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Editorial

It's time to address the recruitment bottleneck

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It is currently estimated that over 55 million people worldwide are living with dementia with 10 million new cases developing each year. The number of cases is projected to grow to 139 million by 2050 [1]. In the face of this impending tsunami there is an increasingly urgent need for improved treatments, which will in turn require further research including clinical trials. Yet, of the millions of individuals with Alzheimer's Disease in particular, only about 12,000 successfully enroll in trials each year. This is far short of the estimated 50,000 needed for the 182 clinical trials in the pipeline in 2025 [2]. Poor recruitment leads at best to delayed completion of trials, and at worst to suspended or abandoned programs. These delays, suspensions and abandoned studies in turn hinder our progress toward discovering and developing the treatments we so desperately need.

Hoping in part to address the bottleneck of recruitment the National Institute of Aging (NIA) in the United States convened experts and published a National Strategy for Recruitment and Participation In Alzheimer's Disease and Related Dementias (ADRD) with one goal focused on the development of an applied science of recruitment [3]. Yet despite this call for action, recruitment continues to be a major impediment to clinical trial completion. There are numerous potential causes of poor enrollment, which likely vary significantly across studies and geography. For example, many patients do not have trial sites near their homes, and travel to and from a site several hours away is not practical or possible. In other cases, the burden of trial participation is simply too great. As trials seem to get increasingly complex year after year it can be more difficult for smaller sites to participate, restricting opportunities for patients closer to their homes. Furthermore many patients cannot or will not tolerate many hours of assessments, sometimes at frequent intervals. The time commitment required for a caregiver or study partner may also be impossible. Restrictive inclusion and exclusion criteria can prevent eligibility for many. The need for participation from under-served or under-represented populations is well known, but the level of mistrust in those populations and communities can be significant. And for many even outside of these communities, there can be significant mistrust of research and reluctance to participate.

Against this background comes a welcome contribution to the literature from Mireille Jacobson et al. [4]. This paper provides a review of the literature, establishing the current state of recruitment science in Alzheimer's Disease and Related Dementias (ADRD). Their initial review yielded only 50 publications that met their inclusion criteria, including reporting quantitative data. Twenty examined general recruitment efforts, 20 examined recruitment of under-represented groups and 10 involved recruitment in registries. It is noteworthy that only 4 of these publications reported on pharmacological trials. The authors used a Mixed Methods Appraisal Tool (MMAT) to assess the available studies.

Many trials used a multi-pronged approach, which is not surprising and likely necessary. The authors rightly point out that recruitment strategies probably need to be tailored to different populations and settings. Community engagement was frequently employed, though this can take many forms that can itself be tailored to specific geographies and populations. Social media campaigns were identified as an emerging strategy. Referrals from other health care professionals and word-of-mouth were also important strategies.

One potential weakness of this manuscript is that the papers reviewed may not provide easily generalizable data. Again, only 4 studies reviewed reported on pharmacologic trial recruitment. And it was not easy to evaluate site specific and geographic factors. But arguably the most striking finding from this review is the relative lack of data available on recruitment strategies. There has unfortunately been too little progress in the development of an applied science of recruitment, despite the increasing acuity of the need.

The authors make two clear recommendations that could help address this. First, Alzheimer's Disease and Related Dementia (ADRD) trials should embed methods for evaluating recruitment strategies within the studies themselves. And second, the results should be reported in a standardized way. Related to this second recommendation,

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the authors point out that a great deal of potentially valuable data regarding recruitment does not get published.

As the number of patients with Alzheimer's Disease and Related Dementias continues to grow, we cannot afford unnecessary delays in the pursuit of new and more effective treatments. To address the bottleneck of recruitment, Jacobson et al. provide one path forward as we seek to develop and evaluate better strategies for recruitment. The need for an applied science of recruitment remains true today, eight years after the publication of the NIA's National Strategy for Recruitment and Participation In ADRD in 2018.

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Gregory Cooper: Conceptualization, Writing – original draft, Writing – review & editing.

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