PrEP-ing Primary care
Expanding access to HIV pre-exposure prophylaxis

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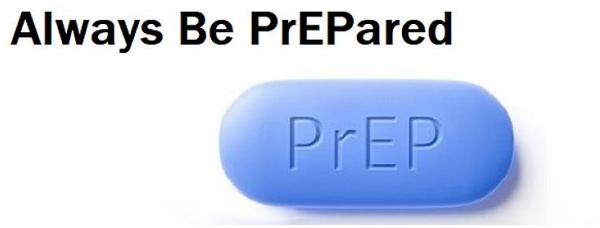


The time is now.

Ending the HIV Epidemic

Diagnose all people with HIV as early as possible.

Treat people with HIV rapidly and effectively to reach sustained viral suppression.

Prevent new HIV transmissions by using proven interventions, including PrEP and syringe services programs (SSPs).

Respond quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.

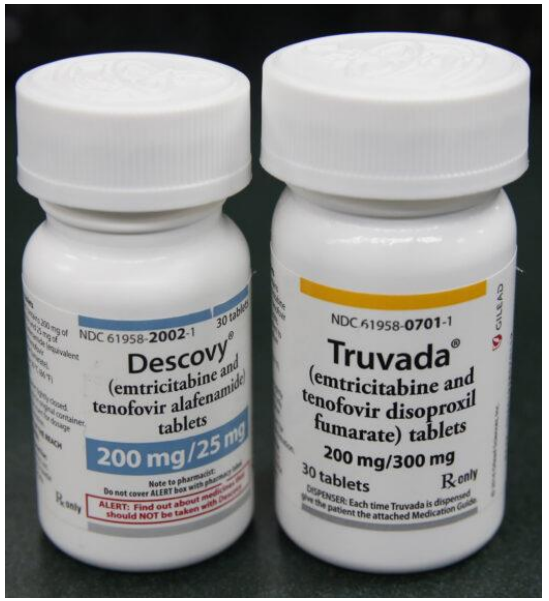
Objectives:

- Gain general knowledge for evidence supporting provision of PrEP and its effectiveness in prevention of HIV transmission.
- Describe current gaps and barriers to PrEP prescription in primary care.
- Be able to counsel your patients on oral PrEP and incorporate oral PrEP into your practice

Pre-exposure prophylaxis (PrEP)

- HIV prevention method that uses anti-retroviral medication to prevent HIV in HIV-negative individuals.

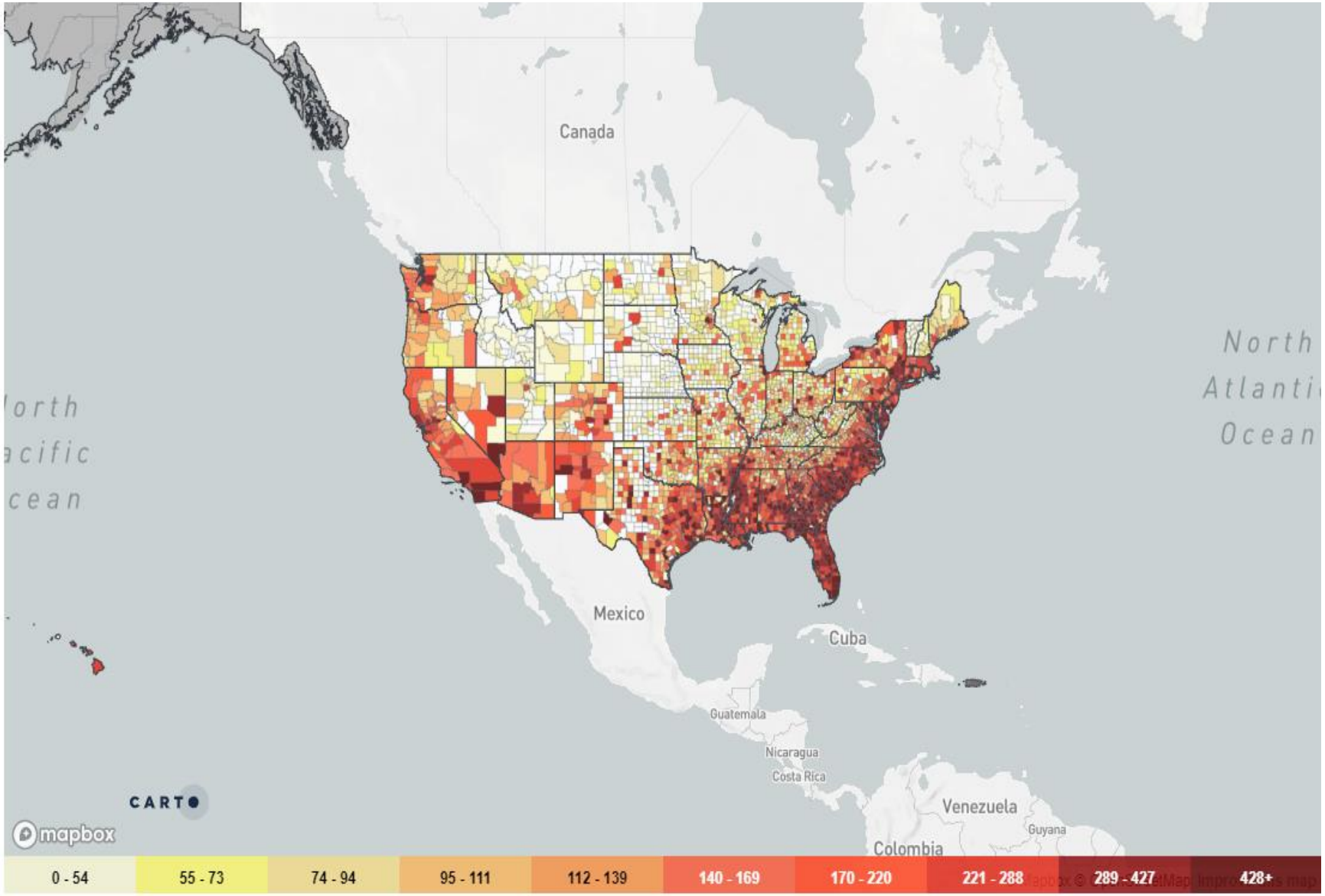
- 3 FDA approved regimen:
  - TDF/FTC (Truvada), once daily regimen
  - TAF/FTC (Descovy), once daily regimen
  - Cabotegravir (Apretude), Q2 months IM injectable



In 2020:

1,069,948 people living with HIV

30,636 new HIV infections

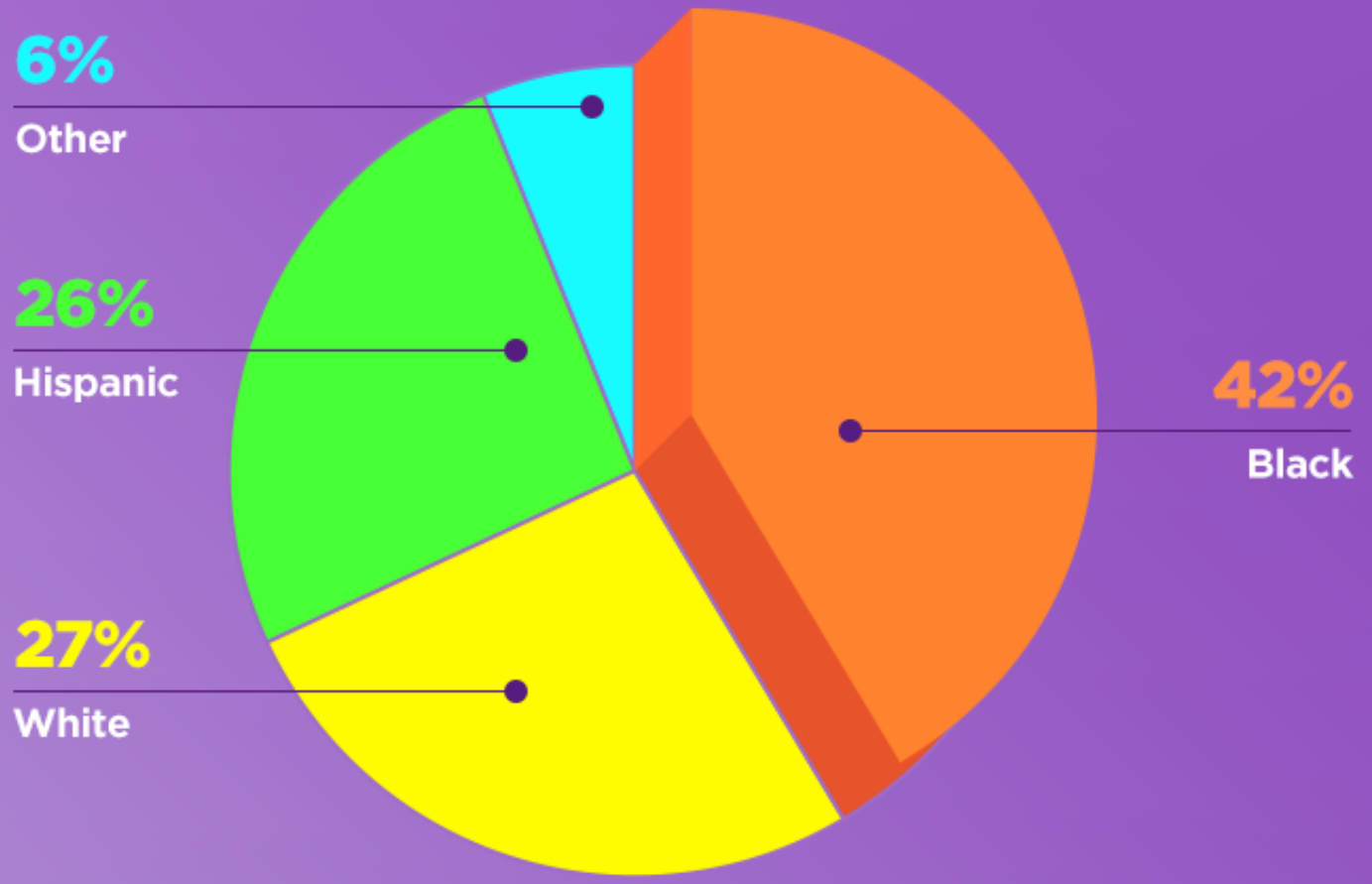


In 2020, men made up **82%** of all new HIV diagnoses.
Of that, **Gay and Bisexual Men** made up **83%** of new HIV diagnoses.

New Diagnoses by Sex, 2020

New HIV Diagnoses Among Men, 2020

In 2020, **30,632** people were **newly diagnosed with HIV**. **Black** individuals made up **nearly half** (42%) of new HIV diagnoses and had a **new diagnosis rate 7 times higher** than **White** individuals.



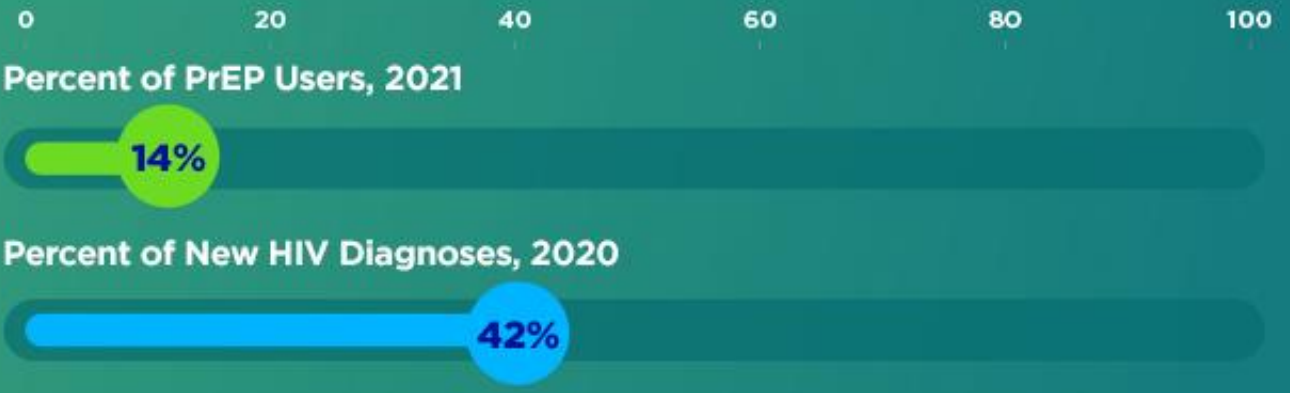
*Due to rounding, percentages may not add up to 100%.

Percentage of New HIV Diagnoses, by Race/Ethnicity, 2020

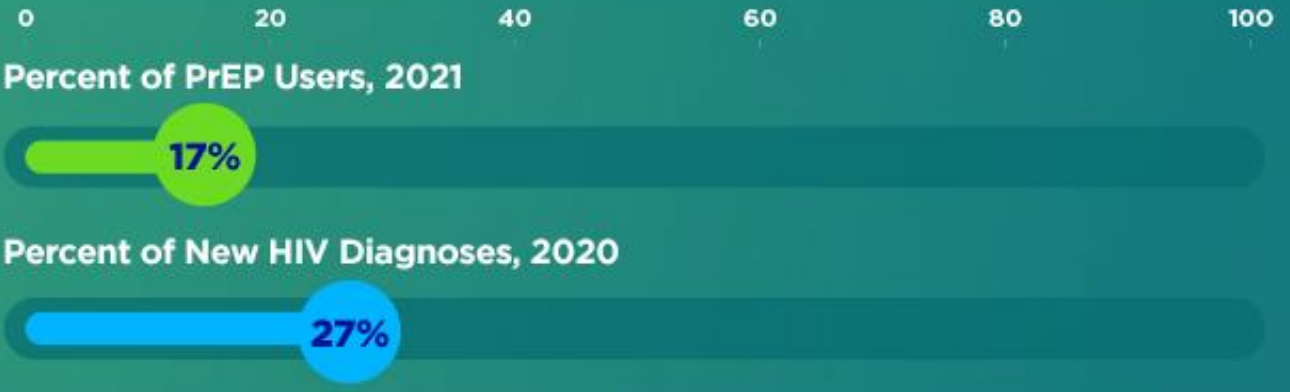
Due to the COVID-19 pandemic, data from 2020 should be interpreted with caution.

Black people represented only **14% of PrEP users (2021) but accounted for 42% of new HIV diagnoses (2020),** indicating a **significant unmet need for PrEP**.

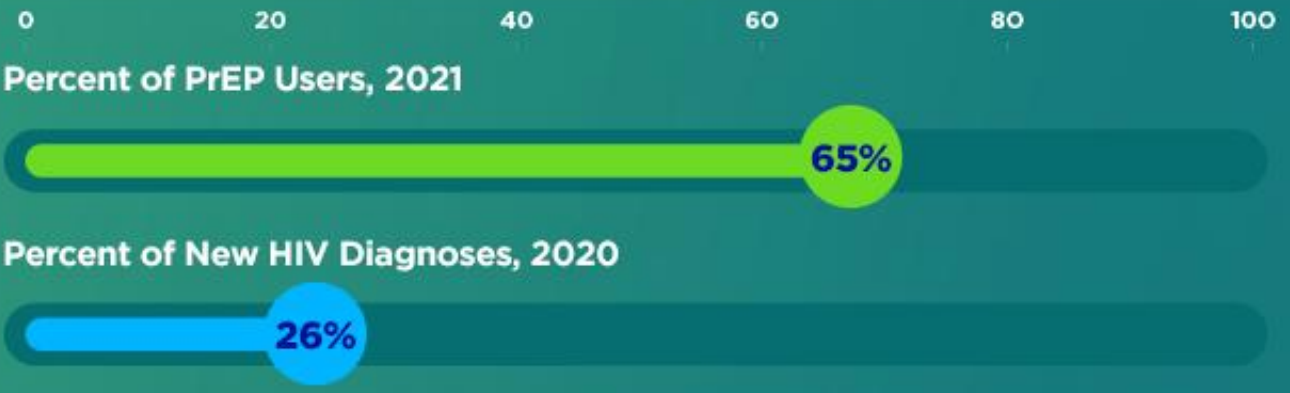
Black People



Hispanic/ Latinx People

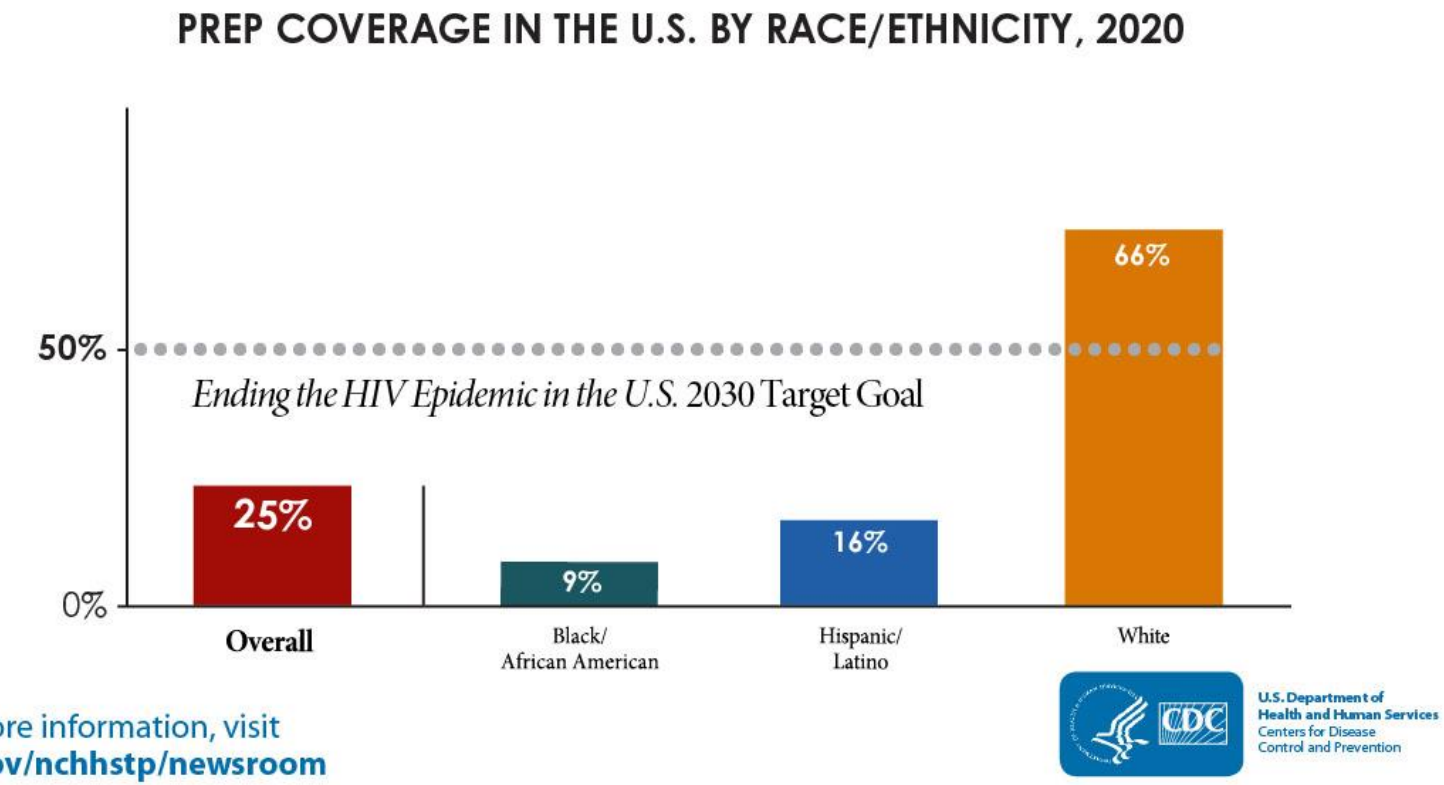


White People



SOURCE: AIDSVu

WHILE 25% OF PEOPLE ELIGIBLE FOR PREP WERE PRESCRIBED IT IN 2020, COVERAGE IS NOT EQUAL

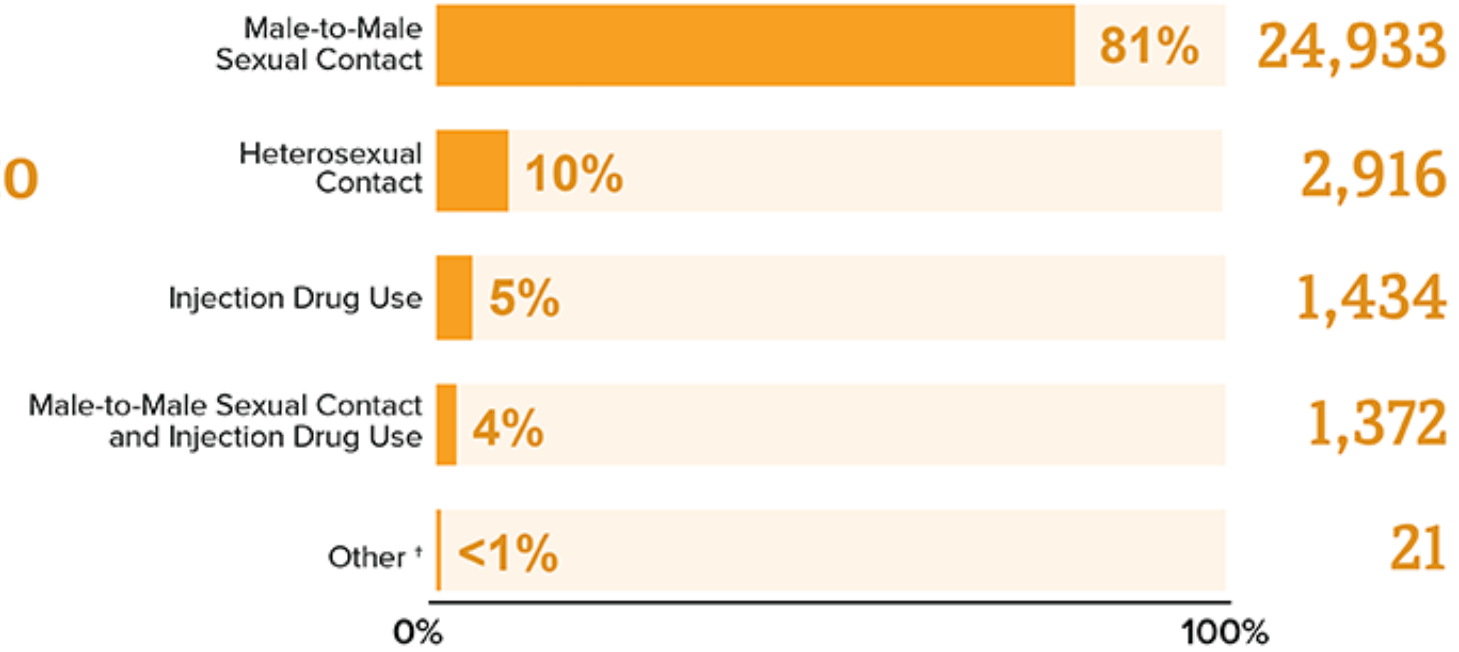


Preliminary CDC data[1] show that **in 2020, about 25% of the 1.2 million people for whom PrEP is recommended were prescribed it, compared to only about 3% in 2015.**

https://www.cdc.gov/nchhstp/newsroom/fact-sheets/hiv/PrEP-for-hiv-prevention-in-the-US-factsheet.html

New HIV Diagnoses Among Men in the US and Dependent Areas by Transmission Category, 2018*

Most new HIV diagnoses among men were attributed to male-to-male sexual contact.



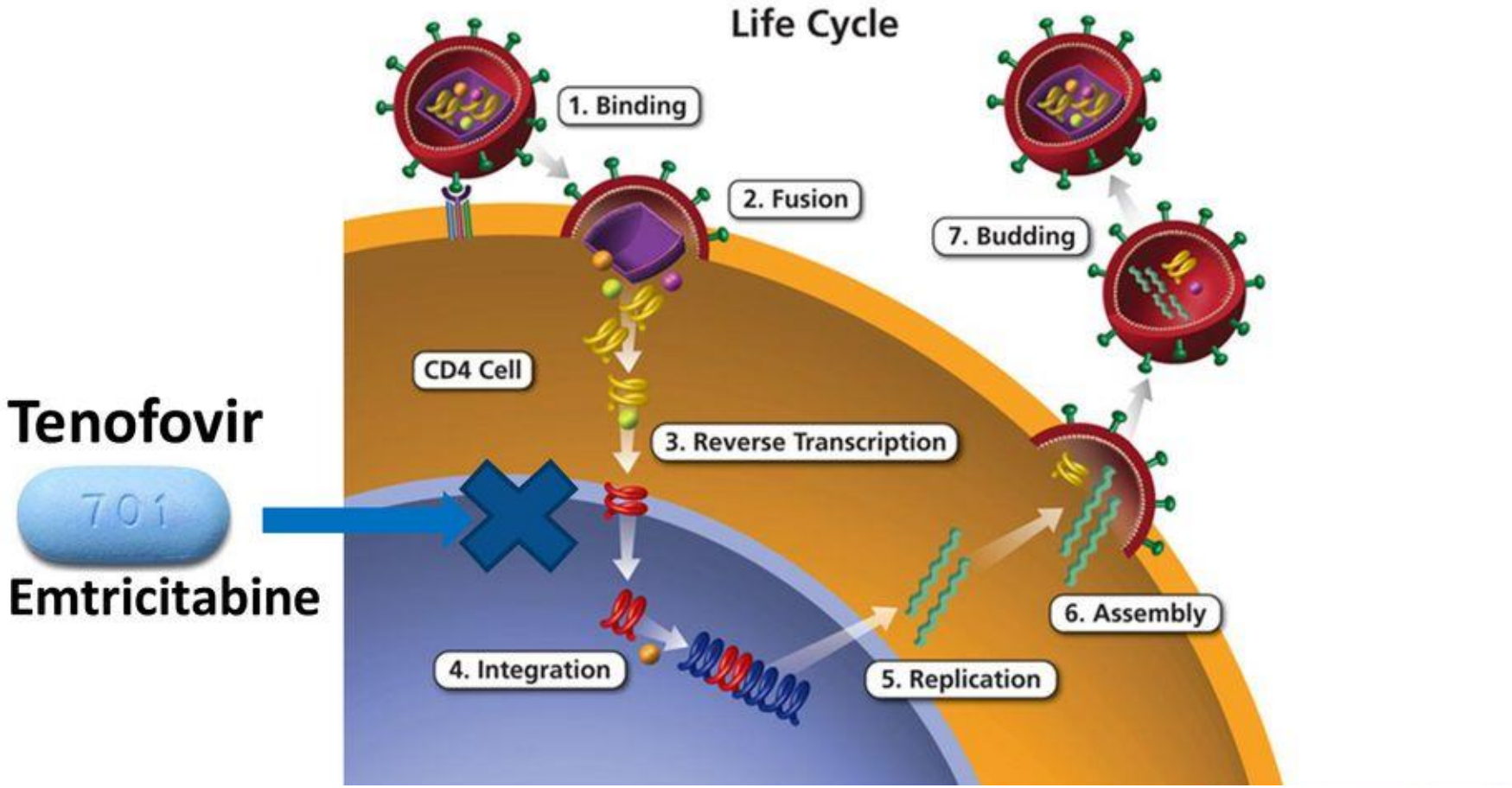
*Based on sex at birth and includes transgender people.

† Includes hemophilia, blood transfusion, perinatal exposure, and risk factors not reported or not identified.

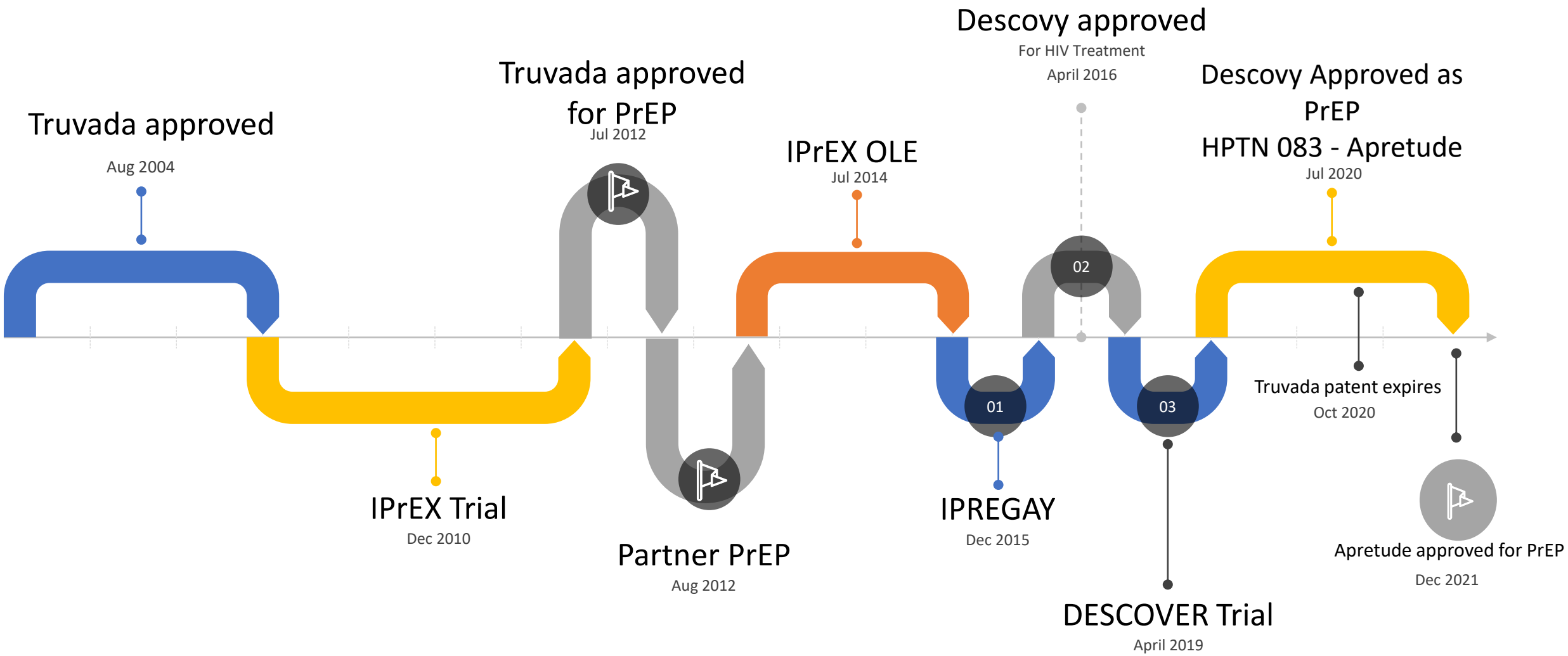
Source: CDC. Diagnoses of HIV infection in the United States and dependent areas, 2018 (updated).*HIV Surveillance Report* 2020;31.

Tdf/ftc as PrEP:

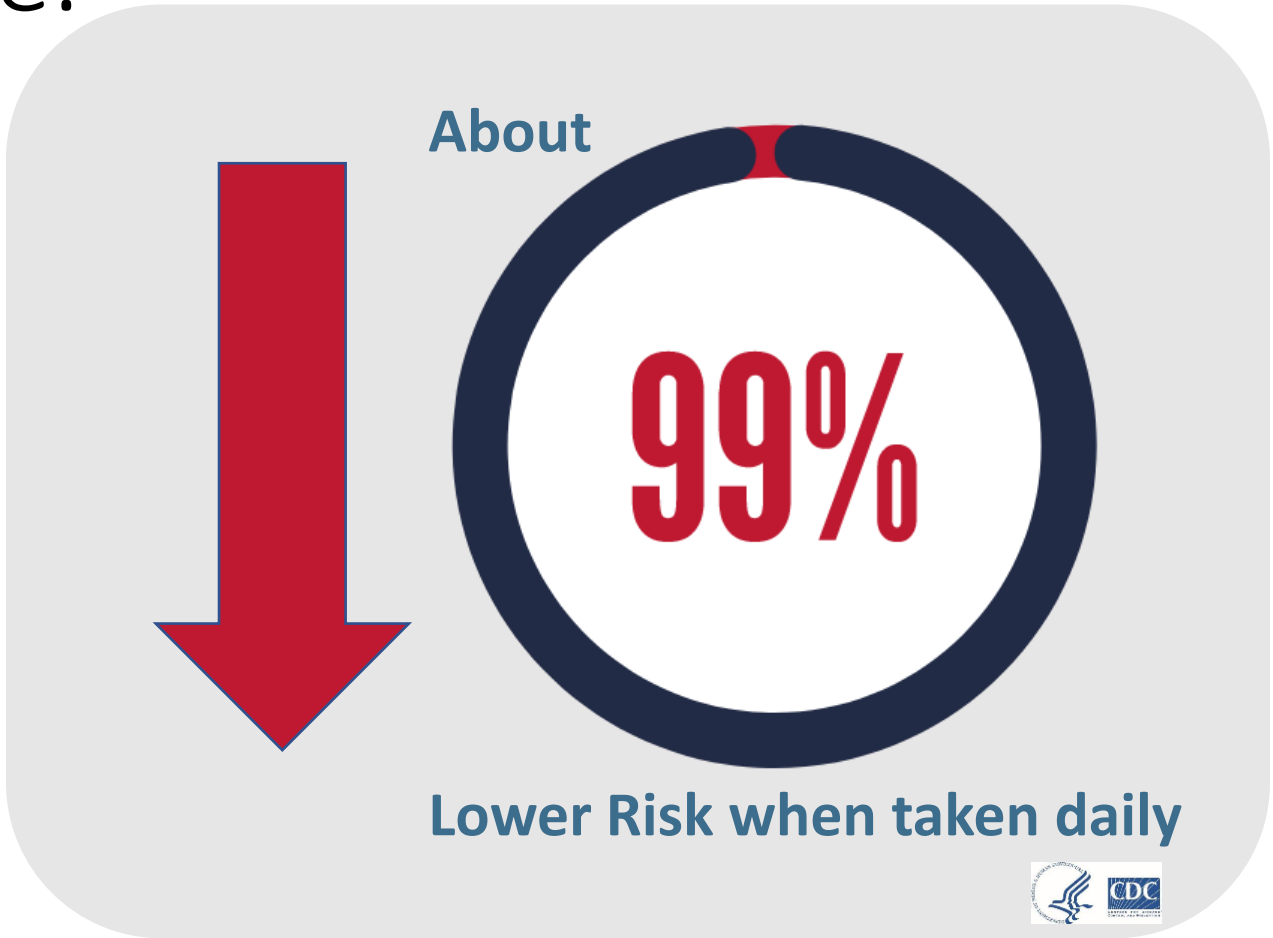
Mechanism of Action



PrEP Through the Ages

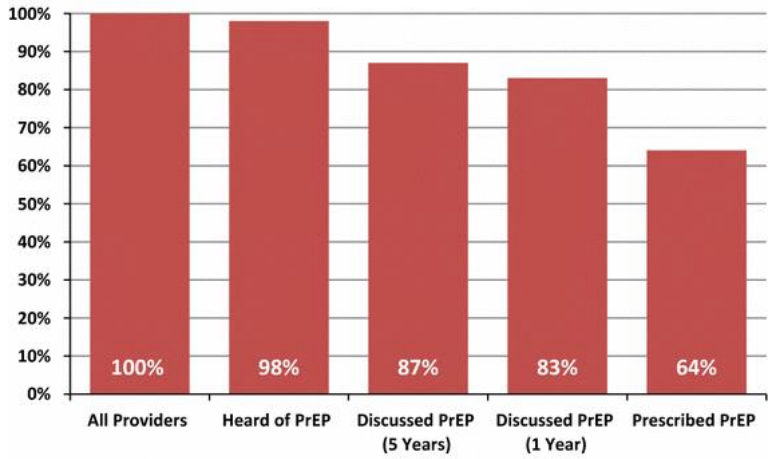


PrEP effectiveness directly relates to adherence.

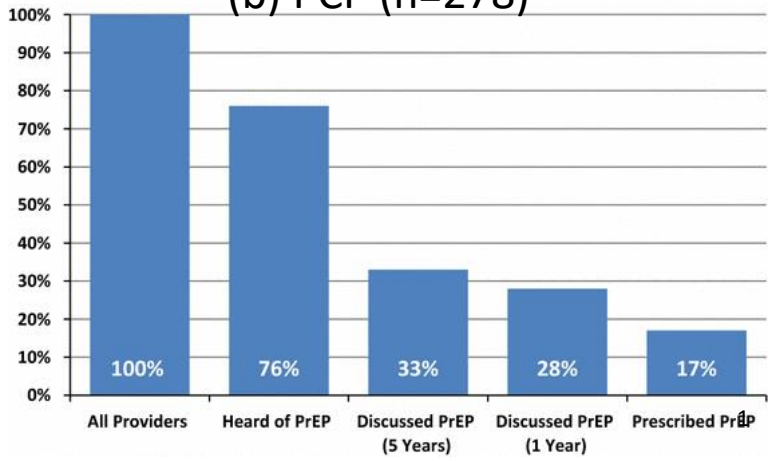


Barriers

(a) HIV Providers (n=237)



(b) PCP (n=278)



85% PCP favors incorporation of PrEP into primary care

<u>Most commonly identified barriers:</u>

- Lack of provider familiarity
- Access to resource/guidelines/protocol
- Peers who are knowledgeable about or supportive for PrEP provision in your practice[12]

Purview Paradox

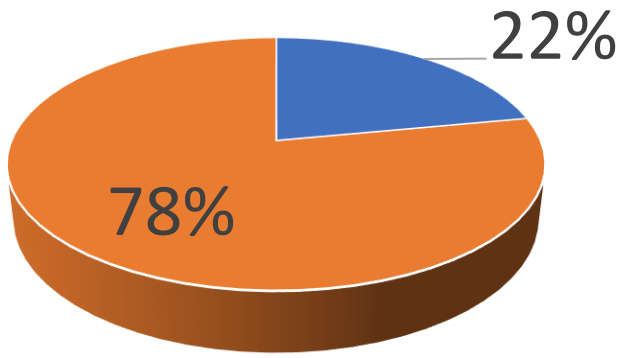
1. Petroll, A. E., Walsh, J. L., Owczarzak, J. L., McAuliffe, T. L., Bogart, L. M., & Kelly, J. A. (2017). PrEP Awareness, Familiarity, Comfort, and Prescribing Experience among US Primary Care Providers and HIV Specialists. AIDS and behavior, 21(5), 1256–1267.
2. Edelman EJ, Moore BA, Calabrese SK, Berkenblit G, Cunningham CO, Ogbuagu O, Patel VV, Phillips KA, Tetrault JM, Shah M, Blackstock O. Preferences for implementation of HIV pre-exposure prophylaxis (PrEP): Results from a survey of primary care providers. Prev Med Rep. 2019 Oct 21;17:101012. doi: 10.1016/j.pmedr.2019.101012. PMID: 31890474; PMCID: PMC6926349.

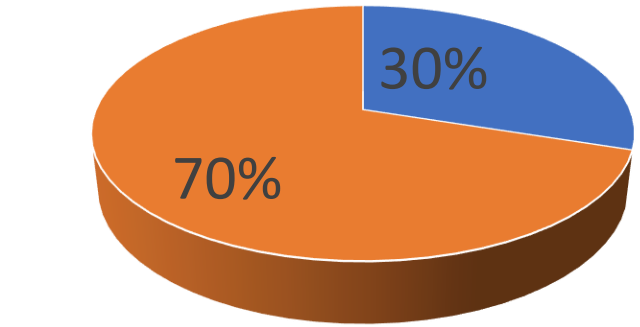
PrEP training is associated with increased provision of PrEP

*Residency programs with significant training in PrEP are **7x** more likely to have majority of "PrEP-appropriate" patients receiving PrEP.*

(Jasper et al., 2022)

Baseline:

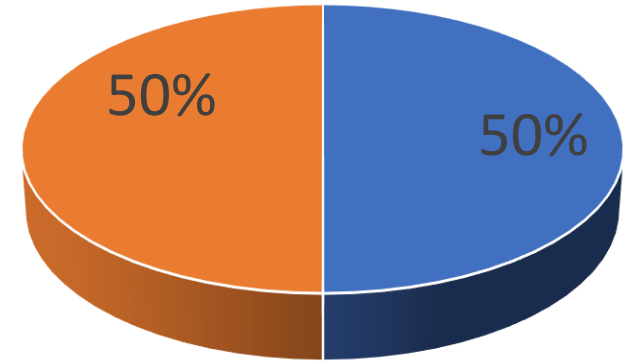




Intervention:

- 1hr didactics + learning modules
- order set/note template
- 2 page pocket guide

Results:



(Gregg et al., 2020)

Barriers: provider attitude

I am not comfortable prescribing for this purpose.

Informed him PrEP is effective only 50% of the time, maybe less.

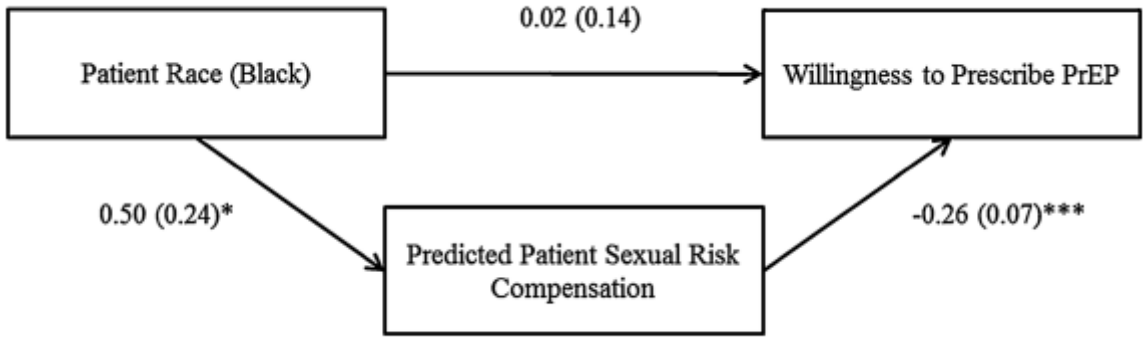
Tested for HIV, was neg. I informed him this medication is not provided for preventive measures, needs to protect himself by practicing safe sex and avoiding risky behaviors.

I suggested a monogamous relationship.

Skolnik, A.A., Bokhour, B.G., Gifford, A.L. et al. Roadblocks to PrEP: What Medical Records Reveal About Access to HIV Pre-exposure Prophylaxis. J GEN INTERN MED 35, 832–838 (2020). https://doi.org/10.1007/s11606-019-05475-9

Racial bias

Black patients were rated as more likely than White patients to engage in increased unprotected sex if prescribed PrEP, which, in turn, was associated with reduced willingness to prescribe PrEP to the patient.[1]

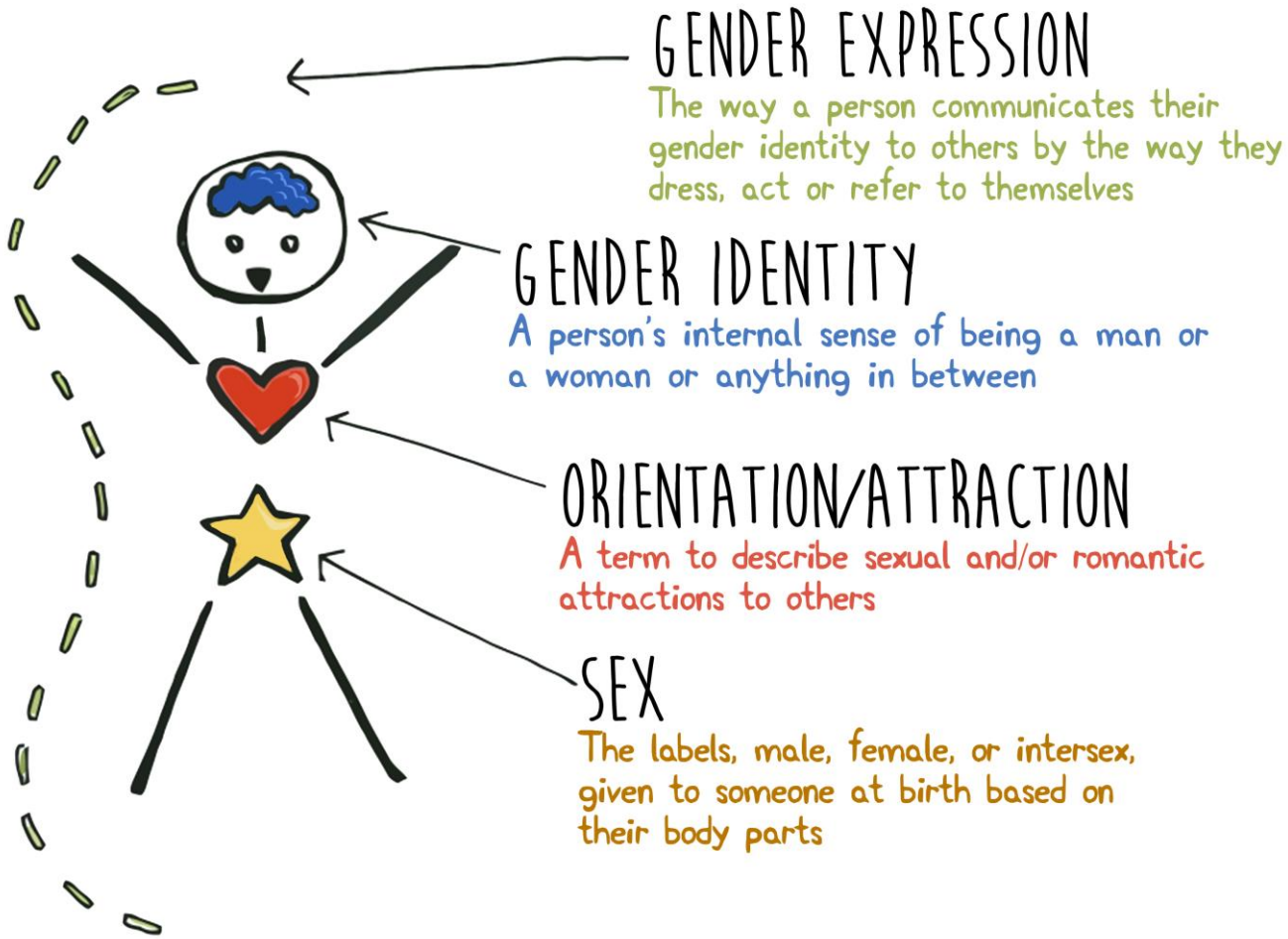


1.Calabrese, S.K., Earnshaw, V.A., Underhill, K. et al. The Impact of Patient Race on Clinical Decisions Related to Prescribing HIV Pre-Exposure Prophylaxis (PrEP): Assumptions About Sexual Risk Compensation and Implications for Access. AIDS Behav 18, 226–240 (2014). https://doi.org/10.1007/s10461-013-0675-x

Addressing barriers:

- Provider and staff training on cultural competency and bias.
- Developing clinic protocol or adopt existing protocol.
- Discuss PrEP with anyone who has sex or who asks for it.

History

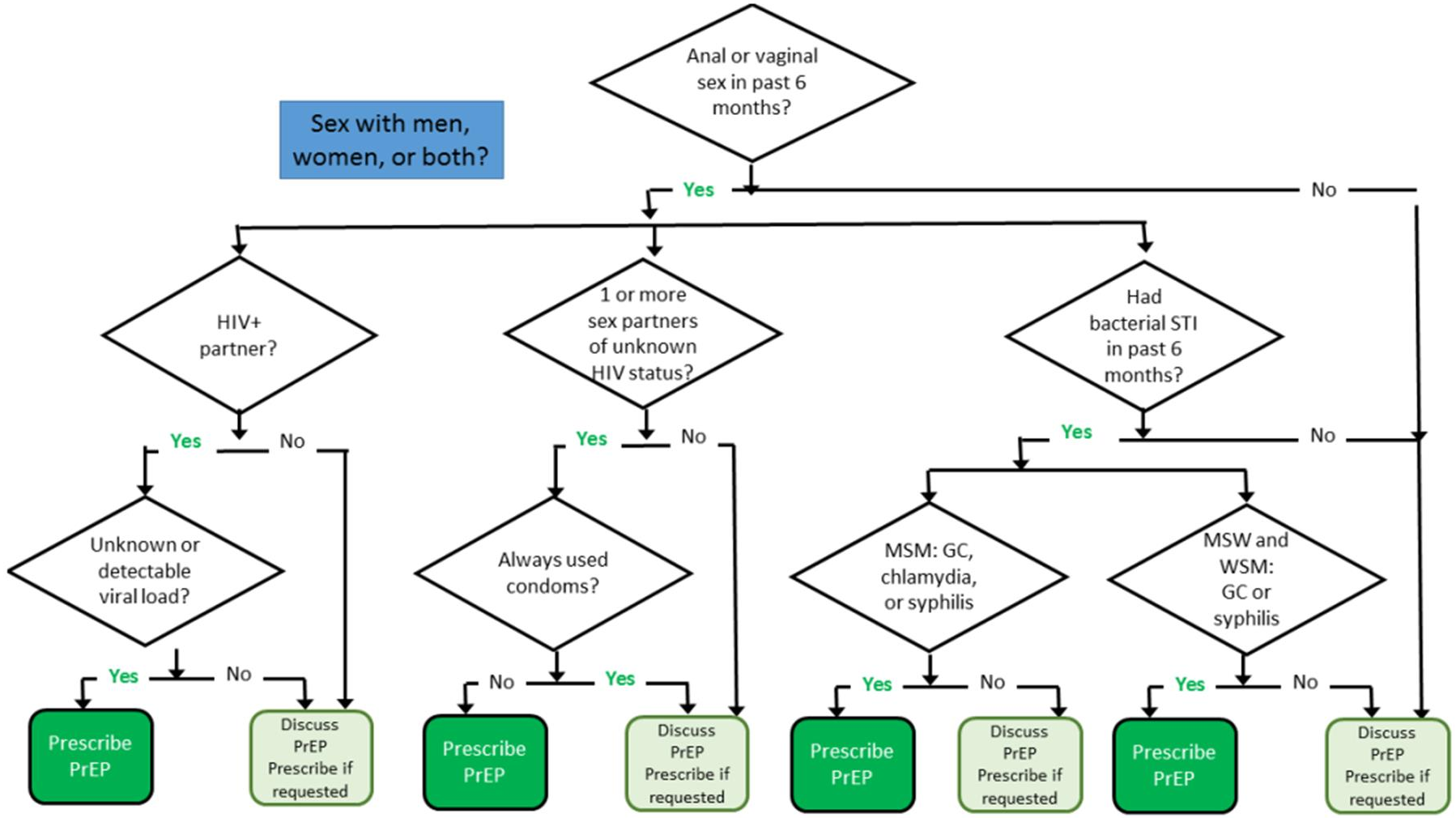


5-P's

- Partners
- Practice
- Protection/Past history of STI
- Pregnancy

- Injection drug use history

USPSTF: Grade A recommendation

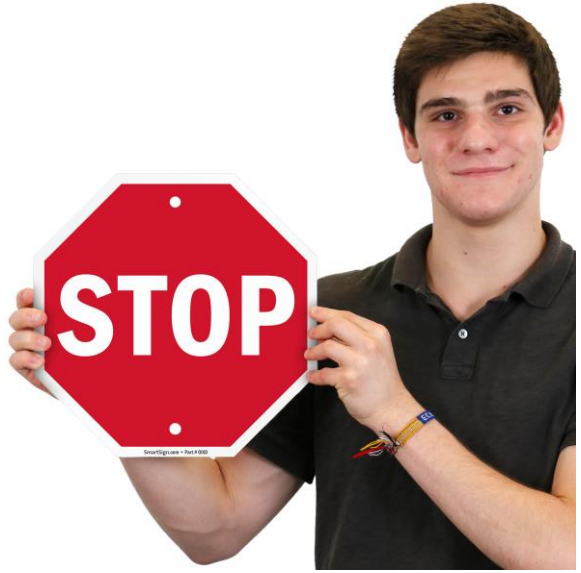


Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update Clinical Practice Guideline

Contraindications:

- HIV +
- Signs and symptoms of acute HIV infection/Or suspect HIV

- Renal impairment: GFR< 30 -> Consider Injectable PrEP



CDC PrEP clinical guideline

Table 1a: Summary of Clinician Guidance for Daily Oral PrEP Use

	Sexually-Active Adults and Adolescents[1]	Persons Who Inject Drug[2]
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: • HIV-positive sexual partner (especially if partner has an unknown or detectable viral load) • Bacterial STI in past 6 months[3] • History of inconsistent or no condom use with sexual partner(s)	HIV-positive injecting partner OR Sharing injection equipment
Clinically eligible	**ALL OF THE FOLLOWING CONDITIONS ARE MET:** • Documented negative HIV Ag/Ab test result within 1 week before initially prescribing PrEP • No signs/symptoms of acute HIV infection • Estimated creatinine clearance ≥30 ml/min[4] • No contraindicated medications	
Dosage	• Daily, continuing, oral doses of F/TDF (Truvada®), ≤90-day supply OR • For men and transgender women at risk for sexual acquisition of HIV; daily, continuing, oral doses of F/TAF (Descovy®), ≤90-day supply	
Follow-up care	**Follow-up visits at least every 3 months to provide the following:** • HIV Ag/Ab test and HIV-1 RNA assay, medication adherence and behavioral risk reduction support • Bacterial STI screening for MSM and transgender women who have sex with men[3] – oral, rectal, urine, blood • Access to clean needles/syringes and drug treatment services for PWID **Follow-up visits every 6 months to provide the following:** • Assess renal function for patients aged ≥50 years or who have an eCrCl <90 ml/min at PrEP initiation • Bacterial STI screening for all sexually-active patients[3] – [vaginal, oral, rectal, urine- as indicated], blood **Follow-up visits every 12 months to provide the following:** • Assess renal function for all patients • Chlamydia screening for heterosexually active women and men – vaginal, urine • For patients on F/TAF, assess weight, triglyceride and cholesterol levels	

PrEP Initiation

- Appropriateness for therapy
- Choice of agent (Truvada/Descovy)
- Counseling
- Do not prescribe more than 30days at the time of initiation.

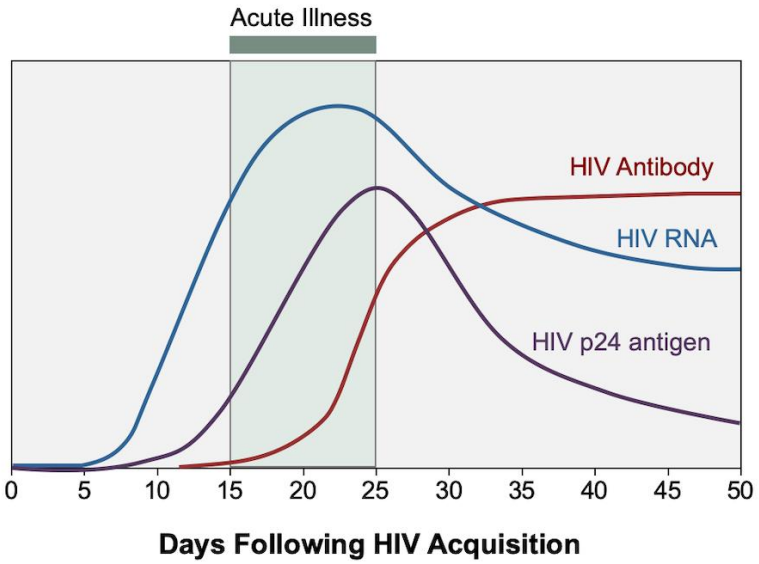
Labs at initial visit

- **Required-Determine eligibility:**

HIV- 4th gen ag/ab– documented HIV negative within 1 week of initiation.

If symptoms of acute HIV/High risk exposure – sent HIV RNA

Renal function



- **Recommended:**

STI testing

HBV/HCV

Pregnancy

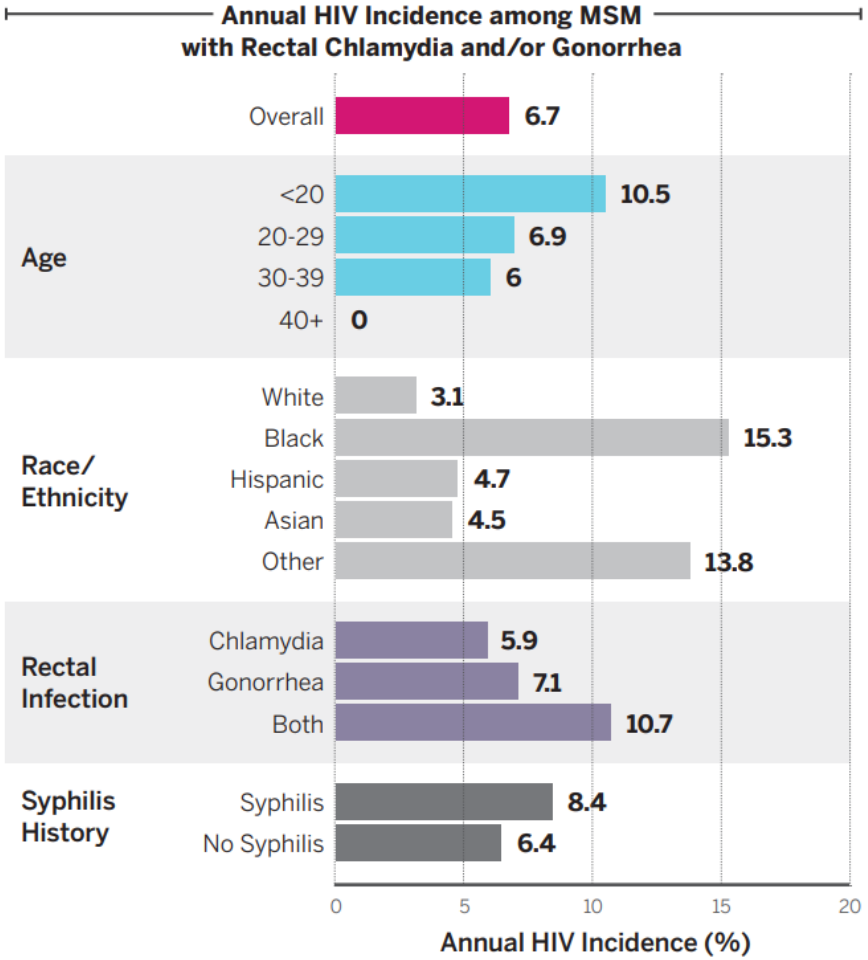
STI Testing:

- Syphilis testing for all adults prescribed PrEP, at initial and semi-annual.

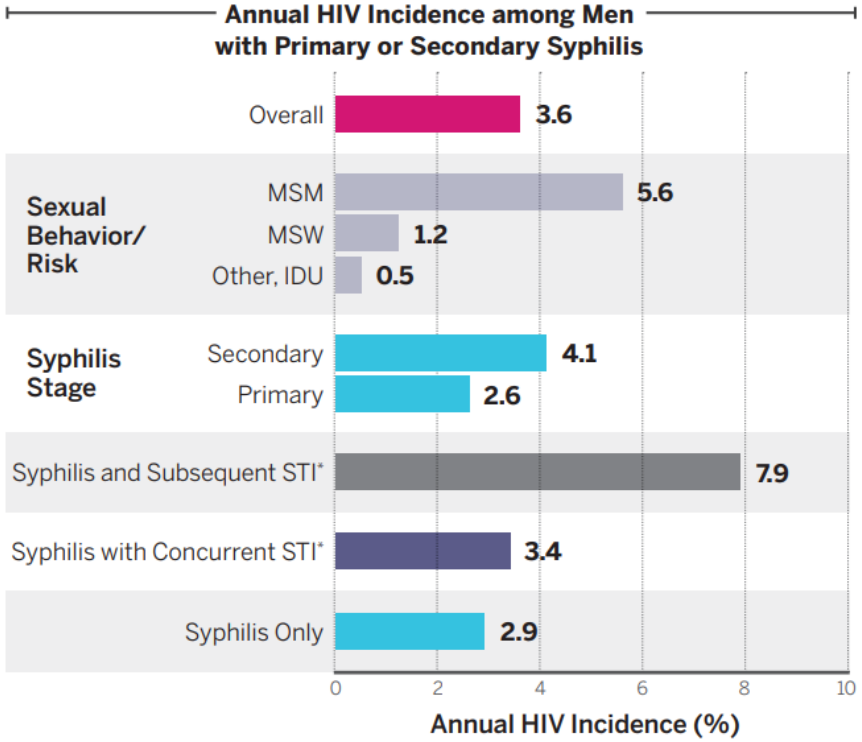
- GC/Chlamydia – MSM (Quarterly), Women (Semi-annual)
  - For MSM: **3-site test** approach is recommended.
  - Urine testing alone would have missed most infections with CT (74.6%) and GC (82.3%)[1].
  - Patient self-collected swabs has been shown to be equivalent to clinician collected swabs.

1. Ali F, Kaushik GN, Carr ND, Hayes E, Plax KL (2016) Screening for Urethral, Rectal and Pharyngeal Gonorrhea & Chlamydia among Asymptomatic Male Adolescents and Young Men who have Sex with Men. J Fam Med Dis Prev 2:046. 10.23937/2469-5793/1510046

1 in 15 MSM patients with rectal Gc/Ct acquires HIV within 1 year.



Source: Pathela P., et al. HIV incidence among men with and without sexually transmitted rectal infections: estimates from matching against an HIV case registry. *Clinical Infectious Diseases* (2013): 57(8) 1203-9.

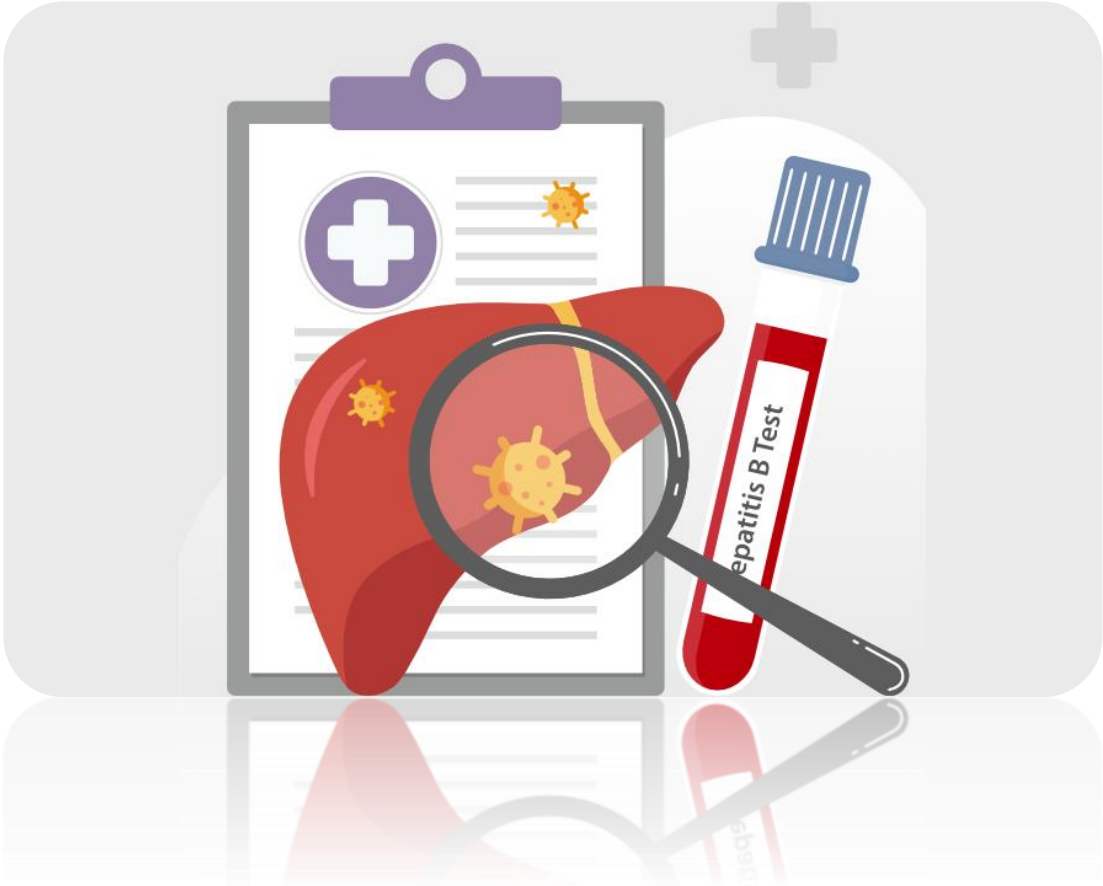


MSM=men who have sex with men
MSW=men who have sex with women
IDU=injection drug users
STI=sexually transmitted infection
*Includes diagnoses of chlamydia, gonorrhea or lymphogranuloma venereum

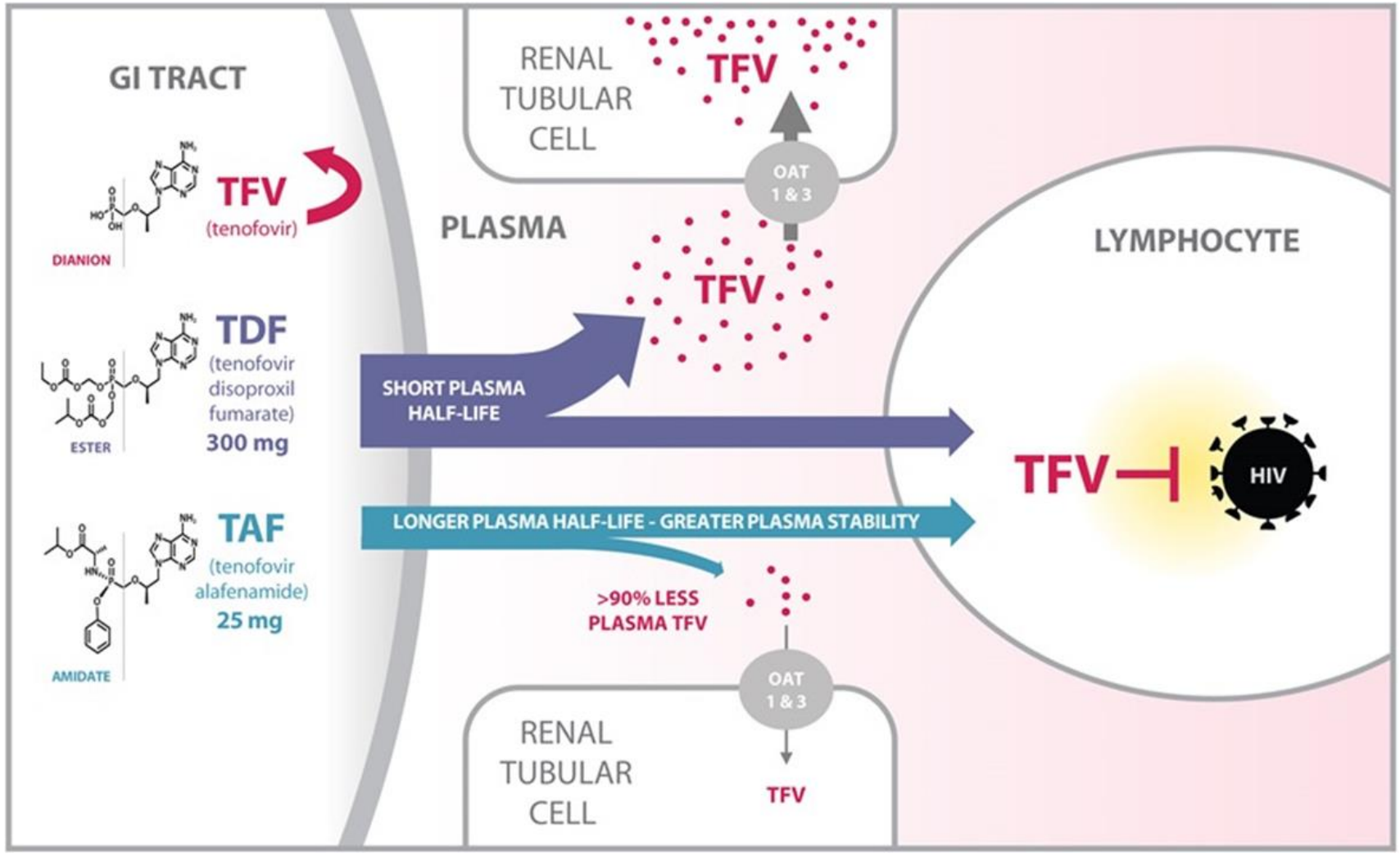
Source: Pathela P., et al. The high risk of an HIV diagnosis following a diagnosis of syphilis: a population-level analysis of New York City men. *Clinical Infectious Diseases* 61.2 (2015): 281-287.

Hepatitis B

- Routine screening prior to initiating PrEP.
- Tenofovir and Emtricitabine are both used to treat chronic HepB. Possible flare when discontinued.
- +HepB is not a contraindication, but consultation with infectious disease should be considered.

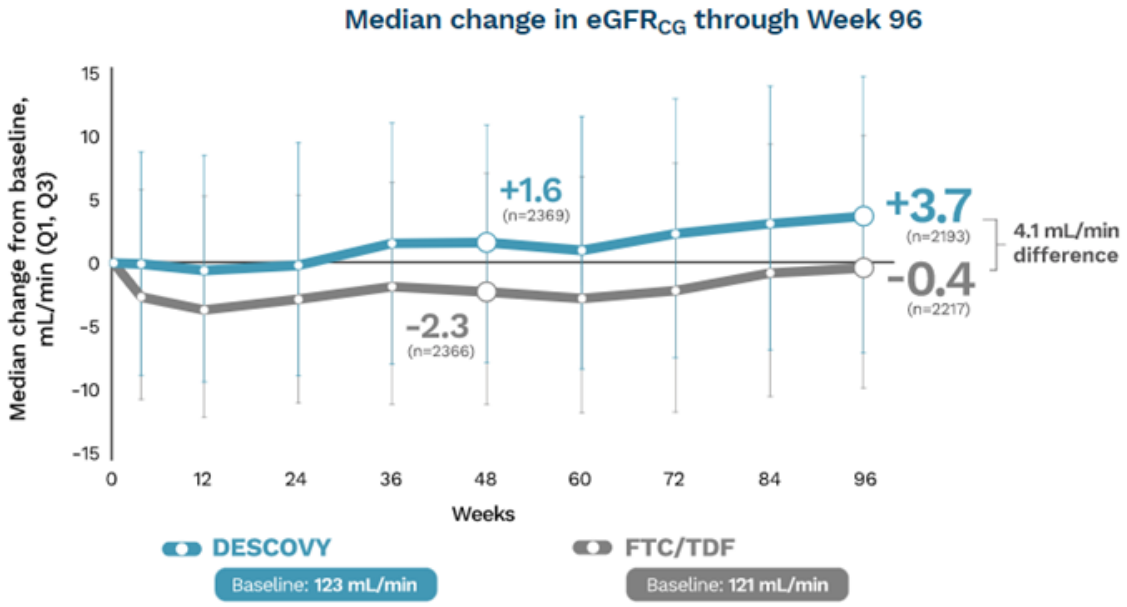


Truvada (FTC-TDF) vs Descovy (FTC-TAF)



Renal function

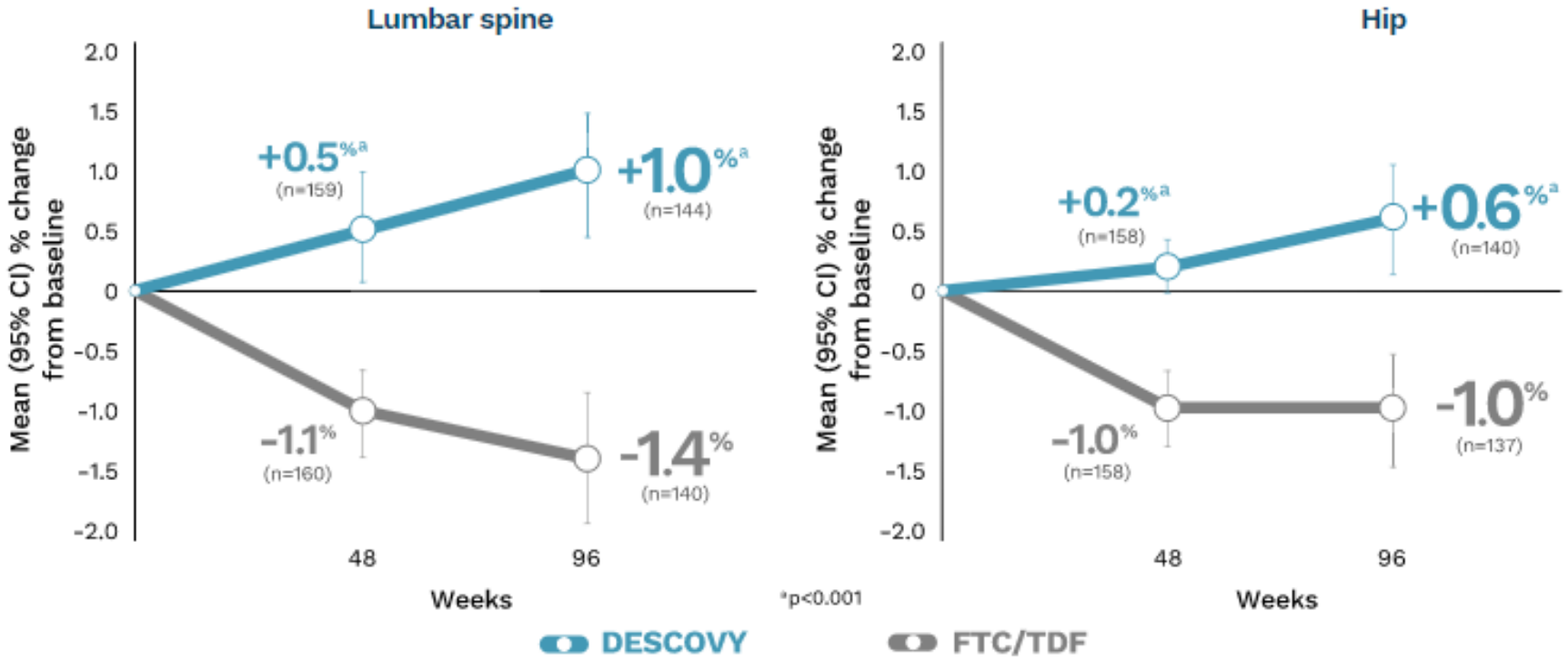
- Small/mild decrease in eGFR has been reported for both Truvada/Descovy.
- Rare, but reported cases for acute renal failure and Fanconi syndrome.
- No difference in clinically significant renal outcome between Truvada/Descovy.



Bone health

24% to 29% of participants in this substudy had osteopenia or osteoporosis at baseline

Mean % change in lumbar spine and hip BMD at Weeks 48 and 96 by DXA scans



The long-term clinical significance of changes in BMD is not known.

CDC currently does not recommend DEXA scan

Truvada (FTC-TDF) vs Descovy (FTC-TAF)

	Truvada/Generic	Descovy $
Regimen	Daily , 2-1-1 (Not FDA approved)	Daily
Indication	Gay & bisexual cis men Trans women Trans men Heterosexuals Cis women People who inject drugs	Gay & bisexual cis men Trans women
Safety	-May consider avoid at risk of kidney disease or osteoporosis -min eGFR>60 -Small weight loss	-Safer in patient with or at higher risk of kidney disease or osteoporosis -min eGFR>30 -Small weight gain/Increase LDL

Time to effectiveness

How long does PrEP take to work?

- For **receptive anal sex (bottoming),** PrEP pills reach maximum protection from HIV at about **7 days** of daily use.
- For **receptive vaginal sex** and **injection drug use**, PrEP pills reach maximum protection at about **21 days** of daily use.
- No data are available for PrEP pill effectiveness for **insertive anal sex (topping)** or **insertive vaginal sex**.
- We don't know how long it takes for PrEP shots to reach maximum protection during sex.

1 Month follow-up visit

- 1 Month

- Assess/counsel on adherence to daily dosing
- Assess risk behaviors; counsel
- Labs: HIV test, Renal function, STI testing as needed
- Prescribe 90day supply, no refills.

3-6Month follow-up visit

3 Month

- Assess adherence to daily dosing, risk behaviors.
- HIV every 3months

- STI testing:
  - Every 3 months for MSM
  - Semi annually for heterosexual men/women even if asymptomatic

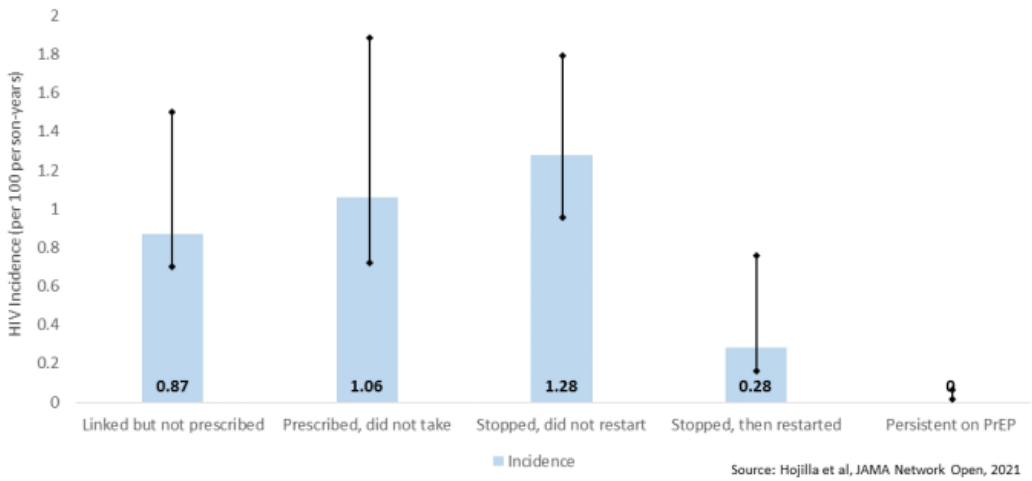
- Renal function:
  - Every 6 months: Age >50, baseline abnormal eGFR, risk factor (DM, HTN…etc).
  - Every 12 month for all PrEP patients

- Lipid panel: Annually if prescribed Descovy.

At discontinuation of therapy

- Protection wane within 7-10days.
- Continuing until 1 month post last high risk activity
- HIV test at time of discontinuation.
- Document reason for discontinuation, recent medication adherence, and risk behaviors.

Figure 6 HIV Incidence in MSM Before, While Taking, and After Discontinuing F/TDF PrEP Use[140, 141]



Source: Hojilla et al, JAMA Network Open, 2021

Pregnancy and breastfeeding

World Health Organization (WHO)

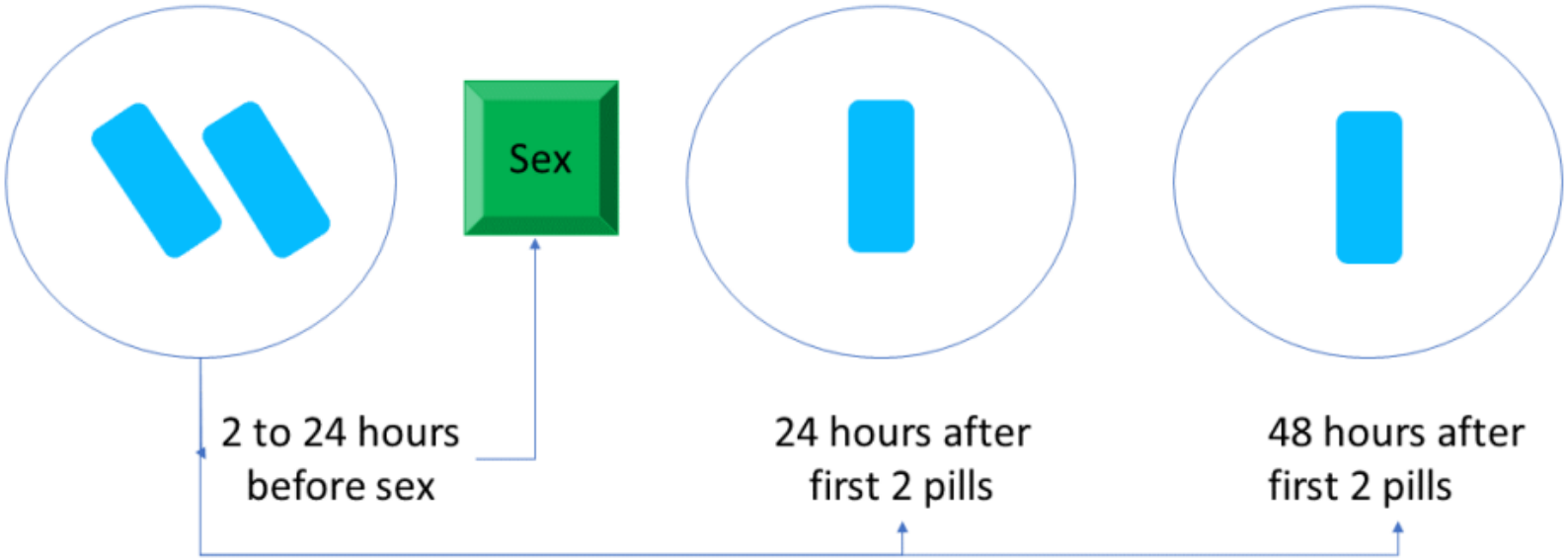
- WHO supports provision of PrEP to pregnant and breastfeeding people (PBFP) who are at continuing substantial risk of HIV infection.

ACOG

- Can use PrEP when trying to become pregnant, and during pregnancy. Esp if partner viral load is detectable or unknown.
- Can be used during breastfeeding if mother continues to be at risk of HIV infection.
- There are no known reports of birth defects caused by PrEP.

On demand PrEP – off label use

- Endorsed in Europe/British/WHO guidelines, but not FDA approved.
- IPREGAY/PREVENIR: 87% relative risk reduction but take avg 4 or more pills weekly.
- Prescribe only 30day supply at a time.



Examples of other clinical protocol

PrEP in Primary Care

Pre-exposure prophylaxis (PrEP) is an effective way to prevent HIV infection for people who are at high risk.

The FDA approved medication for PrEP consists of tenofovir (TDF) 300 mg and emtricitabine (FTC) 200 mg (Truvada) combined into a single tablet taken once daily

To prescribe PrEP at WLA VA, prescribers need to complete **TMS training #36785** then submit certificate for approval. Prescribers will be notified when approved.

Assess HIV Risk
- Discuss sexual health and practices
- Discuss injection drug use

Indications for PrEP
- Any Veteran who has sex and/or shares injection equipment with HIV infected or HIV status unknown individuals

Assess for CURRENT HIV infection
- Order HIV testing. Negative test must result within 1 week of starting PrEP.
- Check for s/sx of acute HIV infection
- ***Do NOT use PrEP in Veterans with positive HIV testing or strong suspicion for recent exposure***

Check Other Baseline Labs
- Creatinine clearance (Consider PrEP only in Veterans with CrCl >= 60 mL/min.)
- STIs: gonnorhea/chlamydia (GC/CT), syphilis (RPR)
- Pregnancy status (not a contraindication)
- Hep B/C (not a contraindication but may need additional evaluation)

Prescribe PrEP
- Truvada 1 tab PO daily
- INITIATE with no more than 30-day supply & REFILL with no more than 90-day supply
- Adherence determines efficacy

Follow-up
- 1 month: Repeat HIV test
- Q 3 months: HIV status
- Q 6 months: STI and Creatinine clearance
- Annually: Reassess need

Sexual History Questions: The Five P's

Partners
- Do you have sex with men, women, or both?
- In the past 6 months, have you had unprotected sex? With anyone who's HIV status you did not know?
- Is it possible that any of your sex partners in the past year had sex with someone else while they were still in a sexual relationship with you?

Practices
- Can you describe the type of sex you have with your partner(s)?
- Do you use barrier protection (condoms, dental dams, rubber gloves, etc.) or other types of protection? If not, why not? If sometimes, in what situations do you use protection?
- Have you ever had sex in exchange for something you needed (food, shelter, drugs, $$)?
- Is there anything else I should know about your sexual practices?

Protection from and Past history of sexually transmitted infections (STIs)
- Do you know your HIV status?
- Past history of STIs? Are you concerned about getting an STI?
- How do you protect yourself from STIs and HIV?
- Have any of your partners had STIs?

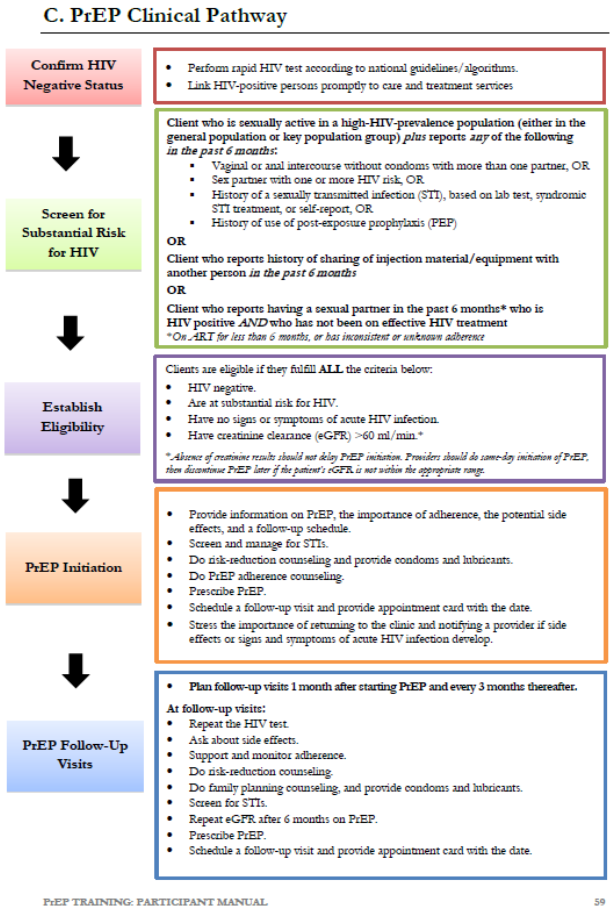
Pregnancy
- What are your plans regarding pregnancy?
- What (if anything) are you doing to prevent pregnancy?

Injection Drug History Questions

Put questions in context: "Some of my patients have used drugs, such as heroin, cocaine or methamphetamine--- have you ever used drugs?"
- Have you ever injected drugs that were not prescribed for you or in a way other than were prescribed to you by a health care provider? If yes:
  - When did you last inject drugs that were not prescribed for you?
  - In the past 6 months, have you injected using needles, syringes, or other drug preparation equipment that had already been used by another person?
  - In the past 6 months, have you been in a methadone, buprenorphine/naloxone, or other medication-based drug treatment program?

At minimum, a sexual health hx should be performed on an annual basis OR when NEW risk factors are identified

Examples of other clinical protocol



C. PrEP Clinical Pathway

Confirm HIV Negative Status

- Perform rapid HIV test according to national guidelines/algorithms.
- Link HIV-positive persons promptly to care and treatment services

Screen for Substantial Risk for HIV

Client who is sexually active in a high-HIV-prevalence population (either in the general population or key population group) *plus* reports *any* of the following *in the past 6 months*:

- Vaginal or anal intercourse without condoms with more than one partner, OR
- Sex partner with one or more HIV risk, OR
- History of a sexually transmitted infection (STI), based on lab test, syndromic STI treatment, or self-report, OR
- History of use of post-exposure prophylaxis (PEP)

OR

Client who reports history of sharing of injection material/equipment with another person *in the past 6 months*

OR

Client who reports having a sexual partner in the past 6 months* who is HIV positive *AND* who has not been on effective HIV treatment

**On ART for less than 6 months, or has inconsistent or unknown adherence*

Establish Eligibility

Clients are eligible if they fulfill **ALL** the criteria below:

- HIV negative.
- Are at substantial risk for HIV.
- Have no signs or symptoms of acute HIV infection.
- Have creatinine clearance (eCFR) >60 ml/min.*

**Absence of creatinine results should not delay PrEP initiation. Providers should do same-day initiation of PrEP, then discontinue PrEP later if the patient's eGFR is not within the appropriate range.*

PrEP Initiation

- Provide information on PrEP, the importance of adherence, the potential side effects, and a follow-up schedule.
- Screen and manage for STIs.
- Do risk-reduction counseling and provide condoms and lubricants.
- Do PrEP adherence counseling.
- Prescribe PrEP.
- Schedule a follow-up visit and provide appointment card with the date.
- Stress the importance of returning to the clinic and notifying a provider if side effects or signs and symptoms of acute HIV infection develop.

PrEP Follow-Up Visits

- **Plan follow-up visits 1 month after starting PrEP and every 3 months thereafter.**

At follow-up visits:

- Repeat the HIV test.
- Ask about side effects.
- Support and monitor adherence.
- Do risk-reduction counseling.
- Do family planning counseling, and provide condoms and lubricants.
- Screen for STIs.
- Repeat eGFR after 6 months on PrEP.
- Prescribe PrEP.
- Schedule a follow-up visit and provide appointment card with the date.

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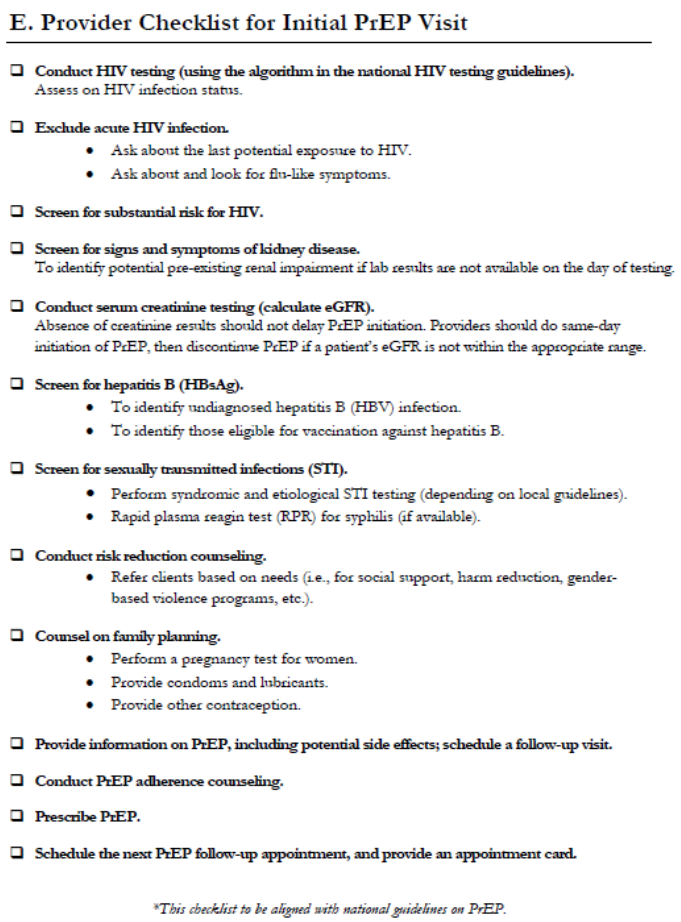
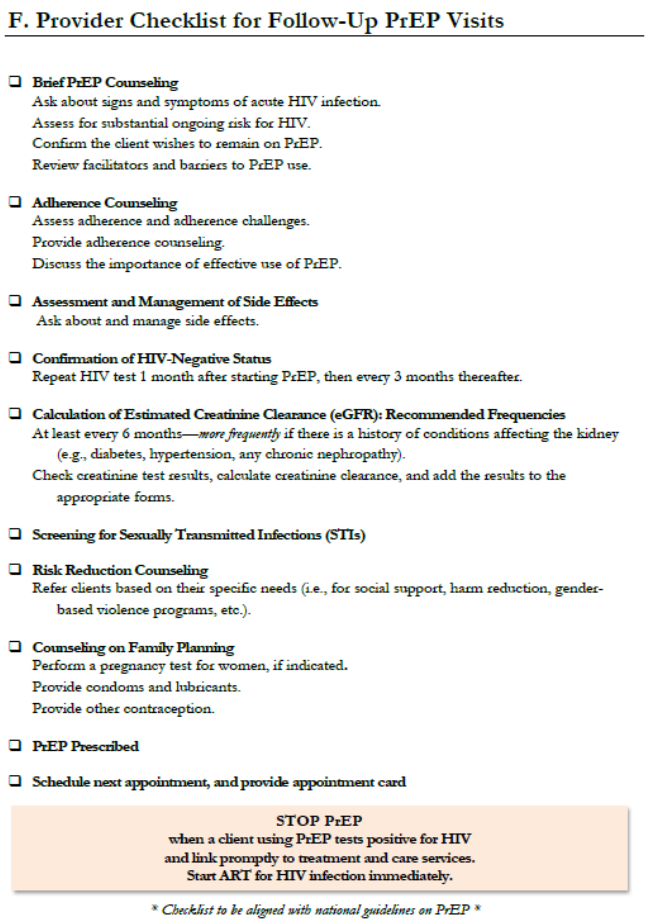


E. Provider Checklist for Initial PrEP Visit

- ❑ **Conduct HIV testing (using the algorithm in the national HIV testing guidelines).**
  Assess on HIV infection status.
- ❑ **Exclude acute HIV infection.**
  - Ask about the last potential exposure to HIV.
  - Ask about and look for flu-like symptoms.
- ❑ **Screen for substantial risk for HIV.**
- ❑ **Screen for signs and symptoms of kidney disease.**
  To identify potential pre-existing renal impairment if lab results are not available on the day of testing.
- ❑ **Conduct serum creatinine testing (calculate eGFR).**
  Absence of creatinine results should not delay PrEP initiation. Providers should do same-day initiation of PrEP, then discontinue PrEP if a patient's eGFR is not within the appropriate range.
- ❑ **Screen for hepatitis B (HBsAg).**
  - To identify undiagnosed hepatitis B (HBV) infection.
  - To identify those eligible for vaccination against hepatitis B.
- ❑ **Screen for sexually transmitted infections (STI).**
  - Perform syndromic and etiological STI testing (depending on local guidelines).
  - Rapid plasma reagin test (RPR) for syphilis (if available).
- ❑ **Conduct risk reduction counseling.**
  - Refer clients based on needs (i.e., for social support, harm reduction, gender-based violence programs, etc.).
- ❑ **Counsel on family planning.**
  - Perform a pregnancy test for women.
  - Provide condoms and lubricants.
  - Provide other contraception.
- ❑ **Provide information on PrEP, including potential side effects; schedule a follow-up visit.**
- ❑ **Conduct PrEP adherence counseling.**
- ❑ **Prescribe PrEP.**
- ❑ **Schedule the next PrEP follow-up appointment, and provide an appointment card.**

**This checklist to be aligned with national guidelines on PrEP.*



F. Provider Checklist for Follow-Up PrEP Visits

- ❑ **Brief PrEP Counseling**
  Ask about signs and symptoms of acute HIV infection.
  Assess for substantial ongoing risk for HIV.
  Confirm the client wishes to remain on PrEP.
  Review facilitators and barriers to PrEP use.
- ❑ **Adherence Counseling**
  Assess adherence and adherence challenges.
  Provide adherence counseling.
  Discuss the importance of effective use of PrEP.
- ❑ **Assessment and Management of Side Effects**
  Ask about and manage side effects.
- ❑ **Confirmation of HIV-Negative Status**
  Repeat HIV test 1 month after starting PrEP, then every 3 months thereafter.
- ❑ **Calculation of Estimated Creatinine Clearance (eGFR): Recommended Frequencies**
  At least every 6 months—*more frequently* if there is a history of conditions affecting the kidney (e.g., diabetes, hypertension, any chronic nephropathy).
  Check creatinine test results, calculate creatinine clearance, and add the results to the appropriate forms.
- ❑ **Screening for Sexually Transmitted Infections (STIs)**
- ❑ **Risk Reduction Counseling**
  Refer clients based on their specific needs (i.e., for social support, harm reduction, gender-based violence programs, etc.).
- ❑ **Counseling on Family Planning**
  Perform a pregnancy test for women, if indicated.
  Provide condoms and lubricants.
  Provide other contraception.
- ❑ **PrEP Prescribed**
- ❑ **Schedule next appointment, and provide appointment card**

STOP PrEP
when a client using PrEP tests positive for HIV
and link promptly to treatment and care services.
Start ART for HIV infection immediately.

** Checklist to be aligned with national guidelines on PrEP **

Summary

- Significant gap still exists in provision of PrEP to reach the national goal of 50% by 2030.
- There is inequitable provision of PrEP in racial groups, and systemic/provider bias contributes to this gap in care. Training in implicit bias must be incorporated.
- PrEP is highly effective and should be made available to everyone who is HIV negative.
- Initiating oral PrEP is oftentimes straightforward, and there are plenty of easy-to-access resources and established protocol to help with this.

Thank you!

Any questions?

You can email me at:

lwang@crhc.org

Trouble Shooting 

- Start up syndrome

- ~10% will experience “start up syndrome”.
- Most commonly GI, nausea, headache.
- Transient, self-resolves usually within 1 month.
- Manage with OTC

- Missed dose

- Not to panic.
- Take the dose as soon as you remember it.
- Resume normal schedule.

- If close to normal schedule, just take the normal dose slightly earlier.

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WHO

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