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Women are missing from HIV drug trials

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(Reuters Health) - Although women make up roughly half of the world's HIV cases, they remain largely excluded from clinical trials testing drugs, vaccines and potential cures for the virus, a research review confirms.

In an analysis spanning several decades that included work done as recently as 2012, researchers found that women typically comprised about 11 percent of participants in trials investigating cures for HIV. Similarly, drug studies were only about 19 percent female and just 38 percent of vaccine trial subjects were women.

“Based on previous studies in other health areas, it wasn’t surprising, but perhaps disappointing given that nearly half of those living with HIV are women,” lead study author Dr. Mirjam Curno, who did the analysis while working as managing editor of the Journal of the International AIDS Society, said by email.

Research in areas such as heart disease, cancer and depression has also had historically low female participation, as have advanced human trials testing experimental drugs, Curno and colleagues note in the *Journal of Acquired Immune Deficiency Syndromes*.

While it may make sense to have fewer women in studies focused on diseases that disproportionately affect men, research findings may overlook gender-specific harms or benefits when the proportion of men and women in the study is wildly different from what happens in the real world, said senior study author Dr. Shirin Heidari by email.

That's because even when the disease is the same, women may have different symptoms than men and respond in unique ways to the treatments being tested.

"Failing to systematically study sex and gender differences in health research leads to less evidence-based medicine for one sex or another," said Heidari, who is chair of the gender policy committee for the European Association of Science Editors.

The analysis of gender disparities in HIV trials included more than 500 studies published in prominent medical journals over several decades.

One limitation of the analysis is that by relying on published work, it may not capture any differences in the gender makeup of more recent trials that haven't yet been completed, the authors acknowledge.

It's possible that at least some studies in the analysis didn't set out to favor men, but ended up enrolling fewer female participants due to obstacles that can disproportionately impact women such as lack of child care or elder care or limited transportation or time to participate, noted Mary Foulkes, a biostatistics researcher at George Washington University in Washington, D.C.

One question not answered by the analysis is why eligible women may have decided not to participate, Foulkes, who wasn't involved in the study, said by email.

Sometimes, trial enrollment criteria can be too restrictive to enroll enough women, for example by barring women who are pregnant, nursing or of childbearing age. In the past, eligibility criteria have excluded large numbers of women even in HIV trials designed to study female patients, noted Dr. Monica Gandhi, an HIV specialist at the University of California, San Francisco.

Women's underrepresentation in HIV trials can make the findings of limited use in treating female patients, Gandhi, who wasn't involved in the study, said by email.

"When I take care of an HIV-infected woman in my clinic, I do not know if this new and exciting treatment or strategy applies specifically to her if the trial did not include enough people in their study that look like her," Gandhi said.

SOURCE: bit.ly/1JKDP44 Journal of Acquired Immune Deficiency Syndromes, online September 8, 2015.

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