

The Role of Ethnicity in Willingness to Participate in Rheumatoid Arthritis Clinical Trials



Participation of people with rheumatoid arthritis (RA) in clinical trials is essential if they, as a community, are going to benefit worldwide from research advances. In this issue of *The Journal*, Lee and colleagues report on a critically important aspect of clinical trial participation: What influences people with RA, both positively and negatively, to participate¹.

As Lee and colleagues note, the results of clinical trials apply generally only when the people under study share the same characteristics as those of the general population. However, when scanning the medical literature of the last several decades, one learns that the vast majority of participants in seminal RA clinical trials were Caucasian. Considering that the number of non-Hispanic whites may represent half of the United States population by 2050 and that Hispanics will soon outnumber African Americans², arthritis researchers today need to make a concerted effort to determine what negatively associated factors predict whether Hispanics and other racial/ethnic groups will participate in RA clinical trials.

In Lee and colleagues' study¹, Hispanics made up 57% of the study participants (Hispanics and Latinos make up about 25% of San Diego's population³). In the study, Hispanics differed significantly from Caucasians, with lower education and annual income, but had similar disease characteristics. Both participant groups shared similar views on the potential advantages of being in a clinical trial: Opportunity to help others; possibility of improved health; early access to a new therapy; and availability of free treatment.

However, it is interesting that Caucasians and Hispanics differed in terms of their views on negative influences to participate in clinical trials. Caucasians identified 2 factors as being potential disadvantages of participation — unknown side effects of the study drug and the requirement to stop current therapy. This did not hold true for Hispanics, who reported no negatively associated factors to participating in clinical trials — a result that contradicts those from studies done in racial/ethnic groups (including Hispanics) in other disease settings.

A number of other studies (including those cited by Lee and colleagues) report that race/ethnicity does play a role in a person's unwillingness to participate in clinical trials. For example:

Recruitment strategies/process. There is evidence to suggest recruitment for improving participation of racial/ethnic groups requires strategic planning involving participants representative of the study population. The plan should be tailored to the target group, presented as a credible study, designed to reflect trust in the medical care team, and implemented through a continuous educational process⁴.

Informed consent. The translation and backtranslation of informed consent forms does not take into account cross-cultural differences. A diabetes study that looked at the informed consent process in a Navajo population concluded that the consent process often leads to embarrassment, confusion, and misperceptions that promoted mistrust of study investigators⁵.

Familiarity with the study investigator. Two studies point to the importance of potential study participants' familiarity with the study investigator/physician. A study in gynecologic cancer patients published in 2005 reported on whether differences exist between those who participate in clinical trials and those who do not. It concluded that the most important factor affecting clinical trial participation appeared to be the patients' level of familiarity with the physician-investigator who described the trial to them⁶. Similarly, a study from the United Kingdom on South Asians' views of participation in clinical trials reported a number of barriers, including trial burden, language, and discriminatory practices in the UK National Health Service. Barriers noted by female study participants included issues of modesty and preference for female clinical trial staff. These findings strongly suggest that race/ethnicity, as well as gender, are negatively associated factors of willingness to participate in clinical trials⁷.

Access to medical care. In 1997, a review article identified

See Factors affecting RA patients' decisions to participate in clinical trials, page 2317

a number of potential factors responsible for low participation levels of African Americans in medical research studies. Among them, poor access to primary medical care — a key information source on clinical trials — and the alienation of minority health professionals⁸.

In summary, the results from Lee and colleagues' study¹ leave the arthritis clinical research community a number of questions to pursue in future studies.

What factors negate Hispanics' willingness to participate in arthritis clinical trials? Distrust of the medical/scientific community; poor access to primary medical care; failure of researchers to actively recruit minorities; alienation of minority health professionals; lack of knowledge about clinical trials; as well as language barriers, beliefs, and cultural barriers have all been reported as reasons Hispanics are unwilling to participate in clinical trials.

What impact, if any, does the racial/ethnic background of arthritis clinical trial study investigators have on the successful recruitment of Hispanics and African Americans? As noted here, evidence from other disease settings suggests that background of the study investigators could have a negative influence on different racial/ethnic groups' willingness to participate in clinical trials.

How do we improve communication between arthritis clinical trials investigators and potential Hispanic, African American, and other racial/ethnic groups' clinical trial participants? Effective communication is essential to overcoming the racial, cultural, and socioeconomic barriers that separate today's arthritis clinical trial investigators from their clinical trial participants.

How do Hispanics and African Americans find out about arthritis clinical trials? Until we research the best ways to communicate information about arthritis clinical trials to

Hispanics and African Americans, it is unlikely that their participation will increase to levels such that the results from these trials will be generalizable in these growing populations.

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