PrEP for Transgender and Gender-Diverse People

Kevin L. Ard, MD, MPH
Medical Director, The National LGBTQIA+ Health Education Center
Director, Sexual Health Clinic, Massachusetts General Hospital
Assistant Professor of Medicine, Harvard Medical School

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Outline

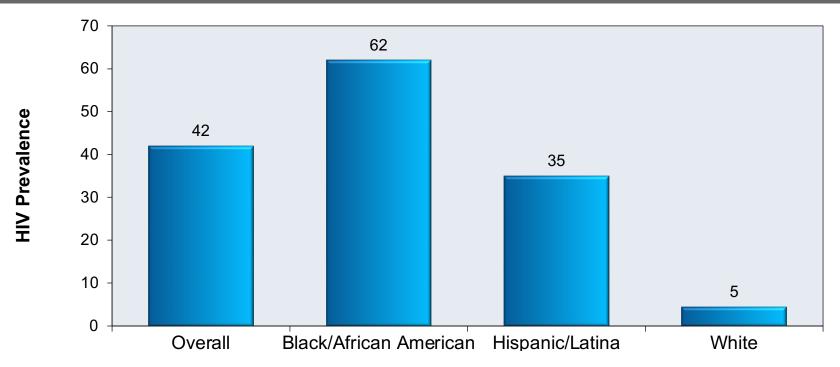
- 1. HIV disproportionately burdens transgender and gender diverse people, and uptake of PrEP is not commensurate with need in these populations.
- 2. PrEP is effective for transgender and gender diverse people.
- 3. Embedding PrEP within gender-affirming care may increase access to and uptake of PrEP for transgender and gender diverse people.





Transgender women are disproportionately affected by HIV.

HIV prevalence among transgender women overall and by race and ethnicity in 7 U.S. cities, 2019-2020



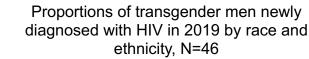
Source: Adapted from: HIV infection, risk, prevention, and testing behaviors among transgender women – National HIV Behavioral Surveillance – 7 U.S. cities, 2019-2020. CDC. HIV Surveillance Report 2021.

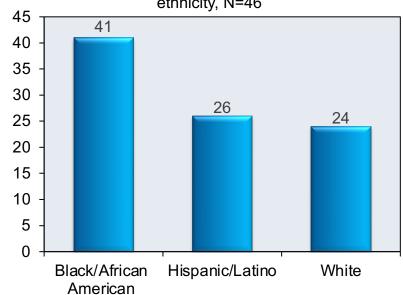




Data on HIV among transgender men are more limited

- HIV is likely less common among transgender men; in 2019, 46 transgender men were diagnosed with HIV in the U.S. compared to 625 transgender women.
- Disparities in HIV prevalence by race and ethnicity are also present among transgender men.
- Some transgender men have sex with cisgender men; these partners are often gay or bisexual men.





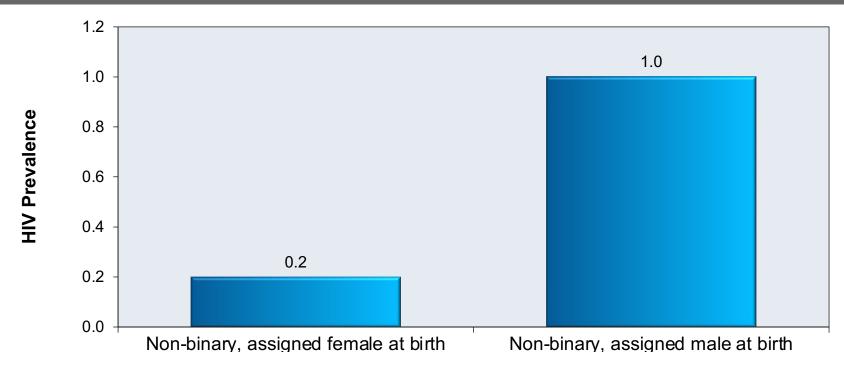
- 1. Diagnoses of HIV infection in the United States and dependent areas, 2019. CDC. HIV Surveillance Report 2021.
- 2. Reisner SL, Murchison GR. A global research synthesis of HIV and STI biobehavioural risk in female-to-male transgender adults. Global Public Health. 2016;11(7-8):866





Data on HIV among non-binary people are also limited

HIV prevalence by self-report, 2015 U.S. Transgender Survey





PrEP use among transgender and gender diverse people is likely not commensurate with need

Among transgender women without HIV in 7 U.S. cities:

- 92% were aware of PrEP
- 32% had used PrEP

Potential barriers to PrEP among transgender and gender diverse people:

- Lack of clinician expertise
- Lack of health insurance
- Competing priorities
- Concerns about drug-drug interactions with gender affirming hormone therapy



Case

Antonia is a 45-year-old transgender woman who takes estrogen and spironolactone. At her annual physical, she reports a new sexual relationship with a cisgender man who has HIV. He is not consistently in care for HIV, and she is not sure that his viral load is suppressed. She engages in oral and receptive anal sex with her partner; they use condoms about half of the time. She is interested in PrEP and has normal baseline laboratory studies.

Antonia asks what is known about the effectiveness of PrEP for transgender people and if PrEP interacts with her hormones. How would you counsel her?





What is the evidence for PrEP among transgender people?

- **iPrEX:** This trial of TDF/FTC versus placebo included 339 transgender women out of 2499 total participants. Drug level monitoring suggested that good adherence to PrEP prevented HIV among the transgender participants.
- **DISCOVER:** This trial of TDF/FTC versus TAF/FTC for PrEP included 74 transgender women out of 5387 total participants. TAF/FTC was non-inferior to TDF/FTC for PrEP overall. No transgender woman acquired HIV in the study.
- **HPTN 083**: This trial of TDF/FTC versus CAB-LA for PrEP included 570 transgender women out of 4566 total participants. CAB-LA was superior to TDF/FTC for HIV overall, with a similar result in a pre-specified subgroup analysis of transgender women.



Considerations for selecting a medication for PrEP

| What does the patient prefer? | Comorbidities | Nature of HIV exposure | Logistics |
|---|--|--|---|
| Which PrEP agent do they want, and why? | Renal or bone disease favors TAF/FTC or CAB | No efficacy data are available for TAF/FTC in the setting of receptive vaginal sex | A desire for telehealth/limited in- person visits favors oral PrEP |
| | Hepatitis B favors oral PrEP | TDF is the only agent studied among people who inject drugs | Same-day initiation favors oral PrEP |
| | Hyperlipidemia, weight concerns favor TDF/FTC or CAB | | Insurance considerations may favor a specific agent |



Does PrEP interact with gender affirming hormone therapy?

First, a brief overview of gender-affirming hormone therapy:

- Goal: To better align physical characteristics and the hormonal milieu with gender identity
- Common approaches:

| For people assigned male at birth | For people assigned female at birth |
|---|-------------------------------------|
| Estradiol | Testosterone |
| An anti-androgen (e.g., spironolactone, leuprolide) | |

Treatments vary based on anatomy, prior surgery, and patients' goals.





Does PrEP interact with gender affirming hormone therapy?

- Hormone therapy is a priority for many transgender and gender diverse people.
- Concerns about drug-drug interactions between PrEP and hormones may impact willingness to take PrEP and/or adherence.
- The medications currently available for PrEP do not significantly impact levels of estrogen or testosterone.
- Hormone therapy does not appear to impair the effectiveness of PrEP, provided patients take PrEP as prescribed.
 - Small studies have differed in whether tenofovir levels are lower in those taking oral PrEP and estrogen.
 - However, there were no HIV infections in those with high PrEP adherence in iPrEx.
 - Tenofovir concentrations adequate in women taking hormones in DISCOVER





Barriers and facilitators to PrEP: Qualitative research

- PrEP messaging has been focused on men who have sex with men (MSM):
 - MSM media do not reach transgender women
 - Off-putting to transgender women
- Interest is generally high when PrEP is explained
- Desire to obtain PrEP from a prescriber of gender affirming hormones
- Concerns about:
 - Adding another medication to the multiple medications that many transgender people take
 - Interactions between PrEP and hormone therapy

^{2.} Rael CT, Martinez M, Giguere R, et al. Barriers and facilitators to oral PrEP use among transgender women in New York City. AIDS Behav. 2018. doi 10.1007/s10461-018-2102-9.





^{1.} Sevelius JM, Keatley J, Calma N, Arnold E. "I am not a man": Trans-specific barriers and facilitators to PrEP acceptability among transgender women. Global Public Health. 2016;11(7-8):1060.

Overcoming potential barriers to PrEP for transgender and gender diverse people

- Lack of health insurance Medication assistance programs
- Competing priorities Same-day PrEP, offering one-stop shopping for PrEP, primary care, and gender affirming hormone therapy
- Concerns about drug-drug interactions with gender-affirming hormones
 - Provide reassurance and counsel about what is know and not known



Providing PrEP for transgender and gender-diverse people

In addition to the recommended baseline testing and monitoring, holistic PrEP care for transgender people includes:

- 1. Making clinical environments welcoming
- 2. Providing transgender-related information, resources, and referrals
- Inquiring about sexual behavior in way that does not convey assumptions about anatomy, gender identity, or sexual orientation
- 4. Providing mental health or psychosocial counseling, if necessary
- 5. Comprehensive sexual health care





Summary

- 1. HIV disproportionately burdens transgender and gender diverse people, and uptake of PrEP is not commensurate with need in these populations.
- All approved medications for PrEP can be used for transgender and gender diverse people, but TAF/FTC should not be recommended for people whose HIV risk stems from receptive vaginal sex.
- Embedding PrEP within gender-affirming care may increase access to and uptake of PrEP for transgender and gender diverse people.



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