

# TOGETHER WE MAKE THE DIFFERENCE: NATIONAL STRATEGY FOR RECRUITMENT AND PARTICIPATION IN ALZHEIMER'S AND RELATED DEMENTIAS CLINICAL RESEARCH

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The National Alzheimer's Project Act identifies the effective treatment and prevention of Alzheimer's by 2025 as an urgent public health mission. This priority is reflected in the recent increases in public funding that is accelerating Alzheimer's and related dementias research. Many drugs and clinical interventions are in rapid development, with the promising ones moving to clinical trials to be tested. There are currently more than 200 on-going clinical trials, seeking more than 270,000 participants, which will require screening of more than a million individuals. With the race to treatment, how inclusive will screenings be to ensure diversification of the citizens volunteering to become trial participants? Underrepresented groups are chronically under-enrolled in clinical research studies. This under-enrollment leads to conclusions about disease risk factors and processes without all the necessary data because the studies are not representative of all people and all life experiences. *Ethn Dis.* 2020;30(Suppl 2):705-708; doi:10.18865/ed.30.S2.705

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## INTRODUCTION

The National Alzheimer's Project Act identifies as an urgent public health mission to effectively treat or prevent Alzheimer's by 2025.<sup>1</sup> This priority is reflected in the recent increases in public funding that is accelerating Alzheimer's and related dementias research.<sup>2</sup> Many drugs and

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## UNMET RECRUITMENT TARGETS AND BARRIERS TO REFORM

Many research sites are slow to meet volunteer recruitment targets, while other sites do not reach their targets at all. How are research sites allowed to continue clinical research without a clear recruitment framework and methods that continuously evaluate progress and failures? Why is there no consequence for poor recruitment and poor performers? Recruitment of diverse populations is the first necessary step for equitable inclusion in research studies. Successful recruitment requires intentional evaluation, acceptance of feedback and a constant evolution for improvement. In-

stitutional sites are not exempt from reforming and refining recruitment.

An unwillingness to reform can be the main barrier to successful recruitment. Many research protocols are deficient in recruitment procedures, lack a community-driven framework and are reported in ways that limit reproducibility. In 2010, a supplemental journal issue focused on the recruitment and retention challenges and opportunities for the NIA-funded Alzheimer's Disease Centers Program with lessons learned and frameworks to be adopted.<sup>4</sup> However, 10 years later, a systematic literature review reports the continuation of low quantity and quality of evidence in research on recruitment and retention for studies on Alzheimer's disease (AD) and AD-related dementias (ADRD) and an underappreciation and lack of integration of participant feedback.<sup>5</sup>

## **STRENGTHENING RECRUITMENT INFRASTRUCTURES**

The NIA continues work to overcome deficient recruitment protocols by contributing targeted funding opportunities and accessible resources. For example, in April 2018, (PAR-18-749) "Examining Diversity, Recruitment and Retention in Aging Research" was released to support and strengthen recruitment infrastructures.<sup>6</sup> Currently, nine research teams are working to design innovative outreach that include the recruitment of diverse volunteers into research and become a collective resource for NIA by enrolling participants into NIA-funded clinical studies. NIA continu-

ously supports recruitment outreach and education, most recently at the Alzheimer's Association International Conference (AAIC) in July 2020, "NIA-AA Symposium: Developing an Applied Science of Recruitment and Retention for Alzheimer's Disease and Related Dementia (AD/ADRD) Clinical Research." In October 2018, NIA developed the National Strategy for Recruitment and Participation in Alzheimer's and Related Dementias Research with the following areas of focus: 1) increase awareness and engagement; 2) build and improve infrastructure; 3) engage local communities and support participants; and 4) develop an applied science of recruitment.<sup>7</sup> Our efforts require engagement from a wide variety of stakeholders: industry, clinicians, public, researchers, and advocates.

## **NIA-SUPPORTED ALZHEIMER'S DISEASE RESEARCH CENTERS AND CLINICAL TRIALS**

For more than 35 years, NIA-supported Alzheimer's Disease Research Centers (ADRCs) have served local communities and implemented recruitment and outreach improvements. The recruitment and outreach efforts focus on: expanding research on recruitment and retention strategies, ensuring inclusion across disease spectrum, incorporating caregivers into research, encouraging the hire of staff, scientists, and trainees who reflect local community, educating primary care providers, and fostering collaboration among Centers.<sup>8</sup> In October 2018, more than 400 individuals from all ADRCs and St. Louis Af-

rican American community members were part of the African American Participation in AD Research: Effective Strategies Conference.<sup>9</sup> The workshop summary notes that ADRCs have a unique opportunity to create a systematic effort to increase research participation in underrepresented groups, but the effort remains lacking.

Additionally, the NIA Alzheimer's Clinical Trials Consortium (ACTC) has 35 sites across the United States and a centralized minority outreach and recruitment team to develop and test innovations in recruitment to support partnerships with diverse communities.<sup>10</sup> First, the Trial Ready Cohort for the Prevention of Alzheimer's Dementia (TRC-PAD) will establish a trial ready, AD biomarker positive cohort, for trials at multiple sites across North America.<sup>11</sup> Second, the Alzheimer's Clinical Trials Consortium – Down Syndrome (ACTC-DS) will build a trial ready cohort of adults with Down Syndrome.<sup>12</sup> Last, the Institute for Methods and Protocols for Advancement of Clinical Trials in AD and Related Dementias (IMPACT-AD) is a comprehensive learning experience in ADRD clinical trial design.<sup>13</sup> In addition, NIA Alzheimer's and Dementia Outreach, Recruitment, and Engagement (ADORE) Resources is a searchable collection of clinical trial recruitment and retention materials from NIA grantees and programs.<sup>14</sup> Users can locate and download flyers, toolkits, recruitment plans, and browsing is by engagement goals, participant characteristics and dozens of focused topics. A Recruitment Planning Guide is also available for instruction in designing targeted recruitment strategies.<sup>15</sup>

## IN THIS ISSUE

The reports in this special issue highlight advances in the science of recruitment and retention of diverse older adults. Glover et al highlight that the request for brain donation results in differing information needs across races. Portacolone et al conclude that institutional modification and researcher performance require improvements to increase African American recruitment in research. Marshall et al evaluate the implementation and sustainability of providing

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chronic disease management programs in locations that are within the community of the targeted populations. Mitchell and colleagues describe successful recruiting and retaining strategies with an emphasis on the role that a community advisory board plays as gatekeeper of community-engaged research efforts. Stewart et al provide a step-by-step instruction to increasing recruitment feasibility and guides re-evaluating assumptions about recruitment. Ajrouch et al summarize their lessons learned in creating two participant resource pools, underlining the

need for investigators to gauge their own implicit bias about the targeted community. Maestre et al examine their use of community health workers to engage low-income neighborhoods and their efforts to increase targeted representation in research studies. Finally, Harawa offers strategies for earning trust necessary for recruitment and retention of research participants.

## LESSONS LEARNED IMPORTANT TO COVID-19 VACCINE DEVELOPMENT

These issues are crucial for Alzheimer's clinical trials, but the lessons learned can also be applied to other priority issues. For example, on July 14, 2020, a first human phase 1 clinical trial of a vaccine for the SARS CoV-2 virus reported interim results. Of the 45 participants, 82% were White, even though evidence was growing that the pandemic was affecting underrepresented minorities disproportionately.<sup>16,17</sup> Under-enrollment of racial/ethnic minorities and other underrepresented groups is commonplace during the 2020 SARS-CoV-2 pandemic and repeated calls for inclusive studies continue to have a limited effect. What will the results of our SARS-CoV-2 vaccine developments mean for the individuals disproportionately affected if they are not a prominent feature of the research design? Events in summer 2020 spotlighted the impact of race in America and numerous publications reminded scientists that there is scientific racism, and this racism excludes people in research recruitment. There is a history of racializing diseases,

which then works to continue to racially marginalize communities.<sup>18</sup> A recent publication that provides a succinct summary of the scientific examination of racial health inequities proposes rigorous standards for scientific publishing on racial health inequities and describes the lack of inclusion of underrepresented groups in studies.<sup>19</sup> Even during a public health emergency, studies remain not representative and our peer-reviewed publication system perpetually accepts participant underrepresentation as a continued feature in scientific research.

## CONCLUSION

There are a multitude of improvements that need consideration for recruitment and retention of underserved populations in scientific studies. The reports provided in this special issue address many of these challenges and some required improvements that can be adopted to build healthy communities and lives. Inclusion, diversity, and representation is part of the scientific process and the scientific community needs to challenge the status quo to require research and recruitment questions that go beyond the surface.

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