



# HIV Prevention in Primary Care

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“Primary care physicians are Ideally positioned to prescribe PrEP for their patients because they have longitudinal relationships: They get to know their patients”

---Brandon Pollak, MD, a primary care physician and HIV specialist at the Ohio State University College of Medicine, Columbus.



Picture:  
MSO365 Stock



# PrEP cuts the risk of contracting HIV according to the Centers for Disease Control and Prevention...

- ***PrEP cuts the risk of contracting HIV through sex by around 99%***

- when taken as prescribed, according to the Centers for Disease Control and Prevention

- ***The Effectiveness Estimate for Injection drug use is at least 74%***
  - based on tenofovir alone and not necessarily when taken daily. The effectiveness may be greater for the two-drug oral therapy and if used daily

<sup>1</sup> Centers for Disease Control and Prevention. Effectiveness of prevention strategies to reduce the risk of acquiring or transmitting HIV. Updated June 17, 2022. Accessed January 20, 2023. <https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html>

<sup>2</sup> 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*. Published December 2021. Accessed January 20, 2023. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>

# PrEP Considerations

- Primary care physicians get to know their patients, and hopefully their patients feel comfortable talking with them about their sexual health
- Clinicians should consider PrEP for all patients who have sex with someone who has HIV, do not use condoms, or have had a sexually transmitted infection within the previous 6 months.
- Men who have sex with men, and people who inject illicit drugs or engage in transactional sex are also at risk.
- The majority of patients on PrEP tend to be young, fit people without complicated medical histories and the medications are well-tolerated

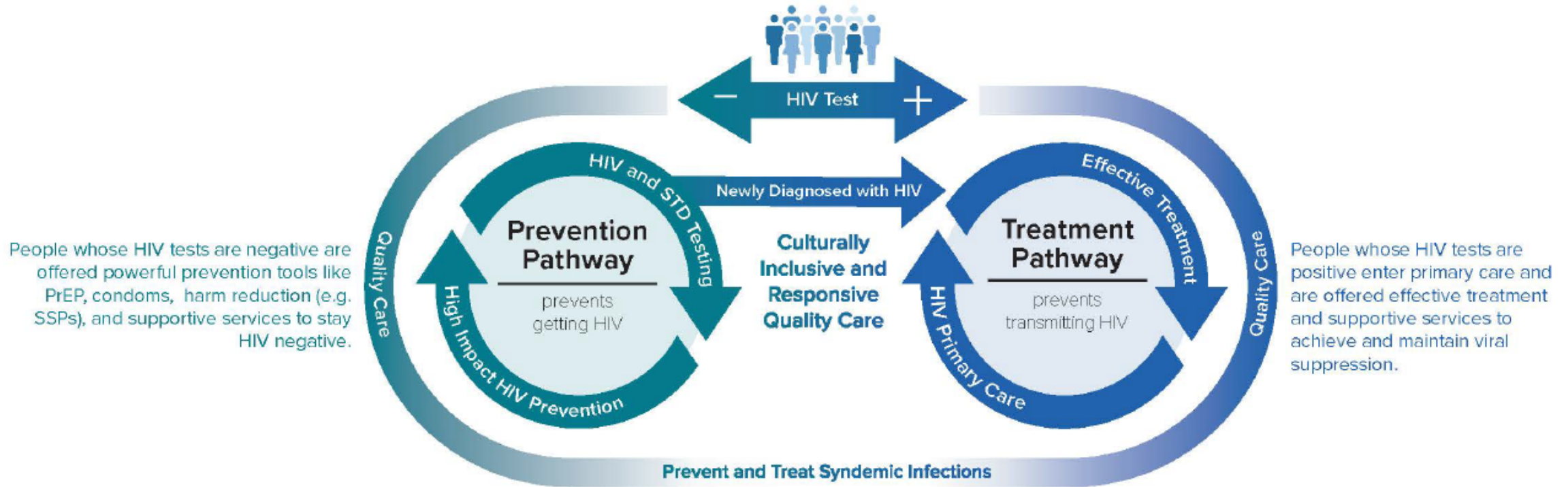
# HIV Status - Neutral

Getting people to do the following should be the focus of the strategy to end AIDS:

- Test for HIV
- Start antiretroviral therapy (ART) immediately if tested positive to achieve the undetectable equals untransmittable (U=U) goal
- Offering pre-exposure prophylaxis (PrEP) immediately if tested negative to achieve the goal of having negligible risk of acquiring HIV



# Status Neutral HIV Prevention and Care



Follow CDC guidelines to test people for HIV. Regardless of HIV status, quality care is the foundation of HIV prevention and effective treatment. Both pathways provide people with the tools they need to stay healthy and stop HIV.



# Benefits of the Status Neutral Approach

- Dramatically decrease new HIV infections
- Supports and enables optimal health through continual engagement in comprehensive, “whole person” care and supports syndemic-related services and health promotion
- Increases opportunities for more efficient service delivery
- Improves health equity given intersection of HIV stigma and other biases



Picture: MSO365 stock

## CDC's Approach



**Making HIV testing simple, accessible, and routine.**



**Quickly linking people with HIV to care and treatment, and re-engaging those who have stopped receiving care.**



**Increasing availability and use of PrEP among populations who could benefit most.**



**Partnering with other agencies and working with local communities to implement SSPs where they are needed and permitted by law.**



**Ensuring all jurisdictions have the capacity to identify, investigate, and respond to potential HIV outbreaks quickly.**



# Global Overview 2021



- According to UNAIDS (Joint United Nations Programme on HIV/AIDS), about 38.4 million people were living with HIV worldwide during 2021 – the latest year for which data are available.

Of this total:

- 36.7 million were adults (aged 15 years and older)
- 1.7 million were children
- An estimated 1.5 million people worldwide were newly infected with HIV.
  - The annual number of new infections has declined about 53% since the peak of about 3.2 million in 1996.
- About 650,000 people died of AIDS-related illnesses.
  - Global AIDS-related deaths have fallen 54% since 2010, and 67% from the peak of about 2.0 million in 2004.



# Global Overview 2021

- An estimated 81% of pregnant women with HIV had access to ART (antiretroviral therapy) to prevent transmission of HIV to their babies.
- Continuum of HIV Care: In 2021, an estimated 85% of people with HIV globally knew their HIV status, 75% were accessing ART, and 68% were virally suppressed.
- 1.6 million eligible people worldwide received at least one dose of PrEP (pre-exposure prophylaxis) in 2021.

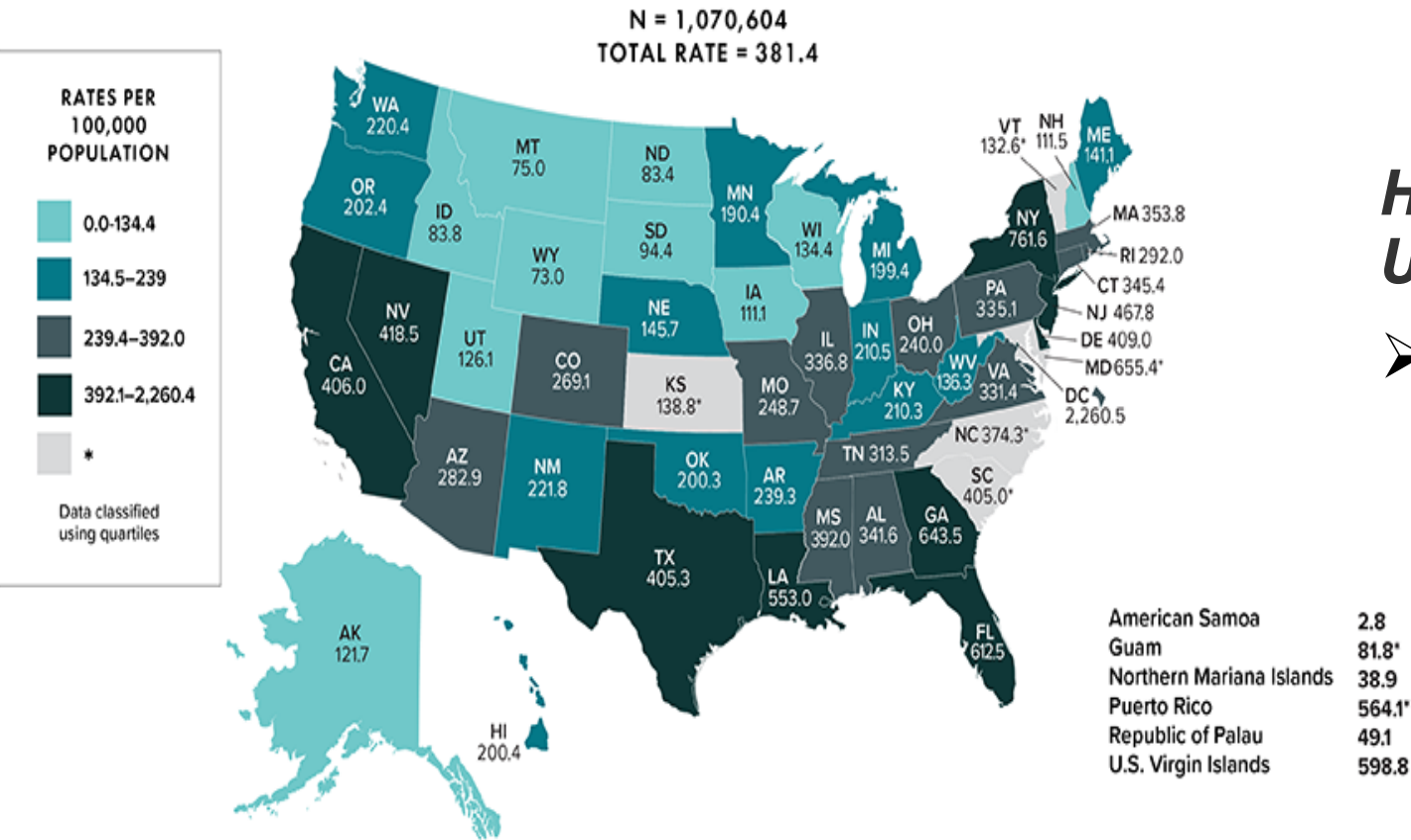
# HIV in the United States

(2020 the most recent year)

## *How many people have HIV in the United States?*

- 1,072,051 persons were living with diagnosed HIV infection at year-end 2020 in the United States and 6 dependent areas

(persons aged  $\geq 13$  years: 1,070,604)



- The overall rate of persons living with diagnosed HIV infection was 321.9 (persons aged  $\geq 13$  years: 381.4)

- 30,635 people received an HIV diagnosis in the U.S. and 6 dependent areas In 2020



# HIV in the Dakotas



## ***HIV in North Dakota, 2021***

520 people were living with HIV

37 people were newly diagnosed with HIV

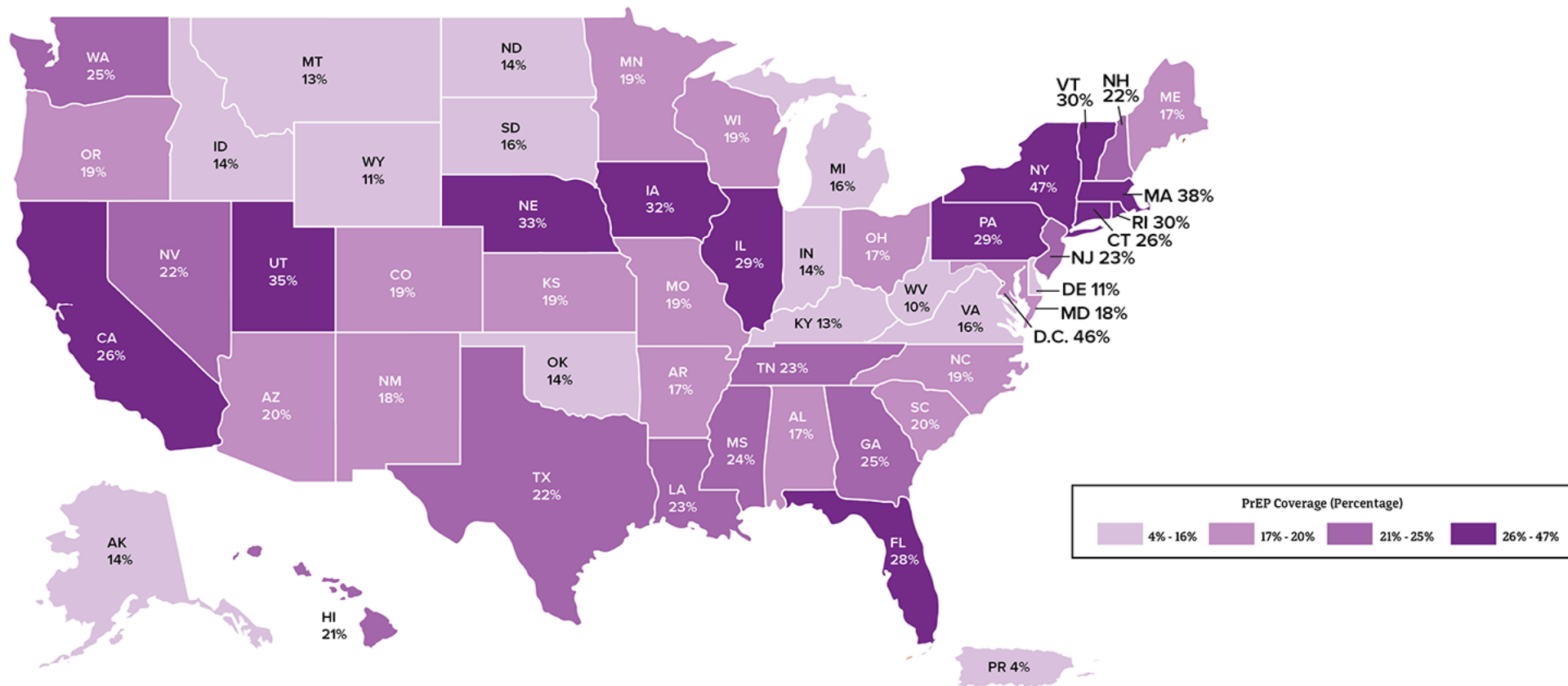


## ***HIV in South Dakota, 2021***

723 people were living with HIV

31 people were newly diagnosed with HIV

# PrEP Coverage in the US and Puerto Rico by Area of Residence, 2020\*



Data for 2020 should be interpreted with caution due to the impact of the COVID-19 pandemic on access to HIV testing, care-related services, and case surveillance activities in state and local jurisdictions.

\* Among people aged 16 and older.

Source: CDC. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2020. *HIV Surveillance Supplemental Report* 2022;27(3).



# The time is now.



Ending  
the  
HIV  
Epidemic

- 71% of new HIV infections in the U.S. are among MSM (men who have sex with men), followed by Black cisgender women (11-fold higher than white)
- HIV prevalence among transgender women is estimated at 42%, driven by high rates among Black and Hispanic transgender women
- Black and Hispanic people disproportionately account for 42% and 27% of new HIV diagnoses yet are only 9% and 16% of PrEP users respectively
- People living in the South account for more than half of new infections and yet have disproportionately low rates of PrEP use



# 30,635 New HIV Infections

(the most recent available data)

80% of new HIV infections were due to people who did not know they had HIV or were not receiving regular care in 2019

39% of the U.S. population have ever been tested for HIV1

15% (1 in 7) people with HIV were unaware of their status

56% of people with HIV were virally suppressed in 2019

Only 25% of the ½ million eligible, HIV-negative people in the U.S. took PrEP in 2022

# HIV U.S. National Strategic Plan

## Vision

- The United States will be a place where new HIV infections are prevented, every person knows their status, and every person with HIV has high-quality care and treatment and lives free from stigma and discrimination.



## This HIV National Strategic Plan (HIV Plan)

- The nation's third consecutive national HIV strategy, sets forth bold targets for ending the HIV epidemic in the United States by 2030.
- Reduction in new HIV infections:
  - 75% reduction by 2025
  - 90% reduction by 2030

# Four High-Level Goals of the HIV Plan



**Goal 1: Prevent New HIV Infections**



**Goal 2: Improve HIV-Related Health Outcomes of People with HIV**



**Goal 3: Reduce HIV-Related Disparities and Health Inequities**



**Goal 4: Achieve Integrated, Coordinated Efforts That Address the HIV Epidemic among All Partners and Stakeholders**



# USPSTF HIV Screening Recommendations

Updated June 2019

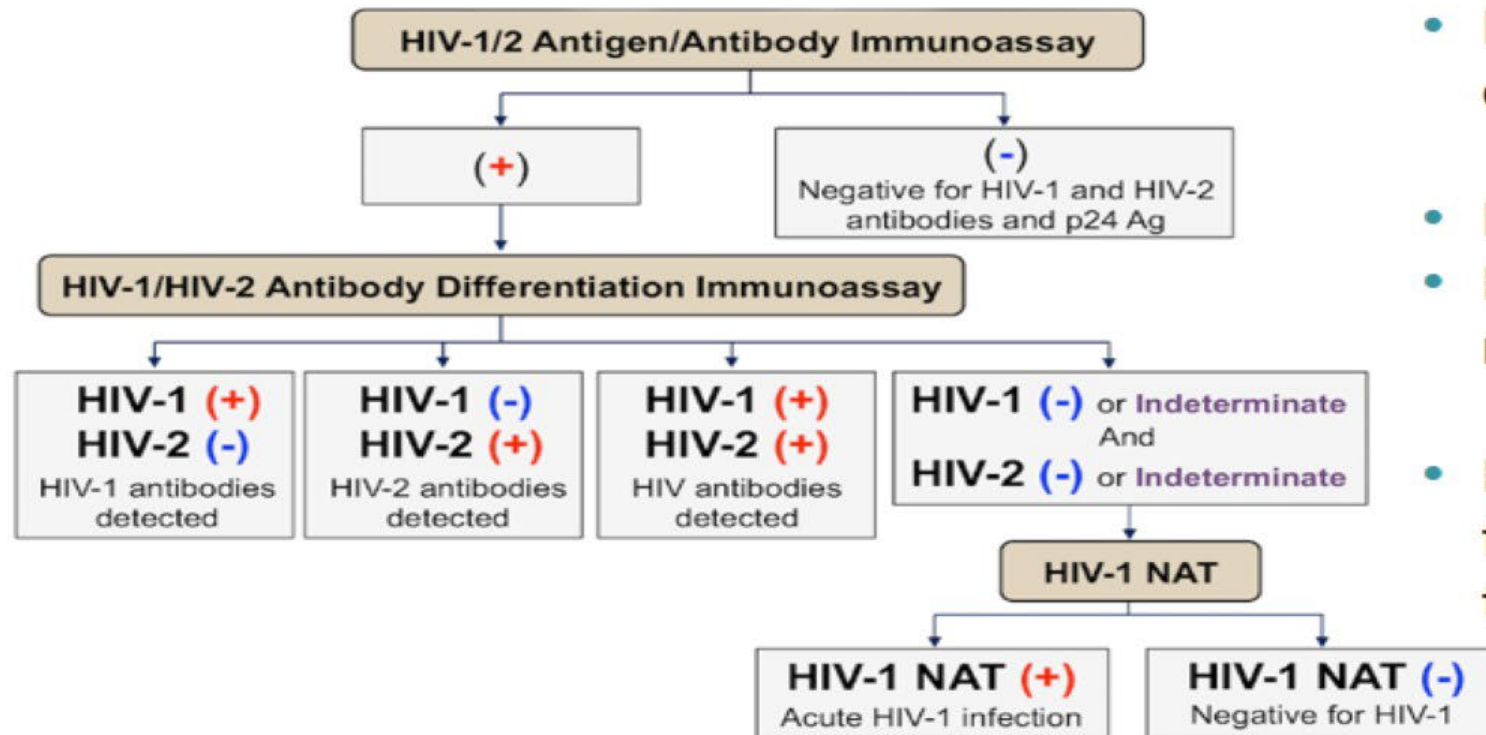
Population	Recommendation	Grade (What's This?)
Adolescents and adults aged 15 to 65 years	The USPSTF recommends that clinicians screen for HIV infection in adolescents and adults aged 15 to 65 years. Younger adolescents and older adults who are at increased risk of infection should also be screened.	A
Pregnant persons	The USPSTF recommends that clinicians screen for HIV infection in all pregnant persons, including those who present in labor or at delivery whose HIV status is unknown.	A

# USPSTF Grade Definitions

Grade	Definition	Suggestions for Practice
<b>A</b>	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
<b>B</b>	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
<b>C</b>	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
<b>D</b>	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
<b>I</b> Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

# Screening Tests

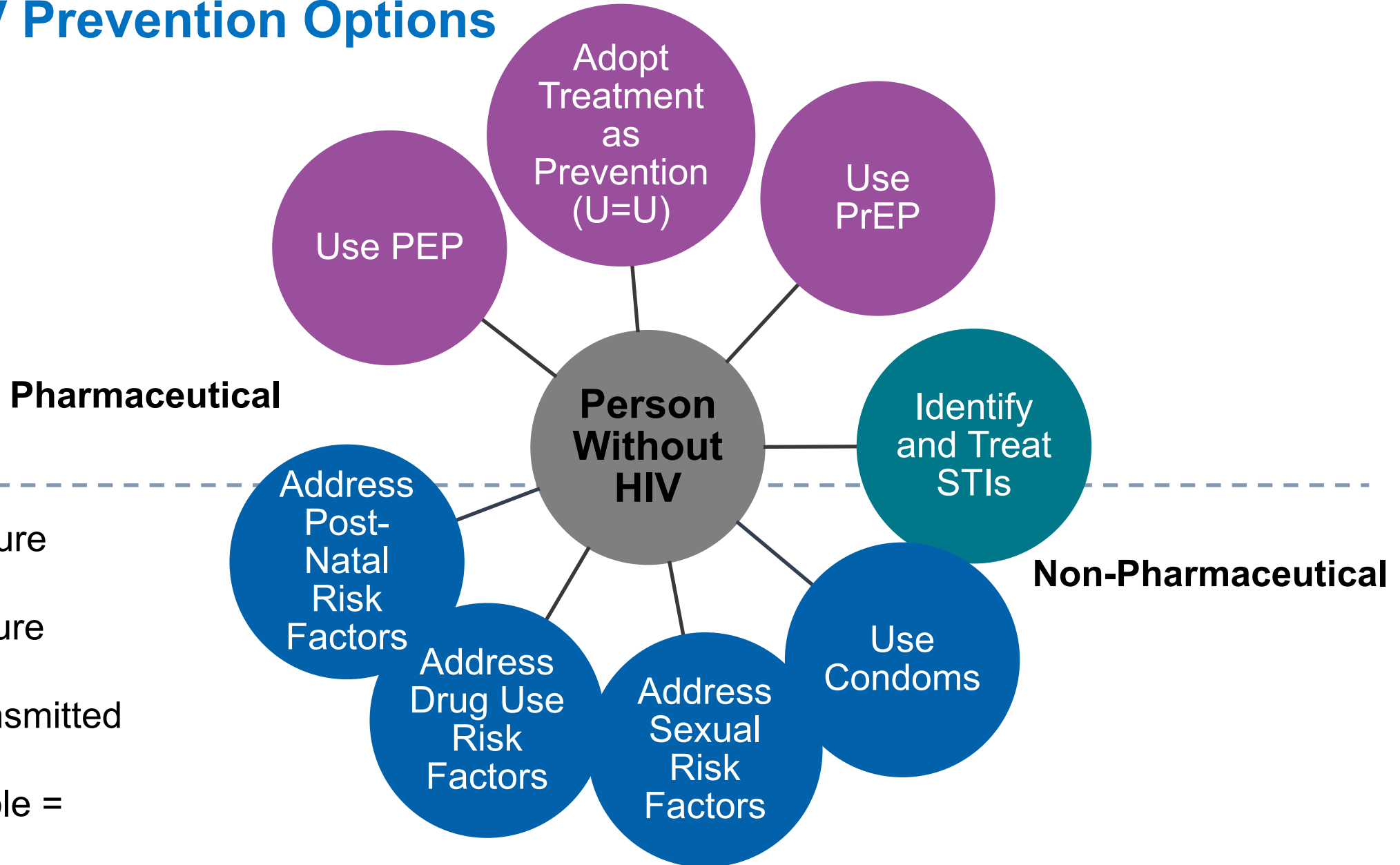
## CDC and the APHL 2018 HIV Diagnostic Algorithm



- More accurate diagnosis of acute HIV-1
- More diagnosis of HIV-2
- Fewer indeterminate results
- Faster turnaround time for completion of the testing algorithm



# Current HIV Prevention Options



**PEP:** post-exposure prophylaxis

**PrEP:** pre-exposure prophylaxis

**STI:** sexually transmitted infection

**U=U:** Undetectable = Untransmittable

# What Is PrEP?

**PrEP** is the use of antiretroviral medications by people without HIV to protect themselves from getting HIV

**PrEP** is recommended for adults and adolescents weighing at least 35 kg (77 lb) who are at risk of getting HIV

## Injectable PrEP

**Cabotegravir (CAB)  
600 mg injection**  
(brand name  
Apretude®)

## Oral PrEP

**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®)\*

\*F/TAF is not approved for use by women or other people who could get HIV through receptive vaginal sex

# PrEP Efficacy

Multiple studies have demonstrated that PrEP is highly effective when taken as prescribed.<sup>1,2</sup>

Transmission Route	Effectiveness Estimate	Interpretation
Sexual	~99%	Very high levels of adherence to PrEP provide maximum effectiveness
Injection drug use	at least 74%	<p>This estimate is based on tenofovir alone and not necessarily when taken daily</p> <p>The effectiveness may be greater for the two-drug oral therapy and if used daily</p>

<sup>1</sup> Centers for Disease Control and Prevention. Effectiveness of prevention strategies to reduce the risk of acquiring or transmitting HIV. Updated June 17, 2022. Accessed January 20, 2023. <https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html>

<sup>2</sup> 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*. Published December 2021. Accessed January 20, 2023. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>

# Who Are PrEP Providers?





# PrEP Is Appropriate for Primary Care



You do not need to be an infectious disease or HIV specialist to prescribe PrEP. **Any licensed prescriber can provide PrEP.**<sup>1</sup>

PrEP can be easily integrated into primary care practice, similar to other regularly prescribed preventive measures<sup>2</sup> :

- Metformin for pre-diabetes
- Statins for cardiovascular disease
- Oral contraceptives for pregnancy

**Making PrEP part of primary care can improve access for all who could benefit, and help address disparities.**

<sup>1</sup> 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*. Published December 2021. Accessed January 20, 2023. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. <sup>2</sup> Calabrese SK, Krakower DS, Mayer KH. Integrating HIV preexposure prophylaxis (PrEP) into routine preventive health care to avoid exacerbating disparities. *Am J Public Health*. 2017;107(12):1883-1889. doi: 10.2105/AJPH.2017.304061.

# Who Is PrEP For?

PrEP is for adults and adolescents without HIV who are at risk of getting HIV from sex or injection drug use.



CDC's PrEP guidelines include telling all sexually active adults and adolescents that PrEP can protect them from getting HIV as a graded recommendation (IIB).

Giving patients information about PrEP:

- Increases the number of people who know about PrEP and equips them to share the information with their social networks and family members
- Helps patients overcome embarrassment and stigma so they can respond accurately to risk assessment questions

**PrEP can be prescribed to any adult or adolescent patient who asks for it**, even if they do not report HIV risk factors, as part of their comprehensive prevention plan.

# Examples of Brief Risk-Assessment Questions

**First, start the conversation:** Inform all adult and adolescent patients who may be at risk for HIV through sex or injection drug use about PrEP.

**Then, assess behavior:**

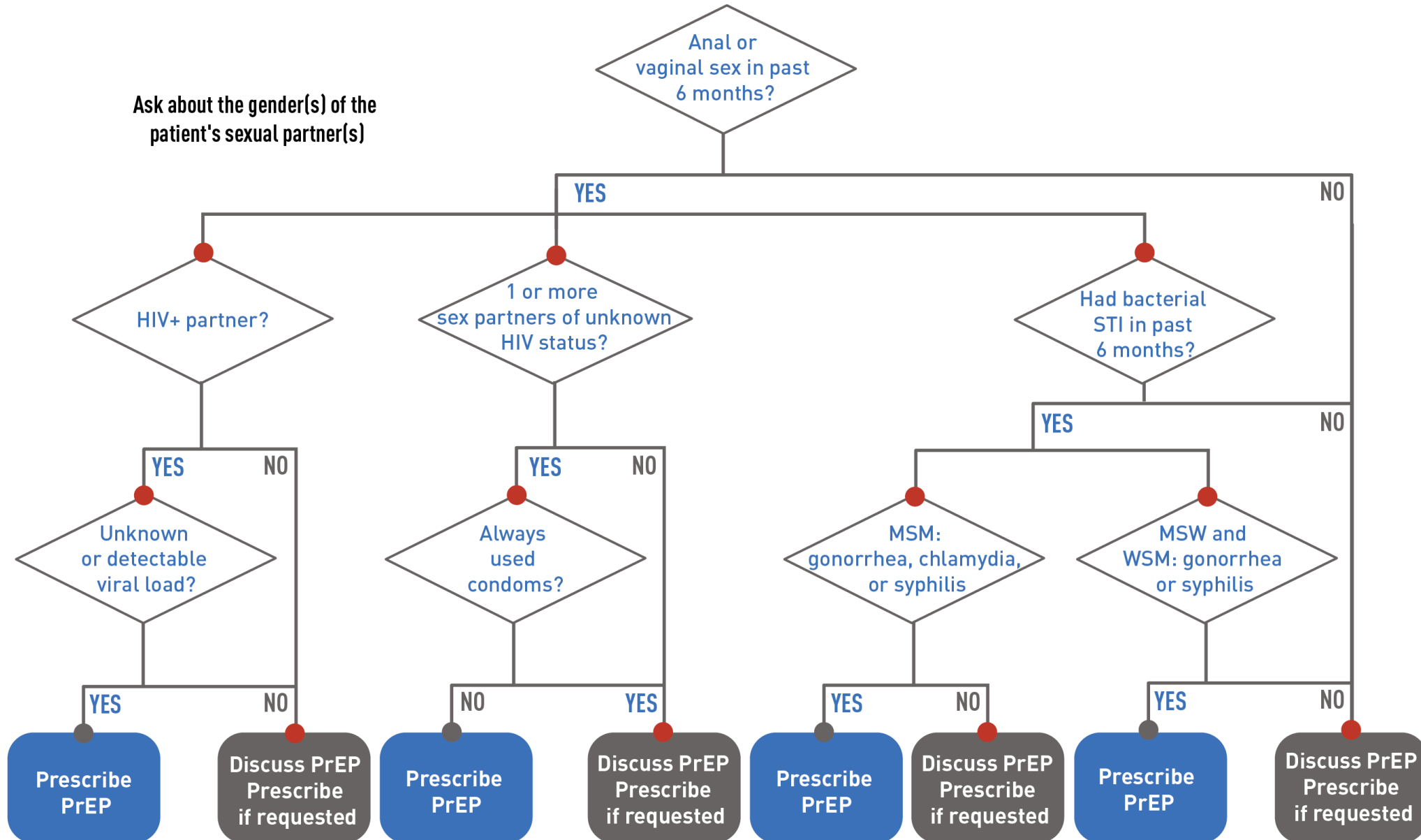
## Sexual Behavior:

- ? In the past 6 months, how many partners have you had sex with?
- ? What are the genders of your sexual partners?
- ? Do you use condoms consistently?
- ? Did any of your partners have HIV?

## Drug Injection Behavior:

- ? Have you ever injected drugs that were not prescribed for you?
- If YES:**
- ? When did you last inject drugs?
  - ? Do you ever inject using works that were used by another person?

# Assessing a Sexually Active Patient for PrEP



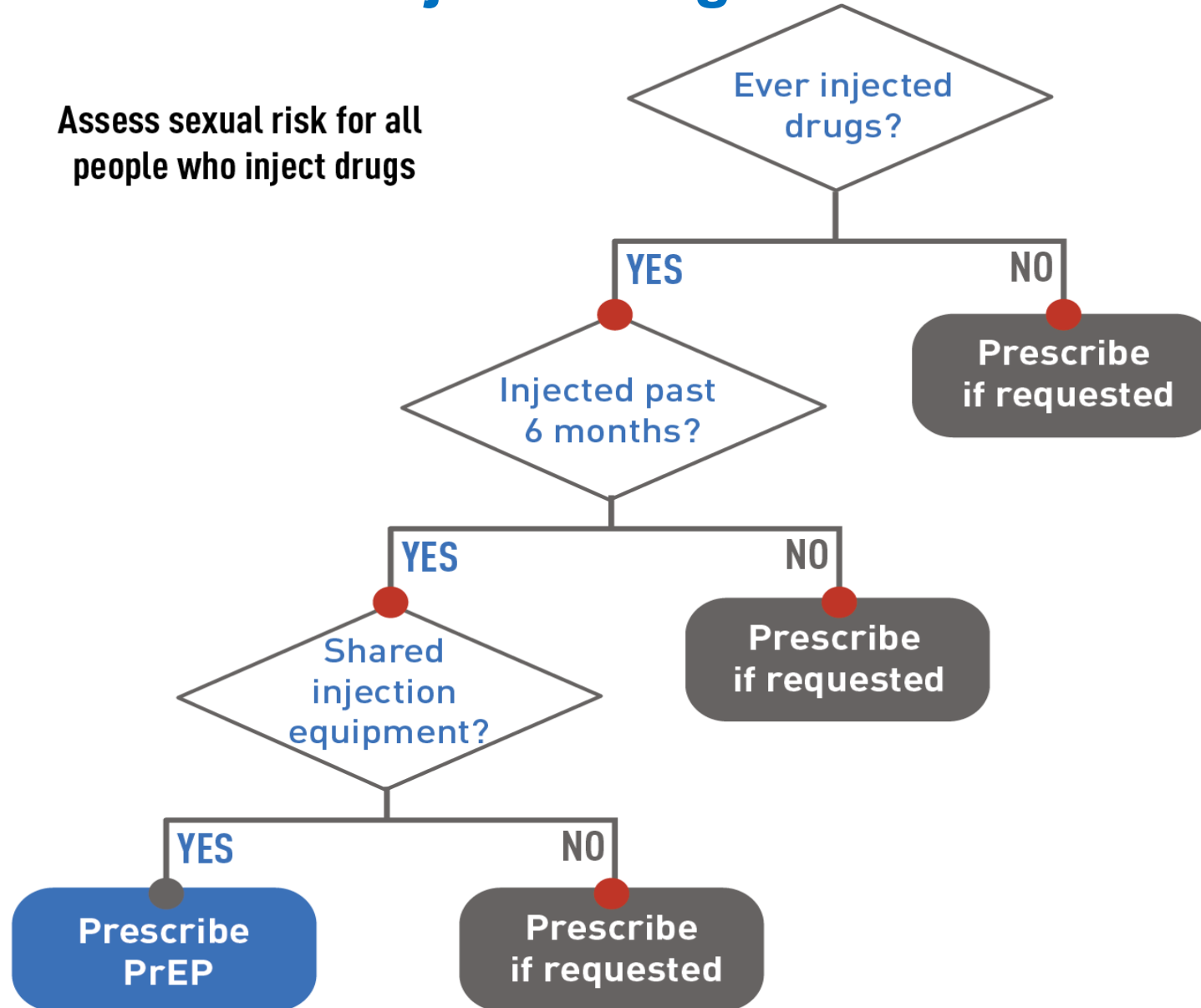
Note:

- MSM** - men who have sex with men;
- MSW** - men who have sex with women;
- STI** - sexually transmitted infection;
- WSM** - women who have sex with men.











# Assessing a Patient Who Injects Drugs for PrEP

Assess sexual risk for all  
people who inject drugs



# Summary of guidance for daily oral PrEP

	Sexually-Active Adults and Adolescents <sup>1</sup>	Persons Who Inject Drug <sup>2</sup>
Identifying substantial risk of acquiring HIV infection	<p>Anal or vaginal sex in past 6 months AND any of the following:</p> <ul style="list-style-type: none"> <li>• HIV-positive sexual partner (especially if partner has an unknown or detectable viral load)</li> <li>• Bacterial STI in past 6 months<sup>3</sup></li> <li>• History of inconsistent or no condom use with sexual partner(s)</li> </ul>	<p>HIV-positive injecting partner OR Sharing injection equipment</p>
<p>Clinically eligible</p> 	<p><b><u>ALL OF THE FOLLOWING CONDITIONS ARE MET:</u></b></p> <ul style="list-style-type: none"> <li>• Documented negative HIV Ag/Ab test result within 1 week before initially prescribing PrEP</li> <li>• No signs/symptoms of acute HIV infection</li> <li>• Estimated creatinine clearance <math>\geq 30</math> ml/min<sup>4</sup></li> <li>• No contraindicated medications</li> </ul>	
<p>Dosage</p> 	<ul style="list-style-type: none"> <li>• Daily, continuing, oral doses of F/TDF (Truvada®), <math>\leq 90</math>-day supply</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>• For men and transgender women at risk for sexual acquisition of HIV; daily, continuing, oral doses of F/TAF (Descovy®), <math>\leq 90</math>-day supply</li> </ul>	
<p>Follow-up care</p>      	<p><b><u>Follow-up visits at least every 3 months to provide the following:</u></b></p> <ul style="list-style-type: none"> <li>• HIV Ag/Ab test and HIV-1 RNA assay, medication adherence and behavioral risk reduction support</li> <li>• Bacterial STI screening for MSM and transgender women who have sex with men<sup>3</sup> – oral, rectal, urine, blood</li> <li>• Access to clean needles/syringes and drug treatment services for PWID</li> </ul> <p><b><u>Follow-up visits every 6 months to provide the following:</u></b></p> <ul style="list-style-type: none"> <li>• Assess renal function for patients aged <math>\geq 50</math> years or who have an eCrCl <math>&lt; 90</math> ml/min at PrEP initiation</li> <li>• Bacterial STI screening for all sexually-active patients<sup>3</sup> – [vaginal, oral, rectal, urine- as indicated], blood</li> </ul> <p><b><u>Follow-up visits every 12 months to provide the following:</u></b></p> <ul style="list-style-type: none"> <li>• Assess renal function for all patients</li> <li>• Chlamydia screening for heterosexually active women and men – vaginal, urine</li> <li>• For patients on F/TAF, assess weight, triglyceride and cholesterol levels</li> </ul>	

# PrEP Prescribing Considerations

- ***Prescribing PrEP is similar in complexity to prescribing hypertension or diabetes medications.***
- 
- Consider medication adherence and whether a patient is likely to take a pill once a day or could benefit from receiving an injection every 2 months.
  - Patients must have a negative HIV test before prescribing PrEP because taking the medications while already infected can lead to the emergence of drug-resistant HIV.
  - The USPSTF also recommends testing for other STIs and for pregnancy, if appropriate.



# Resources Are Available to Support Prescribing PrEP

Any licensed prescriber can provide PrEP.<sup>1</sup> Resources can be accessed from CDC:

## Comprehensive guidelines for prescribing PrEP:

- *A Clinical Practice Guideline<sup>2</sup>*
- *Clinical Providers' Supplement<sup>3</sup>*

## Clinicians' Quick Guides on PrEP:

- *What Is HIV PrEP?<sup>1</sup>*
- *What Is Oral HIV PrEP?<sup>4</sup>*
- *What Is Injectable HIV PrEP?<sup>5</sup>*

These resources can be accessed at:  
[cdc.gov/HIVNexus](https://cdc.gov/HIVNexus)



<sup>1</sup> Centers for Disease Control and Prevention. What Is HIV PrEP?. Updated August 2022. Accessed January 20, 2023. <https://www.cdc.gov/stophivtogether/library/topics/prevention/brochures/cdc-lsht-prevention-brochure-clinicians-quick-guide-what-is-hiv-prep.pdf>

<sup>2</sup> 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*. Published December 2021. Accessed January 20, 2023. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>

<sup>3</sup> Centers for Disease Control and Prevention, US Public Health Service. *Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 update: clinical providers' supplement*. Published December 2021. Accessed January 20, 2023. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2021.pdf>

<sup>4</sup> Centers for Disease Control and Prevention. What Is Oral HIV PrEP?. Updated August 2022. Accessed January 20, 2023. <http://www.cdc.gov/stophivtogether/library/topics/prevention/brochures/cdc-lsht-prevention-brochure-clinicians-quick-guide-what-is-oral-hiv-prep.pdf>

<sup>5</sup> Centers for Disease Control and Prevention. What Is Injectable HIV PrEP?. Updated August 2022. Accessed January 20, 2023. <https://www.cdc.gov/stophivtogether/library/topics/prevention/brochures/cdc-lsht-prevention-brochure-clinicians-quick-guide-what-is-injectable-hiv-prep.pdf>



# Patient and Provider Checklist for Initiating PrEP

The checklist is available in the *Clinical Providers' Supplement* that accompanies the updated PrEP guideline and includes:

- Services provided to PrEP patients
- Follow-up recommendations for PrEP patients
- Patient actions to maximize PrEP efficacy and safety

The image shows two overlapping pages of a checklist form. The top page is titled 'Section 1 - Patient/Provider Checklist' and 'CHECKLIST FOR INITIATING PREENEXPOSURE PROPHYLAXIS'. It includes fields for 'Organization/Clinic Name', 'Print name of provider', 'Today's date (month/day/year)', and 'Print'. Below these is the 'Provider Section' with checkboxes for various services provided to the patient, such as 'Assessment for possible acute HIV infection', 'Indicated laboratory screening to determine whether PrEP is indicated', 'An HIV risk assessment to determine whether PrEP is indicated', 'A medication fact sheet listing dosing instructions and side effects', 'Counseling or a referral for counseling on condom use and other reduction methods this patient may need', 'Advice on methods to help the patient to take medication as prescribed', 'Information about PrEP use during conception and pregnancy', 'The following PrEP regimen (choose only one)', 'Prescribed Truvada (300 mg tenofovir disoproxil fumarate/emtricitabine)', 'daily dosing', 'Prescribed Descovy (25 mg tenofovir alafenamide, 20 mg emtricitabine)', 'daily dosing (MSM)', 'Prescribed Truvada (300 mg tenofovir disoproxil fumarate/emtricitabine)', '2-1-1 dosing (MSM)', 'Administered a gluteal IM injection of cabotegravir (Veklury) as the provider, I will:', and 'A follow-up appointment date'. The bottom page is titled 'Patient Section - Daily Oral Dosing' and includes a section for 'It has been explained to me that:' with bullet points about taking PrEP medication every day, the effectiveness of PrEP, the importance of taking medication as prescribed, and the importance of seeing the provider for advice. It also includes a section for 'Therefore, I will:' with bullet points about taking medication as prescribed, talking to the provider about any problems, not sharing medication, attending all appointments, and calling to reschedule if unable to attend. The form is labeled 'Give one copy to patient' and 'Page 7 of 53' and 'Page 9 of 53'.

## Resources Are Available to Support Prescribing PrEP (cont'd)

**Additional prescribing advice** can be obtained from  
the

**National Clinician Consultation Center PrEPline:**

**855-448-7737 (9:00 AM – 8:00 PM EST)**

# PrEP Use During Conception, Pregnancy, and Breastfeeding



## Benefits of PrEP Use

- The risk of getting HIV is higher during conception, pregnancy, and breastfeeding<sup>1,2</sup>
- PrEP with F/TDF or CAB can help protect people\* who are seeking to conceive or who are pregnant or breastfeeding and have a sexual partner with HIV<sup>3,4</sup>

## Safety Profile

- No difference in pregnancy outcomes<sup>5</sup>
- No adverse effects among fetuses exposed to antiretroviral medications during pregnancy<sup>6</sup>
- Limited drug exposure to antiretroviral medications through breast milk<sup>7-9</sup>

\*Most research on PrEP use during conception, pregnancy, and breastfeeding has been conducted in cisgender women. No data are yet available about transgender men or genderqueer or nonbinary individuals who have become pregnant and given birth while taking PrEP medication.<sup>4</sup>

<sup>1</sup> Mugo NR, Heffron R, Donnell D, et al. Increased risk of HIV-1 transmission in pregnancy: a prospective study among African HIV-1-serodiscordant couples. *AIDS*. 2011;25(15):1887-1895. doi: 10.1097/QAD.0b013e32834a9338

<sup>2</sup> Thomson KA, Hughes J, Baeten JM, et al. Increased risk of HIV acquisition among women throughout pregnancy and during the postpartum period: a prospective per-coital act analysis among women with HIV-infected partners. *J Infect Dis*. 2018;218(1):16-25. doi: 10.1093/infdis/jiy113

<sup>3</sup> Hoffman RM, Jaycocks A, Vardavas R, et al. Benefits of PrEP as an adjunctive method of HIV prevention during attempted conception between HIV-uninfected women and HIV-infected male partners. *J Infect Dis*. 2015;212(10):1534-1543. doi: 10.1093/infdis/jiv305

<sup>4</sup> 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*. Published December 2021. Accessed January 20, 2023. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>

<sup>5</sup> Dettinger JC, Kinuthia J, Pintye J, et al. Perinatal outcomes following maternal pre-exposure prophylaxis (PrEP) use during pregnancy: results from a large PrEP implementation program in Kenya. *J Int AIDS Soc*. 2019;22(9):e25378. doi: 10.1002/jia2.25378

<sup>6</sup> The Antiretroviral Pregnancy Registry. Interim Report: 1 January 1989 through 31 July 2022. Published December 2022. Accessed January 20, 2023. <http://apregistry.com/forms/exec-summary.pdf>

<sup>7</sup> Mugwanya KK, John-Stewart G, Baeten J. Safety of oral tenofovir disoproxil fumarate-based HIV pre-exposure prophylaxis use in lactating HIV-uninfected women. *Exp Opin Drug Saf*. 2017;16(7):867-871. doi: 10.1080/14740338.2017.1338271

<sup>8</sup> Benaboud S, Pruvost A, Coffie PA, et al. Concentrations of tenofovir and emtricitabine in breast milk of HIV-1-infected women in Abidjan, Cote d'Ivoire, in the ANRS 12109 TEMAA Study, Step 2. *Antimicrob Agents Chemother*. 2011;55(3):1315-1317. doi: 10.1128/AAC.00514-10

<sup>9</sup> Waitt C, Olagunju A, Nakalema S, et al. Plasma and breast milk pharmacokinetics of emtricitabine, tenofovir and lamivudine using dried blood and breast milk spots in nursing African mother–infant pairs. *J Antimicrob Chemother*. 2018;73(4):1013-1019. doi: 10.1093/jac/dkx507

# Summary



**PrEP**—medication to prevent HIV—is for adults and adolescents at risk of getting HIV

Obtaining a brief sexual history from all patients ensures providers have the information they need, **helps to reduce stigma and discomfort**, and facilitates identifying teachable moments

**PrEP can be easily integrated into primary care settings** as it is similar to other preventative medications, such as statins for cardiovascular disease

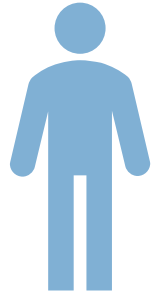
**Three PrEP medications** are approved by the U.S. Food and Drug Administration:

- F/TDF (Truvada® or generic equivalent)
- F/TAF (Descovy®)
- CAB (Apretude®)

Resources are available to help patients **pay for PrEP**



## Summary (cont'd)



**PrEP should be considered** as part of a **comprehensive HIV-prevention plan** and can be provided by any licensed prescriber

**When taken as prescribed, PrEP is well tolerated and reduces the risk of getting HIV** from sex by about 99% and from injection drug use by at least 74%

**Three forms of PrEP medication are available:**


1. Oral F/TAF (Descovy®)
2. Oral F/TDF (Truvada® or generic equivalent)
3. Injectable CAB (Apretude®)



PrEP can be prescribed to **any adult or adolescent patient who asks for it**, even if they don't report specific risk factors for HIV

# HIV Medications

35 years of HIV  
Treatment...  
Now 34 drugs



Zidovudine  
(AZT, Retrovir) 1987 –  
Cabotegravir  
(Cabenuva) 2022

- <https://www.thebodypro.com/article/aids-2022-new-hiv-drugs>



# Why seeking new drugs when there are 34 drugs available?

- 1 pill once a day has long been the desired but now long-acting drugs are being sought
- New mechanisms of action needed for those with multi-drug resistance

# Making Therapy Easier

**1987**  
**In the beginning**



AZT

**1996**  
**The Past**



Up to 10 pills tid;  
food restrictions;  
poor tolerability

**2018**  
**The Present**



One pill once a day

**The ~~Future~~**

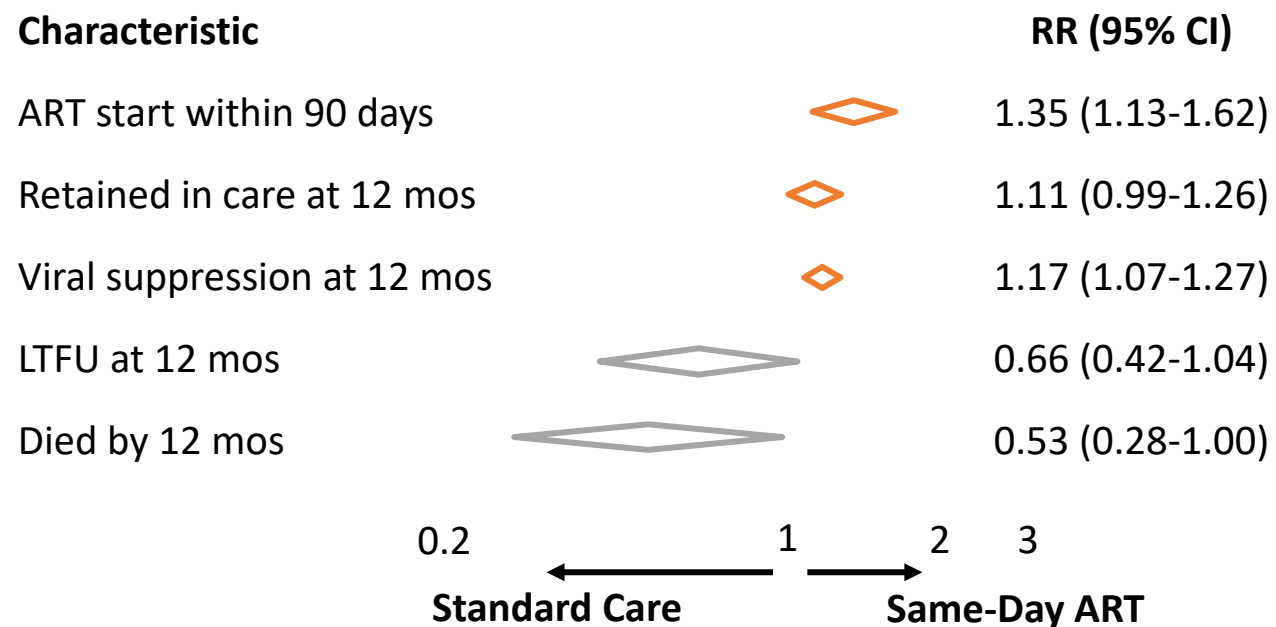


Injection once a month  
**APPROVED Jan 2021**



# Improved Clinical Outcomes With Rapid ART Initiation

- Systematic review of rapid ART initiation (including 4 RCTs)<sup>[1]</sup>



**Same-day ART associated with:**

- **Increased** likelihood of ART initiation, retention in care, viral suppression
- **Decreased** likelihood of loss to follow-up and death

- In addition, earlier ART initiation reduces the viral reservoir in the individual<sup>[2-5]</sup>

# Current Recommendations for Same-Day ART Initiation

- Rapid start or initiating ART on same day as HIV is diagnosed is an emerging strategy to **reduce loss to follow-up and decrease time to viral suppression**
- Evidence base limited but growing, and outcomes favorable thus far

## DHHS<sup>[1]</sup>

- **Recommended** at time of diagnosis (when possible) or soon afterward
  - Resource intensive
  - US experience from observational trials

## WHO<sup>[2]</sup>

- **Recommended** for all PWH, including same day, if patient is ready\*

## IAS-USA<sup>[3]</sup>

- Start ART as soon as possible, **including immediately after diagnosis**, if patient is ready

\*Rapid initiation defined as within 7 days of diagnosis. Priority should be given to patients with advanced disease.



# Recommended Regimens for Rapid ART

## DHHS<sup>[1]</sup>

### Recommended Regimens

BIC/FTC/TAF

DTG + (TAF or TDF) + (3TC or FTC)

(DRV/RTV or DRV/COBI) + (TAF or TDF) + (3TC or FTC)

### Regimens Not Recommended

NNRTI-based regimens or DTG/3TC due higher rate of transmitted NNRTI and NTRI drug resistance

Regimens requiring ABC until HLA-B\*5701 test results received

## IAS-USA<sup>[2]</sup>

### Recommended Regimens

DTG + (FTC or 3TC)/(TAF or TDF)

BIC/FTC/TAF

DRV/RTV + (FTC or 3TC)/(TAF or TDF)

### Regimens Not Recommended

NNRTI-based regimens due to concerns over transmitted drug resistance (K103N)

Regimens requiring ABC until HLA-B\*5701 test results received

# Patient Information Before Initiating Rapid ART

## Need prior to start

- Patient prepared for ART and interest in rapid initiation
- **Physical examination**
  - **Active cryptococcal meningitis or TB (Tuberculosis) infection could increase risk for IRIS (Immune reconstitution inflammatory syndrome) and *may warrant a short ART delay***
  - **Other AIDS-defining conditions could increase risk of morbidity/mortality in the setting of rapid ART initiation**
- Counsel on medication adherence

## Not needed prior to start

- CD4+ cell count
- HIV viral load
- HIV genotype
- Resistance test results
- Hepatitis A/B/C status
- HLA-B\*5701 status
- STI screening results
- Pregnancy test results



U=U

This means that people who take Antiretroviral Therapy (ART) daily as prescribed and achieve and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to an HIV-negative partner.



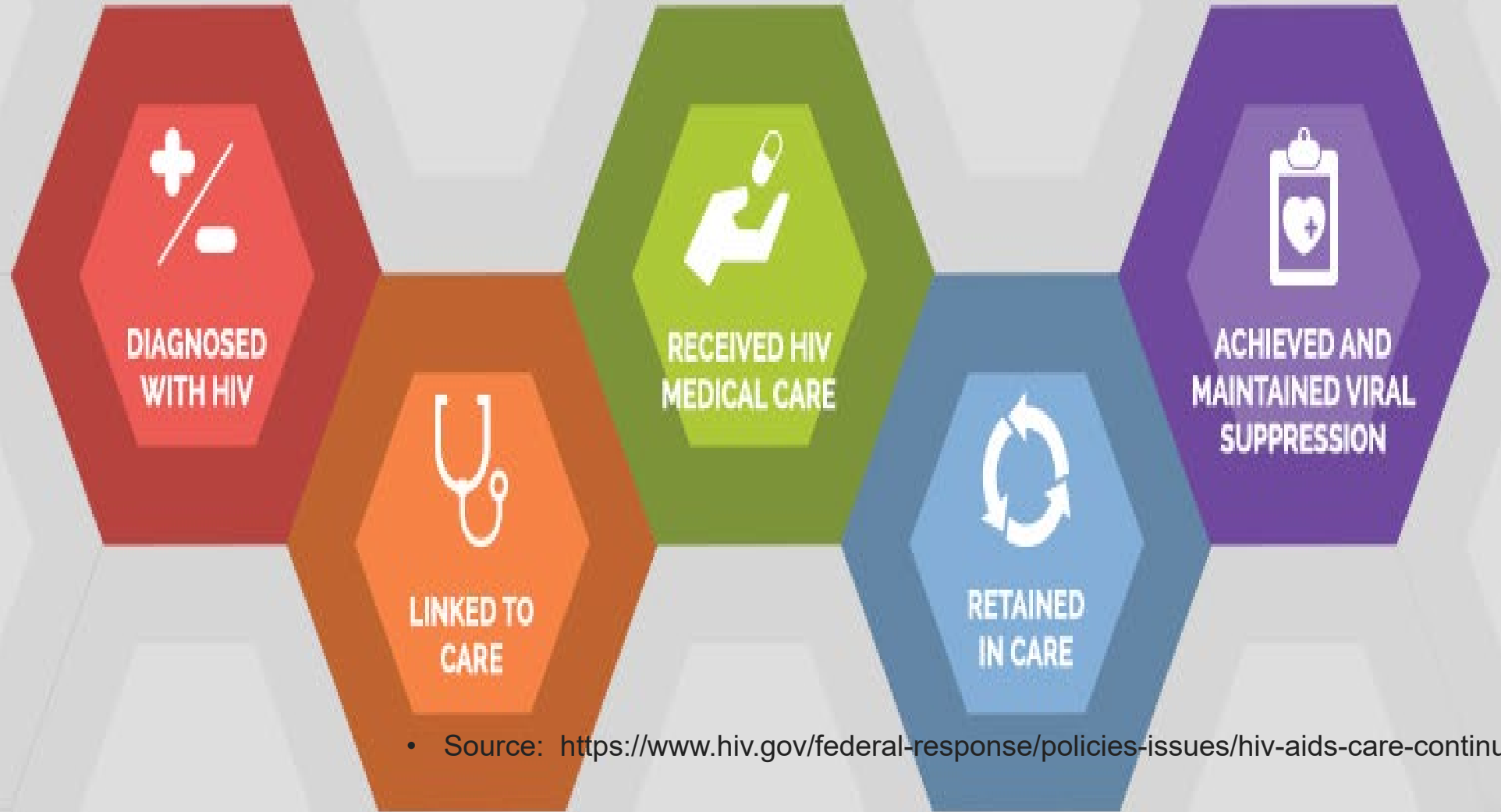
# Access To Care:

## The importance of Quality Supportive and Preventative Care for HIV Patients



# HIV CARE CONTINUUM:

The steps that people with HIV take from diagnosis to achieving and maintaining viral suppression.



- Source: <https://www.hiv.gov/federal-response/policies-issues/hiv-aids-care-continuum>

# Insurance Coverage for PrEP

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- Based on the highest quality scientific evidence, the United States Preventive Services Task Force (USPSTF) gave an “A” rating to PrEP meaning that the USPSTF recommends PrEP as routine preventive care and federal law requires most private insurers to cover preventive care strongly recommended by the USPSTF.
- PrEP medications greatly reduce the likelihood that partners of people with HIV will contract the virus. It has been reported to reduce the likelihood of transmission by 99%.
- The ACA provision requires all insurers to cover certain preventive services free of charge, but this may go away.

# Insurance Coverage for PrEP

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- As of June 2020, under the Affordable Care Act (ACA), insurers were required to cover PrEP without cost sharing inclusive of the medicine, labs, and associated office visits.
- In September 2022, a Federal district judge in Texas ruled in favor of plaintiffs challenging federal mandates requiring that private insurance policies cover pre-exposure prophylaxis (PrEP).
- PrEP is one of several preventive services and treatments that the plaintiffs in the lawsuit, known as Braidwood v. Becerra, do not want to cover for their employees because, they say, doing so violates their religious beliefs.

*Preventive  
Services Ruled  
Unconstitutional*

- The plaintiffs argued that the ACA requirement for insurers to pay for certain preventive services was unconstitutional, because it encouraged behavior that clashed with their personal and religious beliefs.
- While the lawsuit would eliminate the mandate ***for all preventive services***, some plaintiffs appeared most concerned about services related to reproductive and sexual health.

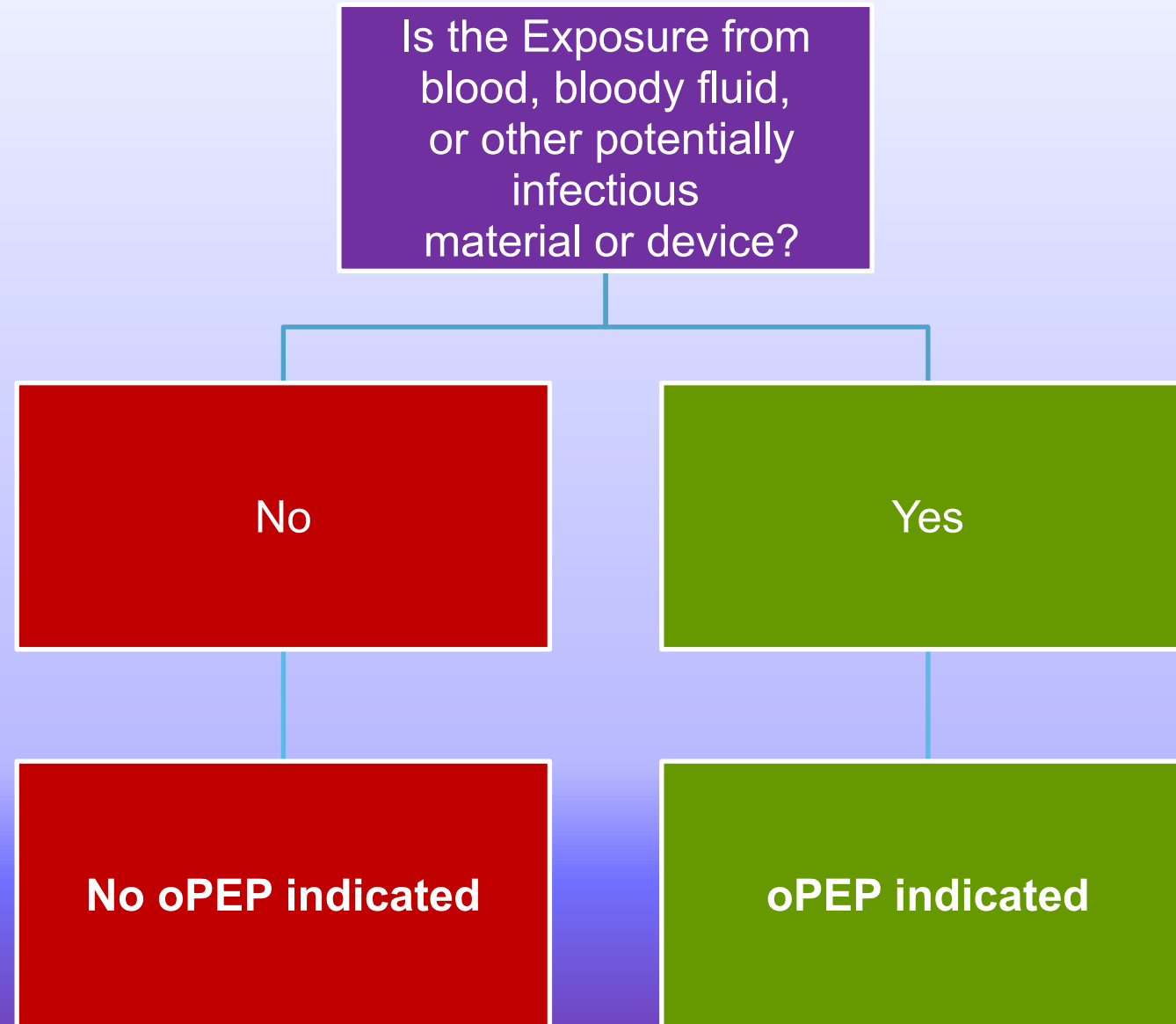


# HIV oPEP (formerly PEP)

**“PEP is not justified for exposures that pose a negligible risk for transmission.”**

Consultation with an expert can help determine if the exposure poses a “negligible risk” to explore whether alternative approaches, including a modified regimen, are appropriate.

# When Is HIV oPEP Indicated



# HIV oPEP: What to Give

Three-drug oPEP regimens are now the recommended regimens for all exposures.

Guidelines no longer require assessing the degree of risk for the purpose of choosing a “basic” two-drug regimen vs. an “expanded” three-drug regimen.

There are some special circumstances, however, in which a two-drug regimen can be considered/used, especially when recommended antiretroviral medications are unavailable or there is concern about potential toxicity or adherence difficulties. In addition,

# oPEP Regimen

## Preferred HIV 3-Drug Occupational PEP Regimen:

Truvada™ 1 tablet by mouth once daily  
[co-formulated Tenofovir DF (Viread®; TDF) 300mg +  
emtricitabine (Emtriva™; FTC) 200mg]

**PLUS**

dolutegravir (Tivicay™) 50mg PO once daily  
Duration: 28 days

**or**

raltegravir (Isentress®; RAL) 400mg by mouth twice daily

# oPEP Regimen

## Alternative HIV Occupational PEP Regimens:

May combine one drug or drug pair from Column One with one pair of nucleoside/nucleotide reverse transcriptase inhibitors from Column Two

Column One	Column Two
Raltegravir (Isentress® ; RAL)	
Dolutegravir (Tivicay™; DTG)	Tenofovir DF (Viread® ; TDF) + lamivudine (Epivir® ; 3TC)
Darunavir (Prezista® ; DRV) + ritonavir (Norvir® ; RTV)	Zidovudine (Retrovir™ ; ZDV; AZT) + lamivudine (Epivir® ; 3TC); available co-formulated as Combivir®
Atazanavir (Reyataz® ; ATV) + ritonavir (Norvir® ; RTV)	Zidovudine (Retrovir™ ; ZDV ; AZT) + emtricitabine (Emtriva™ ; FTC)
Lopinavir/ritonavir (Kaletra® ; LPV/RTV)	
Etravirine (Intelence® ; ETR)	
Rilpivirine (Edurant™ ; RPV)	



# Doxy-PEP: Doxycycline for STI Prevention

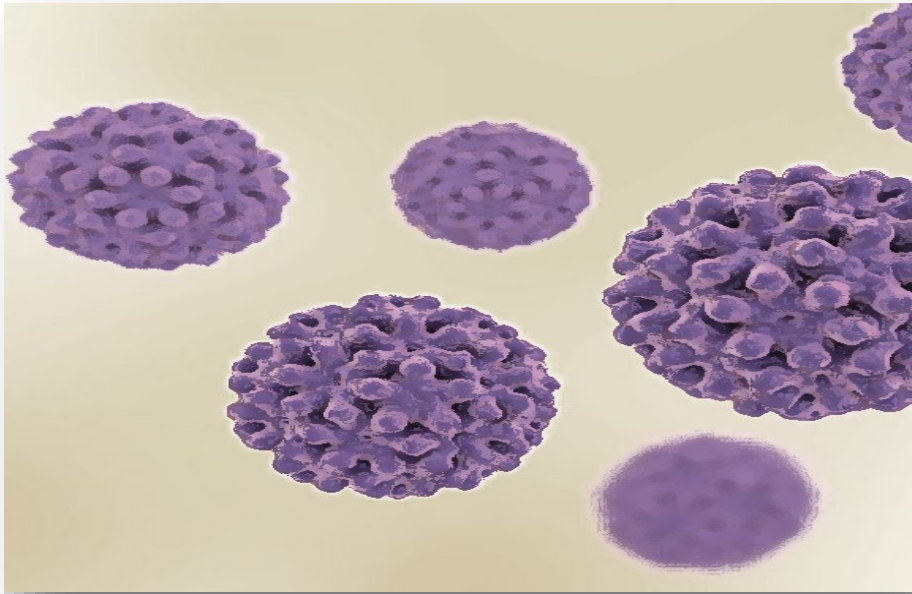
- ***Doxy-PEP stands for doxycycline post-exposure prophylaxis.***
- A study led by University of California San Francisco, the San Francisco Department of Public Health and the University of Washington was found to be a highly effective sexual health strategy. Reported at CROI 2023 on 2/20/2023.
- For people who have a history of sexually transmitted infections (STIs) where they take doxycycline after condomless sex.
- It involves taking one 200mg pill of doxycycline, a kind of tetracycline, as soon as possible but no later than three days after having sex without a condom.
- The study observed its effects over the course of a year in men who have sex with men (MSM) and transgender women and found it reduced bacterial STIs, specifically gonorrhea, chlamydia and syphilis, by two-thirds each quarter.

# Doxycycline continues to show promise for STI prevention, but not in cisgender women

Studies continue to show that taking doxycycline after having unprotected sex can prevent STIs in transgender women and men who have sex with men. What has been unclear is whether it also works for cisgender women.

STIs reported by cisgender women in study of Doxycycline as postexposure prophylaxis (doxy-PEP)





## Universal Adult Hepatitis B Screening and Vaccination As the Path to Elimination

- New CDC recommendations for one-time universal screening of adults aged 18 and older for hepatitis B virus (HBV) infection are a major step toward reducing chronic hepatitis B (CHB)-related morbidity and mortality in the U.S.
- 1.6 million to 2.4 million people are living with CHB
- Universal hepatitis B screening of pregnant individuals, recommended by the Advisory Committee on Immunization Practices (ACIP) since 1988 and by the U.S. Preventive Services Task Force (USPSTF) since 2009 has led to annual screening for hepatitis B in 85% to 90% of pregnant people in the U.S. has resulted in a significant decrease in perinatal CHB through prophylaxis with hepatitis B vaccine and immune globulin

# Ending the HIV Epidemic

## Success depends on...

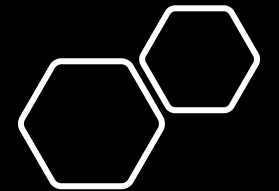
- reaching the 13% of 1.2 million people with HIV who are unaware of their status
- Helping the 1 in 3 people with HIV who are not receiving treatment or who are not virally suppressed engage in medical care
- Scaling up treatment for the large proportion of the more than 1 million people who could benefit from but are not taking HIV preexposure prophylaxis (PrEP.)



**The time is now.**

Ending  
the  
HIV  
Epidemic

- The U.S. Department of Health and Human Services (HHS) launched the Ending the HIV Epidemic in the U.S. (EHE) initiative in 2019.
- The initiative aims to reduce new HIV infections in the U.S. by 90% by 2030 by scaling up key HIV prevention and treatment strategies.





“People Worry  
About”...

- Saying the wrong things
- Causing offense



- “But once you get comfortable discussing sexuality, you may open conversations around other health issues”

---Matthew M. Hamill, MBChB, PhD, MPH a specialist in sexually transmitted diseases at Johns Hopkins Medicine, Baltimore

# Questions?





# Contact Info

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