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Large-scale review of COVID-19 clinical trials highlights multiple disparities

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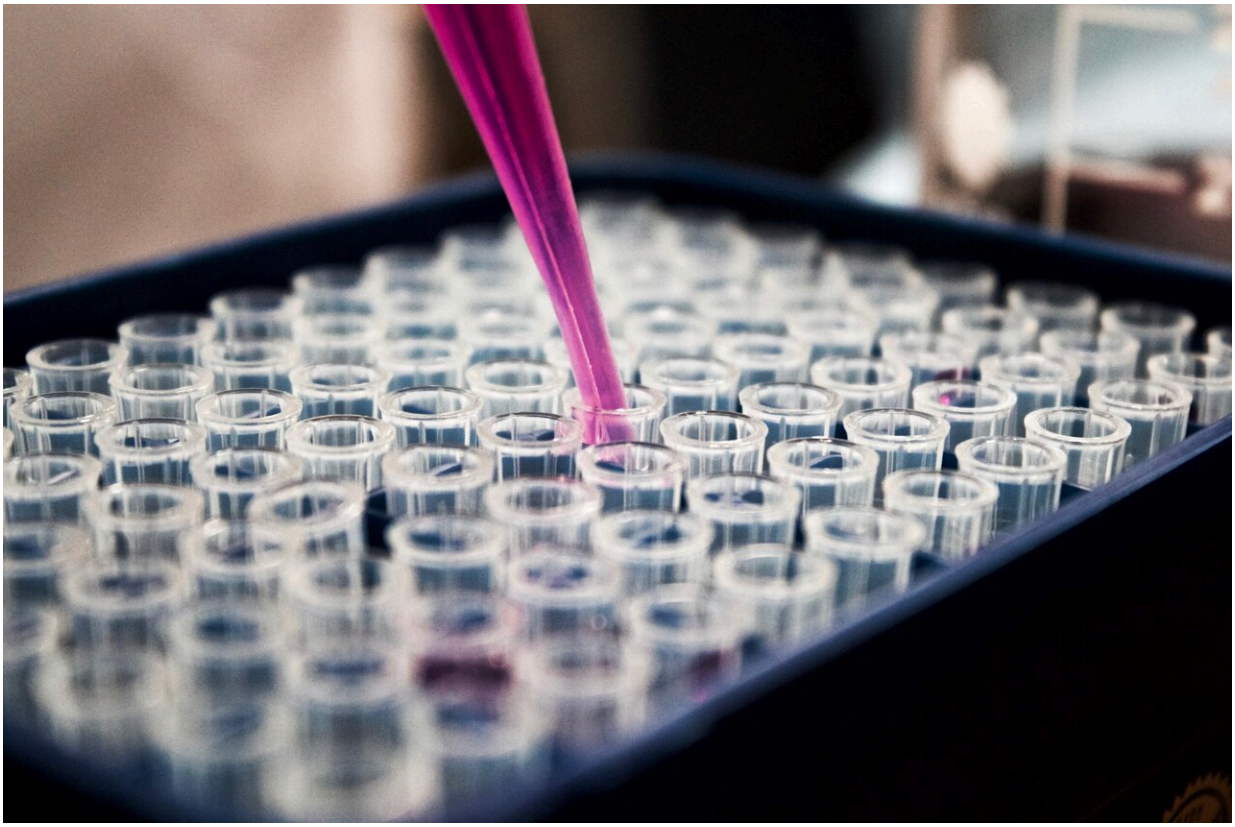

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Women were underrepresented in COVID-19 treatment clinical trials, and some racial and ethnic groups were underrepresented in COVID-19 prevention trials, according to a new meta-analysis conducted by Fred

Hutchinson Cancer Center in collaboration with researchers from Beijing and London.

The study, published Dec. 5 in *JAMA Internal Medicine*, identified system-wide differences in representation among several key demographic groups in COVID-19 prevention and treatment trials in the U.S.

"To our knowledge, this is the first study to comprehensively examine demographic representation across the landscape of both COVID-19 prevention and treatment trials over the first two years of this pandemic," said Hong Xiao, Ph.D., researcher in the Public Health Sciences Division at Fred Hutch and the lead author for the study.

By the numbers

Overall, the meta-analysis examined 122 U.S.-based clinical trials for COVID-19 vaccines or treatments, involving more than 175,000 participants. The selected trials were those registered on ClinicalTrials.gov or published in PubMed from October 2019 to February 2022.

Only studies that provided data about enrolled participants by sex, race or ethnicity were analyzed in this study. Representation rates from trials were compared to expected rates in the U.S. COVID-19 population.

Takeaways

Key findings from their review included:

- Sex, race, and ethnicity were reported in 89.3%, 77.9%, and 71.3% of U.S.-based COVID-19 clinical trials, respectively,

suggesting there was a meaningful gap for many studies in this important aspect of trial reporting.

- Female participants were underrepresented in treatment trials (85% of expected participants) but were well represented in COVID-19 prevention trials.
- Black and Asian individuals were underrepresented in COVID-19 prevention trials (53.7% and 64.4% of expected participants, respectively), but were well represented in COVID-19 treatment trials.
- Hispanic individuals were overrepresented in treatment trials (more than 200% of expected participants).

Author commentary

The study authors noted that female participants historically have been underrepresented in clinical trials in general for various reasons. Pregnant women have routinely been excluded from clinical trials; as such, women of reproductive age may have had greater concerns about how developmental COVID-19 treatments would affect their health and current or future fertility.

The authors also speculated that Hispanic overrepresentation might have occurred for several reasons, including the fact that one-third of the U.S.-based COVID-19 trial sites were in California, Texas and Florida—areas with large Hispanic populations. Additionally, COVID-19 treatment trials were typically conducted among inpatient populations, which may have disproportionately affected Hispanic populations due to a lack of primary care and increased risk for COVID-associated hospitalizations.

"In many instances, our findings highlight achievements in the successful enrollment of historically underrepresented patients. However, our findings also underscore that despite efforts to eliminate sex, racial and

ethnic disparities, gaps in reporting and differences in representation in U.S.-based COVID-19 trials have persisted," said Joseph M. Unger, Ph.D., MS, Fred Hutch biostatistician and health services researcher and the study's senior author. "Clearly, more progress needs to occur to fully close these gaps and achieve greater diversity among participants."

Equitable access

"This vital work by Fred Hutch researchers and their collaborators highlights the ongoing disparities in who accesses and enrolls in clinical research," added Rachel Bender Ignacio, MD, medical director of the COVID-19 Clinical Research Center at Fred Hutch. "We must remain laser-focused on ensuring that clinical-trial participation is representative of the general population, which both requires trust in and access to research, and also ensures that the products of that research are acceptable to and appropriate for everyone."

Xiao, Unger and the rest of the study authors concluded that additional strategies are needed to ensure that all trial sponsors, whether federally supported or industry-funded, are held accountable for appropriate representation of females and racial and ethnic groups in clinical trials.

More information: Hong Xiao et al, *JAMA Internal Medicine* (2022). DOI: 10.1001/jamainternmed.2022.5600

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