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The Impact of Violence on PrEP Adherence Among Cisgender Women and PrEP Use Among MSM in the US

PrEP Adherence in Cisgender Women[1]

Open-label trial in CGW ≥18 years old taking F/TDF for PrEP with AEGiS intervention, San Diego and Los Angeles, CA (N=136)

- 22% reported physical and/or sexual violence in past year
- 30% reported sexual violence over life course

Odds of Adherence† Four Weeks Post-PrEP Initiation

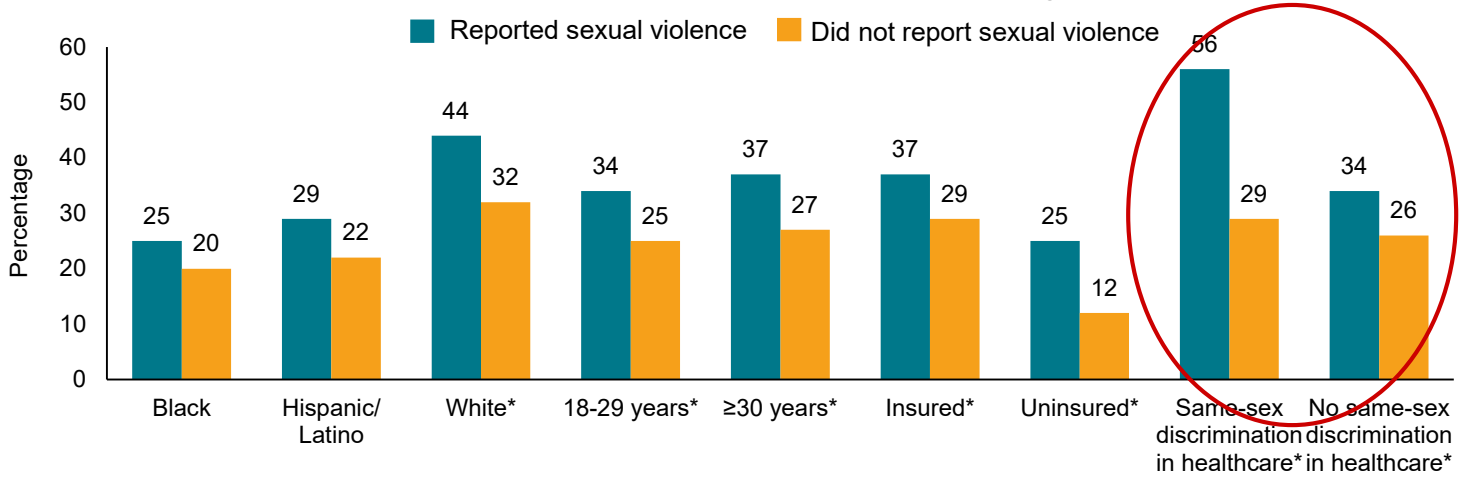
Violence or Abuse Experienced in Past Year	aOR‡	*P*-value
Physical abuse	0.24	0.03
Sexual abuse	0.25	0.04
Physical or sexual violence	0.20	< 0.01
Lifetime sexual abuse	0.27	< 0.01

PrEP Use in MSM[2]

NHBS survey data in sexually active HIV-negative MSM in 23 U.S. cities, 2017 (N=7,121)

- 5% reported sexual violence in the past 12 months
- Those reporting sexual violence were **more likely** to:
  - Have a PrEP indication (83% vs. 77%, P=0.08)
  - Have used PrEP in the past 12 months (35% vs. 26%, P=0.01)

Proportions Who Used PrEP in Past 12 Months by Characteristics



Screening for violence may better identify HIV risk and opportunities to improve PrEP adherence

*P<0.05, †Defined as having DBS TFV-DP concentrations consistent with ≥4 doses/week, ‡Adjusted for birth year, race, ethnicity, education, employment, and relationship status
MSM, men who have sex with men; CGW, cisgender women; F/TDF, emtricitabine/tenofovir disoproxil fumarate; AEGiS, adherence enhancement guided by individualized texting and drug levels; NHBS, National Health Behavior Surveillance; aOR, adjusted odds ratio

1. Anderson K, et al. vCROI 2021. #711. 2. Freeman J, et al. vCROI 2021. #712

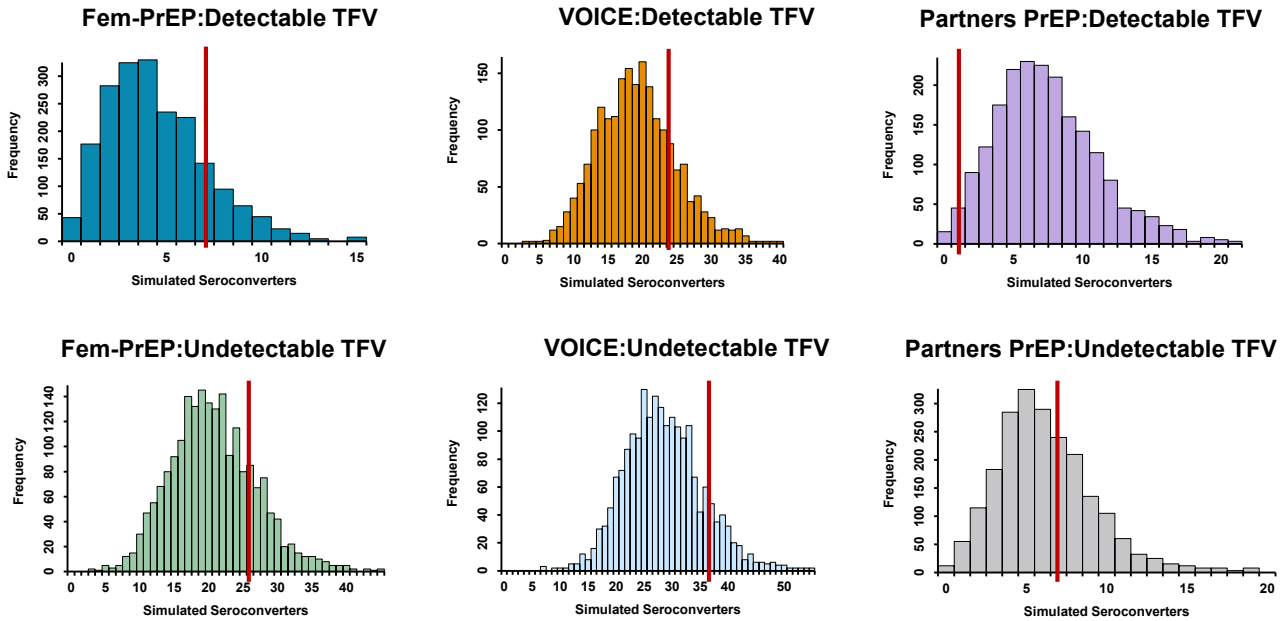
Predicting Efficacy in Women with Partial Adherence to F/TDF for PrEP

Mathematical modeling to determine efficacy of F/TDF for PrEP in women using results of 3 RCT's (VOICE, FEM-PrEP, and Partners PrEP) that examined TFV plasma concentrations with data imputed from HPTN 082

Results:

- Calibrated model enabled reproduction of detectable TFV in sero-converters in the 3 RCTs
- Implied underlying relationship between intracellular TFV levels and PrEP efficacy

Simulation of Seroconversions Among Individuals with Detectable and Undetectable TFV*



*Histogram shows results from 2000 model runs, vertical red line is the observation in the study

This model predicts that among women on F/TDF for PrEP, taking 2, 4, or 7 pills/week would reduce HIV risk by 62%, 87% and 97%, respectively

F/TDF, emtricitabine/tenofovir disoproxil fumarate; MSM, men who have sex with men; TFV, tenofovir; TFV-DP, tenofovir diphosphate; RCT, randomized controlled trials

Moore J, et al. vHIV R4P 2021. #775

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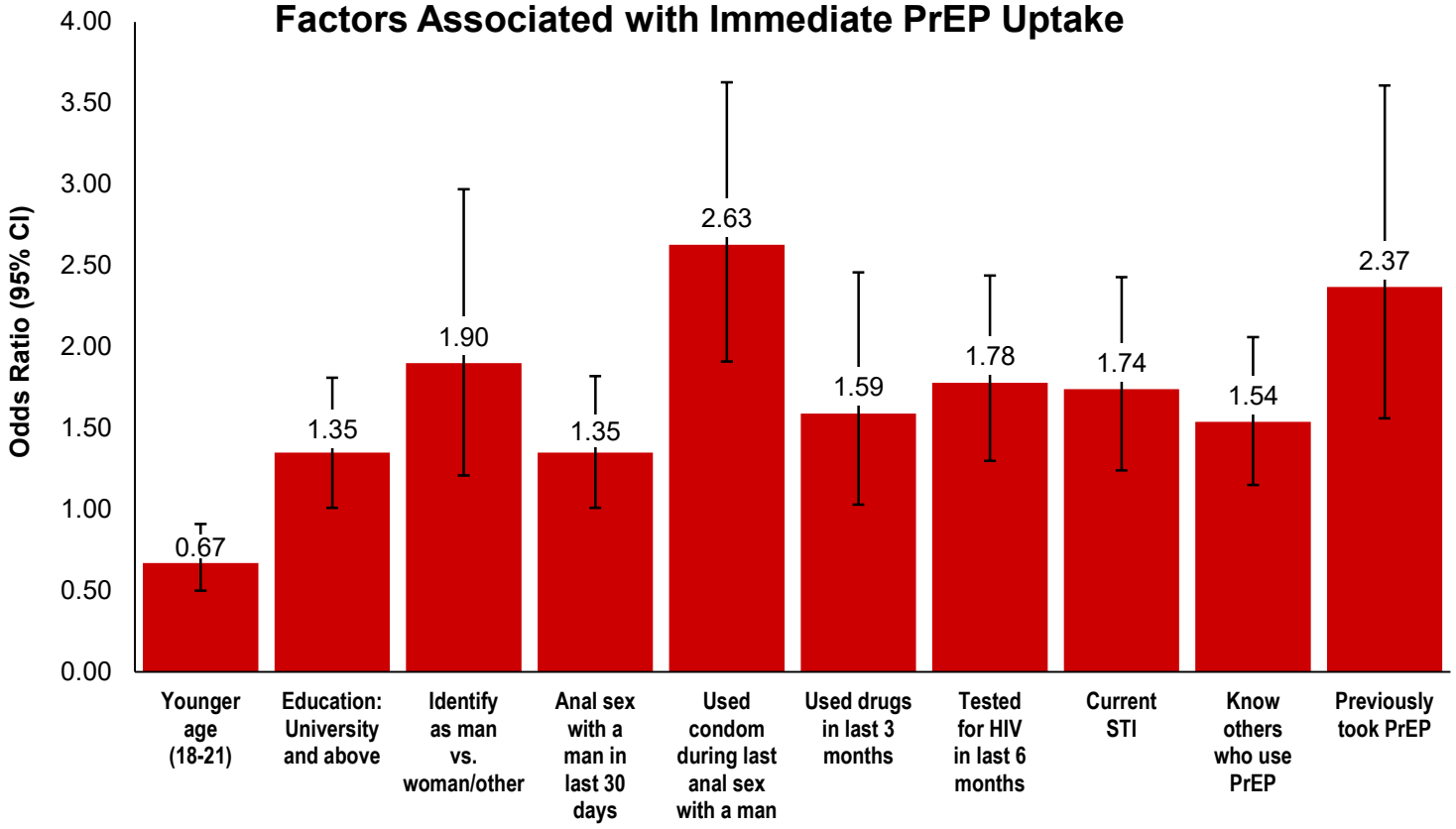
Immediate PrEP Medication Uptake in Young MSM and TGW Who Exchanged Money or Commodities for Sex

Evaluation of immediate PrEP uptake (within 7 days) among young MSM and TGW aged 18-26 from October 2017 – August 2020 (N=846)

Results:

- Immediate PrEP (<7 days): 62%
- Delayed PrEP (>7 days): 13%

  (median delay = 6 weeks, IQR= 4-17)
- No PrEP uptake: 26%
- Younger individuals and TGW were less likely to initiate PrEP compared to older participants and cisgender MSM



More tailored approaches may be needed to better engage young MSM and TGW in same-day PrEP

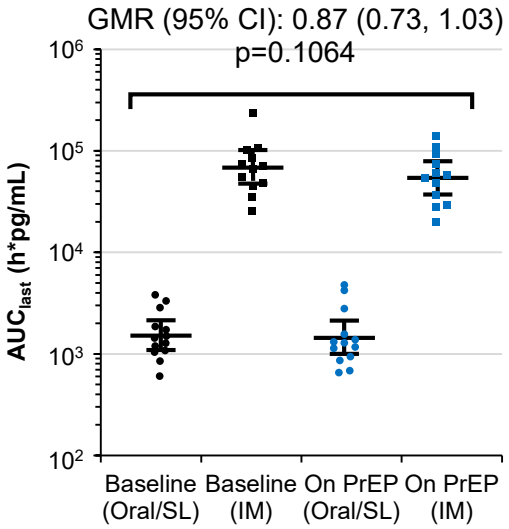
MSM, men who have sex with men; TGW, transgender women

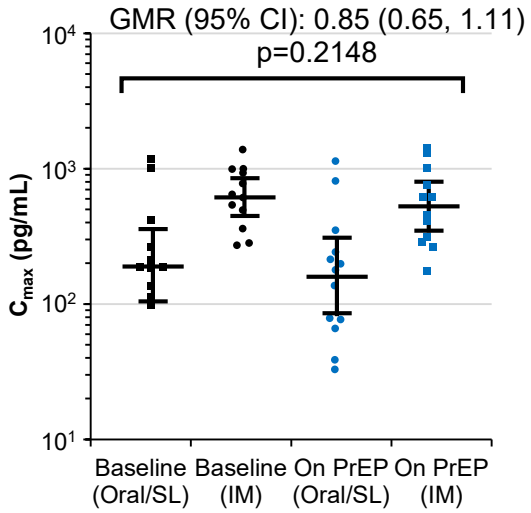
Weir BW, et al. vHIV R4P 2021. #1455

Exogenous Hormone Pharmacokinetics In Transgender Adolescents Receiving Oral F/TDF for PrEP

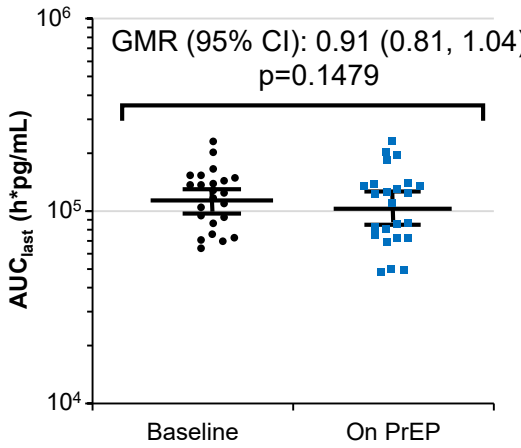
DOT study analyzing the effects of F/TDF on serum estradiol and testosterone concentrations among HIV-negative TGW (n=25) and TGM (n=24) ages 16-24 on GAHT (N=49)

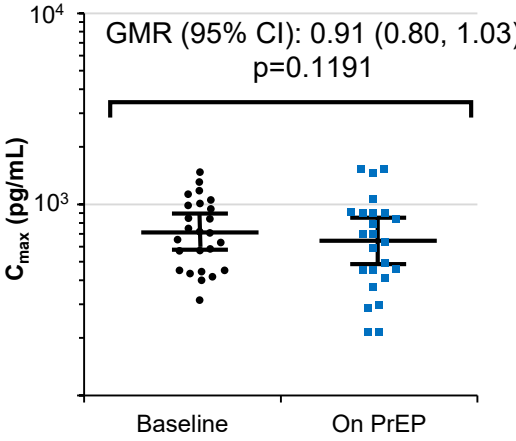
Serum Estradiol at Baseline and After F/TDF





Serum Total Testosterone at Baseline and After F/TDF





F/TDF does not significantly alter serum estradiol or testosterone pharmacokinetics in transgender adolescents

F/TDF, emtricitabine/tenofovir disoproxil fumarate; DOT, directly observed therapy; TGW, transgender women; TGM, transgender men; GAHT, gender-affirming hormone therapy; GMR, geometric mean ratio; AUC, area under the curve

Yager et al. vCROI 2021. #366

Sustained Delivery and Long-Acting Agents for HIV Prevention

Product	Drug Class	Route	Dosing Frequency	Status
Lenacapavir	Capsid inhibitor	Subcutaneous injection	Every 6 months (twice a year)	Phase 3 studies in MSM/TGI and CGW to begin
Cabotegravir	INSTI	Intramuscular injection	Every 8 weeks	Phase 3 in MSM/TGW and CGW ongoing
Dapivirine	NNRTI	Intravaginal ring	Every month	Phase 3 completed. Approved by EMA; WHO recommends for low/middle income countries; being submitted to FDA
Dapivirine	NNRTI	Intravaginal ring	Every 3 months	Acceptability, PK in humans
bNAbs	(Broadly neutralizing antibodies)	Intravenous infusion	Every 2 months	Prevention efficacy for HIV sensitive to the specific bNAb
Islatravir	NRTTI	Oral	Every month	Phase 3 in MSM/TGW and CGW to begin
Islatravir	NRTTI	Subcutaneous implant	Once a year? (removable)	PK in humans
TAF	NRTI	Subcutaneous implant	?	Non human primate PK and SHIV prevention
Cabotegravir	INSTI	Reservoir implant	?	Non human primate PK and SHIV prevention

Long-acting agents could offer additional options for HIV prevention

INSTI, integrase strand inhibitor; NRTI, nucleoside reverse transcriptase inhibitor; NRTTI, nucleoside reverse transcriptase translocation inhibitor; TAF, tenofovir alafenamide; TGI, transgender individuals; TGW, transgender women; CGW, cisgender women; MSM, men who have sex with men; PK, pharmacokinetic

Bekker LG, et al. vCROI 2021. Oral #47