PrEP for HIV Prevention
PrEP for Transgender Patients (Update)

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Only FTC/TDF (Truvada), FTC/TAF (Descovy), and CAB-LA (Apretude) are approved by the U.S. Food and Drug Administration (FDA) and only for use in some, but not all, populations. This talk may include discussion of non-FDA approved strategies for HIV prevention.
Funding for this presentation was made possible by U1OHA29296 from the Human Resources and Services Administration HIV/AIDS Bureau. The views expressed do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government. *Any trade/brand names for products mentioned during this presentation are for training and identification purposes only.*
Data Considerations

Data in this presentation offer a limited perspective of how systemic, social, and economic factors impact health. We recognize that racism, not race, creates and perpetuates health disparities.

To Learn More: https://www.cdc.gov/minorityhealth/racism-disparities
New HIV Diagnoses Among Transgender People by Race/Ethnicity in the US and Dependent Areas, 2019

Most new HIV diagnoses among transgender people were among Black/African American people.

<table>
<thead>
<tr>
<th></th>
<th>Transgender Women (N=625)</th>
<th>Transgender Men (N=46)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black/African American*</td>
<td>46% (285)</td>
<td>41% (19)</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>35% (221)</td>
<td>26% (12)</td>
</tr>
<tr>
<td>White</td>
<td>13% (80)</td>
<td>24% (11)</td>
</tr>
<tr>
<td>Multiracial</td>
<td>2% (14)</td>
<td>7% (3)</td>
</tr>
<tr>
<td>Asian</td>
<td>3% (11)</td>
<td>3% (1)</td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td>1% (5)</td>
<td></td>
</tr>
<tr>
<td>Native Hawaiian/Other Pacific Islander</td>
<td>1% (5)</td>
<td></td>
</tr>
</tbody>
</table>

* Black refers to people having origins in any of the Black racial groups of Africa. African American is a term often used for people of African descent with ancestry in North America.

† Hispanic/Latino people can be of any race.


Racial and ethnic disparities exist among transgender women with HIV.

Among transgender women interviewed, 42% had HIV.

- 62% of Black/African American transgender women had HIV
- 35% of Hispanic/Latina transgender women had HIV
- 17% of White transgender women had HIV

PrEP is highly effective for preventing HIV from sex or injection drug use.

92% of transgender women without HIV were aware of PrEP

32% of transgender women without HIV used PrEP

* Among people aged 18 and older.

### Who should be prescribed PrEP

<table>
<thead>
<tr>
<th></th>
<th>IAS-USA (2022)</th>
<th>HHS/CDC (2021)</th>
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</table>
| Sexually active adults and adolescents | Discuss without criteria for risk behavior or screening tools. Encourage consideration if:  
- MSM/TGPSM  
- young adult/adolescent  
- partner from generalized epidemics  
- exchange sex for $  
- partners are incarcerated  
- recent bacterial STI | Everyone should receive info. Recommended for persons at substantial ongoing risk.  
- HIV positive sex partner  
- Bacterial STI last 6 months  
- h/o inconsistent condom use |
| Persons with substance use disorders | Discuss without criteria for risk behavior or screening tools. | Recommended for persons at substantial ongoing risk. |
| At-risk individuals who are pregnant or breastfeeding | Recommended | Discuss PrEP |
## What to prescribe as PrEP

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<th>IAS-USA (2022)</th>
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</thead>
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<tr>
<td>FTC/TDF</td>
<td>All persons at risk from sexual or injection exposures.</td>
<td>All persons at risk from sexual or injection exposures.</td>
</tr>
<tr>
<td></td>
<td>- Preferred if eCrCl 30-60 mL/min or known osteoporosis</td>
<td>- Preferred if eCrCl 30-60 mL/min or known osteoporosis</td>
</tr>
<tr>
<td></td>
<td>- Limited to anyone whose risks do not include receptive vaginal or neovaginal</td>
<td>- Recommended for men and TGW who have sex with men.</td>
</tr>
<tr>
<td></td>
<td>sex or exclusive IDU</td>
<td></td>
</tr>
<tr>
<td>CAB</td>
<td>All persons at risk from sexual exposures and PWID with sexual risk.</td>
<td>All persons at risk from sexual exposures.</td>
</tr>
</tbody>
</table>

**IAS-USA:** The optimal PrEP regimen for a given person is the one most acceptable to that person and congruent with their sexual behavior, ability to take medications reliably, likelihood of anticipating sexual activity, and adverse effect profile.
2-1-1 dosing POLL

Who do you prescribe 2-1-1 (event-based) PrEP for?

1) Only cisgender men.
2) Only cisgender men and transgender women.
3) Anyone who asks about it.
4) I don’t ever prescribe 2-1-1 PrEP.
### 2-1-1 dosing (FTC/TDF only)

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<tr>
<td>Cisgender men</td>
<td>Recommended regardless of sexual orientation</td>
<td>For adult MSM who have sex less than 1x/week and can anticipate sex</td>
</tr>
<tr>
<td>Transgender women</td>
<td>Use with caution in TGW receiving hormone therapy</td>
<td></td>
</tr>
<tr>
<td>Cisgender women, transgender men, PWID</td>
<td>Insufficient data</td>
<td></td>
</tr>
</tbody>
</table>
Transgender participants in iPrEx

- 339 (14%) of 2499 iPrEx participants
- Efficacy
  - 10 HIV infections in placebo arm
  - 11 HIV infections in active arm (HR = 1.1, 95% CI 0.5 to 2.7)
- Adherence – 0 of 11 had any drug detectable at seroconversion visit
- Conclusions:
  - TGW less adherent than cisgender MSM in iPrEx
  - ? Hormone – PrEP interactions?
  - Need studies specifically for TGW

Transgender women on oral HIV pre-exposure prophylaxis have significantly lower tenofovir and emtricitabine concentrations when also taking oestrogen when compared to cisgender men.

Participants
- 8 TGW
- 8 CGM

Methods
- Daily observed FTC/TDF x 7d
- Plasma levels, PBMC, colon bx

Conclusions
- 24-32% ↓ plasma level in TGW

Participants:
- 24 transgender women (TGW) on estradiol for >6 months
- 24 transgender men (TGM) on testosterone for >6 months

Methods
- Daily observed FTC/TDF
- Blood collection weekly for DBS for TFV-DP drug concentrations
- Compared with cisgender controls from prior studies

Conclusions
- No interactions between PrEP and hormones.
- While gender affirming hormones should not reduce PrEP efficacy, the relationship between PrEP levels and HIV risk is most confidently known for cisgender men
Sex Hormone Therapy and Tenofovir Diphosphate Concentration in Dried Blood Spots: Primary Results of the iBrEATHe Study

Comparisons

• Levels ↓23% in TGM v 17 CGW

• No difference in wk 4 TFV-FP levels in TGW v 15 CGM

• All participants expected to reach TFV-DP > 800 by 8 wks

Grant et al, CID 2021; 73(7).
Additional Studies: TransPrEP Study

Yager et al., AIDS Research Human Retroviruses 2022; 38(11)
Retrospective analysis.

No clinically significant interactions were seen between hormone therapy and either FTC/TDF or FTC/TAF.
Adherence counseling for transgender persons POLL

Will and/or how will this information change how you counsel transgender persons about adherence to daily PrEP?

1) Taking PrEP 4 days a week is sufficient for protection.
2) Taking PrEP 6 days a week is sufficient for protection.
3) Transgender men and women really need to adhere to daily PrEP.
4) We don’t know what any of this data really means.
Conclusions

• Previously well-established that PrEP has no impact on hormone levels.

• Evidence gathering to suggest no impact of gender affirming hormone on PrEP medication levels.

• Still unclear how relates to efficacy or potential for 2-1-1 dosing.

• Barriers to uptake and persistence remain among TGP
  - Concern about side effects
  - Stigma and mistrust of medical providers
  - Co-location of PrEP and gender affirming care services may ↑ PrEP uptake
What to watch for

- Manufacturer’s 5000 person trial of FTC/TAF and lenacapavir for women
  - Estimated primary completion date: March 2024

- No studies
  - Efficacy study of 2-1-1 dosing among transgender persons
  - Injectable CAB among persons who inject drugs
Questions?
Acknowledgment

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