AETC AIDS Education & Training Center Program Mountain West

Pre-Exposure Prophylaxis for HIV Infection 2023 Update

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Disclaimer

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Disclosures

This talk will include discussion of commercial products as well as off-label and investigational use of products.

I have no conflicts of interests or relationships to disclose.

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

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Question #1

Casey is a 28-year-old transgender man who injects methamphetamine, occasionally sharing needles with selected partners. He engages in sex work with inconsistent condom use. Which of the following should be offered to prevent HIV infection from injection drug use?

- Emtricitabine/ tenofovir disoproxil fumarate (FTC/TDF), once daily
- Emtricitabine/ tenofovir alafenamide (FTC/TAF), once daily
- Long-acting injectable cabotegravir (CAB-LA), monthly for 2 months, and then every 2 months thereafter
- None of the above; PrEP is not indicated for individuals actively injecting drugs

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Outline

- What is PrEP?
- PrEP efficacy and effectiveness
- Side effects, STIs, HIV-1 drug resistance, and other concerns

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What is PrEP?

PrEP (Pre-Exposure Prophylaxis) = HIV-negative persons taking HIV medicine to prevent them from getting HIV infection.

FDA-approved PrEP (October 2023)

Daily emtricitabine/tenofovir disoproxil fumarate (FTC/TDF: Truvada)

- All populations
- Requires CrCl > 60 mL/min

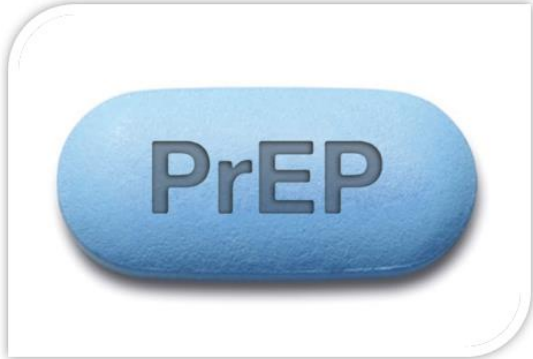
Daily emtricitabine/tenofovir alafenamide (FTC/TAF: Descovy)

- For cisgender men and transgender women (sexual exposure)
- Requires CrCl > 30 mL/min

Injectable cabotegravir (Apretude)

- All populations (sexual exposure)

Dapivirine vaginal ring has been withdrawn.



Key HIV PrEP Trials Using Oral TDF, FTC/TDF, or FTC/TAF

Study	Study Population	Study Randomization	HIV Incidence Impact
IPrEx (Brazil, Ecuador, South Africa, Thailand, US)	2499 MSM and transgender women	Daily oral TDF-FTC or placebo	TDF-FTC: 44% ↓
Partners PrEP Study (Kenya, Uganda)	4147 heterosexual HIV discordant couples	Daily oral TDF, TDF-FTC, or placebo	TDF: 67% ↓ TDF-FTC: 75% ↓
TDF2 Study (Botswana)	1219 heterosexual men and women	Daily oral TDF-FTC or placebo	TDF-FTC: 63% ↓
FEM-PrEP (Kenya, South Africa, Tanzania)	2120 women	Daily oral TDF-FTC or placebo	TDF-FTC: no protection
VOICE (South Africa, Uganda, Zimbabwe)	5029 women	Randomized to daily oral TDF, TDF-FTC, oral placebo, TDF vaginal gel, or gel placebo	TDF: no protection TDF-FTC: no protection TDF gel: no protection
Bangkok TDF Study (Thailand)	2413 injection drug users	Randomized to daily oral TDF or placebo	TDF: 49% ↓
IPERGAY (France, Quebec)	400 MSM	Randomized to “on-demand” TDF-FTC or placebo	TDF-FTC: 86% ↓
PROUD (United Kingdon)	545 MSM and transgender women	Randomized to daily oral TDF-FTC immediately or delayed	Immediate TDF-FTC: 86% ↓
DISCOVER (Canada, Europe, US)	5387 MSM and transgender women	Daily oral FTC/TDF or FTC/TAF	F/TDF incidence: 0.3% F/TAF incidence: 0.16%

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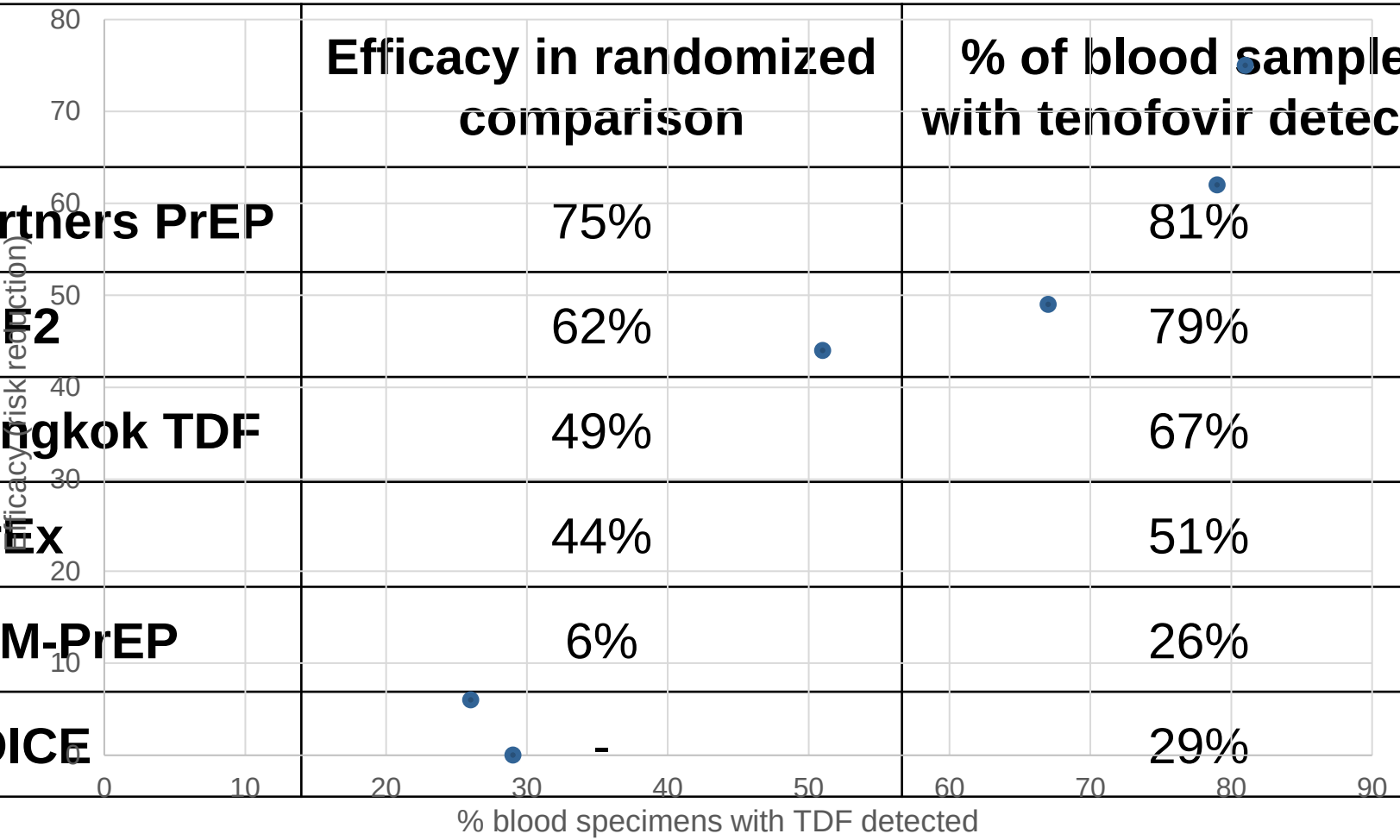
How well does PrEP work?
Adherence & efficacy

	Efficacy in randomized comparison	% of blood samples with tenofovir detected
Partners PrEP	75%	81%
TDF2	62%	79%
Bangkok TDF	49%	67%
iPrEx	44%	51%
FEM-PrEP	6%	26%
VOICE	-	29%



Baeten et al N Engl J Med 2012
Grant et al N Engl J Med 2010
Choopanya et al Lancet 2013

Van Damme et al N Engl J Med 2012
Thigpen et al N Engl J Med 2012
Marrazzo et al N Engl J Med 2015

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How well does PrEP work?
Real life effectiveness

Estimated adherence (TDF in DBS)	Incidence	Protection
Not detected	4.7/100 person-years	
<2 tab/week	2.3/100 person-years	51%
2-3 tab/week	0.6/100 person-years	87%
4-7 tab/week	0/100 person-years	100%

Source: Grant et al (iPrEx OLE), Lancet. 2014: 14; 819-829.

There have been <10 well-documented cases of persons who became HIV-positive despite excellent adherence to PrEP. But there are probably others.

Examples: **Knox et al NEJM 2017; 376: 501-502**
Markowitz et al JAIDS 2017; 76(4): e104-106
Hoornenborg et al, Lancet HIV 2017; 4: e522-28

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What are the short-term side effects of oral PrEP?

Short-term side effects in the DISCOVER TRIAL

	FTC/TAF N=2694	FTC/TDF N=2693
Diarrhea	5%	6%
Nausea	4%	5%
Headache	2%	2%
Fatigue	2%	3%
Abdominal pain	2%	3%

Neither needs to be taken with food

Descovy package insert, 10/2019

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What are the long-term side effects of oral PrEP?

	FTC/TAF	FTC/TDF
Drug-related AE's		
Mean change (%), spine BMD	1.0	-1.4
Mean change (%), hip BMD	0.6	-1.0
Mean change (mL/min), eGFR	-0.6	-4.1
Weight and lipids		
Mean change (kg)	1.7	0.5
Mean change total cholesterol (mg/dL)	-3	-14
Mean change LDL (mg/dL)	-2	-7

Source: Mayer et al Lancet 2020 Jul 25; 396: 239-254.

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Injectable cabotegravir (CAB)

Superior to oral FTC/TDF

HPTN 083 (4570 cisgender men and transgender women)

- 13 infections in the CAB arm (incidence rate 0.41%)
- 39 infections in the FTC/TDF arm (incidence rate 1.22%).
- Hazard ratio for CAB versus FTC/TDF was **0.34 (95% CI 0.18-0.62)**

HPTN 084 (3223 cisgender women).

- 4 infections in the CAB arm (incidence rate 0.21%)
- 34 infections in the FTC/TDF arm (incidence rate 1.79%)
- Hazard ratio for CAB versus FTC/TDF was **0.11 (95% CI 0.04-0.32)**

HPTN 083: N Engl J Med 2021; 385:595-608
HPTN 084: Lancet 2022; 399: 1779-1789

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LifeStyles
701
ANOTHER BLUE PILL FOR SEX

Additional benefits of PrEP

- Decreased anxiety
- Increased communication and disclosure
- Increased self-efficacy
- Increased sexual pleasure and intimacy
- Reframing of sexual health in a positive framework

Gimore et al. IAPAC 2014.

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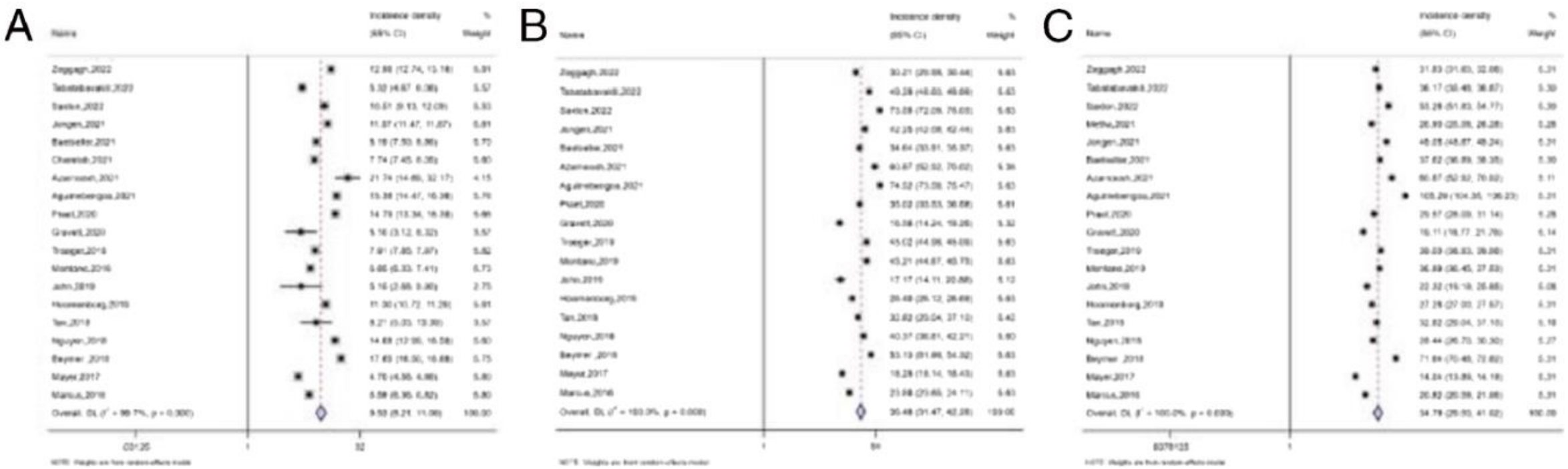
Risks of PrEP: STIs



Zhou et al. Sexually transmitted diseases , 2022, Vol.49(11), p.733-739

Risks of PrEP: HIV drug resistance

	Acute HIV at enrollment		HIV infection post-enrollment	
	PrEP	Placebo	PrEP	Placebo
BTS	0/0	0/2	0/17	0/33
FEM-PrEP	0/1	0/1	4/33	1/35
iPrEx	2/2	1/8	0/48	0/83
Partners	2/8	0/6	0/27	0/51
TDF2	1/1	0/2	0/9	0/24
VOICE	2/14	0/1	1/113	0/60
Total	**7/26 (27%)**	**1/20 (5%)**	**5/247 (2%)**	**1/286 (0.3%)**

Excluding acute infections when PrEP was started:
10 (39/4) infections averted per drug resistant infection.

IAS: Grant, oral abstract TUAC0104 Fonner et al, JAIDS 2016; 30(12): 1973-1983, supplement

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Question #2

Which of the following has significant drug-drug interactions with gender-affirming hormone therapy?

- Emtricitabine/ tenofovir disoproxil fumarate (FTC/TDF)
- Emtricitabine/ tenofovir alafenamide (FTC/TAF)
- Long-acting injectable cabotegravir (CAB-LA)
- None of the above

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PrEP and transgender patients

- 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 transgender persons
  - Concern about side effects
  - Stigma and mistrust of medical providers
  - Co-location of PrEP and gender affirming care services may ↑ PrEP uptake

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How to prescribe PrEP

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2021 UPDATE

A CLINICAL PRACTICE GUIDELINE

JAMA | Special Communication

Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults

2022 Recommendations of the International Antiviral Society–USA Panel

Rajesh T. Gandhi, MD; Roger Bedimo, MD; Jennifer F. Hoy, MBBS; Raphael J. Landovitz, MD; Davey M. Smith, MD; Ellen F. Eaton, MD; Clara Lehmann, MD; Sandra A. Springer, MD; Paul E. Sax, MD; Melanie A. Thompson, MD; Constance A. Benson, MD; Susan P. Buchbinder, MD; Carlos del Rio, MD; Joseph J. Eron Jr, MD; Huldrych F. Günthard, MD; Jean-Michel Molina, MD; Donna M. Jacobsen, BS; Michael S. Saag, MD

IMPORTANCE Recent advances in treatment and prevention of HIV warrant updated recommendations to guide optimal practice.

OBJECTIVE Based on a critical evaluation of new data, to provide clinicians with recommendations on use of antiretroviral drugs for the treatment and prevention of HIV, laboratory monitoring, care of people aging with HIV, substance use disorder and HIV, and new challenges in people with HIV, including COVID-19 and monkeypox virus infection.

EVIDENCE REVIEW A panel of volunteer expert physician scientists were appointed to update the 2020 consensus recommendations. Relevant evidence in the literature (PubMed and Embase searches, which initially yielded 7891 unique citations, of which 834 were considered relevant) and studies presented at peer-reviewed scientific conferences between January 2020 and October 2022 were considered.

FINDINGS Initiation of antiretroviral therapy (ART) is recommended as soon as possible after diagnosis of HIV. Barriers to care should be addressed, including ensuring access to ART and adherence support. Integrase strand transfer inhibitor–containing regimens remain the mainstay of initial therapy. For people who have achieved viral suppression with a daily oral regimen, long-acting injectable therapy with cabotegravir plus rilpivirine given as infrequently as every 2 months is now an option. Weight gain and metabolic complications have been linked to certain antiretroviral medications; novel strategies to ameliorate these complications are needed. Management of comorbidities throughout the life span is increasingly important, because people with HIV are living longer and confronting the health challenges of aging. In addition, management of substance use disorder in people with HIV requires an evidence-based, integrated approach. Options for preexposure prophylaxis include oral medications (tenofovir disoproxil fumarate or tenofovir alafenamide plus emtricitabine) and, for the first time, a long-acting injectable agent, cabotegravir. Recent global health emergencies, like the SARS-CoV-2 pandemic and monkeypox virus outbreak, continue to have a major effect on people with HIV and the delivery of services. To address these and other challenges, an equity-based approach is essential.

CONCLUSIONS AND RELEVANCE Advances in treatment and prevention of HIV continue to improve outcomes, but challenges and opportunities remain.

Multimedia

Supplemental content

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Who should be prescribed PrEP?

- All sexually active adults and adolescents should receive information about PrEP **(IIIB)**
- For both men and women, PrEP with daily FTC/TDF is recommended for sexually-active adults and adolescents (>35 kg) who report sexual behaviors that place them at substantial ongoing risk of HIV exposure and acquisition **(IA)**
- For both men and women, PrEP with daily FTC/TDF is recommended for persons who inject drugs (PWID) and report injection practices that place them at substantial ongoing risk of HIV exposure and acquisition **(IA**)
- PrEP should be prescribed in discordant couples
  - If the sex partner with HIV has been inconsistently virally suppressed
  - If their VL is unknown
  - If the HIV-negative partner has other sex partners
  - If the HIV-negative partner wants the additional reassurance of protection

General Principles of Taking a Sexual Health History

- Setting should offer complete privacy and patient should be alone
  - No partners, children, parents, friends, etc.
- Let them know these are questions that you ask of all your patients
- **If you are comfortable, patient will comfortable**
- Be sensitive, but clear and direct
- Normalize behaviors
- Best to mirror patient's language insofar as you feel comfortable
- Ask only questions you NEED to know; do not ask things you are curious about

Slide courtesy of Sarah McDougal, PA-C

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Starting the Conversation

- “Do you have any questions about your keeping yourself sexually safe and healthy?”
- ”Do you have any questions or concerns about your sexual health?”
- ”I usually ask questions about sexual health as part of routine care for my patients. Is it OK if I ask you some about your sexual health now?”
- “May I ask some questions about your sexual health habits? I know that these are sensitive questions, but I promise I will only be asking questions that help us make the best plan for your care today.”
- “Have you been sexually active in the last year?”

Slide courtesy of Sarah McDougal, PA-C

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CDC's 5 P's of Sexual Health History Taking

Partners

Practices

Protection from STIs

Past history of STIs

Prevention intention

https://www.cdc.gov/stophivtogether/library/topics/prevention/brochures/cdc-lsht-prevention-brochure-clinicians-quick-guide-discussing-sexual-health-your-patients.pdf

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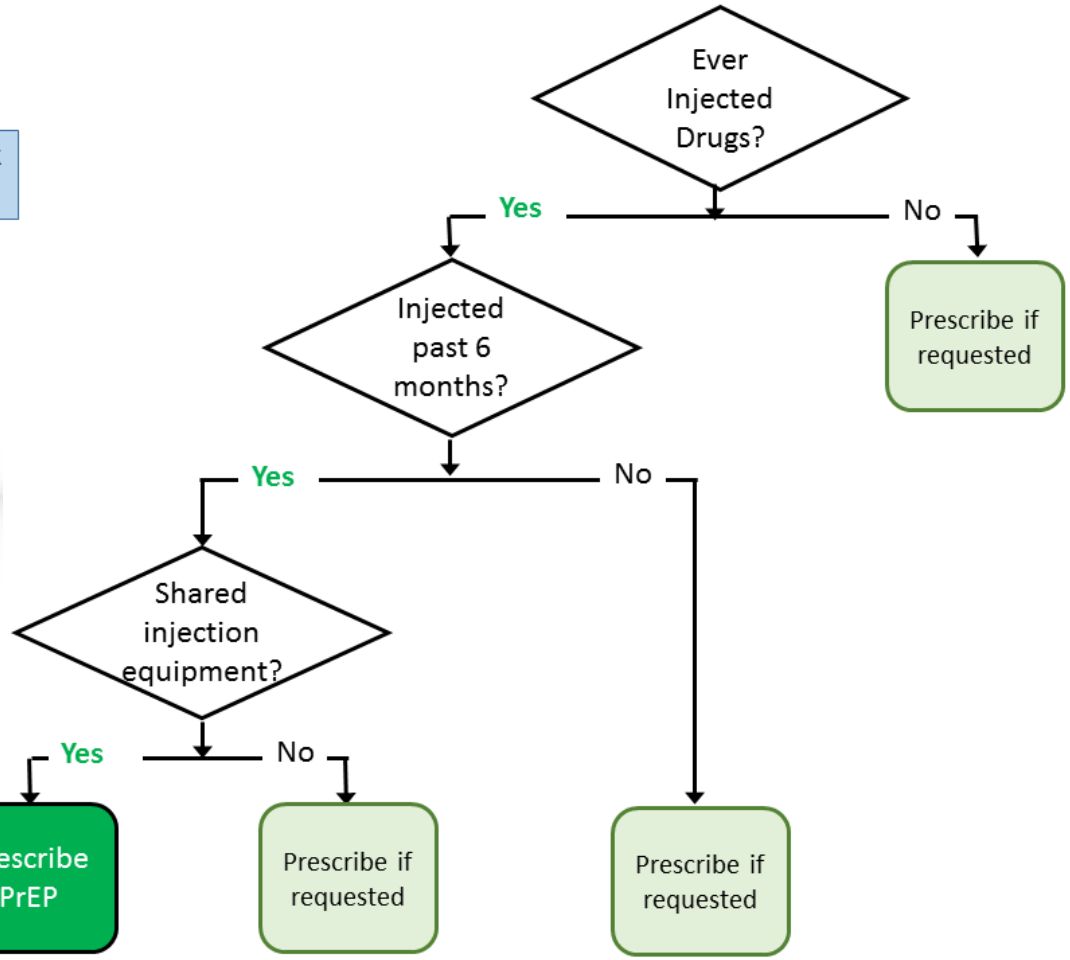
Assessing Indications for PrEP in Sexually Active Persons

Assessing Indications for PrEP in Persons Who Inject Drugs

Assess sexual risk for all PWID



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	- Preferred if eCrCl 30-60 mL/min or known osteoporosis - Limited to anyone whose risks do not include receptive vaginal or neovaginal sex or exclusive IDU	- Preferred if eCrCl 30-60 mL/min or known osteoporosis - Recommended for men and TGW who have sex with men.
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.

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What to prescribe as PrEP?

- FTC/TAF is a recommended option for men. FTC/TAF has not yet been studied in persons at risk through receptive vaginal sex. **(IA)**
- For transgender women who have sex with men, FTC/TAF is a recommended option. **(IIB)**
- For most patients, there is no need to switch from FTC/TDF to FTC/TAF.
- FTC/TAF is indicated for patients with eCrCl 30-60.
- Clinicians may prefer FTC/TAF for patients with previously documented osteoporosis or related bone disease.
- Other daily oral antiretroviral medications for PrEP have not been studied extensively and are not recommended. **(IIIA)**
- Conditioned on a PrEP indication approved by FDA, PrEP with intramuscular cabotegravir (CAB) injections is recommended for HIV prevention in adults and adolescents who report sexual behaviors that place them at substantial ongoing risk of HIV exposure and acquisition. **(IA).**

Baseline testing

	IAS-USA (2022)	HHS/CDC (2021)
HIV Ag/Ab testing	Lab based test should be performed even if PrEP started based on POC.	Lab based test should be performed even if PrEP started based on POC. Oral fluid tests should not be used.
HIV RNA testing	Recommended if: - high risk exposure in last 4 wks - Signs/sx acute HIV infection - CAB	Recommended for CAB
Serum creatinine	For oral PrEP only	For oral PrEP only
Lipid panel	Not mentioned	For persons receiving FTC/TAF
Hepatitis serologies	HAV Ab for MSM/PWID if not immune HBV sAg and sAb HCV Ab	Oral PrEP: HBV testing Others: not indicated* (but follow primary care guidelines)
STI screening	Genital/non-genital GC/CT, syphilis	Genital/non-genital GC/CT, syphilis
Pregnancy testing	If relevant	If relevant

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Monitoring

	IAS-USA (2022)	HHS/CDC (2021)
HIV Ag/Ab testing	Month 1 for everyone Q3 mo for oral PrEP, Q4 mo for CAB	Oral PrEP: Q3mo CAB: Q2mo
HIV RNA testing	For CAB only: Month 1, then Q4 mo	Oral PrEP: Q3mo CAB: Q2mo
Serum creatinine	Month 3 for oral PrEP Q 3-6 mo for >50 or eCrCl<90 baseline Or Annually	Month 3 for everyone Q 3-6 mo for >50 or eCrCl<90 baseline Or Annually
Lipid panel	Not mentioned	Annual
Hepatitis serologies	HCV Ab annually, Q3-6 months for MSM, people who use drugs, or abnl LFT	
STI screening	Q3-4 months	Oral PrEP: every 3 months for MSM CAB: every 4 months for MSM/TGW, Q6mo hetero
Pregnancy testing	Q3-4 months	

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How to prescribe oral PrEP
Same day dosing

Same-day PrEP initiation **is not appropriate** for:

- Patients who express ambivalence about starting PrEP (e.g., need more time to think)
- Patients for whom blood cannot be drawn for laboratory testing
- Patients with signs/symptoms and sexual history indicating possible acute HIV infection
- Patients with history of renal disease or associated conditions (e.g., hypertension, diabetes)
- Patients without insurance or a means to pay when picking up the prescribed medication that day
- Patients who do not have a **confirmed** means of contact should laboratory test indicate a need to discontinue PrEP (e.g., HIV infection, unanticipated renal dysfunction)

Same-day PrEP initiation **may not be appropriate** for:

- Patients with a very recent possible HIV exposure but no signs and symptoms of acute infection (should be evaluated for nPEP before PrEP)
- Patients who may not be easily contacted for return appointments
- Patients with mental health conditions that are severe enough to interfere with understanding of PrEP requirements (adherence, follow-up visits)

CDC/HHS guidelines

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How to prescribe oral PrEP
2-1-1 dosing

	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	

Contraindicated in hepatitis B virus infection

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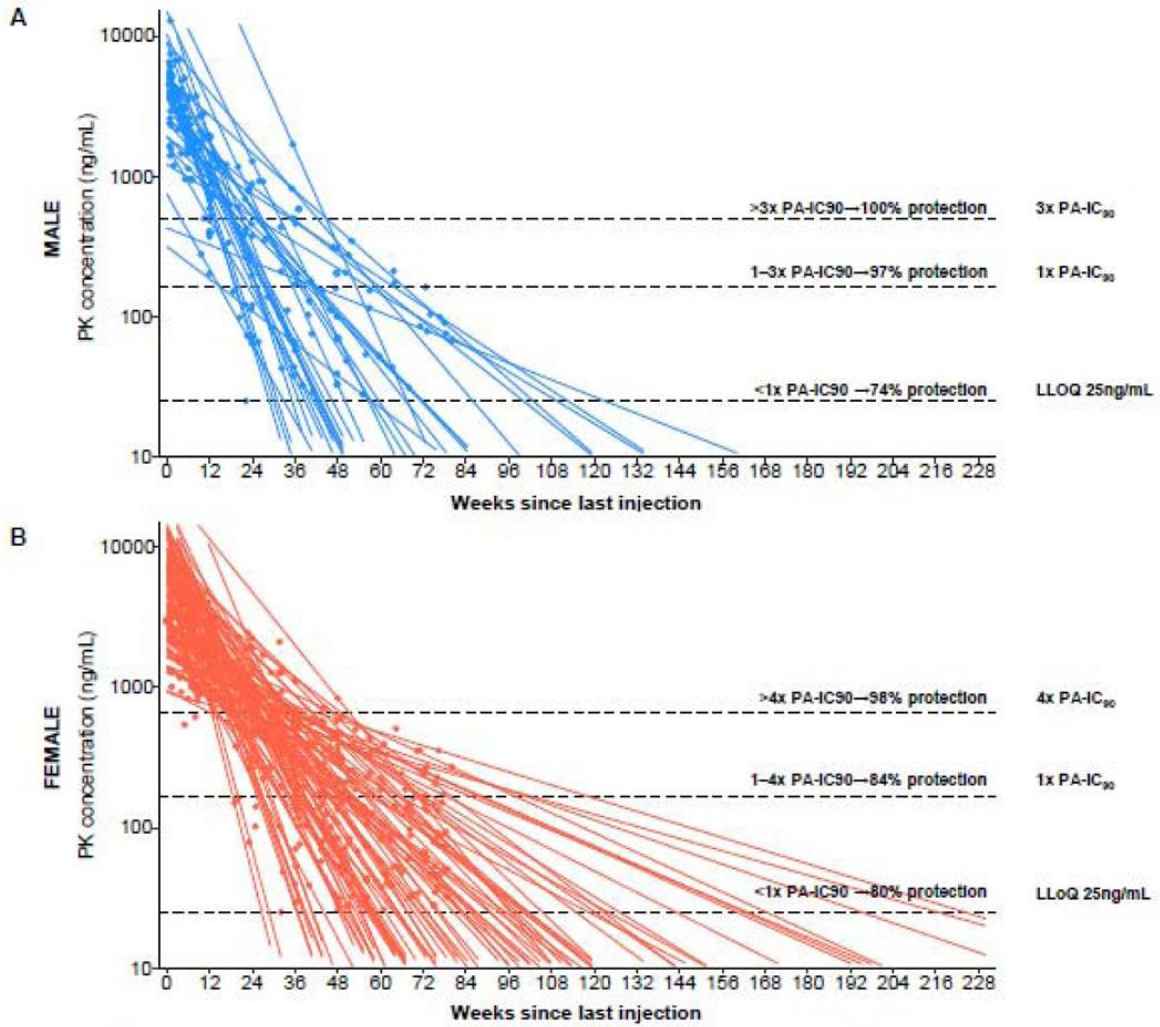
How to prescribe injectable PrEP
The cabotegravir tail

Median time to…

- Men:
  - CAB below LLOQ: 43.7 wks
- Women:
  - CAB below LLOQ: 67.3 wks



Curves are fitted for each individual extrapolated to the intersection with LLoQ and often extend beyond the observed concentrations. Dots represent individual participant values based on days elapsed since the last injection. The horizontal dashed lines are estimates of protection based on the SHIV challenge model indicating the proportion of rectal or vaginal challenges protected for males and females, respectively.

Landovitz, Lancet HIV 2020, 7(7): e472-481

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Adherence support

Box B: Key Components of Oral Medication Adherence Counseling

Establish trust and bidirectional communication

Provide simple explanations and education

- Medication dosage and schedule
- Management of common side effects
- Relationship of adherence to the efficacy of PrEP
- Signs and symptoms of acute HIV infection and recommended actions

Support adherence

-
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A Brief Medication Adherence Question

"Many people find it difficult to take a medicine every day.

Thinking about the last week – on how many days have you not taken your medicine?"

Structural interventions for increased PrEP persistence

- Low-barrier care models
  - Telehealth
  - Mail-order medications
  - Mobile clinics
  - Pharmacy-based PrEP
- For transgender and nonbinary people
  - Integrate PrEP with gender-affirming care
- For people who use alcohol or other substances:
  - Integrate PrEP delivery with syringe exchange and harm reduction

Slide courtesy of Chase Cannon, MD.

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Options in cases of suspected PrEP failure

Open Forum Infectious Diseases

MAJOR ARTICLE

A Strategy for PrEP Clinicians to Manage Ambiguous HIV Test Results During Follow-up Visits

Dawn K. Smith, William M. Switzer, Philip Peters, Kevin P. Delaney, Timothy C. Granade, Silvina Masciotra, Luke Shouse, and John T. Brooks

Division of HIV/AIDS Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, Atlanta, Georgia

1) Continue PrEP while conducting additional tests
2) Initiate ART while conducting additional tests
3) Discontinue PrEP to reassess status/conduct additional tests after a brief medication-free interval

PrEPline consultation: 855-448-7737 (11a-6p EST)

Paying for PrEP
U.S. Preventative Services Task Force

Recommendation Summary

Population	Recommendation	Grade
Persons at high risk of HIV acquisition	The USPSTF recommends that clinicians offer preexposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition. See the Clinical Considerations section for information about identification of persons at high risk and selection of effective antiretroviral therapy.	A

- All non-grandfathered private health plans must cover PrEP without cost-sharing (such as a copay or coinsurance) beginning no later than the 2021 plan year.
- However, prior authorizations are allowed, as is placing generics on zero cost-sharing tiers with cost sharing for brand equivalents.
- Sept 2022: Braidwood Management Inc v Becerra struck down this requirement in TX. Appeal pending.

JAMA 2023; 330 (8): 736-745.

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ICD-10 codes to consider for PrEP prescribing

Visit and HIV/STD testing	
Z20	
Z20.6	Contact with and (suspected) exposure to HIV
Z72.5	High risk behavior (main category not billable)
Z72.51 Z72.52 Z72.53	High risk heterosexual behavior High risk homosexual behavior High risk bisexual behavior
Z11	Encounter for screening infectious and parasitic diseases (not billable)
Z11.3 Z11.4	Encounter for screening for infectious with a predominantly sexual mode of transmission Encounter for screening for HIV

Laboratory monitoring	
Z51.81	Encounter for therapeutic drug level monitoring
Z79.899	Other long-term (current) use of drug/prophylactic therapy

Source: US Public Health Service. Clinical practice guidelines for PrEP. May 2014

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Family Planning
Food Safety
Healthy Aging
Healthy Home
Illness and Disease
Animal Transmitted Diseases
Antibiotic Resistance
Asthma
Autism
Avian Influenza
Birth Defects
Brucellosis
Campylobacter
Cancer
Chickenpox (Varicella)
Cryptococcosis
Cryptosporidium
Death with Dignity Act
Diabetes
Diphtheria
Ebola
E. coli
Enterovirus D68
Epilepsy
Flu

Pre-Exposure Prophylaxis Drug Assistance Program (PrEP DAP)

What is PrEP?

Pre-Exposure Prophylaxis (PrEP) is an HIV prevention method in which HIV-negative people take a daily pill to reduce their risk of becoming infected.

When used consistently, PrEP has been shown to reduce the risk of HIV-1 infection among adult men and women at very high risk for HIV infection through sex or injection drug use. TRUVADA® has been approved by the Federal Drug Administration for use in PrEP.

If you are interested, your prescribing medical provider can answer your questions.

Where can I find additional information on PrEP?

- What is PrEP?
- PrEP Facts

What is PrEP DAP?

PrEP DAP is a drug assistance program for HIV-negative people who have risk factors that expose them to HIV. PrEP DAP will pay for TRUVADA® for people who want to be on PrEP.

Learn about PrEP DAP in our brochure - English (PDF)

PrEP DAP brochure - Spanish version (PDF)

Questions without answers

- How long does it take to achieve protection on PrEP?
- When discontinuing PrEP, how long does someone need to continue PrEP after their exposure?
- How will injectable PrEP be implemented?
- Will healthcare insurance cover injectable PrEP?

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The HIV Prevention Pipeline

Currently available

HIV treatment for people living with HIV/U=U

Male & female condoms

Voluntary medical male circumcision

Syringe exchange programs

Daily oral PrEP

Event-driven for some populations.

Newly Approved and Recommended

Dapivirine vaginal ring

Long-acting injectable

And in implementation science projects:

www.prepwatch.org/resources/implementation-study-tracker/

In development: Efficacy trials under way

Long-acting injectable

Preventive vaccines

Daily & monthly oral PrEP[1]

Combo oral PrEP/OC

Possible dual pill to market by 2024.[2]

In development: Preclinical and clinical

Long-acting implants

Preventive vaccines

Multipurpose vaginal ring

Broadly neutralizing antibodies

Vaginal/ Mucosal Inserts

Patches

Long-acting vaginal ring

Douche

Vaginal Film

Vaginal Gel

[1]In Oct 2019, US FDA approved F/TAF for adults and adolescents who have no HIV risk from receptive vaginal sex; still in development for cisgender women.
[2]Efficacy trials not required; bioequivalency of the two approved products when dosed together may be all that is required.

AVAC Global Advocacy for HIV Prevention

www.avac.org
February 2023

https://avac.org/resource/infographic/the-hiv-prevention-pipeline/

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Resources

CDC/HHS
www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf
www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2021.pdf

IAS-USA
www.iasusa.org/resources/guidelines/

Consultation and assistance
MWAETC Prevention Detailing Program
mwaetc.org/washington-state-hiv-prevention-detailing-program

Consultation PrEPLine (855-448-7737)
For urgent questions or ambiguous test results

Acknowledgment

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AETC AIDS Education & Training Center Program Mountain West

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

Grant, CID 2021; 73(7).

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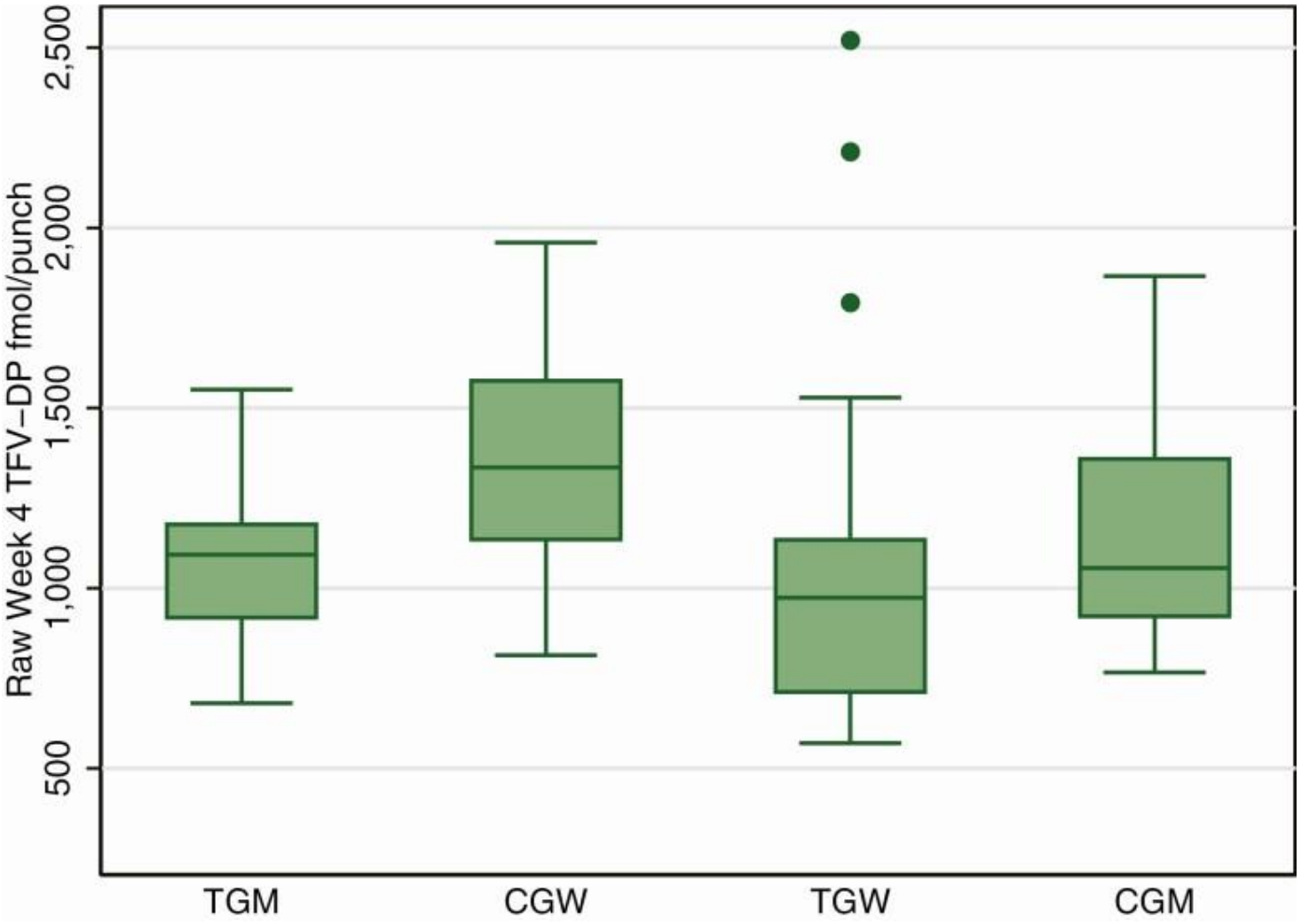
Sex Hormone Therapy and Tenofovir Diphosphate Concentration in Dried Blood Spots: Primary Results of the iBrEATHe Study

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).

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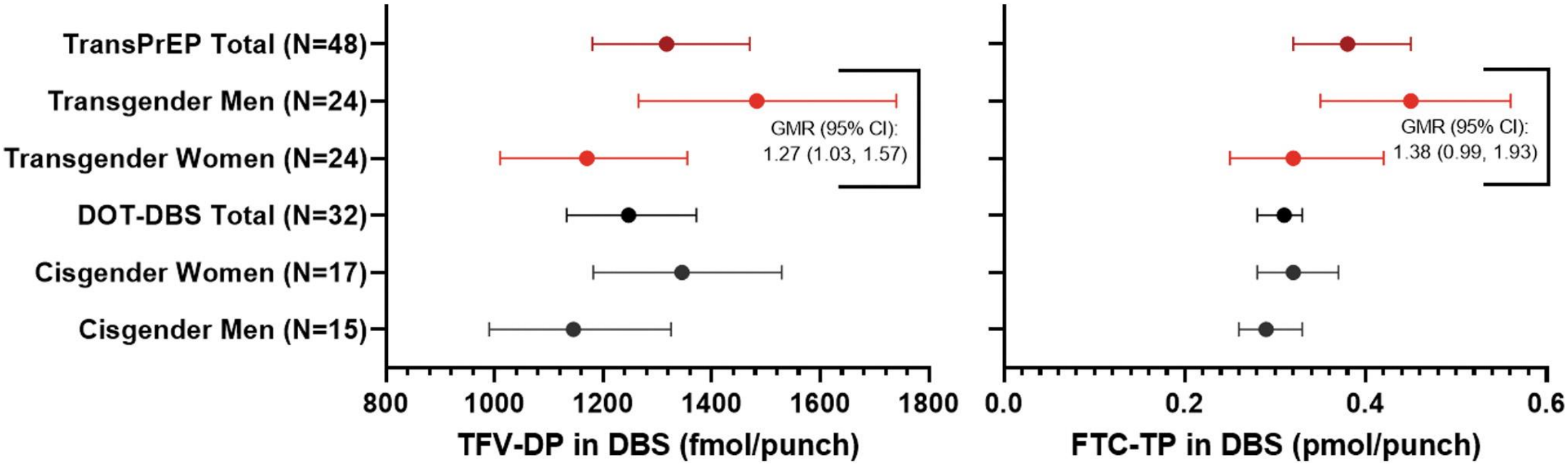
Additional Studies: TransPrEP Study

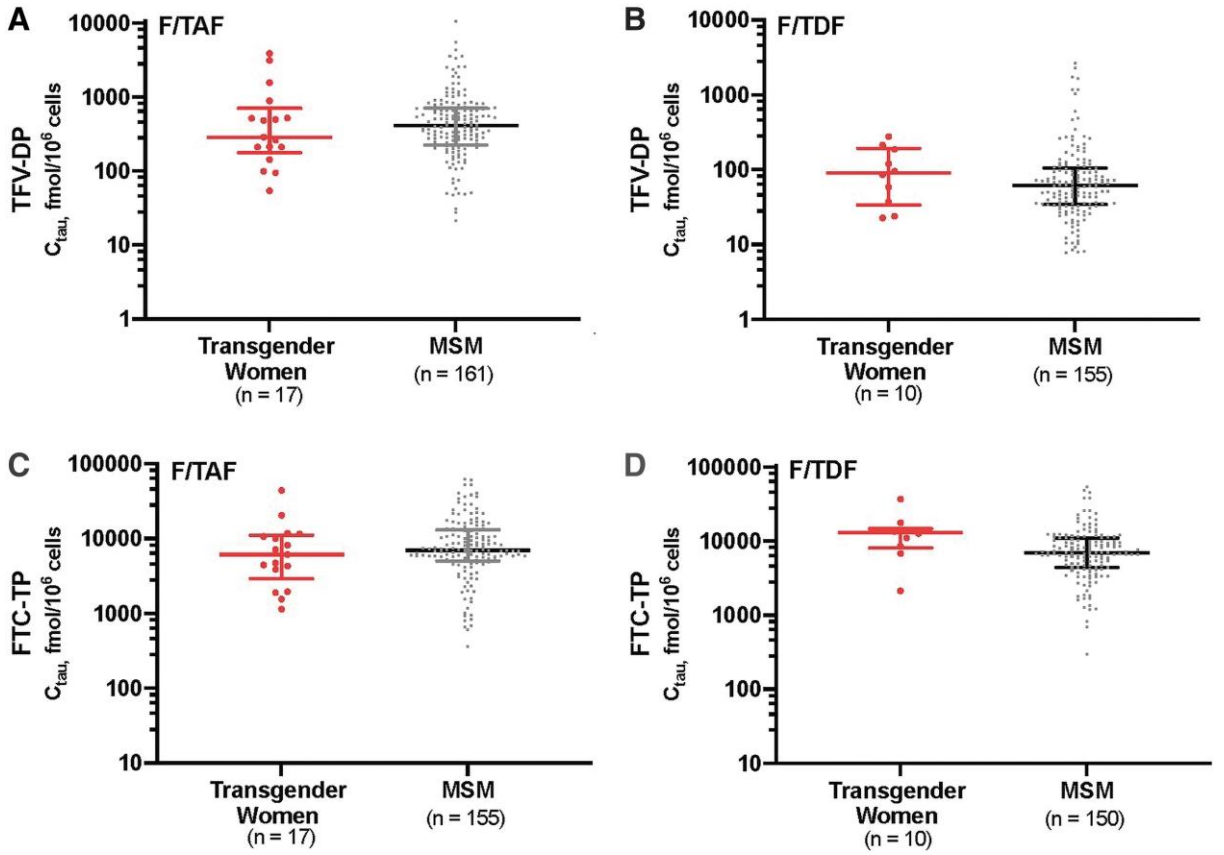


Yager et al., AIDS Research Human Retroviruses 2022; 38(11)

Additional Studies: DISCOVER Trial

Retrospective analysis.

No clinically significant interactions were seen between hormone therapy and either FTC/TDF or FTC/TAF.



Cespedes et al. Transgender Health 2022

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