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Uptake and effectiveness of PrEP for transgender women

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Worldwide, transgender women (individuals assigned a male sex at birth and who identify as women, female, male-to-female, or on the transfeminine spectrum) contend with exceptionally high risks for HIV acquisition.[1] These risks are a product of— and exacerbated by—pervasive exposure to adverse social and structural conditions, including violence, systemic barriers to legal recognition, widespread discrimination, enacted stigma, and transphobia. As a result, transgender women face substantial obstacles to formal employment, stable housing, health care, and engagement in HIV prevention and treatment, and also experience psychosocial problems, including depression, substance-related disorders, and suicidality.[2] Despite consistently documented social, health, and HIV-related inequities, inclusion of transgender women in HIV prevention trials, including pre-exposure prophylaxis (PrEP) studies, has been limited.[3]

In *The Lancet HIV*, Madeline Deutsch and colleagues[4] present the first investigation of PrEP effectiveness among transgender women. The iPrEx trial was a randomised, double-blind, placebo-controlled, phase 3 clinical trial examining the efficacy of a once-daily oral pill (emtricitabine plus tenofovir disoproxil fumarate) for prevention of HIV acquisition.[5] Although not designed to test the efficacy of PrEP among transgender women specifically, the investigators did a post hoc analysis of transgender women enrolled in the trial and subsequent open-label extension study.[6] The authors relied on questions assessing self-reported gender identity and a review of medical history (ie, the use of feminising hormones or receipt of gender affirming surgery) to identify 339 transgender participants, representing 14% of the sample.

In the modified intention-to-treat analysis, PrEP did not reduce the risk of HIV infection in transgender women compared with placebo. To explain these results, the authors did a rigorous analysis of risk behaviour and drug concentrations in both the iPrEx randomised controlled trial and the open-label extension study. Importantly, emtricitabine plus tenofovir disoproxil fumarate was not detected at the time of infection in any of the transgender participants who acquired HIV. Moreover, HIV incidence was high among transgender women who did not have study drug detected (4·9 per 100 person-years), notably higher than in their male-identified counterparts (2·8 per 100 person-years). In the open-label study, the relation between drug concentration and HIV incidence among transgender participants

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was similar to that in men who have sex with men: no infections were observed among people whose drug concentrations were indicative of use of four or more tablets per week.

In September, 2015, WHO published revised antiretroviral treatment and prevention guidelines recommending oral PrEP for all people at substantial risk of HIV infection (defined as groups in which HIV incidence is more than three per 100 person-years among individuals for which PrEP in indicated).[7] Deutsch and colleagues provide clear evidence that transgender women in this sample meet these criteria, and show that transgender women should be offered PrEP if indicated to prevent HIV infection.

These results also emphasise the need for additional studies to identify approaches that improve PrEP uptake among transgender women and ensure adherence, particularly during periods of HIV exposure. Such work is now underway in the USA, Peru, and other countries.[8] Among iPrEx participants, drug concentrations were lower in transgender women who used feminising hormones than in other transgender participants, perhaps because of concerns regarding drug interactions. Although PrEP efficacy is not affected by use of hormonal contraceptives in women,[9] more research is needed to examine the concurrent use of PrEP and hormone therapy for feminisation among transgender populations and possible pharmacokinetic interactions. The meaningful inclusion of transgender women in the design and implementation of these studies is necessary and critical.

Despite much interest in and willingness to use PrEP among transgender women worldwide, uptake has been low.[10] Population effectiveness in transgender women, therefore, hinges on the development of widespread PrEP education programmes, and structural and legislative reforms to eliminate barriers to health care and HIV prevention services. Provider, policy, and public health interventions that reduce housing instability, improve employment opportunities, mitigate distrust of the medical community, and establish and enforce universal non-discrimination laws that include gender identity and expression are needed. In Argentina, the federal government passed legislation in 2012 that recognises the right to self-defined gender identity, ensures access to transgender health services, and expressly prohibits discrimination on the basis of gender identity throughout all government services.[11] Research is needed to determine the extent to which legislative reforms and policy changes such as that in Argentina improve access to HIV prevention services for transgender populations. Nonetheless, the results of this important study further emphasise that intensive and progressive strategies, grounded in public health and human rights frameworks, are needed to ensure that transgender people benefit from PrEP.

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