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DOI: 10.1377/hlthaff.2013.1314
HEALTH AFFAIRS 33,
NO. 4 (2014): 574–579

Obstacles And Opportunities In Alzheimer's Clinical Trial Recruitment

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ABSTRACT The 2012 National Plan to Address Alzheimer's Disease set an ambitious goal: to both prevent and effectively treat Alzheimer's disease by 2025. To reach this goal, tens of thousands of volunteers will be needed to participate in clinical trials to test promising new interventions and therapies. To mobilize these volunteers and their health care providers to participate in future clinical trials, it will be necessary to achieve a better understanding of the barriers keeping people from participating in Alzheimer's research; form innovative partnerships among researchers, health care and social service providers, and the public; and develop more-effective outreach strategies. In this article we explore recruitment issues, including those unique to Alzheimer's studies, and we suggest concrete steps such as establishing a structured consortium linking all of the registries of Alzheimer's trials and establishing new partnerships with community and local organizations that can build trust and understanding among patients, caregivers, and providers.

Forty years of intensifying research have brought an explosion of new knowledge about Alzheimer's disease. Studies in genetics; basic biology; drug discovery; and translational, clinical, behavioral, and social science research have helped redefine the disease and clarify ways to approach the study of treatments and prevention.[1] Yet despite significant progress in understanding the disease, there is still no effective treatment or cure for Alzheimer's.

The progress of research to date is not only the product of a cadre of dedicated scientists. In large part, it comes from the thousands of volunteers who participate in epidemiological and clinical studies, taking part in neuropsychological tests of memory and cognitive function; contributing DNA, blood, and cerebrospinal fluid samples; and undergoing brain scans. These study participants are why we know what we know about Alzheimer's disease.

The relationship between Alzheimer's researchers and the public is at a critical juncture. More than 150 clinical trials and studies in the United States, sponsored by government, private industry, and research foundations, seek at least 70,000 participants to enroll.[2] Using the conservative rule of thumb of ten people screened for each enrolled participant, researchers will need to screen upward of 700,000 potential volunteers to help investigate promising therapies emerging from the discovery of newer targets and risk factors.

Pharmaceutical Research and Manufacturers of America (PhRMA), in its report on Alzheimer's drug development, noted that recruiting and retaining clinical trial participants is "currently the greatest obstacle to developing new Alzheimer's treatments."[3] A number of factors related to research recruitment generally and to Alzheimer's trials specifically must be addressed in the near future if obstacles to re-

cruitment are to be overcome. Furthermore, upcoming trials to test interventions at a presymptomatic stage of the disease, when it is thought treatment will be more effective, will seek a new cohort of participants who are cognitively healthy but at risk for developing Alzheimer's.

The National Plan to Address Alzheimer's Disease, introduced by the Department of Health and Human Services in 2012, directs the United States to "increase enrollment in clinical trials and other clinical research through community, national, and international outreach," including stepped-up enrollment of racial and ethnic minorities in Alzheimer's studies.[4] We outline some of the challenges to increased enrollment and offer specific solutions to enhance awareness and facilitate participation at all stages of the disease in the urgent search for a cure.

Challenges To Alzheimer's Trial Recruitment

Recruitment has historically been a major bottleneck in conducting clinical research, specifically for clinical trials.[5,6] Studies of Alzheimer's disease research participation have identified factors that inhibit recruitment. These include primary care physicians' lack of capacity and resources to assess cognition and refer patients to research; barriers to participation for underrepresented communities, such as lack of cultural sensitivity; the requirement for a study partner (someone who can report on cognitive changes) for most Alzheimer's trials; and the use of invasive procedures, such as lumbar punctures or brain imaging with an injected tracer agent.

BARRIERS FOR PRIMARY CARE PROVIDERS The majority of people with cognitive impairment or concerns about their memory will first encounter a primary care provider in an outpatient setting. Research shows that providers' lack of time, lack of available diagnostic clinical tools, concern over risks to patients of experimental protocols, and lack of proximity to a research center, along with patient comorbidities, are among the barriers physicians cite as challenges to Alzheimer's clinical trials referral.[7]

In the United States, time and productivity partially rule the health care provider's day. The provider is compelled to prioritize the ten to fifteen minutes that are typically available for interacting with each patient. Those at greatest risk for late-onset Alzheimer's disease are people ages sixty-five and older, who often have multiple chronic conditions such as hypertension, diabetes, heart disease, and cancer, some of which may contribute to dementia risk. Confronted with this panoply of conditions juxtaposed against the lack of effective interventions for Alzheimer's and lack of diagnostic and support resources, providers understandably favor treatment of overt diseases or screening for illnesses for which there are clear and available diagnostic procedures and treatments.

To refer a patient for a clinical trial, the clinician must recognize that the patient might have or be at risk for cognitive impairment. Yet some studies show that physicians are unaware of cognitive impairment in more than 40 percent of their cognitively impaired patients.[8] This may reflect, in part, the fact that health care leaders and organizations hold varying opinions about the value of clinical screening for cognitive impairment.

On the one hand, estimates suggest that there may be benefits to screening and diagnosis for providers to better manage care for their impaired patients and for patients and families to understand the cause of impairment and be able to plan for the future.[9] Given the lack of treatment options, detection of cognitive impairment also offers an opportunity to refer patients to research studies that may contribute to understanding the disease and future treatment options. On the other hand, there are significant costs associated with screening for cognitive impairment in people older than age sixty-five. One investigator found this cost to be as much as $39,000 per case detected, based on the cost of the screening process and diagnostic assessment for a typical primary care physician.[10]

Physicians' lack of awareness of research opportunities and concerns about referring elderly patients also present barriers to recruitment. A recent European study found that physicians had a low awareness of clinical research opportunities for their patients but expressed a high willingness to refer patients to such studies.[11] One small US study found that physicians were reluctant to refer patients because of concerns about perceived harm (such as risk of invasive procedures and stigma of diagnosis in the absence of effective treatment) and fear of losing patients to other providers caring for patients in the clinical research setting.[12]

Finally, primary care providers are responsive to the clinical care guidelines issued by highly regarded expert panels, which to date have not come to consensus on the benefit of routine screening for cognitive impairment. The US Preventive Services Task Force's recent draft recommendations on routine screening for dementia concluded that the evidence should be rated I, indeterminate, based on a meta-analysis that found no empirical evidence that screening improves decision making.[13,14] A National Institutes of Health (NIH)–funded study is under way to

shed more light on this question, weighing the benefits and harms of dementia screening in a diverse population of older adults attending primary care clinics.[15]

BARRIERS TO PARTICIPATION BY UNDERREPRESENTED POPULATIONS Clinical trials struggle to include people from diverse racial and ethnic backgrounds, traditionally underrepresented in research participation. Barriers to their participation may include understandable and long-standing mistrust of the medical establishment and particular local academic research institutions; language; logistical barriers and cost (for example, time, travel); lack of cultural sensitivity and ethnic and cultural similarity of staff to participants; and invasive procedures.[16] This is particularly concerning because many of these groups are considered to be higher risk for dementia.[17] In addition, many studies' exclusion criteria eliminate people with comorbid conditions that are prevalent in some racial or ethnic groups, such as diabetes and vascular disease.

STUDY PARTNER REQUIREMENT Alzheimer's disease research typically requires the participation of a study partner who knows the participant well enough to provide accurate information about daily functioning. A retrospective analysis of six Alzheimer's Disease Cooperative Study (ADCS) studies reported that two-thirds of the study partners were spouses.[18] However, recent data suggest that an increasing number of older people with dementia are without a spouse or live alone.[19] This analysis found that in Alzheimer's studies, the dropout rate was somewhat higher among participants with nonspousal study partners. Further research and specific strategies are needed to facilitate participation in trials among those who do not have a spousal caregiver, as those individuals form the majority of the population of potential volunteers.[20]

INVASIVE PROCEDURES Although clinical trials for other diseases involve invasive procedures, current Alzheimer's disease research may involve both brain scans with radioactive materials and lumbar puncture. In some cases, these procedures are part of screening for inclusion in the study before a potential participant is even accepted into a trial. Further, such procedures may occur on multiple occasions throughout a study. A few therapeutic candidates currently being tested (such as solanezumab, a monoclonal antibody, which in preclinical studies promoted clearance of amyloid [protein] deposits from the brain, characteristic of Alzheimer's)[21] will require infusions to administer the drug, which can take many hours. Finally, because the disease involves memory and thinking, there are frequently hours of cognitive assessments, also repeated throughout the course of the investigation. The extensive time and effort involved in taking part in Alzheimer's studies can give pause and ultimately deter potential volunteers and their study partners or family members.

New Challenge: Presymptomatic Alzheimer's Disease Trials

Previously, most interventions were tested in people with overt memory loss, from mild cognitive impairment[22] to more severe symptoms. Given the growing body of evidence suggesting that underlying pathology precedes the onset of clinically detectable Alzheimer's disease by a decade or more, researchers are now testing interventions targeting the preclinical or presymptomatic phase of the disease.[6] This focus on people who are free of clinical symptoms but at risk for Alzheimer's disease because of either genetic risk or evidence of Alzheimer's-related brain changes is new territory and will require genetic or biomarker screening of large numbers of volunteers.

One groundbreaking prevention trial, the Anti-Amyloid Treatment in Asymptomatic Alzheimer's Disease, or A4, trial, will start in 2014. The A4 trial is a large, multisite study testing the anti-amyloid immunotherapy solanezumab in 1,000 symptom-free but at-risk older volunteers who have abnormally high levels of the beta amyloid protein in the brain as detected by brain imaging. Similarly, the newly funded Alzheimer's Prevention Initiative APOE4 (API APOE4) Trial will test an anti-amyloid agent in 650 cognitively healthy people ages 60–75 who are at genetic risk for late-onset Alzheimer's. Prevention trials such as A4 and API APOE4 face the challenge of recruiting and screening thousands of people who have not been diagnosed with disease.

The requirement that a participant demonstrate a possible Alzheimer's-like biomarker profile or "positive" biomarker such as high amyloid burden, or genetic risk such as APOE4, or both, to enter a trial will further complicate recruitment. Little research has been done to determine how healthy people are affected by learning their Alzheimer's risk status. It may be necessary to establish two tiers for recruitment, the first being a general registry of interested people and a second consisting of those willing to undergo biomarker or genetic testing if called.[20] Once participants are enrolled in these trials, retaining them will be a challenge. Factors such as study invasiveness and participant burden may be an even greater issue in a symptom-free, albeit at-risk, population.

Strategy Recommendations

To help address challenges to participation, the National Institute on Aging (NIA) at the NIH issued a formal Request for Information (RFI) in November 2012 on ways to increase enrollment in clinical trials for all stages of dementia.[23] Public and expert comment focused on several strategies: bridging the gap between research and clinical care; expansion or coordination of existing registries; modification of trials to increase access for participants and caregivers; collaborations among researchers, clinicians, providers, advocates, and others to increase awareness and build trust; and relationships with local and particularly underrepresented communities.

BRIDGING THE GAP BETWEEN RESEARCH AND CLINICAL CARE More can be done to partner researchers and clinicians, since both are interested in the development of interventions to prevent or treat Alzheimer's disease. Proactive efforts, such as educating physicians about specific local trials and providing access to research experts, would help bridge the gap between research and primary care and engender patients' trust of scientific research when the message is delivered by a trusted clinician in a primary care setting.

Studies show that, for example, proximity to a research center can influence the likelihood of Alzheimer's disease trial referral.[7] Measures to increase the knowledge of primary care providers about research at local centers could assist them in making referrals. Additionally, primary care providers' concern over risks to patients of experimental protocols[13,14] could be addressed by additional education of patients and providers about the potential benefits and risks of trials. A recent European Union/United States task force report endorses this approach.[24]

Alzheimer's disease biomarkers and the new diagnostic criteria may also help minimize the number of subjects needed for trials by allowing recruitment of more appropriately targeted subjects.[25] Concerns about losing patients through clinical research participation may be overcome by developing trusting relationships between researchers and primary care providers.

CONNECTING REGISTRIES As the need for more participants in Alzheimer's clinical trials expands, the effort to recruit the right participant for the right trial at the right time and location becomes ever more critical.[6] Increasing public awareness about the urgency of research—sometimes sparked by news reports—often results in spikes in interest in participation at study sites, but many expressing interest may not meet criteria for a current trial in the local area.

A number of registries have been established at local clinics and research sites to help streamline the recruitment process, offering a pool of screened potential participants who can be invited to join new trials.[26,27] New efforts are also under way at the national level—most notably, the Alzheimer's Prevention Registry (http://www.endalznow.org/)—to enlist large numbers of people for future prevention trials. Other programs, such as the Alzheimer's Association's TrialMatch (http://www.alz.org/research/clinical_trials/find_clinical_trials_trialmatch.asp), the NIH-funded ResearchMatch (https://www.researchmatch.org/), and the Brain Health Registry (http://brainhealthregistry.org), similarly seek to enroll people in a database to be matched to current and future trials as they arise and to communicate regularly with registry enrollees to keep them engaged and aware of Alzheimer's research. Online patient communities and support groups (such as PatientsLikeMe) may be another source of partnership for recruitment. Coordination between national group registry efforts and local site registries could be an effective strategy for expanding the pool of participants where they are needed and drawing on the strengths of both.[28]

Registries for Alzheimer's and cognitive impairment trials are a local, regional, and national patchwork. The NIA-funded Alzheimer's Disease Centers and Alzheimer's Disease Cooperative Study sites offer some coordination and ongoing contact with potential volunteers, but they are limited in number and geographic scope. One possible direction, submitted in response to the NIA's RFI, is a government and industry collaboration to support and establish a structured consortium of existing registries. The consortium would ideally include established longitudinal aging studies, memory and cognitive impairment cohorts, and private medical practices that specialize in memory, for which subjects have been enrolled and characterized but have not previously been used for Alzheimer's-related trial recruitment. Linking this broader group of research sites and cohorts into a larger network; instituting data standards; and assembling an inventory of study site populations, capabilities, and equipment could greatly increase the efficiency and speed of trial recruitment by building on existing resources. This effort could also increase the number of available trial sites, which has been strongly recommended as the most straightforward approach to improving the rate of trial enrollment.[29]

ACCOMMODATING PARTICIPANTS' NEEDS Researchers also must consider how to accommodate the location and time needs of participants and study partners, particularly those who are not the participant's spouse, such as adult chil-

dren, other relatives, and friends. For example, nonspousal caregivers may have work or other family responsibilities that preclude accompanying the participant to a clinic visit during usual business hours. To better serve participants and their study partners directly, study sites can be conveniently located, or, more effectively, study visits can take place in a participant's home.[11,30] Such alterations in study design, such as in-home visits or altering the likelihood of receiving a drug versus placebo, may prove cost-effective by improving the recruitment and retention of participants with nonspousal study partners and help build trust to gain participation from underrepresented groups.

Awareness, Outreach, Building Trust

Multiple studies across diverse populations have demonstrated that successful and effective clinical trial recruitment is a long-term effort, dependent on raising awareness about research participation opportunities, building relationships and trust between researchers and local communities, and taking an inclusive approach to trial design.[27,31–34] Overcoming barriers, such as lack of awareness or understanding about research and historical mistrust of the research community, requires a sustained effort. Yet researchers are typically funded on a trial-by-trial basis and may not have the resources needed to build sustained relationships and infrastructure with the community.

Some steps are being taken at the federal level to help build awareness and recruit participants. The NIH has established a web-based resource, NIH Clinical Research Trials and You (http://www.nih.gov/health/clinicaltrials/index.htm) and seeks to promote awareness of and provide information about clinical trials. Another transagency effort, Recruiting Older Adults into Research (ROAR), is under way, with the NIH, the Administration for Community Living, and the Centers for Disease Control and Prevention working to raise awareness about clinical trials and increase participation among older adults by communicating through aging services providers and the public health network.

The most effective strategies, however, may take place on the local level. Investigators who are successful in recruitment report that on-the-ground, sustained community relationships are the key to engagement. They cite building partnerships with local organizations, identifying and working with clinical trial advocates within a community, and employing outreach staff that mirror the racial and ethnic identity of the community. One Alzheimer's research center emphasizes the idea of "giving first" (for example, making community presentations, performing health screenings at health fairs, or providing clinical services in convenient locations) before expecting a return from partners or potential participants.[33]

Conclusion

Opportunities for improved understanding remain. The challenge of overcoming physicians' reluctance to screen for cognitive impairment will require additional study, as will the impact of imaging studies and lumbar punctures on the willingness to refer patients for Alzheimer's disease clinical trials.[24] Better insights are needed into what motivates patients and physicians to participate in clinical trials and strategies to overcome cultural and psychological barriers.

While there is much to learn about what enhances or inhibits Alzheimer's research recruitment, there are effective strategies that can be put into action now. And there is evidence to indicate that with awareness and favorable conditions, Americans are ready, willing, and able to join researchers in studies for Alzheimer's disease prevention and treatment. A recent Research!America poll found that although 86 percent of Americans have not participated in research, 76 percent said that they are very or somewhat likely to volunteer for a research study, particularly if referred by a physician.[35]

Together, the community of researchers, individuals and families, clinicians, and the public can address barriers and improve the prospects for clinical trials. By doing so, the chances of finding ways to prevent or effectively treat Alzheimer's disease as soon as possible can be greatly increased. ■

NOTES

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