

# PrEP for HIV Prevention PrEP for Transgender Patients (Update)

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# Disclosures

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.

# Disclaimer

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.*

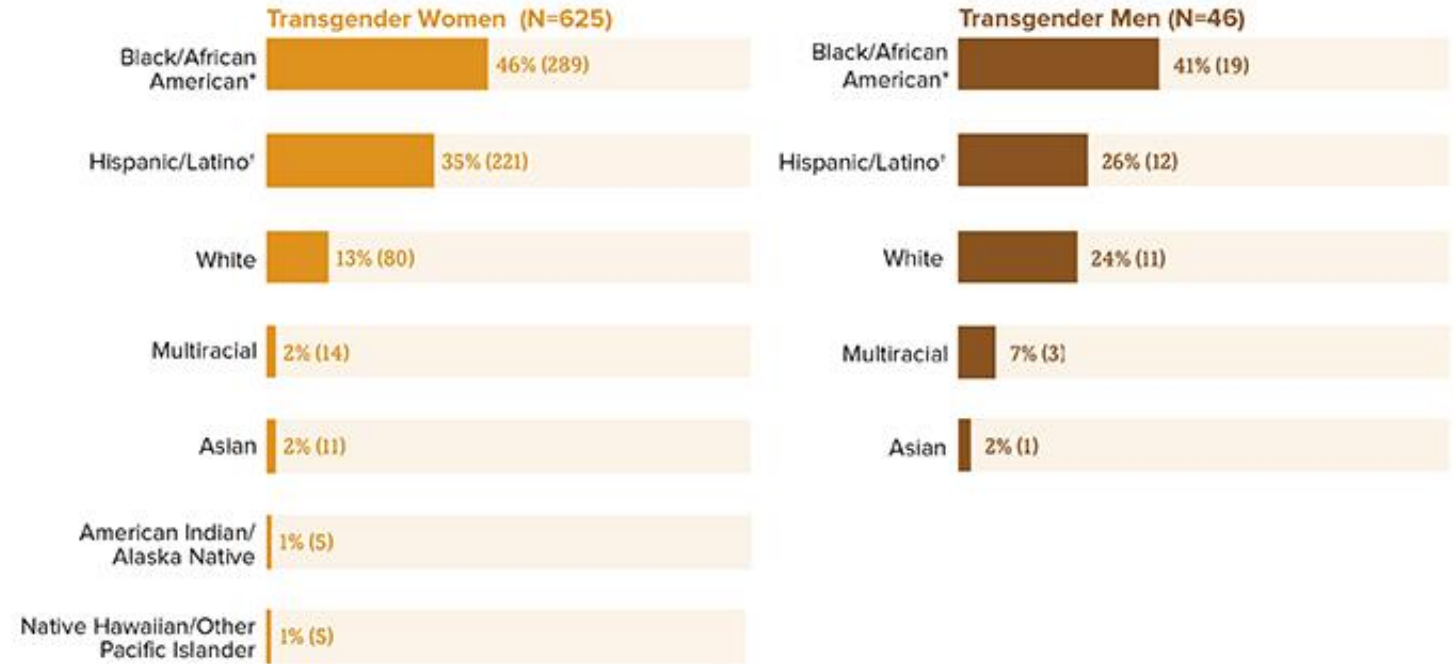


To Learn More:

<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.



\* *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.

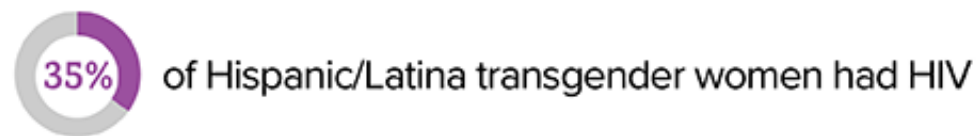
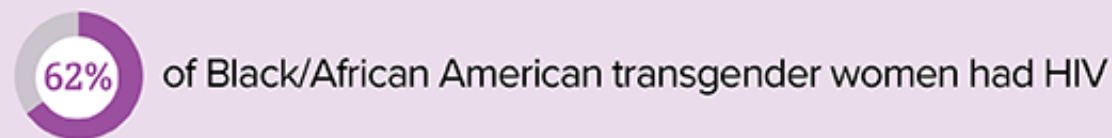
Source: CDC. Diagnoses of HIV infection in the United States and dependent areas, 2019. *HIV Surveillance Report* 2021;32.

# HIV Prevalence Among Transgender Women in 7 US Cities, 2019-2020

Racial and ethnic disparities exist among transgender women with HIV.



Among transgender women interviewed, 42% had HIV.



Source: CDC. HIV infection, risk, prevention, and testing behaviors among transgender women—National HIV Behavioral Surveillance—7 U.S. Cities, 2019-2020. *HIV Surveillance Special Report 2021*.



# PrEP Awareness and Use Among Transgender Women in 7 US Cities, 2019-2020\*

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



of transgender women without HIV were aware of PrEP



of transgender women without HIV used PrEP

\* Among people aged 18 and older.

Source: CDC. HIV infection, risk, prevention, and testing behaviors among transgender women—National HIV Behavioral Surveillance—7 U.S. Cities, 2019-2020. *HIV Surveillance Special Report 2021*.

# Who should be prescribed PrEP

	IAS-USA (2022)	HHS/CDC (2021)
Sexually active adults and adolescents	<p>Discuss without criteria for risk behavior or screening tools. Encourage consideration if:</p> <ul style="list-style-type: none"> <li>- MSM/TGPSM</li> <li>- young adult/adolescent</li> <li>- partner from generalized epidemics</li> <li>- exchange sex for \$</li> <li>- partners are incarcerated</li> <li>- recent bacterial STI</li> </ul>	<p>Everyone should receive info. Recommended for persons at substantial ongoing risk.</p> <ul style="list-style-type: none"> <li>- HIV positive sex partner</li> <li>- Bacterial STI last 6 months</li> <li>- h/o inconsistent condom use</li> </ul>
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

	IAS-USA (2022)	HHS/CDC (2021)
FTC/TDF	All persons at risk from sexual or injection exposures.	All persons at risk from sexual or injection exposures.
FTC/TAF	<ul style="list-style-type: none"><li>- Preferred if eCrCl 30-60 mL/min or known osteoporosis</li><li>- Limited to anyone whose risks do not include receptive vaginal or neovaginal sex or exclusive IDU</li></ul>	<ul style="list-style-type: none"><li>- Preferred if eCrCl 30-60 mL/min or known osteoporosis</li><li>- Recommended for men and TGW who have sex with men.</li></ul>
CAB	All persons at risk from sexual exposures and PWID with sexual risk.	All persons at risk from sexual exposures.

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)

	IAS-USA (2022)	HHS/CDC (2021)
Cisgender men	Recommended regardless of sexual orientation	For adult MSM who have sex less than 1x/week and can anticipate sex
Transgender women	Use with caution in TGW receiving hormone therapy	
Cisgender women, transgender men, PWID	Insufficient data	

# 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

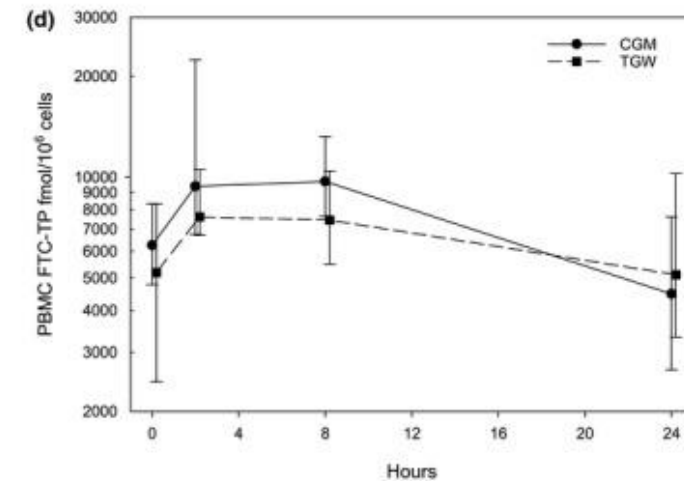
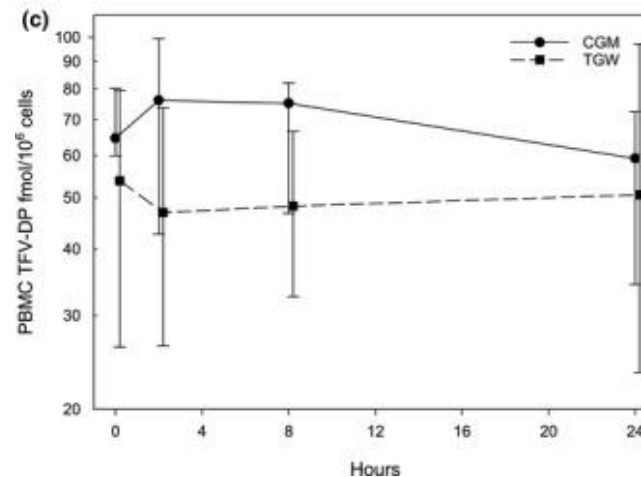
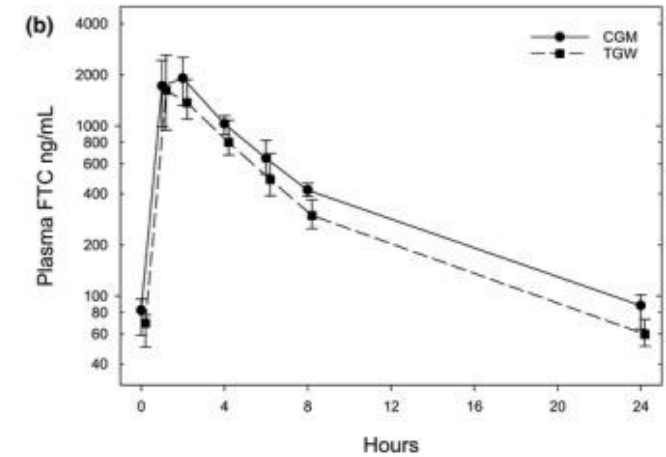
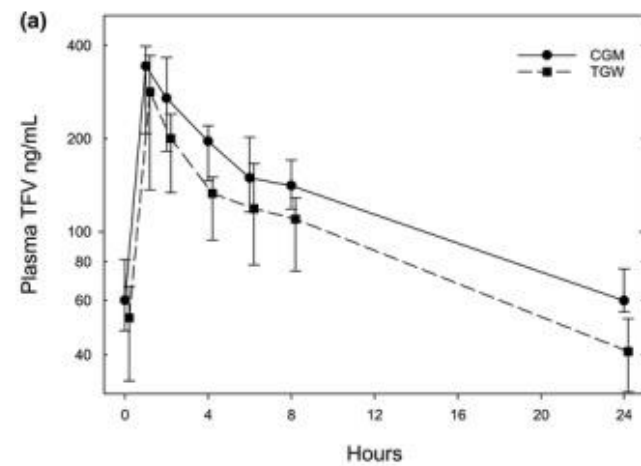
- 8 TGW
- 8 CGM

## Methods

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

## Conclusions

- 24-32% ↓ plasma level in TGW



# Sex Hormone Therapy and Tenofovir Diphosphate Concentration in Dried Blood Spots: Primary Results of the iBrEATHe Study.

## 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

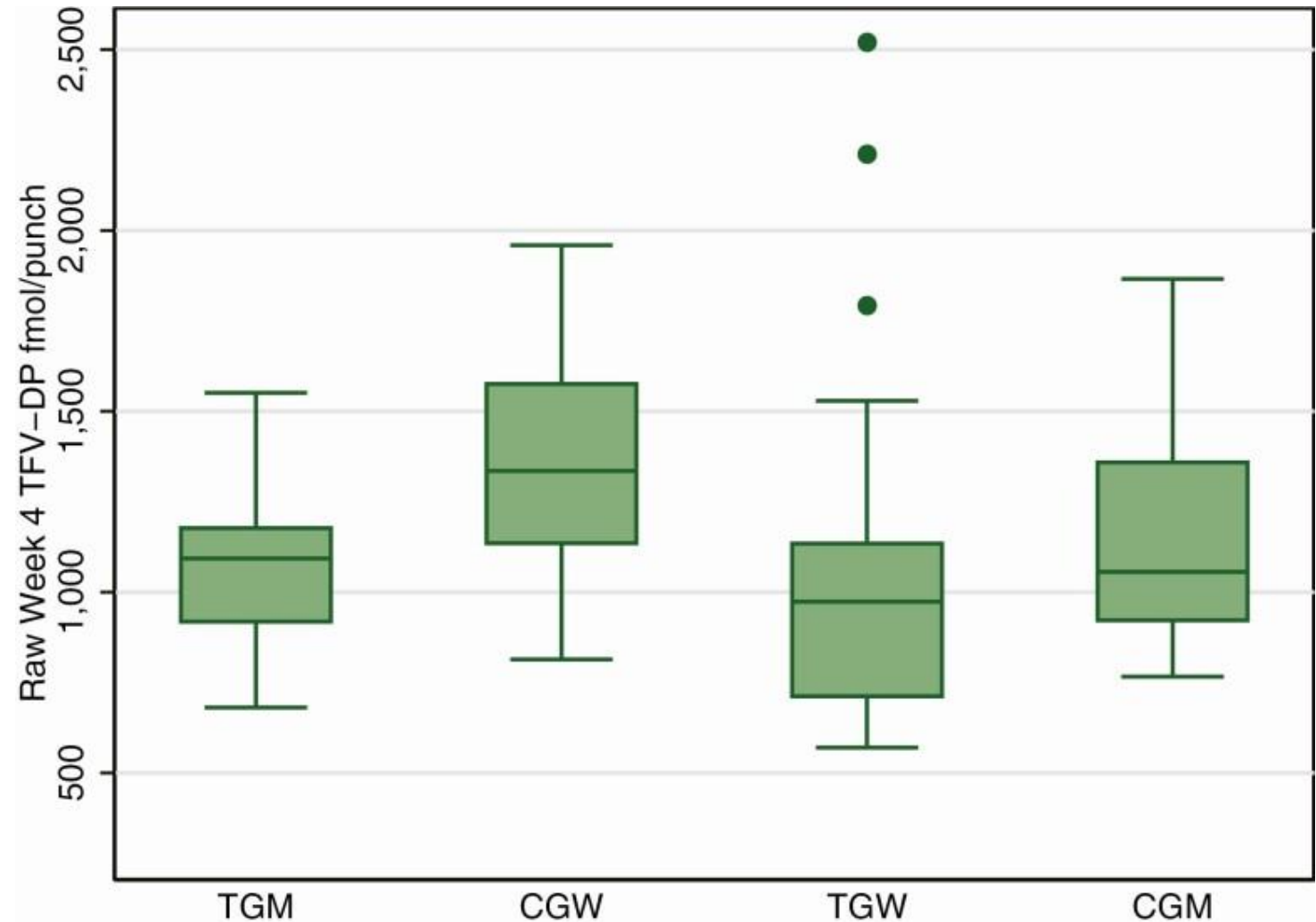
## Conclusions

- 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

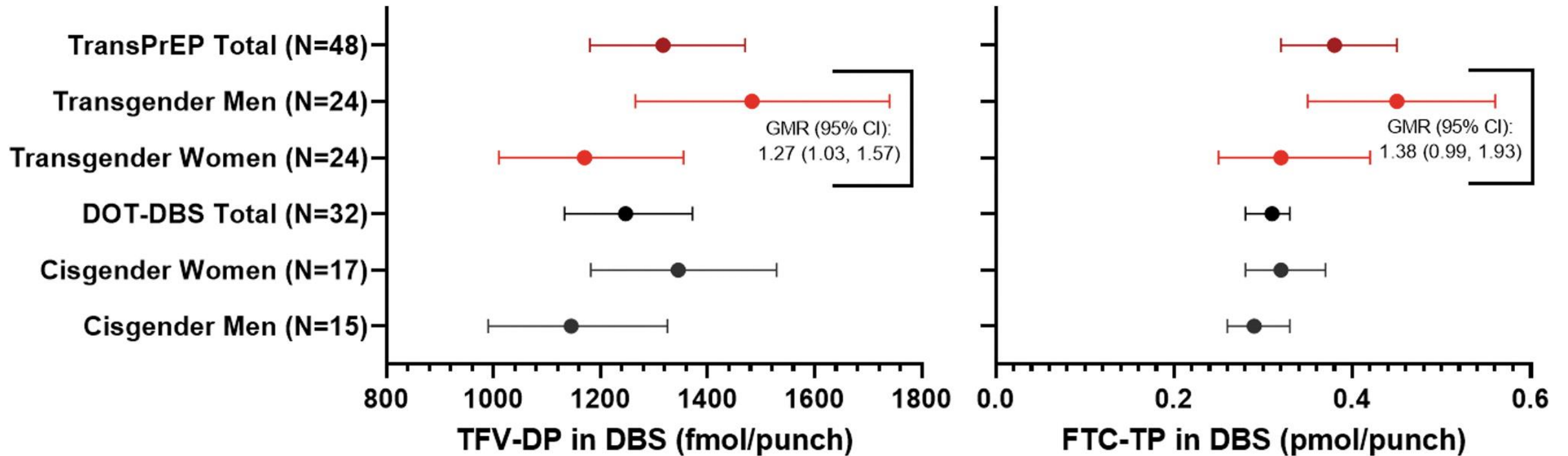
## Comparisons

- 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





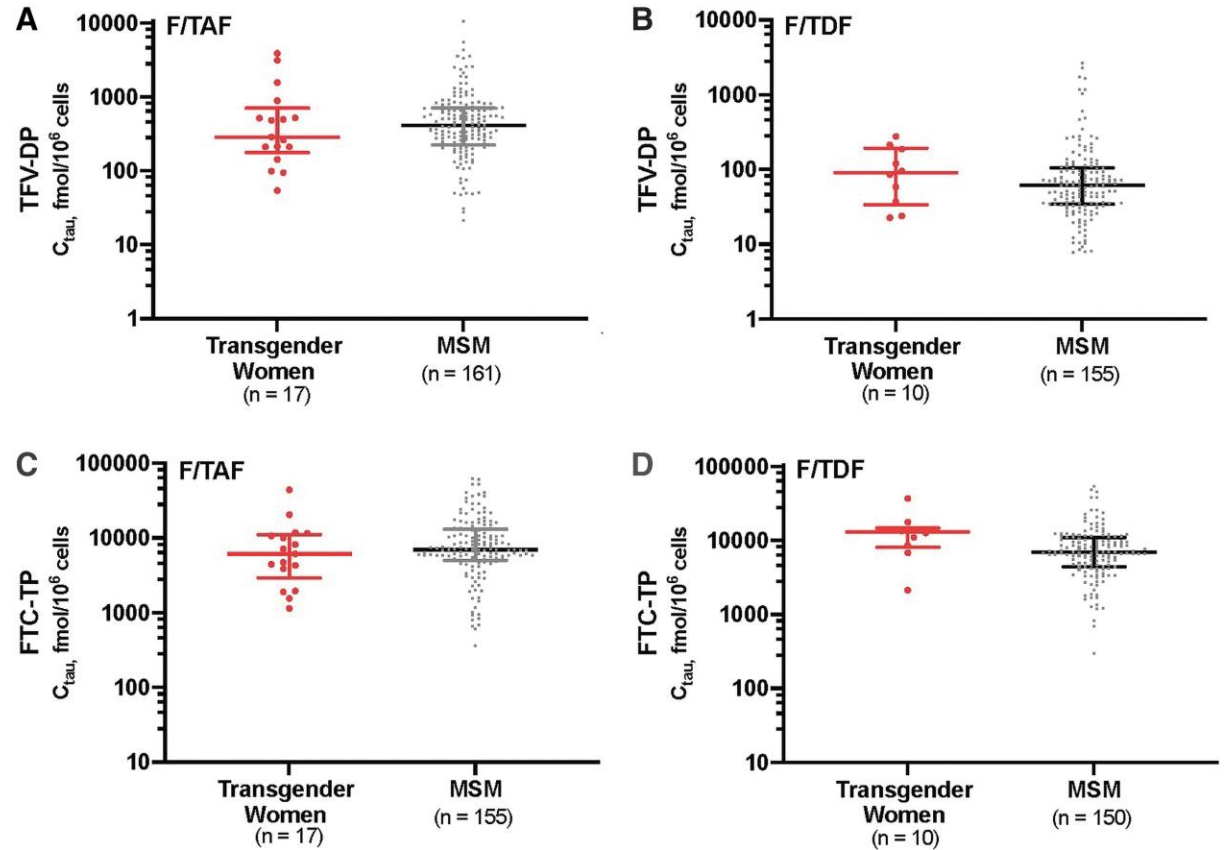
# Additional Studies: TransPrEP Study



# Additional Studies: DISCOVER Trial

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.

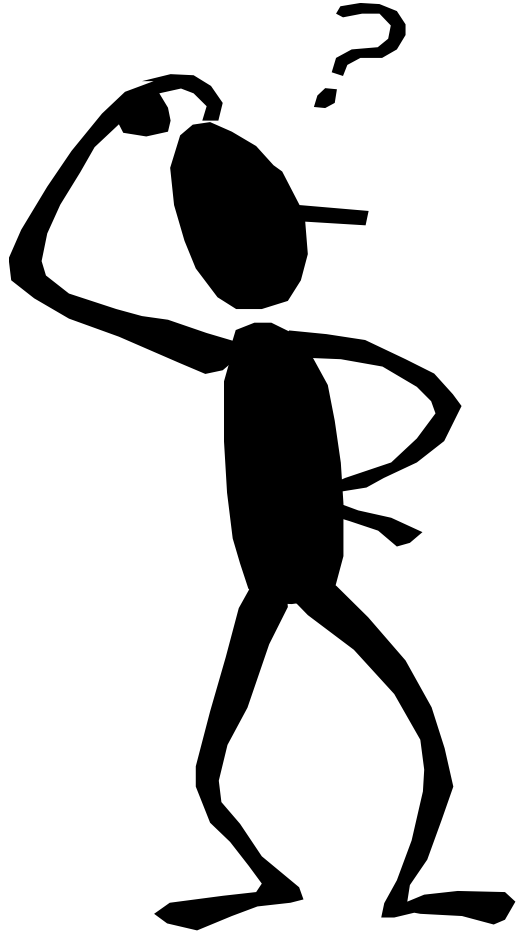
# Conclusions

- 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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