

A photograph of a Black female doctor in a white lab coat with a stethoscope, smiling warmly at a patient whose back is to the camera. The setting is a bright, modern clinical office with a white shelf in the background.

“STATUS NEUTRAL” IN PRIMARY CARE

*A Fresh Look at the PCP’s
Role in HIV Prevention*

Faculty Disclosures

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- Consulting Fees: Gilead Sciences, Inc.
- Fees for Non-CE Services Received Directly From an Ineligible Entity or Their Agents: Gilead Sciences, Inc.
- Speakers Bureau: Gilead Sciences, Inc.

Target Audience & Learning Objectives

Target Audience

- This activity is intended for physicians, nurse practitioners, physician associates, and other health care providers delivering primary care to adolescents and adults.

Learning Objectives

- Identify strategies to assess HIV risk and discuss prevention options without stigma or judgment
- Describe PrEP regimens and dosing options based on clinical evidence, guidelines, and patient characteristics and preferences
- Implement PrEP in the primary care setting with guideline-directed strategies for treatment initiation, monitoring, and follow-up care

Credit Information

Physician Continuing Medical Education

Integritas Communications designates this live activity for a maximum of 1.0 *AMA PRA Category 1 Credit*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Joint Accreditation Statement

In support of improving patient care, this activity has been planned and implemented by the Postgraduate Institute for Medicine and Integritas Communications. Postgraduate Institute for Medicine is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.



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INTERPROFESSIONAL CONTINUING EDUCATION

Continuing Nursing Education

The maximum number of hours awarded for this Continuing Nursing Education activity is 1.0 contact hours. Approved for 0.25 pharmacotherapy contact hours for Advanced Practice Registered Nurses.

Continuing Physician Assistant Education

Postgraduate Institute for Medicine has been authorized by the American Academy of PAs (AAPA) to award AAPA Category 1 CME credit for activities planned in accordance with AAPA CME Criteria. This activity is designated for 1 AAPA Category 1 CME credit. PAs should only claim credit commensurate with the extent of their participation.



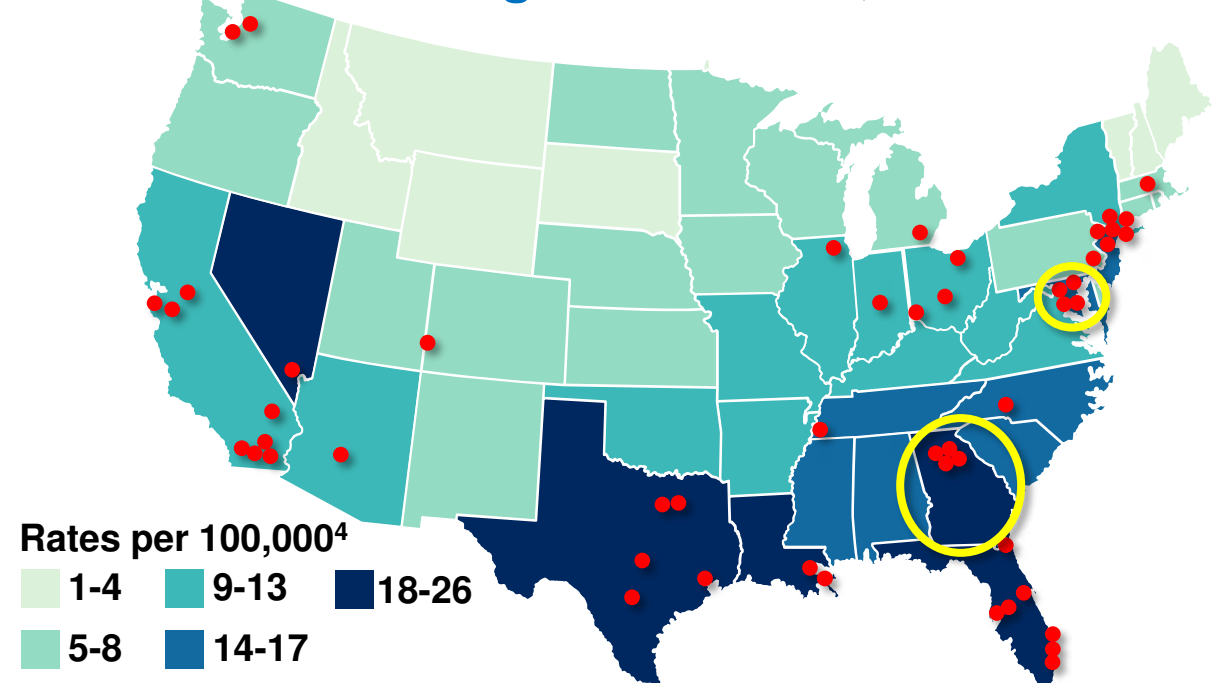


CALL TO ACTION

Who Is Most Affected by HIV?

- There are 1.2 million PLWH in the US¹
- Of the approximately 38,000 new HIV diagnoses in 2022²:
 - 79% are among men
 - 67% are among MSM, the population most affected by HIV
 - 56% are among people aged 13-34 years
 - 7% are among PWID

HIV Infection Diagnosis Rates Among Persons Aged ≥13 Years, 2021³



The South accounted for 52% of HIV diagnoses in 2022.³

CDC, Centers for Disease Control and Prevention; MSM, men who have sex with men; PLWH, people living with HIV.

1. CDC.gov. <https://www.cdc.gov/hiv-data/nhss/estimated-hiv-incidence-and-prevalence.html>. Accessed May 24, 2024; 2. CDC.gov. <https://www.cdc.gov/hiv-data/nhss/hiv-diagnoses-deaths-prevalence.html>. Accessed June 4, 2024; 3. AIDSvu. <https://map.aidsvu.org/nd/state/rate/none/none/usa?geoContext=national>. Accessed May 24, 2024.



Who Will Contract HIV in Their Lifetimes Without Using Preventive Measures?

MSM¹	Overall	1 in 6	
	African American	1 in 2	
	Hispanic/Latino	1 in 5	
	White	1 in 11	

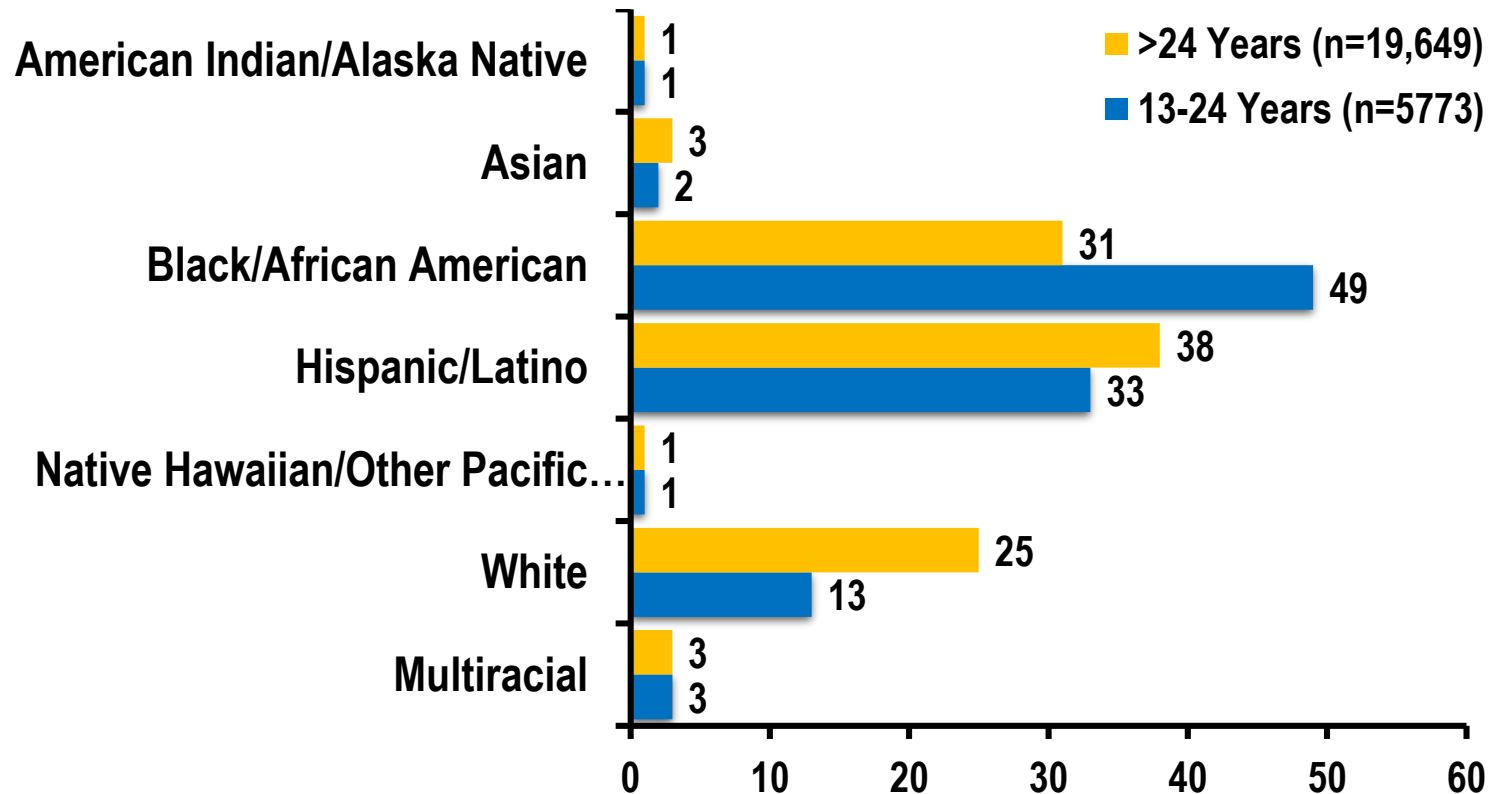
Heterosexual¹		Men	Women
	Overall	1 in 524	1 in 266

Overall		Men	Women
	Overall ²	1 in 76	1 in 309
	African American ²	1 in 27	1 in 75
	PWID	1 in 42	1 in 26
	Hispanic/Latino ²	1 in 50	1 in 287
	White ²	1 in 171	1 in 874

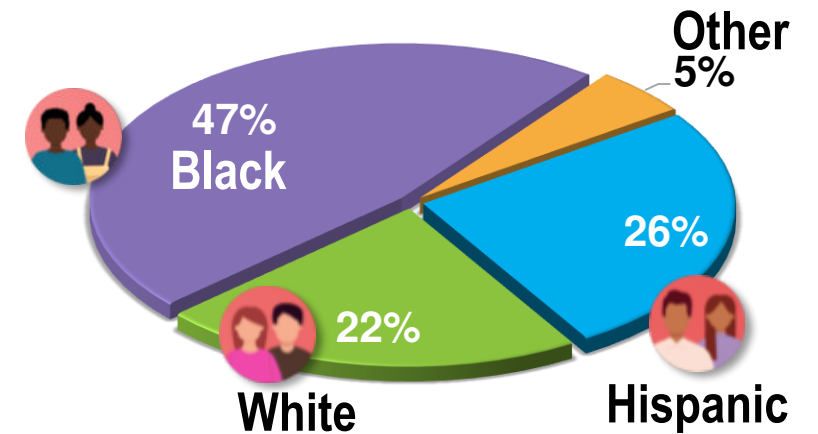
1. Hess KL, et al. *Ann Epidemiol.* 2017;27(4):238-243; 2. Singh S, et al. [CROI Abstract 43] In Special Issue: Abstracts From the 2022 Conference on Retroviruses and Opportunistic Infections. *Top Antivir Med.* 2022;31(1s):16.

Disparities in the US

US HIV Diagnoses Among MSM by Age and Race/Ethnicity, 2022



New HIV Diagnoses in the South, by Race, 2022

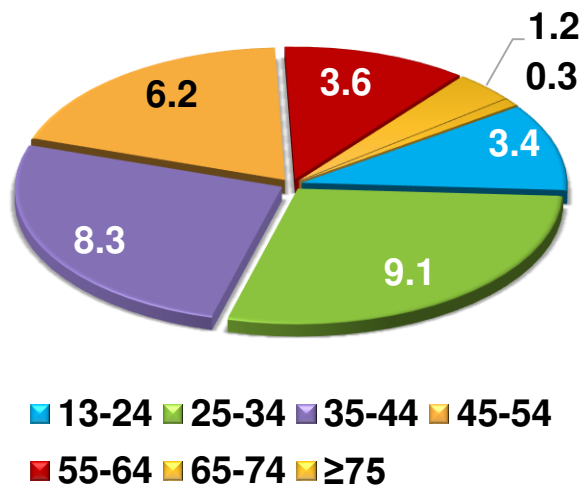


Black Americans comprised only 19% of the Southern population in 2022 but represent almost **HALF** of all new HIV diagnoses in the region.

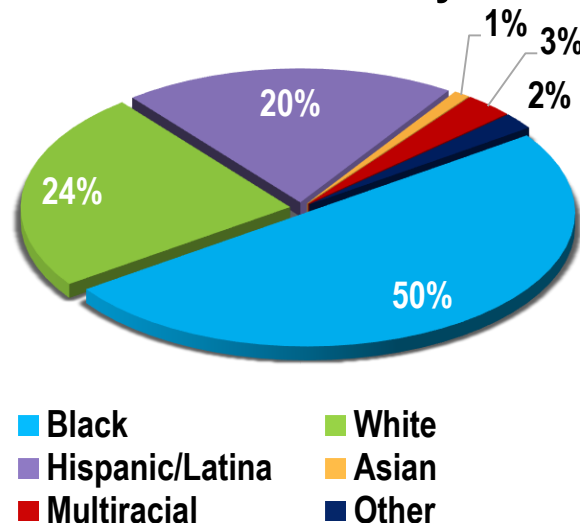
~1 in 5 New HIV Diagnoses in the US Is Among Women

Burden in Women Seen Across Adulthood

Rates of HIV Diagnosis in Women, by Age¹



Percentage of Women With New HIV Diagnosis, by Race/Ethnicity¹



- **New HIV diagnoses among women**
 - 18% of new HIV diagnoses were among women in 2022¹
 - 84% acquired from heterosexual transmission; 16% acquired from IDU¹
- **Black women in the US**
 - Have 15 times the AIDS rate compared with White women²
 - Are 15.3 times more likely to die from HIV infection complications as White women²
 - Are less likely to have been infected through IDU than White women³

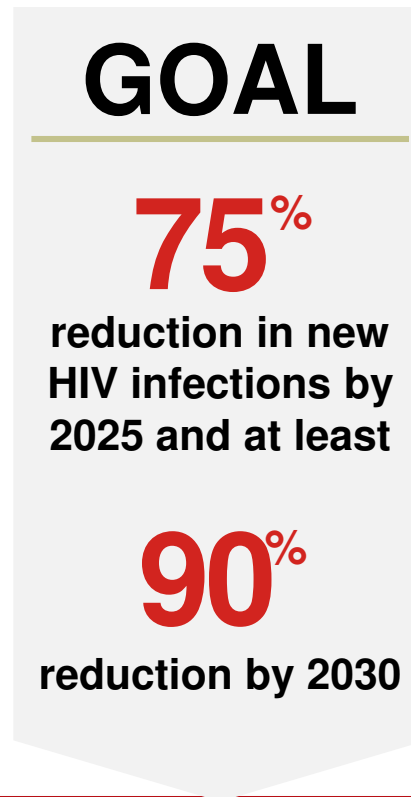
IDU, injection drug use.

1. CDC. HIV Surveillance Report, 2022; vol. 35. <http://www.cdc.gov/hiv-data/nhss/hiv-diagnoses-deaths-prevalence.html>. Published May 2024. Accessed June 4, 2024; 2. US Department of Health and Human Services Office of Minority Health. HIV/AIDS and African Americans. <https://minorityhealth.hhs.gov/hivaids-and-african-americans>. Accessed May 24, 2024; 3. Kaiser Family Foundation. Black Americans and HIV/AIDS: the basics. <https://www.kff.org/hivaids/fact-sheet/black-americans-and-hivaids-the-basics/>. Accessed May 24, 2024.

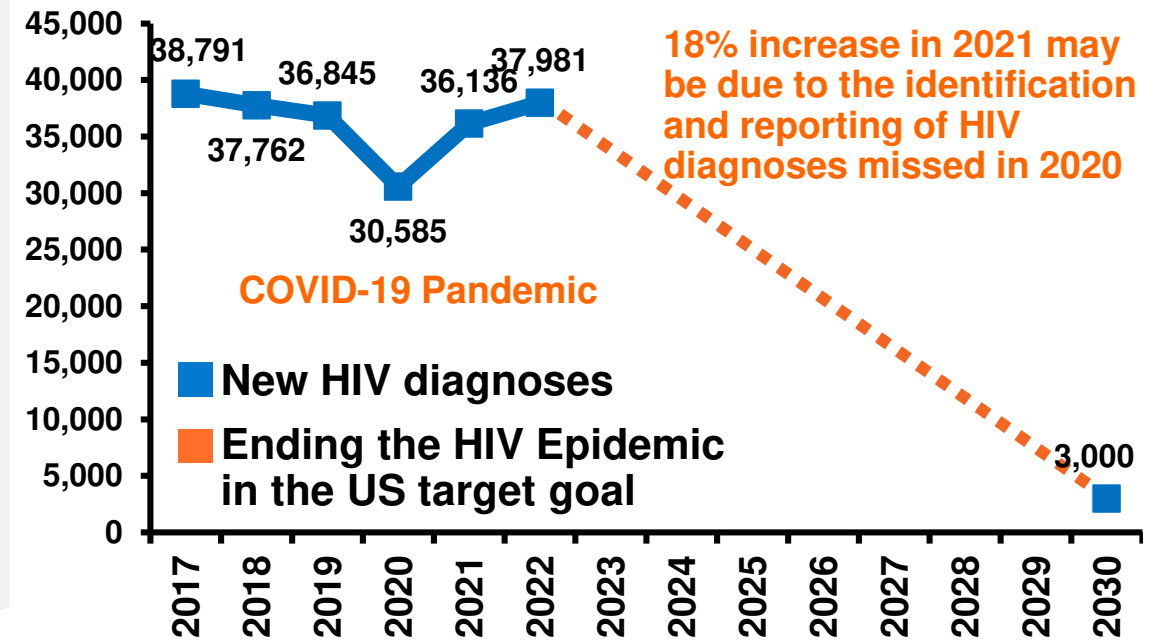
Ending the HIV Epidemic in the US

Target Goals for New Diagnoses, 2019-2030

- **EHE** is the HHS plan to reduce new HIV diagnoses¹:
 - By targeting prevention efforts, resources, and infrastructure where HIV transmission is most prevalent
- >700K lives in the US have been lost to HIV since 1981
- The decrease in new infections has stalled



New HIV Diagnoses in the US, 2017-2022²



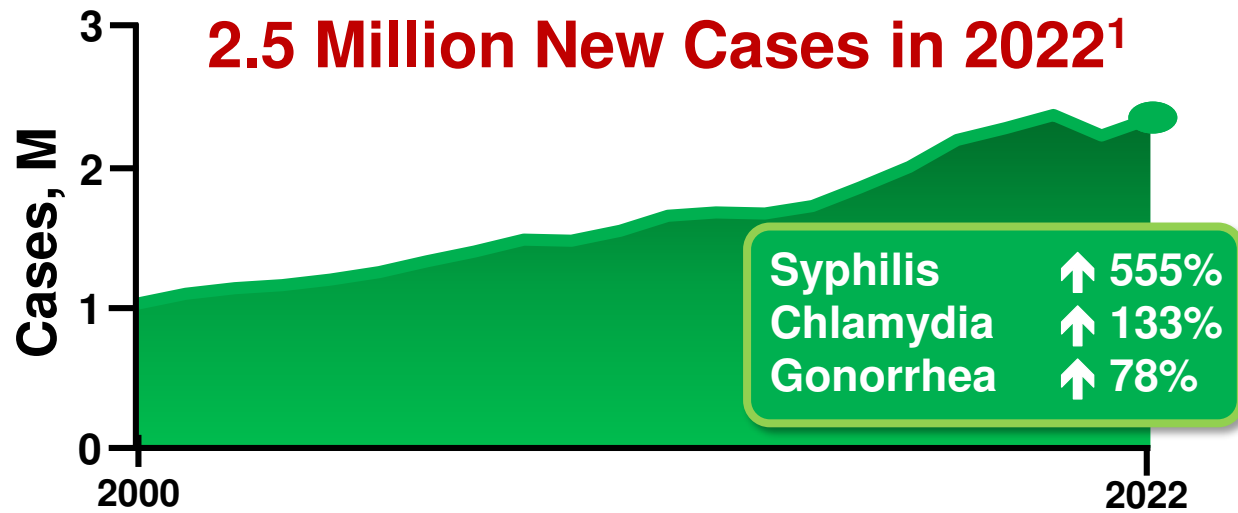
Primary care providers can help end the HIV epidemic

EHE, Ending the HIV Epidemic; HHS, US Department of Health and Human Services.

1. HIV.gov. Overview. <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview>. Accessed October 1, 2023; 2. CDC. CDC. HIV Surveillance Report: Diagnoses, Deaths, and Prevalence of HIV in the United States and 6 Territories and Freely Associated States, 2022. <https://stacks.cdc.gov/view/cdc/156509>. Accessed June 24, 2024.

Having an STI Increases Risk for Acquiring HIV

Chlamydia, gonorrhea, and syphilis cases have been increasing for years¹



Syndemic: epidemics that co-occur and are socially produced and intertwined²

- Having an STI such as chlamydia, gonorrhea, and/or syphilis places people at higher risk for acquiring HIV
- 6% of sexually acquired HIV infections are attributed to chlamydia, gonorrhea, and syphilis
- HIV, substance use, and viral hepatitis affect similar populations as STIs
- Opioids and other substance use is linked to increasing STIs and outbreaks of infectious diseases¹

HIV is one part of a syndemic¹

STD, sexually transmitted disease; STI, sexually transmitted infection.




*Note: 2021 and 2022 data reflect the effect of COVID-19 on STD surveillance trends.

1. CDC. STI fact sheet. www.cdc.gov/sti/media/pdfs/syndemic-infographic.pdf. Accessed May 24, 2024; 2. Salway T, et al. *BMC Health Serv Res.* 2022;22(1):750.

HIV Prevention is Primary Care!

Prescribe PrEP

PrEP is a ***comprehensive set of services*** to reduce risk of HIV infection

- 3 FDA-approved medications for PrEP
 - May only be used in persons without HIV
- Comprehensive services include:
 - Regular HIV screening
 - Regular STI screening
 - Safer sex + risk-reduction counseling
- Available medication options for PrEP:
 -  – Oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC; Truvada®); available in generic
 -  – Oral tenofovir alafenamide/emtricitabine (TAF/FTC; Descovy®); not for use in people at risk of HIV through vaginal receptive sex
 -  – Cabotegravir long-acting injectable (CAB LAI; Apretude®)

PrEP, preexposure prophylaxis; FDA, US Food and Drug Administration

CDC. USPHS. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Accessed June 24, 2024.

A PCP Paradox?

A spring 2023 survey conducted by Integritas found that:

- A majority of PCPs spend >50% of their clinical time on preventive care
- The PCPs polled reported seeing an average of 8 patients/week with an STI:
 - Two-thirds are confident in treating STIs
- ~75% agree that HIV prevention is a core part of the PCP's role

Then why do . . .

- 40% NEVER perform one-time HIV testing?
 - 81% perform one-time HIV testing in less than 25% of patients
- 73% rarely/never discuss HIV prevention or PrEP
- 75% have never prescribed PrEP
- 45% do not consider themselves “PrEP providers”

PCP, primary care provider.

Integritas survey of primary care providers. May 30-June 1, 2023. N=353.

PrEP Is for the Individual Who...

- **Has had anal or vaginal sex in the past 6 months and¹:**
 - Has inconsistent or no condom use
 - Has a sexual partner with HIV, with unknown or detectable viral load
 - Has been diagnosed with an STI in the past 6 months
- **Is planning to get pregnant, is pregnant or breastfeeding, and^{1,2}:**
 - Has a partner with HIV; oral PrEP may protect mother and baby from HIV transmission
- **Is an adolescent and¹:**
 - Is at risk for HIV infection from sex or drug use
- **Lives in a high-prevalence geographic area or network¹**
- **Injects drugs and¹**
 - Has an injection partner with HIV or
 - Shares needles, syringes or other drug injection equipment
- **Was prescribed nPEP and¹**
 - Reports continued behavior that puts them at risk
 - Has had multiple courses of nPEP

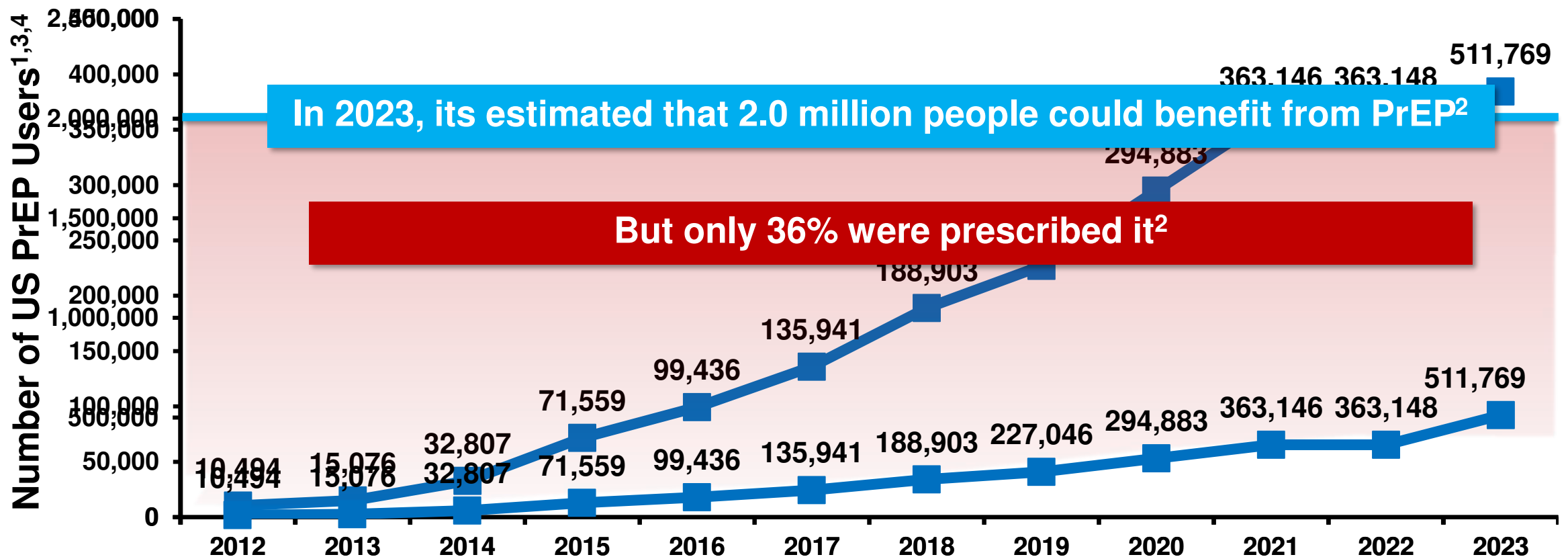
According to the 2021 Updated Guidelines: clients who request PrEP should be offered it, even if no specific risk behaviors are evident or mentioned by the client³

nPEP, nonoccupational postexposure prophylaxis (ie, the use of antiretroviral drugs after a potential exposure event to stop HIV acquisition).

1. CDC. Is PREP right for me? <https://www.cdc.gov/hiv/prevention/prep.html>. Accessed June 24, 2024; 2. Stewart J, Stekler JD. *J Fam Pract*. 2019;68(5):254-261; 3. CDC. USPHS. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Accessed June 24, 2024.

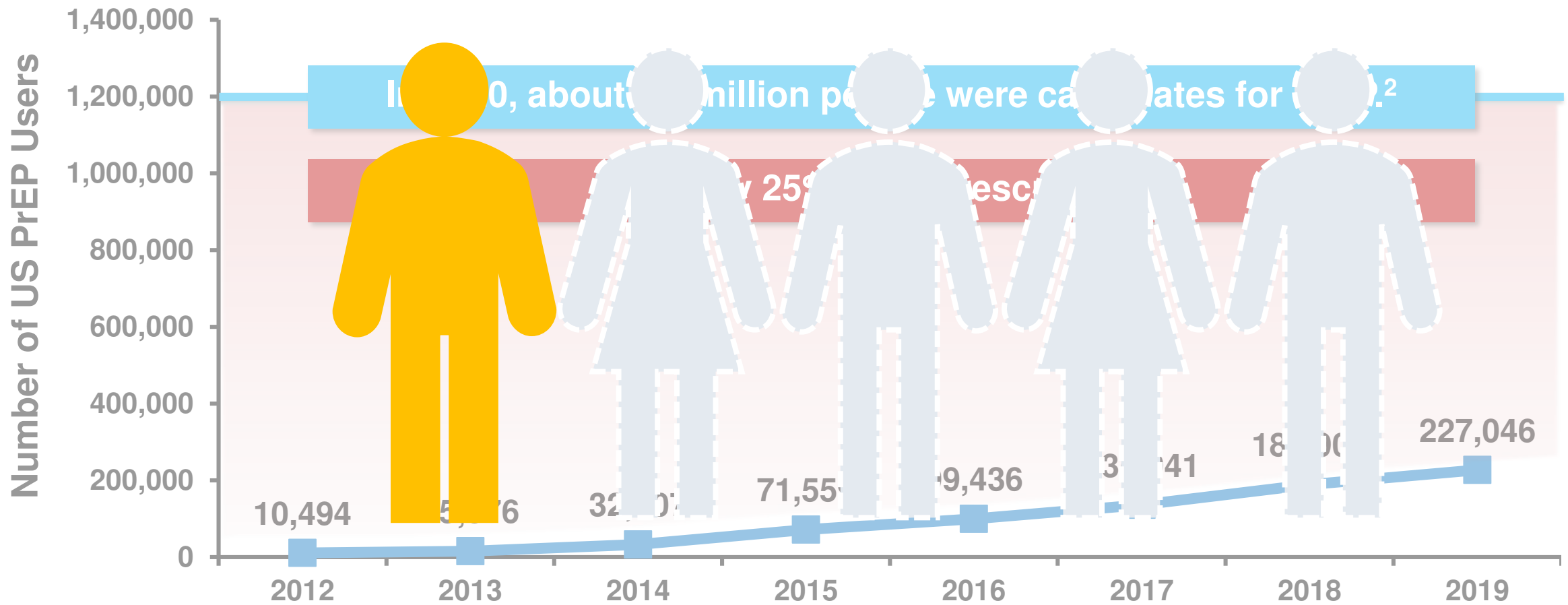
PrEP Gap in the US

Most of Those Eligible for PrEP Are Not Receiving It



1. AIDSvu. Local data: United States. <https://map.aidsvu.org/profiles/nation/usa/prevention-and-testing#1-1-PrEP>. Accessed July 22, 2024; 2. CDC. Ending the HIV epidemic in the US goals. <https://www.cdc.gov/ehe/php/about/goals.html>. Accessed July 3, 2024; 3. CDC. HIV surveillance data tables. 2021;2(4). <https://www.cdc.gov/hiv/pdf/library/reports/surveillance-data-tables/vol-2-no-4/cdc-hiv-surveillance-tables-vol-2-no-4.pdf>. Accessed September 29, 2023; 4. PrEPWatch. The global PrEP tracker. <https://data.prepwatch.org>. Accessed September 29, 2023.

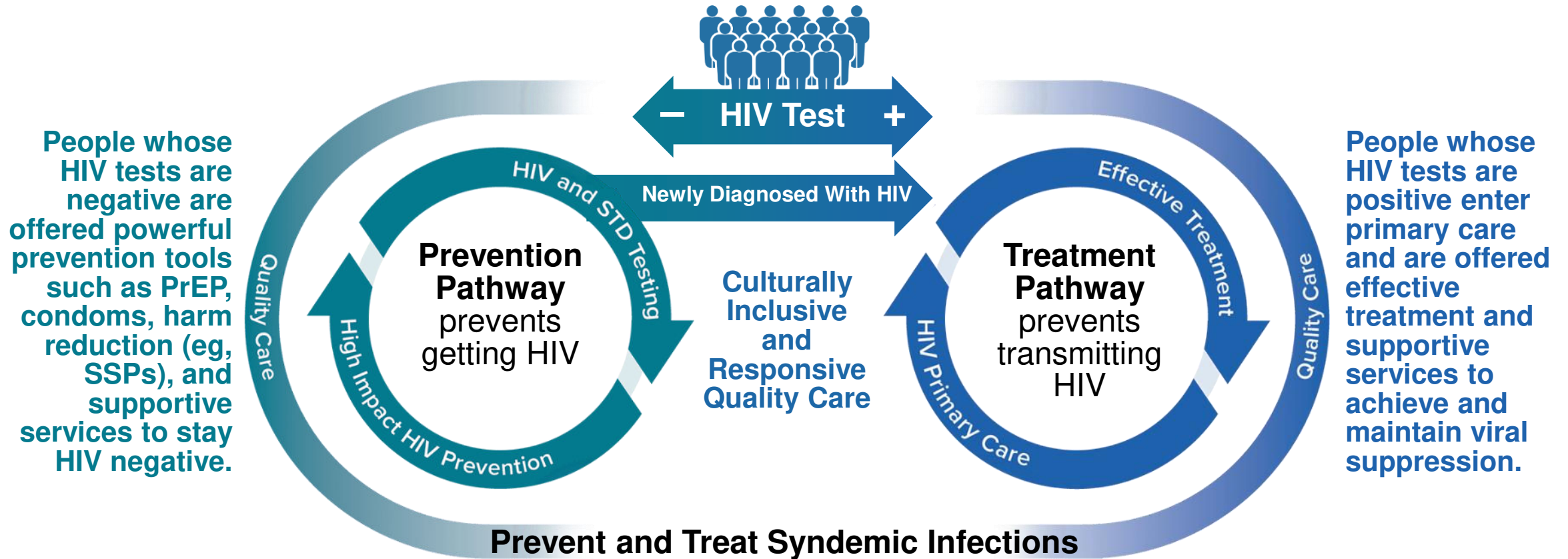
And Only 1 in 5 US Clinicians Has Ever Prescribed PrEP



A blue-tinted photograph of a doctor in a white coat talking to a patient with curly hair. The doctor is on the right, smiling and looking towards the patient on the left. The text is overlaid in the center.

WHOLE PERSON APPROACH TO HIV PREVENTION

Using a Status-Neutral Approach in Primary Care Is Essential in HIV Prevention



The approach to care for people with HIV or those without HIV should be indistinguishable

SSP, syringe services program; STD, sexually transmitted disease.

CDC. ISSUE BRIEF: status neutral HIV care and service delivery.

<https://www.cdc.gov/hiv/policies/data/status-neutral-issue-brief.html>. Accessed June 4, 2024.

Not Normalizing PrEP Is a Barrier

“Normalizing it and making it everywhere, making it common knowledge that my grandmother could know about it...I think that would be great overall of just that awareness as a society.”



Discuss Sexual Health With Patients *As Well as HIV Prevention*

- **According to the CDC:**
 - All clinicians should talk to their sexually active teenage and adult patients about sexual health in general and about PrEP
 - Everyone between the ages of 13 and 64 years should be tested for HIV at least once as part of routine health care
- **We screen and treat other STIs, why not HIV?**
- **We discuss many sensitive topics every day with patients (eg, mental health, constipation); sexual health should be no different**

“Clinicians should initiate a discussion about PrEP with ANY sexually active adolescent and adult patient so that it may be considered an option for them.” –Updated 2021 CDC PrEP Guidelines

Use the “5 Ps” of Sexual Risk Assessment to Open Dialog



Partners¹



Practices¹



Past History of STIs¹



Protection From STIs¹

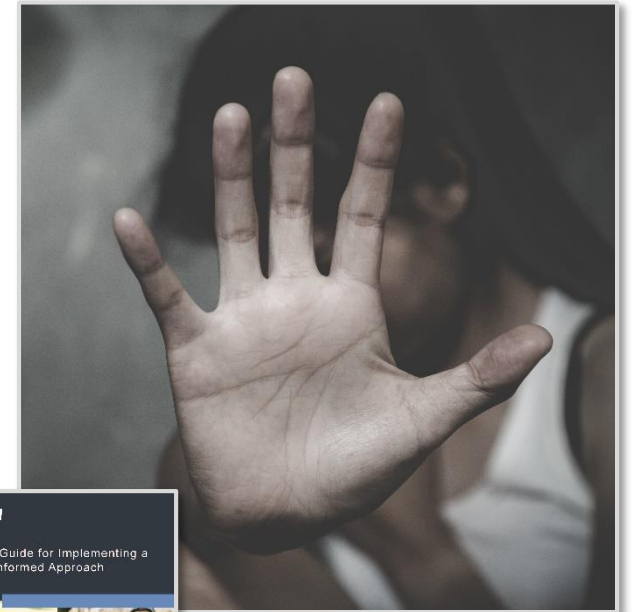


Pregnancy Plans¹

Don't forget the 6th “P”: pleasure!²

SCREEN FOR INTIMATE PARTNER VIOLENCE (IPV), A BARRIER TO PrEP USE IN WOMEN

- **1 in 4** women in the United States will experience IPV in their lifetime
 - Female survivors of IPV are at higher risk for acquiring HIV than women in nonviolent relationships
- **1 in 2** women with HIV have experienced IPV
- PrEP is one part of a comprehensive safety planning strategy for women at increased risk for HIV due to IPV
 - BUT women experiencing IPV are concerned that violence will escalate if their partner finds out they are taking PrEP
- Providers should apply a trauma-informed lens to PrEP initiation and keep it undisclosed¹
- Resource for using trauma-informed care²:
<https://store.samhsa.gov/sites/default/files/pep23-06-05-005.pdf>



“If the partner finds out, there will be trouble.”

1. Jeffers NK, et al. *AIDS Behav.* 2022;26(7):2266-2278; 2. Substance Abuse and Mental Health Services Administration (SAMHSA). Practical guide for implementing a trauma-informed approach. <https://store.samhsa.gov/sites/default/files/pep23-06-05-005.pdf>. Accessed June 4, 2024.

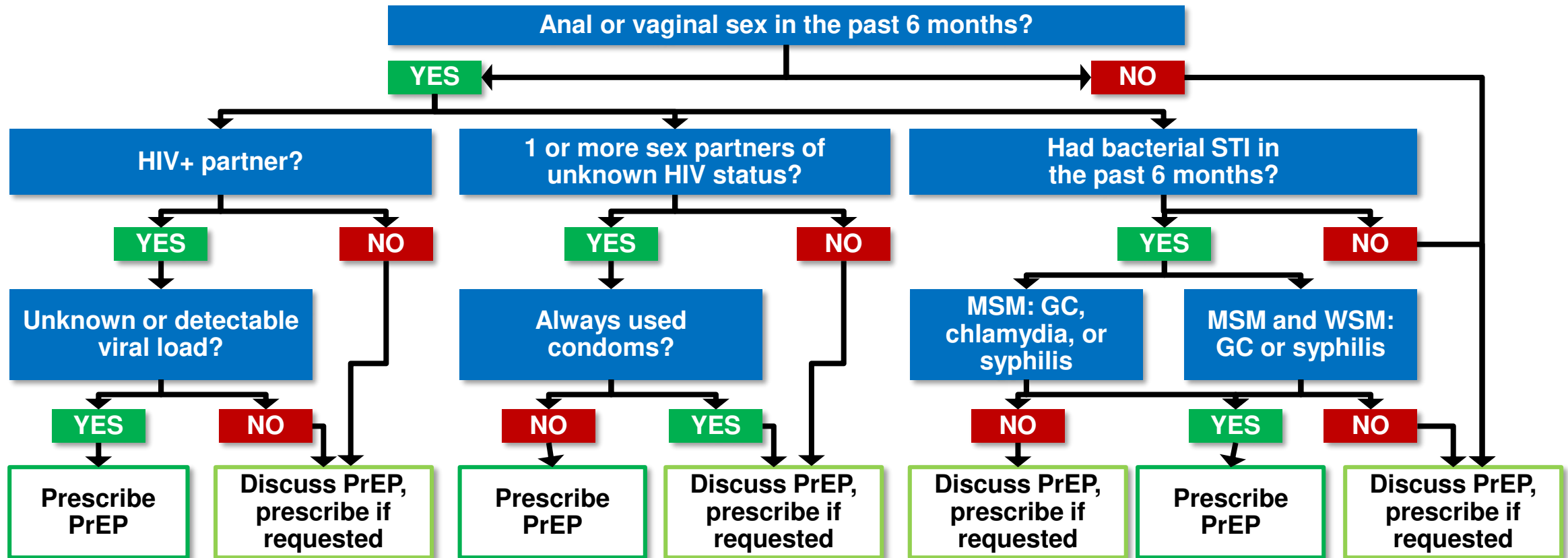


ASSESSING HIV RISK

2021 Updated Guidelines

Assessing HIV Risk

Assess HIV Risk in All Sexually Active Teens/Adults



GC, gonorrhea; WSM, women who have sex with men.

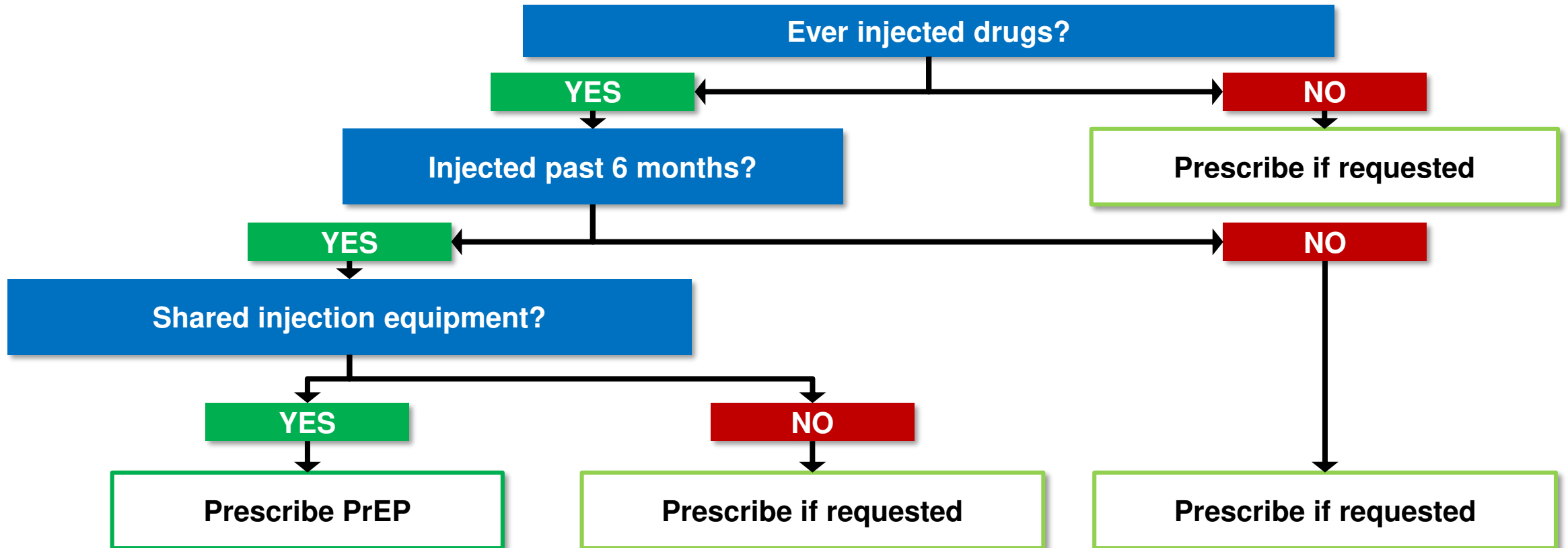
CDC. USPHS. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>.

Accessed June 24, 2024.

2021 Updated Guidelines

Assessing HIV Risk

Assess HIV Risk in All PWID





**DETERMINING
CLINICAL ELIGIBILITY
AND CONFIRMING
HIV-NEGATIVE STATUS**

Use Shared Decision-Making (SDM) From the Beginning

- **SDM is about collaboration¹**
 - Goal: develop a treatment plan that considers both the patient's preferences and the clinician's medical recommendations
 - Can lead to greater adherence and improved health outcomes
- **SDM can¹**
 - Reduce stigma by normalizing conversations about HIV prevention
 - Promote clinicians' cultural competence and cultural humility
 - Increase trust in the patient-provider relationship
- **3 parts to SDM approach²**

1. Choices Talk

- Inform the patient of the availability of choices

2. Options Talk

- Ask what the patient has heard or read about PrEP
- Describe each option in practical terms
- Point out pros/cons of each

3. Decision Talk

- Consider the patient's preferences and decide with them what is best
- "What, from your point of view, matters most to you?" "Are there more things we should discuss?"



1. McNulty MC, et al. *Cult Health Sex.* 2022;24(8):1033-1046; 2. Blackstock O. ID Week 2020.

<https://www.poz.com/article/doctorpatient-shared-decisionmaking-can-help-guide-prep-use-choices>. Accessed June 24, 2024.

Learning About PrEP From Commercials but Not From HCPs Is a Barrier to PrEP

“...cause you know TV commercials could be just trying to promote the product. I don’t believe it works 100%. I probably think it’s like 50%.”



Picture is of a model, not a real patient.

Groves AK, et al. *Obstet Gynecol.* 2022;139(4):537-544.

Clinical Eligibility for PrEP

2021 Updated CDC Practice Guidelines



The Following Conditions Must Be Met for Daily Oral PrEP Use:

- HIV-1/2 Ag/Ab test result within 1 week before initially prescribing PrEP
 - No signs/symptoms of AHI
 - Estimated creatinine clearance ≥ 30 mL/min/1.73 m²
 - No contraindicated medications
-



The Following Conditions Must Be Met for PrEP With CAB LAI:

- HIV-1/2 Ag/Ab test result within 1 week before initially prescribing PrEP
 - No signs/symptoms of AHI
 - No contraindicated medications or conditions
-

Ag/Ab, antigen/antibody; AHI, acute HIV infection.

CDC. USPHS. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Accessed June 24, 2024.

HIV and STI Testing for PrEP Initiation

- **Any patient requiring HIV/STI screening should be offered 3-site testing¹**
- **3-site STI screening for chlamydia and gonorrhea¹:**
 - Swab oropharynx, rectum, and test urine or vagina (depending on anatomy)
 - Genital testing with a swab is preferred for patients with a vagina, but urine is acceptable
 - Patients can self-swab all sites
 - Chlamydia/GC often missed with urine/genital testing only
 - A study of MSM living with HIV found that all GC and 75% of chlamydia infections would be missed with urine screening alone²
 - A recent analysis confirmed that vaginal swabs are optimal sample type for testing women for chlamydia and GC³
- **Blood tests:**
 - HIV-1/2 Ag/Ab blood test (preferred), HIV-1 RNA assay, or a rapid, point-of-care, FDA-approved, fingerstick Ag/Ab blood test⁴
 - Syphilis serology¹



1. CDC. USPHS. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Accessed June 24, 2024; 2. Sandkovsky U, et al. *Open Forum Infect Dis*. 2015;2(suppl 1):120; 3. Aaron KJ, et al. *Ann Fam Med*. 2023;21(2):172-179; 4. Workowski KA, Bolan GA; Centers for Disease Control and Prevention. *MMWR Recomm Rep*. 2015;64(RR-03):1-137.

Doxycycline Post-Exposure Prophylaxis for Bacterial STIs (Doxy PEP)

New 2024 CDC Clinical Guidelines

- Providers should counsel **all gay, bisexual, and other MSM and transgender women (TGW)** with a history of **≥1 bacterial STI (syphilis, chlamydia, or gonorrhea) during the past 12 months about the benefits and harms of using doxy PEP** and should offer it through shared decision-making
 - Doxycycline (any formulation) 200 mg once within 72 hours (not to exceed 200 mg per 24 hours) of oral, vaginal, or anal sex
 - Ongoing need for doxy PEP should be assessed every 3 to 6 months
- No recommendation on the use of doxy PEP for cisgender women, cisgender heterosexual men, transgender men, and queer and nonbinary persons

For Clients Testing Positive for HIV and/or STIs

The Role of Partner Services Programs

- **Partner services programs^{1,2}**

- Help newly diagnosed clients notify their sexual and drug injection partners of their potential exposure and provide counseling, testing, and referral to treatment and other services
- Referral methods^{1,2}



Health department tells partners



Patient tells partners



Health department and patient tell partners

- **Expedited partner therapy³**

- Providing prescriptions or medications to a patient diagnosed with **chlamydia or gonorrhea** to take to their sex partner (without a health care provider first examining the sex partner)

- **If a patient has a positive HIV test^{1,2}**

- Refer them immediately to an HIV treatment provider to start antiretroviral therapy (ART)

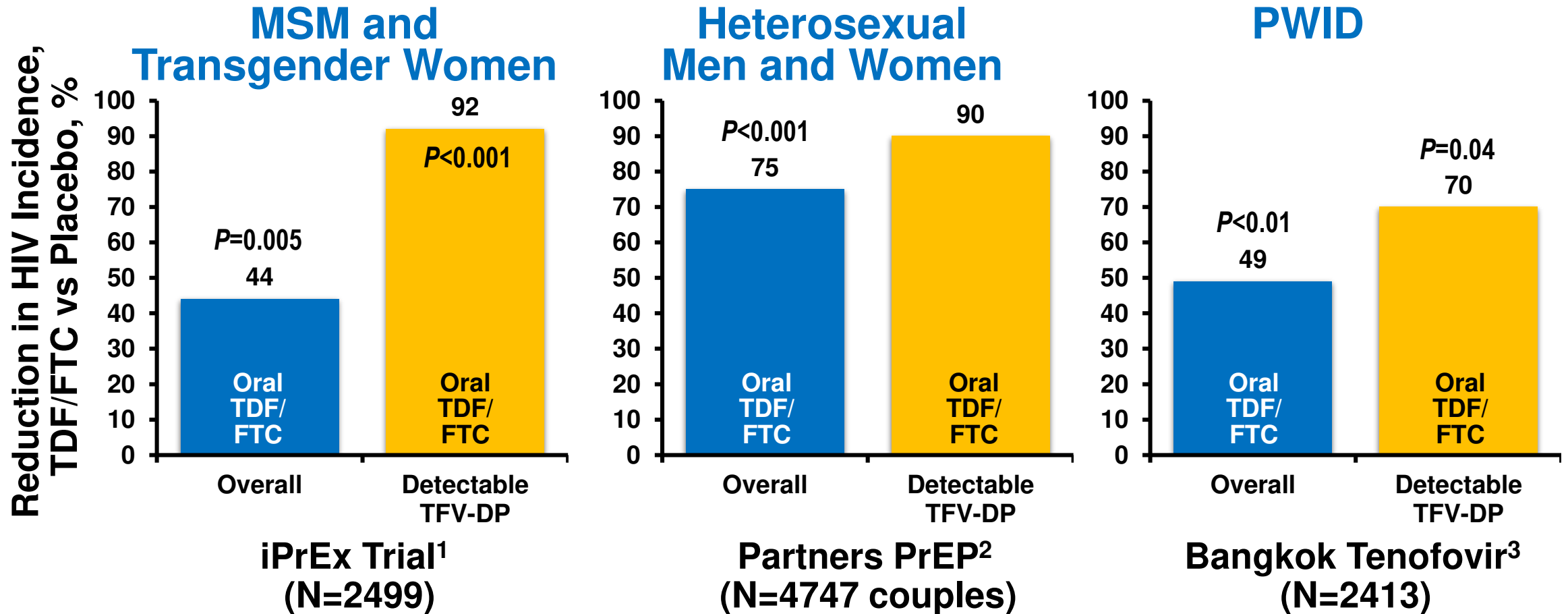
15% of partners tested by Partner Services were positive for HIV and previously undiagnosed.

1. CDC. Partner services. <https://www.cdc.gov/hiv/nexus/hcp/partner-services/>. Accessed June 24, 2024; 2. Task Force on Community Prevention Services. Recommendations to increase testing and identification of HIV-positive individuals through partner counseling and referral services. *Am J Prev Med.* 2007;33(2 suppl):S88; 3. CDC. Expedited partner therapy. <https://www.cdc.gov/std/ept/>. Accessed June 24, 2024.



EVIDENCE FOR ORAL PrEP

Efficacy of TDF/FTC for PrEP



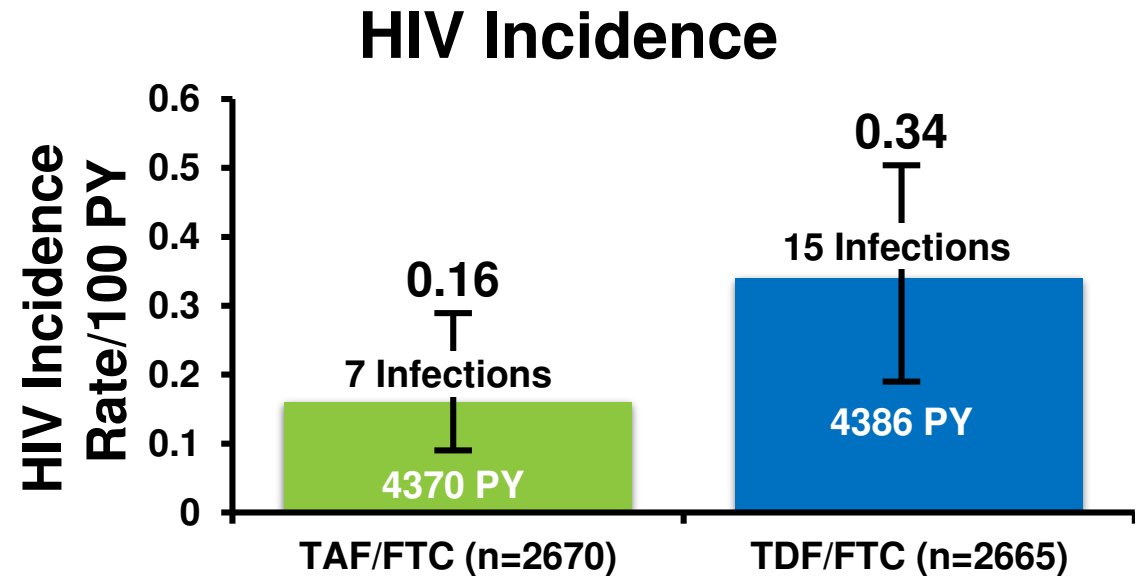
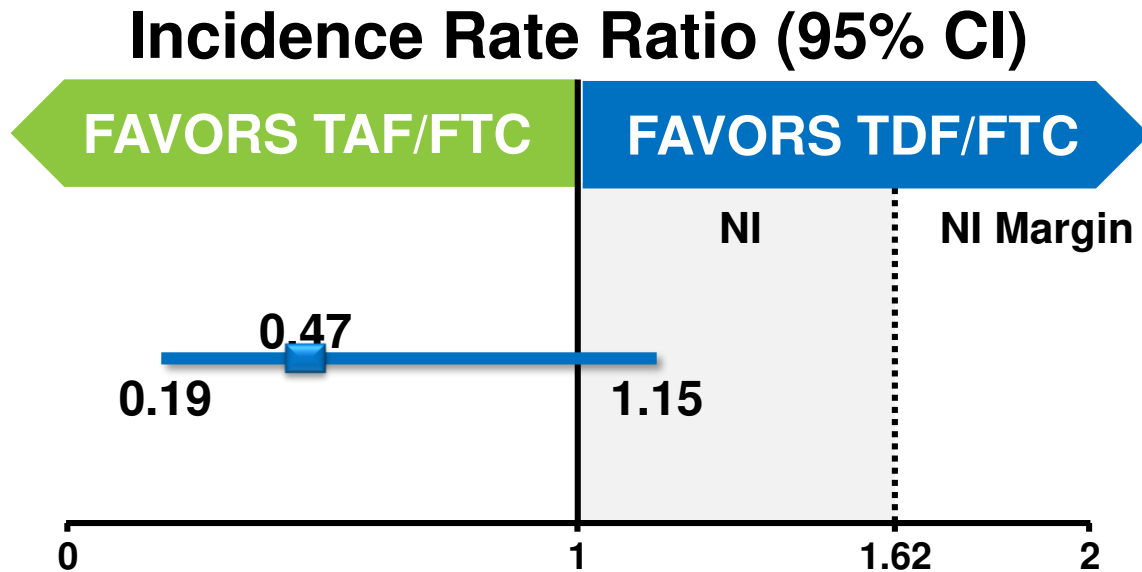
TFV-DP, tenofovir diphosphate.

1. Grant RM, et al; iPrEx Study Team. *N Engl J Med.* 2010;363(27):2587-2599; 2. Baeten JM, et al; Partners PrEP Study Team. *N Engl J Med.* 2012;367(5):399-410; 3. Choopanya K, et al; Bangkok Tenofovir Study Group. *Lancet.* 2013;381(9883):2083-2090.

PrEP Efficacy

TAF/FTC vs TDF/FTC

DISCOVER Trial: HIV Incidence



Daily TAF/FTC was statistically noninferior to daily TDF/FTC for HIV prevention, with TAF/FTC showing more favorable effects on BMD and biomarkers of renal safety

BMD, bone mineral density; NI, noninferiority; PY, patient-years; TGW, transgender women.

Double-blind phase 3 NI trial in 94 community, hospital-associated clinics in Europe and North America among cisgender MSM and TGW who have sex with men randomly assigned 1:1 to TAF/FTC or TDF/FTC (both with matched placebo) tablets daily. Efficacy outcome (HIV infection) assessed when all participants had completed 48 weeks of follow-up and half had completed 96 weeks of follow-up.

Mayer KH, et al. *Lancet*. 2020;396(10246):239-254.

PrEP Only Works If It's Taken as Prescribed

- A systematic review and meta-analysis of oral PrEP effectiveness, safety, adherence, and risk compensation in all populations showed that:
 - Efficacy is strongly linked to adherence
 - On average, a 10% decrease in adherence causes a 13% decrease in efficacy

Trial	Author, Year
Partners PrEP	Baeten, 2012
Bangkok Tenofovir Study	Choopanya, 2013
iPrEx	Grant, 2010
VOICE	Marrazzo, 2015
PROUD	McCormack, 2015
IPERGAY	Molina, 2015
FEM-PrEP	Van Damme, 2012



PrEP IMPLEMENTATION

A doctor in a white coat is smiling and talking to a patient with curly hair. The scene is overlaid with a blue tint. The text 'PRESCRIBING ORAL PrEP' is centered in white.

PRESCRIBING ORAL PrEP

Lab Testing and Monitoring for Oral PrEP

Test/Screen	Initiation	Every 3 Mo	Every 6 Mo	Every 12 Mo
HIV Assessment <ul style="list-style-type: none"> Signs/Symptoms AHI Discuss whether continued need for PrEP; adherence, side effects, etc 	X	X	X	X
HIV Status <ul style="list-style-type: none"> HIV-1/2 Ag/Ab test (lab preferred) HIV RNA assay 	(HIV-1/2 Ag/Ab test only)	X	X	X
Renal Status <ul style="list-style-type: none"> eCrCl >60 mL/min/1.73 m² (TDF/FTC or TAF/FTC) eCrCl >30 mL/min/1.73 m² (TAF/FTC) If at baseline >50 yo OR eCrCl <90 mL/min/1.73 m ² (TDF/FTC or TAF/FTC) ^a	TAF/FTC (Descovy) for reduced renal function		X ^a	X
STI Screen (for anal sex) ^b	X	X	X	X
STI Screen (for vaginal insertive or receptive sex) ^b	X		X	CT only
Lipid Screen (only for persons prescribed TAF/FTC)	X			X
Hepatitis Screens (HBV and HCV serologies; HAV serology for those having anal sex or if at risk) ^{1,2}	X		X (if not done at initiation)	
Pregnancy Test (if of childbearing potential) ²	X	X	X	X

^alf at baseline >50 yo OR eCrCl <90 mL/min/1.73 m² test every 6 months (TDF/FTC or TAF/FTC); ^bsyphilis testing; gonorrhea and chlamydia NAATs (all potential exposure sites). CT, chlamydia trachomatis; eCrCl, estimated creatinine clearance; HAV, hepatitis A virus; HBV, hepatitis B virus; HCV, hepatitis C virus; NAAT, nucleic acid amplification test; yo, years old.

1. CDC. USPHS. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Accessed June 24, 2024; 2. NYSDOH AIDS Institute. Clinical guidelines program. <https://www.hivguidelines.org/guideline/hiv-prep/>. Accessed June 24, 2024.

Prescribing Oral PrEP

Once You've Taken the Following Steps¹:

- Identified patient at risk of HIV infection (or a patient expressed interest in starting PrEP)
 - Confirmed their interest and clinical eligibility
 - Patient weighs ≥ 35 kg
 - Obtained negative HIV test result
 - Confirmed no HIV exposure event within last 4 weeks
 - No sign/symptoms of AHI
- Ordered necessary labs

Prescription	Pill Supply	Return for Follow-Up
Daily Oral PrEP	<ul style="list-style-type: none">• 1 fixed-dose combination tablet• 90-day supply TDF/FTC² <p>OR</p> <ul style="list-style-type: none">• 90-day supply TAF/FTC³<ul style="list-style-type: none">– Not for those having receptive vaginal sex• Optional: some clinicians prefer to give a 30-day supply at initiation to enable them to check on the patient sooner	Schedule follow-up visit for 30 or 90 days (depending on number of pills supplied)

You may initiate PrEP as long as there is a negative HIV test; you do not need to withhold PrEP until other tests are back!

1. CDC. USPHS. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Accessed June 24, 2024; 2. Drugs@FDA. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/021752s064lbl.pdf. Accessed June 30, 2024; 3. Drugs@FDA. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208215s019lbl.pdf. Accessed June 30, 2024.

Safety Considerations

TDF/FTC and TAF/FTC Black Box Warnings^{1,2}

Risk of drug resistance with use of TDF/FTC or TAF/FTC for PrEP in patients with undiagnosed early HIV infection

- **Use of TDF/FTC and TAF/FTC for PrEP is only for HIV-negative individuals**

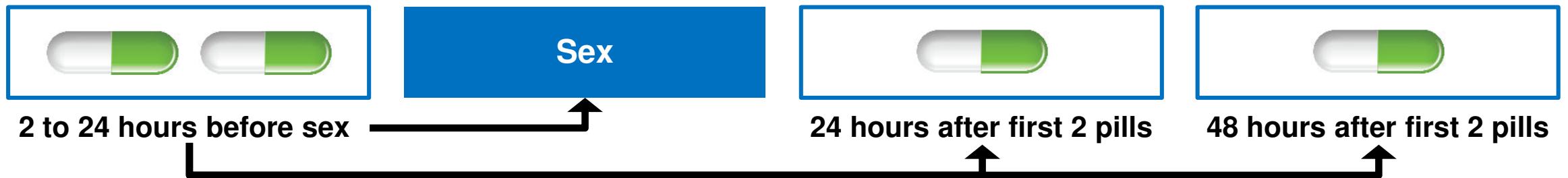
Posttreatment acute exacerbation of HBV infection

- Severe acute exacerbations of HBV have been reported in HBV-infected patients who have discontinued TDF/FTC and may occur with TAF/FTC
- Hepatic function should be monitored closely in these patients

On-Demand PrEP With Oral TDF/FTC

An Alternative to a Daily Pill

- **On-demand (also called event-driven or 2:1:1) dosing¹**
 - Taken at specific time points only around times of anal intercourse
 - Recommendations are only for MSM
 - Not for those having receptive vaginal sex or whose HIV risk is solely from IDU
- **Effective HIV prevention for MSM with infrequent sexual encounters and an alternative to daily TDF/FTC¹**
- **Not FDA approved; however, it is included in the CDC and other US and WHO guidelines^{1,2}**



WHO, World Health Organization.

1. Saag MS, et al. *JAMA*. 2020;324(16):1651-1669; 2. CDC. USPHS. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. June 24, 2024.

Pill Burden Can Be a Barrier to Using Oral PrEP

“With the pill, I might forget to take it every day. So, that’s just like when I was on birth control. The pill wasn’t good for me because I would forget to take it every day.”



Picture is of a model, not a real patient.

Groves AK, et al. *Obstet Gynecol.* 2022;139(4):537-544.



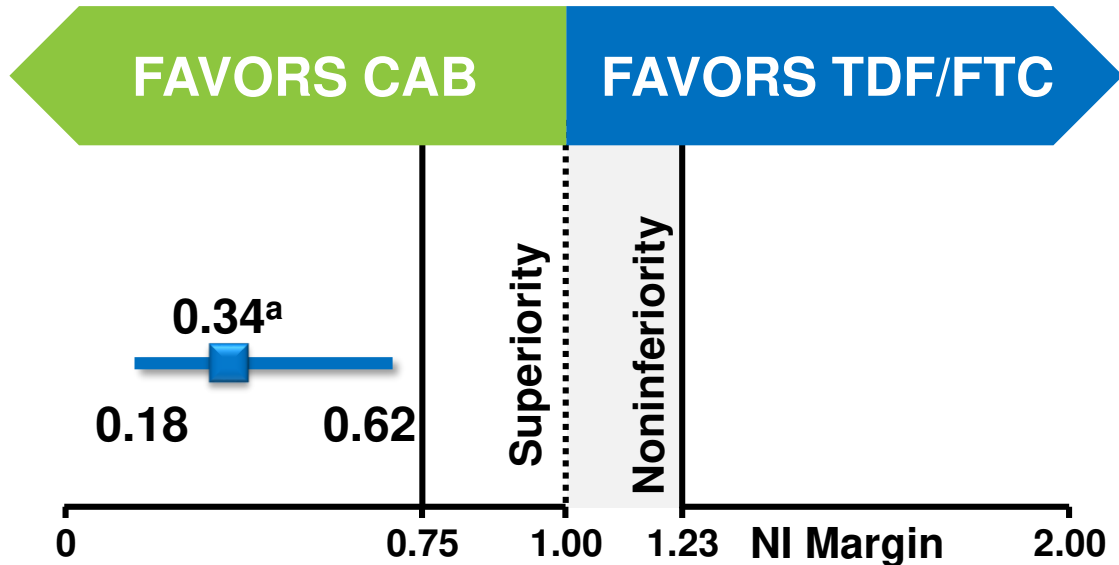
EVIDENCE FOR CAB LAI PrEP

PrEP Efficacy

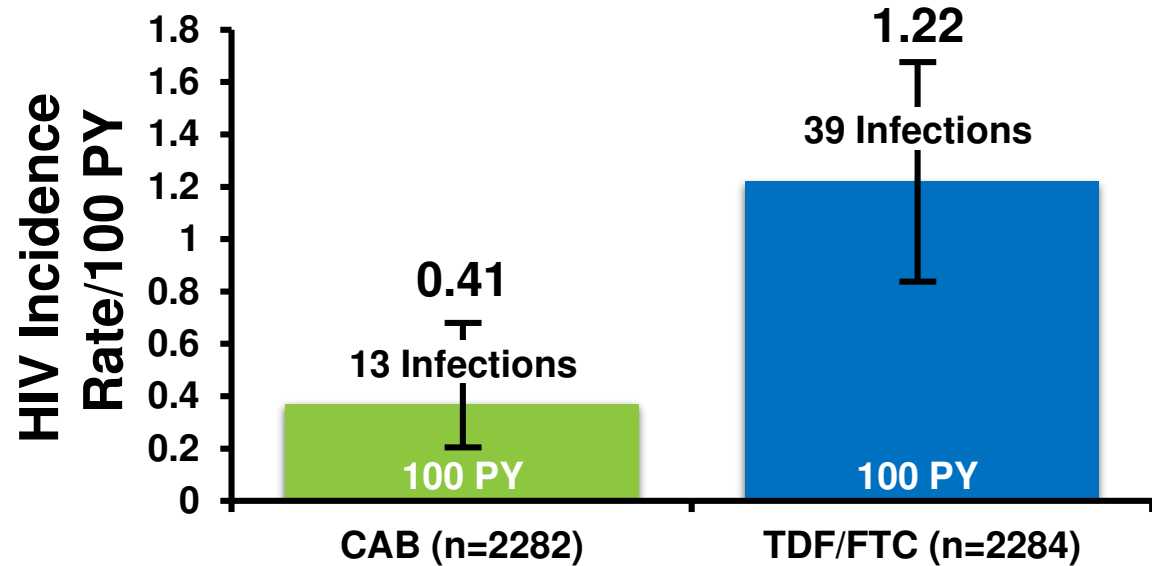
CAB vs TDF/FTC in MSM and TGW

HPTN 083 Trial Results

HIV Incidence Hazard Ratio (95% CI)



HIV Incidence



CAB was statistically superior to TDF/FTC in preventing HIV infection among MSM and TGW

^aP<0.0001.

HPTN, HIV Prevention Trials Network; IM, intramuscular.

N=4566, double-blind, double-dummy, noninferiority trial to compare LAI CAB at 600 mg IM every 8 weeks with daily oral TDF/FTC in cisgender MSM and TGW who have sex with men over 153 weeks.

Landovitz RJ, et al.; HPTN 083 Study Team. *N Engl J Med.* 2021;385(7):595-608.



PRESCRIBING CAB LAI

Lab Testing and Monitoring for CAB LAI

Test/Screen	Initiation	1 Mo Visit	Every 2 Mo	Every 4 Mo	Every 6 Mo	Every 12 Mo	When Stopping CAB
HIV Assessment							
<ul style="list-style-type: none"> • Signs/Symptoms AHI • Discuss whether continued need for PrEP; adherence, side effects, etc 	X		X	X	X	X	
HIV Status							
<ul style="list-style-type: none"> • HIV-1/2 Ag/Ab test (lab preferred) • HIV RNA assay 	X	X	X	X	X	X	X
STI Screen (MSM/TGW)^a	X		X	X	CT only	GC/Syphilis only	X
STI Screen (heterosexually active men and women)^a	X				GC/Syphilis only	CT only	
Pregnancy Test (if of childbearing potential)²	X	X	X	X	X	X	

^aSyphilis testing; gonorrhea and chlamydia NAATs (all potential exposure sites).

1. CDC. USPHS. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Accessed June 30, 2024; 2. NYSDOH AIDS Institute. Clinical guidelines program. <https://www.hivguidelines.org/guideline/hiv-prep/>. Accessed June 24, 2024.

Prescribing CAB LAI

Once You've Taken the Following Steps¹:

- Identified patient at risk of HIV infection (or a patient expressed interest in starting PrEP)
- Confirmed their interest and clinical eligibility
- Patient weighs ≥35 kg
- Obtained negative HIV test result
 - Confirmed no HIV exposure event within last 4 weeks
 - Patient not part of, or located in, high-incidence population
 - No signs/symptoms AHI
- Ordered necessary labs
 - You may initiate CAB LAI as long as there is a negative HIV test; you do not need to withhold PrEP until other tests are back

Prescription	With Oral Lead-In ²	Without Oral Lead-In ²
CAB LAI PrEP	<p>At initiation provide Prescription for CAB daily oral lead-in for 4 weeks</p> <p>1 month later (on the last day of oral lead-in) CAB single 600 mg (3 mL, gluteal IM only) injection</p> <p>1 month later CAB IM injection</p> <p>2 months later and thereafter Provide CAB IM injection</p>	<p>At initiation provide CAB IM injection</p> <p>1 month later CAB IM injection</p> <p>2 months later and thereafter CAB IM injection</p>

Oral lead-in dosing may be used for 1 month prior to starting injections to determine tolerability for CAB; may be used by those having receptive vaginal sex

1. CDC. USPHS. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Accessed June 24, 2024; 2. Drugs@FDA. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215499s002lbl.pdf. Accessed June 24, 2024.

Safety Considerations

CAB LAI Warnings

Black Box Warning: Risk of drug resistance with use of CAB LAI (or oral CAB) for PrEP in patients with undiagnosed early HIV infection

- Use of CAB LAI for PrEP is only for HIV-negative individuals; must test for HIV-1 infection prior to initiating injection or oral regimen and with each subsequent injection

Warnings/Precautions: Hypersensitivity reactions have been reported in association with other integrase inhibitors and hepatotoxicity has been reported in patients receiving oral CAB; discontinue CAB LAI if either of these develop

- Depressive disorders have been reported with CAB LAI for PrEP; patients with depressive symptoms should be evaluated promptly



MONITORING AND FOLLOW-UP CARE

How Long Until PrEP Works?

Time to Maximum HIV Protection (Tissue Concentration), by Mode of HIV Exposure

Tissue/Fluid	Approximate Time to Maximum Protection With Oral PrEP (Days)¹	Approximate Time to Maximum Protection With CAB LAI PrEP (Days)²
Rectal Tissue	7	7
Rectal Fluid	Unknown	7
Cervical Tissue	21	7
Cervical Vaginal Fluid	Unknown	7
Penile Tissue	Unknown	Unknown

1. CDC. USPHS. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Accessed June 24, 2024; 2. Shaik JS, et al. *Br J Clin Pharmacol*. 2022;88(4):1667-1678.

For Patients Who Miss a Dose of Daily Oral PrEP

Patients missing a dose of daily oral PrEP should be informed of the following¹:

- Take a single missed dose as soon as they remember it, unless it is almost time for the next dose
- If it is almost time for the next dose, skip the missed dose and continue with the regular dosing schedule

For Patients Who Miss a Dose of CAB

Patients missing a dose, or planning to miss a scheduled monthly injection visit, should be informed the following^{1,2}:

- Oral dosing may be used to replace up to 2 consecutive monthly injections
- If patients are more than 4 weeks late for their injections, counsel them to determine if an ongoing risk of HIV exposure is anticipated; if so
 - "Reload" with a 4-week interval between the next 2 injections and then return to 8-week intervals OR
 - Discuss with them the need for daily oral PrEP or other effective HIV prevention methods



SHARED DECISION- MAKING FOR PrEP THERAPY SELECTION

Medical Mistrust Is a Barrier to Using PrEP

“People [providers] inject me with stuff. I don’t really know what it is, so I don’t prefer any injections.”



Picture is of a model, not a real patient.

Groves AK, et al. *Obstet Gynecol.* 2022;139(4):537-544.

Comparing PrEP Options

Consider for	TDF/FTC	TAF/FTC	CAB LAI
Renal Function ¹⁻⁵		✓	✓
Bone Mineral Density ^{1,3,4-6}		✓	✓
Lipids ⁴⁻⁸	✓		
Gender-Affirming Hormones ⁵	✓	✓	✓
Other Considerations			
Side Effects ⁵	Diarrhea (6%); nausea (5%)	Diarrhea (5%); nausea (4%)	Injection-site reaction (32%-81%); mostly mild and greatest initially
Approved to Prevent HIV From IDU ⁶	✓		
Receptive Vaginal Sex ⁶	✓		✓
On-Demand Use ⁶	✓		
Frequency of Dose ⁶	1 pill daily	1 pill daily	Injection in buttocks every 2 months

1. Drugs@FDA. Drugs@FDA. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/021752s064lbl.pdf. Accessed June 30, 2024; 2. Gandhi M, et al. *Lancet HIV*. 2016;3(11):e521-e528; 3. Drugs@FDA. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215499s002lbl.pdf. Accessed June 30, 2024; 4. Drugs@FDA. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208215s020lbl.pdf. Accessed June 24, 2024; 5. NYSDOH AIDS Institute. Clinical guidelines program. <https://www.hivguidelines.org/guideline/hiv-prep/>. Accessed June 24, 2024; 6. CDC. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Accessed June 4, 2024; 7. Shah S, et al. *AIDS*. 2021;35(suppl 2):S189-S195; 8. Wood BR, Huhn GD. *Open Forum Infect Dis*. 2021;8(12):ofab542.

Perceived Billing and Coverage Problems Are a Barrier to PrEP

“...for a lot of people that don't have insurance, I know there are programs to help people, but I'm sure that the costs are still pretty expensive. Not only that, but the doctor's visits are also expensive too.”



Ready, Set, PrEP!

- **What is it?**

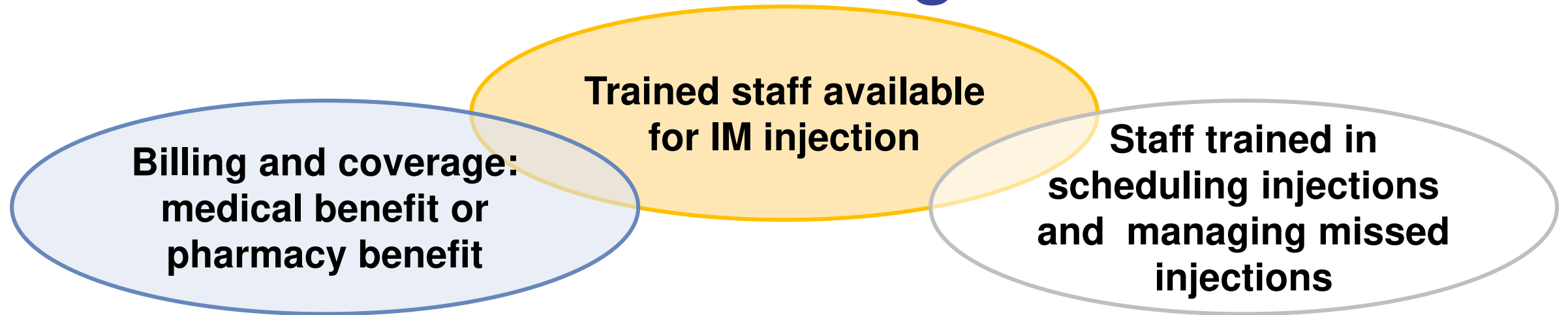
- Ready, Set, PrEP provides free PrEP HIV-prevention medication
 - Clinic visits and lab tests vary depending on income
- If PrEP medication is a good option for your client, they can choose the application process that is most convenient
 - GetYourPrEP.com
 - By phone: 855-447-8410
 - In person at a health care provider's office, including a community health center where trained staff can assist
 - Patients can receive PrEP medication through a pharmacy of their choice

- **Clients can apply for this program if they**

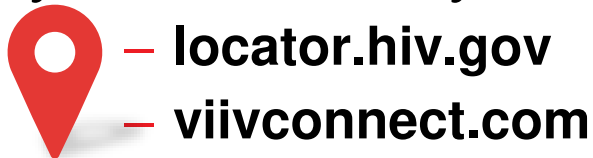
- Don't have health insurance coverage for prescription drugs
- Have taken an HIV test and received a negative result before starting the program
- Have a prescription for PrEP
- Live in the US, including tribal lands or territories



Considerations for LAI Implementation and Referring Out



- If it is not feasible for your clinic to implement CAB LAI, know where in your community to refer patients:



- **LAI PrEP in development:**
 - Lenacapavir (LEN) is a long-acting HIV capsid inhibitor in studies as a SQ injectable administered every 6 months¹
 - In the PURPOSE 1 trial in cisgender women aged 16 to 25 years, LEN had 100% efficacy in preventing HIV infections²

PrEP Posters, Brochures, and Pins

Ayuda Para Pagar la PrEP

La PrEP está cubierta por la mayoría de los programas de seguros médicos y Medicaid. Según la Ley del Cuidado de Salud a Bajo Precio, la PrEP debe ser gratuita en casi todos los planes de seguro médico. Eso significa que no te pueden cobrar por la medicación de la PrEP ni por las visitas a la clínica y las pruebas de laboratorio que necesitas para seguir tomando la PrEP.

Algunos estados ofrecen ayuda para pagar la PrEP, las visitas a la clínica o las pruebas de laboratorio si no tienes seguro:

- <https://nastad.org/prepost-resources/prep-assistance-programs>

Toma el Control de tu Salud!

PROTÉGETE DEL VIH

Es tan fácil como tomar 1 pastilla una vez al día o una inyección cada 2 meses.

¿Lo Sabías?

-1 de cada 5 nuevos diagnósticos de VIH se da en mujeres

No sólo los jóvenes corren riesgo: **personas de todas las edades pueden contraer el VIH**

Otros programas que puedes consultar:

Preparados, listos, PrEP!
(Si no tienes seguro o cobertura de Medicaid)

- <https://readysetprep.hiv.gov/>
- O lláma al **855-447-8410**

Para Truvada® y Descovy®
(Si no tienes seguro)

- Programa de Asistencia al Paciente Advancing Access: <https://www.gileadadvancingaccess.com/financial-support/en/usa/>
- Programa de Asistencia al Paciente Advancing Access: <https://www.gileadadvancingaccess.com/copy-coupon-card>
- Avancing Access: <https://www.gileadadvancingaccess.com/copy-coupon-card>
- O lláma al **1-877-505-6986**

Para Aprelude®

- VIV Connect: <https://www.vivconnect.com/savings-information/aprelude>

¿Cómo Empiezo?

La PrEP es sólo para personas que **no tienen el VIH**.

Acude a su médico para que te haga análisis de sangre y te diga si la PrEP es adecuada para ti.

¿Dónde Puedo Obtener la PrEP?

Utilizar preservativos o tomar un medicamento llamado PrEP puede evitar que contraigas el VIH. No es sólo para las personas cuyas parejas sexuales tienen el VIH, ni sólo para los hombres homosexuales.

¿Cómo Empiezo?

La PrEP es sólo para personas que **no tienen el VIH**.

Acude a su médico para que te haga análisis de sangre y te diga si la PrEP es adecuada para ti.

¿Cuáles Son Mis Opciones de PrEP?

Haz 3 medicamentos diferentes que previenen el VIH.

Una pastilla diaria OR Pastillas sólo cuando las necesites OR Una inyección cada 2 meses

Los son píldoras — TRUVADA® y DESCOVY® — y una es una inyección — APRELUDE®.

Si crees que sólo a veces corres el riesgo de contraer el VIH, pregunta a tu médico si la PrEP a demanda es adecuada para ti.

Cómo Se Debe Utilizar la PrEP?

Truvada® y Descovy®

- Toma la píldora de la PrEP **todos los días**
- Acude a su médico **cada 3 meses** para que te haga pruebas de laboratorio para asegurarse de que no tienes el VIH

Aprelude®

- Acude al médico mensualmente durante los **2 primeros meses** y después **cada 2 meses** para que te haga pruebas de laboratorio para asegurarse de que no tienes el VIH y para que te ponga la vacuna

Help paying for PrEP

PrEP is covered by most health insurance programs and Medicaid. Under the Affordable Care Act, PrEP must be free under almost all health insurance plans. That means you can't be charged for your PrEP medication or the clinic visits and lab tests you need to stay on PrEP.

Some states offer help to pay for PrEP, clinic visits, or lab tests if you don't have insurance:

- <https://nastad.org/prepost-resources/prep-assistance-programs>

Take Control of your Health!

Protect Yourself from HIV

It's as easy as taking 1 pill once a day or a shot every 2 months.

Did You Know?

-1 in 5 new HIV diagnoses is in women

It's not just young people at risk — **people of all ages can acquire HIV**

Some geographic regions in the US, such as the South, have a **higher incidence of HIV**

Other programs to check out:

Ready, Set, PrEP!
(If you don't have insurance or Medicaid coverage)

- <https://readysetprep.hiv.gov/>
- Or call: **855-447-8410**

For Truvada® and Descovy®
(If you don't have insurance)

- Advancing Access Patient Assistance Program: <https://www.gileadadvancingaccess.com/financial-support/en/usa/>
- Advancing Access: <https://www.gileadadvancingaccess.com/copy-coupon-card>
- Or call: **1-877-505-6986**

For Aprelude®

- VIV Connect: <https://www.vivconnect.com/patient/get-savings-information/aprelude>

Who can I get PrEP?

PrEP stands for preexposure prophylaxis (pro-fil-lax-is).

PrEP pills means to take steps to prevent getting a disease or to protect your health.

Who can I get PrEP?

<https://www.pleaseprepme.org/find-a-provider/>
<https://www.pleaseprepme.org/online-provider/>

¿Qué Más Debo Saber Sobre la PrEP?

No dejes que nadie más tome tus pastillas de la PrEP.

Guarda las pastillas de la PrEP en el frasco, mantén el frasco cerrado y fuera del alcance de los niños

Toma la píldora de la PrEP todos los días o ponte la inyección cada 2 meses para prevenir el VIH

Adapta su horario de medicación a su vida. Acostumbra de tomar las píldoras de la PrEP a las cosas que ya haces cada día, como lavarte los dientes o comer algo

Utiliza un calendario o su teléfono para recordarte su próxima inyección de PrEP o su cita para ver a su proveedor de atención sanitaria

What are my PrEP Options?

There are 3 different medicines that prevent HIV.

A daily pill OR Pills only when you need them OR A shot every 2 months

Two are pills — TRUVADA® and DESCOVY® — and one is a shot — APRELUDE®.

If you feel like you are at risk for getting HIV only sometimes, ask your doctor if on-demand PrEP is right for you.

How should PrEP be used?

Truvada® and Descovy®

- Take your PrEP pill **every day**
- See your health care provider **every 3 months** for lab tests to make sure you do not have HIV

Aprelude®

- See your health care provider **monthly** for the first 2 months and then **every 2 months** for lab tests to make sure you do not have HIV and to get the shot

What I need?

PrEP is an important tool for protecting yourself from HIV. PrEP pills means to take steps to prevent getting a disease or to protect your health.

Who can I get PrEP?

<https://www.pleaseprepme.org/find-a-provider/>
<https://www.pleaseprepme.org/online-provider/>

What else should I know about PrEP?

- Do not let anyone else take your PrEP pills
- **Keep PrEP pills in the bottle;** keep the bottle closed and away from children
- **Take the PrEP pill every day** or get the shot every 2 months to prevent HIV
- **Match your medicine schedule to your life.** Add taking your PrEP pill to things you already do each day, like brushing your teeth or eating a meal
- **Use a calendar or your phone** to remind you about your next PrEP shot or your appointment to see your health care provider

How do I start PrEP?

Discuss options with your health care provider

Undergo blood work, including HIV testing

Undergo repeat blood work every 2 to 3 months while on PrEP

Take Control of Your Sexual Health!

Learn About PrEP to Prevent HIV.

What is PrEP?

PrEP (preexposure prophylaxis) is a way to prevent HIV infection and ensure you can enjoy a healthy sex life!

PrEP can be FREE or LOW cost and is available as:

A daily pill OR Pills only when you need them OR A shot every 2 months

Who may benefit from PrEP?

- Anyone **sexually active** who doesn't always use a condom
- **Teens and adults** of all ages, regardless of gender
- People who are planning to get **pregnant**, are pregnant, or are breastfeeding
- Anyone who has had chlamydia, gonorrhea, or syphilis in the **past 6 months**
- Anyone with a **partner** living with HIV
- People who live in an area where many people are living with HIV
- Anyone who injects **nonprescription drugs**

PrEP is SELF care and HEALTH care

- ♥ Keeps you **SAFE**
- ♥ Gives you **PEACE** of mind
- ♥ Is **PREVENTIVE** medicine
- ♥ **EMPOWERS** you

How do I start PrEP?

Discuss options with your health care provider

Undergo blood work, including HIV testing

Undergo repeat blood work every 2 to 3 months while on PrEP

ASK ME ABOUT PrEP!

You're in Control With PrEP!

Take the first step — Ask your health care provider if PrEP is right for you!

PrEP Access, Assistance, and Information

- **Patient and provider assistance: PleasePrEPMe.org**

- <https://pleaseprepme.org/>
- Information about PrEP, nPEP, insurance and insurance rights, finding a PrEP/nPEP provider, and a list of PrEP resources, by state

- **Provider assistance: AETC; AIDS Education & Training Center Program: National Coordinating Resource Center**

- Supports national HIV priorities by providing training, consultation, and resources
- <https://aidsetc.org/>

- **Patient assistance (without insurance)**

- The PrEP patient assistance program will provide medication at no cost for those who meet income guidelines
- <https://www.gilead.com/purpose/medication-access/us-patient-access>
 - Uninsured 24/7 support online, by phone during business hours and fax enrollment:
 - <https://www.gileadadvancingaccess.com/financial-support/uninsured>

- **Co-pay assistance (for patients with nongovernment insurance)**

- <https://www.gileadadvancingaccess.com/copay-coupon-card>
- Phone number: 1-800-226-2056

- **Co-pay assistance/out-of-pocket costs**

- ViiV Connect <https://www.viivconnect.com/hcp/get-financial-support/>

Visit our Clinical Resource Center for additional information about PrEP
www.ExchangeCME.com/PrEPpcp2024Resources



QUESTION & ANSWER SESSION

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