



WELCOME to the

*Get PrEP'd ECHO:
HIV Pre-Exposure Prophylaxis*

Session 1, HIV Epidemiology, September 5, 2023

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organization into CHAT*

Series created in partnership with the

New England AIDS Education and Training Center

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Get PReP'd ECHO: HIV [re-exposure prophylaxis

SESSION/TITLE	DATE
<u>1 - HIV epidemiology, U.S. PrEP coverage and brief overview of EHE goals</u>	9/5/2023
<u>2 - Sexual history taking, inclusive language</u>	9/19/2023
<u>3 - HIV risk assessment and indications for PrEP</u>	10/3/2023
<u>4 - HIV diagnostics and interpretation particularly in the context of PrEP usage</u>	10/17/2023
<u>5 - Oral PrEP medication and indications</u>	10/31/2023
<u>6 - Injectable PrEP medication and indications</u>	11/7/2023
<u>7 - PrEP monitoring and required labs, STI screening</u>	11/21/2023

Series Learning Objectives

Learner will be able to:

- Use understanding of current epidemiology of HIV to identify patients at risk
- Correctly utilize HIV diagnostics testing and interpret results
- Select from currently available PrEP medications to prescribe appropriately
- Provide effective monitoring and follow up for patients on PrEP
- Implement current STI screening guidelines



The Landscape of HIV in the U.S. Today

How YOU can help End the HIV Epidemic

Antonia Altomare, DO, MPH

Associate Professor of Medicine, Geisel School of Medicine

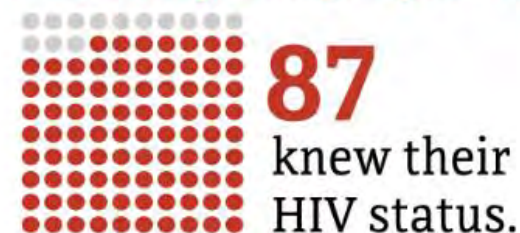
Co-program Director the HOPE Program, Dartmouth Health

Medical Director, NH AETC

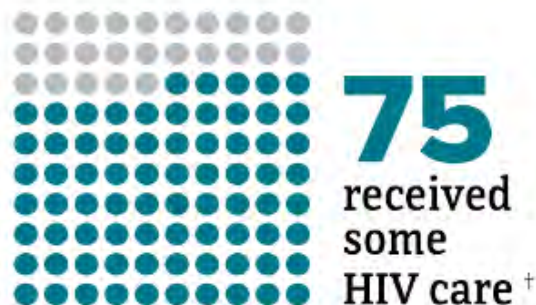


In 2021, an **estimated 1.2 million people** had HIV.

For every 100 people with HIV



More than half of people with diagnosed HIV are virally suppressed. For every **100 people overall with diagnosed HIV**:

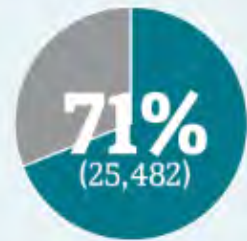


U=U
undetectable
=
untransmittable

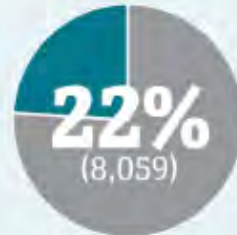
It's important for people to know their HIV status so they can **take medicine to treat HIV** if they have the virus. Taking HIV medicine as prescribed can make the viral load undetectable. People who **get and keep an undetectable** viral load (or remain virally suppressed) can stay healthy for many years and **will not transmit HIV** to their sex partners.



There were **36,136 new HIV diagnoses*** in the US and dependent areas in 2021. Of those:



were among gay, bisexual, and other men who reported male-to-male sexual contact[†]



were among people who reported heterosexual contact

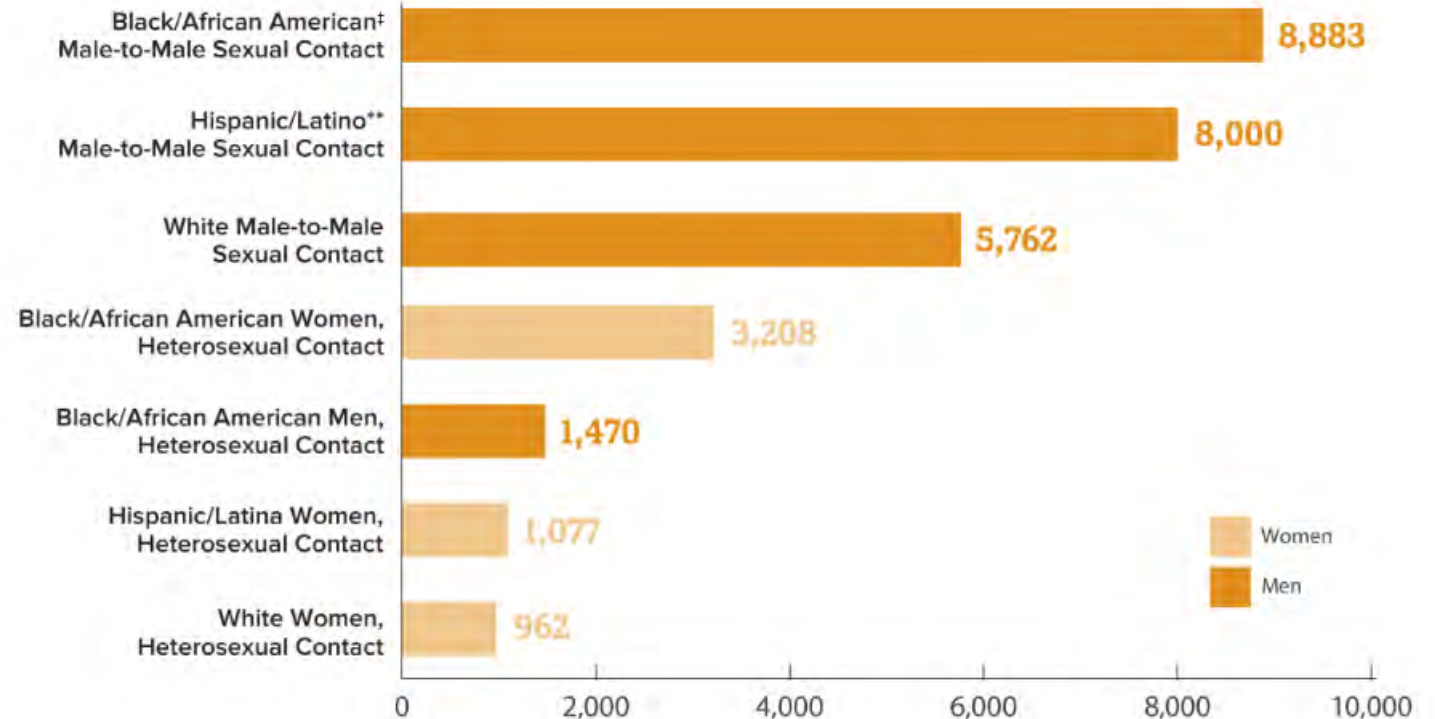


were among people who inject drugs

*Among people aged 13 and older.

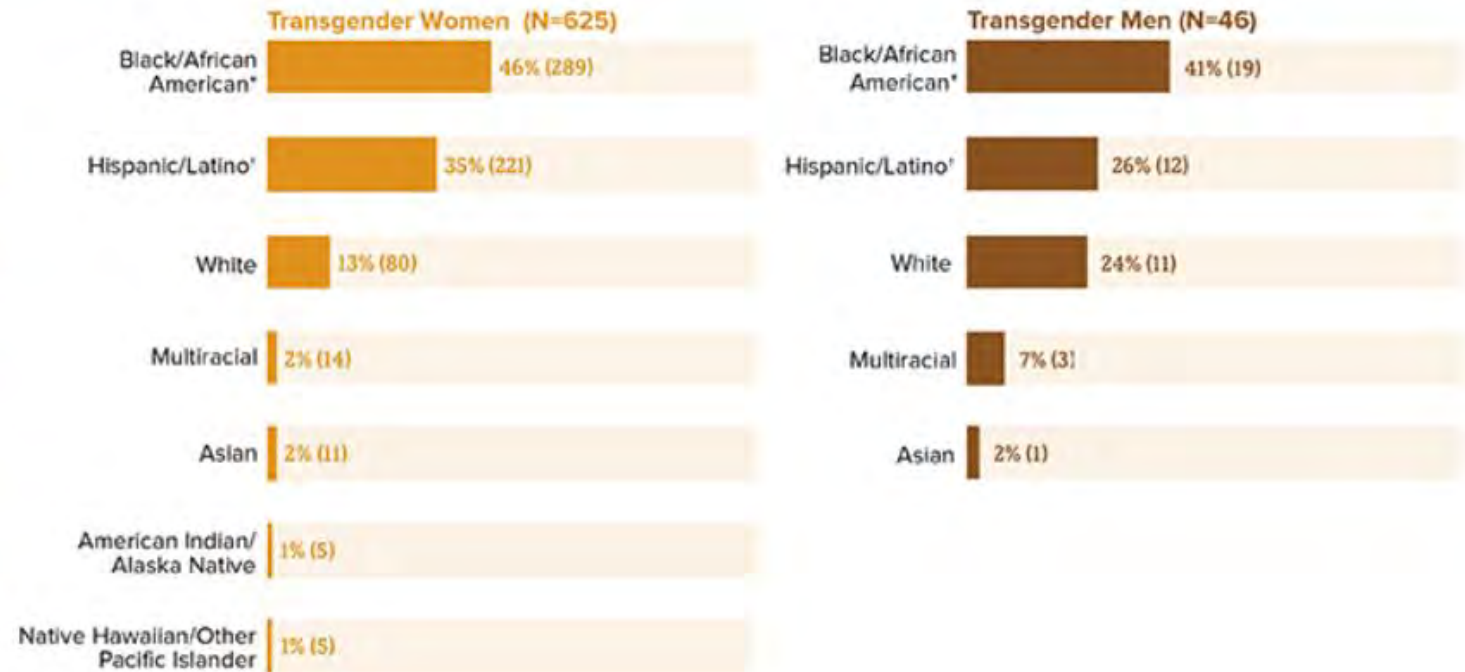
†Includes infections attributed to male-to-male sexual contact and injection drug use (men who reported both risk factors).

Gay and bisexual men are the population most affected by HIV.



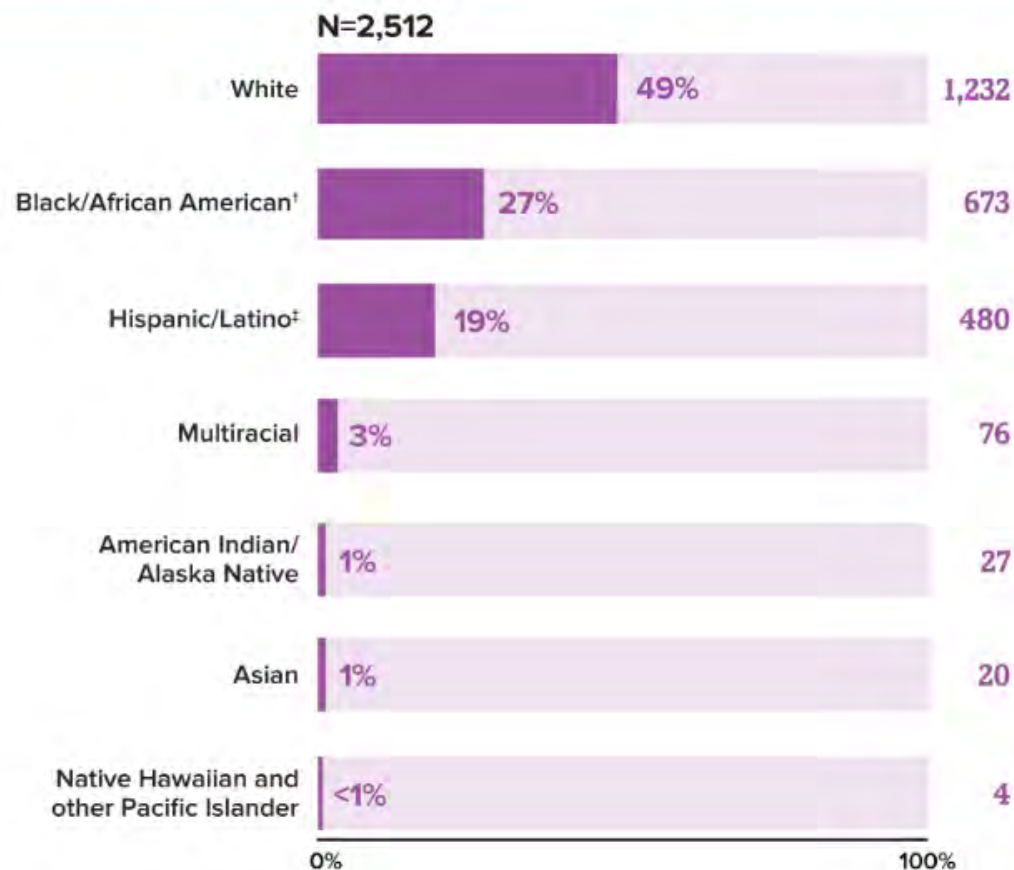
New HIV Diagnoses Among Transgender People by Race/Ethnicity in the US and Dependent Areas, 2019

Most new HIV diagnoses among transgender people were among Black/African American people.



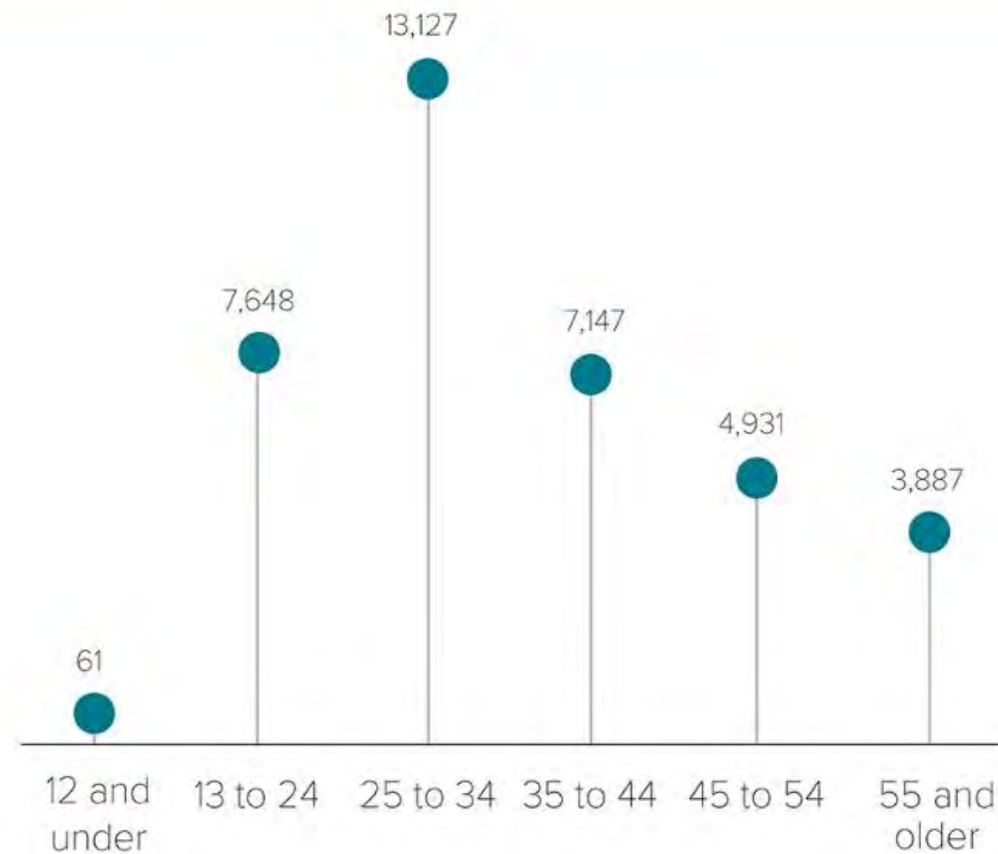
New HIV Diagnoses Among People Who Inject Drugs in the US and Dependent Areas by Race and Ethnicity, 2021*

White people accounted for the highest number of new HIV diagnoses among people who inject drugs.



New HIV Diagnoses in the US and Dependent Areas by Age, 2019

The number of new HIV diagnoses was highest among people aged 25 to 34.



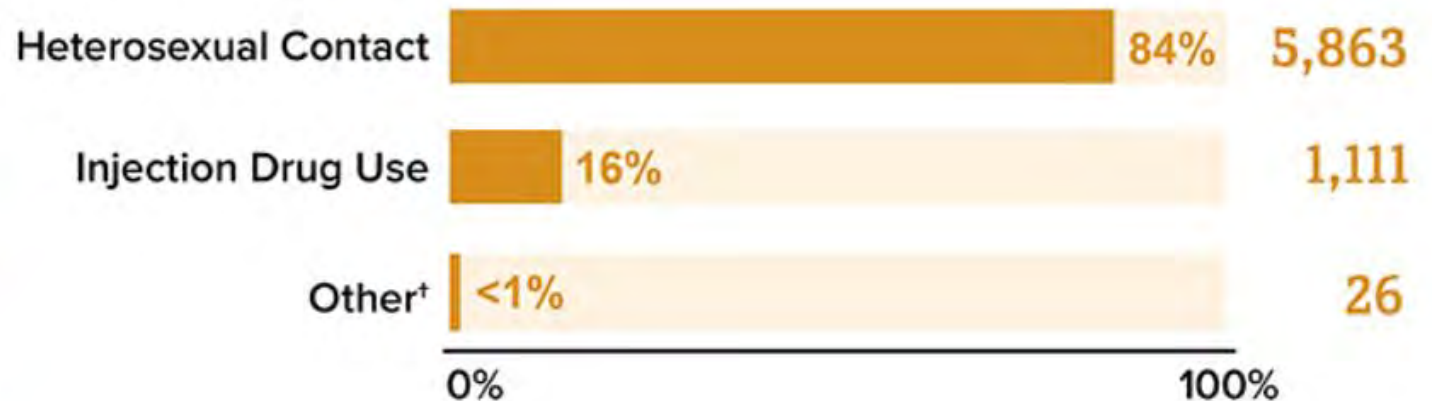
Source: CDC. Diagnoses of HIV infection in the United States and dependent areas, 2019. *HIV Surveillance Report* 2021;32.



There were **36,801 new HIV diagnoses** in the US and dependent areas in 2019. Of those, 19% (6,999) were among women.

New HIV Diagnoses Among Women by Transmission Category in the US and Dependent Areas, 2019*

Most new HIV diagnoses among women were attributed to heterosexual contact.

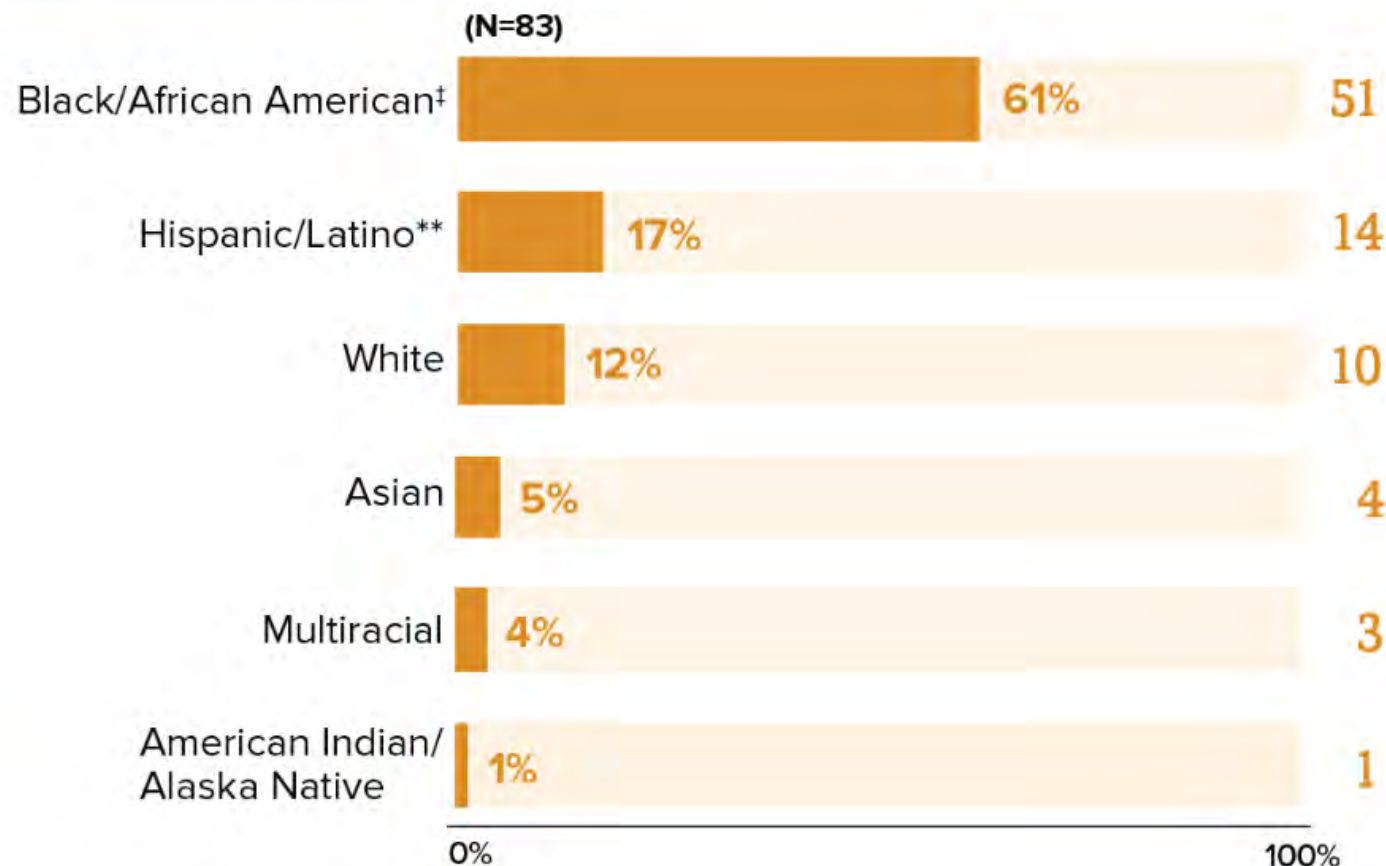




Of the **36,801 new HIV diagnoses** in the US and dependent areas in 2019, <1% (84) were due to perinatal transmission.*

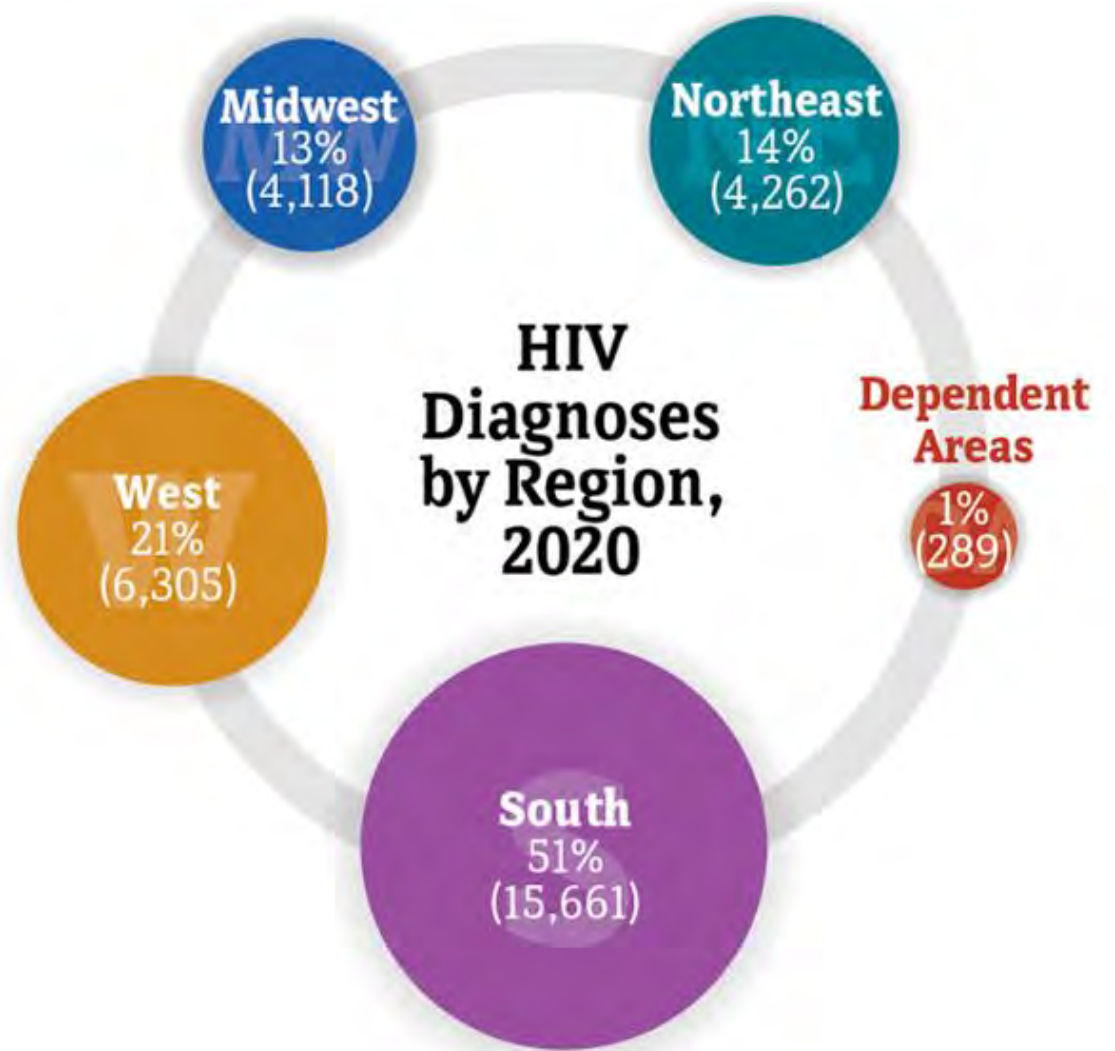
New Perinatal HIV Diagnoses in the US and Dependent Areas by Race and Ethnicity, 2019*†

New perinatal HIV diagnoses disproportionately affect certain racial and ethnic groups.





Of the **30,635 NEW HIV DIAGNOSES** in the US and dependent areas in 2020, 51% (15,661) were among adults and adolescents in the South.



New HIV Diagnoses Among Adults and Adolescents by Top 10 States, 2020

State	Number of Diagnoses
California	3,924
Texas	3,548
Florida	3,408
Georgia	1,977
New York	1,963
Illinois	1,096
North Carolina	1,079
Ohio	888
New Jersey	805
Pennsylvania	775

Friday, February 19, 2021

To end HIV epidemic, we must address health disparities

Expert report cites unequal progress in Southern U.S. and among marginalized groups.

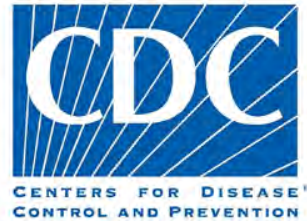
- “Scientific advances have transformed the course of HIV in individuals. To transform the course of the epidemic, we need to expand care and prevention strategically to those who need it most,” said NIDA Director Nora D. Volkow, M.D.
- “That means taking a hard look at who has been excluded from services and take immediate steps to overcome systemic barriers like stigma, structural racism, and other forms of discrimination to connect hardly reached people — such as individuals with substance use disorders — with HIV testing, prevention, and treatment.”

The time is now.

Ending
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U.S. Department of Health and
Human Services



Centers for Disease Control and
Prevention



Commissioned Corps of the U.S.
Public Health Service



National Institutes of Health



Health Resources & Services
Administration



HIV.gov



Indian Health Service



Substance Abuse and Mental
Health Services Administration

The time is now.

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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.



Ending
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GOAL:

75% (2025)
reduction in new
HIV infections
in 5 years
and at least
90% (2030)
reduction
in 10 years.



www.hiv.gov

The time is now.

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Overall Goal: Decrease the number of new HIV diagnoses to 9,588 by 2025 and 3,000 by 2030.



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Overall Goal: Increase the estimated percentage of people with HIV who have received an HIV diagnosis to at least 95% by 2025 and remain at 95% by 2030.



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Overall Goal: Increase the percentage of people with diagnosed HIV who are virally suppressed to at least 95% by 2025 and remain at 95% by 2030.



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Overall Goal: Increase the estimated percentage of people with indications for PrEP classified as having been prescribed PrEP to at least 50% by 2025 and remain at 50% by 2030.



Pre-Exposure Prophylaxis (PrEP)

- Antiviral medication used to prevent HIV.
- Component of the **Prevent** pillar of the United States government's Ending the HIV Epidemic initiative.
- 3 medication available (2 oral and 1 long-acting injectable).
- Highly effective when taken as prescribed.



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

HIV PrEP Recommendations

USPSTF 2019 Recommendation:

Recommendation Summary

Population	Recommendation	Grade
Persons at high risk of HIV acquisition	The USPSTF recommends that clinicians offer preexposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition. See the Clinical Considerations section for information about identification of persons at high risk and selection of effective antiretroviral therapy.	A

CDC 2021 Recommendation:

All sexually active adults and adolescents should be informed about PrEP for prevention of HIV acquisition.

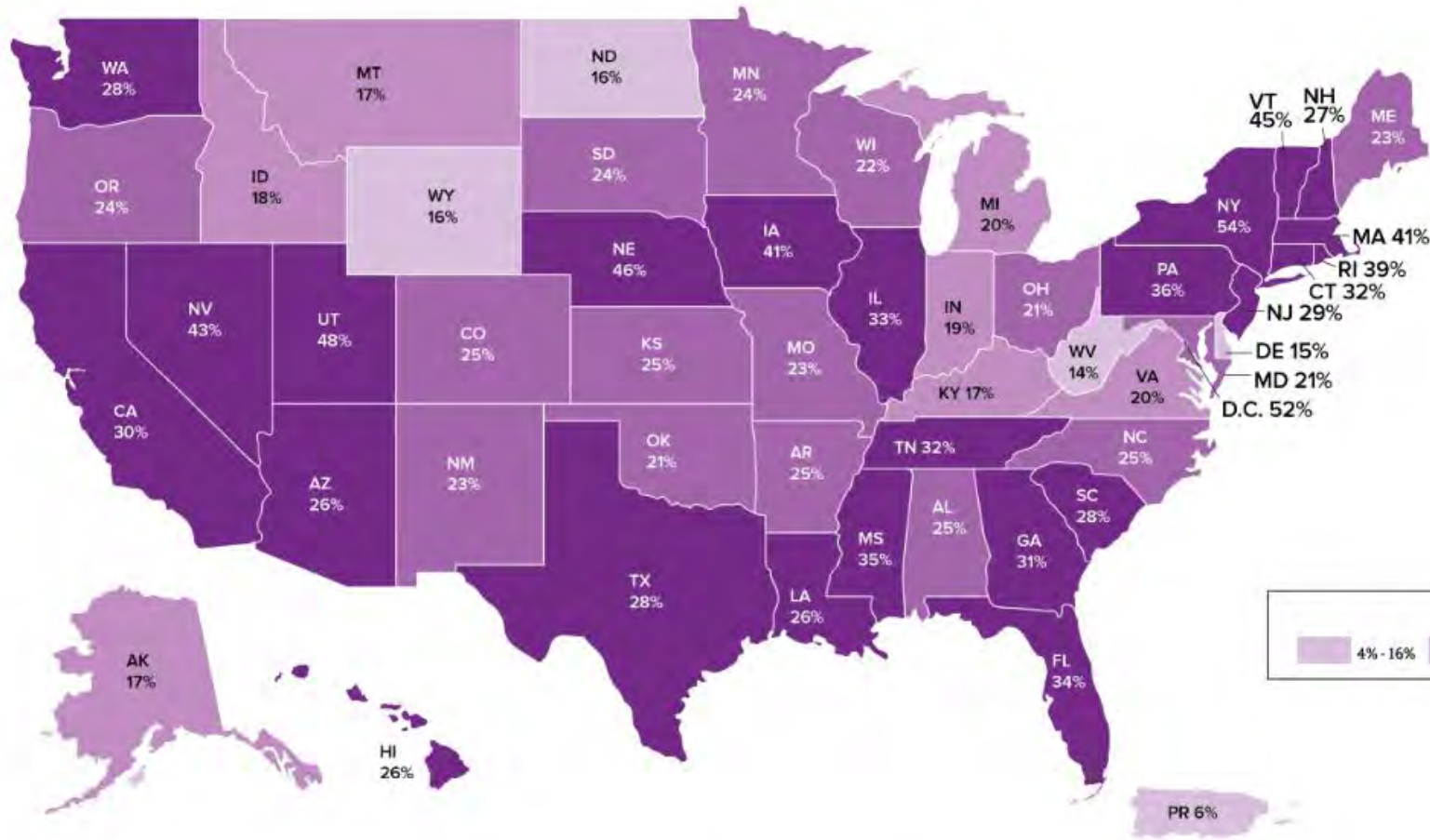
USPSTF 2023 Recommendation:

Population	Recommendation	Grade
Adolescents and adults at increased risk of HIV	<p>The USPSTF recommends that clinicians prescribe preexposure prophylaxis using effective antiretroviral therapy to persons who are at increased risk of HIV acquisition to decrease the risk of acquiring HIV.</p> <p>See the Practice Considerations section for more information about identification of persons at increased risk and about effective antiretroviral therapy.</p>	A

ONLY



Of the 1.2 million people in the United States who could benefit from PrEP, only 30% were prescribed PrEP in 2021.



* Among people aged 16 and older



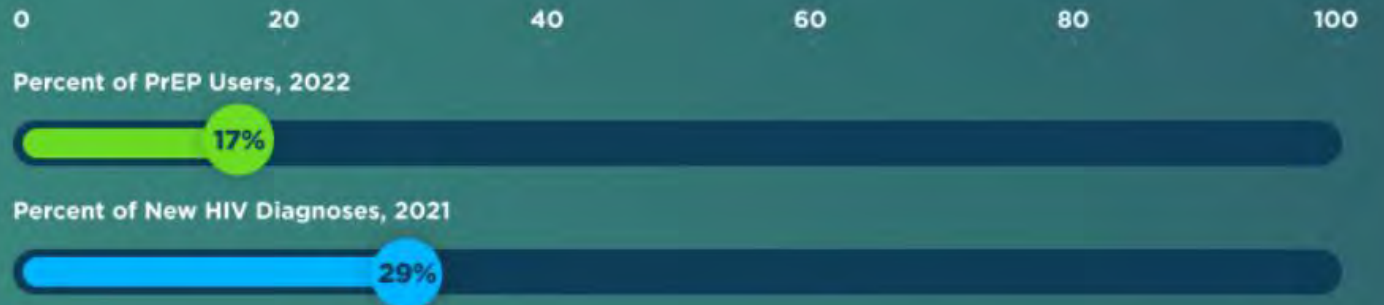
Black people represented only **14% of PrEP users (2022)** but accounted for **40% of new HIV diagnoses (2021)**, indicating a significant unmet need for PrEP.



Black People



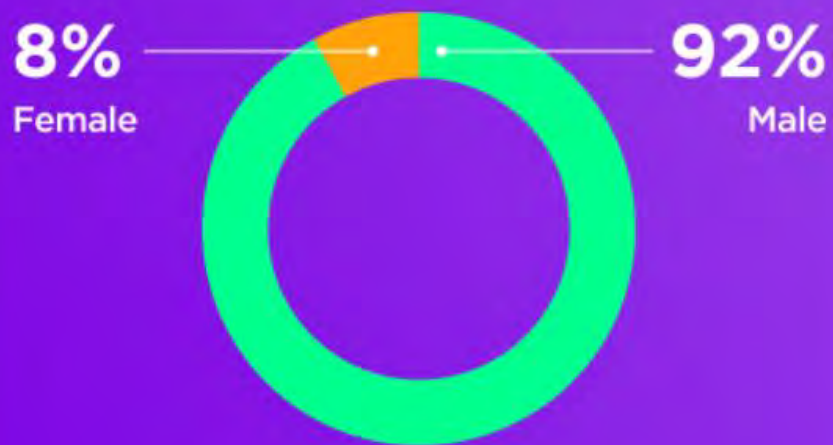
Hispanic/Latinx People



White People



In 2022, **92% of all PrEP users were male** and only **8% were female**, despite the fact that women represented 18% of new diagnoses in 2021.



PrEP Users by Sex, 2022

There were **16 male PrEP users** for every new HIV diagnosis among men.



There were **6 female PrEP users** for every new HIV diagnosis among women.

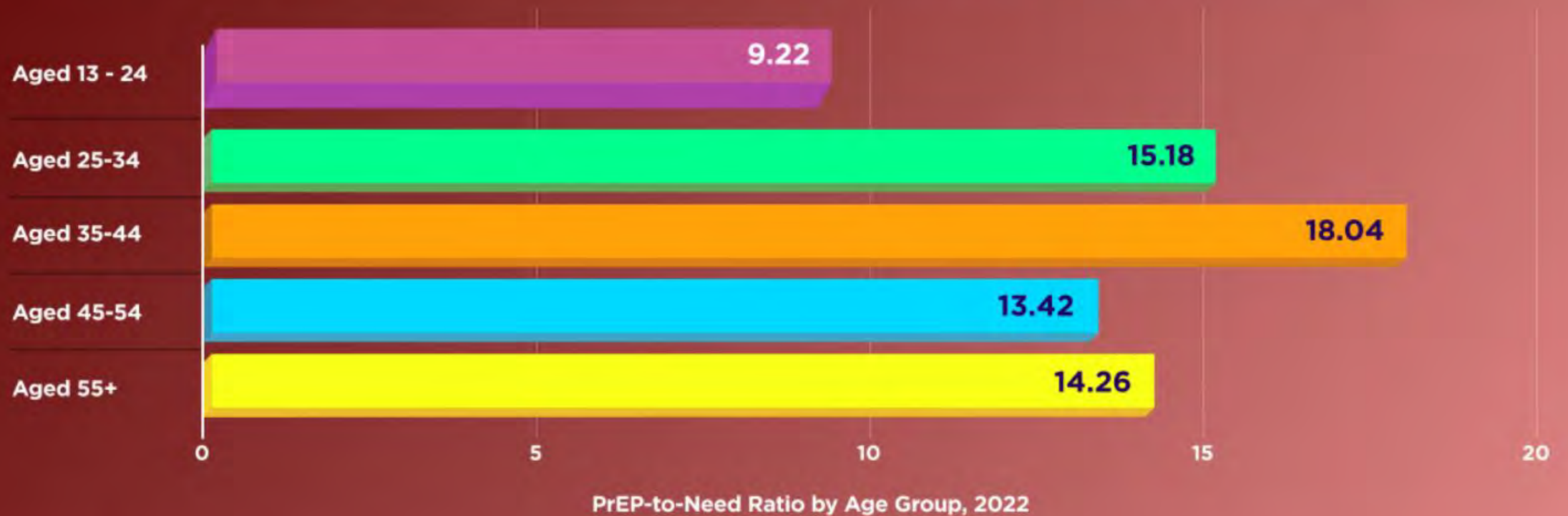


40% of PrEP users
in 2022 were
25-34 years old,
the **highest percentage**
of any age group.



Percentage of PrEP Users by Age Group, 2022
**Due to rounding, data does not add up to 100%.*

In 2022, **teenagers and young adults (aged 13-24 years)** had the **greatest unmet need for PrEP** among all age groups, with a **PnR of 9**. That means for every person in that age group diagnosed with HIV, there were only 9 people using PrEP.



**PrEP-to-Need Ratio (PNR) is the ratio of the number of PrEP users in 2022 to the number of people newly diagnosed with HIV in 2020. It is a measurement for whether PrEP use appropriately reflects the need for HIV prevention. A lower PNR indicates more unmet need.*

What are the barriers?

- 2020 systematic review assessing provider barriers
 - Lack of knowledge about PrEP guidelines
 - Purview paradox - discordance in beliefs about who should prescribe PrEP
 - Concerns about cost
 - Concerns about behavioral and health consequences
 - Interpersonal stigma
 - Concern about patient adherence

Table 1 Summary of key barriers to PrEP uptake as identified in the recent literature and potential approaches to removing barriers to PrEP

Key barriers	Potential approaches to removing barriers
Awareness of PrEP	Patient and provider education Better communication between providers
HIV risk perception	Patient and provider education
Stigma	Improved cultural humility (via education and advocacy) Improved communication and understanding between patient and provider
Provider bias and distrust of healthcare system	Patient and provider education Addressing systemic entrenched bias (via education, advocacy, and recruitment of more Black, Latinx, and LGBTQ healthcare professionals)
Access to medical care	Patient and provider education Extending access to PrEP (e.g., substance use clinics, emergency rooms, pharmacies, correctional institutions, etc.) Leveraging technology to improve access (e.g., telemedicine) Addressing competing priorities (e.g., food, shelter, safety, other healthcare, childcare)
Lack of access to financial assistance	Help for patients in navigating financial aid options
Side effects	Patient and provider education

HIV human immunodeficiency virus, *LGBTQ* lesbian, gay, bisexual, transgender, and queer, *PrEP* pre-exposure prophylaxis

What does PrEP cost?

Drug	Cost per month	Cost per year
Truvada (generic)	\$2,100	\$25,200
Descovy	\$2,591	\$31,092
Apretude	\$4,574 (per vial–q2 mo)	\$32,018

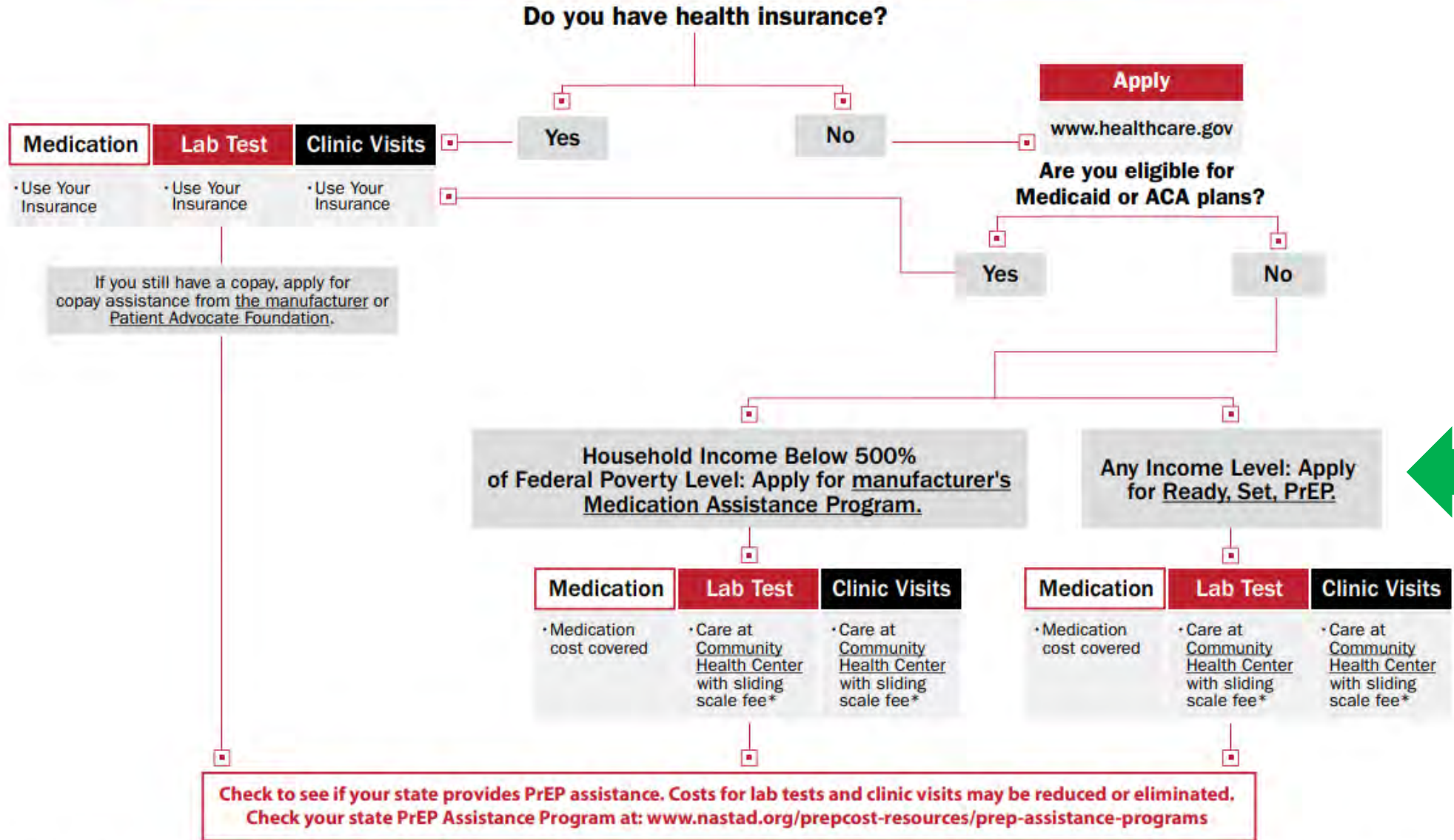
*average wholesale price

Good news

- The **USPSTF** recommends that PrEP be provided to “persons who are at high risk of HIV acquisition” with an **A grade** indicating that there is high certainty that the net benefit is substantial.
- This rating requires most commercial insurers and some Medicaid programs to provide oral PrEP with **no out-of-pocket cost** to patients. In addition to PrEP **medication**, DHHS has determined that **laboratory tests** necessary for PrEP are included in this provision as well as **clinic visits** when the primary purpose of the office visit is the delivery of PrEP care.



How do I Pay for Pre-Exposure Prophylaxis (PrEP)?






* To find a Community Health Center: findahealthcenter.hrsa.gov



Ending the HIV Epidemic

Table 9 NASTAD Table of State PrEP Financial Assistance Programs (as of August 2022)

STATE	 DRUG ASSISTANCE		 CLINICAL VISITS AND LAB TEST ASSISTANCE	 PATIENT INCOME LIMIT
	CO-PAY ASSISTANCE	MEDICATION ASSISTANCE		
California	Yes	Yes	Any participating provider	Up to 500%
Colorado	Yes	Yes	Any participating provider	Below 500%
District of Columbia	Yes	No	Local health department clinician	Up to 500%
Florida	No	Yes*	Local health department clinics	No threshold
Illinois	Yes	No	Select grantees	No threshold
Indiana	Yes	No	Contracted Providers	400%
Iowa	Yes	No	Sub-recipients	No threshold
Massachusetts	Yes	No	Select Grantees	Up to 500%
New Mexico	Yes	Yes	Contracted Providers	No threshold
New York State	No	No	Any participating provider	Up to 435%
Ohio	Yes	No	Any participating provider	Up to 500%
Oklahoma	Yes	Yes	Contracted Providers	No threshold
Virginia	No	Yes*	Local health departments and contracted providers	No Threshold
Washington State	Yes	Yes	Any participating provider	No Threshold

** Table provided by NASTAD (source: <https://www.nastad.org/prepcost-resources/prep-assistance-programs>)

Minors

- As of 2022, all jurisdictions have laws that explicitly allow a minor of a particular age (as defined by each state) to give informed consent to receive STI diagnosis and treatment services. In some jurisdictions, a minor might be legally allowed to give informed consent to receive specific STI or HIV services, including PrEP, even if the law is silent on those disease-related services.
- [Minors' Consent Laws | Law | Policy and Law | HIV/AIDS | CDC](#)

Table. Age of Majority and Youngest Age of Legal Capacity of Mentally Competent Minors to Consent to STI and HIV Services and Confidentiality Protections for Minors' STI and HIV Information in the US, 2021^{a,b} (continued)

State	Age of majority, y	Youngest age of legal capacity to consent, y/confidentiality protections					
		STI			HIV		
		Testing	Treatment	Prevention	Testing	Treatment	Prevention, including HIV PrEP
Vermont	18	12/No	12/No	18/-	12/No	12/No	18/-
New Hampshire	18	14/CD	14/CD	18/-	14/CD	14/CD	18/-

- A dash (–) indicates that minors do not have the legal capacity to consent to that service.
- CD, clinician discretion
- No, no confidentiality protections

The time is now.

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Epidemic

Percentage of people with indications for PrEP classified as having been prescribed PrEP nationwide.





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*Get PrEP'd ECHO:
HIV Pre-Exposure Prophylaxis*

Session 2, Sexual history Taking, September 19, 2023

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Taking a Sexual History using Inclusive Language

Bobby Kelly, MD, MPH, FAAFP

Medical Director of Quality Improvement & Innovation

Population Health | Family Medicine | Addiction Medicine | LGBTQ Medicine

Beth Israel Lahey Health Core Physicians, Exeter, NH

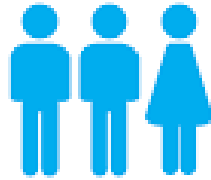
The importance of sexual health & taking an accurate sexual history

- An essential element of overall health and well-being
- Not always discussed by patients or providers
 - As healthcare providers, we can help remove stigma by normalizing the conversation
- Opportunity to:
 - Screen and treat STIs and other sexual health concerns
 - Counsel/share information about behaviors to reduce STI risk
 - Gain a deeper understanding of your patients' overall health
- Important to be aware of your patient's specific needs and modify language as needed
 - Try not to make any assumptions (avoid “obviously”, “husband”, “wife”, etc.)
 - Important to start with inclusive and gender-neutral language (generally safe to use “they/them”)
 - Take your patient's lead regarding answers

Getting the Conversation Started

- Assess your own comfort, and identify any biases you may have
 - If you are uncomfortable talking about sex & sexuality, patients will be too
- Uses gender neutral language – “partner”
- Ask for correct pronouns, you can offer yours
 - Intake forms can help with this
- Let patient know that you ask everyone these questions (and then ask everyone these questions! 😊)
- Try not to react to answers overtly
 - Pay attention to your body language

CDC's 5P model



Partners



Practices



Past History
of STDs



Protection
from STDs



Pregnancy
Plans



To learn more about taking a sexual history, visit:

[cdc.gov/HIVNexus](https://www.cdc.gov/HIVNexus)



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Sources: Fenway Health, CDC

<https://www.cdc.gov/stophivtogether/library/topics/prevention/brochures/cdc-lsht-prevention-brochure-clinicians-quick-guide-discussing-sexual-health-your-patients.pdf>

Partners



- Are you currently having sex of any kind—oral, vaginal, or anal—with anyone? (Are you having sex?)
 - “Any parts of your body touching parts of someone else’s body?” (see “Practices” section)
- If no, have you ever had sex of any kind with another person?
- In recent months, how many sex partners have you had?
- What is/are the gender(s) of your sex partner(s)?
 - “Any chance of pregnancy between you and your partner?”
 - For patients with ovaries: “Does/can your partner produce sperm?”
 - For patients with testes: “Does your partner have a uterus?”
- Do you or your partner(s) currently have other sex partners?
 - Just because your patient may be monogamous with their partner, that doesn’t mean they don’t have any exposures

Practices



- I need to ask some more specific questions about the kinds of sex you have had over the last 12 months to better understand if you are at risk for sexually transmitted infections or STIs. Would that be OK?
- We have different tests that are used for the different body parts people use to have sex. What kinds of sexual contact do you have, or have you had? What parts of your body are involved when you have sex?
 - Do you have genital sex (penis in the vagina)?
 - Anal sex (penis in the anus)?
 - Oral sex (mouth on penis, vagina, or anus)?
 - Are you a top and/or bottom? Versatile?
 - Other sex?
- Have you or any of your partners used drugs? Have you exchanged sex for your needs (money, housing, drugs, etc.)?
 - Both increase STI acquisition risk, may be candidate for PrEP

Past History of STDs/STIs



- Have you ever been tested for STIs and HIV? Would you like to be tested?
- Have you been diagnosed with an STI in the past? When? Did you get treatment?
 - If patient has tested positive (and even treated) for syphilis, their initial screen may always be “positive”
- Have you had any symptoms that keep coming back?
- Has your current partner or any former partners ever been diagnosed or treated for an STI? Were you tested for the same STI(s)? Do you know your partner’s (or partners’) HIV status?

Protection from STDs/STIs



- Do you and your partner(s) discuss STI prevention?
- If you use prevention tools, what methods do you use? (For example, external or internal condoms— also known as male or female condoms—dental dams, etc.)
- How often do you use this/these method(s)? More prompting could include specifics about:
 - Frequencies: sometimes, almost all the time, all the time.
 - Times they do not use a method.
 - If “sometimes,” in which situations, or with whom, do you use each method?
- Have you received human papilloma virus (HPV), hepatitis A, and/or hepatitis B shots?
- Are you aware of pre-exposure prophylaxis or PrEP, a medicine that can prevent HIV? Have you ever used it or considered using it?

Pregnancy plans



- Do you think you would like to have (more) children at some point?
- When do you think that might be?
- How important is it to you to prevent pregnancy (until then)?
- Are you or your partner using contraception or practicing any form of birth control? Would you like to talk about ways to prevent pregnancy? Do you need any information on birth control?
 - Reminder that gender affirming hormone therapy is NOT birth control
 - Reminder that testosterone is considered a teratogen

Consider adding the 6th P – “Pleasure”



- <https://nationalcoalitionforsexualhealth.org/tools/for-healthcare-providers/video-series>



PrEP ECHO
TAKING A SEXUAL HISTORY USING
INCLUSIVE LANGUAGE

Thank you!
Questions?

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WELCOME to the

*Get PrEP'd ECHO:
HIV Pre-Exposure Prophylaxis*

*Session 3, HIV Risk Assessment and Indications for
PrEP, October 3, 2023*

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Today's Program

- Brief housekeeping
- Didactic: HIV Risk Assessment and Indications for PrEP
– *Antonia Altomare, DO, MPH*
- Case presentation: Bryan Marsh
- Case discussion
- Summary
- Up Next



HIV Risk Assessment and PrEP Indications

Antonia Altomare, DO, MPH

Associate Professor of Medicine, Geisel School of Medicine

Co-program Director the HOPE Program, Dartmouth Health

Medical Director, NH AETC

HIV PrEP Recommendations

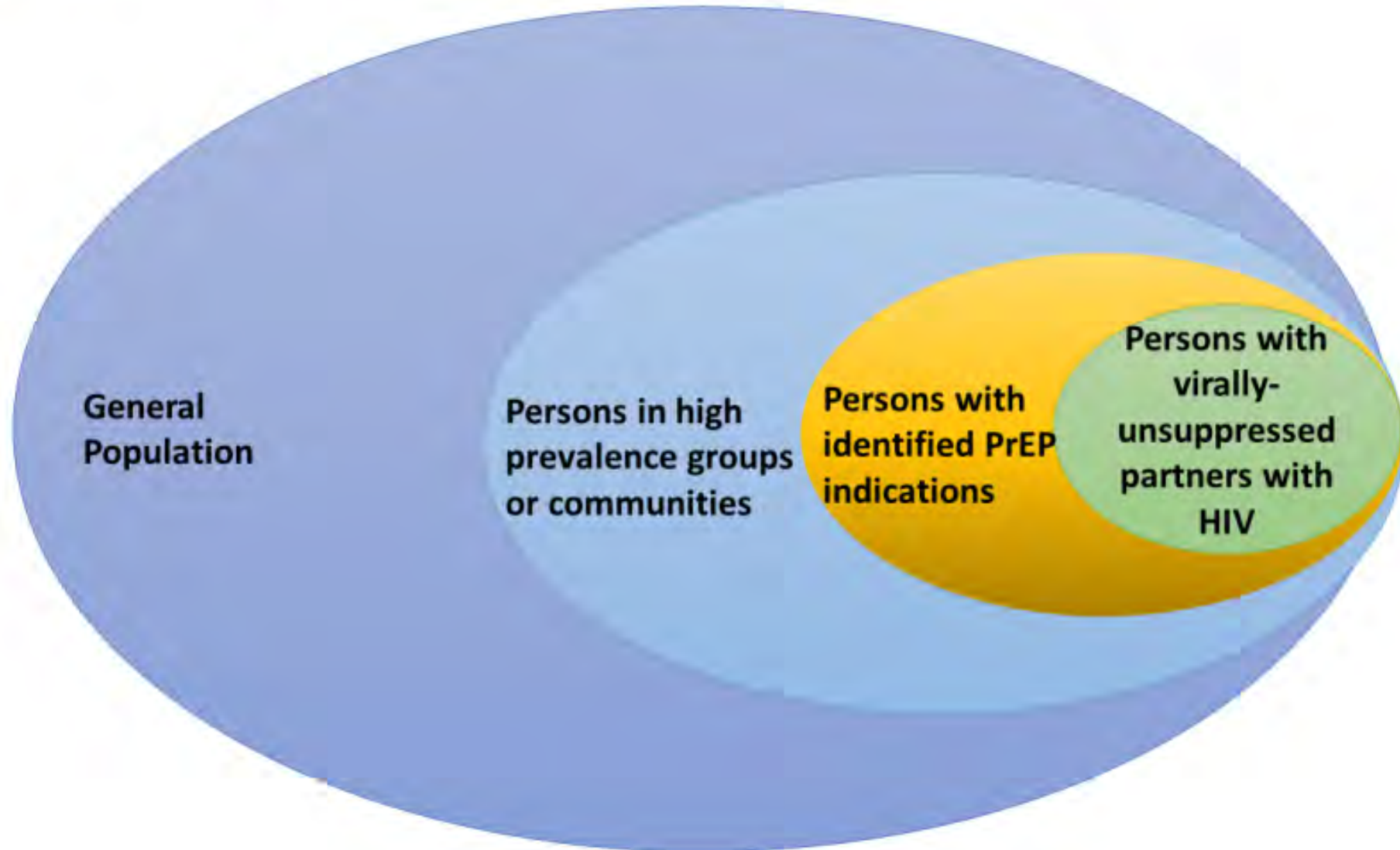
CDC 2021 Recommendation:

All sexually active adults and adolescents should be informed about PrEP for prevention of HIV acquisition.

USPSTF 2023 Recommendation:

Population	Recommendation	Grade
Adolescents and adults at increased risk of HIV	<p>The USPSTF recommends that clinicians prescribe preexposure prophylaxis using effective antiretroviral therapy to persons who are at increased risk of HIV acquisition to decrease the risk of acquiring HIV.</p> <p>See the Practice Considerations section for more information about identification of persons at increased risk and about effective antiretroviral therapy.</p>	A

Figure 1 **Populations and HIV Acquisition Risk**



Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act*

Type of Exposure	Risk per 10,000 Exposures
Parenteral	
Blood Transfusion	9,250
Needle-Sharing During Injection Drug Use	63
Percutaneous (Needle-Stick)	23
Sexual	
Receptive Anal Intercourse	138
Insertive Anal Intercourse	11
Receptive Penile-Vaginal Intercourse	8
Insertive Penile-Vaginal Intercourse	4
Receptive Oral Intercourse	Low
Insertive Oral Intercourse	Low
Other[^]	
Biting	Negligible
Spitting	Negligible
Throwing Body Fluids (Including Semen or Saliva)	Negligible
Sharing Sex Toys	Negligible

* Factors that may increase the risk of HIV transmission include sexually transmitted diseases, acute and late-stage HIV infection, and high viral load. Factors that may decrease the risk include condom use, male circumcision, antiretroviral treatment, and pre-exposure prophylaxis. None of these factors are accounted for in the estimates presented in the table.

[^] HIV transmission through these exposure routes is technically possible but unlikely and not well documented.

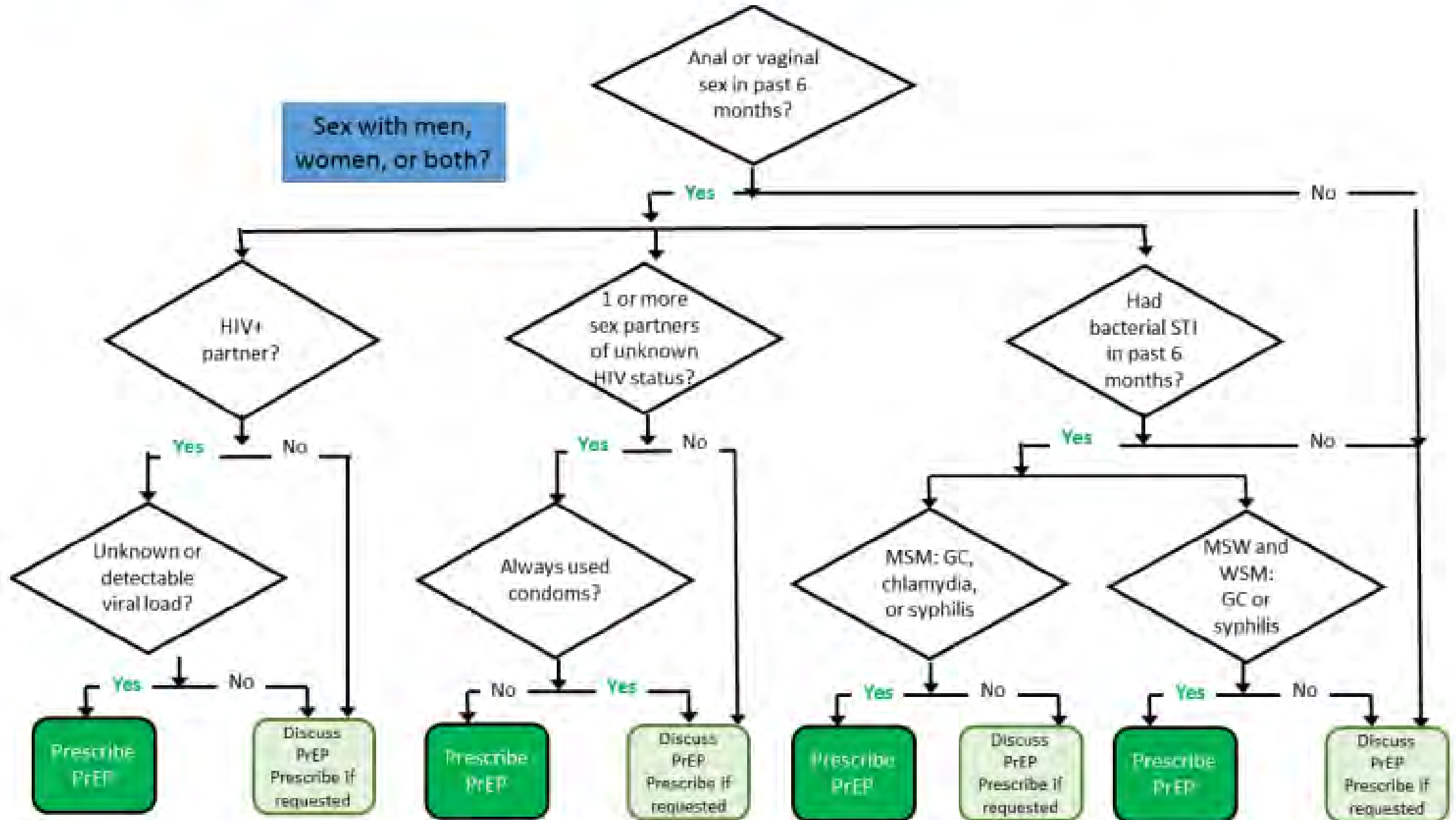
Source:

- Patel P, Borkowf CB, Brooks JT. Et al. Estimating per-act HIV transmission risk: a systematic review. AIDS. 2014. doi: 10.1097/QAD.0000000000000298.
- Pretty LA, Anderson GS, Sweet DJ. Human bites and the risk of human immunodeficiency virus transmission. Am J Forensic Med Pathol 1999;20(3):232-239.

Risk Assessment

- Taking a sexual history on ALL patients is the first step to identifying risk.
- Assess for IVDU.
- Assess for ‘chemsex’ (the use of drugs before or during sex).
- Patients may request PrEP because of concern about acquiring HIV but not feel comfortable reporting sexual or injection behaviors.
- **Patients who request PrEP should be offered it, even when no specific risk behaviors are elicited.**

Figure 2 Assessing Indications for PrEP in Sexually Active Persons



MSM Risk Index ¹³

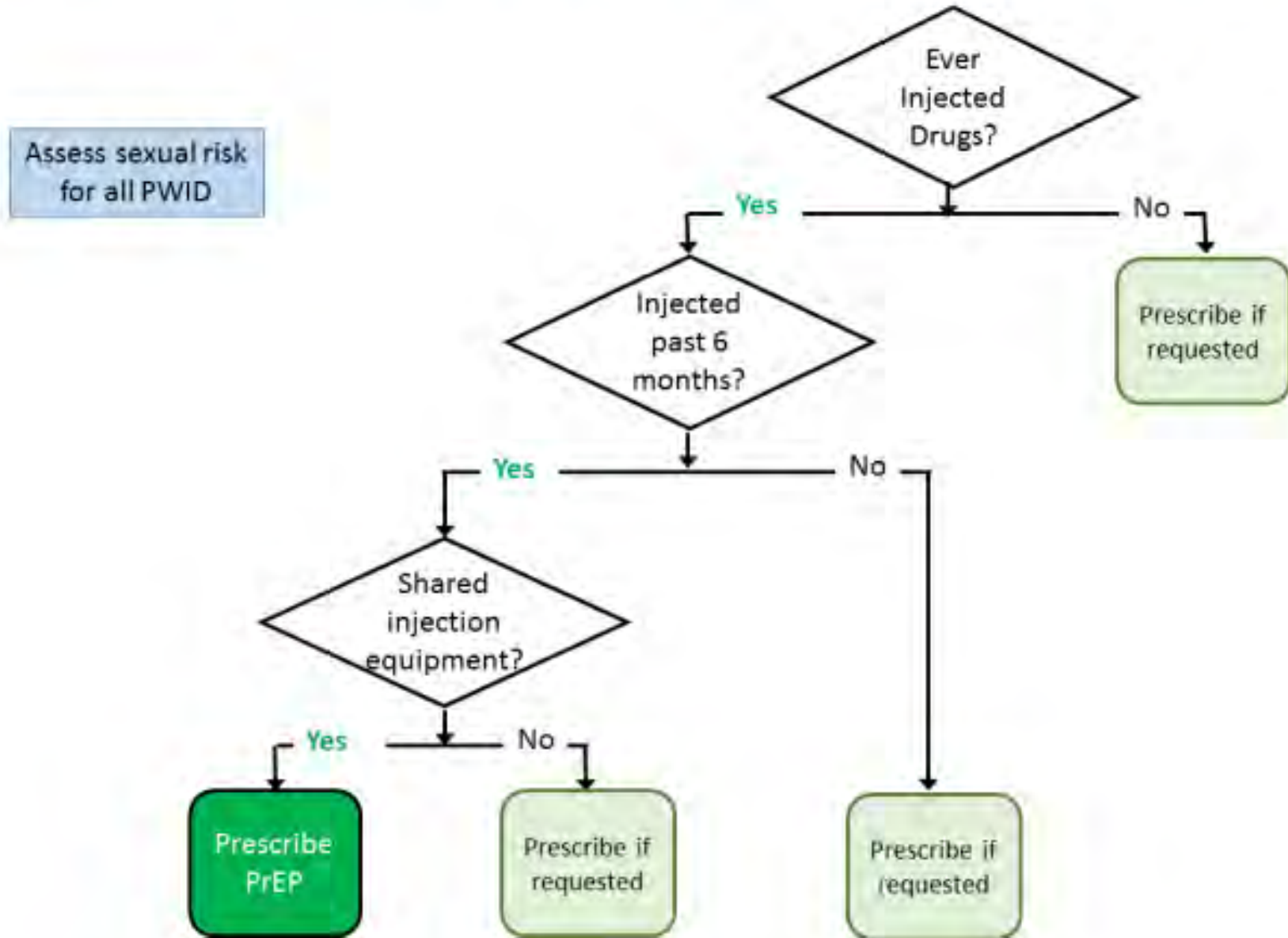
1	How old are you today?	If <18 years, score 0	
		If 18-28 years, score 8	_____
		If 29-40 years, score 5	
		If 41-48 years, score 2	
		If 49 years or more, score 0	
2	In the last 6 months, how many men have you had sex with?	If >10 male partners, score 7	
		If 6-10 male partners, score 4	_____
		If 0-5 male partners, score 0	
3	In the last 6 months, how many times did you have receptive anal sex (you were the bottom) with a man when he did not use a condom?	If 1 or more times, score 10	
		If 0 times, score 0	_____

<p>4 In the last 6 months, how many of your male sex partners were HIV-positive?</p>	<p>If >1 positive partner, score 8 If 1 positive partner, score 4 If <1 positive partner, score 0</p>	<p>_____</p>
<p>5 In the last 6 months, how many times did you have insertive anal sex (you were the top) with a man who was HIV- positive when you did not use a condom?</p>	<p>If 5 or more times, score 6 If 0-4 times, score 0</p>	<p>_____</p>
<p>6 In the last 6 months, have you used methamphetamines such as crystal or speed?</p>	<p>If yes, score 6 If no, score 0</p>	<p>_____</p>
<p>Add down entries in right column to calculate total score</p>		<p>_____</p>
		<p>TOTAL SCORE*</p>

* If score is 10 or greater, evaluate for intensive HIV prevention services, including PrEP. If score is below 10, provide indicated standard HIV prevention services.

Figure 3

Assessing Indications for PrEP in Persons Who Inject Drugs





PWID (IDU) Risk Index ¹⁴

1	How old are you today (in years)?	If <30 years, score 38 If 30- 39 years, score 24 If 40-49 years, score 7 If ≥50 years, score 0	_____
2	In the last 6 months, were you in a methadone maintenance program?	If yes, score 0 If no, score 31	_____
3	In the last 6 months, how often did you inject heroin?	If 1 or more times, Injection sub-score 1 If 0 times, Injection sub-score 0	_____
	In the last 6 months, how often did you inject cocaine?	If 1 or more times, Injection sub-score 1 If 0 times, Injection sub-score 0	_____
	In the last 6 months, how often did you share a cooker?	If 1 or more times, Injection sub-score 1 If 0 times, Injection sub-score 0	_____
	In the last 6 months, how often did you share needles?	If 1 or more times, Injection sub-score 1 If 0 times, Injection sub-score 0	_____
	In the last 6 months, how often did you visit a shooting gallery?	If 1 or more times, Injection sub-score 1 If 0 times, Injection sub-score 0	_____
	Add the five injection subscores to obtain a Composite Injection Subscore	If sum of five injection subscores is; then Composite Injection Score is: 0 0 1 7 2 21 3 24 4 24 5 31	_____
	Add the scores for age and methadone use to the Composite Injection Subscore to yield a Total Score		<u> </u> Total Score*

* If the total score is 46 or greater, evaluate for PrEP or other intensive HIV prevention services for PWID. If score is 45 or less, provide indicated standard HIV prevention services for PWID. To identify active PWID in a clinician’s practice, we recommend asking all their patients a routine question: “Have you ever injected drugs that were not prescribed for you by a physician?” If yes, ask, “When was the last time you injected any drugs?” Only complete PWID risk index if they have injected any nonprescription drug during the past 6 months.

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

	Sexually-Active Adults and Adolescents¹	Persons Who Inject Drug²
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: <ul style="list-style-type: none"> • HIV-positive sexual partner (especially if partner has an unknown or detectable viral load) • Bacterial STI in past 6 months³ • History of inconsistent or no condom use with sexual partner(s) 	HIV-positive injecting partner OR Sharing injection equipment
Clinically eligible	<p style="text-align: center;"><u>ALL OF THE FOLLOWING CONDITIONS ARE MET:</u></p> <ul style="list-style-type: none"> • 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/min⁴ • No contraindicated medications 	

Table 1b: Summary of Clinician Guidance for Cabotegravir Injection PrEP Use

	Sexually-Active Adults	Persons Who Inject Drugs¹
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: <ul style="list-style-type: none"> • HIV-positive sexual partner (especially if partner has an unknown or detectable viral load) • Bacterial STI in past 6 months² • History of inconsistent or no condom use with sexual partner(s) 	HIV-positive injecting partner OR Sharing injection equipment
Clinically eligible	<p style="text-align: center;"><u>ALL OF THE FOLLOWING CONDITIONS ARE MET:</u></p> <ul style="list-style-type: none"> • 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 	

Risk Reduction Counseling

- USPSTF recommends behavioral counseling for all sexually active adolescents and for adults at increased risk for STIs and HIV.
- Provided in a nonjudgmental and empathetic manner appropriate to the patient's culture, language, sex and gender identity, sexual orientation, age, and developmental level.
- The goal is to develop a risk reduction plan that meets the patient's needs while keeping their risk as low as possible.

Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention



The *Compendium* is a composition or collection of HIV interventions in the form of info sheets. Info sheets are categorized by Evidence-Based Interventions (EBIs) or Evidence-Informed Interventions (EIs).

Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention

PrEP Chapter +

Structural Interventions (SI) Chapter +

Linkage to, Retention in, and Re-engagement in HIV Care (LRC) Chapter +

Medication Adherence (MA) Chapter +

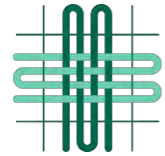
Risk Reduction (RR) Chapter -

RR Efficacy Criteria

Complete List of RR EBIs

RR Archived Interventions

The Risk Reduction Chapter identifies evidence-based interventions that reduce HIV-transmission risk by decreasing sex and drug-injection risk behaviors.



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*Get PrEP'd ECHO:
HIV Pre-Exposure Prophylaxis*

*Session 4, HIV Diagnostics and Interpretation
Particularly in the Context of PrEP Usage,
October 17, 2023*

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organization into CHAT*



HIV Diagnostics

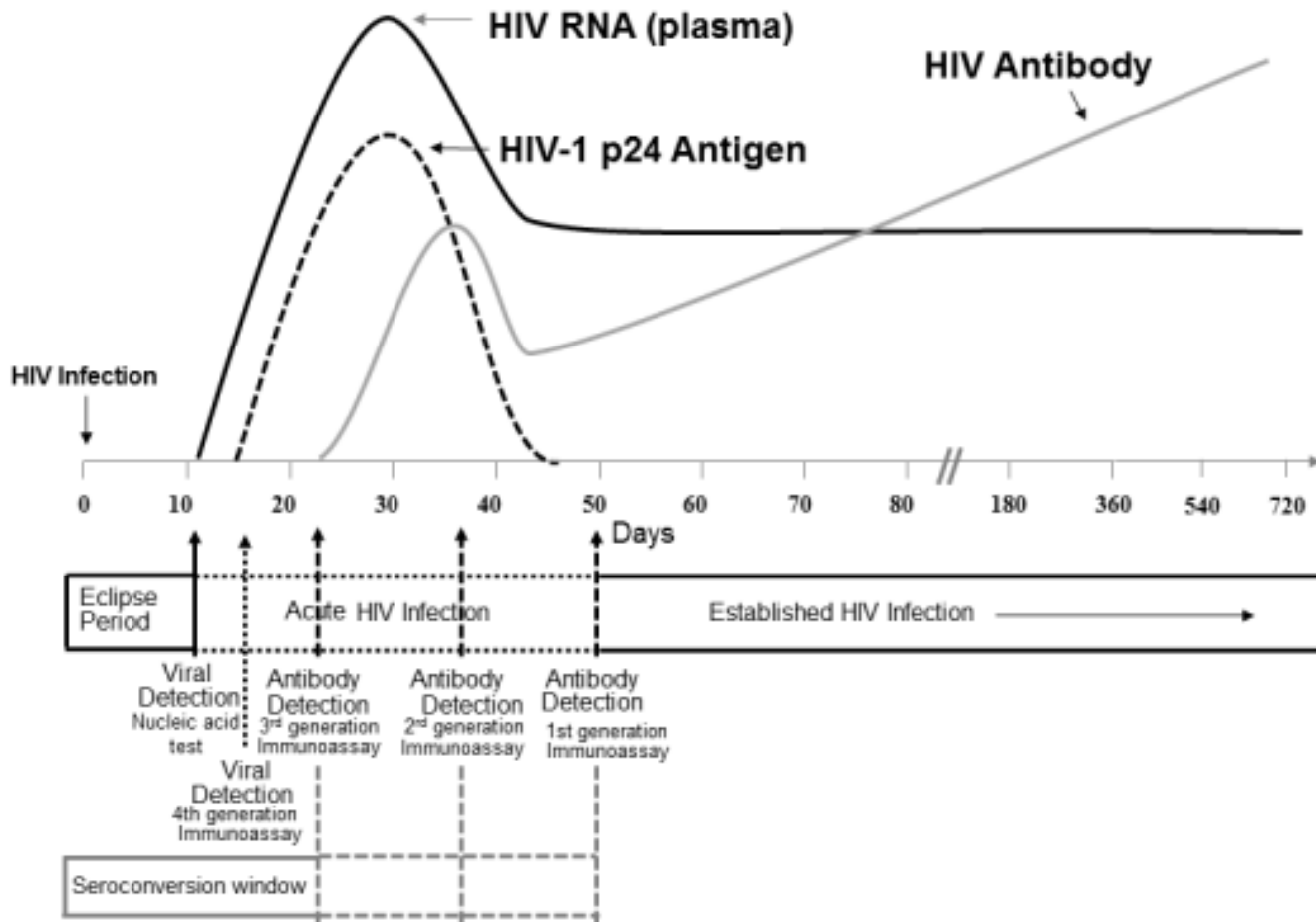
Bryan J. Marsh, MD

Associate Professor of Medicine, Geisel School of Medicine

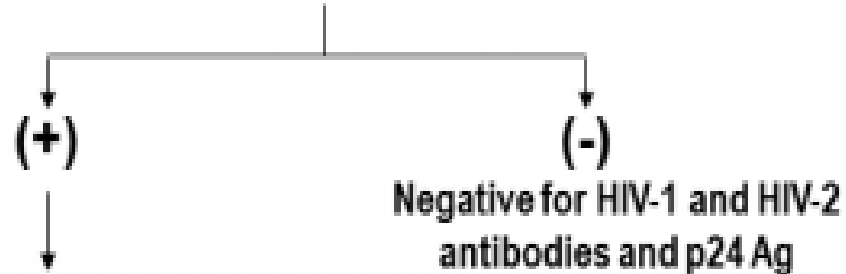
Co-program Director the HOPE Program, Dartmouth Health

Chief, Section of Infectious Diseases and International Health, Dartmouth Health

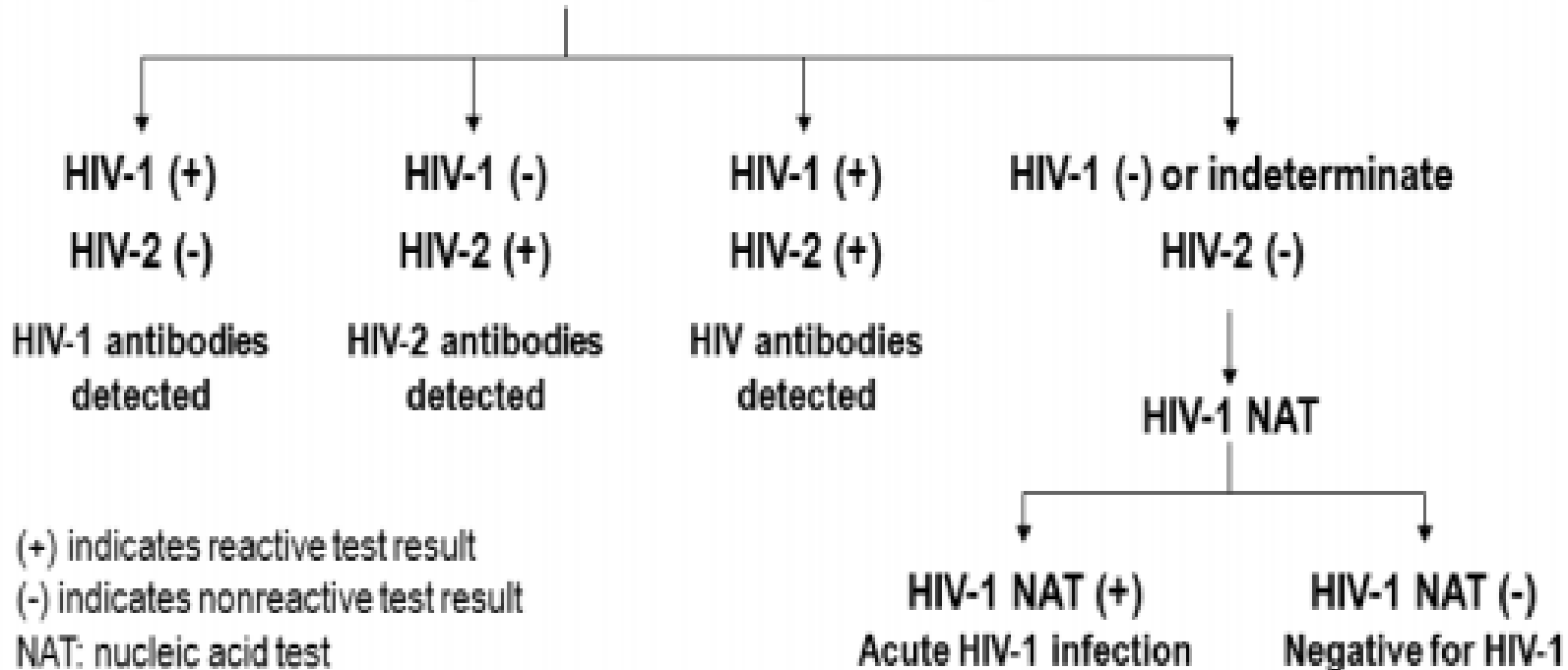
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HIV-1/2 antigen/antibody combination immunoassay



HIV-1/HIV-2 antibody differentiation immunoassay



What are benefits of the 4th generation Antigen/Antibody Tests?

Catch early
HIV via
antigen
assays

Avoid false
negatives and
indeterminant
results of
Western blot

Use
expensive
NAT tests
sparingly

Discriminate
b/w HIV-1 and
HIV-2
systematically

FDA Approved HIV Tests

Antigen/Antibody Laboratory Tests



Antibody Laboratory Tests



Antigen/Antibody Rapid Tests



Antibody Self-Tests



Antibody Rapid Tests: Point-of-care



Diagnostic Nucleic Acid Laboratory Tests



Supplemental Antibody Laboratory Tests



Nucleic Acid Monitoring Tests – Not for Diagnosis



Last Reviewed: May 1, 2023

Source: Division of HIV Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention

Figure 4a Clinician Determination of HIV Status for PrEP Provision to Persons without Recent Antiretroviral Prophylaxis Use

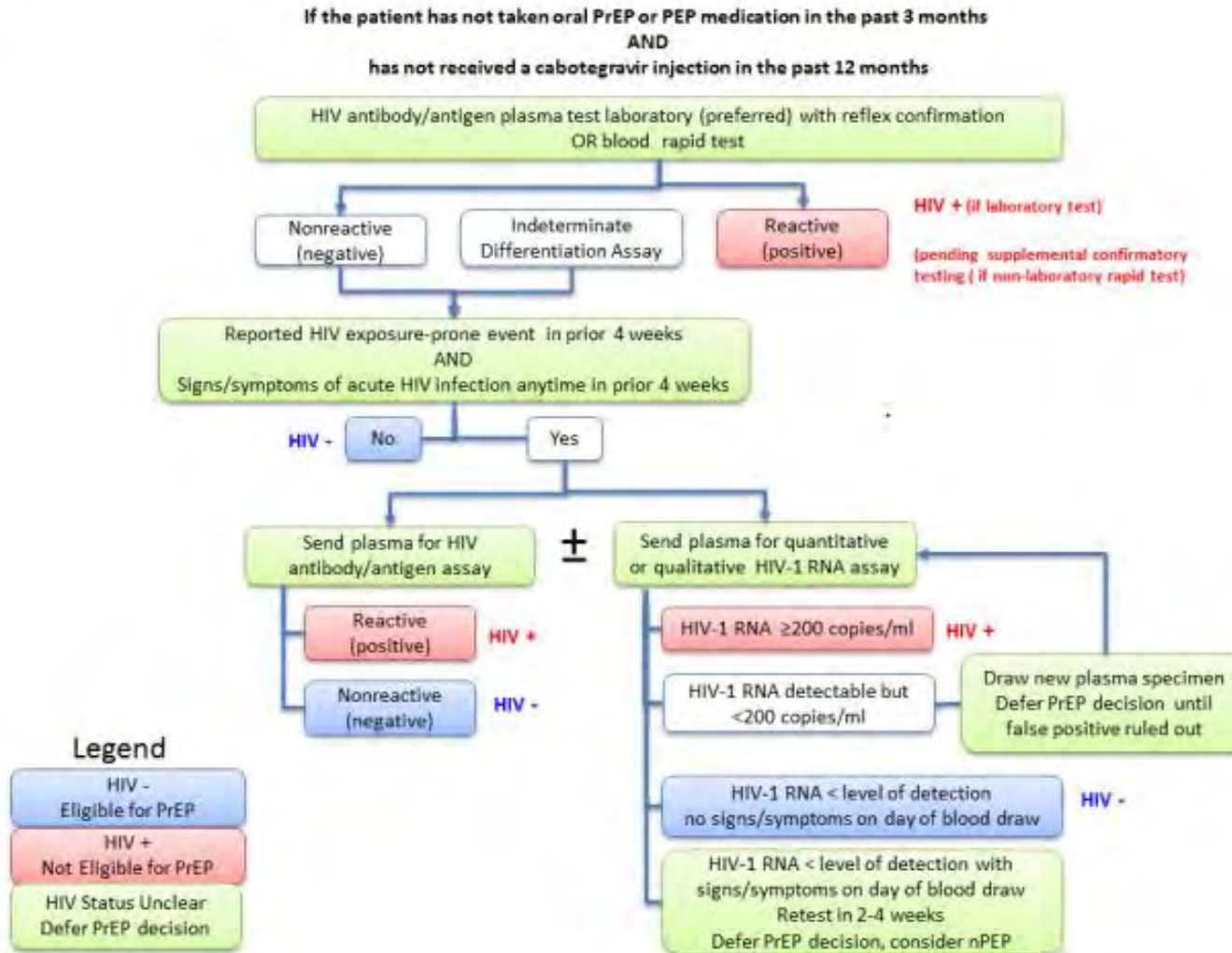
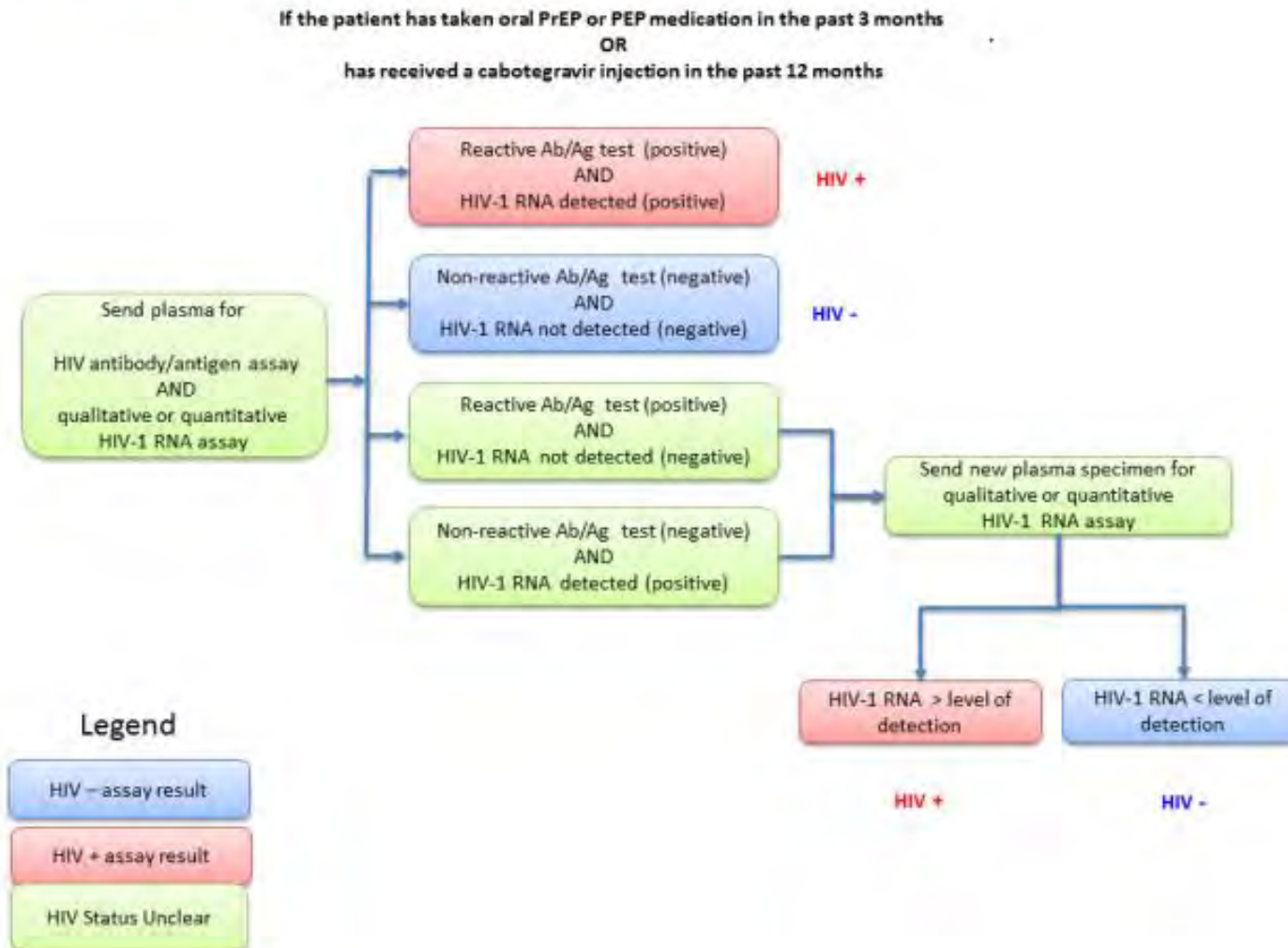
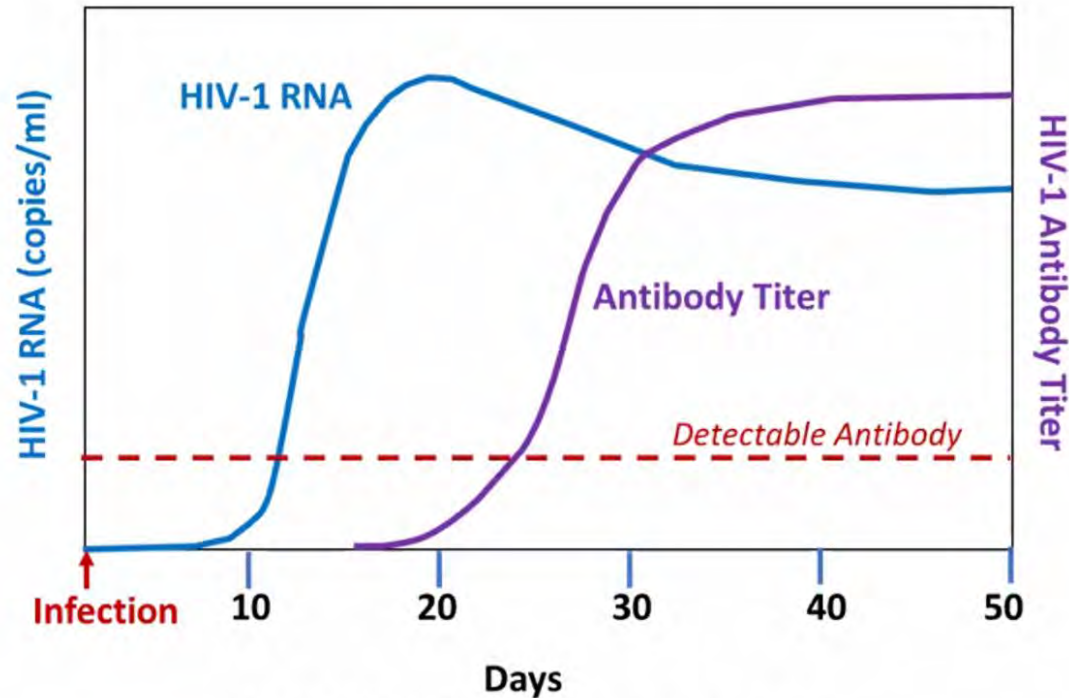


Figure 4b Clinician Determination of HIV Status for PrEP Provision to Persons with Recent or Ongoing Antiretroviral Prophylaxis Use

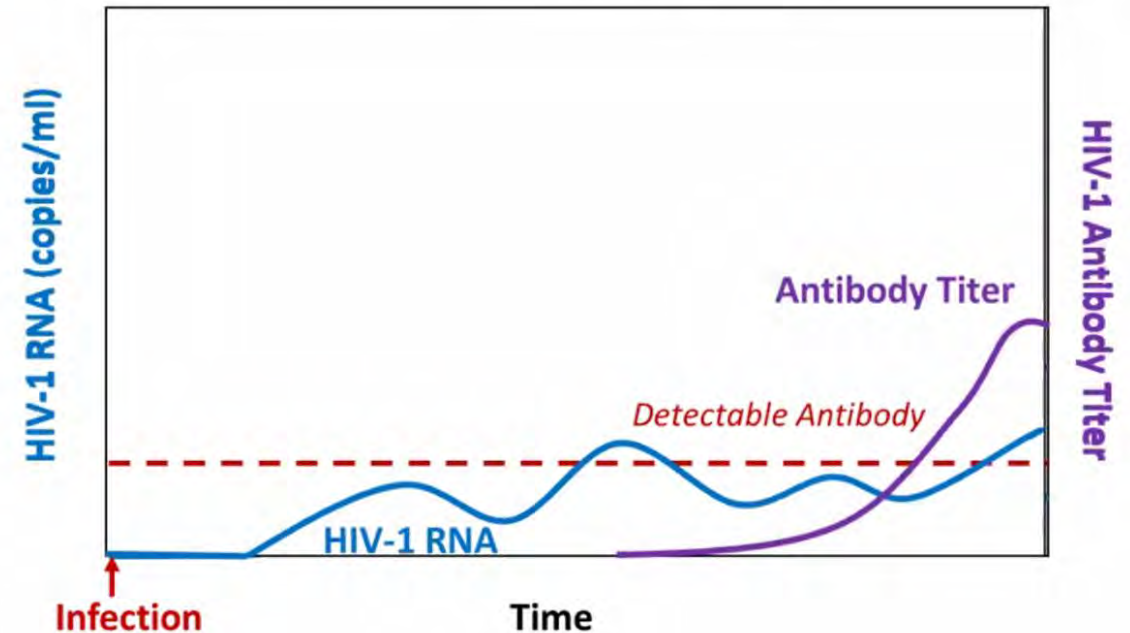


Diagnosing Acute HIV Infection

No Antiretrovirals



On PrEP (Cabotegravir)



HIV RNA "spike" precedes production of HIV antibody

Delay between 1st reactive qualitative HIV-1 RNA test and 1st reactive Ag/Ab test (HPTN 083)

	Cabotegravir Arm			F/TDF Arm	
	Baseline n=4	Incident No CAB n=5	Incident On CAB n=7	Baseline n=3	Incident n=30
Participant number (%)	3 (75)	0	7 (100)	3 (100)	8 (21)
Duration of delay, median, (range), days (among those with delayed Ag/Ab test result)	62 (28-72)	NA	98 (35-185)	34 (14-36)	31 (7-68)

Table 2: Clinical Signs and Symptoms of Acute (Primary) HIV Infection⁷¹

Features	Overall (n = 375) %	Sex		Route of transmission	
		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

Case Study

- 31 year old cisgender gay man
- Testing for acute fevers but no focal complaints
- Sex with at least one new partner in last few weeks; no condoms; no PrEP
- HIV-1/2 Ab and Ag: “presumptive positive”
 - HIV-1 Antibody: negative
 - HIV-2 Antibody: negative

Case Study 1

- 31 year old cisgender gay man
- Testing for acute fevers but no focal complaints
- Sex with at least one new partner in last few weeks; no condoms; no PrEP
- HIV-1/2 Ab and Ag: “presumptive positive”
 - HIV-1 Antibody: negative
 - HIV-2 Antibody: negative
 - HIV PCR: 251,000

Case Study 2

- 31 year old cisgender gay man
- Testing for acute fevers but no focal complaints
- Sex with at least one new partner in Brazil last summer vacation; no condoms; no PrEP
- HIV-1/2 Ab and Ag: “presumptive positive”
 - HIV-1 Antibody: negative
 - HIV-2 Antibody: positive

Case Study 2

- 31 year old cisgender gay man
- Testing for acute fevers but no focal complaints
- Sex with at least one new partner in Brazil last summer vacation; no condoms; no PrEP
- HIV-1/2 Ab and Ag: “presumptive positive”
 - HIV-1 Antibody: negative
 - HIV-2 Antibody: positive
 - HIV PCR: <20 (not detected)

Case Study 3

Note: All result statuses are Final unless otherwise noted.

Tests: (1) HIV 1/O/2 ANTIBODIES, P24 Ag (HIV12P)

HIV1/O/2 Abs, P24Ag [A] REACTIVE

NON-REACTIVE

All reactive results are confirmed by replicate analysis, reported to Public Health Laboratory, and referred for Multispot confirmation.

Results verified by repeat analysis.

Interpretation of the hepatitis B serologic panel

Tests	Results	Interpretation
HBsAg	Negative	Susceptible
anti-HBc	Negative	
anti-HBs	Negative	
HBsAg	Negative	Prior infection (inactive)
anti-HBc	Positive	
anti-HBs	Positive	
HBsAg	Negative	Immune due to hepatitis B vaccination*
anti-HBc	Negative	
anti-HBs	Positive	
HBsAg	Positive	Acutely infected
anti-HBc	Positive	
IgM anti-HBc	Positive	
anti-HBs	Negative	
HBsAg	Positive	Chronically infected
anti-HBc	Positive	
IgM anti-HBc	Negative	
anti-HBs	Negative	
HBsAg	Negative	Four interpretations possible [¶]
anti-HBc	Positive	
anti-HBs	Negative	

¶ Four interpretations:

1. Might be recovering from acute HBV infection.
2. Might have had prior infection and test not sensitive enough to detect very low level of anti-HBs in serum.
3. Might be susceptible with a false positive anti-HBc.
4. Might be undetectable level of HBsAg present in the serum, and the person is actually chronically infected.



WELCOME to the

*Get PrEP'd ECHO:
HIV Pre-Exposure Prophylaxis*

*Session 5, Oral PrEP Medication and Indications,
October 31, 2023*

*Please let us know you are here: Type your name, email,
organization into CHAT*

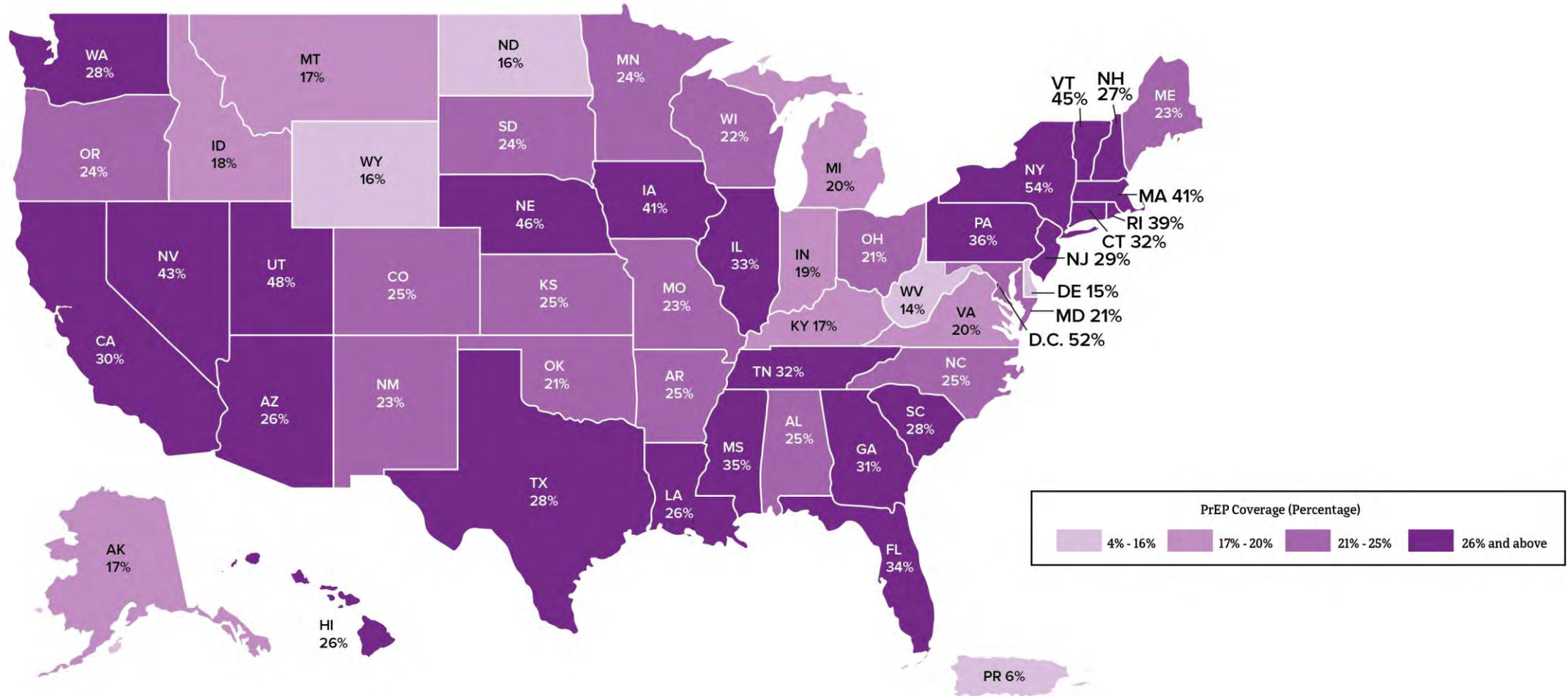


Oral PrEP Medication and Indications

Mario A Torres, MD

Chief Academic Fellow, Section of Infectious Diseases and International Health, Dartmouth Health

PrEP Stats USA 2021 (Oral only)



Source: CDC. [Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2021. HIV Surveillance Supplemental Report 2023;28\(4\).](#)

Who Should Be Offered PrEP?

Engage in unprotected anal or vaginal intercourse with partners whose HIV status is unknown, have untreated HIV, or who do not have undetectable viral load while on treatment for HIV

Engage in unprotected anal or vaginal intercourse with partners who have HIV and undetectable viral load but wish to be on PrEP for additional protection

Are receiving nPEP and demonstrate continued high-risk behavior or have used multiple courses of nPEP.

Self-identify as being at risk, without disclosing specific risk behaviors.

Have, or whose partners may have, multiple or anonymous sex partners. Engage, or whose partners may engage, in sexual activity at sex parties or other high-risk venues.

Report injecting substances, or have partners who inject substances, including illicit drugs and hormones.

Are involved, or whose partners may be involved, in transactional sex, such as sex for money, drugs, or housing, including commercial sex workers and their clients

Report recreational use of mood-altering substances during sex

Have been diagnosed with at least one sexually transmitted infection in the previous 12 months. .

Do Not Withhold PrEP From Those Who:

- Are pregnant or planning a pregnancy
- Have mental health disorders, including serious persistent mental illness
- Report intimate partner violence
- Have unstable housing or limited social support.



Patient Education

- ✓ How PrEP works and its purpose.
- ✓ Benefits and risks.
- ✓ The need for adherence to the dosing schedule for PrEP to be protective.
- ✓ How other safer sex and safer IDU practices decrease the risk of acquiring drug-resistant HIV, other STIs, HCV, and pregnancy.
- ✓ Importance of adherence, scheduled HIV testing, and routine monitoring.
- ✓ Potential side effects.
- ✓ Process for obtaining regular pharmacy refills.
- ✓ Methods of payment or access to payment assistance for PrEP and related care.

Which available oral options do we have?



Table 4. Recommendations for Biomedical HIV Prevention by Population and Transmission Risk Behavior^a

	TDF/FTC (evidence rating) ^b		Daily oral TAF/FTC (evidence rating)
	Daily oral	On-demand oral	
Cisgender men/women			
Insertive sex (vaginal/anal)	Yes (A1a)	Yes (B1a)	Yes (A1a)
Receptive vaginal sex	Yes (A1a)	Insufficient data	Insufficient data
Receptive anal sex	Yes (A1a)	Yes (A1a)	Yes (A1a)
Injection drug use (if sexual risk as well, apply appropriate category above) ^c	Yes (A1a)	Insufficient data	Insufficient data
Transgender women			
Insertive sex (vaginal/anal)	Yes (A1a)	Yes (AIII/CIII) ^d	Yes (A1a)
Receptive (neo) vaginal sex	Yes (BIII)	Insufficient data	Insufficient data
Receptive anal sex	Yes (A1a)	Yes (AIII/CIII) ^d	Yes (B1a)
Injection drug use (if sexual risk as well, apply appropriate category above) ^c	Yes (A1a)	Insufficient data	Insufficient data

IAS-USA Antiretroviral Drugs for Treatment of Prevention of HIV infection in Adults. JAMA. 2022.

Benefits of TDF/FTC (Truvada) and TAF/FTC (Descovy) as PrEP

- ✓ 99% effective in reducing the risk of HIV acquisition when used as prescribed
- ✓ 74% for patient who inject drugs (TDF/FCT)
- ✓ Single tablet taken daily
- ✓ Good safety profiles
- ✓ Minimal side effects, most of which resolve fairly quickly or can be managed
- ✓ Safe for use during attempts to conceive and during pregnancy
- ✓ Can decrease anxiety regarding HIV acquisition
- ✓ Engages sexually active at-risk individuals in care who are then screened regularly for STIs

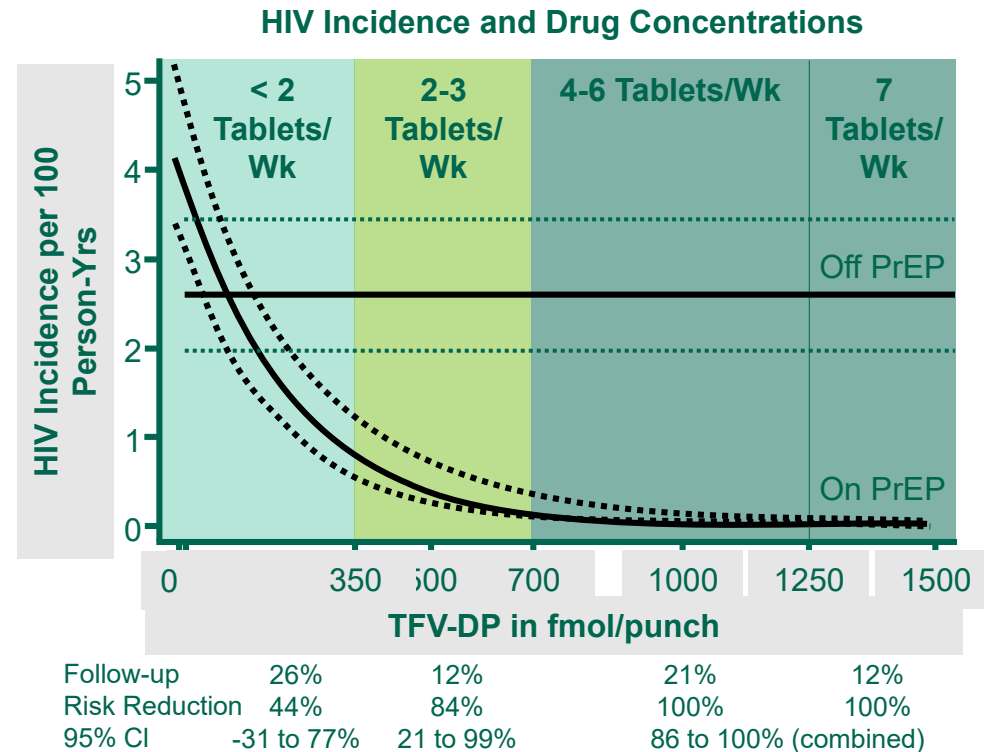
TDF/FTC (Truvada) vs. TAF/FTC (Descovy) as PrEP

	TDF/FTC	TAF/FTC
Effectiveness	All populations.	Cisgender men and transgender women.*
Renal safety	<ul style="list-style-type: none"> • Potential effect on renal tubular function. Meta-analysis shows good safety. • Discontinue if confirmed CrCl <50 mL/min. 	<ul style="list-style-type: none"> • Improved renal biomarkers compared to TDF. • Can be used with stage 3 chronic kidney disease (CrCl 30-59 mL/min).
Bone safety	Potential decrease in bone mineral density. Meta-analysis shows good safety.	Favorable bone biomarkers compared with TDF.
Weight	Weight neutral.	Mild weight gain observed in studies.
LDL cholesterol	Small decreases.	Small increases.
Dosing	Daily dosing is preferred. On-demand dosing is an option in cisgender MSM.	Daily dosing only.

*Transgender women made up only 1% of the DISCOVER study population.

Oral PrEP Reduces Incidence of HIV in MSM, Even With Incomplete Adherence

- iPreX OLE: open-label extension of iPrEX trial of daily TDF/FTC oral PrEP in MSM and transgender women (N = 1603)
- 100% adherence was not required to attain full benefit from PrEP
 - Benefit of 4-6 tablets/wk similar to 7 tablets/wk
 - 2-3 tablets/wk also associated with significant risk reduction
- Higher levels of sexual risk taking at baseline were associated with greater adherence to PrEP



Side Effects

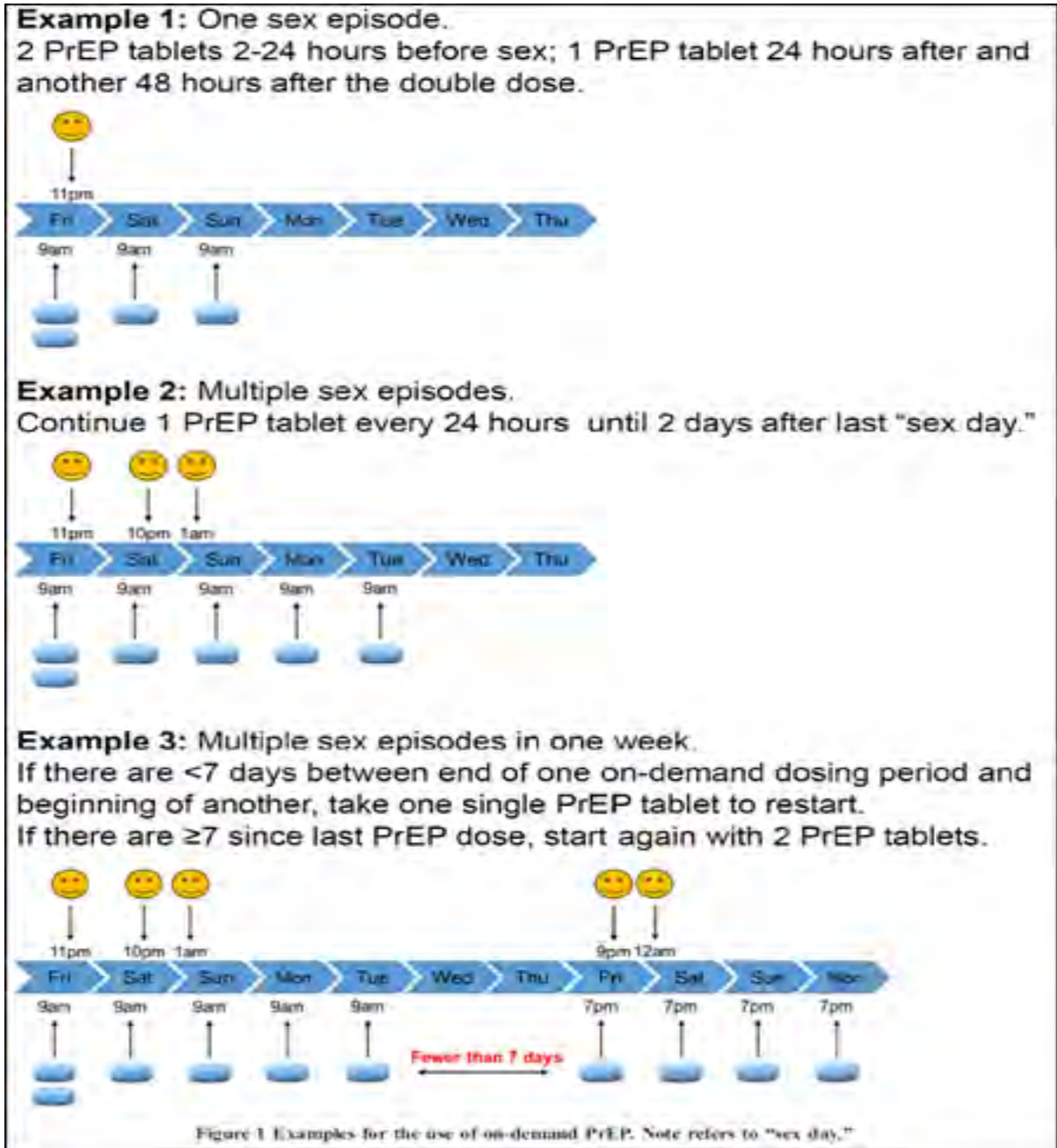
- Side effects associated with TDF/FTC and TAF/FTC used as PrEP are generally mild and resolve within **3 months after initiation.**
- In clinical trials, rash was not a commonly observed side effect among participants taking TDF/FTC as PrEP and should prompt assessment for syphilis and acute HIV.
- TAF/FTC is an alternative to TDF/FTC in MSM and transgender women who are at risk for or exhibit renal or bone toxicity.

	TDF/FTC	TAF/FTC
Diarrhea	6%	5%
Nausea	5%	4%
Headache	2%	2%
Fatigue	3%	2%
Stomach discomfort	3%	2%

What is the Time to Protection?

- Time to protection is based on pharmacokinetic modeling studies and has not been clinically determined.
- For rectal exposure, protection against HIV acquisition is achieved after **7 days** of TDF/FTC daily dosing and possibly earlier.
- For genital and blood exposure, protection against HIV acquisition is likely achieved after 7 days of TDF/FTC daily dosing, but optimal drug levels are achieved after **20 days** of daily dosing.

On Demand PrEP?



Laboratory test for PrEP initiation and monitoring

	PrEP Initiation Visit	Follow-Up Visits (q 3 months)
HIV Status	<ul style="list-style-type: none"> HIV Ag/Ab test (lab preferred) 	<ul style="list-style-type: none"> HIV-1 qualitative RNA + Ag/Ab
Renal Status	<ul style="list-style-type: none"> eCrCl <ul style="list-style-type: none"> >60 mL/min (F/TDF or F/TAF) >30 mL/min (F/TAF) 	<ul style="list-style-type: none"> Assess q 6 months if baseline <ul style="list-style-type: none"> Age ≥50 years or eCrCl <90 mL/min Otherwise assess q 12 months
STI Infection Status	<ul style="list-style-type: none"> Syphilis serology for all <i>Neisseria gonorrhoeae</i> (GC) and <i>Chlamydia trachomatis</i> (CT) nucleic acid amplification testing (NAAT) at sites of exposure for MSM and transgender women (TGW) GC for women 	<ul style="list-style-type: none"> Repeat STI screen for MSM/TGW q 3 months Repeat STI screen for heterosexually active men and women q 6 months CT screen for heterosexually active men and women q 12 months
Lipid Screen	<ul style="list-style-type: none"> Only for persons prescribed F/TAF 	<ul style="list-style-type: none"> Repeat q 12 months for persons prescribed F/TAF
Screen for Active HBV	Hepatitis B serology	If not done at initiation visit
Prescription	90-day supply	90-day refill if HIV test is negative

Interpretation of the hepatitis B serologic panel

Tests	Results	Interpretation
HBsAg	Negative	Susceptible
anti-HBc	Negative	
anti-HBs	Negative	
HBsAg	Negative	Prior infection (inactive)
anti-HBc	Positive	
anti-HBs	Positive	
HBsAg	Negative	Immune due to hepatitis B vaccination*
anti-HBc	Negative	
anti-HBs	Positive	
HBsAg	Positive	Acutely infected
anti-HBc	Positive	
IgM anti-HBc	Positive	
anti-HBs	Negative	
anti-HBe	Positive	
HBsAg	Positive	Chronically infected
anti-HBc	Positive	
IgM anti-HBc	Negative	
anti-HBs	Negative	
HBsAg	Negative	Four interpretations possible [¶]
anti-HBc	Positive	
anti-HBs	Negative	

¶ Four interpretations:

1. Might be recovering from acute HBV infection.
2. Might have had prior infection and test not sensitive enough to detect very low level of anti-HBs in serum.
3. Might be susceptible with a false positive anti-HBc.
4. Might be undetectable level of HBsAg present in the serum, and the person is actually chronically infected.

PrEP in the Setting of CKD

If an individual is at risk of chronic kidney disease (e.g., age >50 years, hypertension, or diabetes) or has preexisting mild kidney disease with CrCl <60 mL/min:

- The greater possibility of kidney disease in those with preexisting risk factors is an essential component of the risk-benefit discussion and shared decision-making regarding initiation of TDF/FTC or TAF/FTC as PrEP.
- More frequent renal monitoring may be required for patients at risk of renal disease or aged >50 years who elect to use TDF/FTC or TAF/FTC as PrEP.
- TDF/FTC should not be initiated in individuals who have a CrCl <60 mL/min. TAF/FTC is an option for PrEP in MSM and transgender women with renal disease and a CrCl >30 mL/min.

Discontinuing PrEP

Clinicians should discontinue PrEP in any patient who:

- No longer at risk of HIV acquisition because they have eliminated the sex or drug use behaviors that put them at risk.
- Has a confirmed positive HIV test. (A1) In this case, the ARV regimen should be converted to a fully active ART regimen. (A1)
- Develops a CrCl <60 mL/min while taking TDF/FTC as PrEP. (A2). Consider TAF/FTC for MSM and for transgender women if CrCl >30 mL/min.
- Does not adhere to HIV testing requirements. (A3)

PrEP with Hepatitis B coinfection

Clinicians should closely monitor patients who have chronic HBV for potential viral rebound when PrEP with TDF/FTC or TAF/FTC is discontinued and develop an alternative treatment plan if necessary. (A2)

Case Study

- 28 year old cisgender gay man,
- Monogamous relationship. Serodiscordant couple, Undetectable
- Currently using condoms with sexual intercourse
- No Hx of STIs
- HIV 4th gen negative
- Interested in initiating Oral PrEP

Case Study 2

- 35 year old Transgender male, Hx of CKD (CrCl 45) due to uncontrolled HTN
- Recent history of Rectal chlamydia
- Multiple sex partners in the last year
- HIV 4TH gen negative
- Repeated GC and chlamydia testing negative
- He is interested in initiation of Oral PreP



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*Get PrEP'd ECHO:
HIV Pre-Exposure Prophylaxis*

*Session 6, Injectable PrEP Medication and Indications,
November 7, 2023*

*Please let us know you are here: Type your name, email,
organization into CHAT*



Injectable PrEP Medication and Indications

Bryan J. Marsh, MD

Associate Professor of Medicine, Geisel School of Medicine

Co-program Director the HOPE Program, Dartmouth Health

Chief, Section of Infectious Diseases and International Health, Dartmouth Health

Patient Education

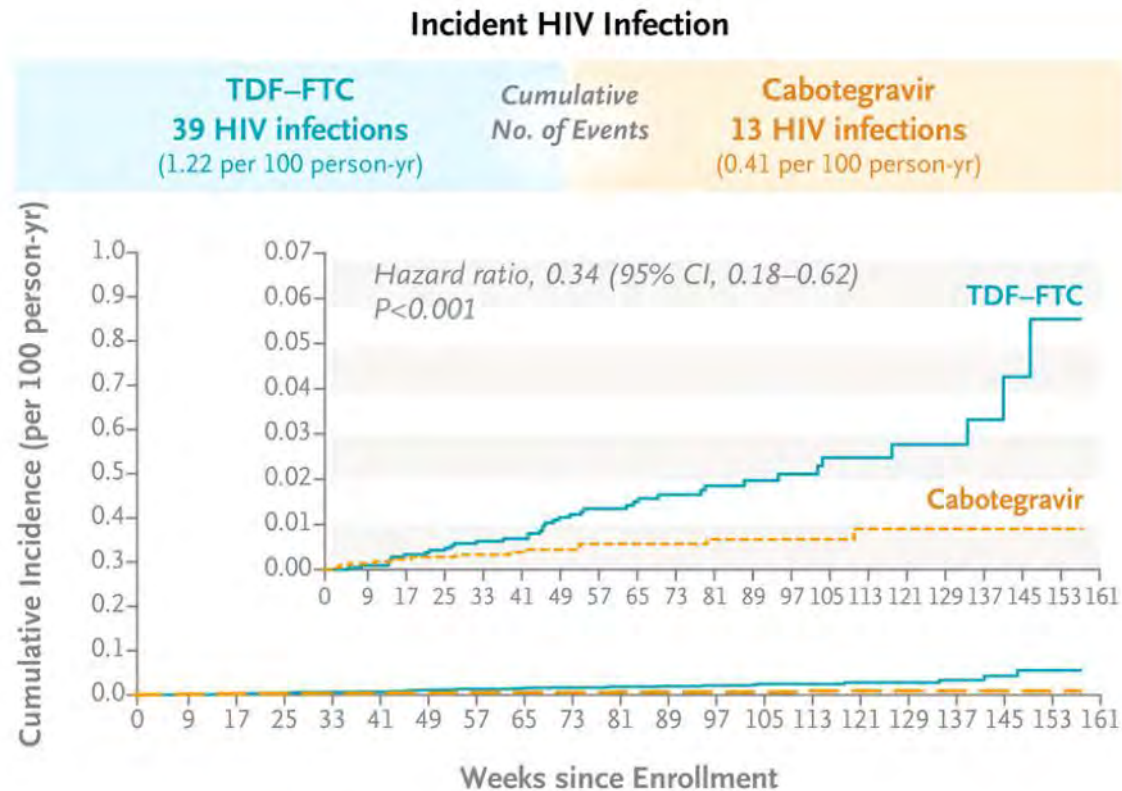
- ✓ How PrEP works and its purpose.
- ✓ Benefits and risks.
- ✓ The need for adherence to the dosing schedule for PrEP to be protective.
- ✓ How other safer sex and safer IDU practices decrease the risk of acquiring drug-resistant HIV, other STIs, HCV, and pregnancy.
- ✓ Lack of data in pregnancy.
- ✓ Importance of adherence, scheduled HIV testing, and routine monitoring.
- ✓ Potential side effects.
- ✓ The long “tail” if they stop – need for oral PrEP, monitoring, and risk of resistance.
- ✓ Methods of payment or access to payment assistance for PrEP and related care.

Which available injectable options do we have?



Cabotegravir for HIV Prevention in Cisgender Men and Transgender Women

Raphael J. Landovitz, M.D., Deborah Donnell, Ph.D., Meredith E. Clement, M.D., Brett Hanscom, Ph.D., Leslie Cottle, B.A., Lara Coelho, M.D., Robinson Cabello, M.D., Suwat Charialertsak, M.D., Dr.P.H., Eileen F. Dunne, M.D., M.P.H., Ian Frank, M.D., Jorge A. Gallardo-Cartagena, M.D., Aditya H. Gaur, M.D., *et al.*, for the HPTN 083 Study Team*



Safety

Adverse Events	TDF-FTC (N=2282)	Cabotegravir (N=2280)
	no. (%)	no. (%)
Any adverse event of grade 2 or higher	2216 (92.7)	2106 (92.4)
Any adverse event of grade 3 or higher	767 (33.6)	727 (31.9)
Serious adverse event	121 (5.3)	120 (5.3)
Adverse events of special interest		
Seizure	5 (0.2)	2 (0.1)
Liver-related adverse event resulting in discontinuation of oral tablets or both oral tablets and injections	48 (2.1)	47 (2.1)

CONCLUSIONS

Injectable cabotegravir given every 8 weeks was superior to daily oral TDF-FTC for preventing HIV infection among high-risk cisgender men and transgender women who have sex with men.

Cabotegravir for the prevention of HIV-1 in women: results from HPTN 084, a phase 3, randomised clinical trial



Sinead Delany-Morethwe, James P Hughes, Peter Bock, Samuel Gurrion Ouma, Partia Hunidzarina, Dishiki Kalonji, Noel Kayange, Joseph Makhema, Patricia Mandima, Carrie Mathew, Elizabeth Spooner, Juliet Mpendo, Pamela Mukwekwerere, Nyaradzo Mgodzi, Patricia Nahirya Ntege, Gonasagrie Nair, Clemensia Nakabiito, Harriet Nuwagaba-Binbonwoha, Ravindre Panchia, Nishanta Singh, Bekezela Siziba, Jennifer Farrior, Scott Rose, Peter L Anderson, Susan H Eshleman, Mark A Marzinke, Craig W Hendrix, Stephanie Beigel-Orme, Sybil Hosek, Elizabeth Tolley, Nirupama Sista, Adeola Adeyeye, James F Rooney, Alex Rinehart, William R Spreen, Kimberly Smith, Brett Hariscorn, Myron S Cohen, Mina C Hosseinipour, on behalf of the HPTN 084 study group



Lancet 2022; 399: 1779-89

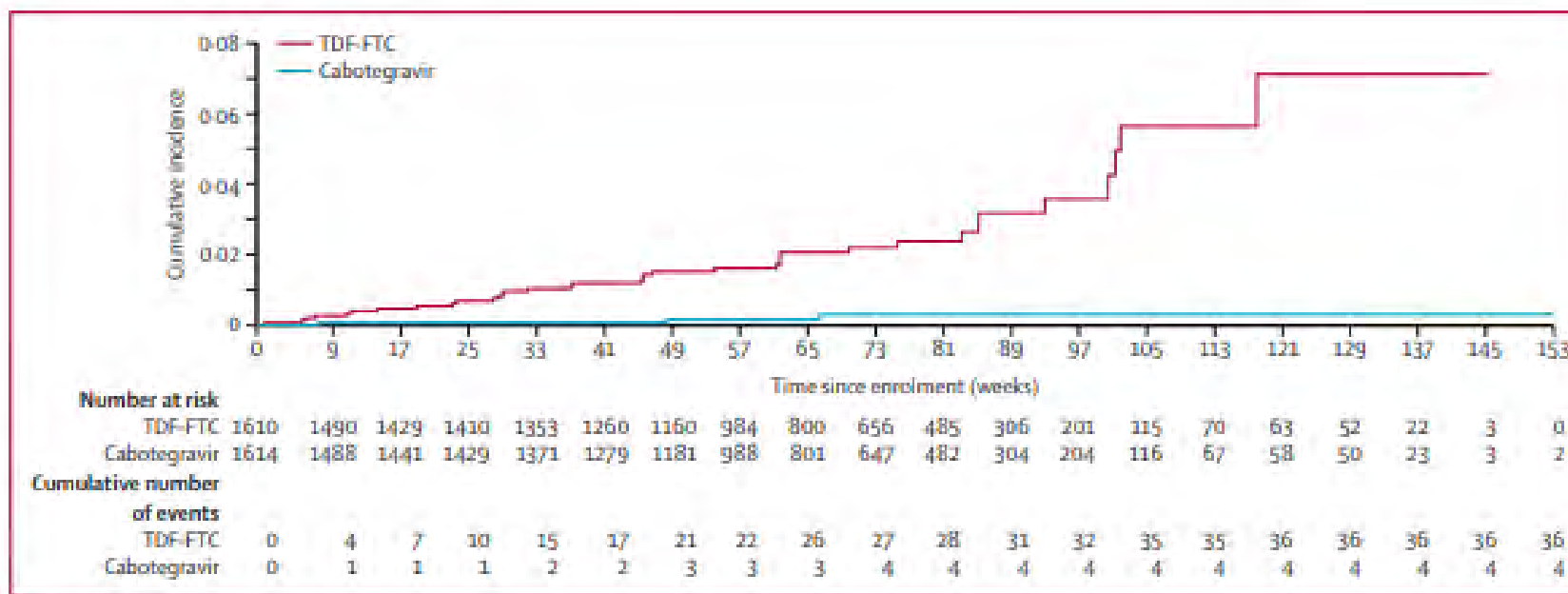


Figure 3: Cumulative HIV incidence by study group

Kaplan-Meier estimates of HIV infection are shown. Four HIV infections were observed in the cabotegravir group (HIV incidence 0.20 per 100 person-years [95% CI 0.06-0.52]) and 36 in the TDF-FTC group (1.85 per 100 person-years [1.3-2.57]). Participants in the cabotegravir group had an 88% lower risk of HIV infection than those in the TDF-FTC group (hazard ratio 0.12 [0.05-0.31]; $p < 0.0001$). TDF-FTC=tenofovir disoproxil fumarate plus emtricitabine.

Delay between 1st reactive qualitative HIV-1 RNA test and 1st reactive Ag/Ab test (HPTN 083)

	Cabotegravir Arm			F/TDF Arm	
	Baseline n=4	Incident No CAB n=5	Incident On CAB n=7	Baseline n=3	Incident n=30
Participant number (%)	3 (75)	0	7 (100)	3 (100)	8 (21)
Duration of delay, median, (range), days (among those with delayed Ag/Ab test result)	62 (28-72)	NA	98 (35-185)	34 (14-36)	31 (7-68)

INDICATIONS AND USAGE

APRETUDE is an HIV-1 integrase strand transfer inhibitor (INSTI) indicated in at-risk adults and adolescents weighing at least 35 kg for PrEP to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to initiating APRETUDE (with or without an oral lead-in with oral cabotegravir) for HIV-1 PrEP. (1)

DOSAGE AND ADMINISTRATION

- HIV-1 Screening: Screen all individuals for HIV-1 infection immediately prior to initiating APRETUDE for HIV-1 PrEP and prior to each injection while taking APRETUDE. (2.2)
- Prior to initiating APRETUDE, an oral lead-in dosing may be used for approximately 1 month with the recommended dosage to assess the tolerability of APRETUDE. (2.4)
- For gluteal intramuscular injection only. (2.5, 2.6)
- Recommended Dosing Schedule: Initiate APRETUDE with a single 600-mg (3-mL) injection given 1 month apart for 2 consecutive months on the last day of an oral lead-in if used or within 3 days and continue with the injections every 2 months thereafter. (2.5)

DOSAGE FORMS AND STRENGTHS

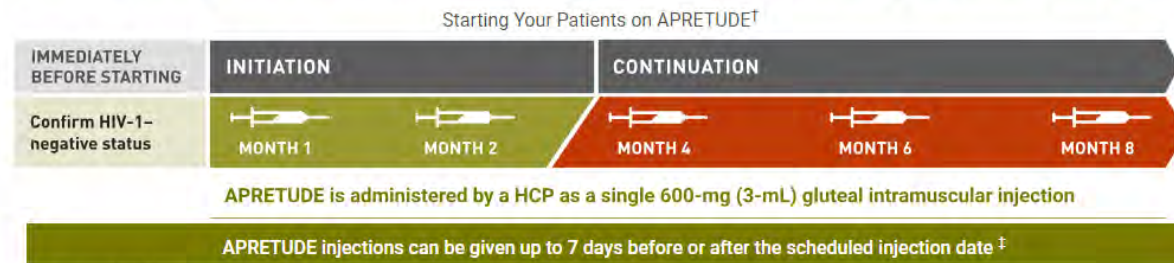
Injection: Single-dose vial of 600 mg/3 mL (200 mg/mL) of cabotegravir extended-release injectable suspension. (3)

CONTRAINDICATIONS

- Unknown or positive HIV-1 status. (4)
- Previous hypersensitivity reaction to cabotegravir. (4)

Dosing and Testing Schedule

Adherence you can confirm with as few as 6 in-office injections per year*



*After optional oral lead-in and initiation injections.

†For patients concomitantly receiving rifabutin, please see the full Prescribing Information for the adjusted recommended dosing schedule for APRETUDE.

‡After the first injection.

Optional oral lead-in

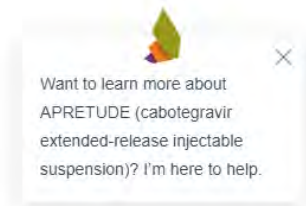
Oral lead-in is not required but may be used prior to the initiation of APRETUDE to assess the tolerability of cabotegravir.



The recommended oral lead-in dose is one 30-mg tablet of cabotegravir daily for approximately 1 month (at least 28 days).

Initiation injections should be administered on the last day of oral lead-in, if used, or within 3 days thereafter.

<https://apretudehcp.com/dosing>



Injection:

11. Prepare the injection site.



Figure K

APRETUDE must be administered to a gluteal site. **See Figure K.**

Select from the following areas for the injection:

- Ventrogluteal, as shown (recommended)
- Dorsogluteal, not shown (upper outer quadrant)

Note: For gluteal intramuscular use only.
Do not inject intravenously.

14. Stretch the skin.



Figure N

Use the z-track injection technique to minimize medicine leakage from the injection site.

- Firmly drag the skin covering the injection site, displacing it by about an inch (2.5 cm). **See Figure N.**
- Keep it held in this position for the injection.

15. Insert the needle.

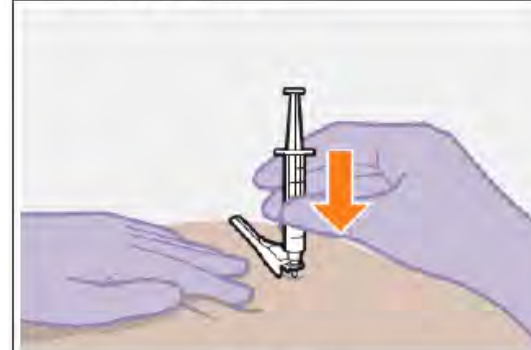


Figure O

- Insert the needle to its full depth, or deep enough to reach the muscle. **See Figure O.**

16. Inject the dose of medicine.

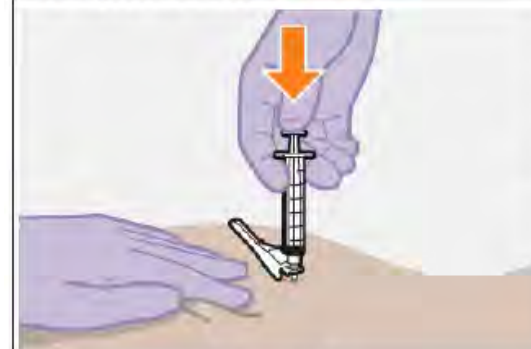


Figure P

- Still holding the skin stretched – slowly press the plunger all the way down. **See Figure P.**
- Ensure the syringe is empty.
- Withdraw the needle and release the stretched skin immediately.

What is the Time to Protection?

→ Unknown.

→ “Likely to be approximately 7 days after first injection.”

PrEP with Hepatitis B coinfection

Clinicians should closely monitor patients who have chronic HBV for potential viral rebound when PrEP with TDF/FTC or TAF/FTC is discontinued and develop an alternative treatment plan if necessary. (A2)

Table 4. Recommendations for Biomedical HIV Prevention by Population and Transmission Risk Behavior^a

	TDF/FTC (evidence rating) ^b		Daily oral TAF/FTC (evidence rating)	Intramuscular cabotegravir (evidence rating)
	Daily oral	On-demand oral		
Cisgender men/women				
Insertive sex (vaginal/anal)	Yes (A1a)	Yes (B1a)	Yes (A1a)	Yes (A1a)
Receptive vaginal sex	Yes (A1a)	Insufficient data	Insufficient data	Yes (A1a)
Receptive anal sex	Yes (A1a)	Yes (A1a)	Yes (A1a)	Yes (A1a)
Injection drug use (if sexual risk as well, apply appropriate category above) ^c	Yes (A1a)	Insufficient data	Insufficient data	Insufficient data
Transgender women				
Insertive sex (vaginal/anal)	Yes (A1a)	Yes (AIII/CIII) ^d	Yes (A1a)	Yes (A1a)
Receptive (neo) vaginal sex	Yes (BIII)	Insufficient data	Insufficient data	Yes (BIII)
Receptive anal sex	Yes (A1a)	Yes (AIII/CIII) ^d	Yes (B1a)	Yes (A1a)
Injection drug use (if sexual risk as well, apply appropriate category above) ^c	Yes (A1a)	Insufficient data	Insufficient data	Insufficient data
Transgender men				
Receptive vaginal ("front-hole") sex	Yes (AIII)	Insufficient data	Insufficient data	Yes (AIII)
Receptive anal sex	Yes (AIII)	Yes (AIII)	Yes (AIII)	Yes (AIII)
Injection drug use (if sexual risk as well, apply appropriate category above) ^c	Yes (AIII)	Insufficient data	Insufficient data	Insufficient data

Table 4. Recommendations for Biomedical HIV Prevention by Population and Transmission Risk Behavior^a

	TDF/FTC (evidence rating) ^b		Daily oral TAF/FTC (evidence rating)	Intramuscular cabotegravir (evidence rating)
	Daily oral	On-demand oral		
Prerequisites and safety considerations				
Creatinine clearance, mL/min	>60	>60	>30	No restrictions; caution with end-stage kidney disease not yet receiving dialysis
Drug-drug interactions	NA	NA	NA	Do not use with certain anticonvulsants and antimycobacterials ^c Adjust dosing if using with rifabutin ^d
Other	Avoid use if individual has known osteopenia or osteoporosis	Avoid use if individual has known osteopenia or osteoporosis; caution during first use for transgender woman who uses exogenous estrogens or androgen blockers	Not applicable	Use caution if gluteal fillers or implants are present or if patient is using anticoagulants or has bleeding diathesis or thrombocytopenia

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

2.2 HIV-1 Screening for Individuals Receiving APRETUDE for HIV-1 PrEP

Individuals must be tested for HIV-1 infection prior to initiating APRETUDE or oral cabotegravir, and with each subsequent injection of APRETUDE, using a test approved or cleared by the FDA for the diagnosis of acute or primary HIV-1 infection. If an antigen/antibody-specific test is used and provides negative results, then such negative results should be confirmed using an RNA-specific assay, even if the results of the RNA-assay are

2

available after APRETUDE or oral cabotegravir administration [*see Contraindications (4), Warnings and Precautions (5.1)*].

Table 4. Recommendations for Biomedical HIV Prevention by Population and Transmission Risk Behavior^a (continued)

	TDF/FTC (evidence rating) ^b		Daily oral TAF/FTC (evidence rating)	Intramuscular cabotegravir (evidence rating)
	Daily oral	On-demand oral		
Every 3-4 mo ^c	HIV Ag/Ab Creatinine ^p Gonorrhea/chlamydia NAAT ¹ Syphilis ^q Pregnancy test ^m	HIV Ag/Ab Creatinine ^p Gonorrhea/chlamydia NAAT ¹ Syphilis ^q Pregnancy test ^m	HIV Ag/Ab Creatinine ^p Gonorrhea/chlamydia NAAT ¹ Syphilis ^q Pregnancy test ^m	HIV Ag/Ab HIV RNA Gonorrhea/chlamydia NAAT ¹ Syphilis ^q Pregnancy test ^m
Annually	Creatinine HCV IgG ^r	Creatinine HCV IgG ^r	Creatinine HCV IgG ^r	HCV IgG ^r
HIV testing considerations	If discordant or difficult-to-interpret HIV test results, call CDC (800-232-4636) for additional guidance	If discordant or difficult-to-interpret HIV test results, call CDC (800-232-4636) for additional guidance	If discordant or difficult-to-interpret HIV test results, call CDC (800-232-4636) for additional guidance	Results of HIV Ag/Ab test and HIV RNA are not needed before administering follow-up injections If discordant or difficult-to-interpret HIV test results, call CDC (800-232-4636) for additional guidance

MANAGING INJECTION SITE REACTIONS

In the clinical trials, injection site reactions (pain, tenderness, induration) were frequent following CAB injections. These reactions were generally mild or moderate, lasted only a few days, and occurred most frequently after the first 2-3 injections. Patients should be informed that these reactions are common and transient. In addition, they should be provided with proactive management advice

- for the first 2-3 injections
 - take an over-the-counter pain medication within a couple of hours before or soon after the injection and continue as needed for one to two days
 - apply a warm compress or heating pad to the injection site for 15-20 minutes after the injection (e.g., after arriving back at home)
- thereafter, as needed for subsequent injections

Missed Injections

Continuing APRETUDE after *planned* missed injections



Adherence to the injection dosing schedule is strongly recommended. Individuals who miss their Target Injection Date should be clinically reassessed to ensure resumption of APRETUDE remains appropriate.



The first dose of oral cabotegravir should be taken approximately 2 months after the last injection dose of APRETUDE.



If your patient plans to miss their Target Injection Date by >7 days, daily oral cabotegravir can be prescribed for a duration of up to 2 months to replace 1 missed scheduled every-2-month injection of APRETUDE.[§]



Restart injections with APRETUDE on the day oral dosing completes or within 3 days.

How much time has passed since your patient's missed Target Injection Date?

≤1 month since missed
Target Injection Date

- Resume injections on final day of oral cabotegravir or within 3 days
- Continue with every-2-month dosing schedule thereafter

>1 month since missed
Target Injection Date

- Repeat initiation injections (2 injections 1 month apart) on the final day of oral cabotegravir or within 3 days
- Continue with every-2-month dosing schedule thereafter

[§]For oral PrEP durations greater than 2 months, an alternative oral regimen is recommended.

Continuing APRETUDE after *unplanned* missed injections



Adherence to scheduled injection visits is important.



If your patient missed their Target Injection Date by >7 days and did not plan for it by taking oral cabotegravir, clinically reassess them to determine whether APRETUDE remains appropriate, and if so, confirm HIV-1 –negative status prior to injection.

How much time has passed since your patient's missed Target Injection Date?

≤1 month since missed Target Injection Date

- Resume injections on final day of oral cabotegravir or within 3 days
- Continue with every-2-month dosing schedule thereafter

>1 month since missed Target Injection Date

- Repeat initiation injections (2 injections 1 month apart) on the final day of oral cabotegravir or within 3 days
- Continue with every-2-month dosing schedule thereafter

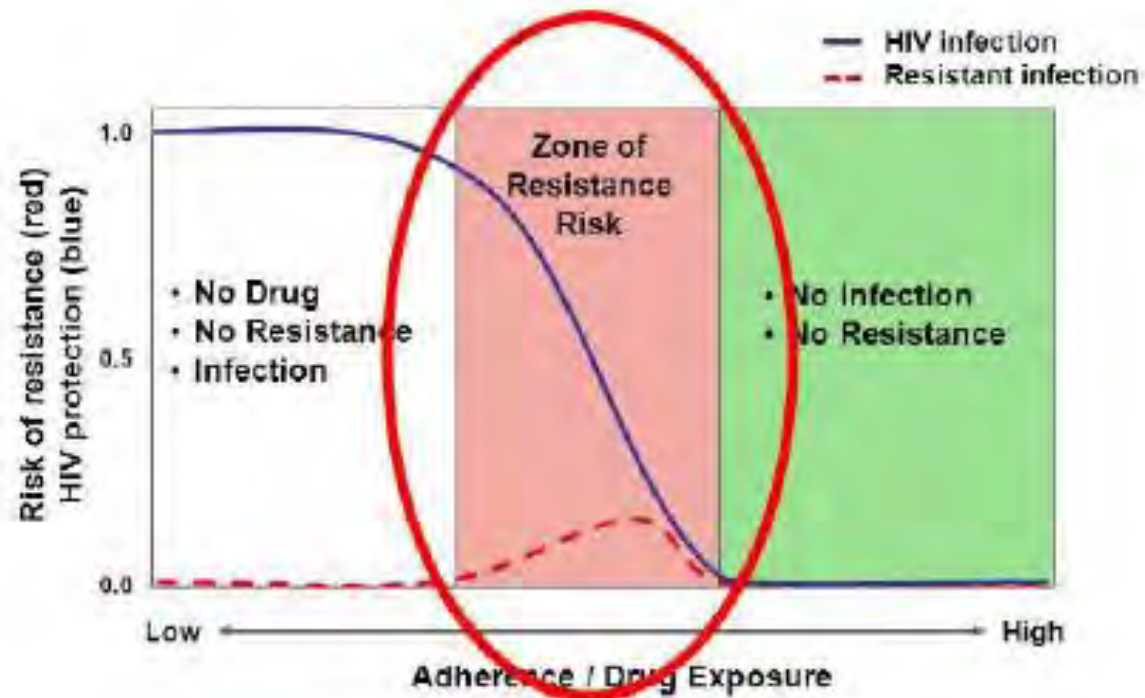
Table 6 Cabotegravir PrEP Drug Interactions (<https://www.hiv-druginteractions.org/>)

Rifampicin, rifapentin	<p>Do not co-administer with CAB</p> <p>Rifampicin and rifapentine increase metabolism of CAB and may result in significantly reduced exposure to protective levels of CAB^{142, 143}</p>
Rifabutin	<p>Co-administer with caution</p> <p>Rifabutin moderately increases metabolism of CAB and may result in somewhat reduced exposure to protective levels of CAB¹⁴⁴</p>
Hormonal contraceptives	No significant effect ¹⁴⁵
Feminizing hormones (Spironolactone, estrogens)	No data yet available ¹⁴⁶
Carbamazepine, oxcarbazepine, phenytoin, phenobarbital	<p>Do not co-administer with CAB</p> <p>Concern that these anticonvulsants may result in significantly reduced exposure to protective levels of CAB but strength of evidence is weak</p>

When helping patients discontinue CAB PrEP safely, clinicians should:

- Re-educate patients about the “tail” and the risks during declining CAB levels
- Assess ongoing risk/indications
- If PrEP is indicated, prescribe daily oral F/TDF or F/TAF beginning within 8 weeks after last injection
- Educate about nPEP
- Continue follow-up visits quarterly for 12 months
- Conduct HIV-1 RNA tests at each quarterly follow-up visit after discontinuing CAB injections

PrEP and HIV resistance



**CLINICIANS CAN CALL THE NATIONAL
CLINICIANS CONSULTATION CENTER
PREPLINE AT 855-448-7737 FOR
ADVICE ABOUT INTERPRETATION OF
HIV TEST RESULTS AND
MANAGEMENT OF PATIENTS WHO
ACQUIRE HIV INFECTION WHILE
TAKING PREP MEDICATION.**



WELCOME to the

*Get PrEP'd ECHO:
HIV Pre-Exposure Prophylaxis*

*Session 7, PrEP Monitoring and required labs, STI
Screening, November 21, 2023*

*Please let us know you are here: Type your name, email,
organization into CHAT*



PrEP Monitoring and Required Labs, and STI Testing

Aubrey Byron, BSN, RN,
HIV Community Health Nurse, Dartmouth Health

Getting Started...

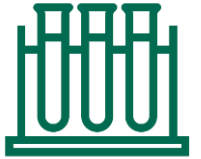


Baseline Assessments required for individuals beginning PrEP

- Before prescribing PrEP, perform the required baseline assessments.
 - [HIV Testing](#)
 - [STI Testing](#)
 - [Kidney Function](#)
 - [HBV Serology](#)
 - [Lipid Profile](#)
- HIV testing is required to confirm that patients do not have HIV



Baseline Laboratory Testing



REQUIRED



HIV test (antigen/antibody test, preferably laboratory based) to confirm negative status

Hepatitis B screening (F/TAF and F/TDF) because active infection is a potential safety issue



Kidney function

F/TDF: Estimated creatinine clearance (must be >60 mL/min)

F/TAF: Estimated creatinine clearance (must be >30 mL/min)

CAB: Not required

Lipid profile (triglyceride and cholesterol levels) for patients prescribed **F/TAF**, as this medication may be associated with triglyceride elevation

STI tests for chlamydia, gonorrhea, and syphilis for all sexually active adults

F/TDF: emtricitabine/tenofovir disoproxil fumarate (Truvada® or generic equivalent)

F/TAF: emtricitabine/tenofovir alafenamide (Descovy®)

CAB: cabotegravir (Apretude®)



Daily Oral PrEP Protocol







	PrEP Initiation Visit	Follow-Up Visits (q 3 months)
HIV Status	<ul style="list-style-type: none"> HIV Ag/Ab test (lab preferred) 	<ul style="list-style-type: none"> HIV-1 qualitative RNA + Ag/Ab
Renal Status	<ul style="list-style-type: none"> eCrCl <ul style="list-style-type: none"> >60 mL/min (F/TDF or F/TAF) >30 mL/min (F/TAF) 	<ul style="list-style-type: none"> Assess q 6 months if baseline <ul style="list-style-type: none"> Age ≥50 years or eCrCl <90 mL/min Otherwise assess q 12 months
STI Infection Status	<ul style="list-style-type: none"> Syphilis serology for all <i>Neisseria gonorrhoeae</i> (GC) and <i>Chlamydia trachomatis</i> (CT) nucleic acid amplification testing (NAAT) at sites of exposure for MSM and transgender women (TGW) GC for women 	<ul style="list-style-type: none"> Repeat STI screen for MSM/TGW q 3 months Repeat STI screen for heterosexually active men and women q 6 months CT screen for heterosexually active men and women q 12 months
Lipid Screen	<ul style="list-style-type: none"> Only for persons prescribed F/TAF 	<ul style="list-style-type: none"> Repeat q 12 months for persons prescribed F/TAF
Screen for Active HBV	Hepatitis B serology	If not done at initiation visit
Prescription	90-day supply	90-day refill if HIV test is negative



Cabotegravir Injection PrEP Protocol

	PrEP Initiation Visit	Follow-Up Visits (q 2 months)
HIV Status	<ul style="list-style-type: none"> • HIV-1 qualitative (or quant) RNA + Ag/Ab 	<ul style="list-style-type: none"> • HIV-1 qualitative (or quant) RNA + Ag/Ab
STI Infection Status	<ul style="list-style-type: none"> • Syphilis serology for all • GC and CT NAAT at sites of exposure for MSM and TGW • GC for women 	<ul style="list-style-type: none"> • Repeat STI screen for MSM/TGW q 4 months • Repeat STI screen for heterosexually active men and women q 6 months • CT screen for heterosexually active men and women q 12 months
Prescription	<ul style="list-style-type: none"> • Provide cabotegravir injection at initiation visit and again 1 month later 	<ul style="list-style-type: none"> • Provide cabotegravir injection q 2 months if HIV test is negative

PrEP Side Effects and Safety

Side Effects	F/TDF (oral PrEP)	F/TAF (oral PrEP)	CAB (injectable PrEP)
 Start-up Syndrome	<ul style="list-style-type: none"> <10% of patients Headache, nausea, abdominal discomfort lasting <1 month¹ 	<ul style="list-style-type: none"> <10% of patients Headache, nausea, abdominal discomfort lasting <1 month¹ 	<ul style="list-style-type: none"> No reported start-up syndrome¹
 Kidney Safety	<ul style="list-style-type: none"> Small decrease in creatinine clearance Resolves after stopping drug² 	<ul style="list-style-type: none"> Less risk of kidney-related side effects³ 	<ul style="list-style-type: none"> No reported risk of kidney-related side effects¹
 Bone Safety	<ul style="list-style-type: none"> Small decreases in bone mineral density Not associated with fractures⁴ 	<ul style="list-style-type: none"> No reported bone safety issues¹ 	<ul style="list-style-type: none"> No reported bone safety issues¹
 Injection Site Reactions	<ul style="list-style-type: none"> N/A 	<ul style="list-style-type: none"> N/A 	<ul style="list-style-type: none"> Pain, tenderness, local skin swelling Typically, mild/moderate, brief⁵
 Weight and Lipids	<ul style="list-style-type: none"> No reported effects on weight or lipid levels¹ 	<ul style="list-style-type: none"> Weight gain Increased triglycerides³ 	<ul style="list-style-type: none"> No reported effects on weight or lipid levels¹
 Overall Safety	<p>All three types of PrEP are generally well tolerated, with side effects that are usually mild/moderate, manageable, and temporary¹</p>		

¹ 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>

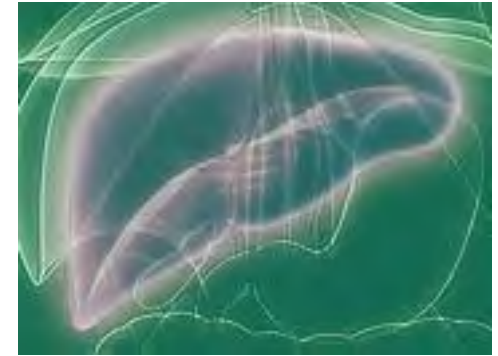
² Mugwanya KK, Wyatt C, Celum C, et al. Changes in glomerular kidney function among HIV-1-uninfected men and women receiving emtricitabine-tenofovir disoproxil fumarate preexposure prophylaxis: a randomized clinical trial. *JAMA Intern Med*. 2015;175(2):246-254. doi: 10.1001/jamainternmed.2014.6786

³ Mayer KL, Molina, J-M, Thompson, MA, et al. Emtricitabine and tenofovir alafenamide vs emtricitabine and tenofovir disoproxil fumarate for HIV pre-exposure prophylaxis (DISCOVER): primary results from a randomised, double-blind, multicentre, active-controlled, phase 3, non-inferiority trial. *Lancet*. 2020;396(10246):239-254. doi: 10.1016/S0140-6736(20)31065-5

⁴ Grohskopf LA, Chillag KL, Gvetadze R, et al. Randomized trial of clinical safety of daily oral tenofovir disoproxil fumarate among HIV-uninfected men who have sex with men in the United States. *J Acquir Immune Defic Syndr*. 2013;64(1):79-86. doi: 10.1097/QAI.0b013e31828e333

⁵ Landovitz RJ, Li S, Grinsztejn B, et al. Safety, tolerability, and pharmacokinetics of long-acting injectable cabotegravir in low-risk HIV-uninfected individuals: HPTN 077, a phase 2a randomized controlled trial. *PLoS Med*. 2018;15(11):e1002690. doi: 10.1371/journal.pmed.1002690

Hepatitis B



- Emtricitabine and tenofovir can be used to treat active hepatitis B virus (HBV) infection.
- However, in people with active HBV, stopping these medicines can result in a rebound of HBV replication leading to liver damage.
- HBV infection is **not a contraindication** to PrEP, but all people considered for oral PrEP with F/TDF or F/TAF must be screened for HBV.
 - Patients with active HBV infection should be educated about the risks of stopping oral PrEP without appropriate follow-up so that if they stop using oral PrEP, their liver function can be closely monitored for reactivation of HBV replication.

Hepatitis B Serological Test Results

Test and Result	Interpretation	Action
HBsAg—Positive Total anti-HBc — Positive IgM anti-HBc — Positive Anti-HBs — Negative	Acute infection	Link to hepatitis B care
HBsAg — Positive Total anti-HBc — Positive IgM anti-HBc — Negative ¹ Anti-HBs — Negative	Chronic Infection	Link to hepatitis B care
HBsAg — Negative Total anti-HBc — Positive Anti-HBs — Positive	Resolved Infection	Counsel about HBV infection reactivation risk
HBsAg — Negative Total anti-HBc — Negative Anti-HBs — Positive ²	Immune from receipt of prior vaccination (if documented complete series)	If no documentation of full vaccination, then complete vaccine series per ACIP recommendations.
HBsAg — Negative Total anti-HBc — Positive Anti-HBs — Negative	<i>Only core antibody is positive. See possible interpretations and corresponding actions:</i>	
	Resolved infection where anti-HBs levels have waned	Counsel about HBV infection reactivation risk
	Occult Infection	Link to hepatitis B care
	Passive transfer of anti-HBc to an infant born to an HBsAg-positive gestational parent	No action
	A false positive, thus patient is susceptible	Offer HepB vaccine per Advisory Committee on Immunization Practices (ACIP)
	A mutant HBsAg strain that is not detectable by laboratory assay	Link to hepatitis B care
HBsAg — Negative Total anti-HBc — Negative Anti-HBs — Negative ³	Susceptible, never infected (if no documentation of HepB vaccine series completion)	Offer HepB vaccine per ACIP recommendations

STIs

- Tests to screen for chlamydia, gonorrhea, and syphilis are recommended for all sexually active adults before starting oral or injectable PrEP.
- Taking a sexual history will help guide the physical exam and screening of all exposed sites



STI Screening-The "Triple Dip"



HIV/Syphilis/Hepatitis Serologies



Blood



Pharyngeal GC NAAT

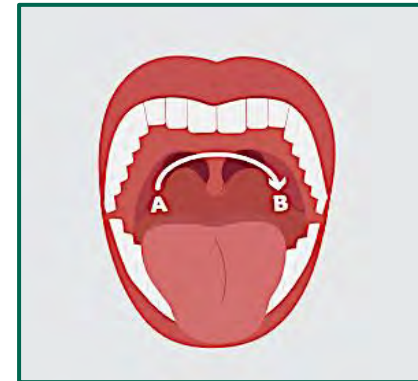
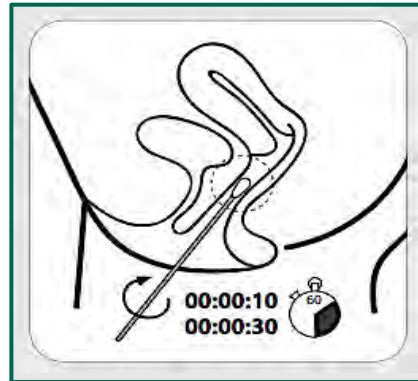
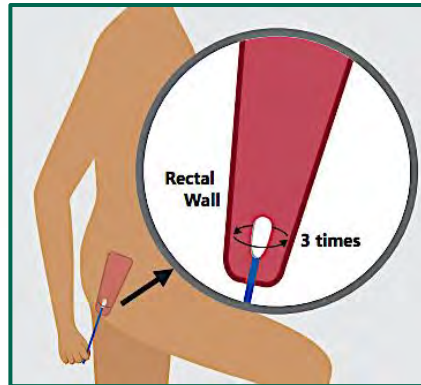


Urine GC/CT NAAT

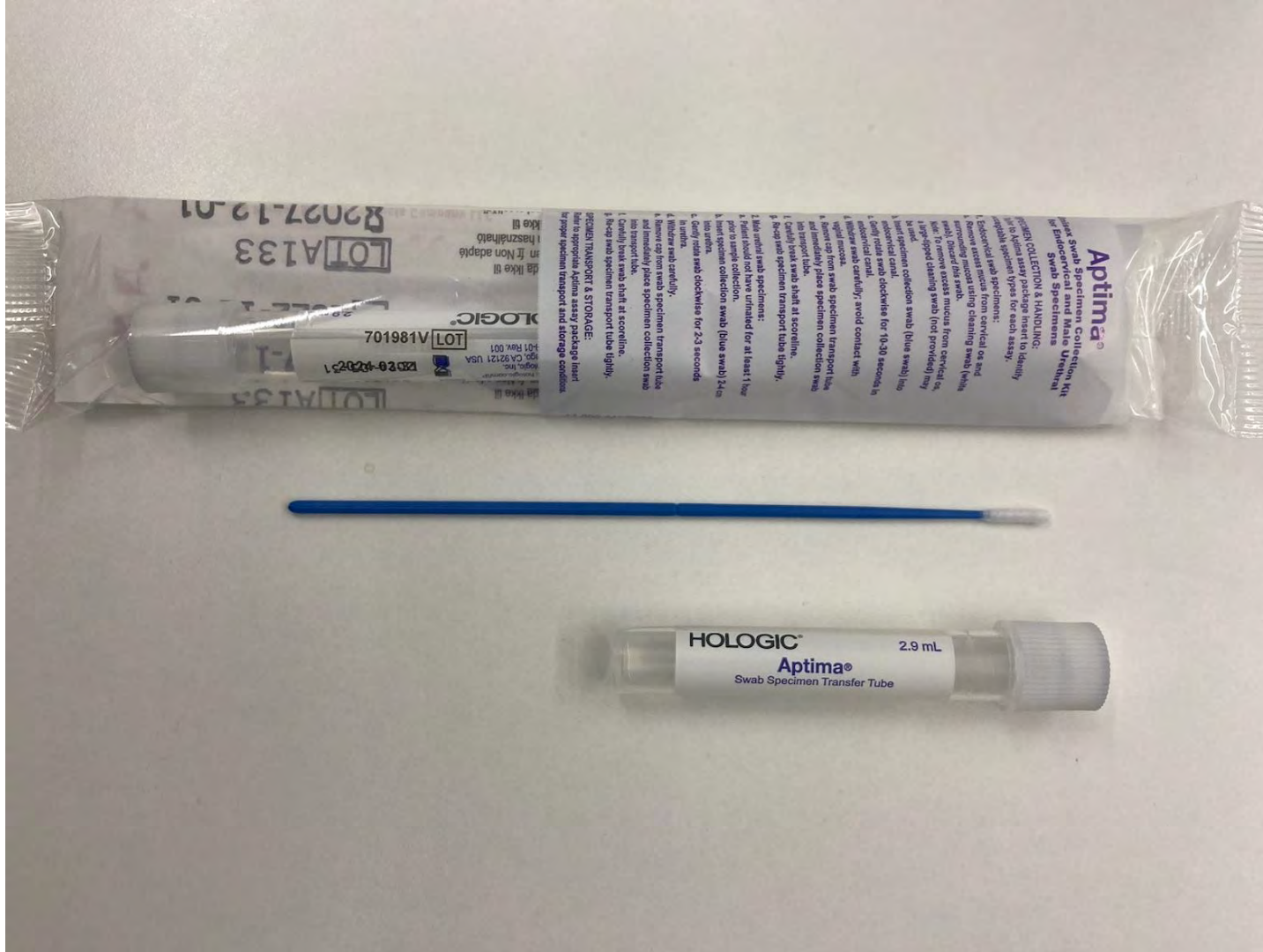


Rectal GC/CT NAAT

Swab of site

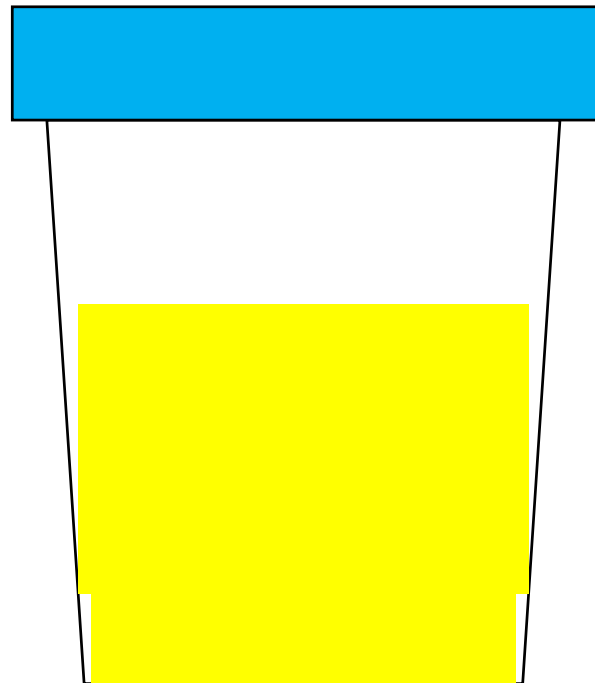


Aptima Swabs



Urethral

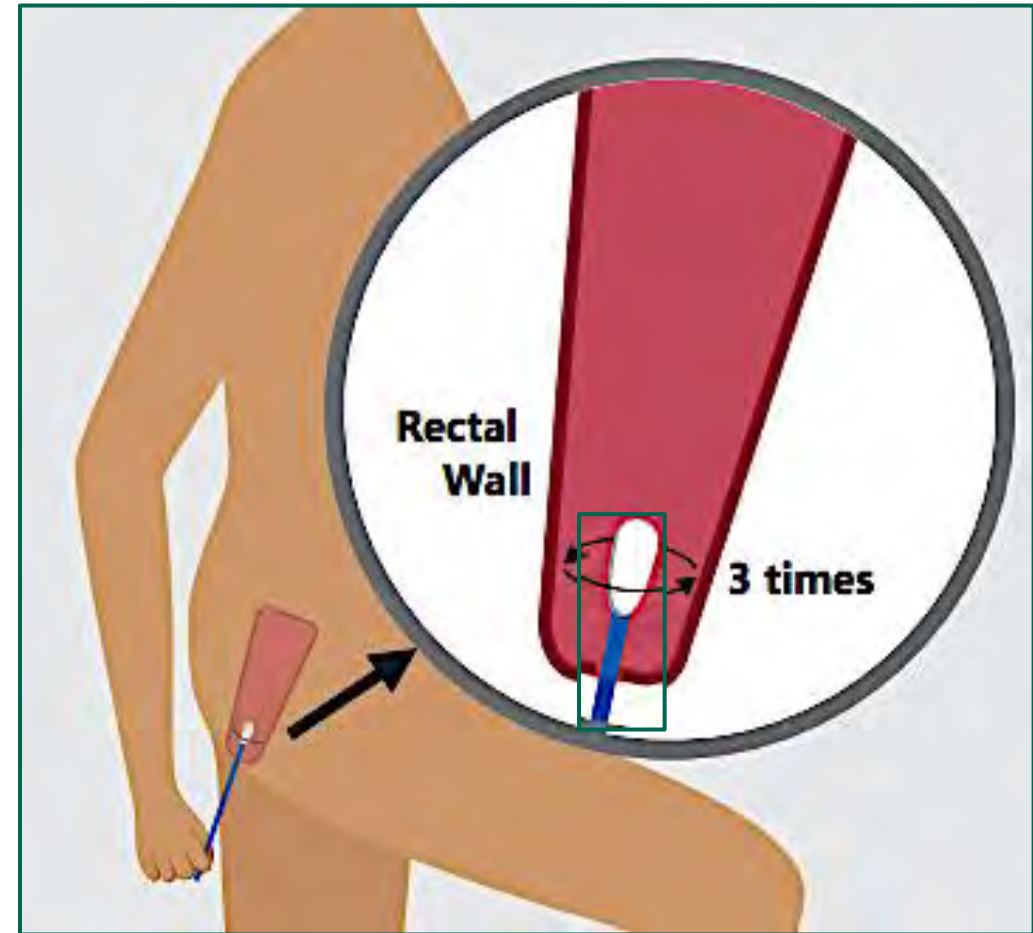
Self Collection – Lab Specimen (GC/CT)



Rectal

Self Collection – Lab Specimen (GC/CT)

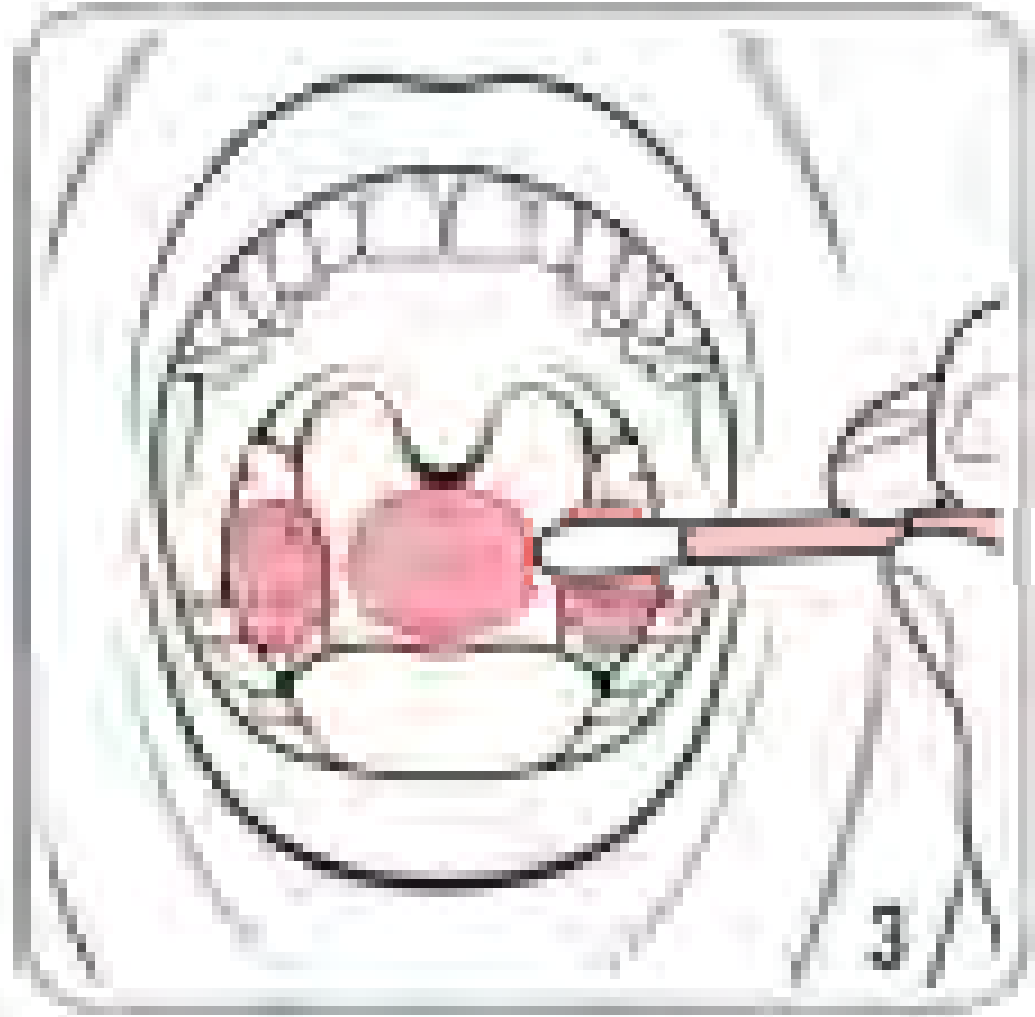
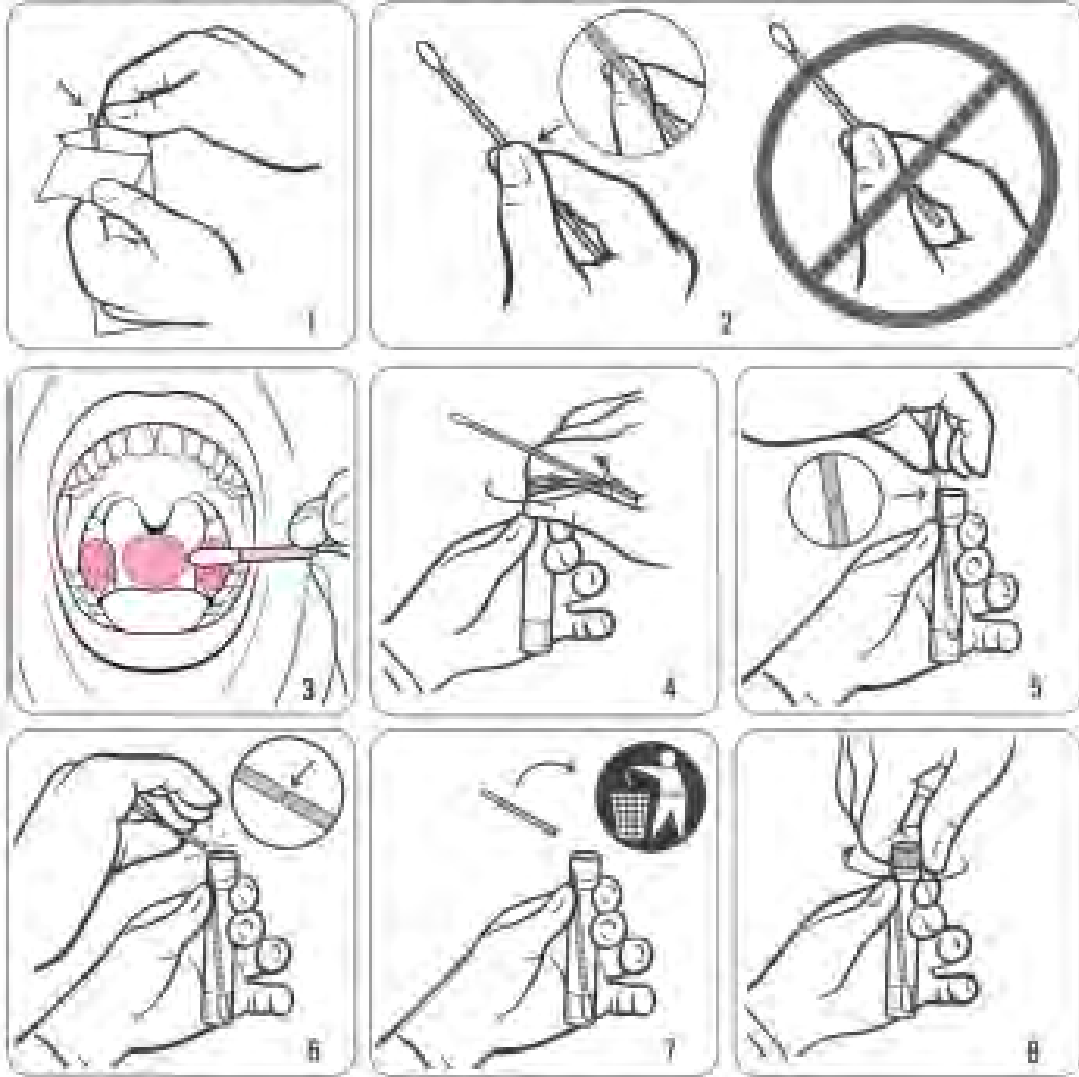
Rectal Swab Specimen Collection



Pharyngeal

Self Collection – Lab Specimen (GC)

Throat Swab Specimen Collection



Recommended First Line Therapies

- Gonorrhea (GC)

Recommended Regimen for Uncomplicated Gonococcal Infection of the Cervix, Urethra, or Rectum Among Adults and Adolescents

Ceftriaxone 500 mg* IM in a single dose for persons weighing <150 kg

If chlamydial infection has not been excluded, treat for chlamydia with doxycycline 100 mg orally 2 times/day for 7 days.

* For persons weighing ≥ 150 kg, 1 g ceftriaxone should be administered.

Recommended First Line Therapies

- Chlamydia (CT)

Recommended Regimens for Chlamydial Infection Among Adolescents and Adults

Doxycycline 100 mg orally 2 times/day for 7 days

Alternative Regimens

Azithromycin 1 g orally in a single dose

OR

Levofloxacin 500 mg orally once daily for 7 days

Test of Cure and Other Management Considerations

- Gonorrhea (GC)
 - To minimize disease transmission, persons treated for gonorrhea should be instructed to abstain from sexual activity for 7 days after treatment and until all sex partners are treated
 - A test of cure (i.e., repeat testing after completion of therapy) is:
 - Unnecessary for persons who receive a diagnosis of uncomplicated urogenital or rectal gonorrhea
 - Recommended for those with pharyngeal gonorrhea, return 7–14 days after initial treatment for a test of cure by using either culture or NAAT
- Chlamydia (CT)
 - To minimize disease transmission to sex partners, persons treated for chlamydia should be instructed to abstain from sexual intercourse for 7 days after single-dose therapy or until completion of a 7-day regimen and resolution of symptoms if present
 - Test of cure to detect therapeutic failure is not advised for nonpregnant persons treated with the recommended or alternative regimens

Syphilis

- "The Great Imitator"
- **Penicillin G, administered parenterally, is the preferred drug for treating patients in all stages of syphilis.** The preparation used (i.e., benzathine, aqueous procaine, or aqueous crystalline), dosage, and length of treatment depend on the stage and clinical manifestations of the disease.
 - Primary and Secondary Syphilis
 - Latent Syphilis
 - Tertiary Syphilis
 - Neurosyphilis, Ocular Syphilis, and Ootosyphilis
- More to come on this as part of future STI Testing and Treatment ECHO series...

Thanks!