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NHMA
National Hispanic Medical Association

PrEP 101: Increasing Uptake of PrEP in the Hispanic and Latinx Community

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This activity is jointly provided by the Postgraduate Institute for Medicine and the American Academy of HIV Medicine.

This activity is supported by independent educational grants from Gilead Sciences, Janssen Therapeutics, and ViiV Healthcare.

Target Audience

This activity has been designed to meet the educational needs of physicians, physician assistants, nurse practitioners, and pharmacists; other healthcare providers, such as nurses, nutritionists, social workers, and case managers are also encouraged to attend.

Statement of Need/Program Overview

Academy credentialed providers and members are very adept at prescribing and retaining patients on PrEP, however, shelter in place and stay at home orders from the early COVID pandemic in the U.S. interrupted patients abilities to test for HIV and STIs and have associated laboratory monitoring. Recognizing that the recommended quarterly testing and monitoring requirements may serve as a barrier to engaging and retaining “hard to reach” patients that may benefit rom PrEP. This series will serve as an elevated discussion on higher-level PrEP topics including different formulations of PrEP and when to use them; HIV testing, laboratory monitoring, and taking a sexual health history; interpreting clinical laboratory information for the rare adherent patient that fails on PrEP and recommendations for initial ARV treatment therapies, future PrEP formulations, and how to reach and retain hard to engage PrEP patients.

Joint Accreditation Statement

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

Physician Continuing Medical Education

CREDIT DESIGNATION

- The Postgraduate Institute for Medicine designates this live activity for a maximum of 0.75 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Pharmacist Continuing Education

CREDIT DESIGNATION

- Postgraduate Institute for Medicine designates this continuing education activity for 0.75 contact hour(s) (0.075 CEUs) of the Accrediting Council for Pharmacy Education. Universal Activity Number #UAN - JA4008162-9999-22-189-L02-P.
- Type of Activity: Knowledge

Nursing Continuing Education

CREDIT DESIGNATION

- The maximum number of hours awarded for this Continuing Nursing Education Activity is 0.75 contact hours. Designated for 0.5 contact hours of pharmacotherapy credit for Advanced Practice Registered Nurses.

Disclosure Information

Disclosure of Conflicts of Interest

Postgraduate Institute for Medicine (PIM) requires instructors, planners, managers, and other individuals who are in a position to control the content of this activity to disclose any real or apparent conflict of interest (COI) they may have as related to the content of this activity. All identified COI are thoroughly vetted and resolved according to PIM policy. PIM is committed to providing its learners with high quality activities and related materials that promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

Faculty Disclosures:

- Carly Floyd has nothing to disclose.

Planners and Managers Disclosures

American Academy of HIV Medicine (AAHIVM)

The Academy planners and managers have nothing to disclose

Postgraduate Institute of Medicine (PIM)

The PIM planners and managers have nothing to disclose

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In this activity the faculty do discuss the use of investigational antiretroviral agents and treatment regimens that are not approved by treatment guidelines.

Disclaimer

Participants have an implied responsibility to use the newly acquired information to enhance patient outcomes and their own professional development. The information presented in this activity is not meant to serve as a guideline for patient management. Any procedures, medications, or other courses of diagnosis or treatment discussed or suggested in this activity should not be used by clinicians without evaluation of their patient's conditions and possible contraindications on dangers in use, review of any applicable manufacturer's product information, and comparison with recommendations of other authorities.

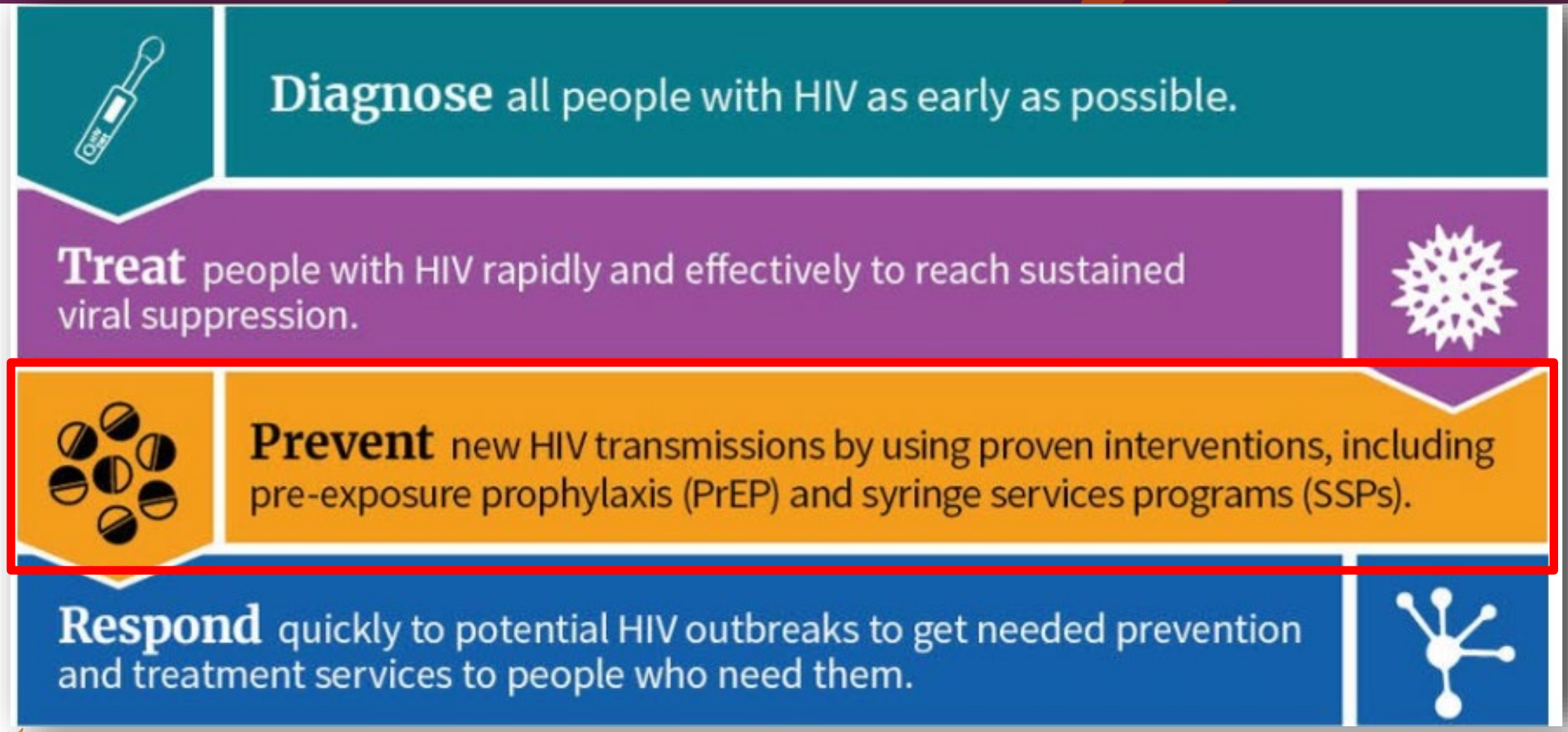
Fee Information

There is no fee for this educational activity.

Program Learning Objectives

- Differentiate HIV pre-exposure prophylaxis (PrEP) from HIV post-exposure prophylaxis (PEP) and identify the indications for each.
- Identify appropriate candidates for HIV PrEP and PEP.
- Recognize the key counseling points & monitoring parameters for HIV PrEP regimens.
- Understand challenges and opportunities to reach populations in need of HIV prevention, including Hispanic and Latinx communities.

HIV National Strategic Plan 2021-2025



https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview
https://files.hiv.gov/s3fs-public/HIV-National-Strategic-Plan-2021-2025.pdf

Reducing Acquisition of HIV

- Increased testing & linkage to care
- Delayed or fewer partners
- Less risky activities
- Increased condom use
- Empowerment & negotiation skills
- Reducing alcohol & drug use
- Reduce psychosocial barriers
- Circumcision
- STI treatment
- HIV PEP & HIV PrEP

Let's Talk About Sex

Recognizing and Supporting Patients Who May Benefit From PrEP

New prescriptions for bacterial STIs or HIV post-exposure prophylaxis can prompt assessment for PrEP eligibility

Sexual history taking

Partners	Practices	Past History of STDs	Protection From STDs	Pregnancy Plans

HIV risk reduction counseling

- ✓ Limiting number of sexual partners
- ✓ Ask partner about their sexual partners
- ✓ Consistent condom use
- ✓ Regular HIV testing
- ✓ Testing and treatment of other STIs
- ✓ Ask HIV-positive partner(s) about their HIV medications and viral load (U = U)

U=U
UNDETECTABLE = UNTRANSMITTABLE

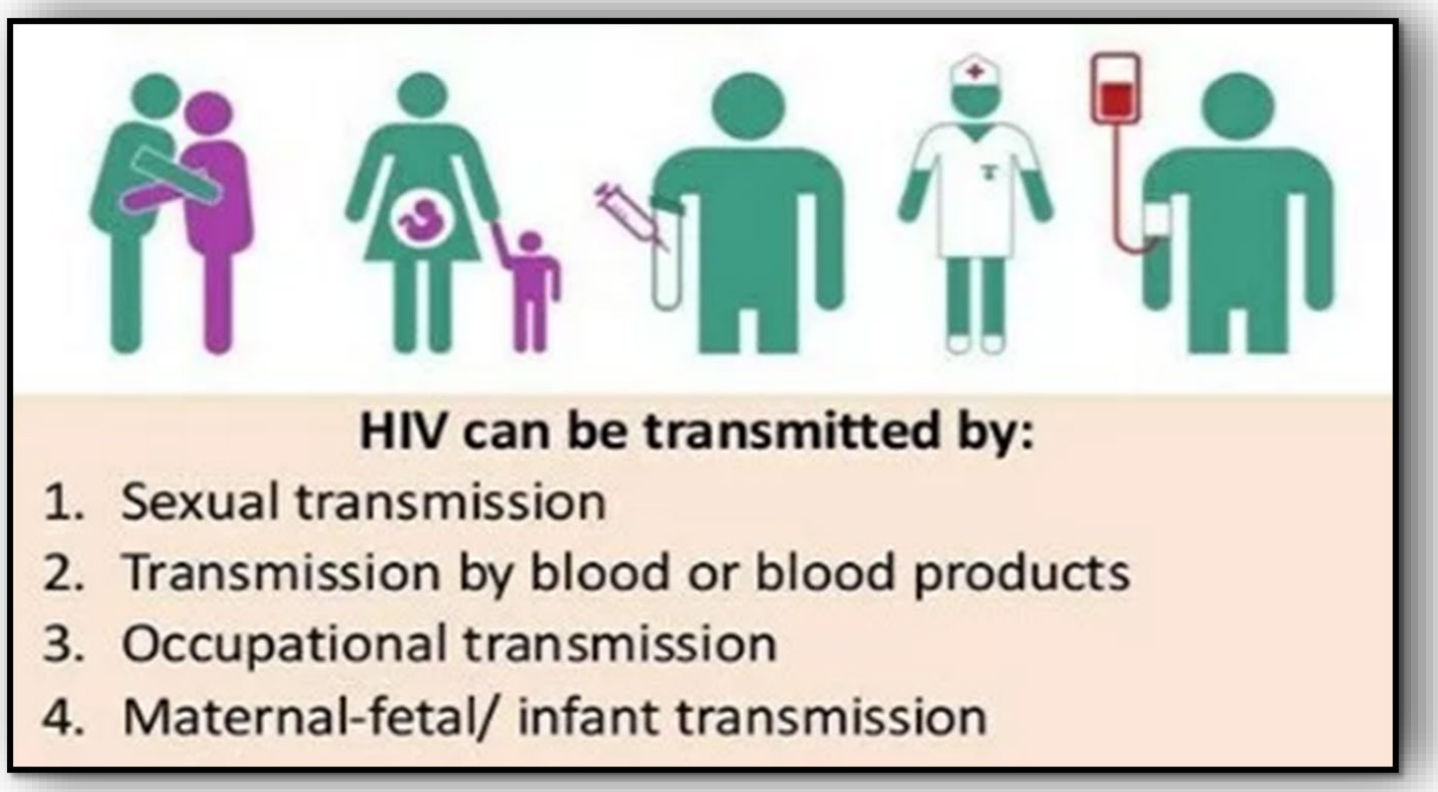
CDC. A Guide to Taking a Sexual History. Available at: https://www.cdc.gov/std/treatment/sexualhistory.pdf. Accessed 6/15/2021;

Risks of HIV

- 1.2 million people are at increased risk for acquiring HIV and would benefit from PrEP
- Barriers:
  - Misinformation about HIV risk within sexual networks and via social media
  - Lack of access to healthcare (COVID-19 impact)
  - HIV stigma
  - Lack of discussions on importance of HIV & STI prevention in healthcare

https://www.cdc.gov/stophivtogether/campaigns/hiv-stigma/index.html

HIV Transmission Risks



Potentially infectious fluids:

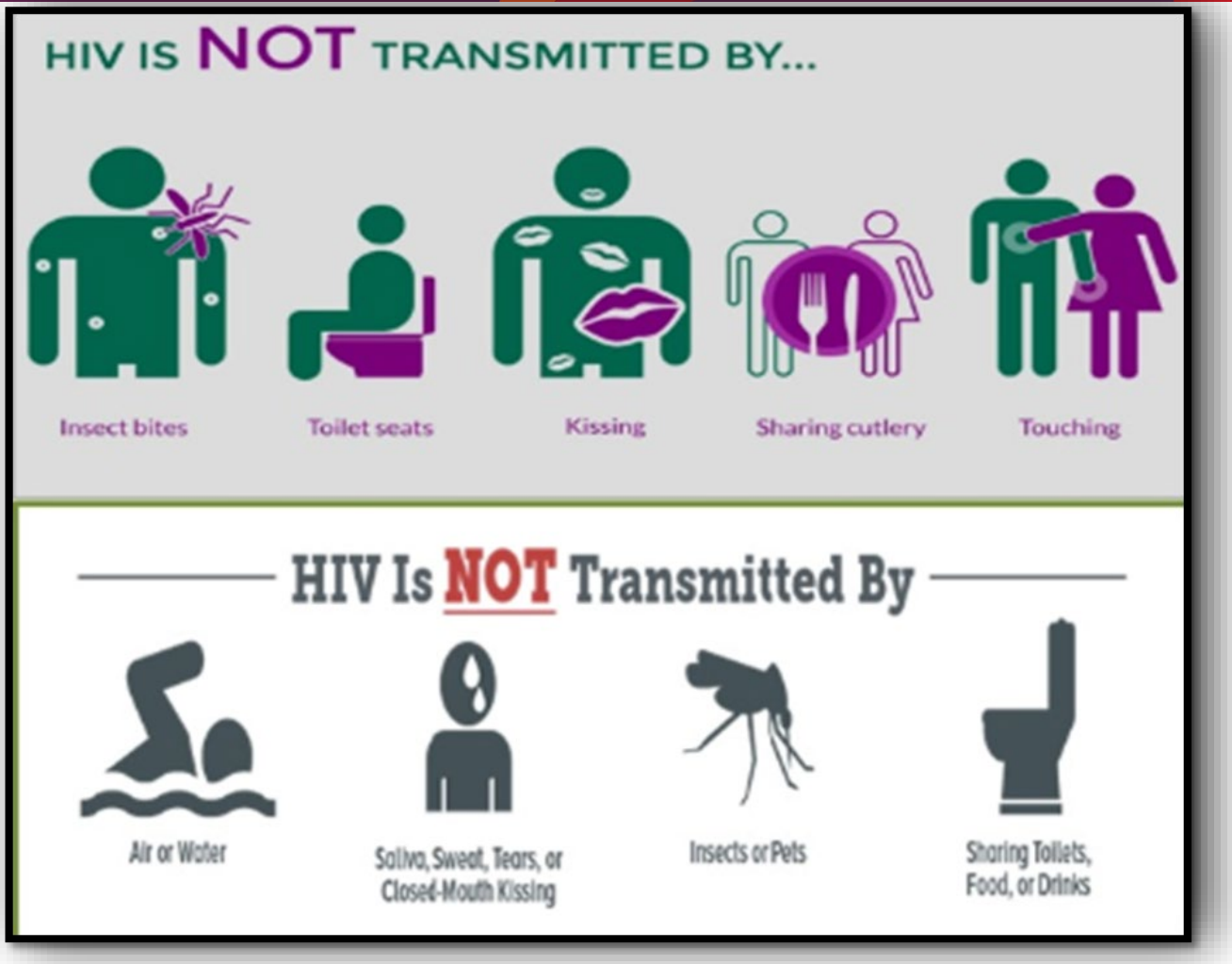
- blood, breast milk, tissue, semen, vaginal secretions, visibly bloody fluids
- exposure across mucosal surface, open wound, or injection

https://www.cdc.gov/hiv/risk/estimates/riskbehaviors.html

HIV Transmission Risks

Not infectious:

- Urine
- Saliva
- Sweat
- Tears
- Nasal secretions
- Sputum vomitus
- Stool



https://www.cdc.gov/hiv/risk/estimates/riskbehaviors.html
Image: https://healthylife.werindia.com/your-road-to-healthy-life/hiv-is-not-transmitted-by

HIV Transmission Risks

Higher Risk

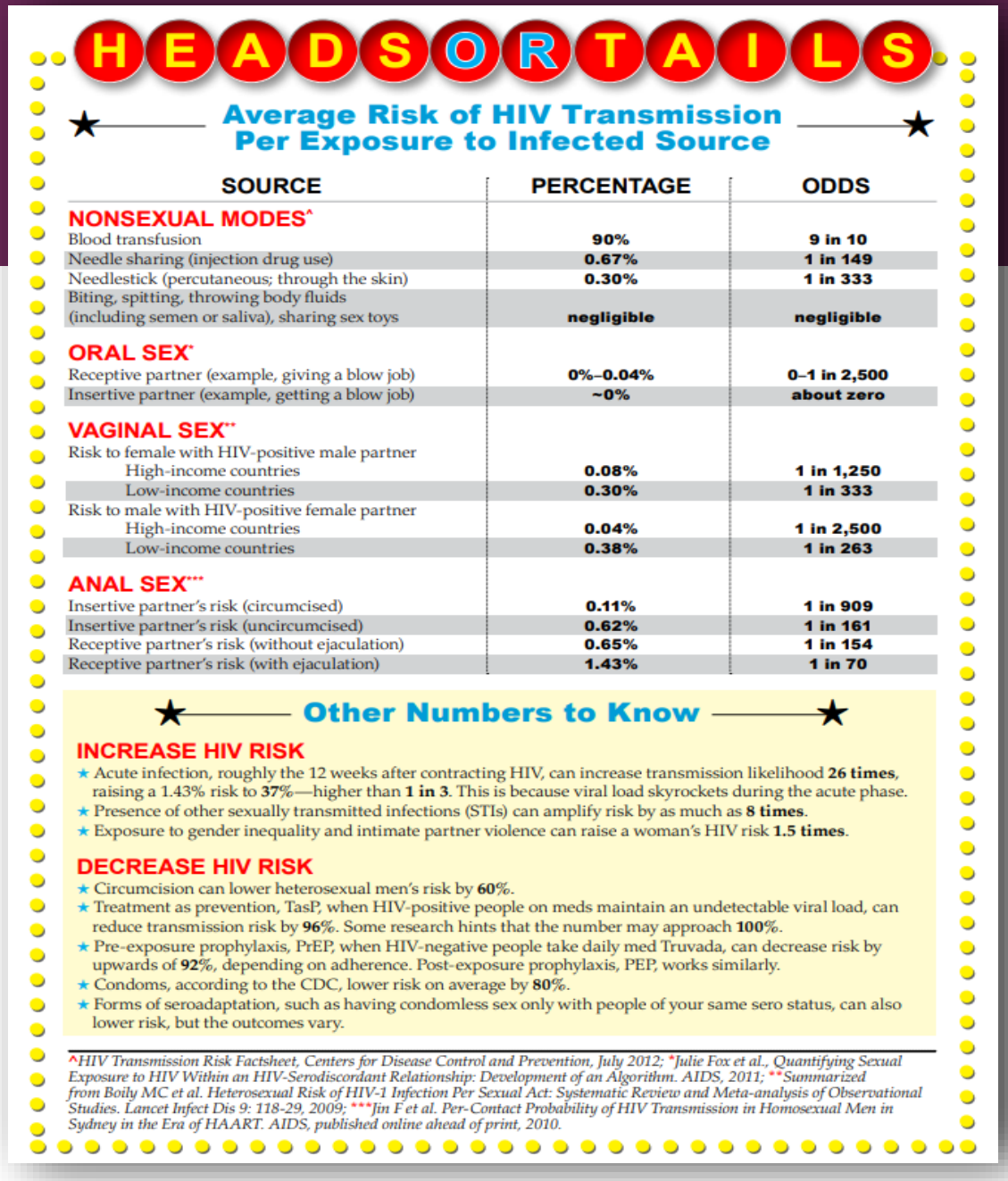
- receptive anal sex
  - per episode: 0.3 - 3%
- needle sharing
  - per episode: 0.67%

Lower Risk

- oral sex
  - per episode: 0.06%
- insertive sex
  - per episode 0.03 – 0.14%

1. Bell DM. Am J Med 1997;102(suppl5B):9--15. 2. Ippolito G et al. Arch Int Med 1993;153:1451--8. 3. Am J Epi 1999; 150:306-11. 4. MMWR 47;RR-17, 1998. 5. NEJM 336(15):1072-8. 6. Am J Epi 1999;150:306-11. 7. Rothenberg RB et al. AIDS 1998;12:2095-2105. 8. MMWR 47;RR-17, 1998.

Risk Reference



HEADSORTAILS

Average Risk of HIV Transmission Per Exposure to Infected Source

SOURCE	PERCENTAGE	ODDS
NONSEXUAL MODES^		
Blood transfusion	90%	9 in 10
Needle sharing (injection drug use)	0.67%	1 in 149
Needlestick (percutaneous; through the skin)	0.30%	1 in 333
Biting, spitting, throwing body fluids (including semen or saliva), sharing sex toys	negligible	negligible
ORAL SEX*		
Receptive partner (example, giving a blow job)	0%–0.04%	0–1 in 2,500
Insertive partner (example, getting a blow job)	~0%	about zero
VAGINAL SEX**		
Risk to female with HIV-positive male partner		
High-income countries	0.08%	1 in 1,250
Low-income countries	0.30%	1 in 333
Risk to male with HIV-positive female partner		
High-income countries	0.04%	1 in 2,500
Low-income countries	0.38%	1 in 263
ANAL SEX***		
Insertive partner's risk (circumcised)	0.11%	1 in 909
Insertive partner's risk (uncircumcised)	0.62%	1 in 161
Receptive partner's risk (without ejaculation)	0.65%	1 in 154
Receptive partner's risk (with ejaculation)	1.43%	1 in 70

Other Numbers to Know

INCREASE HIV RISK

- Acute infection, roughly the 12 weeks after contracting HIV, can increase transmission likelihood **26 times**, raising a 1.43% risk to **37%**—higher than **1 in 3**. This is because viral load skyrockets during the acute phase.
- Presence of other sexually transmitted infections (STIs) can amplify risk by as much as **8 times**.
- Exposure to gender inequality and intimate partner violence can raise a woman's HIV risk **1.5 times**.

DECREASE HIV RISK

- Circumcision can lower heterosexual men's risk by **60%**.
- Treatment as prevention, TasP, when HIV-positive people on meds maintain an undetectable viral load, can reduce transmission risk by **96%**. Some research hints that the number may approach **100%**.
- Pre-exposure prophylaxis, PrEP, when HIV-negative people take daily med Truvada, can decrease risk by upwards of **92%**, depending on adherence. Post-exposure prophylaxis, PEP, works similarly.
- Condoms, according to the CDC, lower risk on average by **80%**.
- Forms of seroadaptation, such as having condomless sex only with people of your same sero status, can also lower risk, but the outcomes vary.

*^HIV Transmission Risk Factsheet, Centers for Disease Control and Prevention, July 2012; *Julie Fox et al., Quantifying Sexual Exposure to HIV Within an HIV-Serodiscordant Relationship: Development of an Algorithm. AIDS, 2011; **Summarized from Boily MC et al. Heterosexual Risk of HIV-1 Infection Per Sexual Act: Systematic Review and Meta-analysis of Observational Studies. Lancet Infect Dis 9: 118-29, 2009; ***Jin F et al. Per-Contact Probability of HIV Transmission in Homosexual Men in Sydney in the Era of HAART. AIDS, published online ahead of print, 2010.*

- Print and laminate
- Review with patients while rapid test is processing

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https://www.poz.com/pdfs/P04-14p53.risk_transmission.pdf

Self-Perception of HIV Risk

Low in populations *actually* at risk

- 5871 individuals in Philadelphia 2007-2009 rapid HIV tested
  - Those with no condom use – 90% *thought* they had no or low risk
- 66% of those who tested positive *thought* they were no or low risk

Nunn A, et al. J Natl Med Assoc. 2012;104(1-2):5-13

HIV Screening for Prevention

- A person who knows they have HIV is able to:
  - Protect others from becoming infected
  - Make safer decisions about sex, needle use, & their health care
- People with HIV (PWH) who know their status may avoid behaviors that spread infection
- Those at high risk but test negative can start PrEP

Coates, et al JAMA 1987;258:1889. Doll et al. Health Psychol 1990;9:253-65. Fox, et al. AIDS 1987;1:241-6. Gibson, et al. AIDS and Behavior 1999;3:3-12. Rietmeijer, et al. AIDS 1996; 10:291-8. van Griensven et al. Am J Epidemiol 1989;129:596-603.

Screening as Prevention

CDC 2006

- Test ***all*** pts 13-64 yo
- Test ***all*** pregnant women
- Test all pts with TB or STI
- Test high risk patients at least annually

USPSTF 2013

- Test ***all*** 15-65 yo
- Test ***all*** pregnant women
- Test <15 & >65 yo if at risk
- Grade A recommendation

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Branson, Bernard, et al. MMWR 2006;55(RR14):1-17.
Moyer, Virginia et al. Annals of Internal Medicine. 2013

Treatment IS Prevention

Studies from 2008-2016 show zero linked HIV transmissions after >100,000 condomless sex acts

- PWH had a **durably undetectable viral load**

HPTN 052

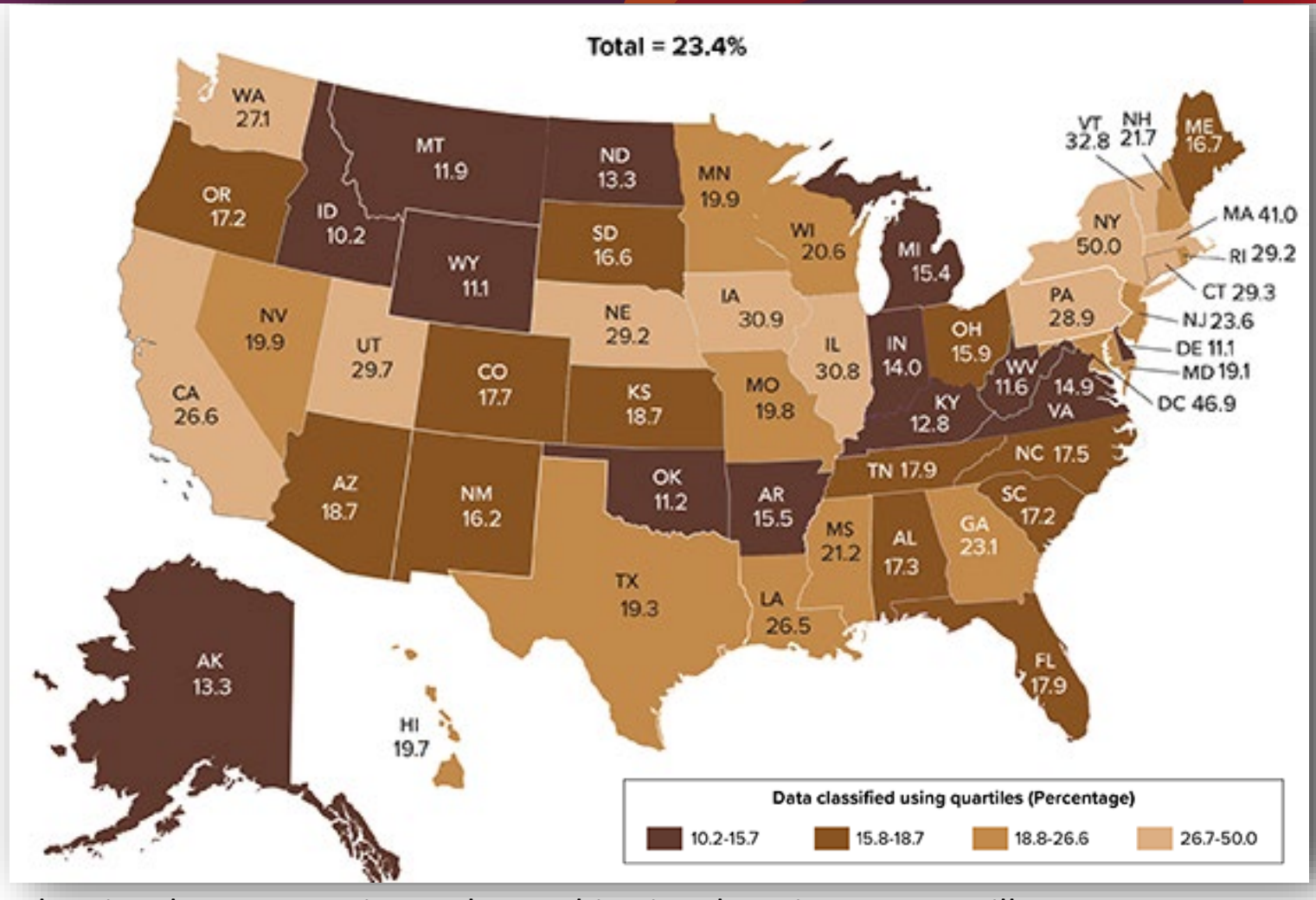
PARTNER

Opposites Attract

PARTNER 2

PrEP Coverage

- Nationally, 23% of the people who are considered at considerable risk of HIV infections are receiving pre-exposure prophylaxis



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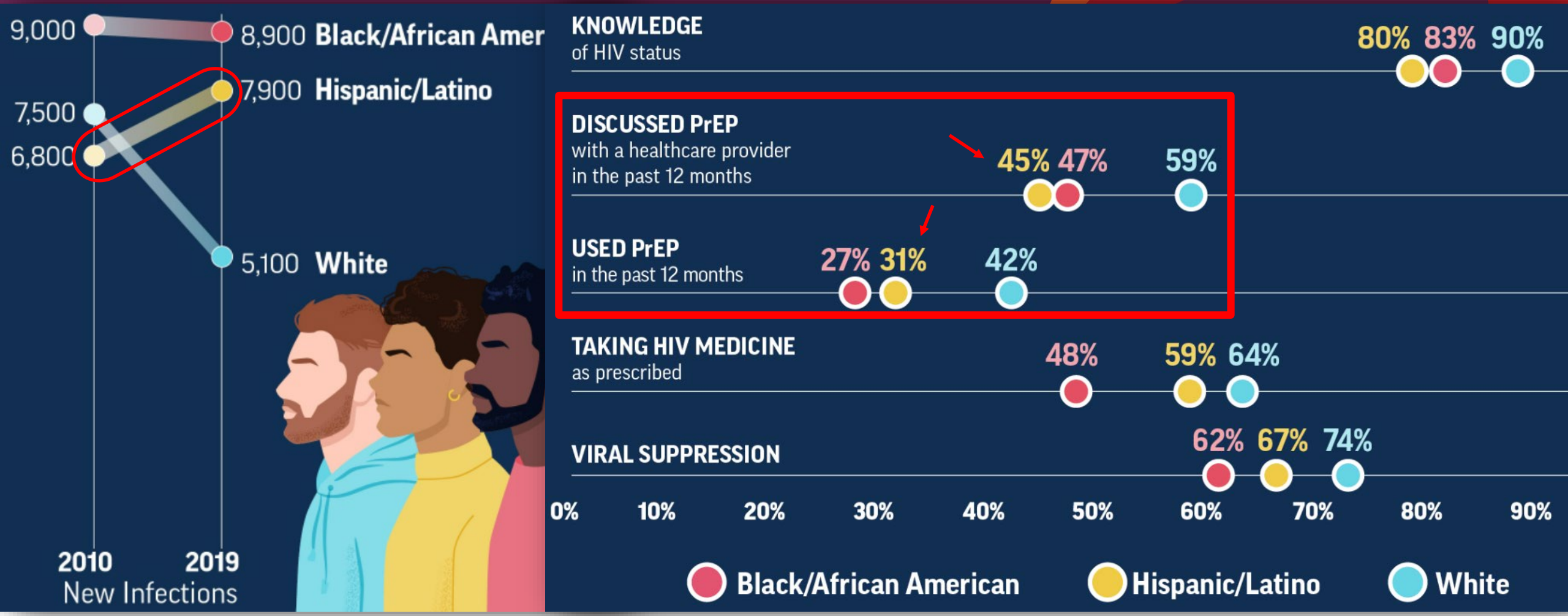
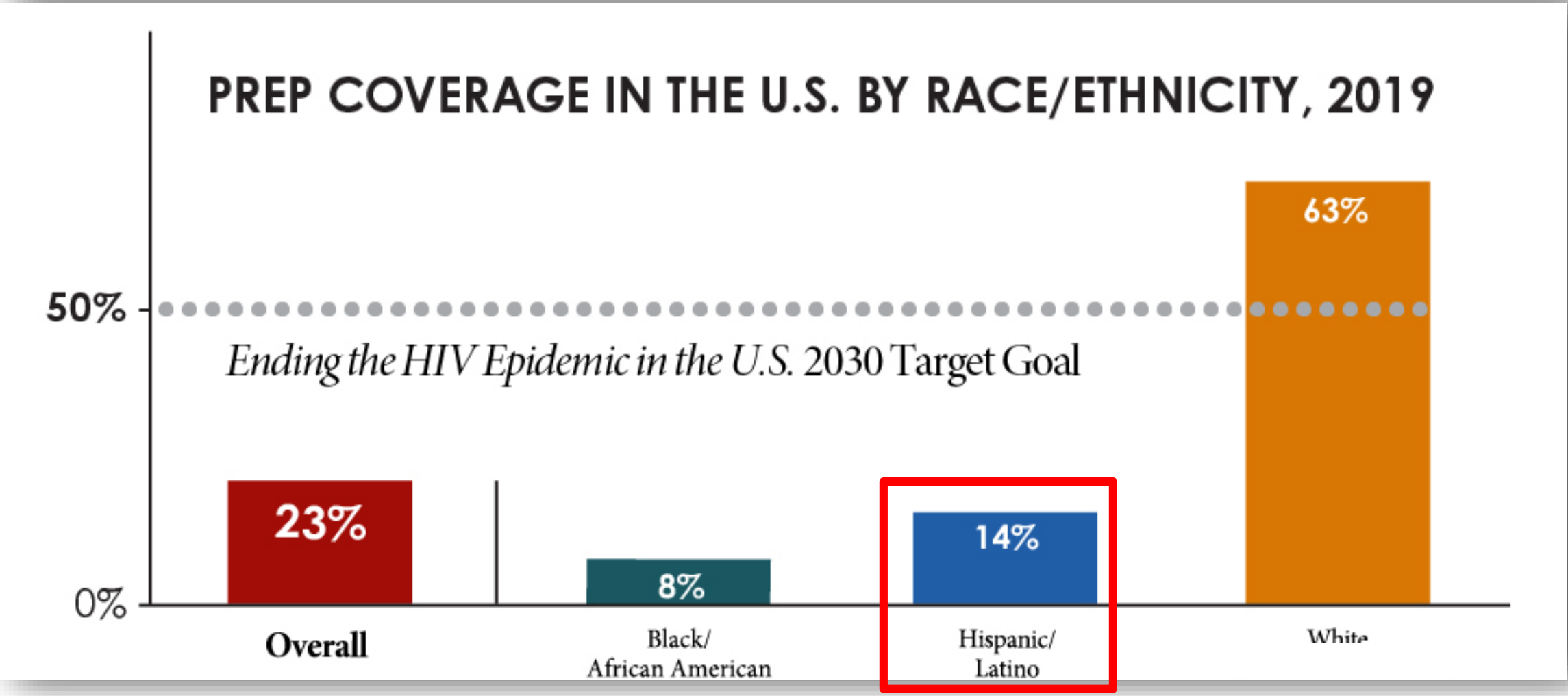
CDC. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2019. HIV Surveillance Supplemental Report 2021

PrEP Coverage is Unequal – 2017



https://www.cdc.gov/vitalsigns/hivgaybimen/index.html

PrEP Coverage is Unequal – 2019



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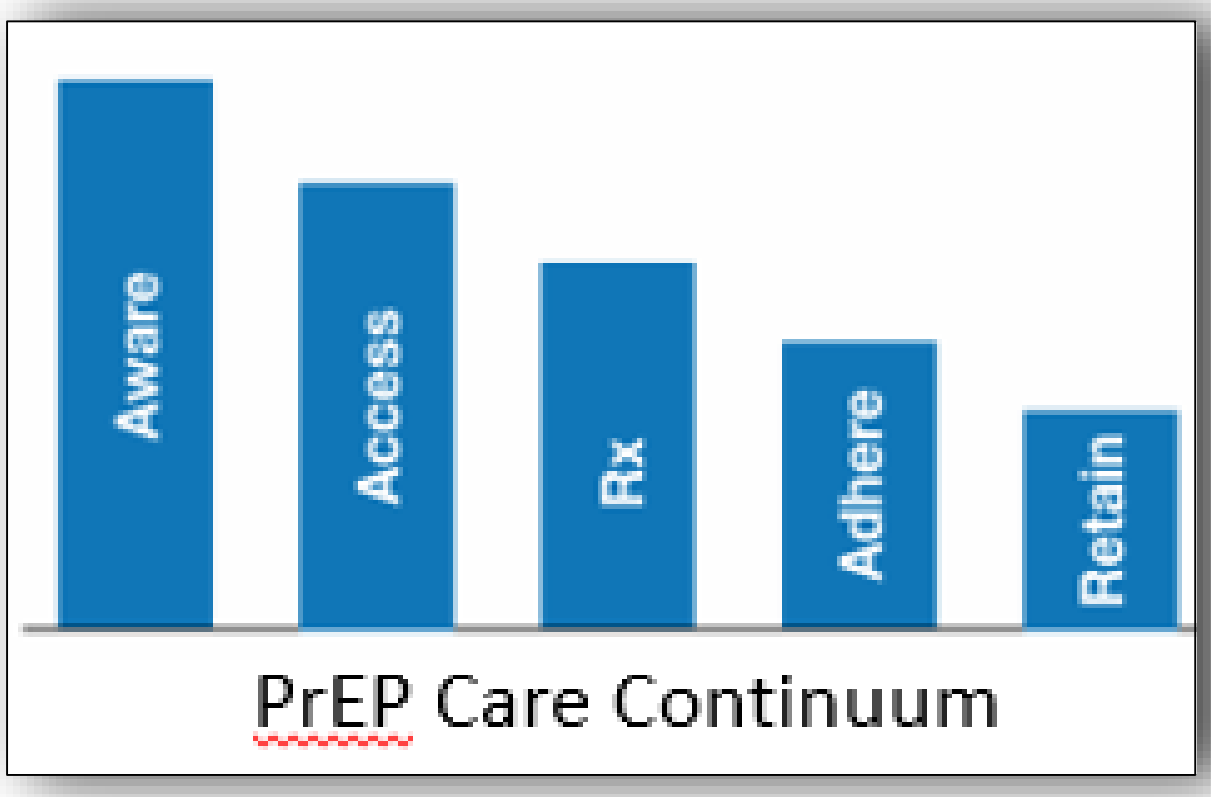
CDC. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2019. HIV Surveillance Supplemental Report 2021

Need PrEP to Reach Most at Risk

- Continued disparities among certain populations with new HIV infections and lack of access to HIV PrEP
- Interventions to improve metrics at each step of PrEP Care Continuum could reduce disparities



Jenness, S et al. CROI2018. Abstract 1149

PEP vs. PrEP

- Post-exposure prophylaxis
- Given **after** high-risk exposure to reduce risk of HIV infection
- Start within 72 hours of exposure
- 28-day course of daily 3-drug regimen

- Pre-exposure prophylaxis
- Given **before** high-risk exposure to reduce risk of HIV infection
- Start at least 7 days prior to exposure
- Daily 2-drug regimen or q 2 month long-acting regimen

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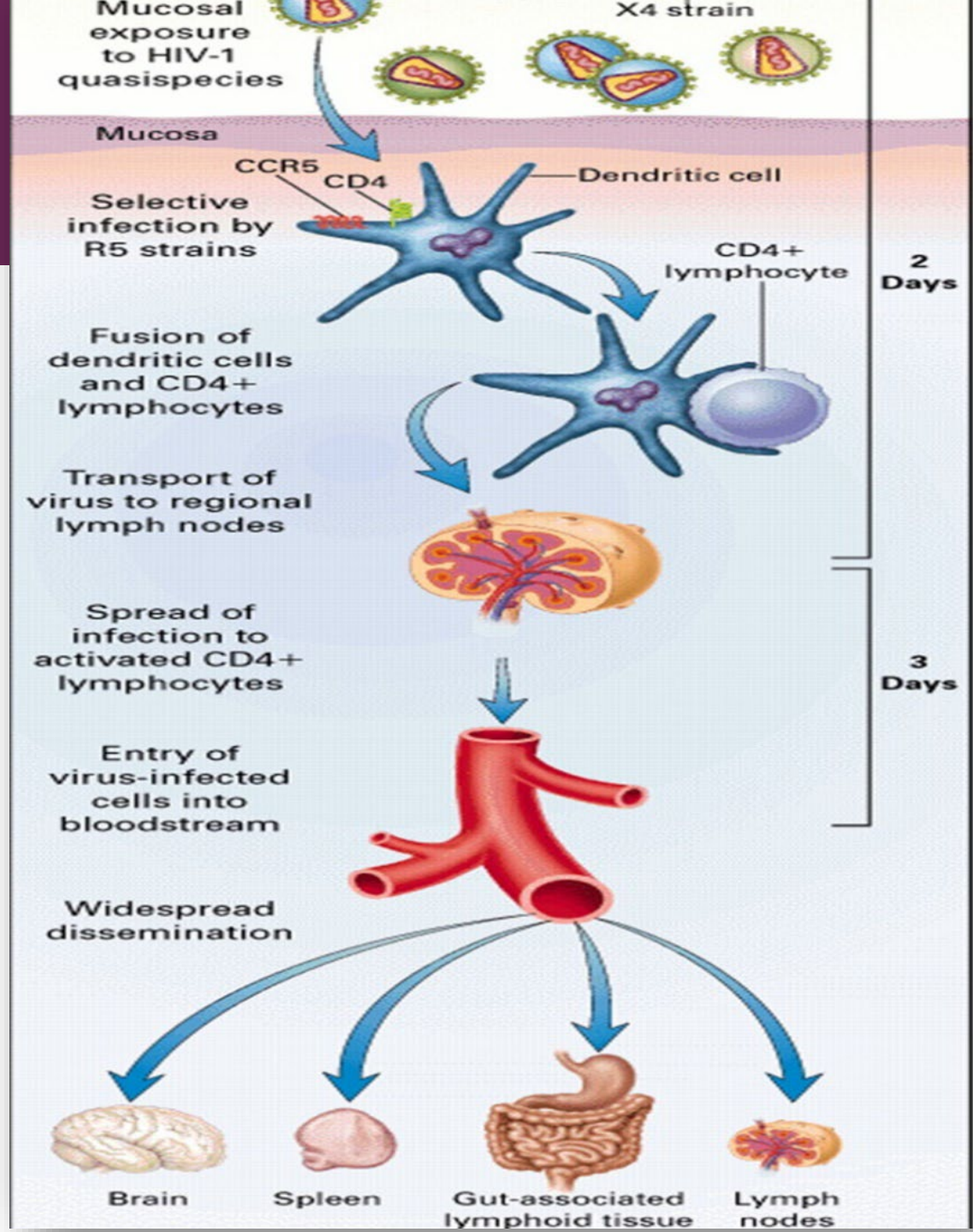
https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf
https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

HIV Infection

- PEP must be given <72 hours after exposure
- PrEP requires therapeutic levels of drug at site of infection
  - Rectal tissue: 7 days
  - Vaginal tissue: 20+ days



https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

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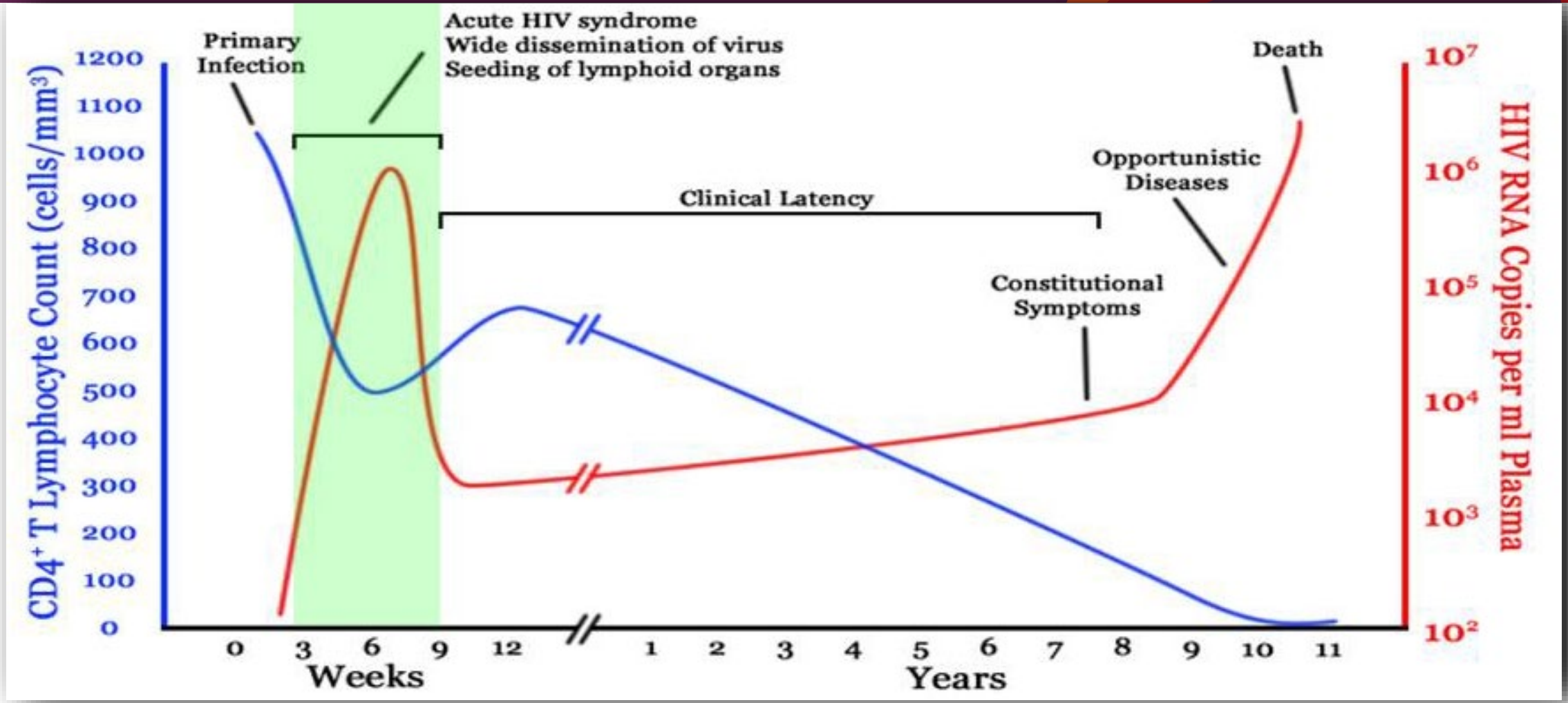
Considerations Before Prescribing

- What was the exposure?
- Is the source known/unknown?
- Likelihood of HIV infection in the source?
- Antiretroviral therapy (ART) resistance in the HIV infected source?
- What is the time period since exposure?
- What is the health of contact & are they taking any medications?

Acute Seroconversion



https://www.researchgate.net/figure/A-generalized-graph-of-the-relationship-between-HIV-copies-viral-load-and-CD4-counts_fig1_242611621

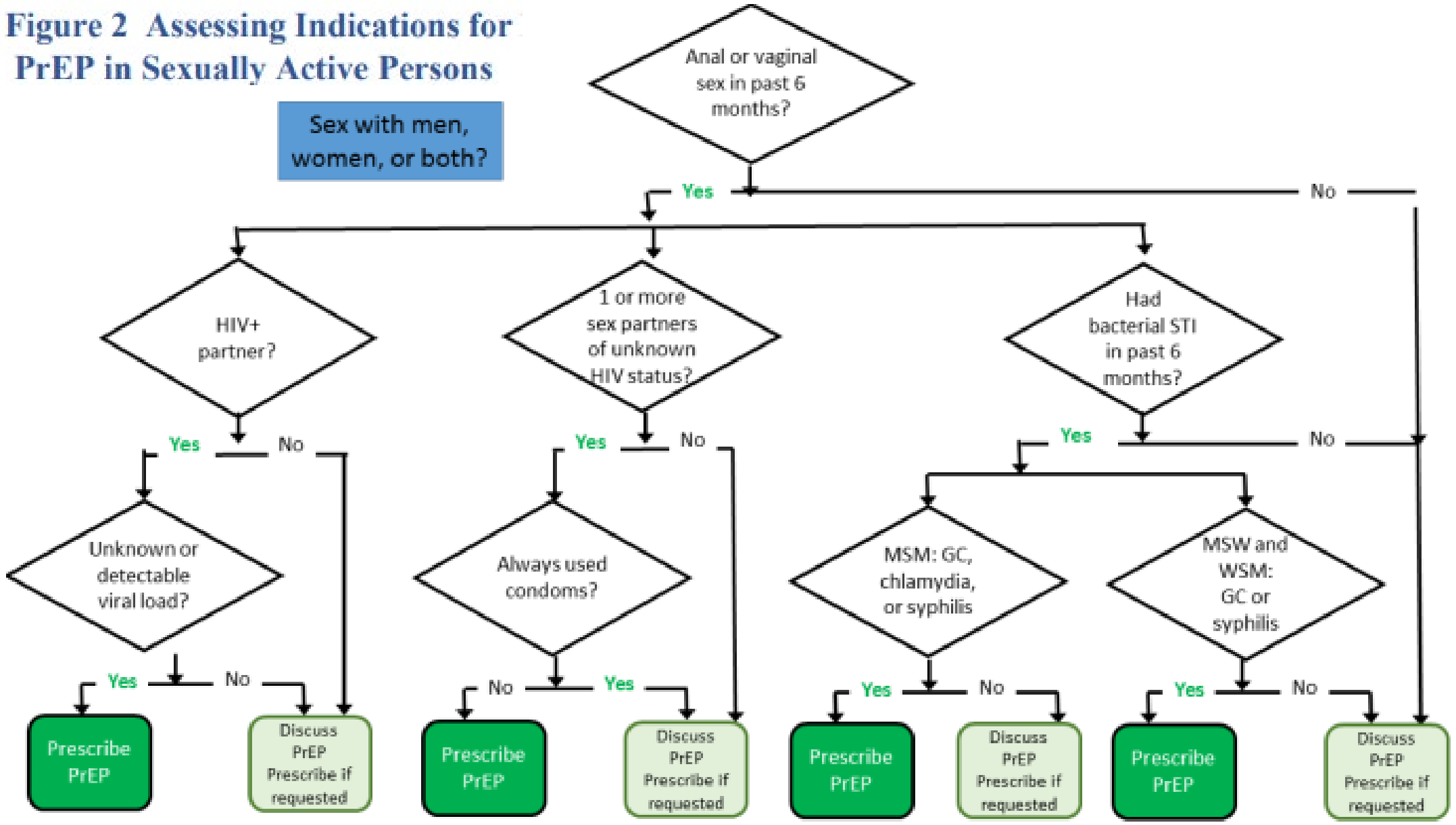
Acute Retroviral Syndrome (ARS)

Table 3. Clinical signs and symptoms of acute (primary) human immunodeficiency virus infection[169,170]

		Sex		Mode of HIV acquisition	
Features	**Overall (n = 375), %**	**Male (n = 355), %**	**Female (n = 23), %**	**Sexual (n = 324), %**	**Injection drug use (n = 34), %**
Fever	75	74	83	77	50
Fatigue	68	67	78	71	50
Myalgia	49	50	26	52	29
Skin rash	48	48	48	51	21
Headache	45	45	44	47	30
Pharyngitis	40	40	48	43	18
Cervical adenopathy	39	39	39	41	27
Arthralgia	30	30	26	28	26
Night sweats	28	28	22	30	27
Diarrhea	27	27	21	28	23

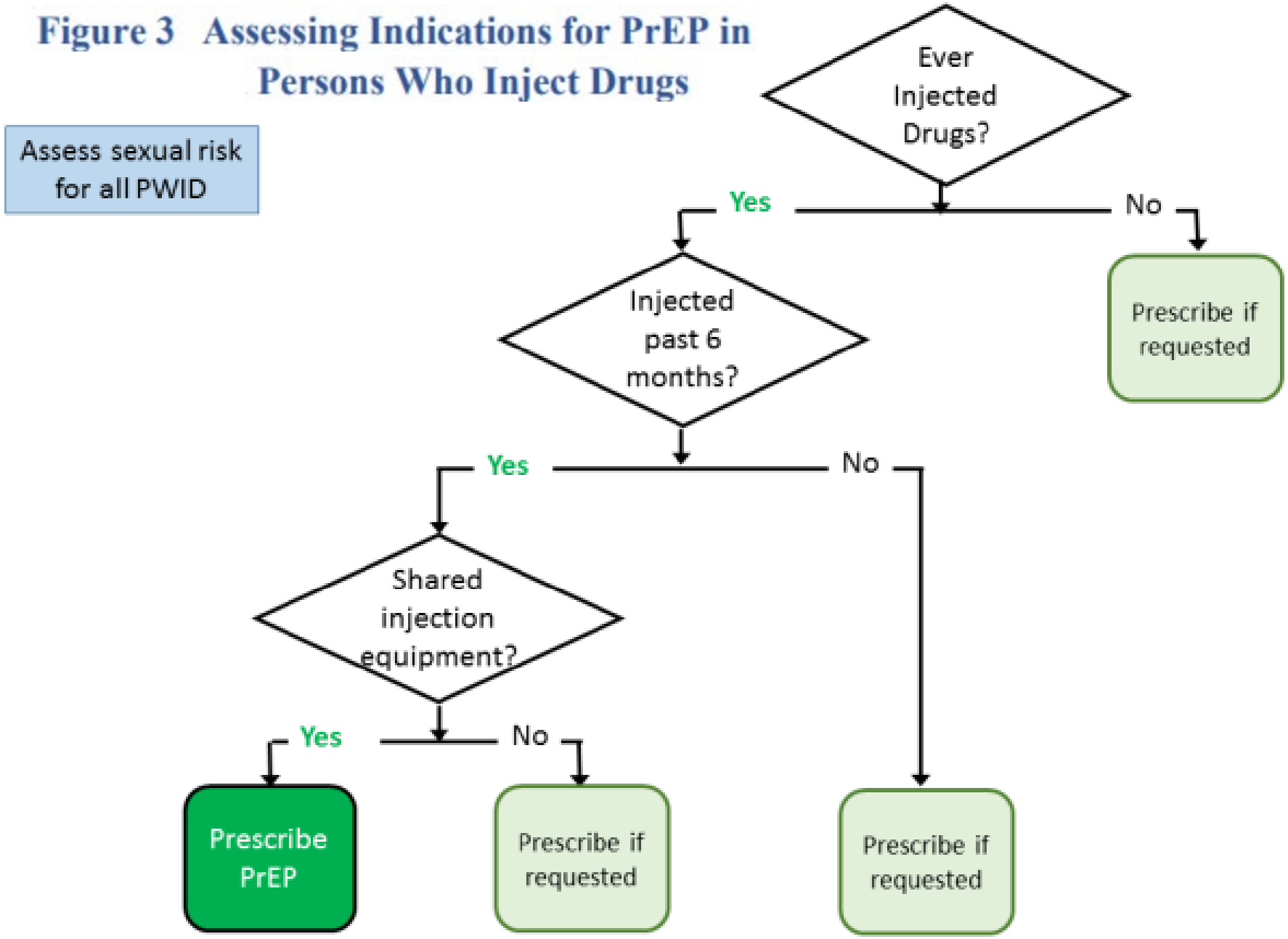
Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV—United States, 2016

Figure 2 Assessing Indications for PrEP in Sexually Active Persons



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

Figure 3 Assessing Indications for PrEP in Persons Who Inject Drugs



https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

Oral Pre-Exposure Prophylaxis

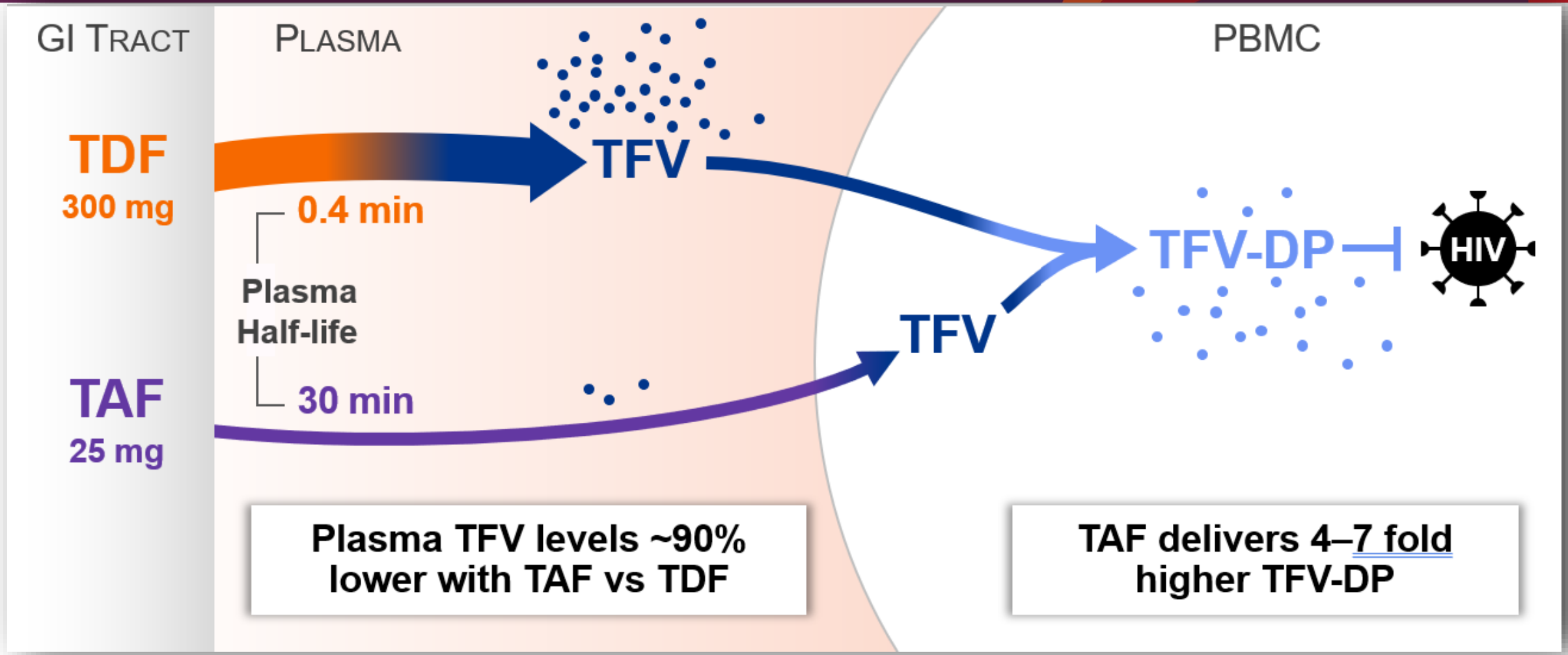
FDA-approved daily oral formulations:

- Tenofovir/emtricitabine (F/TDF* or F/TAF**)
- 1 tablet by mouth once a day
- Prescribe for ≤ 90-day supply
- Approved for adolescents & adults ≥ 35kg (77 lb)*

*F/TDF FDA-approved indication in adults 7/2012 and for youth 5/2018
**F/TAF FDA-approved for PrEP (except receptive vaginal sex) 10/2019
USPSTF Grade A Recommendation, 6/2019

https://www.cdc.gov/hiv/guidelines/preventing.html

TDF vs. TAF



Spinner CD, et al. DISCOVER STUDY for HIV Pre-Exposure Prophylaxis: F/TAF has a more Rapid Onset and Longer Sustained Duration of HIV Protection Compared with F/TDF. 23July IAS 2019, Mexico City.

TDF vs. TAF

F/TDF

- Use if receptive vaginal sex or if IDU is only risk factor (i.e., no sexual risk)
- Renal & bone toxic
  - Do not start if eCrCl <60mL/min
- Generic available

F/TAF

- Not indicated for receptive vaginal sex or IDU alone
- Less renal & bone toxicity
  - Can use if eCrCl > 30 mL/min
  - Consider use if hx of osteoporosis or related bone disease
- Weight gain
  - 1 - 1.7kg vs. 0 - 0.5kg (F/TDF)
- Smaller tablet

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	

[1] adolescents weighing at least 35 kg (77 lb)

[2] Because most PWID are also sexually active, they should be assessed for sexual risk and provided the option of CAB for PrEP when indicated

[3] Sexually transmitted infection (STI): Gonorrhea, chlamydia, and syphilis for MSM and transgender women who have sex with men including those who inject drugs; Gonorrhea and syphilis for heterosexual women and men including persons who inject drugs

[4] estimated creatine clearance (eCrCl) by Cockcroft Gault formula ≥60 ml/min for F/TDF use, ≥30 ml/min for F/TAF use

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

Labs Before Prescribing Oral PrEP

Consider pregnancy screening for people of childbearing potential

Hep B serologies

- Surface antigen
- Surface antibody
- Total core antibody

Table 5 Timing of Oral PrEP-associated Laboratory Tests

Test	Screening/Baseline Visit	Q 3 months	Q 6 months	Q 12 months	When stopping PrEP
HIV Test	X*	X			X*
eCrCl	X		If age ≥50 or eCrCL <90 ml/min at PrEP initiation	If age <50 and eCrCl ≥90 ml/min at PrEP initiation	X
Syphilis	X	MSM /TGW	X		MSM/TGW
Gonorrhea	X	MSM /TGW	X		MSM /TGW
Chlamydia	X	MSM /TGW	X		MSM /TGW
Lipid panel (F/TAF)	X			X	
Hep B serology	X				
Hep C serology	MSM, TGW, and PWID only			MSM,TGW, and PWID only	

* Assess for acute HIV infection (see Figure 4)

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https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

Interpreting Hepatitis B Blood Test Results

Interpretation & Action Needed	HBsAg Hepatitis B Surface Antigen	HBsAb (anti-HBs) Hepatitis B Surface Antibody	HBcAb (anti-HBc) Hepatitis B Core Antibody
Not Immune - Not Protected Has not been infected, but still at risk for possible hep B infection. Vaccine is needed.	—	—	—
***Immune Controlled - Protected** Surface antibodies present due to natural infection. Has recovered from a prior hep B infection. Cannot infect others. No vaccine is needed.	—	+	+
Immune - Protected Has been vaccinated. Does not have the virus and has never been infected. No vaccine is needed.	—	+	—
Infected Positive HBsAg indicates hep B virus is present. Virus can spread to others. Find a doctor who is knowledgeable about hep B for further evaluation. More Testing Needed.	+	—	+
***Could be Infected** Result unclear - possible past or current hep B infection. Find a doctor who is knowledgeable about hep B for further evaluation. More Testing Needed.	—	—	+

*Inform all doctors about a prior or current hepatitis B infection and include this information as part of your health history.
Talk to doctors before taking immune system suppressing medications to understand the risk for possible hep B reactivation.

https://www.hepb.org/assets/Uploads/_resampled/ResizedImageWzg1OSw5MDld-New-Hepatitis-B-Blood-Test-Chart-2019.png

Oral PrEP is Effective

Lessons learned from studies:

- Safe, well tolerated (nausea)
- Adherence is key
  - iPrEx study: 44% reduction in HIV
  - **92% reduction in those with good adherence**
- PrEP as bridge to ART: 95% reduction
- Important to screen & treat STIs

Cost effective if used among high risk

Paltiel AD, et al. CID. 2009;48(6):806-815. Juusola JL, et al. Ann Intern Med. 2012;156(8):541-550. Schneider, et al. CID 2014;58:1027-34. Werner RN et al. PLoS ONE 2018. 13(12):e0208107. Traeger, M et al. JAMA 2019

Daily Oral PrEP Adherence

Figure 5: Adherence and F/TDF PrEP Efficacy in MSM

Weekly Medication Adherence Estimated by Drug Concentration	HIV Incidence per 100 person/years
None	4.2
≤2 pills/week	2.3
2-3 pills/week	0.6
≥4 pills/week	0.0

A brief medication adherence question

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

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

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

Box B: Key Components of Oral Medication Adherence Counseling

Establish trust and bidirectional communication

Provide simple explanations and education

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

Support adherence

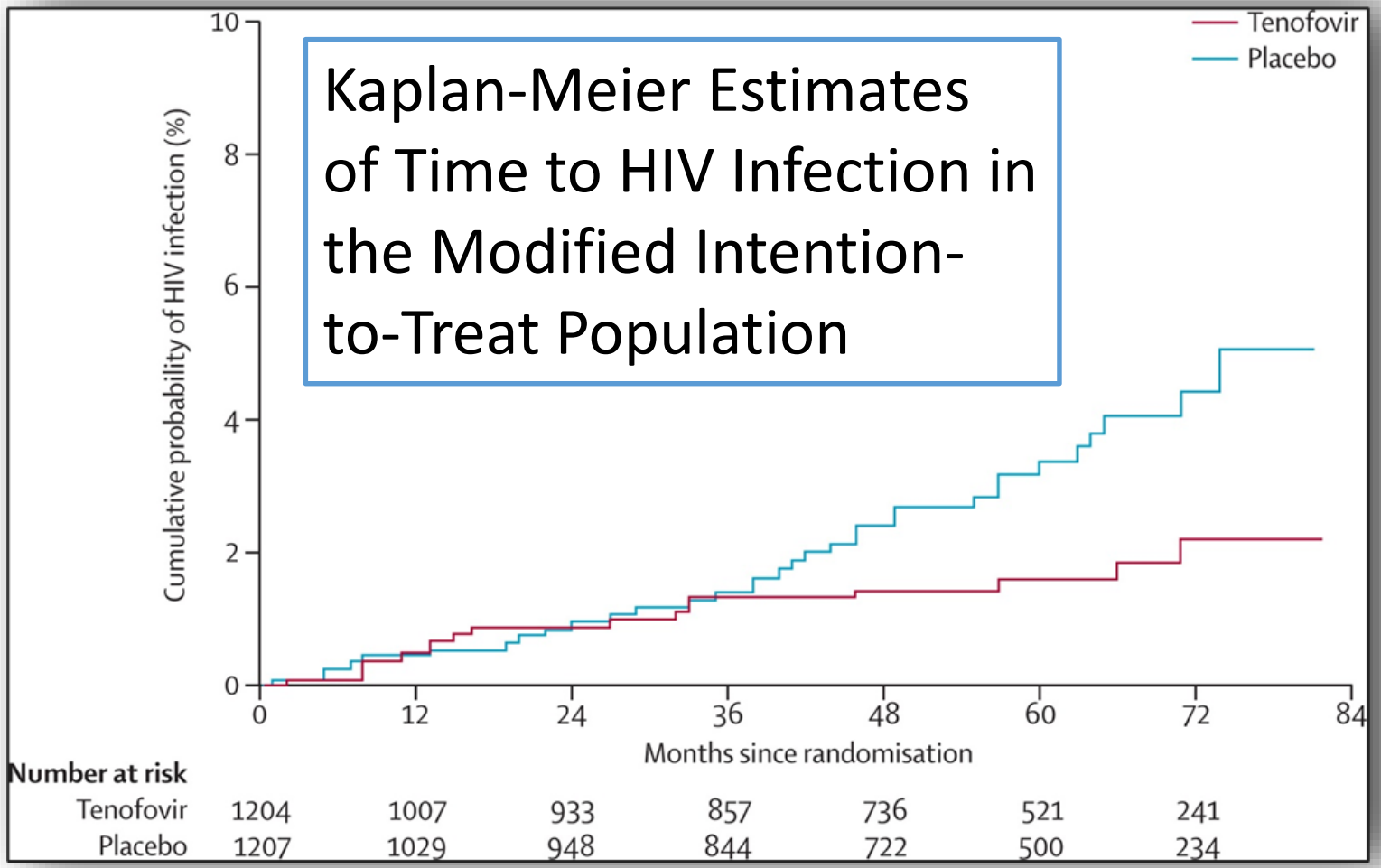
- Tailor daily dose to patient's daily routine
- Identify reminders and devices to minimize forgetting doses
- Identify and address barriers to adherence
- Reinforce benefit relative to uncommon harms

Monitor medication adherence in a non-judgmental manner

- Normalize occasional missed doses, while ensuring patient understands importance of daily dosing for optimal protection
- Reinforce success
- Identify factors interfering with adherence and plan with patient to address them
- Assess side effects and plan how to manage them

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

Bangkok Tenofovir Study (2013) investigated the effects of a PrEP strategy for HIV prevention in 2,413 Thai PWID



- 48.9% reduction in HIV incidence (95% CI,9.6-72.2; *P*=.01)
- 73.5% reduction in HIV incidence in individuals with detectable drug levels (95% CI, 16.6-94.0; *P* =.03)

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PWID = people who inject drugs

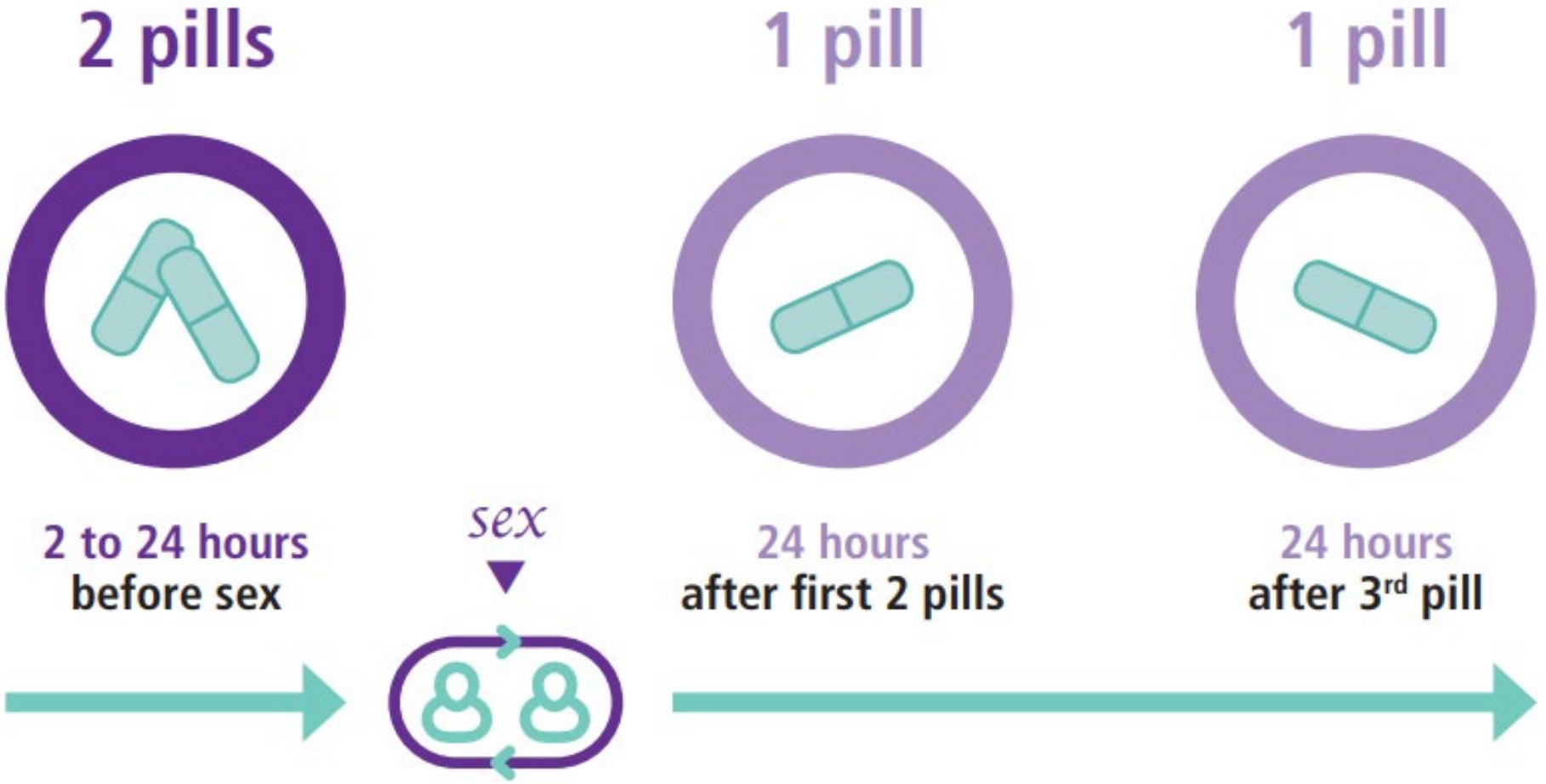
Choopanya K, et al. Lancet. 2013;381:2083-90

Women Who Inject Drugs

- Women who inject drugs (WWID) have higher odds (OR, 1.18) of HIV infection than men who inject drugs (MWID) (95% CI, 1.10-1.26)
- WWID are more likely to have higher risk of sexual and injection exposures than MWID
  - Concomitant or overlapping exposures
- WWID who are unable to negotiate safe sex practices are especially at risk of HIV transmission and could benefit greatly from PrEP for HIV prevention

Des Jarlais DC, et al. Drug Alcohol Depend. 2012;124:95-107; Coleman RL, et al. J Int AIDS Soc. 2016;19:21112

On-Demand F/TDF / “2-1-1” Method



Only for adult men who have sex with men (MSM), if:

- sex is less than twice weekly *and*
- can anticipate sex

https://apps.who.int/iris/rest/bitstreams/1239070/retrieve
https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

Injectable Pre-Exposure Prophylaxis

FDA-approved injectable formulation:

- Cabotegravir (CAB) 600mg/3mL every 2 months
  - Optional 30mg daily oral CAB 4-week lead-in
- Approved for adolescents & adults ≥ 35kg (77 lb)*

*CAB FDA-approved indication in 12/2021

https://www.cdc.gov/hiv/guidelines/preventing.html

Long-Acting Injectable (LAI) CAB

CAB LAI q8weeks for MSM and transwomen who have sex with men (TGWSM) at high risk for HIV

- 4,570 MSM & TGWSM (12%) double-blinded
- CAB LAI HIV incidents - 13
- Daily oral F/TDF HIV incidents - 39
- **66% fewer HIV infections in LAI CAB vs. F/TDF**
- Well-tolerated: injection site reactions (ISRs) – 2.2% discontinued

https://www.hptn.org/research/studies/hptn083

Long-Acting Injectable (LAI) CAB

CAB LAI q8weeks for sexually active cisgender women (not pregnant or breastfeeding, on contraception) at high risk for HIV

- 3,224 participants in Sub-Saharan Africa
- CAB LAI HIV incidents - 4
- Daily oral F/TDF HIV incidents - 34
- **89% fewer HIV infections in LAI CAB for cisgender women vs. F/TDF**
- Well-tolerated: ISRs – no discontinuations due to ISRs

https://www.084life.org/study-results/

Guidance for Injectable PrEP

	Sexually-Active Adults	Persons Who Inject Drugs[1]
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[2] • 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 initial cabotegravir injection • No signs/symptoms of acute HIV infection • No contraindicated medications or conditions	
Dosage	• 600 mg cabotegravir administered as one 3 ml intramuscular injection in the gluteal muscle o Initial dose o Second dose 4 weeks after first dose (month 1 follow-up visit) o Every 8 weeks thereafter (month 3,5,7, follow-up visits etc)	

p 48: “Because of the long duration of drug exposure following injection, exclusion of acute HIV infection is necessary with the most sensitive test available, an HIV-1 RNA assay

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

Guidance for Injectable PrEP

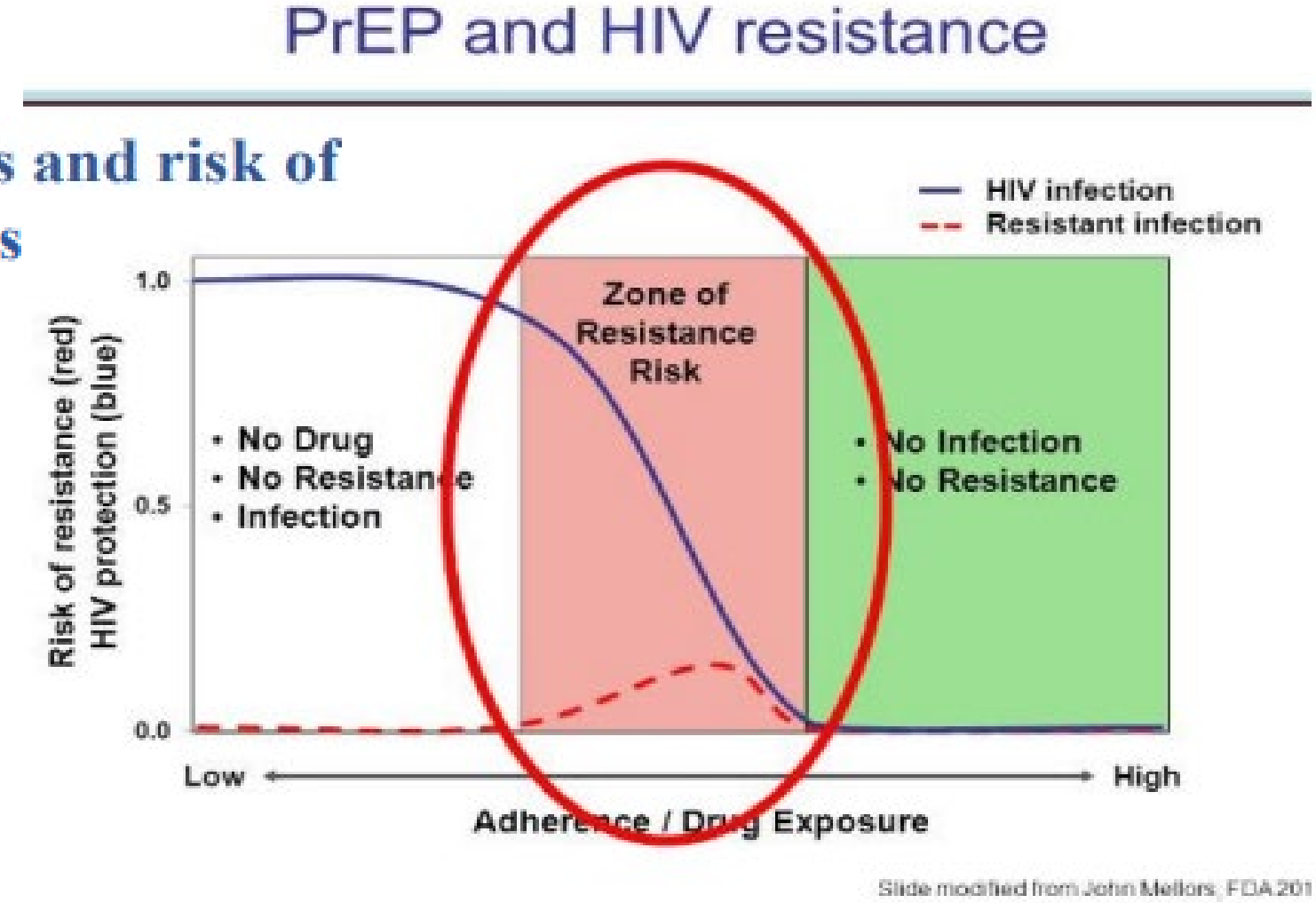
Follow-Up Care	**At follow-up visit 1 month after first injection** • HIV Ab/Ag test and HIV-1 RNA Assay **At follow-up visit every two months (beginning with third injection – month three)** • HIV Ab/Ag test and HIV-1 RNA Assay • Access to clean needles/syringes and drug treatment services for PWID **At follow-up visits every four months (beginning with the third injection – month three)** • Bacterial STI screening for MSM and transgender women who have sex with men – oral, rectal, urine, blood **At follow-up visit every six months (beginning with the fifth injection – month seven)** • Bacterial STI screening for all heterosexually active women and men – (vaginal, rectal, urine - as indicated), blood **At follow-up visits at least every 12 months (after the first injection)** • Assess desire to continue injections as PrEP • Chlamydia screening for heterosexually active women and men – vaginal, urine **At follow-up visits when discontinuing cabotegravir injections provide the following** • Re-educate patients about the "tail" and the risks of declining CAB levels • Assess ongoing HIV risk and prevention plans • If PrEP is indicated, prescribe oral, daily F/TAF or F/TDF beginning within eight weeks of the last injection • Continue follow-up visits with HIV testing quarterly for 12 months

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

Guidance for Injectable PrEP

Figure 7

The trade-off of PrEP drug levels and risk of HIV infection with resistant virus



CAB "tail" – may need oral PrEP to protect from HIV

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https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

Labs Before Prescribing CAB for PrEP

Consider pregnancy screening for people of childbearing potential

Hep C screening!

Hep B serologies

- Surface antigen
- Surface antibody
- Total core antibody

Table 7 Timing of CAB PrEP-associated Laboratory Tests

Test	Initiation Visit	1 month visit	Q2 months	Q4 months	Q6 months	Q12 months	When Stopping CAB
HIV*	X	X	X	X	X	X	X
Syphilis	X			MSM^/TGW~ only	Heterosexually active women and men only	X	MSM/TGW only
Gonorrhea	X			MSM/TGW only	Heterosexually active women and men only	X	MSM/TGW only
Chlamydia	X			MSM/TGW only	MSM/TGW only	Heterosexually active women and men only	MSM/TGW only

* HIV-1 RNA assay
X all PrEP patients
^ men who have sex with men
~ persons assigned male sex at birth whose gender identification is female

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https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

Same-Day PrEP Prescribing

NOT appropriate if patient:

- Is ambivalent about starting
- Can't have blood drawn for lab testing
- Has possible acute HIV
- Has hx of renal disease or associated conditions (e.g., hypertension, diabetes)
- Is uninsured or can't afford cost
- Doesn't have a confirmed means of contact should lab tests indicate need to d/c PrEP (e.g., acute HIV infection, unanticipated renal dysfunction)

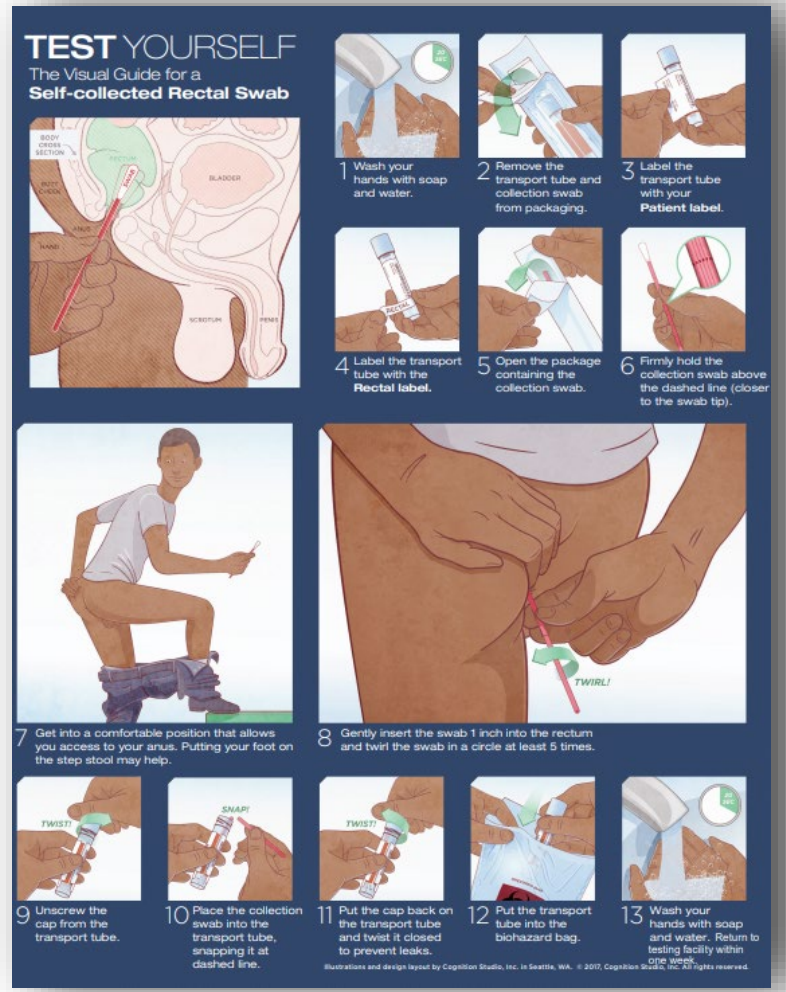
May not be appropriate if:

- Recent possible HIV exposure but no signs of acute HIV (PEP vs. PrEP)
- Person may not be easily contacted for return appointments
- Has mental health conditions severe enough to interfere with PrEP requirements (adherence, follow-up)

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

Sexually Transmitted Infection Screening

- GC/CT NAAT swabs
  - Test <u>all</u> relevant sites
  - Urine, urethral, vaginal
  - Oral
  - Rectal
  - Self-collection
- Syphilis is on the rise in US
  - T.pal Ab & RPR (blood)



https://www.cdc.gov/std/tg2015/default.htm
http://uwptc.org/

When to Stop PrEP

- Oral PrEP
  - F/TDF: eCrCl <60 mL/min
  - F/TAF: eCrCl <30 mL/min
    - Rise in serum creatinine not reason to stop if eCrCl still above cutoffs
  - New proteinuria not due to other causes
    - Discuss NSAID or protein powder use
- HIV seroconversion
- Allergic reaction or severe intolerance
- Non-adherence to medications or visits
- No longer at risk
- Caution in chronic hepatitis B infections- risk of flare & fulminant hepatitis

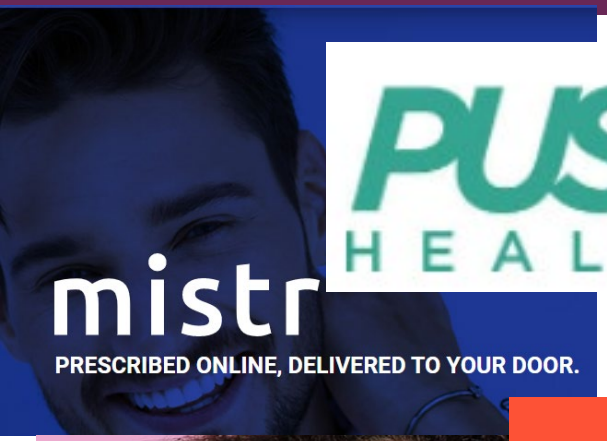
https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

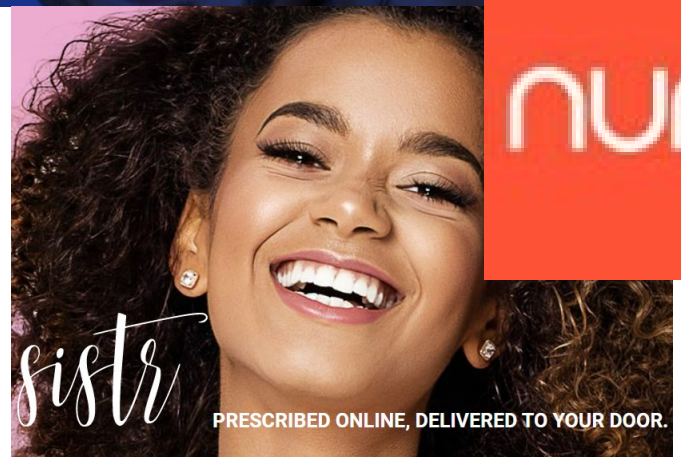
Telemedicine for PrEP

- Benefits to patient
  - Convenience: no travel to clinic
  - Easier access to personalized care
- Challenges
  - Clinic visit might be a one-stop shop (visit, labs, prescription refills)
  - Needs physical exam for STI complaints and/or treatment
  - Unable to conduct STI swabs lab (can get specimen kits online- cost to patient up front)
  - No access to phone and computer/internet

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

Telemedicine for PrEP





- Online PrEP options
  - MISTR/SISTR – partner clinics cover costs
  - Nurx – $15 for visit & $94-$124 for labs
  - Plush - $15/month + copay or $69-$129
  - Folx - monthly cost $90 + cost of labs ($0-$55)
  - Push - "less than insurance co-pays and costs are always clearly displayed“
  - Qcare+ - partner clinic & insurance billed

Take Home Points

- HIV prevention methods can be used in combination to reduce risk.
- Importan to ask about last potential high-risk exposure & properly interpret HIV screening test to determine use of PEP or PrEP.
- PrEP is effective at reducing HIV transmission BUT not enough patients at high risk have access.
- Novel strategies & practices have potential to engage & retain in PrEP care.
  - Incorporate best practice strategies, such as use of telemedicine.
- **Anyone who asks for PrEP should GET IT!**

Prescribing PrEP

- ICD-10 codes:
  - Z20.6 Contact with and (suspected) Exposure to HIV
  - Z20.2 Contact with and (suspected) Exposure to infections with a predominantly sexual mode of transmission
- NASTAD Billing & Coding Guide nastad.org/sites/default/files/2021-12/PDF-Billing-Coding.pdf
- PrEP Toolkit www.cdc.gov/hiv/clinicians/materials/prevention.html

Coverage of Oral PrEP

If large copay: (however, ACA implementation part 47 should = $0)

- Copay cards for oral PrEP (Med D excluded): www.gileadadvancingaccess.com/copay-coupon-card
- Injectable PrEP savings and assistance: www.viivconnect.com/for-providers/viivconnect-programs/medications/
- Patient Advocate Foundation (also for Med D): www.copays.org/diseases/hiv-aids-and-prevention
- Good Days (also for people with Med D): www.mygooddays.org/patients/diseases-covered/hiv-aids-treatment-and-prevention

If uninsured:

- Oral PrEP Assistance Program: 1-800-226-2056 www.gileadadvancingaccess.com/
- Injectable PrEP Assistance Program: 1-844-588-3288
- State PrEP Assistance Programs: nastad.org/prepcost-resources/prep-assistance-programs
- Ready Set PrEP (oral PrEP only at this point): readysetprep.hiv.gov/

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