicate interpretation of results (what is actually affecting the outcome)	Arrange separate time to discuss study. Have protocols for managing missed follow-ups. Consider recruitment and assessments in hospital or postacute facility. Construct analytical strategy to properly examine effect of comorbidities on outcomes (e.g., use a simple sum[18,19] or weighted score of comorbidities;[20] examine each comorbidity's effect on outcomes[21]); adapt recruitment number as needed to accommodate.
Easy fatigability and shortness of breath (e.g., chronic obstructive pulmonary disorder, heart failure, terminal condition)	May be unwilling to enroll, or to continue, because of lengthy surveys and some physical tasks	Reassure during enrollment and periodically through the study. Separate tasks into smaller sections, allowing for breaks. Identify and address subjects' specific concerns.
Acute illness, severe pain	Unwillingness to discuss anything additional with study recruiter	Approach later. Allow subject or caregiver to take study documents home to review, with contact information to discuss questions that arise. Give postage-paid envelope to return signed consent. Separate tasks into smaller sections, allowing for breaks.
Homebound because of chronic conditions or advanced frailty	May be unable to attend study site or participate accurately via telephone	Construct assessment protocols to accommodate in-home assessments when needed.
Limited life expectancy	May feel participation is an unnecessary extra burden at a difficult time (recruitment) or drop out as symptoms worsen (retention) Assessment appointments missed	Make sure study design requires "terminally ill" subjects. Communicate crucial importance of including terminally ill subjects. Use "frequent hospitalization" strategies (above). Include realistic amount of attrition in sample size estimates.
Fall risk	May be reluctant to join or continue if they feel participation would increase their risk of falling	Decide if fall-prone subjects need to be included. If so, recognize them early in process; identify and address their concerns. Train research assistants to acquire physical assessment data safely without increasing fall risk.

PCP = Primary Care Physician

managed by allowing subjects to respond verbally. Cognitive impairment can make enrollment more difficult and increase dropouts if participants become frustrated with testing procedures. Amelioration strategies include sympathetic enrollment and testing staff, adequate time for them to understand study procedures, and appropriate involvement of caregivers. For subjects with dementia or delirium, communication and informed consent are typically conducted through the caregiver.

Multiple comorbidities, frequent hospitalizations, easy fatigability, shortness of breath, acute illness, and severe pain present additional challenges, but their potential adverse effect on recruitment and retention in aging research can be countered using creative approaches, such as permitting the subject and caregiver to take study documents home and returning the signed consent in a self-addressed stamped envelope; making other special arrangements, such as conducting research tasks in the hospital, postacute facility, or home; separating tasks into smaller sections and allowing breaks in between; and identifying and addressing subjects' health concerns.[22,23] The analytical plan must recognize the potential effects of these factors, including greater attrition, uneven follow-up intervals and missed appointments in nonattriters, and the need to effectively manage the confounding effect of comorbidities on the outcomes of interest. All these effects have implications for sample size and analytical power. When hypotheses include predicted effects of subgroups, such as individual comorbid conditions, then sample size typically needs to be considerably larger.

Investigators should carefully consider whether subjects with limited life expectancy are study candidates. If so, there are a number of implications for subject selection and study design.[24,25] If not, the potential effect on the sample's representativeness needs to be considered and exact exclusion criteria determined and applied. If fall-prone persons are included, they may need to be identified early and the protocol and interviewer training adapted accordingly. It is crucial that the research protocol provide specific instructions for field staff should they encounter conditions such as high blood pressure, self-neglect, elder abuse, suicidal ideation, loss of consciousness, severe shortness of breath, and other adverse medical conditions.

RECRUITMENT AND RETENTION OF OLDER ADULTS WITH SOCIAL AND CULTURAL ISSUES

Social and cultural considerations affect the recruitment and retention of all populations. Particular attention must be given to their effect on underrepresented populations of older adults (Table 3). Current population and immigration trends predict an increasingly diverse elderly population, with associated complexity in areas such as language, literacy, socioeconomics, and immigration and acculturation experience.[26] The challenge for researchers seeking to enroll representatively from a diverse older population is the careful and comprehensive planning required to know the target population and to prepare appropriate budget, staff, protocol, and materials for successful recruitment and retention.[27–32] There are no shortcuts to getting to know diverse populations. Neglecting the advance work can result in poor enrollment and create negative experiences that carry adverse consequences for future research recruitment.

It is likely that diverse populations will have specific and complex perceptions and experiences with the medical, academic, and research community at large, as well as the particular research institution. Establishing and maintaining an inclusive, bidirectional relationship with a community advisory board in advance of recruitment, and over the long term, is an effective way to establish trust and obtain guidance and insight. Researchers should be prepared to listen to community members speak about prior abuse and exploitation by researchers and to develop realistic plans to address their concerns and ensure the flow of information about the study or the study topic, both essential steps in establishing trust.[33] Conversely, members of these advisory boards may provide assurances, through letters or hosting presentations, of the study's importance to a particular community. As part of training, study staff must be prepared for questions about the legitimacy and importance of the study. Continuity of staff members in relations with the target population can be an important element in establishing trust. At the level of the individual participant, mistrust may be addressed by including gatekeepers, such as family members or housing managers, in the evaluation of the research opportunity. Advertisements, outreach plans, and study materials should serve equally to educate and inform the people who are influential in the target person's life. These educational efforts can relieve the uncertainty of potential participants and their caregivers. Such materials should be developed collaboratively with community advisers who can assist with appropriate cultural content.[34]

Cultural values may shape privacy concerns, and research staff might not anticipate these issues. It is important to listen to and address the specific concerns of potential subjects concerning privacy protection. Staff training must include knowledge about the technical aspects of privacy protection, as well as sensitivity to the fears of potential study participants.

Motivations for choosing to participate in a research study vary. Particular subgroups may wish to hear how the study aims to benefit them. For instance, will it contribute to the understanding of a particular health burden? The value of monetary stipends, meal vouchers, and reimbursements for transportation and parking may be more compelling to those with low incomes or for whom the expense or lost income required to participate may create financial hardship.

Language and literacy issues also require close attention. Parameters for the level of English language proficiency required to participate should be established, taking into account testing materials and reliance on telephone communication for scheduling, among other things. All study material, updates, and relevant survey forms must be available in the participant's language as well. Even in English-speaking populations, researchers are advised to use readability measures that indicate how difficult a reading passage is to understand. For example, the Flesch Reading Ease and the Flesch–Kincaid Grade Level are available as an option in Microsoft Word.

If the location of the testing site is outside the person's usual domain, it may be unfamiliar or intimidating.

Table 3. Specific Social and Cultural Barriers to Recruitment and Retention

Social or Cultural Barrier	Problems	Potential Strategies
Prerecruitment		
Perception of research or medical community	Prior actual or perceived abuse and exploitation by researchers Negative experiences with the medical establishment Reputation of research institution (may be seen as uncaring about welfare of minority communities) Concern that the research might interfere with their current doctor–patient relationship Fear of side effects or invasive test procedures	Work with or establish a community advisory board for guidance on community and culturally specific concerns. Introduce the study to the medical community in advance. Consider securing the endorsement of physicians whose patients may be targeted for the study. Plan for local dissemination of study results or other related information of value to the community. Ensure that study staff understands barriers, as well as the protections in place for the current study.
General mistrust	Questions about the legitimacy and importance of the particular study Increasing awareness of older adults about scams, making it difficult to discriminate between legitimate opportunities and others	Be aware of scams that target elderly people. Advise police in advance if recruiting door-to-door. Ask community leaders, housing, and service agencies to offer assurance about the legitimacy of the study. All study staff should have photo identification. Provide continuity in research staff/contacts.
Gatekeepers	Family members, caregivers, or service providers may influence the potential subject's participation decision and are especially influential in settings where they share language and culture with the potential participants and are relied on for their opinions.	Modify materials to potential participants and family members. Be flexible regarding willingness to communicate and work with a family member who feels they need to be involved with study process. A prerecruitment community education plan involving resident councils, housing staff, and other key contacts may relieve the uncertainty people feel about sharing personal information.
Culture	One approach does not fit all. Underserved individuals cannot be effectively reached without sensitivity to their cultural context. Meaningful experiences are interpreted within the sphere of one's own culture. Assumptions based on stereotypes or insufficient information will not work.	Build a culturally competent and inclusive research team, including members of the target community. Apply cultural knowledge to the recruitment process. Be aware of culture and assumptions of research institution and staff.
Recruitment and retention		
Privacy	Potential subjects may fear that their privacy will not be protected. Individuals living in assisted living or public housing may fear loss of services, discharge, or eviction. Immigrants may wish to avoid authorities and fear adverse consequences based on prior experience.	Train staff in all levels of privacy protection. Listen to and address the specific concerns of potential subjects concerning privacy issues.
Motivation	Potential participants may need help determining a salient reason to participate.	Plan to address motivations such as monetary stipends, free health screenings, meal vouchers, and newsletters, as well as altruistic motivations, such as contribution to future generations, and relevance of research topic to participant's ethnic/age group.
Language	Communication between staff and potential study subjects may be difficult or unreliable. Enrolling and testing multilingual participants is more complex than providing translations. Participants must receive the same information and telephone support in their language as English-speaking participants. Budgetary implications.	Know the demographics of the study area. Use standardized translations of instruments. Employ staff bilingual in languages common to the population. Use interpreters or a medical translation service. Set parameters on the level of English language proficiency required to qualify subjects.
Literacy	Half the adult population is functionally illiterate at the eighth-grade level.* Recent immigrants may have especially low literacy. The length and complexity of study materials, including consent forms, descriptive materials, and testing materials may constitute a barrier to participation.	Use "readability" guidelines to achieve a suitable grade level. Provide two versions of the consent form: one a shortened, bulleted summary for easier reference.†
Location of testing site	A site outside of participants' community may be unfamiliar or intimidating. This may be especially true for persons with limited English proficiency, those who reside in a cultural enclave in which they feel safer, or those who have mobility or sensory deficits.	Consider which research activities could be conducted in community settings, such as senior centers, housing sites, barber shops, and other places familiar to people. Provide home visits if possible.

(*Continued*)

Table 3. (Contd.)

Social or Cultural Barrier	Problems	Potential Strategies
Competing responsibilities	Potential subjects may have caregiving responsibly for spouses, adult children, or grandchildren. They may also have work, civic, or other commitments.	Provide flexible scheduling opportunities, such as extended hours. Consider options to assist participants with special circumstances.

* National Adult Literacy Survey of 1992.
† Association of American Medical Colleges guide "Universal Use of Short and Readable Informed Consent Documents: How Do We Get There?"

Mobility and safety concerns, as perceived by the older person, may bear on their participation. Spending money to travel to an area where no one else looks like or speaks the same language as the participant is a barrier. Offering community-based or home visits may significantly increase enrollment. Potential subjects, although retired, may still have competing responsibilities, especially in extended ethnic families.[35] They may also have work, civic, church, or other commitments. For these people, flexible scheduling opportunities, such as extended hours, will increase likelihood of participation.

RECRUITMENT IN INSTITUTIONAL SETTINGS

Older adults in institutional settings form an important segment of the aging population. The number of senior citizens receiving care in nursing homes in the United States increased from 1.28 million in 1977 to 1.5 million in 2006.[36] In addition, approximately 33% of all adults admitted to acute care hospitals are aged 65 and older (and they account for nearly 50% of all acute hospital bed-days).

Recruitment and Retention in Nursing Homes

Recruitment of older adults in institutional settings first requires acceptance from the institutions' leadership and staff.[37–39] Acquisition of informed consent from family, caregivers or other designated durable powers of attorney instead of the patient is nearly universal. Institutions are variable in their interpretation of the Health Insurance Portability and Accountability Act as it applies to research. Research projects and findings with any perceived or real potential to affect their state and Joint Commission on the Accreditation of Healthcare Organizations inspections are viewed with some skepticism.

Nursing home staff, residents, and their families often voice mistrust and skepticism about research in general. Nursing home residents are a vulnerable population, and staff and residents' families feel a need to protect the residents from being "exploited" or "being experimented on." In addition, staff may feel threatened by outsiders who will be observing their care routine, as well as by the perception that a research project may lead to "more work." These apprehensions can lead to distorted views on research in general and can be a huge barrier to research participation. Other research methodological challenges include uneven medical record documentation, lack of laboratory test results, high attrition secondary to death, disability and transfers to acute care, and cluster effects if conducting research on multiple residents in more than one facility.

Despite these concerns, a meticulous, methodological, and thoughtful approach can overcome barriers to study recruitment and retention of older adults in nursing facilities. There are a few proven, simple, and practical strategies. First, researchers should generally start by contacting the facility administrators and directors by telephone and then following up with written communication. Subsequently, a face-to-face meeting should be set up with a request to meet with as many individuals on the facility's management team as possible. Often the Administrator, Director of Nursing, and charge nurses attend the meeting. Some facilities like to have their ethics personnel attend the initial meeting. An attractive, informative brochure with a simplified research protocol, consent form, and some relevant prior research should be shared with the facility's representatives at the first meeting. Published prior research directly relevant to their patient care program strongly argues for facility participation in the project.

Discussion of financial costs and staff time should be an integral part of the first meeting. Ideally, facility representatives should be reassured whenever possible that their facility will not incur any costs. Reimbursement for staff time is always desirable. Institutional review board (IRB) approval from the institution initiating the research should be obtained before meeting with facilities, if possible, and informed patient consent and privacy concerns should be discussed during the first meeting. Consideration should be given to obtaining a Federal Wide Assurance (FWA) when working in facilities that do not have their own IRB. The FWA establishes that the facility lacking its own IRB will operate under guidelines established for the protection of human subjects in research and that the IRB of the institution initiating the project will have oversight over the human protections in the project. It also is valuable to ask questions about the facility and to take time to learn about its mission, philosophy of care, and residents and to tour the premises if possible. Many facility managers take great pride in their programs and like to showcase their facilities. The initial meeting with facility staff should be followed up with communications by telephone or face-to-face to address further questions.

Nursing home staffs appreciate recognition of their efforts. Awarding certificates or plaques of study participation are ways to demonstrate this recognition. Quarterly updates and quarterly visits by the principal investigator and members of the research team assist in retention of these facilities for future research projects. Cards and

gift baskets around holiday times or special events demonstrate that the research team values the facility and staff involvement. Occasional lunch meetings or breakfast discussions (with food provided by the research team) allow for provision of project updates and other information that can be useful in resident care and at the same time are a way of letting the facility know that the research team is involved with the facility and willing to assist in promoting its goals. These updates also help facility leaders and staff members perceive research as real, tangible, and ultimately beneficial for patient care.

At least three issues transcend the specific procedures outlined above. The first is the matter of reciprocity. How will the proposed research project enhance the quality of care for their residents and how can it benefit the facility? The second is respect for the facility staff's work and dedication to providing care with limited resources. Both of these issues need to be addressed with facility leaders and staff as part of the initial meeting and throughout the duration of the study. Lead investigators, senior staff, and others associated with the project need to communicate this respect as part of their interaction with facility staff at all levels. The third issue, and perhaps more related to the conduct of the research project itself, is the need to be as flexible as possible while still maintaining the integrity of the scientific protocol. Nursing home researchers need to balance accommodating the needs of the facility and staff with the need to maintain the integrity of the study protocol.

Recruitment and Retention in Acute Care

Observational and interventional investigations of older adults in acute care are important yet challenging.[1,40,41] Conditions such as delirium, deconditioning, and functional decline are common and may jeopardize long-term independent functioning. One of the major challenges is the ever-shortening length of hospital stay. The "sicker, quicker" dictum has two ramifications for researchers. First, there is an increasingly short time interval to screen, approach, and enroll patients. Second, because hospitalized patients have high medical acuity, they may be less receptive to study participation. Research protocols should be designed to address both of these challenges.

As with the nursing home setting, the hospital is a culture in itself, and successful researchers must obtain acceptance from the key decision-makers. Nurses have traditionally been the primary leaders of the acute hospital culture, and it is important to obtain nursing support for research protocols, especially those that require nursing involvement, either for data collection or for delivery of interventions. Another group with rising influence in this culture is hospital medicine physicians. In many hospitals, these physicians provide the bulk of care for the majority of medical inpatients and also provide consultation for many surgical patients. For research on surgical patients, participation of the attending surgeons is paramount. Finally, the primary care physician, although perhaps not directly involved with hospital care, can often influence patient participation. Given the numbers of people involved, effective communication is essential.

Because length of stay is so short, rapid identification of eligible patients and timely approach for study enrollment are other critical features of successful research in the hospital setting. Fortunately, many hospitals, especially academic centers, have sophisticated computerized systems that enable rapid screening for eligibility criteria. Electronic screening is much easier than using the paper record and should be integrated into protocols where possible. Once an eligible subject is identified, approach for research participation should be coordinated with the nurses and physicians to ensure that it is timely and not disruptive to clinical care. A calm, relaxed setting is more conducive to research recruitment than one in which the patient is being rushed off to a test or surgery.

Because hospitalized patients are very sick and may also be delirious, family members are often involved as a substitute decision-maker or in an advisory role.[42] Family members may understandably be protective and initially skeptical about any research project that adds burden to an already difficult situation. Therefore, it is particularly important to ensure that the benefit:risk ratio is favorable. Interviews with patients should not be excessively long (15 minutes may be the limit), and opportunities for rest or returning at a later time should be built into the protocol. Many hospitals routinely collect data on activities of daily living and comorbidities, so these data elements can often be obtained from the medical record, thereby shortening the face-to-face interview time. Phlebotomy should be minimized by coordinating with clinical blood draws if possible and by minimizing the total quantity of blood drawn. The risks of any experimental interventions should be in proportion to the condition being treated and take into consideration the multiple comorbidities and medications typical of patients in the hospital setting.

Because the period of hospital care is often so brief, research subjects enrolled in hospitals are often followed into postacute care. Following research subjects across the continuum of care poses a retention challenge. It is important to review the research protocol schedule carefully with the patient or family member and make plans for the first posthospital contact while the patient is still in the hospital. Additional strategies to increase subject investment in the study, and therefore the likelihood of retention, include providing a partial stipend for completion of the in-hospital portion of the study and providing a study-related gift along with an appointment card for the next contact. Finally, plans for postdischarge care may change, and it is important to obtain contact information from at least three relatives or friends to reduce the likelihood that a patient is "lost to follow-up."

CONCLUSION

Successful recruitment and retention of older adults in research is crucial to inform clinical practice. There are numerous challenges to successful recruitment, but these can be overcome by obtaining acceptance from all interested parties; timely screening, identification, and approach of eligible patients; careful evaluation of the benefit:burden ratio to be sure it is appropriate for the target population and setting; and putting strategies in place to ensure successful retention across the continuum of care. These strat-

egies should be addressed at the earliest stage of planning, with appropriate contingencies to address below-target recruitment. With these elements in mind, clinical research in older adults can be successful and rewarding.

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REFERENCES

1. Lee PY, Alexander KP, Hammill BG et al. Representation of elderly persons and women in published randomized trials of acute coronary syndromes. JAMA 2001;286:708–713.
2. Masoudi FA, Havranek EP, Wolfe P et al. Most hospitalized older persons do not meet the enrollment criteria for clinical trials in heart failure. Am Heart J 2003;146:250–257.
3. Cohen-Mansfield J. Recruitment rates in gerontological research: The situation for drug trials in dementia may be worse than previously reported. Alzheimer Dis Assoc Discord 2002;16:279–282.
4. Witham MD, McMurdo ME. How to get older people included in clinical studies. Drugs Aging 2007;24:187–196.
5. Bandyopadhyay S, Bayer AJ, O'Mahony MS. Age and gender bias in statin trials. Q J Med 2001;94:127–132.
6. Gill SS, Bronskill SE, Mamdani M et al. Representation of patients with dementia in clinical trials of donepezil. Can J Clin Pharmacol 2004;11: e274–e285.
7. Adamis D, Martin FC, Treloar A et al. Capacity, consent and selection bias in a study of delirium. J Med Ethics 2005;31:137–143.
8. Watson JM, Torgerson D. Increasing recruitment to randomized trials: A review of randomized clinical trials. BMC Med Res Method 2006;6:34.
9. Puffer S, Torgerson D. Recruitment difficulties in randomized controlled trials. Control Clin Trials 2003;24:S214–S215.
10. Fitzpatrick AL, Fried LP, Williamson J et al. Recruitment of the elderly into pharmacologic prevention trial: The Ginkgo Evaluation of Memory study experience. Control Clin Trials 2006;27:541–553.
11. Hutchins LF, Unger J, Crowley JJ et al. Underrepresentation of patients 65 years of age or older in cancer-treatment trials. N Engl J Med 1999;341: 2061–2066.
12. Kravitz RL, Duan NH, Braslow J. Evidence based medicine, heterogeneity of treatment effects, and trouble with averages. Millbank Q 2004;82:661–687.
13. Avorn J. Including elderly patients in clinical trials. BMJ 1997;315: 1033–1034.
14. Witham MD, McMurdo ME. How to get older people included in clinical studies. Drugs Aging 2007;24:187–196.
15. Peterson ED, Alexander KP, Malenka DJ et al. Multicenter experience in revasularization of very elderly patients. Am Heart J 2004;148:486–492.
16. Cameron JH, Williams BO. Clinical trials in the elderly. Should we do more? Drugs Aging 1996;9:307–310.
17. Gill TM, McGloin JM, Gahbauer EA et al. Two recruitment strategies for a clinical trial of physically frail community-living older persons. J Am Geriatr Soc 2001;49:1039–1045.
18. Miller DK, Malmstrom TK, Andresen EM et al. Adverse outcomes and correlates of change in the Short Physical Performance Battery over 36 months in the African American health project. J Gerontol A Biol Sci Med Sci 2008;63A:487–494.
19. Schootman M, Andresen EM, Wolinsky FD et al. Neighborhood conditions and risk of incident lower-body functional limitations among middle-aged African Americans. Am J Epidemiol 2006;163:450–458.
20. Charlson ME, Pompei P, Ales KL et al. A new method of classifying prognostic comorbidity in longitudinal studies: Development and validation. J Chronic Dis 1987;40:373–383.
21. Wolinsky FD, Miller DK, Andresen EM et al. Health related quality of life in middle aged African Americans. J Gerontol B Psychol Sci Soc Sci 2004;59B: S118–S123.
22. Counsell SR, Callahan CM, Buttar AB et al. Geriatric Resources for Assessment and Care of Elders (GRACE): A new model of primary care for low-income seniors. J Am Geriatr Soc 2006;54:1136–1141.
23. Miller DK, Carter ME, Miller JP et al. Inner-city older blacks have high levels of functional disability. J Am Geriatr Soc 1996;44:1166–1173.
24. Rinck GC, van den Bos GA, Kleijnen J et al. Methodologic issues in effectiveness research on palliative cancer care: A systematic review. J Clin Oncol 1997;15:1697–1707.
25. Jordhøy MS, Kaasa S, Fayers P et al. Challenges in palliative care research; recruitment, attrition and compliance: Experience from a randomized controlled trial. Palliative Med 1999;13:299–310.
26. U.S. Census Bureau, Population Projections of the United States by Age, Sex, Race, Hispanic Origin, and Nativity: 1999 to 2100; published January 2000 [on-line]. Available at http://www.census.gov/population/www/projections/natproj.html Accessed April 1, 2008.
27. Woods DV, Montgomery SB, Herring PR. Recruiting black/African American men for research in prostate cancer prevention. Cancer 2004; 100:1017–1025.
28. Coleman E, Tyll L, LaCroix A et al. Recruiting African American older adults for a community-based health promotion intervention: Which strategies are effective? Am J Prev Med 1997;13(Suppl 2):51–56.
29. Gorelick P, Harris Y, Burnett B et al. The recruitment triangle: Reasons why African Americans enroll, refuse to enroll, or voluntarily withdraw from clinical trial. J Natl Med Assoc 1998;90:141–145.
30. Trauth JM, Jernigan JC, Siminoff LA et al. Factors affecting older African American women's decision to join the PLCO cancer screening trial. J Clin Oncol 2005;23:8730–8738.
31. Giuliano AR, Mokuau N, Hughes C et al. Participation of minorities in cancer research: The influence of structural, cultural, and linguistic factors. Ann Epidemiol 2000;10:S22–S34.
32. Stahl SM, Vasquez L. Approaches to improving recruitment and retention of minority elders participating in research. J Aging Health 2004;16: 9S–17S.
33. Curry L, Jackson J. The science of including older ethnic and racial group participants in health-related research. Gerontologist 2003;43:15–17.
34. Levkoff S, Sanchez H. Lessons learned about minority recruitment and retention from the Centers on Minority Aging and Health Promotion. Gerontologist 2003;43:18–26.
35. Blustein J, Chan S, Guanais FC. Elevated depressive symptoms among caregiving grandparents. Health Serv Res 2004;39:1671–1689.
36. National Center for Health Statistics, United States 2006 [on-line]. Available at http://www.cdc.gov/nchs/data/hus/hus06.pdf#116 Accessed February 20, 2008.
37. Kiel DP, Magaziner J, Zimmerman S et al. Efficacy of a hip protector to prevent hip fracture in nursing home residents: The HIP PRO randomized controlled trial. JAMA 2007;298:413–422.
38. Loeb M, Brazil K, Lohfeld L et al. Effect of a multifaceted intervention on number of antimicrobial prescriptions for suspected urinary tract infections in residents of nursing homes: Cluster randomized controlled trial. BMJ 2005;331:669–673.
39. Mody L, McNeil SA, Kauffman CA et al. Mupirocin prophylaxis for staphylococcal infection in nursing homes. Clin Infect Dis 2003;37:1467–1474.
40. Inouye SK, Bogardus ST, Charpentier PA et al. A multicomponent intervention to prevent delirium in hospitalized older patients. N Engl J Med 1999;340: 669–676.
41. Marcantonio ER, Goldman L, Mangione CM et al. A clinical prediction rule for delirium after elective noncardiac surgery. JAMA 1994;271:134–139.
42. Connel CM, Shaw BA, Holmes BA et al. Caregivers' attitudes towards family members' participation in Alzheimer's disease research: Implications for recruitment and retention. Alzheimer Dis Assoc Discord 2001;15:137–145.