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FROM THE ALZHEIMER'S ASSOCIATION INTERNATIONAL CONFERENCE 2018

NEW NATIONAL STRATEGY FOR RECRUITMENT AND PARTICIPATION IN ALZHEIMER'S DISEASE CLINICAL TRIALS TAKES SHAPE

Local Programs Show Important Success Recruiting African Americans into Alzheimer's Research Studies

Chicago, July 23, 2018 – Increased public and private investments in Alzheimer's disease research have brought about a proliferation of potential therapeutic targets. Drugs and other interventions to hit those targets are moving into clinical trials. Other studies are helping us better understand risks for dementia and examining best approaches to clinical and long-term care. Yet engagement and participation has not kept pace with the acceleration of research and great need for volunteers.

The impact of low participation impedes progress toward generating study results, keeping potentially effective therapies aching further away from people with and at risk for dementia, and their caregivers.

With the growing global epidemic of Alzheimer's disease and other dementias, and the recent string of negative clinical trial results, the urgency to correct this situation has never been greater.

At the Alzheimer's Association International Conference (AAIC) 2018, representatives of the National Institutes on Aging (NIA) at the National Institutes of Health (NIH) reported progress on the National Strategy for Recruitment and Participation in Alzheimer's Disease Clinical Research, the effort convened to outline practical, proactive approaches to help study sites and researchers recruit and retain volunteers for Alzheimer's and other dementia research studies.

To devise the strategy, the NIA, with facilitation by the Alzheimer's Association, brought together experts and collected insights from a collaborative of government, private, academic, and industry stakeholders, as well as from individuals with Alzheimer's and other dementias, caregivers, and study participants.

"Perhaps most fundamental is the need to understand, in a careful and sensitive way, what motivates and facilitates — or impedes — participation by individuals from diverse communities in Alzheimer's and other dementias research," said Marie A. Bernard, MD, geriatrician and Deputy Director of the NIA.

"The national strategy focuses on the fact that all recruitment and participation is local, and that it is a shared responsibility with shared benefits. Fighting Alzheimer's disease and related dementias depends on us all," Bernard said.

“People with dementia, caregivers, and a wide variety of other volunteers are needed today to help advance Alzheimer’s research,” said Heather Snyder, PhD, Alzheimer’s Association Senior Director of Medical and Scientific Operations. “By participating in clinical research, you can help to accelerate progress and provide valuable insights into potential treatments and preventions, successful caregiving, and better understanding and managing our Alzheimer’s risk.”

National Strategy Development: A Collaborative Effort

The new National Strategy — currently a work in progress — is an outgrowth of the National Plan to Address Alzheimer’s Disease, which calls for expanded research aimed at preventing and treating Alzheimer’s disease. Specific actions outlined in the National Plan seek to (1) increase enrollment in clinical trials and other clinical research through community, national, and international outreach, and (2) monitor and identify strategies to diversify enrollment in Alzheimer’s disease studies.

Challenges to Recruitment

Studies examining Alzheimer’s disease research participation have identified a number of ways participation might be limited:

- Lack of eligibility. Many older adults are ineligible to take part in Alzheimer’s and related dementias research because of stringent, though often necessary, study criteria. In fact, studies show that only 10 to 27 percent of Alzheimer’s disease patients are trial eligible. (Grill & Galvin, 2014)
- Lack of capacity, awareness, and resources among primary care physicians. Primary care physicians may be unaware of research-participation opportunities or have concerns about referring elderly patients to clinical studies. (Watson et al., 2014)
- Study partner requirements. Many studies require concurrent participation of a study partner—typically a spouse, partner, or adult child.
- Use of invasive and time-consuming procedures. Prospective research volunteers and study partners may be reluctant to participate in studies involving procedures perceived as invasive, such as lumbar puncture or brain imaging with radioactive materials. (Grill & Karlawish, 2010; Watson et al., 2014)
- Need for cognitively unimpaired volunteers. Trials testing interventions in people who are at risk of the disease require participation of cognitively unimpaired adults who are willing to undergo gene and biomarker screening. (Watson et al., 2014)

“Fundamentally, the decision to enroll in research involves people weighing the benefits and the risks, upsides and downsides, of choosing to participate. It is critical that we find better ways to facilitate the decision to enroll, by credibly emphasizing the benefits and upsides of participation and appropriately putting the risks and downsides of research studies in context,” Bernard said. “This will involve understanding and responding to the physical, fiscal and psychological barriers to enrollment and devising innovative and feasible tactics to incentivize or encourage potential decision-makers.”

Strategies Address Multiple Perspectives

The National Strategy is built upon the foundation that all recruitment and participation is local, with studies taking place mostly in communities where people live. The National Strategy encompasses:

- Increasing Awareness and Engagement with broad policies and activities at the national and community levels that can identify and support strategies for successful recruitment and retention.
- Engaging Local Communities and Supporting Participants to identify and implement best practices to build trusting relationships within and across communities and individuals toward the shared goals of making a difference for people and families affected by Alzheimer’s and related dementias.

- Building and Improving Infrastructure aimed at changing the way study sites and multisite networks do business, so they can be most effectively structured and staffed for the number and types of clinical studies being undertaken.
- Developing a Science of Recruitment focused on supporting investigators, in collaboration with communities, to develop and test innovative strategies and build an evidence base of effective participant recruitment and retention methods.

Community-Based Outreach Increases African American Participation in Alzheimer's Research at Indiana University

At AAIC 2018, Mary Guerriero Austrom, PhD, Associate Dean for Diversity Affairs and Wesley P. Martin Professor of Alzheimer Disease Education at Indiana University School of Medicine (IUSM), reported on a pilot project that used a collaborative research model to work with a Community Advisory Board (CAB) at the Indiana Alzheimer Disease Center (IADC) and the Alzheimer's Association, Greater Indiana Chapter. The CAB represents a dozen leaders from the minority communities in Central Indiana — predominantly from the African American community — and include pastors, retired volunteers, an elder law attorney, and representatives from the State and County Boards of Health.

Austrom and colleagues engaged the CAB to help with messaging about Alzheimer's research, and created a research recruitment video specifically for minority communities. They identified locations and designed outreach activities where they could work within targeted minority communities.

The Alzheimer's Association collaborated at community outreach and educational events, and partnered with IADC to increase participants in Alzheimer's Association TrialMatch® — a free, easy-to-use clinical studies matching service that connects people with Alzheimer's, caregivers and healthy volunteers with currently recruiting research studies.

Over the course of the pilot study, community-based outreach resulted in 185 African American, 68 White, and 67 other and unspecified referrals to the IADC. Prior to this research, the minority percentage at the IADC was 8.8%. Today it is 19%, which the researchers consider a resounding success. In addition, they added 300 African American volunteers to the TrialMatch database.

“Collaborating with the community as equal partners is essential. The addition of dedicated staff from the minority community was key to our success,” Austrom said. “Working together, we reached out to the African American community in central Indiana to provide education about dementia and Alzheimer's disease, what research is, the importance of diverse populations engaging in research, and finally, asking for the community to volunteer for research at IUSM and register for the Alzheimer's Association TrialMatch program.”

Culturally Diverse Participant Registry at Duke Facilitates Recruitment of African Americans

It is well documented that lack of immediate access to a “research-ready” cohort of volunteers results in significant delays in the pace of Alzheimer's research. The Duke Alzheimer's Prevention Registry (ADPR) was established in 2009 with a goal of providing a research-ready, readily accessed cohort of diverse individuals age 55+ to support clinical trials focused on Alzheimer's prevention and treatment strategies.

At AAIC 2018, the Duke ADPR reported that it currently has 4,300 members, of whom 27% are African American and 73% are female. Twenty-one (21) studies of various types are supported through the registry.

“We have enhanced our ability to quickly identify appropriate participants for specific studies by collecting additional information on a subset of 1,400 individuals,” said Shelytia Cocroft, PhD, a Postdoctoral Fellow at the Center for Study of Aging and Human Development at Duke University’s Medical Center. “This includes cognitive testing, self-reported memory problems, brief medical history, medications, family history of dementia and genotyping of Alzheimer’s risk genes. This subgroup has proportionally fewer African Americans (14%) than the overall registry.”

Cocroft noted that the ADPR is broadly representative of the local community demographics; its success in increasing participation and sustaining involvement in the registry is rooted in several factors:

- Culturally competent recruitment with staff who are sensitive to the community background, and educational materials that are appropriate to the cultural context.
- Dedicated coordinator time to ensure timely responses to member inquiries.
- Regular communication of research opportunities and findings.
- Coordination of requests to members regarding enrolling studies based on their interests and eligibility.

“Recruitment and retention of healthy research volunteers from diverse backgrounds is a national priority in the effort to prevent and treat Alzheimer’s disease and other dementias,” Cocroft said. “Key to retaining participation are regular communications about a broad portfolio of studies. Establishing trust and nurturing community-centric relationships is also vital to the recruitment and retention of underserved groups in clinical research.”

The Alzheimer’s Association International Conference® (AAIC®)

The Alzheimer’s Association International Conference (AAIC) is the world’s largest gathering of researchers from around the world focused on Alzheimer’s and other dementias. As a part of the Alzheimer’s Association’s research program, AAIC serves as a catalyst for generating new knowledge about dementia and fostering a vital, collegial research community.

AAIC 2018 home page: alz.org/aaic

AAIC 2018 newsroom: alz.org/aaic/press

About the Alzheimer’s Association®

The Alzheimer’s Association is the leading voluntary health organization in Alzheimer’s care, support and research. Our mission is to eliminate Alzheimer’s disease through the advancement of research, to provide and enhance care and support for all affected, and to reduce the risk of dementia through the promotion of brain health. Our vision is a world without Alzheimer’s. Visit alz.org or call 800.272.3900.

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- Marie A Bernard, MD, et al. Focused Topic Session: New NIH Policies on Inclusion – Implications for Alzheimer’s Clinical Study Recruitment and Tools to Help. Funder(s): U.S. National Institutes of Health.
- Mary Austrom, PhD, et al. A Community-Based Outreach Model to Increase African American Participation in AD Research. Funder(s): Indiana Clinical and Translational Sciences Institute; U.S. National Institutes of Health; Indiana State Department of Health.
- Shelytia Cocroft, PhD, et al. Culturally Diverse Participant Registries to Facilitate the Recruitment of African Americans into Preclinical Alzheimer’ Disease Studies. Funder(s): The Center of the Study of Aging and Human Development at Duke University; Joseph & Kathleen Bryan Alzheimer’s Disease Research Center.

Focused Topic Session: New NIH Policies on Inclusion – Implications for Alzheimer’s Clinical Study Recruitment and Tools to Help.

Monday, July 23, 4:15-5:45 pm

Proposal ID# 23461

Background: Over the past 30 years, the National Institutes of Health (NIH) has instituted policies to ensure that participants in NIH-supported clinical research are representative of populations affected by the disease of focus. Beginning in the 1980s and early 1990s, policies and legislation required the inclusion of women, minorities and children. Most recently, the 21st Century Cures Act requires NIH to ensure adequate inclusion by age. This led to a new inclusion across the lifespan policy that requires reporting of individual level data regarding age at enrollment, sex/gender, and race/ethnicity for all subjects in clinical studies - <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-116.html>. Additionally, recent NIH policy updates have clarified the requirement to include and analyze data regarding sex/gender and race/ethnicity in phase III clinical trials - <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-014.html>. This portion of the research symposium will elaborate on the background data leading to the policies, and implications for AD researchers.

Methods: As above; **Results:** As above; **Conclusions:** As above.

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Proposal ID# 23469

Background: In an evaluation of Alzheimer’s Disease (AD) and Alzheimer’s Disease related dementias (ADRD), NIA examined how NIH-funded clinical trials fared with regard to the inclusion of participants across a variety of factors including age, race/ethnicity, sex/gender, and exclusion criteria defined in the clinical trial.

Methods: An analysis was conducted looking at all trials with completed recruitment listed in www.Clinicaltrials.gov (n=165).

Results: In the aggregate, it was found that the ratio of White: African-American and White: Hispanics participants for AD clinical trials is 3.8:1 and 8.4:1, respectively. When examining sex/gender differences, the ratio of female: male was 1:1.2. However, the gender divide was larger when examining the female: male ratio in caregiver studies (3.6:1). When looking at exclusion criteria, this evaluation captured 18 broad categories of exclusion and found that large numbers of trials would exclude participants for various reasons, including, but not limited to concomitant medications, various cardiovascular issues, and renal dysfunction.

Conclusions: These data suggest potential opportunities for enhanced recruitment and greater inclusion of various populations in AD/ADRD clinical trials.

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Proposal ID# 23472

Background: Recruiting volunteer participants has been a major, persistent bottleneck in conducting all types of clinical studies. Alzheimer's and related dementias clinical trials face a unique set of challenges to recruitment.

Methods: As the pace of research has accelerated and the number of clinical trials is expected to grow dramatically, the National Institute on Aging (NIA) at NIH, with facilitation by the Alzheimer's Association, has sought to break these barriers, convening a wide range of stakeholders to develop a comprehensive National Strategy for Recruitment and Participation in Alzheimer's Disease Clinical Research. The strategy seeks to engage broad segments of the public in the Alzheimer's and related dementias research enterprise, with a particular focus on underrepresented communities, to successfully and more quickly enroll and retain individuals in studies to better understand, treat and eventually prevent these disorders.

Results: Experts from academia, communications, advocacy, and clinical care and research, assessed recruitment and retention challenges and opportunities from both the national and local perspectives, and recommended actions needed to enhance messaging, partnering, building study site capacity and other opportunities, emphasizing infrastructure and relationships at the community level. As part of the development process, NIA solicited public comment and feedback via an online crowdsourcing platform, which was then incorporated into the strategy.

Conclusions: Based on the recommendations outlined in the strategy, implementation planning and activities are underway.

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Proposal ID# 23471

Background: Recruitment and retention for clinical aging research studies, particularly related to diverse communities, is an enduring priority goal for the National Institute on Aging. A funding opportunity is being provided to the research field to address and overcome the shortcomings that have long stymied successful outreach and community engagement.

Methods: Investigators are being asked to devise better recruitment and retention strategies and demonstrate the success of the improvements by building a large, diverse cohort for aging research participation.

Results: A NIA Funding Opportunity Announcement

Conclusions: It is hoped that this targeted initiative will help focus investigators on the development and evaluation of innovative participant recruitment and retention methods and strategies to expand opportunities for all to join in and enhance the Alzheimer's research enterprise.

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Proposal ID: P2-546

A Community-Based Outreach Model to Increase African American Participation in AD Research

Background: The US legislated National Alzheimer's Plan Act (NAPA) has highlighted the lack of diversity in the groups who participate in Alzheimer's disease (AD) research as a rate-limiting step in the successful search for a treatment or cure. Because minority groups are less likely to volunteer in research, despite a higher burden of risk for AD, it is difficult for researchers to generalize study findings across populations. The Indiana Alzheimer Disease Center (IADC), together with the Alzheimer's Association of Greater Indiana (AAGI), organized a Community Advisory Board (CAB) and worked with local African American (AA) leaders to accomplish four aims: To increase awareness of and provide education about AD, programs, and available services in underrepresented communities; to increase community awareness of the importance of AA participation in AD research; to increase AA enrollment in IADC research studies; and to increase AA enrollment in the Alzheimer's Association TrialMatch.

Methods: Using a community-based participatory research model, we engaged the CAB to help with messaging about AD research (e.g., we developed a research recruitment video for minority communities) and to identify locations and design outreach activities where we could work with the minority community to meet the aims. Through the pilot study we were able to support a part time research engagement specialist who worked closely with the IADC and the community.

Results: Over the course of the pilot study, community-based outreach resulted in 185 AA, 68 white, and 67 other and unspecified referrals to the IADC. Of these, 77 new participants were added to the clinical core (35% AA and 65% Caucasians). In addition, we added 300 AA volunteers to the TrialMatch database.

Conclusions: Our model of collaboration between an academic AD research center and minority community groups like the ones represented by the IADC CAB and our local Alzheimer's Association chapter, increased diversity research participation. The addition of dedicated staff from the minority community to work within these communities was key to our success.

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Proposal ID: P2-657

Culturally Diverse Participant Registries to Facilitate the Recruitment of African Americans into Preclinical Alzheimer' Disease Studies.

Background: Therapeutic trials in the preclinical stages of Alzheimer's disease (AD) typically require large numbers of subjects in order to assess clinical benefit. The Duke AD Prevention Registry (Duke ADPR) was established in 2009 with a goal of providing a ready cohort of demographically diverse individuals age 55+ to enable studies to prevent AD. We report our experience in establishing and sustaining a diverse registry for AD prevention studies.

Methods: Initial infrastructure requirements were 1) development of culturally sensitive print and web-based materials focused on enhancing brain health; 2) collection of minimal personal information to mitigate privacy concerns; 3) implementation of secure data management system accessed only by authorized research personnel; and 4) partnerships with local community stakeholders, including informational outreach activities and presentations by experts in brain health. Sustaining participation in the registry requires a strong data management plan and dedicated coordinator time to ensure timely responsiveness to participant queries, regular communication of research opportunities and findings, and coordination of requests to members regarding enrolling studies based on their known eligibility requirements.

Results: The Duke ADPR currently has 4300 members, of whom 27% are African American (AfAm) and 73% are female. Twenty one studies are supported through the registry including 7 clinical trials, 2 studies assessing novel computerized measures, 8 biomarker studies, and 4 cognitive neuroscience studies. We have enhanced our ability to quickly identify appropriate participants for specific studies by collecting additional information on a subset of 1400. Data include cognitive testing, self-reported memory problems, brief medical history, medications, family history of dementia and genotyping of AD risk genes. This subgroup has proportionally fewer AfAm (14%) than the overall registry.

Conclusions: Research ready cohorts provided by local registries permit rapid acceleration of enrollment in a host of clinical studies. Key to retaining participation are regular communications about a broad portfolio of studies. Focused outreach to AfAms is effective in achieving enrollment in a registry that mirrors the local demographics. Improved understanding of why AfAms are less likely to participate in specific types of studies will be important to ensure inclusivity across all studies.

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