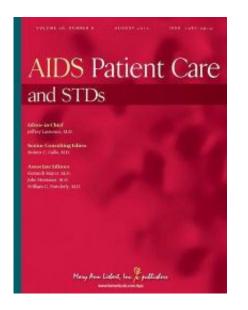


Are there gender differences in anti-HIV drug efficacy?

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Women comprise nearly half of the HIV-infected population worldwide, but these 15.5 million women tend to be under-represented in clinical trials of anti-HIV drug therapies. The U.S. Food and Drug Administration (FDA) has created a database from 40 clinical studies to assess gender differences in the efficacy of antiretroviral treatments. The results of this study are presented in an article in *AIDS Patient Care and STDs*.

Guoxing Soon and coauthors from the FDA and University of Texas



Southwestern Medical Center, Dallas, TX, found that women represented only about 20% of the subjects in randomized clinical trials submitted to the FDA between 2000 and 2008. The article "Meta-Analysis of Gender Differences in Efficacy Outcomes for HIV-Positive Subjects in Randomized Controlled Clinical Trials of Antiretroviral Therapy (2000-2008)" compares the effectiveness of anti-<u>HIV drug</u> regimens reported for women versus men overall and among various subgroups.

The authors found no statistically or clinical significant differences between women and men in outcomes with regard to viral load after 48 weeks. However, they did report significant <u>gender differences</u> favoring males based on subgroup analyses.

"This is a critical area of research in terms of developing new HIV therapies," says Editor-in-Chief Jeffrey Laurence, MD, Director of the Laboratory for <u>AIDS Virus</u> Research at Weill Medical College of Cornell University, New York, NY. "Mounting evidence indicates that metabolism of certain drugs varies in men vs. women, and side effects that interfere with adherence to these medications may also be manifest differently."

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