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New look at PrEP study points to efficacy for transgender women

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In a new look at the groundbreaking iPrEx trial for people at high risk of HIV infection, UC San Francisco researchers have identified strong evidence of efficacy for transgender women when PrEP, a two-drug antiretroviral used to prevent HIV, is used consistently.

"We re-examined the data using a more sophisticated method for determining which participants in the trial were transgender women and found a larger number than the original analysis," said study senior author, Robert M. Grant, MD, UCSF professor of medicine. In addition, we looked at blood levels of the drug in a sub-group of participants. We found no drug in the transgender women who became infected. And, no transgender woman participant with drug levels equal to four or more doses a week became infected with HIV. While this analysis did include a large enough sample group to draw firm conclusions, we did find strong evidence pointing to efficacy. Additional research designed specifically for transgender women is needed to confirm this finding."

The study enrolled 2,499 HIV negative gay and bisexual men and transgender women in Peru, Ecuador, Brazil, Thailand, South Africa and the United States between 2007 and 2011, with an open label extension that ended in 2013. The new analysis identified 339 transgender women participants, 310 more than originally included in the initial report of the trial.

Compared with men who have sex with men (MSM) in the iPrEx study, transgender women had lower drug levels in their blood and were less

likely to take PrEP on a daily basis. While MSM who reported sexual practices with the highest risk of contracting HIV were more likely to have PrEP detected in their blood, the opposite was true for transgender women.

"We think that one factor leading to lower rates of pill-taking may be due to either a fear of, or lack of information about drug-drug interactions between PrEP and gender-affirming hormone medications. For transgender women, their gender-affirming medications are a higher priority," said study first author, Madeline B. Deutsch, MD MPH, assistant clinical professor of Family and Community Medicine at the UCSF Center of Excellence For Transgender Health. "And while there may be a negative behavioral interaction between the two therapies that is affecting pill-taking, we have no evidence to date for a biological interaction between the two, though further research is needed."

The iPrEx trial in 2010 was the first to show efficacy for a daily single pill oral antiretroviral medication consisting of emtricitabane and tenfovir disoproxil fumarate for use in HIV negative gay and bisexual men. On an intent-to-treat basis, efficacy was not found for the transgender women in the trial.

The FDA approved and the U.S. Centers for Disease Control and Prevention recommends this medication for use in gay and bisexual men and heterosexual men and women at risk for acquiring HIV. The U.S. CDC recommendations for PrEP use do not mention transgender women.

Transgender women are at high risk of HIV infection. An analysis from 2008 found that over a quarter of transgender women in the U.S. are HIV positive. A 2013 analysis looking at fifteen countries found a fifth of transgender women are HIV positive. And, the U.S. Centers for Disease Control and Prevention reported that transgender women have

the highest percentage of new infections of any sub-group in their testing programs.

"Transgender women face several structural barriers including lack of legal protection against discrimination and resulting difficulties in employment, access to income, food and housing. They desperately need a tool that they control, one they can use without their partners' consent or knowledge," said Deutsch.

PrEP research and interventions are generally designed to encourage MSM to participate and consider use of PrEP. No evidence based HIV prevention interventions specifically designed for transgender women exist.

"When transgender women take PrEP as prescribed, it appears to work, but to retain and encourage PrEP use, research should be conducted and interventions should be delivered in gender affirming environments. One example would be to integrate PrEP delivery with gender affirming services, including provision of gender affirming hormone therapies. Social marketing campaigns and PrEP delivery programs should not lump transgender women in with MSM but should be explicitly designed to support transgender women," said study co-author JoAnne Keatley, MSW, director of the UCSF Center of Excellence for Transgender Health.

Provided by University of California, San Francisco