Cost of translating consent documents may hinder participation of underrepresented groups in clinical trials

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Cancer research centers conducting clinical trials could enroll more patients from underrepresented racial and ethnic groups by placing

greater emphasis on relieving investigators of the costs of translating consent documents into languages other than English, according to a UCLA Jonsson Comprehensive Cancer Center study.

"We identified a readily addressable weakness in the clinical trial process, and we believe that overcoming this barrier, as we have begun to do, will ensure better representation of trial participants from traditionally underrepresented racial and ethnic groups, enabling researchers to provide more comprehensive, 'generalizable' study results," said senior author of the study Dr. Edward Garon, a medical oncologist and a Director of the Signal Transduction and Therapeutics Program Area at the UCLA Jonsson Comprehensive Cancer Center.

Consent documents presented to potential clinical trial participants are required to be in a language understandable to the patient, and studies sponsored by pharmaceutical companies—about 70% of all randomized cancer clinical trials—typically have budgets that cover the costs of translating documents into languages appropriate for participants.

In studies that are not sponsored by drug companies or device makers, investigators often operate on a fixed, per-patient budget provided by a grant, often from philanthropic organizations or governmental groups. As a result, an unexpected cost, such as the cost of consent document translation, often reduces the funds available for other potentially important aspects of the research.

The UCLA research team, which published its findings in *Nature*, theorized that these additional costs could discourage investigators from recruiting patients for whom consent document translation would be required, contributing to the disproportionately low rates of participants from traditionally underrepresented groups in clinical trials.

Researchers analyzed "consent events"—situations in which consent

documents were signed—and compared those for industry-sponsored studies versus studies not sponsored by industry. Each "event" did not necessarily represent a single patient, because some participants signed consent documents for multiple trials.

Garon and colleagues evaluated potential differences in the two types of trials based on participant primary language and English proficiency, basing their findings on more than 12,000 consent events that included 9,213 participants in trials at UCLA Jonsson Comprehensive Cancer Center between January 2013 and December 2018.

The differences were dramatic. The proportion of consent events for patients with limited English proficiency in studies not sponsored by industry was approximately half of that seen in industry sponsored studies. When patients from this group signed consent documents, the proportion of consent documents translated into the patient's primary language in studies without industry sponsorship was approximately half of that seen in industry sponsored studies.

Among patients signing consent documents, 63.4% were non-Hispanic white, of whom only 1.6% had a primary language other than English. In contrast, 18.3% of participants from other racial and ethnic groups had a primary language other than English, the most common being Spanish with Chinese as the second most common.

"Results suggest that the cost of consent document translation in trials not sponsored by industry could be a potentially modifiable barrier to the inclusion of patients with limited English proficiency," explained Dr. Maria Velez, a fellow in hematology and oncology at the David Geffen School of Medicine at UCLA and the lead author of the study.

"Removing this hurdle and increasing representation is important because efficacy, toxicity and clinical outcomes of a studied treatment

may be different in different populations. Also, many studies focus on screening, prevention, survivorship, and quality of life issues—topics that can best be understood through the inclusion of a diverse patient population," explained Dr. Beth Glenn, co-director for Community Outreach and Engagement at the UCLA Jonsson Comprehensive Cancer Center and co-author of the study.

"In many respects, this work represents the importance of a collaborative environment among investigators focused on cancer care across a wide range of disciplines. Dr. Garon's research primarily focuses on clinical and translational studies while Dr. Glenn's work focuses on engaging the population served by the Cancer Center," said Dr. Amy Cummings, Director of Justice, Equity, Diversity and Inclusion (JEDI) at the UCLA Jonsson Comprehensive Cancer Center.

"The published paper addresses a problem relevant to both investigators and integrates methodologies employed in both of their research efforts. Such cross-cutting efforts epitomize the power of interdisciplinary collaboration in advancing cancer research and care."

"Although it is difficult to acknowledge that those of us involved in conducting clinical trials may bear some responsibility for the lack of enrollment of diverse populations, identifying the forces leading to these findings provides targets for improvement for ourselves and other cancer researchers," explained Dr. Michael Teitell, director of the UCLA Jonsson Comprehensive Cancer Center, also a co-author.

More information: Edward Garon, Consent document translation expense hinders inclusive clinical trial involvement, *Nature* (2023). DOI: 10.1038/s41586-023-06382-0.
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