HIV PREVENTION FOR CISGENDER WOMEN, TRANSGENDER MEN, AND ALL PEOPLE ASSIGNED FEMALE AT BIRTH

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Introduction

Cisgender women, transgender men, and all people assigned female at birth continue to be affected by HIV, both nationally and globally. In 2019, 6,897 HIV infections were diagnosed among cisgender women, and 46 were diagnosed among transgender men, with significant disparities by race [1]. Among people assigned female at birth who have HIV, those who identify as Black or African American are disproportionately affected [1].

HIV pre-exposure prophylaxis (PrEP) is an important tool to prevent new HIV infections but remains underutilized. For example, the Centers for Disease Control and Prevention (CDC) estimates that only 10% of cisgender women who could benefit from PrEP were prescribed it in 2019 [2]. Similarly, in one national survey of 157 transgender men, 51% were eligible for PrEP, but only 26% had received a prescription for it [3]. In this publication, we describe the evidence for PrEP among people assigned female at birth and strategies to improve PrEP uptake for these populations, with a focus on Black cisgender women.

Evidence for PrEP among people assigned female at birth

Three medications are currently FDA-approved for PrEP in the United States: oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC), oral tenofovir alafenamide/emtricitabine (TAF/FTC), and long-acting injectable cabotegravir (CAB). Of these, randomized controlled trials have demonstrated the effectiveness of TDF/FTC and CAB in prevention HIV among people assigned female at birth [4, 5].

TDF/FTC

PrEP with TDF/FTC consists of a single combination table taken by mouth once daily. Effectiveness for HIV prevention correlates with adherence to the medication. In a pooled analysis of observational data from more than 6,000 cisgender women, HIV incidence was 0 per 100 person-years among those who took TDF/FTC daily, whereas incidence was 1.27 per 100 person-years among those who consistently took fewer than two doses per week [6]. TDF/FTC is also the preferred agent for prevention of HIV in people who are pregnant or lactating due to an established safety record in these settings [7].

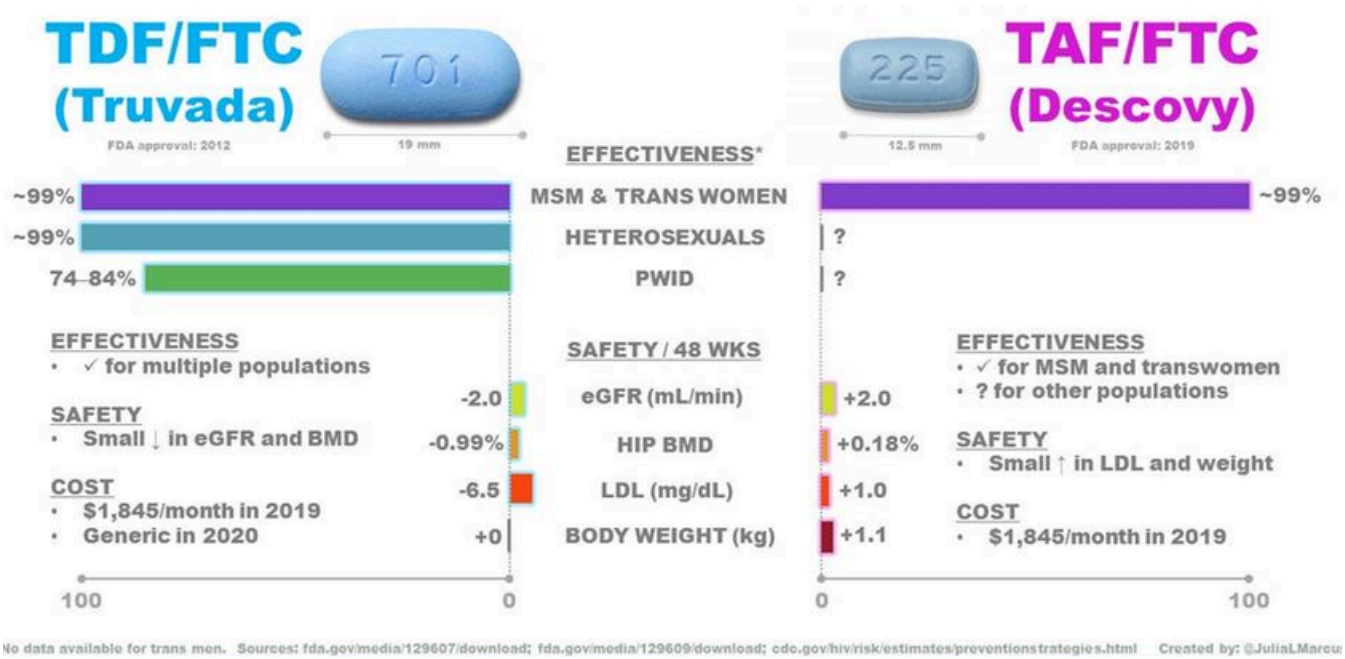
CAB

PrEP with CAB consists of intramuscular injections given once monthly for two doses followed by doses every two months thereafter. In a large, randomized trial of CAB versus TDF/FTC for PrEP among people assigned female at birth in sub-Saharan Africa, CAB was superior for HIV prevention, with a hazard ratio of 0.12 (95% confidence interval 0.05-0.31) in those assigned to CAB versus TDF/FTC [5]. The superiority of CAB is most likely due to lower adherence to oral PrEP. Data on the safety and efficacy of CAB for PrEP in the setting of pregnancy and lactating are limited [7].

Evidence for PrEP among people assigned female at birth

Other agents

While TAF/FTC is approved for PrEP in the United States, the approval explicitly excludes people whose exposure to HIV arises from receptive vaginal sex, due to a lack of evidence for efficacy in that population at the time of the approval [8]. Subsequently, a randomized trial compared TAF/FTC, TDF/FTC, and a new agent called lenacapavir, which is administered by subcutaneous injection every six months, for HIV prevention in cisgender women in sub-Saharan Africa [9]. In that study, HIV incidence with TAF/FTC did not differ significantly from either background HIV incidence or HIV incidence in those assigned to TDF/FTC, though adherence to both oral drugs was low. In a case-control analysis performed within that trial, higher adherence to TAF/FTC was associated with lower odds of HIV infection. Lenacapavir was highly effective for HIV prevention in the same study, with no HIV infections in the group assigned to that intervention [9]. While clinical trials of PrEP have not included a significant number of transgender men or gender diverse people assigned female at birth, a similar study with a small proportion of transgender men (1.3% of the study population) also demonstrated the efficacy of lenacapavir [10]. Lenacapavir is not currently approved for PrEP in the United States.



Strategies to improve PrEP use among people assigned female at birth

With low PrEP use among those assigned female at birth and ongoing disparities in PrEP by race, new strategies are needed to improve access to and uptake of PrEP. Research with Black cisgender women has identified key insights and preferences that may facilitate PrEP use in this population.

Current strategies

Survey data indicate that in the United States, medical providers play a crucial role in Black cisgender women's decisions about PrEP use [11]. This underscores the importance of implementing CDC's recommendations to discuss PrEP with all sexually active adults and adolescents [12]. PrEP discussions should be nonjudgmental and free of stigma, as anticipated stigma is a barrier to PrEP uptake [11].

Research also demonstrates that Black cisgender women would like to learn about PrEP from other members of their community who are taking it [11]. For example, in one nationwide survey, interest in PrEP among Black cisgender women was associated with the perceptions that PrEP use was socially acceptable and was common among community members [13]. These findings have implications for PrEP outreach and navigation activities; clinics that seek to improve PrEP uptake among Black cisgender women may consider partnering with community members around PrEP outreach and/or aiming to hire community members as PrEP navigators.

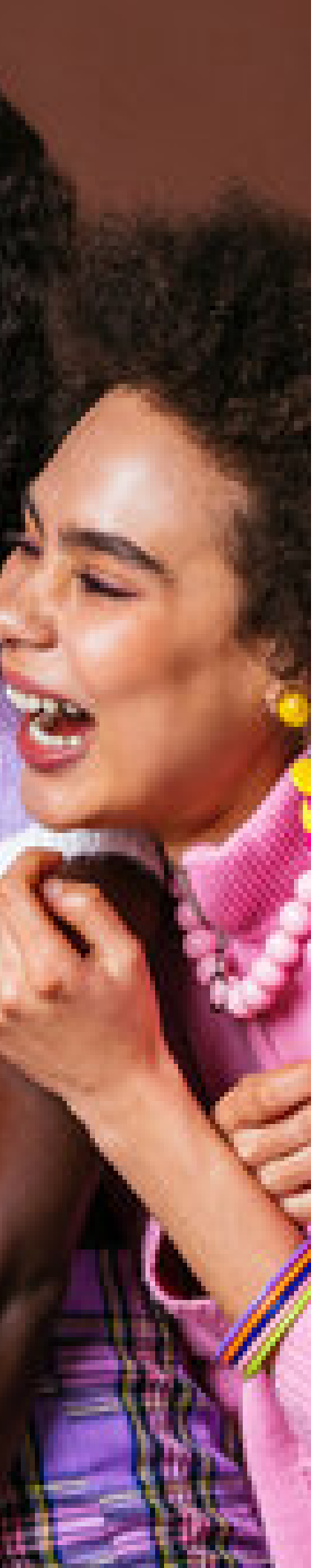
Among transgender men, receipt of gender affirming medical care has been associated with awareness and use of PrEP [14, 15]. While gender affirming care may be a marker of overall health care engagement, visits for gender affirming care may also provide opportunities to discuss, prescribe, and monitor PrEP. Clinicians who provide gender affirming care may consider adding PrEP to the services they offer to facilitate PrEP access among transgender men and other gender diverse people assigned female at birth.

Strategies to improve PrEP use among people assigned female at birth

Future strategies

New product development may improve PrEP uptake in the future. Lenacapavir has been shown to prevent HIV among a diverse population of people assigned female at birth; if it is approved for use in the United States, it may expand the choice of PrEP medications and facilitate broader PrEP coverage among people who are eligible for PrEP. In addition, research with Black cisgender women has identified the desire for multimodal prevention modalities that can prevent HIV and STIs and, to a lesser extent, pregnancy as important influences on PrEP interest [11]. While not currently available, several multipurpose prevention technologies are currently in development [16].

PrEP remains a crucial tool to end the HIV epidemic, but its use is not commensurate with need among people assigned female at birth, particularly among Black cisgender women. Both oral TDF/FTC and injectable CAB have well-documented effectiveness for preventing HIV among people assigned female at birth. Additional agents, some combining HIV prevention with contraception and/or STI prophylaxis, are in development. Regardless of the PrEP agent, however, key strategies to improve uptake include routinely discussing PrEP with patients, collaborating with individuals from affected communities in PrEP outreach and engagement, and for transgender and gender diverse people, offering PrEP alongside gender affirming care.



Key points

- HIV disproportionately affects Black cisgender women and transgender men.
- PrEP use among people assigned female at birth is not commensurate with the burden of HIV in these populations.
- Two drugs are FDA-approved for PrEP for people having receptive vaginal sex. These include oral TDF/FTC and injectable CAB.
- Newer agents may be available for PrEP soon. For example, lenacapavir, an injection administered every 6 months, was highly efficacious for HIV prevention among cisgender women in a randomized trial.
- Strategies to improve PrEP uptake among people assigned female sex at birth include incorporating discussions of PrEP into routine clinical care, collaborating with community members on PrEP outreach and navigation, and offering PrEP alongside gender affirming care for transgender men.

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