

Women Are Missing From HIV Treatment Trials

Women—especially Black women—are underrepresented in late-stage studies of new HIV therapies.

February 15, 2023 By [Liz Highleyman](#)

Women living with HIV are underrepresented in Phase III [clinical trials](#) of new treatments relative to their share of the HIV population, and the disparity is particularly stark for Black women, according to study results [published in the journal AIDS](#). Representative trial participation is important because therapies may work differently or have different side effects in men and women.

[Women](#) account for 19% of people newly diagnosed with HIV and nearly one quarter of people living with HIV in the United States, according to the Centers for Disease Control and Prevention (CDC). About 60% of newly diagnosed women are Black, while white and Latina women each account for around 20% of new cases. Women at risk for HIV are less likely to use [pre-exposure prophylaxis \(PrEP\)](#) than gay men, and those living with HIV are less likely to have an [undetectable viral load](#).

Shuang Zhou, PhD, of the Office of Women's Health Research at the Food and Drug Administration (FDA), and colleagues looked at women's participation in Phase III trials submitted to the FDA since 2010 to support the approval of or major label changes for antiretroviral therapy.

The analysis included 18 multicenter clinical trials conducted in various countries. Together, they enrolled more than 13,000 participants starting HIV treatment for the first time, including about 5,300 in the United States. The trials evaluated a variety of medications, mostly integrase inhibitors, non-nucleoside reverse transcriptase inhibitors and protease inhibitors.

Overall, 15% of trial participants were women; 45% of the women were white and 36% were Black, compared with 69% white and 18% Black among men. Among participants in the United States, only 11% were women, of whom 34% were white and 62% were Black. Women participants were about five years older than men, on average, and they had a lower median CD4 T-cell count.

The researchers calculated the participation-to-prevalence ratio (PPR), meaning the percentage of women among trial participants divided by the proportion of women among people living with HIV. A ratio of 1.0 would mean the percentage of female trial participants equals their share of people

with HIV; ratios between 0.8 and 1.2 reflect similar representation in trials and the HIV population.

In the United States, women—particularly Black women—were not adequately represented in clinical trials, the study authors found. The overall PPR for U.S. women was 0.59. But when broken down by race, white women were better represented in trials, with a PPR close to 1.0. For Black women, in contrast, the PPR was 0.63.

The researchers also assessed sex differences in treatment efficacy (viral suppression) and selected safety outcomes. They saw statistically significant sex differences in efficacy outcomes, favoring men, for both U.S. participants and global study populations. What's more, significant sex differences were observed for some safety outcomes, such as anemia. However, they cautioned, the ability to detect sex differences was hindered by low numbers of female participants overall and within subgroups.

The underrepresentation of women in treatment trials was likely not due to enrollment eligibility criteria, such as pregnancy, the researchers suggested. Previous studies have found that women may not join trials for a variety of reasons, including lack of awareness, family responsibilities and barriers to access, such as a lack of transportation. Some trials have done a better job recruiting women by making a concerted effort to reach them and meet their needs.

“Additional research into innovative approaches to recruit and retain females in clinical trials should continue,” the study authors concluded. They recommended that researchers and drug companies conducting trials should include key opinion leaders, investigators and the HIV community on their advisory boards and in their protocol review process.

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