Improving HIV-PrEP Use in Eligible Minorities with Substance Use Disorders Workshop.

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Disclosure Information

Moronkeji Fagbemi, MD, FASAM, FACP.

- No Disclosures

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Saturday April 26, 2025. 1:15PM – 2:30PM

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Presenters and Workshop Facilitators have **No Disclosures**

Abbreviations

1	HIV	Human Immunodeficiency virus
2,	AIDS	Acquired Immunodeficiency syndrome
3.	SUD	Substance Use Disorder
4.	PWID	People who inject drugs
5.	PrEP	Pre-exposure prophylaxis
6.	F/TDF	Emtricitabine /Tenofovir disoproxil fumarate
7.	F/TAF	Emtricitabine / tenofovir alafenamide
8.	CAB	Cabotegravir
9.	eCfCl	Estimated creatinine clearance

10.	EHE	Ending the HIV Epidemic
11,	HHS	Health and Human Services
12.	STI	Sexually transmitted infection
13.	MSM	Men who have sex with men
14.	MSW	Men who have sex with women
15.	GC	Gonorrhea
16.	PLWH	Patient living with HIV
17.	HIV	Human Immunodeficiency Virus

Workshop Learning Objectives

- Understand the fundamentals of Pre-Exposure Prophylaxis (PrEP).
- Recognize the indications for PrEP use especially among minorities with substance use disorders
- Understand the unique challenges of PrEP among ethnic and racial minorities with Substance Use Disorders (SUDs)

Section A: Workshop Session Plan

- Lecture for 20 minutes
- Small group activity (15 minutes)
- Review the cases discussed and point out some pearls (5 minutes)
- Explain the challenges surrounding PrEP for minorities with SUDs from a clinician's standpoint (5 minutes)
- Role-playing and simulations within small groups (20 minutes).
- Conclusion and wrap-up (5 minutes)

Learning Objectives for Lecture

1. Understand the epidemiology and prevalence of HIV
2. Learn about assessing risk of sexual HIV acquisition and in persons who inject illicit drugs.
3. Understand the disparities related to PrEP use in minorities.
4. Review the indications for PrEP use
5. Understand the fundamentals of PrEP and evidence-based reasons for its use

Section B

Lecture

HIV Globally

- At the end of 2023, about 39.9 million people were living with the Human Immunodeficiency Virus (HIV) of which 38.5 million were age 15+ and 1.4 million children.
- About 20.5 million of the adults living with HIV were women while men accounted for about 18 million.
- 1.3 million individuals acquired HIV in 2023.
- Over 630,000 persons died from HIV-related causes.

HIV Global Situation and Trends. World Health Organization (WHO).

HIV in the United States

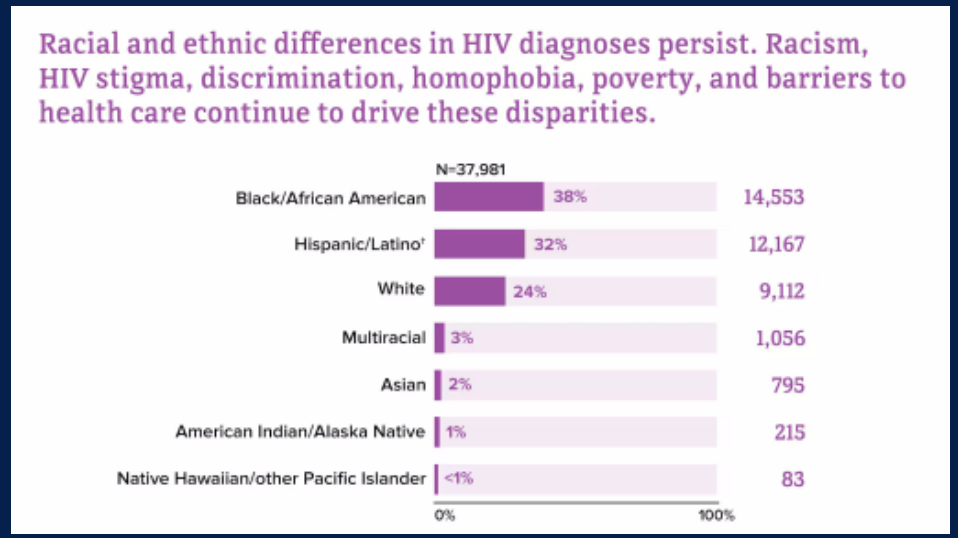
- In 2022, an estimated 1.2 million people were living with HIV In the United States (U.S.)
- Estimated HIV infections decreased 12% overall from 2018 to 2022 in the U.S.
- Of the 31.800 estimated new infections in 2022, 67% were among gay, bisexual, and MSM sexual contacts, 22% among heterosexual contacts, and 7% among PWID.
- *Over 50% of people living with HIV (PLWH) report current or past histories of alcohol /drug use disorders.

- Fast Facts: HIV in the United States. Center for Disease Prevention and control. https://www.cdc.gov/hiv/data-research/facts-stats/index.html .
- Ferguson TF, Theall KP, Brashear M, Maffei V, Beauchamp A, Siggins RW, Simon L, Mercante D, Nelson S, Welsh DA, Molina PE. Comprehensive Assessment of Alcohol Consumption in People Living with HIV (PLWH): The New Orleans Alcohol Use in HIV Study. Alcohol Clin Exp Res. 2020 Jun;44(6):1261-1272. doi: 10.1111/acer.14336. Epub 2020 May 22. PMID: 32441814; PMCID: PMC7282973.

Race/Ethnicity and HIV

- Racial and ethnic minorities bear the greatest burden with Black/African American and Hispanic/Latino people making up more than half of all new HIV infections in the United States.

- 38% of new cases of HIV in the U.S. were among blacks and 32% among Hispanic individuals yet only 14% of eligible Black individuals and 17% of Hispanics individuals eligible for HIV PrEP received it compared to 64% in White individuals.



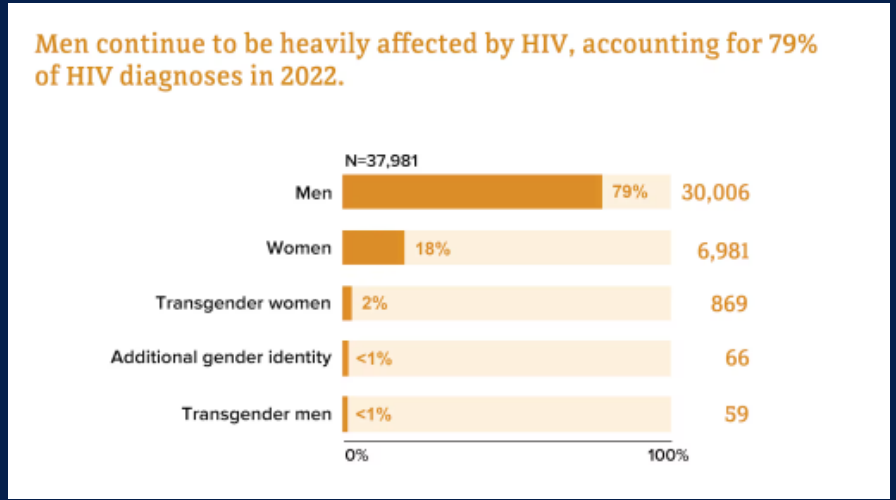
Source, CDC, HIV Diagnoses, Deaths, and Prevalence, 2022, Key Findings

- CDC. Diagnoses of HIV infection in the United States and dependent areas, 2022. HIV Surveillance Report 2024;35.
- AIDSVu Releases New Data Highlighting Ongoing Inequities in PrEP Use among Black and Hispanic People and across Regions of the Country. June 21, 2023.

Gender and HIV

From 2022 Data:

- Black men had the highest rate of new HIV diagnoses in 2022, followed by Latino men.
- Black women had the highest rate of new HIV diagnoses among women in 2022 .
- 34% of new HIV infections among MSM were among Black/African Americans and 38% were among Hispanic/Latinos



- Kaiser Family Foundation (KFF). HIV/AIDS. The Impact of HIV on Black People in the United States.. Sep 09, 2024
- CDC. HIV Diagnoses, Deaths, and Prevalence. May 21, 2024.
- National Center for HIV, Viral Hepatitis, STD, and Tuberculosis Prevention; Division of HIV Prevention

Substance Use Disorder and HIV

- Substance use alters judgement, leading to risky sexual behaviors or sharing of needles and paraphernalia that can make people more likely to acquire and transmit HIV.

- In people living with HIV, substance use can hasten disease progression, affect adherence to antiretroviral therapy (HIV medicine), and worsen the overall consequences of HIV.

- In people living with HIV, substance use can worsen the overall consequences of HIV

HIV and Substance Use. CDC.2016. https://www.cdc.gov/hiv/pdf/risk/cdc-hiv-substanceuse.pdf

Substance Use Disorders and High-Risk Sexual Behaviors.

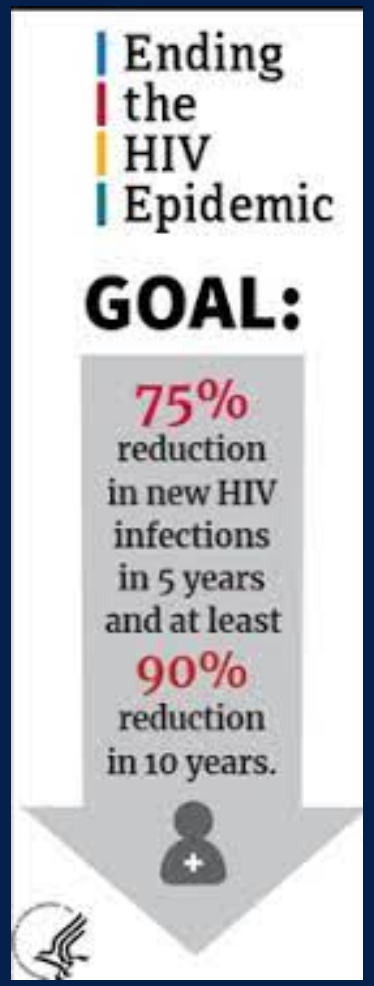
Substance use is associated with sexual risk behavior such as:

- Having early initiation of sexual activity with increased risk for STI and unintended pregnancy.
- Having multiple sex partners
- Unprotected sex or not using a condom.
- Sex under the influence of drugs and alcohol
- Forced (non-consensual) sexual activity and experiencing violence with mental health and suicide risks.

Centers for Disease control and Prevention. Substance use and sexual risks behavior. https://www.cdc.gov/youth-behavior/risk-behaviors/substance-use-sexual-risk-behaviors.html

Ending the HIV Epidemic Initiative

- First launched in 2019 by the U.S. Department of Health and Human Services (HHS).
- Aims to reduce new HIV infections in the U.S. to reducing new HIV infections by 75% by 2025 and 90% by 2030.
- It aims to target the highest burden counties and states with HIV prevention resources.



National Center for HIV, Viral Hepatitis, STD, and Tuberculosis Prevention; Division of HIV Prevention. https://www.cdc.gov/ehe/php/about/index.html

Assessing Risk of Sexual HIV Acquisition

Taking a Sexual History

- Routinely taking a sexual history is a necessary first step to identify which patients in a clinical practice are having sex with same-sex partners, which are having sex with multiple partners, and what specific sexual behaviors may place them at risk for, or protect them from, HIV acquisition.

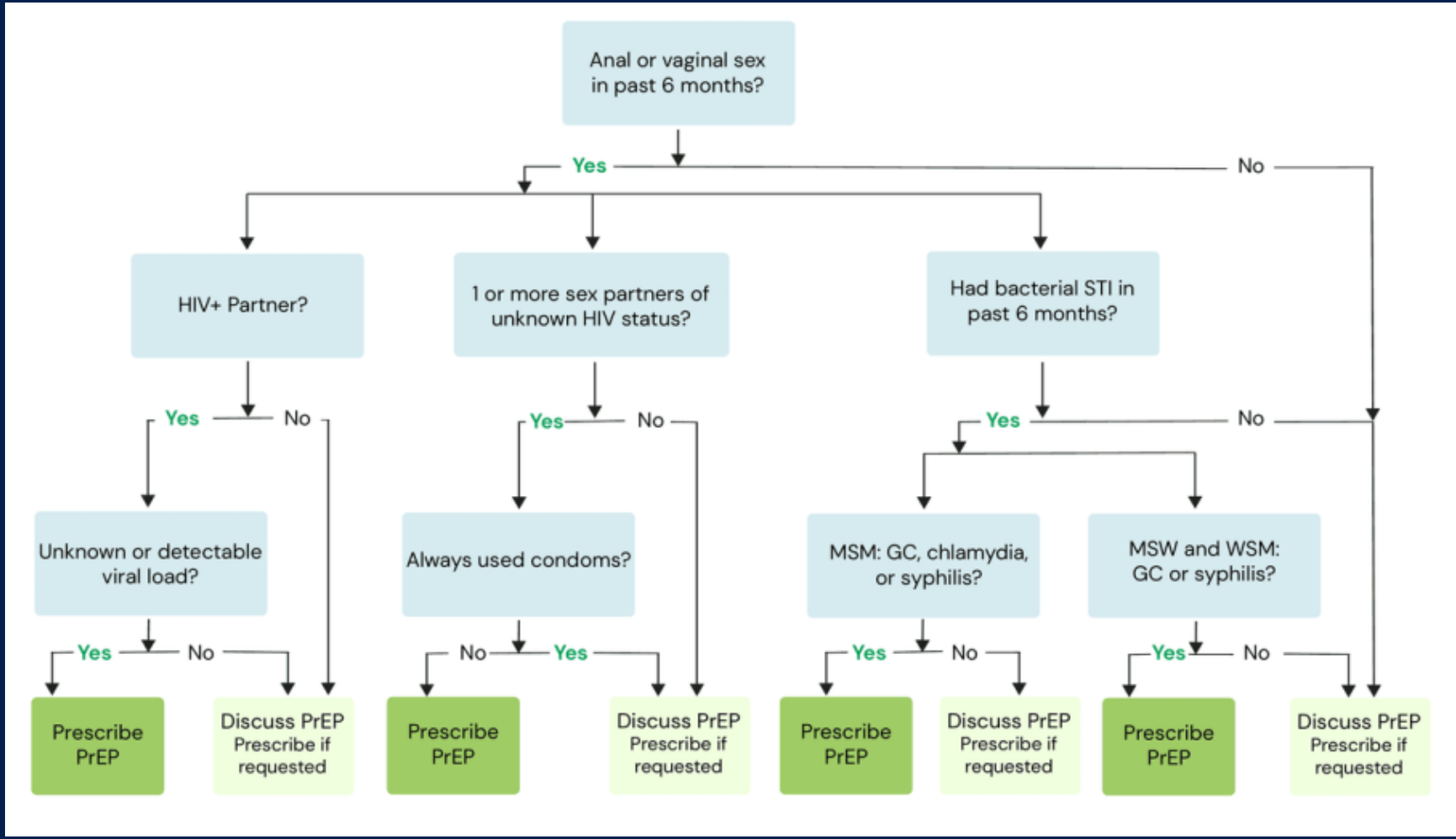
- It should NOT be for only selected patients (e.g., young, unmarried persons, or women seeking contraception), because new HIV infections and STIs are occurring in all adult and adolescent age groups, both sexes, all genders, and both married and unmarried persons.

The 5 P'S of Sexual History

- **Partner: N**umber of partners, gender of partners, and any potential risks associated with their sexual behaviors.
- **Practices:** Types of sexual activities engaged in, including oral sex, vaginal sex, and anal sex.
- **Protection:** Use of condoms, birth control, and other measures to prevent sexually transmitted infections (STIs) and pregnancy.
- **Past History of STIs**: Any previous diagnoses or treatments for STIs.
- **Pregnancy Plans:** Current or future intentions regarding pregnancy.

Center for Disease control and Prevention. A Guide to Taking a Sexual History. https://www.cdc.gov/std/treatment/sexualhistory.pdf

Assessing Risk of Sexual HIV Acquisition



Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. December 2021:1-108.

HIV Acquisition Risks in People Who Inject Drugs

In the United States, PWID account for an estimated 7 to 10% of new infections annually and may have multiple factors that place them at risk of acquiring HIV, including:

- Receptive syringe sharing (RSS)
- Sharing of injection works
- Receipt of syringes and injection supplies from nonsterile sources.

- Multiple sex partners
- Condomless sex
- Exchange of sex for money, goods, or other needs (i.e., transactional sex)

- Centers for Disease Control and Prevention. Estimated HIV Incidence and Prevalence in the United States, 2017–2021. HIV Surveillance Supplemental Report. 2023;28(3). Published May 2023..
- Biello KB, Bazzi AR, Mimiaga MJ, et al. Perspectives on HIV pre-exposure prophylaxis (PrEP) utilization and related intervention needs among people who inject drugs. Harm Reduct J. 2018;15:55.

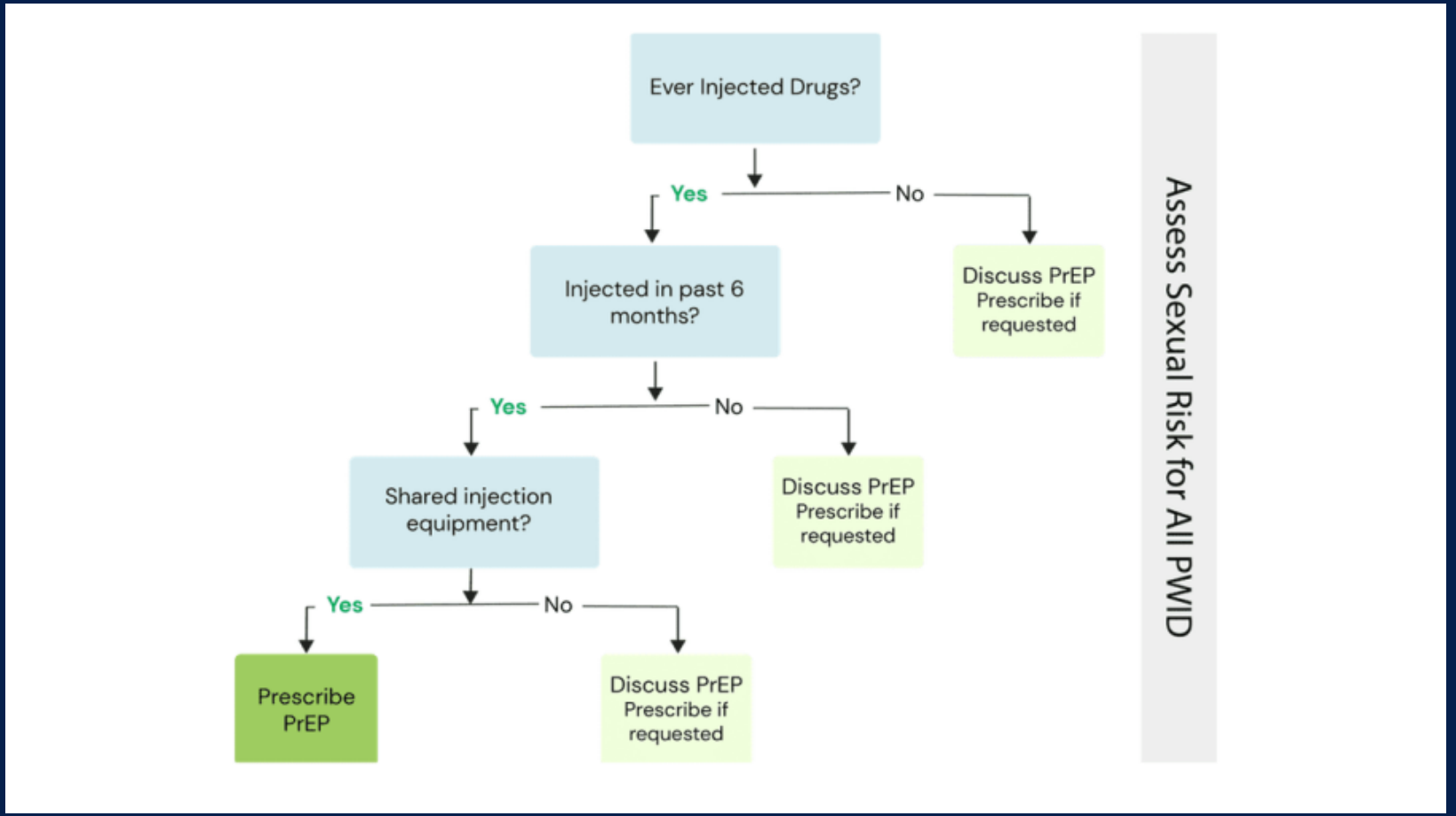
Factors Associated with Receptive Injection Equipment Sharing

- In a recent multi-state study of PWID at 22 substance use disorder treatment programs, one in four people who inject drugs reported having engaged in receptive injection equipment sharing in the past month.

- Factors associated with greater odds of receptive injection equipment sharing included:
  - Having a high school education or equivalent.
  - Experiencing hunger at least weekly
  - Living in a non-metropolitan area

Allen, S.T., Schneider, K.E., Morris, M. et al. Factors associated with receptive injection equipment sharing among people who inject drugs: findings from a multistate study at the start of the COVID-19 pandemic. Harm Reduct J 20, 18 (2023). https://doi.org/10.1186/s12954-023-00746-5

Assessing Indications for HIV-PrEP in Persons Who Inject Drugs.



PWID = people who inject drugs

- Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. December 2021:1-108.

Key Point to Clinicians

- Clinicians should evaluate all adult and adolescent patients who are sexually active or who are injecting illicit drugs and offer to prescribe PrEP to persons whose sexual or injection behaviors and epidemiologic context place them at substantial risk of acquiring HIV infection.

What is HIV PrEP?

- HIV pre-exposure prophylaxis (PrEP) are medications that help prevent HIV infection in people who are at high risk of exposure to the virus.

- They consist of antiretroviral medications (taken daily as pills or injections at specific intervals) that block HIV from entering and replicating in cells.
- Individuals by consistently using PrEP can significantly reduce their risk of acquiring HIV through sexual intercourse or injection drug use.

- HIV.gov. Pre-Exposure Prophylaxis. June 27, 2024. https://www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/pre-exposure-prophylaxis#

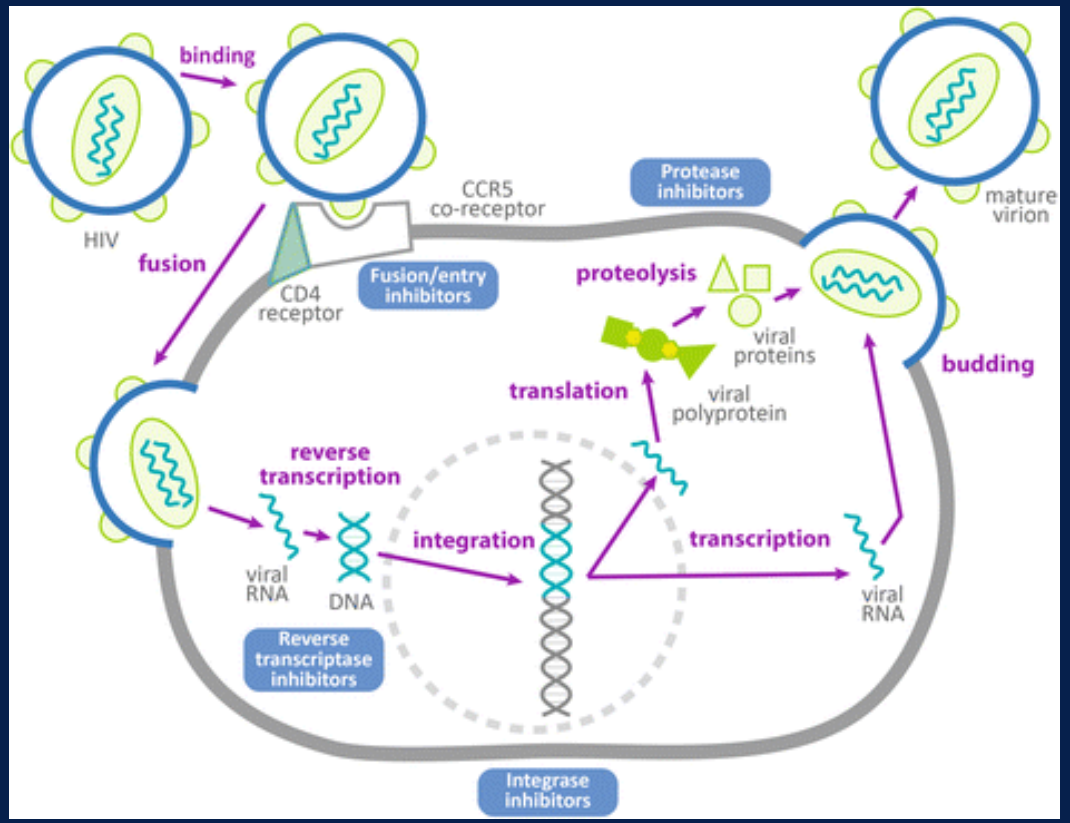
Available Medications for PrEP

There are three FDA-Approved PrEP Medications: Two consist of a combination of drugs in a single oral tablet taken daily. The third is a medication given by injection every 2 months.

- Emtricitabine (F) 200 mg in combination with tenofovir disoproxil fumarate (TDF) 300 mg (F/TDF—brand name Truvada® or generic equivalent).
- Emtricitabine (F) 200 mg in combination with tenofovir alafenamide (TAF) 25 mg (F/TAF—brand name Descovy®).
- Cabotegravir (CAB) 600 mg injection (brand name Apretude®)

PrEP Mechanism of Action

- PrEP (F/TDF and F/TAF) inhibit reverse transcriptase enzyme thereby preventing the virus from replicating by stopping its ability to convert its RNA into DNA.
- **Cabotegravir** is an integrase inhibitor preventing HIV from integrating its genetic material into the host cell's DNA.
- PrEP prevents the HIV from making copies of itself.



Who is Pre-exposure Prophylaxis PrEP for?

- Current guidelines recommend the use of PrEP for the following high-risk groups:

- Men that have sex with men (MSM).
- Heterosexual HIV-discordant couples.
- Those with multiple sexual partners with inconsistent condom use.
- Commercial sex workers.
- People who inject drugs (PWID).

Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published XXX 2021

New York State Department of Health (NYSDOH) Recommendation For PrEP

- People who are at high risk of HIV infection and are HIV-negative
  - People who have unprotected anal or vaginal sex
  - People who have a history of sexually transmitted infections (STIs)
  - People who inject drugs
  - People who have partners who are living with HIV
  - People who have partners who inject drugs
  - People who have multiple or anonymous sex partners
  - People who participate in sex parties or clubs
  - People who are involved in transactional sex
  - People who use mood-altering substances during sex

New York State Department of Health. Preventing HIV by Taking One Pill Once a Day: Pre-exposure Prophylaxis (PrEP).. Revised: July 2022. https://www.health.ny.gov/diseases/aids/general/prep/faqs.htm

Evidence-based Reasons for PrEP Use

- The National Institute of Allergy and Infectious Diseases (NIAID) supported clinical trial called iPrEx (randomized controlled trial) in 2500 MSM which (June 2007 - February 2011) was the first to establish the effectiveness of daily oral PrEP reducing the risk of acquiring HIV.

- Three more large-scale randomized controlled trials of daily oral PrEP found that it substantially reduced the risk of acquiring HIV among people who inject drugs, heterosexual men and women, and heterosexual serodiscordant couples, hence the Food Drug Administration (FDA) approved use of tenofovir disoproxil and emtricitabine (F/TDF) for oral PrEP in 2012.

National Institute of Allergy and Infectious Diseases. Pre-Exposure Prophylaxis (PrEP) to Prevent HIV. September 13, 2024. https://www.niaid.nih.gov/diseases-conditions/pre-exposure-prophylaxis-prep

Preexposure Prophylaxis for the Prevention of HIV Updated Evidence Report and Systematic Review for the US Preventive Services Task Force

1. **Objective:** To update the 2019 review on PrEP, to inform the USPSTF.
2. **Data Sources:** Ovid MEDLINE, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, and Embase (January 2018 to May 16, 2022); surveillance through March 24, 2023
3. **Study Selection:** Randomized clinical trials of PrEP vs placebo or no PrEP or newer vs older PrEP regimens
4. **Main Outcomes and Measures:** HIV acquisition, mortality, and harms; and diagnostic test accuracy.
5. Thirty-two studies were included in the review (20 randomized clinical trials and 12 studies of diagnostic accuracy.

Chou R, Spencer H, Bougatsos C, Blazina I, Ahmed A, Selph S. Preexposure Prophylaxis for the Prevention of HIV: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force. JAMA. 2023;330(8):746–763. doi:10.1001/jama.2023.9865

Systematic Review for PrEP Use

Results:

- Eleven trials in the 2019 review found oral PrEP associated with decreased HIV infection risk vs placebo or no PrEP (n = 18 172; relative risk [RR], 0.46 [95% CI, 0.33-0.66]).
- Higher adherence was associated with greater efficacy.
- One new trial (n = 5387) found oral tenofovir alafenamide/emtricitabine (TAF/FTC) to be noninferior to tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) in men who have sex with men (RR, 0.53 [95% CI, 0.23-1.26]).
- Two new trials found long-acting injectable cabotegravir associated with decreased risk of HIV infection vs oral TDF/FTC (RR, 0.33 [95% CI, 0.18-0.62] in cisgender men who have sex with men and transgender women [n = 4490] and RR, 0.11 [95% CI, 0.04-0.31] in cisgender women [n = 3178]).

Chou R, Spencer H, Bougatsos C, Blazina I, Ahmed A, Selph S. Preexposure Prophylaxis for the Prevention of HIV: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force. JAMA. 2023;330(8):746–763. doi:10.1001/jama.2023.9865

Conclusions and Relevance

- In adults at increased HIV acquisition risk, oral PrEP was associated with decreased risk of acquiring HIV infection compared with placebo or no PrEP. Oral TAF/FTC was noninferior to oral TDF/FTC, and injectable cabotegravir reduced the risk of HIV infection compared with oral TDF/FTC in the populations studied.

- In 2019, the US Preventive Services Task Force (USPSTF) recommended that clinicians offer preexposure prophylaxis (PrEP) with effective antiretroviral medications to persons at increased HIV acquisition risk (A recommendation),

Take Home From the Study

US Preventive Services Task Force. Preexposure prophylaxis for the prevention of HIV infection: US Preventive Services Task Force recommendation statement. JAMA. 2019;321(22):2203-2213. doi:10.1001/jama.2019.6390

USPSTF Grade A Recommendation

A=Absolutely do it. There is high certainty that the net benefit is substantial.

Examples of some other USPSTF grade A recommendations:

- ❑ Colorectal cancer screening
- ❑ Cervical cancer screening
- ❑ Hypertension screening in adult 18 years and above
- ❑ HIV Screening
- ❑ Syphilis screening
- ❑ Tobacco smoking cessation

*PrEP is a Grade A Recommendation

United States Preventive Services Task Force. A & B Recommendations. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations

*How Effective is PrEP?

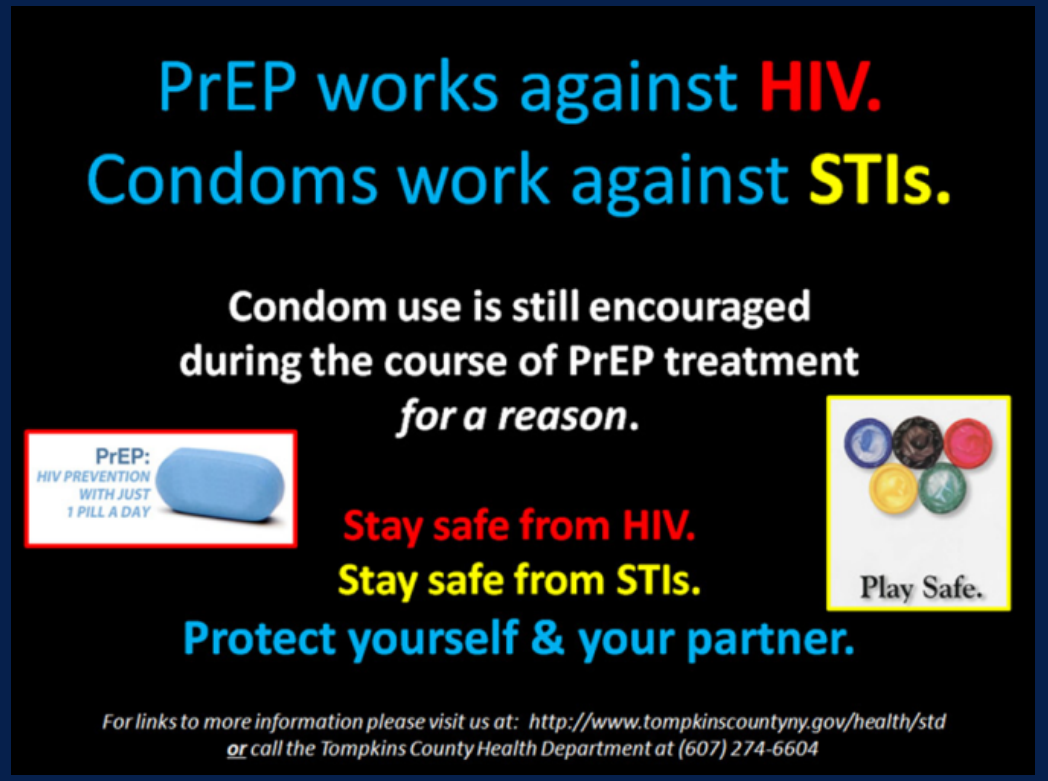
- When taken as prescribed, both oral and injectable PrEP reduce the risk of getting HIV from sex by about 99%.

- Oral PrEP has also been shown to reduce the risk of getting HIV from injection drug use by at least 74%, when taken as prescribed

HIV info. NIH.gov. HIV Prevention. Pre-Exposure Prophylaxis (PrEP). December 11, 2023. https://hivinfo.nih.gov/understanding-hiv/fact-sheets/pre-exposure-prophylaxis-prep#

Other Preventive Measures for HIV infection in addition to PrEP Use

- Getting tested for HIV periodically
- Using harm reduction services e.g., clean needle/ syringe program.
- Limiting sexual partners
- Using condoms



HIVinfo. HIV.gov. The Basics of HIV Prevention. https://hivinfo.nih.gov/understanding-hiv/fact-sheets/basics-hiv-prevention

Initiating PrEP

Before starting PrEP, it is essential to evaluate and document:

1) A negative HIV Test.
2) No signs or symptoms of acute HIV infection.
3) Hepatitis B Status.
4) Normal renal function.

Which PrEP for Which Patients?

- These medications are approved to prevent HIV in adults and adolescents weighing at least 77 lb (35 kg) as follows:

- Daily oral PrEP with F/TDF is recommended to prevent HIV among all people with sex or injection drug use risk factors.

- Daily oral PrEP with F/TAF is recommended to prevent HIV through sexual transmission, excluding people likely to get HIV through receptive vaginal sex. F/TAF has not yet been studied for HIV prevention for people assigned female at birth who could get HIV through receptive vaginal sex.

What about Cabotegravir?

- Injectable PrEP with cabotegravir (CAB) is recommended to prevent sexual transmission of HIV among all people.

- CAB is given as an intramuscular injection (IM). CAB for PrEP is started by administering the first injection followed by a second injection 1 month after the first. CAB injections are given every 2 months thereafter.

- IM CAB provides a long-term option that does not require daily dosage or concerns about pill count and adherence and is recommended by the US Centers for Disease Control and Prevention and European AIDS Clinical Society for any patient who can benefit from PrEP.

European Aids Clinical Society. EACS. EACS guidelines v12.0 (October 2023). https://www.eacsociety.org/media/guidelines-12.0.pdf (PDF)

Side Effects of Cabotegravir?

- Transient injection site reaction.
- Headache
- Diarrhea
- Red or pruritic rash.
- Fatigue. tiredness
- Abnormal dreams /Sleep disorders
- A rare but reported side effect is an increase in depressive mood and suicidal ideation, especially in patients with prior history of depression or suicide attempt
- Hepatotoxicity & abnormal LFTs. People with a history of liver disease may have an increased risk of developing new or worsening liver problems

*Patient Monitoring during Oral PrEP Use

Once PrEP is initiated, patient should be followed every 3 months for:

- ❑ Repeat HIV testing
- ❑ Sexually transmitted infections (STI) Screening
- ❑ Risk reduction counseling
- ❑ Monitoring of renal function at least every 6 months.

Center for Disease Control and Prevention (CDC). Clinical Guidance for PrEP. February 10, 2025. https://www.cdc.gov/hivnexus/hcp/prep/index.html

Monitoring for Cabotegravir PrEP Use

After receiving the initial dose of IM cabotegravir, patients should return in 1 month to be tested for acquisition using both HIV Ag/Ab and HIV RNA tests, and for their second injection, and every 2 months thereafter for ongoing PrEP.

- ❑ Sexually transmitted infections (STI) including gonorrhea, hepatitis B Screening every 6 months and when appropriate.
- ❑ Risk reduction counseling

Renal Monitoring during PrEP Use

- F/TDF and F/TAF are eliminated by the kidneys, hence should be prescribed for PrEP only to patients **without** severe kidney impairment (eCrCl >60)
- Clinicians should be cautious when administering oral PrEP in patients taking other drugs eliminated by the kidneys (eg. acyclovir, ganciclovir, valacyclovir, cidofovir, valganciclovir, adefovir, aminoglycosides, and high-dose or multiple nonsteroidal anti-inflammatory drugs (NSAIDs).
- Instead of oral PrEP, CAB injections are recommended for people who have serious kidney disease with eCrCl <30 mL/min.

Renal Function Assessment

Renal function should be assessed by estimated creatinine clearance (eCrCl) at baseline for PrEP patients taking daily oral F/TDF or F/TAF, and monitored periodically so that persons in whom clinically significant renal dysfunction is developing do not continue to take it.

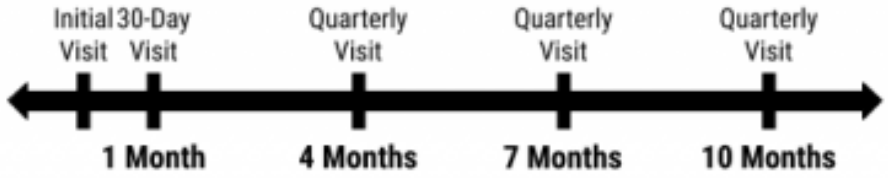
- Estimated creatinine clearance (eCrCl) should be assessed every 6 months for patients over age 50 or those who have an eCrCl <90 ml/min at initiation.

- For all other daily oral PrEP patients, eCrCl should be assessed at least every 12 months.

Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published XXX 2021

PrEP Visit Checklist for Providers

TIMELINE



INDICATIONS

- ❑ **Weighs at least 35 kg (~77 lbs)**
- ❑ **Without evidence of acute or established HIV infection**
- ❑ **Adequate renal function (creatinine clearance ≥60 mL/min)**
- ❑ **Increased risk of HIV acquisition through sex or injection drug use, including one or more of the following for the patient AND/OR their partner(s):**
  - ❑ Condomless vaginal or anal sex (receptive or insertive) with a partner who is HIV infected or of unknown infection status in the past 6 months
  - ❑ An HIV-positive partner with a detectable or unknown viral load
  - ❑ Diagnosis of a bacterial STI (gonorrhea, syphilis, chlamydia) in the past 6 months
  - ❑ A history of stimulant (such as methamphetamine) or injection drug use
  - ❑ A history of transactional sex activity
  - ❑ A history of intimate partner violence

	LABS	PSYCHOSOCIAL EVALUATION	OTHER
INITIAL VISIT	❑ HIV Test - 4th Gen ❑ RPR ❑ GC/CT (3-site, if indicated) ❑ Hep A, B, and C ❑ Metabolic Panel ❑ Urinalysis ❑ Pregnancy Test (if indicated) ❑ Assess for Acute HIV Infection	❑ Assess prospective adherence issues ❑ Provide risk-reduction counseling ❑ Offer condoms ❑ Manage side effects ❑ Mental health screening and referral is needed ❑ Assess reproductive health plans	❑ Provide same day initial PrEP Prescription when possible ❑ No refills, only 30 days of medication
30-DAY VISIT	❑ HIV Test - 4th Gen ❑ RPR ❑ GC/CT (3-site, if indicated) ❑ Metabolic Panel ❑ Urinalysis ❑ Pregnancy Test (if indicated) ❑ Assess for Acute HIV Infection	❑ Assess adherence ❑ Provide risk-reduction counseling ❑ Offer condoms ❑ Manage side effects ❑ Mental health screening and referral is needed ❑ Assess reproductive health plans	❑ Provide PrEP prescription with 3 refills ONLY ❑ Provide any needed vaccinations and contraceptive modalities where necessary ❑ **If notable adherence concerns present, patient should return in 30 days**
QUARTERLY VISIT	❑ HIV Test - 4th Gen ❑ RPR ❑ GC/CT (3-site, if indicated) ❑ Hep C (quarterly to annually per risk) ❑ Metabolic Panel ❑ Urinalysis ❑ Pregnancy Test (if indicated) ❑ Assess for Acute HIV Infection	❑ Assess adherence ❑ Provide risk-reduction counseling ❑ Offer condoms ❑ Manage side effects ❑ Mental health screening and referral is needed ❑ Assess reproductive health plans	❑ Provide PrEP prescription with 3 refills ONLY ❑ Provide any needed vaccinations and contraceptive modalities where necessary ❑ **If notable adherence concerns present, patient should return in 30 days**

Carnevale C, Zucker J, Womack JA, Dixon J, Cohall A, Sobieszczyk ME, et al. Adolescent preexposure prophylaxis administration: an education curriculum for health care providers. J Pediatr Health Care. 2019; 33(3): 288– 95.
Veil, RM, et al. "PrEP to Prevent HIV and Promote Sexual Health: Candidates for PrEP." *New York State Department of Health AIDS Institute Clinical Guidelines Program*. Johns Hopkins University HIV Clinical Guidelines Program. Oct 2019. Web. Retrieved 13 Nov 2019. <https://www.hivguidelines.org/prep-for-prevention/prep/#tab_2>
US Public Health Service. (2017). *Preexposure Prophylaxis or the Prevention of HIV Infection in the United States-A Clinical Practice Guideline*. Retrieved 13 Nov 2019. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>

PrEP and Pregnancy

- F/TDF as PrEP is considered generally safe for people who are pregnant or breast/chest-feeding. If patient concerned, discuss her risk of getting HIV through sex or IVDA.

- If an HIV-negative patient has a partner with HIV and is considering getting pregnant, the patient should talk to the health care provider about PrEP to help protect her and the baby from getting HIV while they try to get pregnant, during pregnancy, or while breastfeeding.

HIVinfo. The Basics of HIV Prevention. December 11, 2023.
https://hivinfo.nih.gov/understanding-hiv/fact-sheets/basics-hiv-prevention

PrEP and Anti-Seizure Medications

- Enzyme inducing anti-seizure medications (ASMs) lower serum levels of tenofovir-containing PrEP regimens and may have clinical significance on the effectiveness of PrEP.

- These ASMs can induce CYP3A4 and other enzymes causing increased metabolism of the ARTs. The serum levels of TDF and TAF were 50% reduced in patients co-treated with carbamazepine or oxcarbazepine.

- For patients with epilepsy who are eligible for PrEP, the primary drug–drug interactions focus on the interaction of TDF, TAF, and cabotegravir with the enzyme inducing ASMs, including phenytoin, phenobarbital, primidone, carbamazepine, and oxcarbazepine

Kerr WT, Gidal B, Avedissian SN, et al. Pre- and Post-Exposure Prophylaxis for HIV in Patients Taking Anti-Seizure Medications. Epilepsy Currents. 2024;24(4):219-231. doi:10.1177/15357597241253500

PrEP and Anti-Seizure Medications

- Antiseizure medications like:
- Levetiracetam
- Lacosamide
- Gabapentin, and pregabalin

are generally considered to have minimal interaction with PrEP, meaning they can be safely taken alongside PrEP with minimal concerns about drug interactions

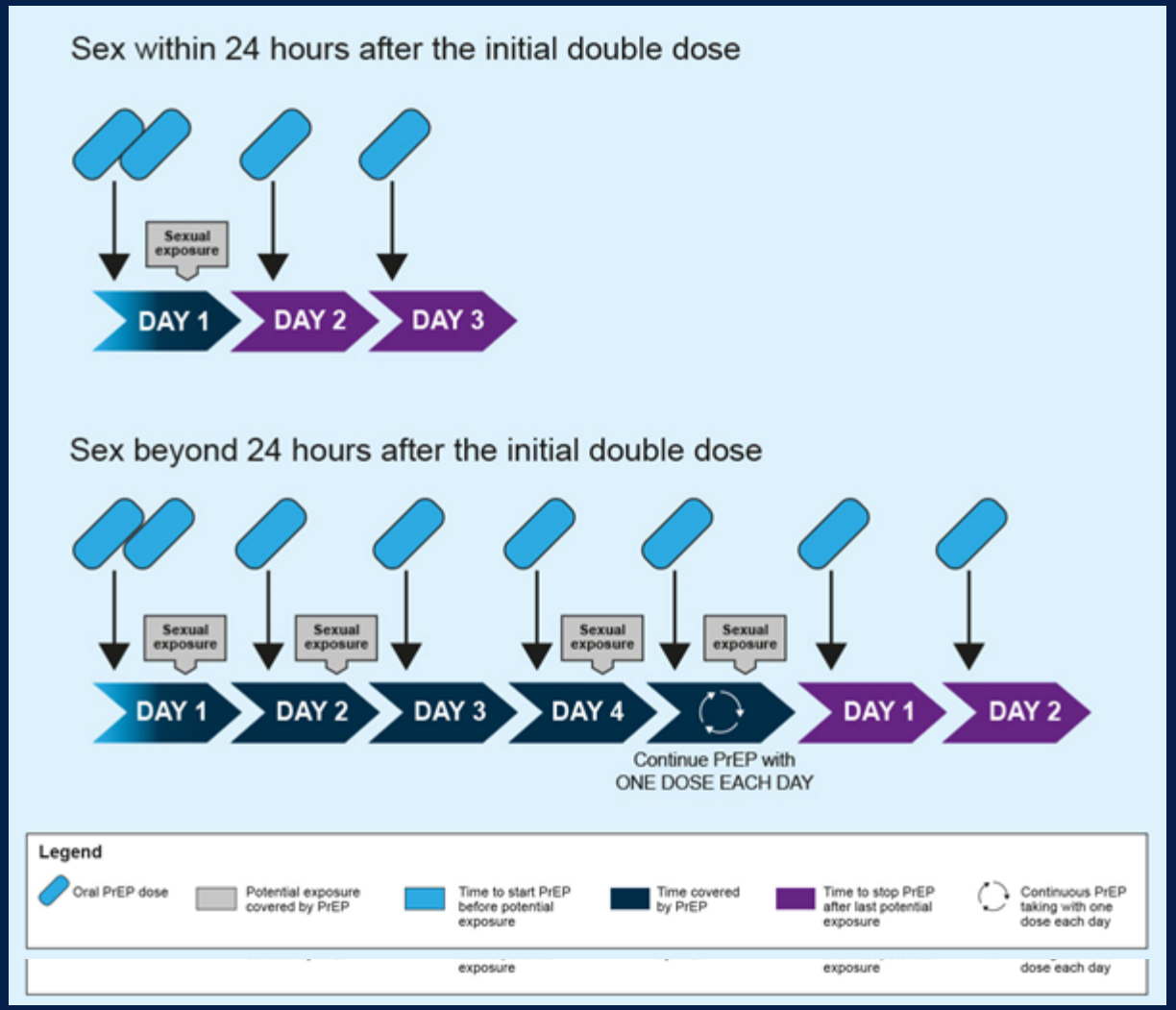
Kerr WT, Gidal B, Avedissian SN, et al. Pre- and Post-Exposure Prophylaxis for HIV in Patients Taking Anti-Seizure Medications. Epilepsy Currents. 2024;24(4):219-231. doi:10.1177/15357597241253500

Event-Driven (On-Demand) PrEP

- This means taking 2 PrEP pills 2-24 hours before sex, 1 pill 24 hours after the first dose, and 1 pill 24 hours after the second dose.
- On-demand PrEP (can be effective and is most convenient for MSM who have less frequent intercourse.
- Take 2 pills: 2-24 hours before sex.
- Sex-free day: Take 1 pill 24 hours after sexual exposure.
- Sex-free day: Take 1 more pill 24 hours after that:

- Sexual Health. PrEP. https://sexualhealth.gov.mt/content/prep
- NYC Health. Taking Pre-Exposure Prophylaxis (PrEP) on Demand. https://www.nyc.gov/assets/doh/downloads/pdf/imm/prep-on-demand.pdf

On-Demand PrEP



World Health Organization. (2022). Differentiated and simplified pre-exposure prophylaxis for HIV prevention: update to WHO implementation guidance: technical brief. World Health Organization. https://apps.who.int/iris/handle/10665/360861.

On-Demand PrEP Randomized Controlled Trial

- On-demand PrEP with tenofovir disoproxil fumarate plus emtricitabine among men who have sex with men with less frequent sexual intercourse: a post-hoc analysis of the ANRS IPERGAY trial.

- 400 participants who were randomly assigned to receive PrEP (n=199) or placebo (n=201) between Feb 22, 2012, and Oct 17, 2014, were included in this analysis.
- Participants in both groups reported a median of 5·0 (IQR 2·0-10·0) episodes of sexual intercourse per month and used a median of 9·5 (6·0-13·0) pills per month.

- Six HIV-1 infections were diagnosed in the placebo group (HIV incidence of 9·2 per 100 person-years; 95% CI 3·4-20·1) and none were diagnosed in the tenofovir disoproxil fumarate plus emtricitabine arm (HIV incidence of 0 per 100 person-years; 0-5·4; p=0·013), with a relative reduction of HIV incidence of 100% (95% CI 39-100).

Antoni G, Tremblay C, Delaugerre C, Charreau I, Cua E, Rojas Castro D, Raffi F, Chas J, Huleux T, Spire B, Capitant C, Cotte L, Meyer L, Molina JM; ANRS IPERGAY study group. On-demand pre-exposure prophylaxis with tenofovir disoproxil fumarate plus emtricitabine among men who have sex with men with less frequent sexual intercourse: a post-hoc analysis of the ANRS IPERGAY trial. Lancet HIV. 2020 Feb;7(2):e113-e120. doi: 10.1016/S2352-

Section C: Small Group Activity

SECTION FOCUS

- Participants to divide into small groups.
- Scan QR Code to review the two short cases .
- Participants are to discuss questions and potential barriers to PrEP initiation in these cases.

- Small group is to report back to the main group
- Cases reviewed

Marie Jean, MD.

NO DISCLOSURES

Small Group Activity (8 minutes)

Time to brainstorm

Small Group Activity: Case Studies

Section D: Review of the Cases

Clinical pearls:

- What patient-related questions did you ask?
- What barriers (patient, systemic, organizational, cultural) to PrEP did you elicit?

Review of the Case 1

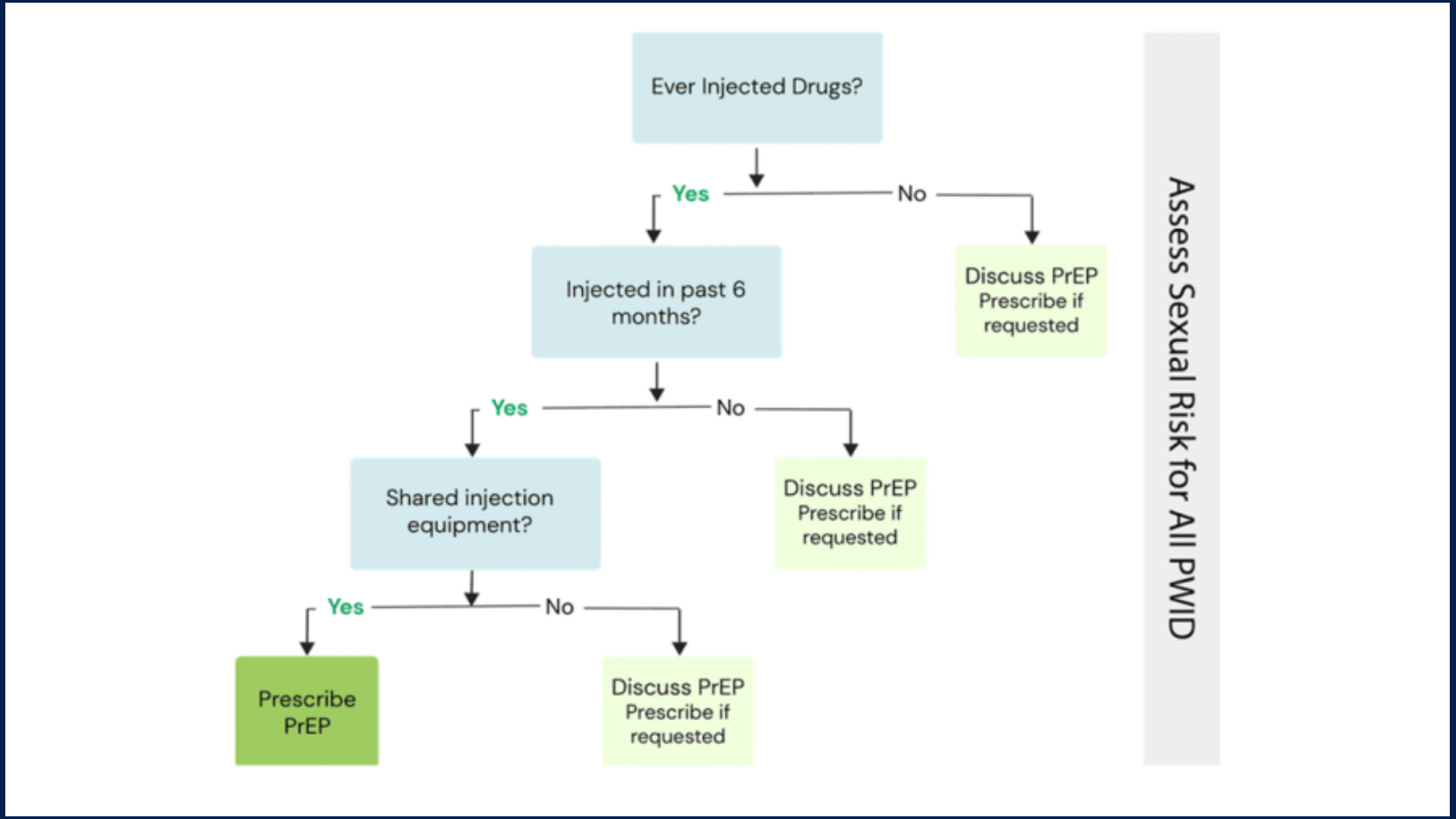
Clinical pearls:

Case: 1

- Young man with history of poly substance use (crack-cocaine and Amphetamine)
- History (cellulitis on left arm, and history of Hepatitis C) Suggestive of Intravenous drug use.
- *An estimated 70% to 90% of persons in the United States who have injected drugs for 10 years or more are infected with HCV
- Socioeconomic factors such as Poverty, lack of stable housing.
- Individual barriers such as substance use disorder

Edlin BR, Carden MR, Ferrando SJ. Managing Hepatitis C in Users of Illicit Drugs. Curr Hepat Rep. 2007;6(2):60-67. doi: 10.1007/s11901-007-0005-8. PMID: 23801897; PMCID: PMC3690289.

Assessing Risk of HIV Acquisition in PWID



Review of the Case 2

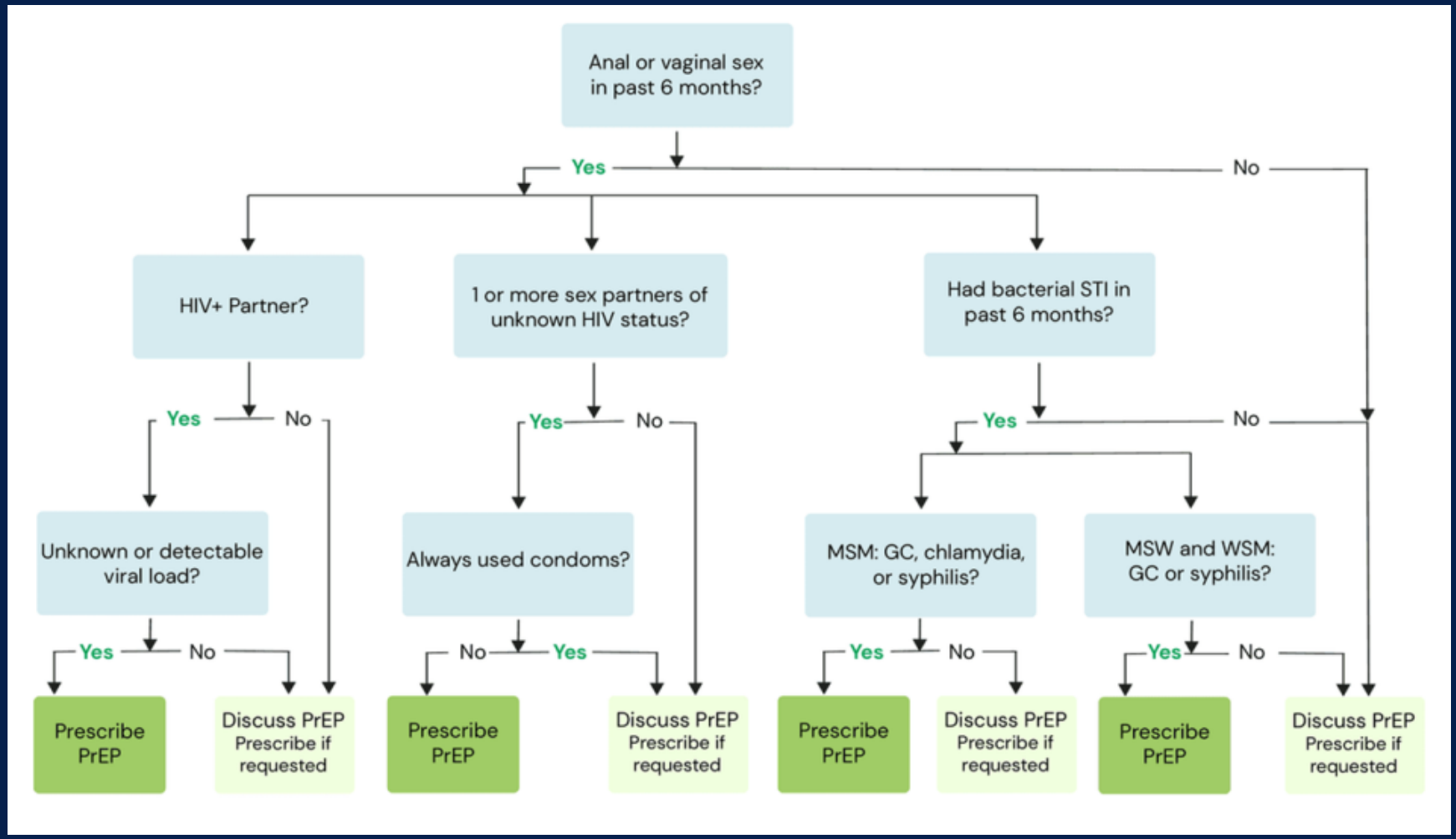
Clinical pearls:

Case: 2

- Young woman with history of opioid use
- Possible history of multiple sexual partners.
- Problem with healthcare access with Lack of health insurance
- Socioeconomic factors such as Poverty, lack of stable housing.
- Individual barriers such as substance use disorder
- Cultural factors such as stigma with commercial sex workers. Sex workers are at a higher risk of HIV infection than the general population, and they are often marginalized in HIV prevention and treatment.

Chen C, Baral S, Comins CA, Mcingana M, Wang L, Phetlhu DR, Mulumba N, Guddera V, Young K, Mishra S, Hausler H, Schwartz SR. HIV- and sex work-related stigmas and quality of life of female sex workers living with HIV in South Africa: a cross-sectional study. BMC Infect Dis. 2022 Dec 6;22(1):910. doi: 10.1186/s12879-022-07892-4. PMID: 36474210; PMCID: PMC9724359.

Assessing Risk of Sexual HIV Acquisition



Case Study Questions

Some questions to ask:

1) Are you sexually active?
2) How often do you have sex (history per month)
3) Do you know your HIV Status
4) Do you know the HIV status of your partner(s)?
5) 5 P's of Sexual history (Partner, Sexual practices, Protection, Past-history of STIs, and Pregnancy)
6) Do you inject drugs?

Case Study Questions Continued

Some other questions to ask:

7) Any allergies including medication allergies?

8) Drug history including any use of antiseizure medications.

9) Past medical history / comorbidities including renal failure, seizure disorders, chronic hepatitis B, C.

10) Do you have health insurance?

11) Have you heard about PrEP before?

Challenges surrounding PrEP Use

- No disclosures

- **SECTION FOCUS**
  - Discuss contributing factors to PrEP disparities.
  - Review how we can address PrEP disparities.
  - Review issues on medication adherence.
  - A word about ED2PrEP.
  - Review role-play simulation.

Zerimar Ramirez-Lopez, MD

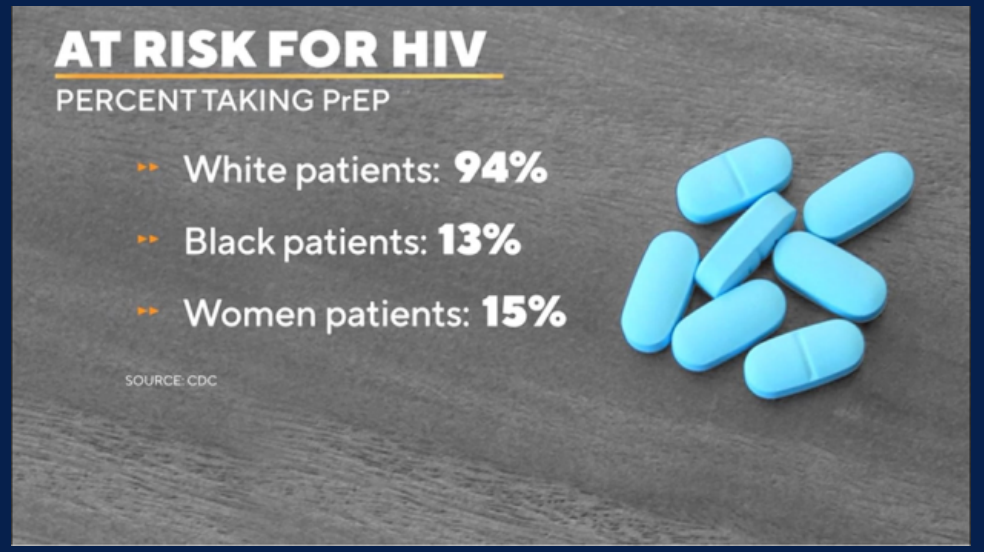
Section E

Challenges surrounding PrEP for minorities with Substance use disorder from a clinician's standpoint.

Disparities in PrEP Use

Racial / Ethnic Disparities

- Black Individuals despite representing a large portion of new HIV cases have very low PrEP Usage than Whites.
- Hispanic/ Latinx individuals also show low rate of PrEP usage despite a high rate of HIV diagnoses.



Gender Disparity

- Women tend to have low PrEP usage compared to men.

Challenges to PrEP

An integrative review of Barriers to PrEP

- Barriers to PrEP use for HIV: an integrative review. Published 2023.
- **Objectives:** to identify and synthesize scientific evidence on the barriers and difficulties for Pre-exposure Prophylaxis (PrEP) use and compliance for HIV.
- **Methods:** an integrative literature review, using the MEDLINE/PubMed, Cumulative Index.
- **Results:** all (100%) the articles included identified that PrEP users experience some type of structural barrier related to health services such as long distance from the units, suboptimal logistics for taking pills and professional resistance to prescribing PrEP. Furthermore, **63.21%** identified social barriers, such as stigma about sexuality and HIV, in addition to individual barriers such as alcohol use, adverse effects, and concerns about long-term toxicity.

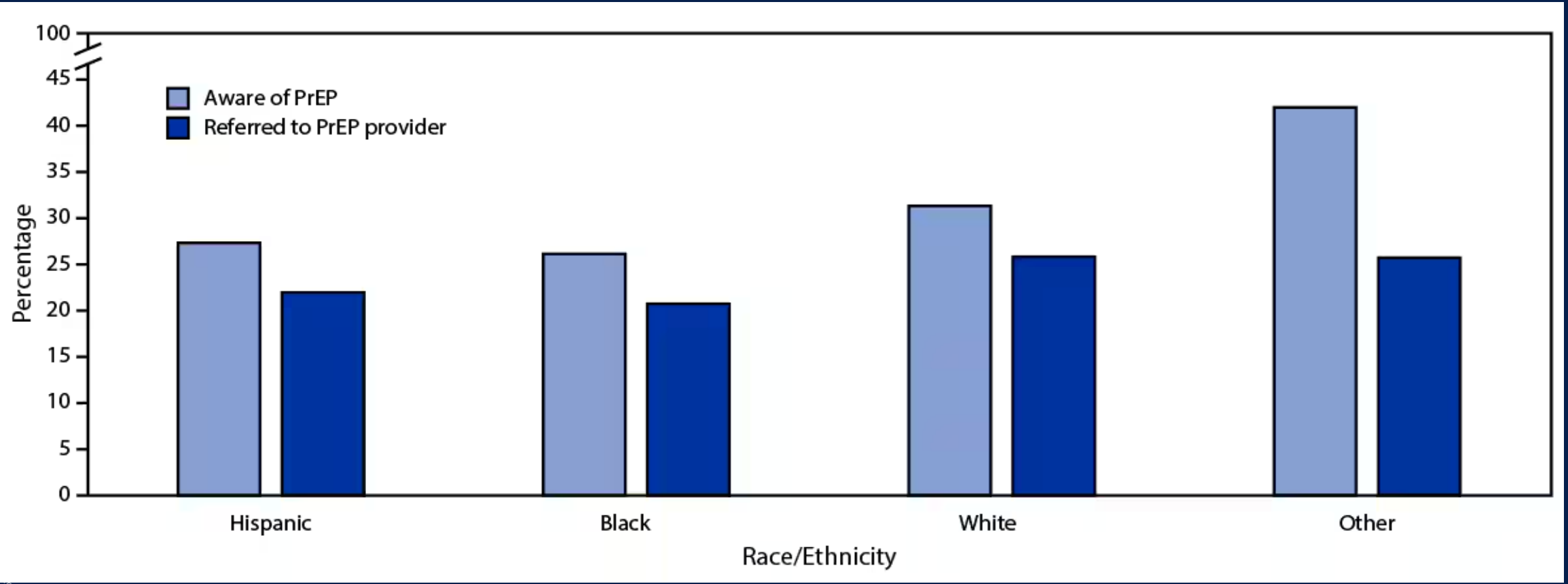
Antonini M, Silva IED, Elias HC, Gerin L, Oliveira AC, Reis RK. Barriers to Pre-Exposure Prophylaxis (PrEP) use for HIV: an integrative review. Rev Bras Enferm. 2023 Jun 26;76(3):e20210963. doi: 10.1590/0034-7167-2021-0963.

*Contributing Factors to PrEP disparities

- **Awareness and access to information:** There is lower awareness about PrEP in minority communities.
- **Healthcare access**: Lack of health insurance, difficulty finding a provider who can discuss PrEP, and the stigma associated with PrEP use.
- **Socioeconomic factors:** Poverty, lack of stable housing, and limited education can hinder access to PrEP.
- **Cultural factors:** Misconceptions about PrEP and stigma related to sexual behavior can discourage usage in certain communities and pose a huge barrier.

Bonacci RA, Smith DK, Ojikutu BO. Toward Greater Pre-exposure Prophylaxis Equity: Increasing Provision and Uptake for Black and Hispanic/Latino Individuals in the U.S. Am J Prev Med. 2021 Nov;61(5 Suppl 1):S60-S72. doi: 10.1016/j.amepre.2021.05.027. PMID: 34686293; PMCID: PMC8668046.

HIV Preexposure Prophylaxis Awareness and Referral to Providers Among Hispanic/Latino Persons — United States, 2019



Rao S, Mulatu MS, Xia M, et al. HIV Preexposure Prophylaxis Awareness and Referral to Providers Among Hispanic/Latino Persons — United States, 2019. MMWR Morb Mortal Wkly Rep 2021;70:1395–1400. DOI: http://dx.doi.org/10.15585/mmwr.mm7040a1

How Can We Address PrEP Disparities?

- **Provider training:** This include ensuring healthcare providers are knowledgeable about PrEP and comfortable discussing it with patients.
- **Addressing stigma:** Increase public health campaigns to reduce stigma associated with PrEP use and HIV risk behaviors especially in substance using patients.
- **Community outreach and education programs:** These are tailored campaigns to raise awareness about PrEP in high-risk communities.
- **Insurance coverage and affordability:** Involves expanding access to PrEP through insurance plans and financial assistance programs.

Insurance Coverage and Affordability

- "Better programs are needed to provide PrEP to communities and people at greatest risk of infection. PrEP use tends to be more equitable in states that have PrEP Drug Assistance Programs, Medicaid expansion, or both."

- Aidsmap. PrEP inequities have worsened in the US over the last decade, both racially and regionally. July 30, 2022. https://www.aidsmap.com/news/jul-2022/prep-inequities-have-worsened-us-over-last-decade-both-racially-and-regionally
- Sullivan P et al. Trends in PrEP Inequity by Race and Census Region, United States, 2012-2021. 24thInternational AIDS Conference (AIDS 2022), Montreal, oral abstract session OALBX01, 2022.

Bronx New York

- The Bronx, NY, with over 80% of the population identifying as Black or Latinx, is an Ending the HIV Epidemic (EHE) priority county with the fifth highest HIV diagnosis rate in the U.S. and the lowest PrEP use in NY.

- ED2PrEP - Patient Focused, Low-burden Strategies for PrEP Uptake Among Emergency Departments

ED2PrEP Project

- Grant given to provide access to PrEP for eligible patients from the emergency department (ED).
- Spearheaded at the Montefiore hospital, New York.

- Strategy #1: A sexual health navigator contacts patient after the ED visit to provide education and enroll them in an ongoing sexual and HIV preventive care.
- Strategy #2: Tele-PrEP program where a specialist had telehealth consultation with patients and provided education , prescribed PrEP and set up appointment with an on-going HIV preventive care.

Eligibility Criteria

Inclusion Criteria for Two-Arm Trial:

- Patient is >=18 years at time of index ED visit
- Patient presents to one of the Montefiore ED study sites
- The ED provider applies at least one of the pre-selected ICD-10 CM codes to the encounter and manual review by SHN confirms the visit is related to sexual health

Exclusion Criteria for Two-Arm Trial:

- Patient is admitted to the hospital from the ED
- Known HIV-positive status

ED2PrEP Study. Clinical Study ID NCT05588193
2021-13724
R01AI169636

Medication Adherence

- Medication adherence is a crucial part of maintaining protection against HIV acquisition.
- Studies have shown that daily PrEP is most effective when taken daily, although it retains some efficacy if taken at least **four** times a week, as skipping or missing doses undermines the benefit of a daily routine in maintaining any type of medication adherence.
- Guideline-based recommendations define low adherence with oral PrEP as taking four or fewer doses weekly.

Pre-exposure prophylaxis uptake, Adherance, and Persistence: A Narrative Review of Interventions in the US. AJPM, 2021. https://www.ajpmonline.org/article/S0749-3797(21)00358-5/fulltext

Meta-Analysis on Medication Adherence

- Oral PrEP to prevent HIV: a systematic review and meta-analysis of clinical effectiveness, safety, adherence and risk compensation in all populations

- **Methods:** Databases (PubMed, Embase and the Cochrane Register of Controlled Trials) were searched up to 5 July 2020. Search terms for 'HIV' were combined with terms for 'PrEP' or 'tenofovir/emtricitabine'.

- **Results:** Of 2803 unique records, 15 RCTs met inclusion criteria. Over 25 000 participants were included, encompassing 38 289 person-years of follow-up data.
- PrEP was found to be effective in **MSM** (RR 0.25, 95% CI 0.1 to 0.61; absolute rate difference (RD) -0.03, 95% CI -0.01 to -0.05), **serodiscordant couples** (RR 0.25, 95% CI 0.14 to 0.46; RD -0.01, 95% CI -0.01 to -0.02) and **PWID** (RR 0.51, 95% CI 0.29 to 0.92; RD -0.00, 95% CI -0.00 to -0.01). Efficacy was strongly associated with adherence ($p<0.01$).

O Murchu E, Marshall L, Teljeur C, Harrington P, Hayes C, Moran P, Ryan M. Oral pre-exposure prophylaxis (PrEP) to prevent HIV: a systematic review and meta-analysis of clinical effectiveness, safety, adherence and risk compensation in all populations. BMJ Open. 2022 May 11;12(5):e048478. doi: 10.1136/bmjopen-2020-048478. PMID: 35545381; PMCID: PMC9096492.

Improving PrEP Adherence

Behavior change interventions and technology-based interventions

- Enhanced counseling, Feedback on adherence measurements

- Take PrEP at the same time each day or take PrEP with another daily activity, like brushing your teeth
- Plan to take PrEP when you're traveling or won't be at home. Electronic pill containers (smart pill box) help by recording when the container is opened

- Use a phone app to remind you when to take your pill [Short Message Service (SMS) reminders]
- Create a plan to manage side effects
- Use Long-acting PrEP formulations

Pre-exposure prophylaxis uptake, Adherance, and Persistence: A Narrative Review of Interventions in the US. AJPM, 2021. https://www.ajpmonline.org/article/S0749-3797(21)00358-5/fulltext

Monitoring PrEP Adherence

- Real-Time Monitoring and Point-of-Care Testing: A Review of the Current Landscape of PrEP Adherence Monitoring.
- **Type of article**: Review article.
- **Objective:** This paper reviews subjective and objective methods for monitoring PrEP including self-report, drug level monitoring (including serum, plasma, peripheral blood mononuclear cells [PBMC], red blood cell dried blood spots [DBS], hair, and urine)
- **Results:** Objective monitoring using DBS and urine will provide a more accurate picture of adherence compared to subjective and non-biomarker objective methods. Monitoring improves adherence, and urine testing is an especially attractive option.

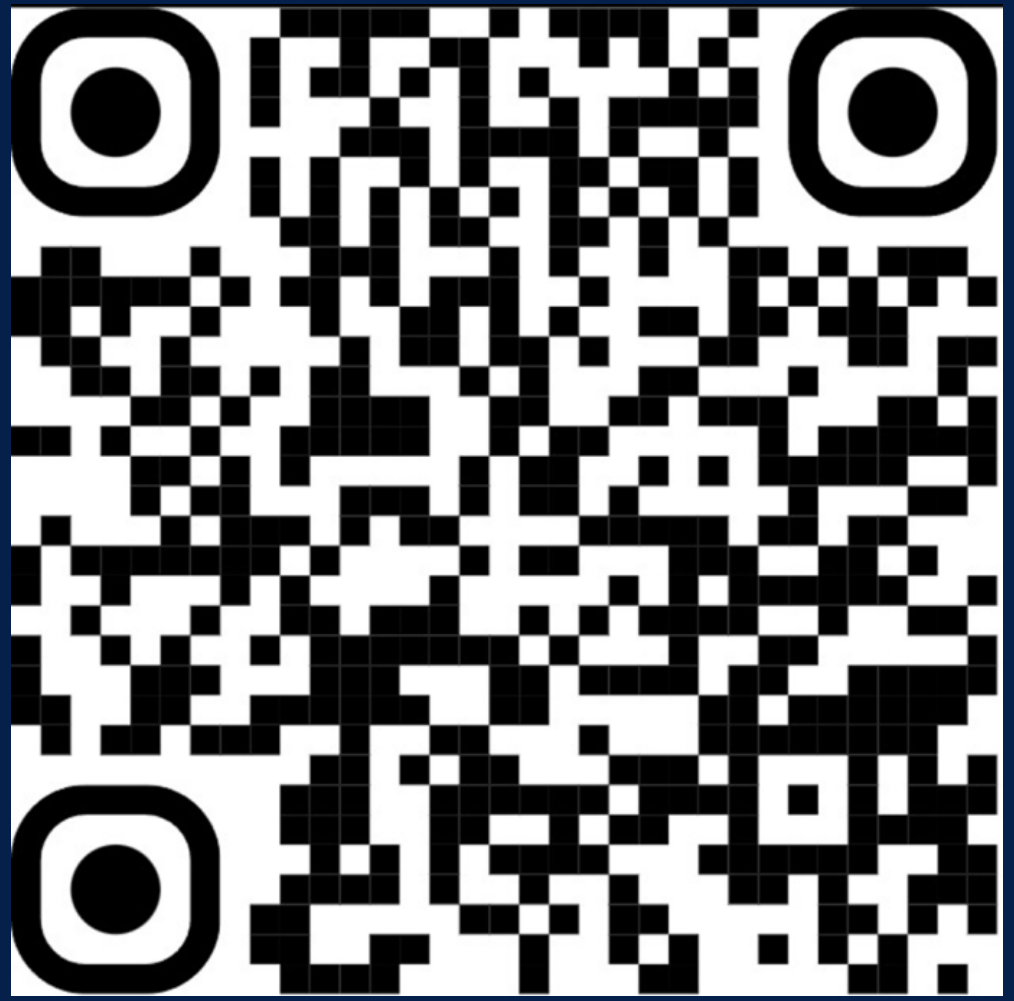
Hannaford A, Arens Y, Koenig H. Real-Time Monitoring and Point-of-Care Testing: A Review of the Current Landscape of PrEP Adherence Monitoring. Patient Prefer Adherence. 2021 Feb 5;15:259-269. doi: 10.2147/PPA.S248696.

Section- F ~20 minutes

Role-playing/ Simulations

- Participants stay in small groups
- Participants to volunteer to play role of clinician, patient, and observer
- Review role-playing instructions, and role-play.
- Provide feedback /reflection

Role-playing/ Simulations



Role-Playing-Simulations

C = Clinician

P = Patient

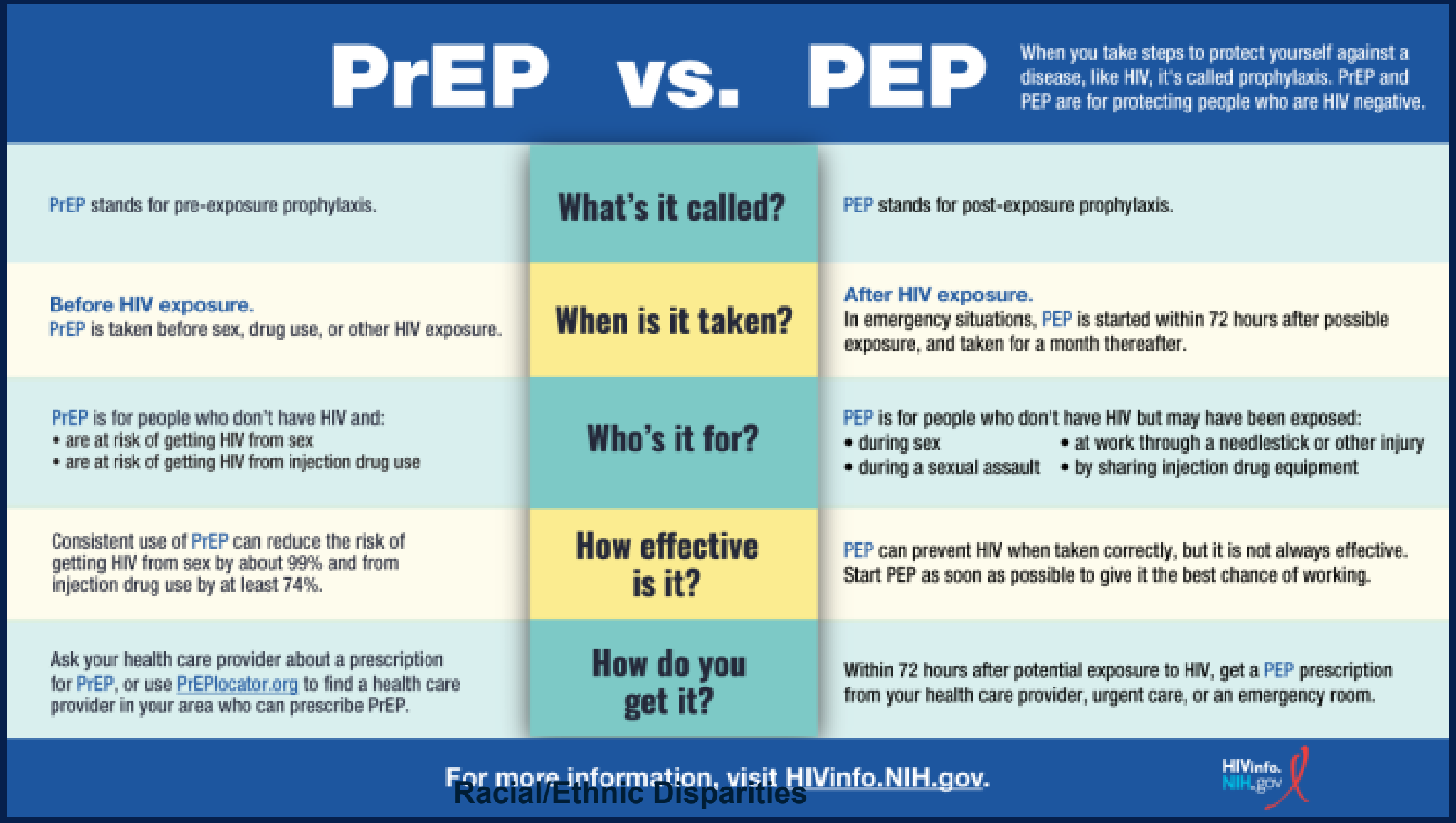
O = Observer

Role-Playing

- **Give a preamble that emphasizes sexual health**. Focuses on sexual health, not risk. Normalizes sexuality as part of health and healthcare and opens the door for the patient's questions. Clearly states a desire to understand and help.
- **Offer opt-out HIV/STI testing and information**. Doesn't commit to specific patient, does normalize testing. Opens the door for the patient to talk about HIV or STIs as a concern.
- **Ask open-ended questions** about patient's sexual history. Lets you hear what the patient thinks is most important first. Lets you hear the language the patient uses to talk about their body, partners, and sex.
- **Listen for relevant information and probe to fill in the blanks.** Makes no assumption about monogamy or about gender of partners. Increases motivation by asking the patient to identify strategies/ interventions.
- **Suggest a course of action.** It allows you to tailor STI testing to the patient, so they don't feel targeted. It allows you to couch education or referral in terms of relevant benefits, tailored to the specific patient.

NYSDOH AIDS INTITUTE: GOALS FRAMEWORK FOR SEXUAL HISTORY TAKING IN PRIMARY CARE
www.hivguidelines.org

PrEP vs PEP



Racial/Ethnic Disparities

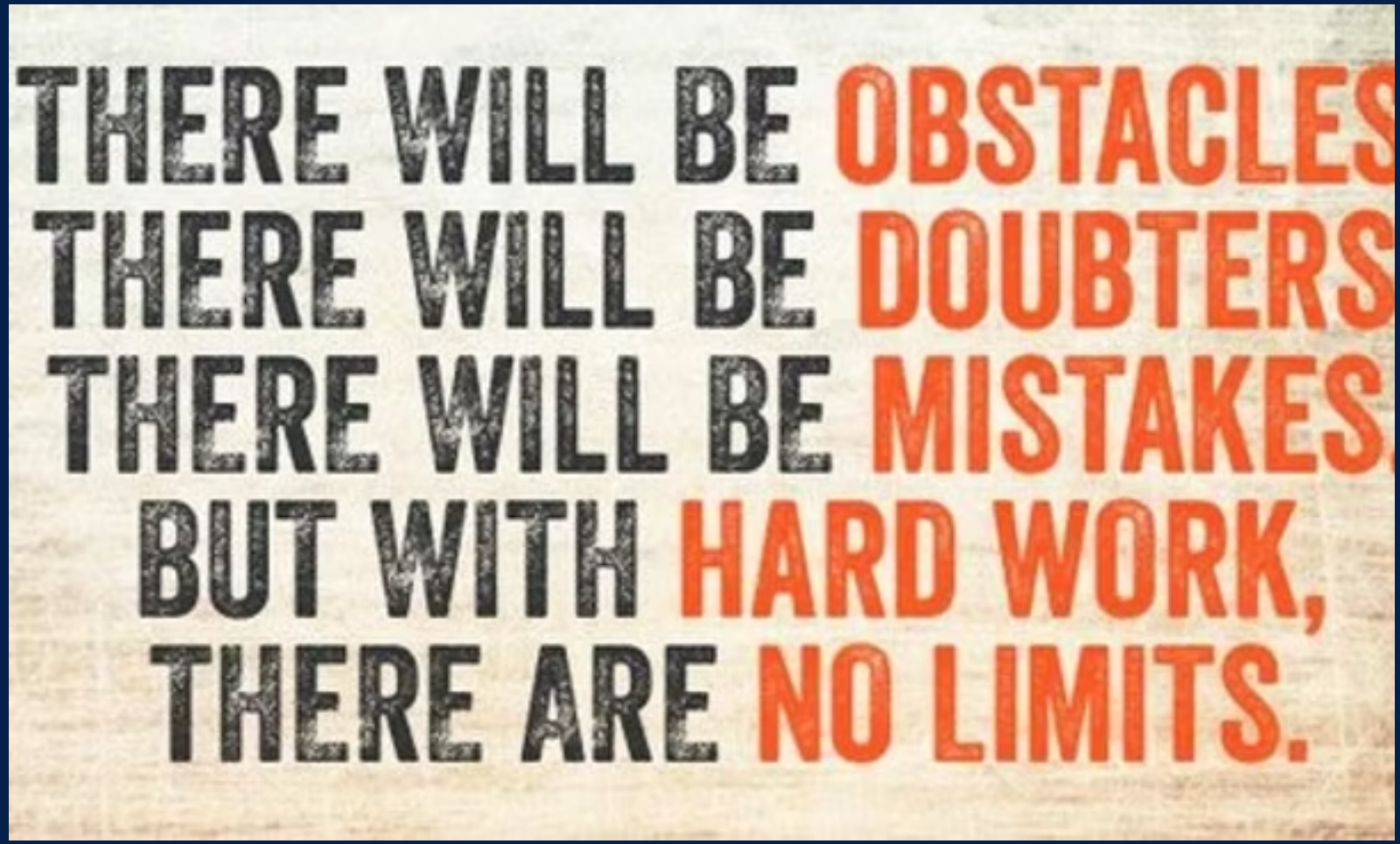
Final Takeaways/Summary

- Despite recent gains in HIV prevention, HIV PrEP use among minorities and individuals with substance use disorder remains a challenge.
- Eliciting good sexual history and evaluation for injection of drugs is important to assessing risk for HIV and initiation of PrEP
- Provider training is paramount to improve knowledge and comfortability with PrEP use while also addressing stigma associated with PrEP use and HIV risk behaviors in substance using patients.

Final Takeaways/Summary

- Efforts should be made to engage individuals with substance use disorder with PrEP use from the emergency department
- There should be concerted effort at providing effective community awareness about PrEP in high-risk communities.
- Efforts should be made to enroll individuals with substance use disorders at risk for HIV acquisition into PrEP Drug Assistance Programs, Medicaid expansion, or both

HIV PrEP Works!!



Always Be PrEPared

Bronxcare Life Recovery Center

Contact

Moronkeji Fagbemi, MD, FASAM, FACP

Email: mfagbemi@bronxcare.org

Thank You

Questions?