Interdisciplinary panel offers solutions to improve recruitment for Alzheimer's clinical trials

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Unless cures are found, Alzheimer's dementia is projected to affect nearly 13 million Americans by 2050—overwhelming families, caregivers and our healthcare system. Yet only one new therapeutic, aducanumab, has come to market in the past 20 years, and therapeutic progress remains hampered for several reasons: recruiting study participants in clinical trials for Alzheimer's is more challenging than other disease areas, the trials take longer to complete and they are more costly. A significant increase in the number of qualified volunteers from diverse backgrounds will be needed in the coming years for clinical trials for Alzheimer's to be successful.

To develop solutions to overcome some of the steepest barriers to recruitment, the USC Schaeffer Center for Health Policy & Economics and the Alzheimer's Therapeutic Research Institute (ATRI) joined with Gates Ventures to convene more than 35 experts from across the private and public sectors. The advisory panel was chaired by Julie Zissimopoulos, Paul Aisen and Jessica Langbaum. A paper published in *Alzheimer's & Dementia* identifies actionable and inclusive solutions to accelerate the development of novel therapies for Alzheimer's disease that resulted from the panel.

"The steepest barriers to more efficient Alzheimer's clinical trials are those that are keeping potential volunteers from ever participating in the first place," says Zissimopoulos, co-director of the Aging and Cognition Program at the Schaeffer Center. "Reducing these barriers to support progress on Alzheimer's treatments—even modest progress—would have a profound impact on the communities affected by this disease."

Barriers limit access

"There is no one answer," says Aisen, who directs ATRI and oversees many clinical trials. "These issues must be addressed from various angles. Recruitment, however, is the major bottleneck."

Current models prevent approximately 99% of eligible volunteers from being referred to or considering trial enrollment. Black and Latino populations are especially underrepresented, even though they face higher risks of Alzheimer's disease than white Americans.

Even if a patient is referred to a clinical trial and considers enrollment, additional barriers exist. Most participants do not meet screening criteria, which leads to screen-failure rates of up to 88%. Furthermore, some of these exclusion criteria—such as chronic conditions like cardiovascular disease—can result in disproportionately screening out

diverse populations.

"We need to increase enrollment of diverse populations in Alzheimer's clinical research," says Langbaum, co-director of the Alzheimer's Prevention Initiative led by Banner Alzheimer's Institute. "These communities are disproportionately affected by the disease, and we can learn more about the disease and how best to detect, treat and prevent it if we have diverse representation in the studies. But to do this, we need to address the unique logistical, financial and trust barriers that keep diverse populations from participating in Alzheimer's research."

Overall strategies

The expert panel convened over the course of a year to identify the critical challenges and potential solutions that are scalable and most likely to turn the tide.

"By bringing together a large, diverse group of thought leaders and stakeholders spanning research, industry, policy and philanthropy, we fostered conversations that normally would happen in silos, resulting in a set of unique and impactful ideas addressing Alzheimer's trial bottlenecks," says Desi Peneva, the research lead at the Schaeffer Center who managed the advisory panel project.

The panel's suggestions include:

- Broadening cognitive screening and early detection efforts in both asymptomatic adults and those showing early symptoms of Alzheimer's disease.
- Developing better tools for primary care providers to identify at-risk populations, recognizing that the disease starts decades before symptoms appear.
- Changing payment models, such as expanding Medicare

reimbursement to encourage earlier diagnosis and clinical trial referrals.
- Broadening the use of blood-based biomarkers for Alzheimer's detection.
- Increasing public awareness and outreach with tailored messages to engage diverse communities.
- Scaling clinical trial architecture to take Alzheimer's trials into diverse communities by leveraging health systems' satellite sites, mobile clinical trial units or local networks of diagnostic clinics.
- Using digital engagement and a screen-fail registry to share enrollees' information across multiple trials, since a potential participant who fails screening for one study might be a good fit for other trials.
- Conducting virtual clinical trials when appropriate to reduce the burdens of travel and time on trial participants—although internet access would have to be provided to some patients to ensure equitable access.

Implementing some of these strategies is already underway. The Schaeffer Center and ATRI are spearheading the new Clinical Trial Recruitment Lab, which launched earlier this year and aims to pilot and evaluate innovative solutions that have the potential to increase access and reduce inequalities in clinical trials.

More information: Jessica B. Langbaum et al, Recommendations to address key recruitment challenges of Alzheimer's disease clinical trials, *Alzheimer's & Dementia* (2022). DOI: 10.1002/alz.12737

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