WELCOME to the

Get PrEP'd ECHO: HIV Pre-Exposure Prophylaxis

Session 1, HIV Epidemiology, September 5, 2023

Please let us know you are here: Type your name, email, 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
1 - HIV epidemiology, U.S. PrEP coverage and brief overview of EHE goals	9/5/2023
2 - Sexual history taking, inclusive language	9/19/2023
3 - HIV risk assessment and indications for PrEP	10/3/2023
4 - HIV diagnostics and interpretation particularly in the context of PrEP usage	10/17/2023
5 - Oral PrEP medication and indications	10/31/2023
6 - Injectable PrEP medication and indications	11/7/2023
7 - PrEP monitoring and required labs, STI screening	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

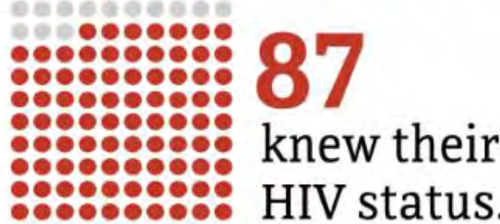
Associate Professor of Medicine, Geisel School of Medicine

Co-program Director the HOPE Program, Dartmouth Health

Medical Director, NH AETC

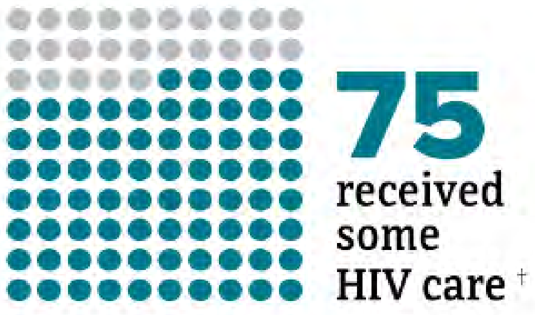
In 2021, an **estimated 1.2 million people** had HIV.

For every 100 people with HIV



87 knew their HIV status.

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



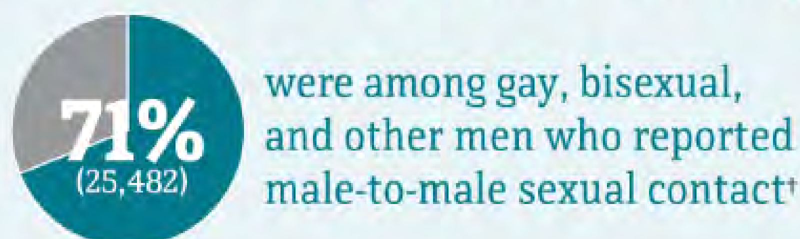
75 received some HIV care †

54 were retained in care ‡

66 were virally suppressed **

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†

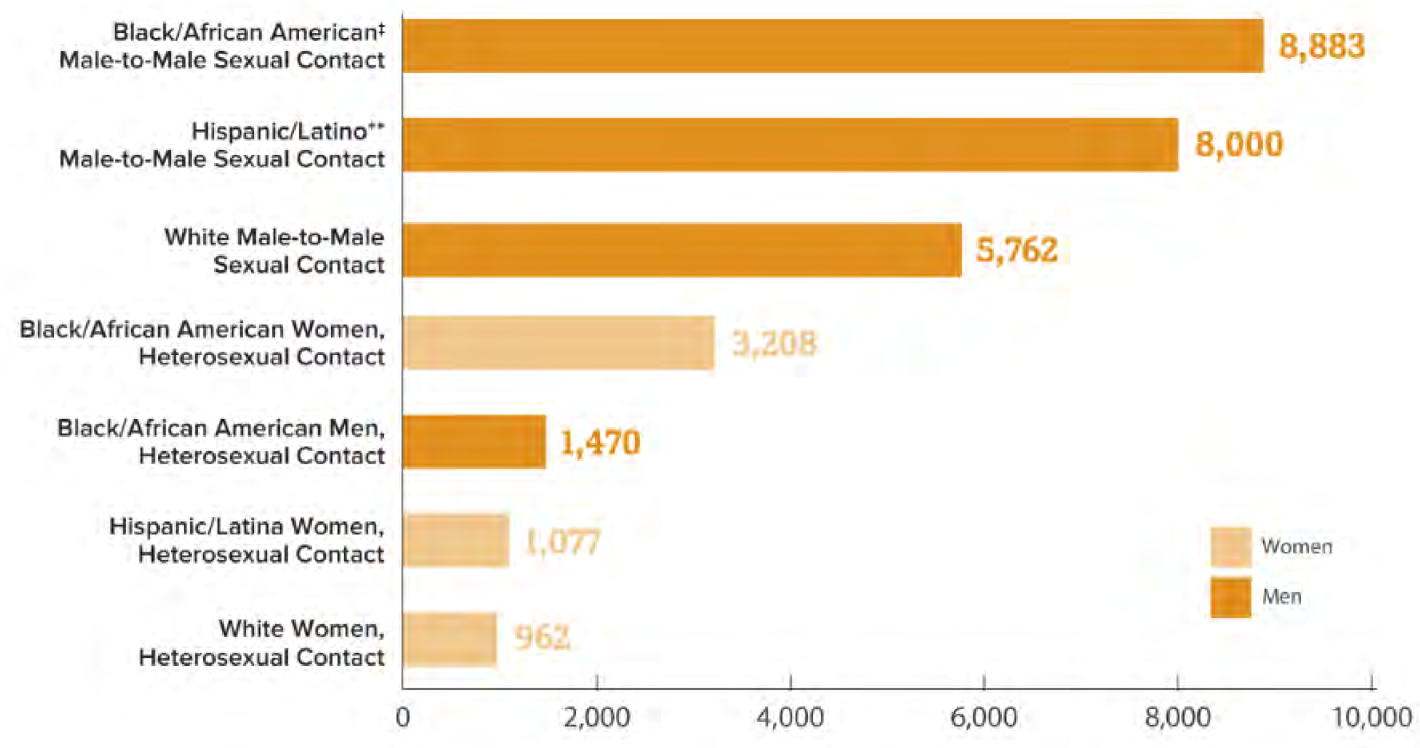
were among people who reported heterosexual contact

were among people who inject drugs

*Among people aged 13 and older.

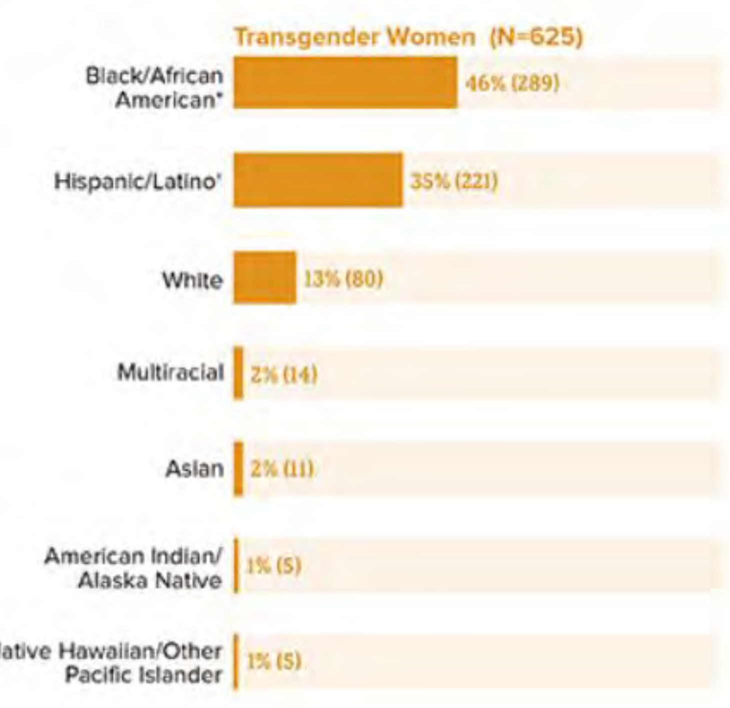
†Includes infections attributed to male-to-male sexual contact and injection drug use (men who reported both risk factors).

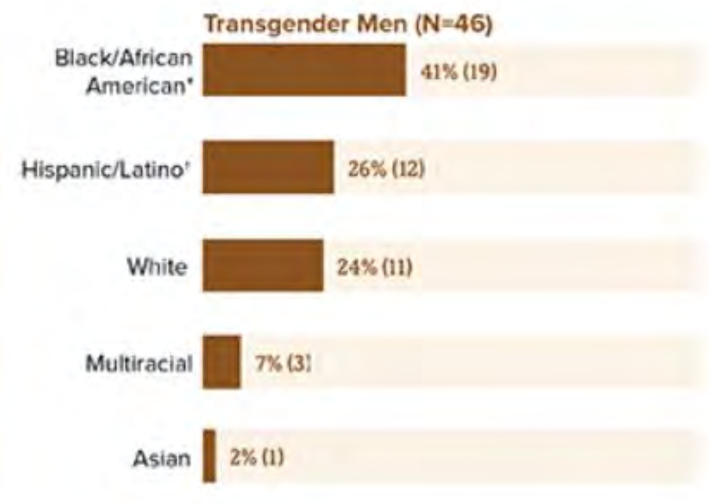
Gay and bisexual men are the population most affected by HIV.



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

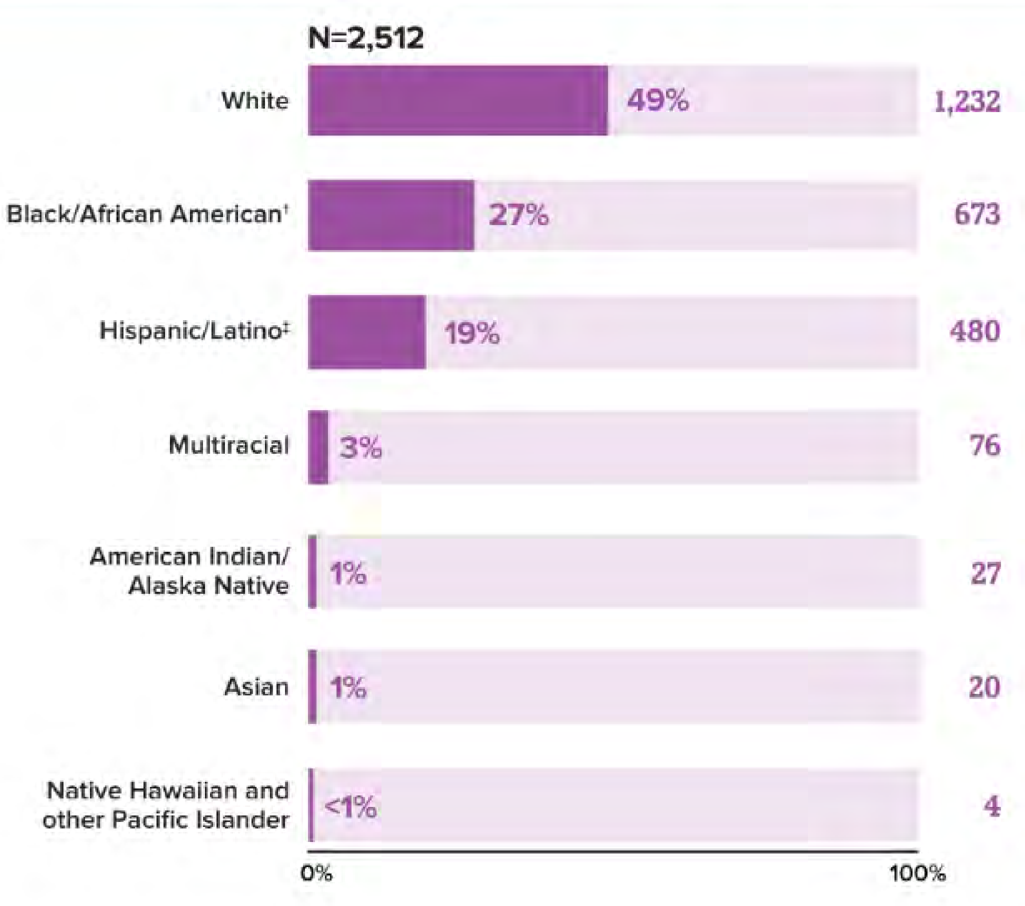
Most new HIV diagnoses among transgender people were among Black/African American people.





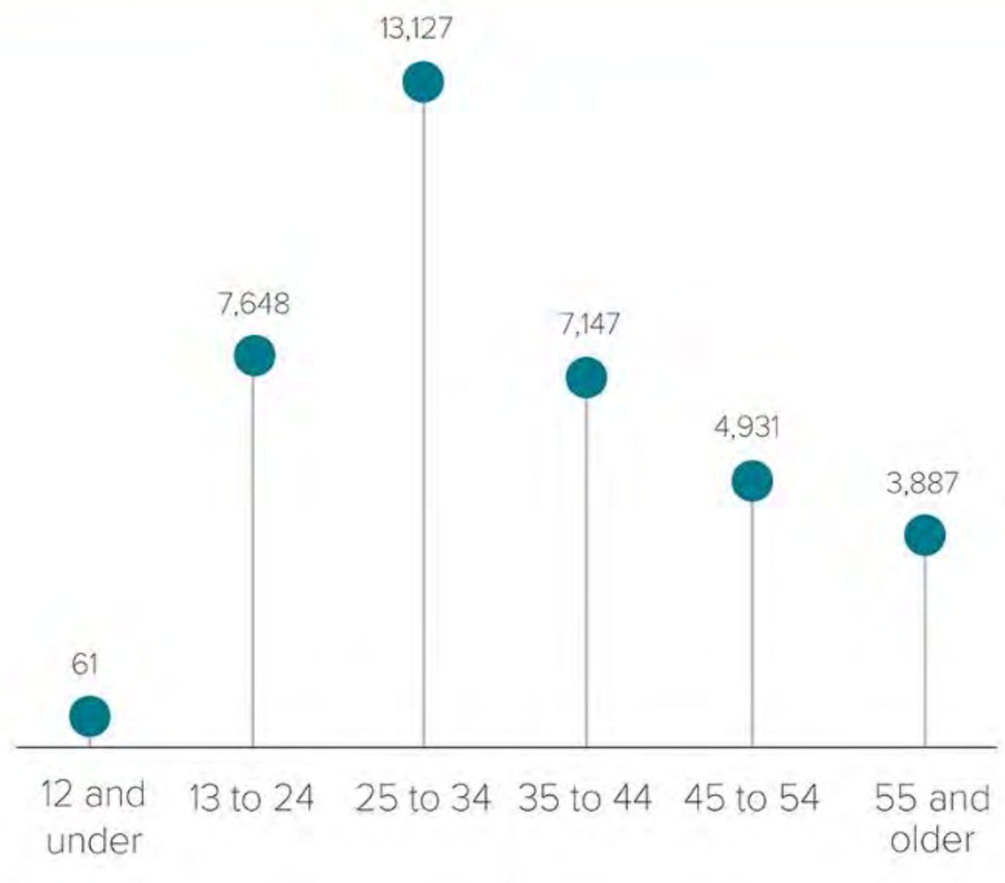
New HIV Diagnoses Among People Who Inject Drugs in the US and Dependent Areas by Race and Ethnicity, 2021*

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.

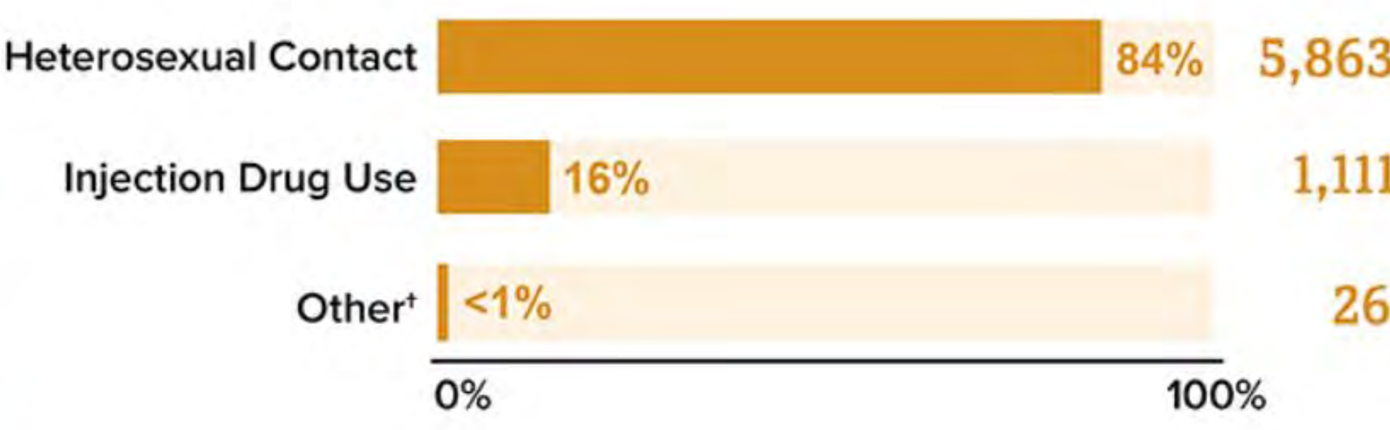


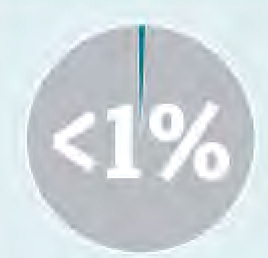
Source: CDC. Diagnoses of HIV infection in the United States and dependent areas, 2019. *HIV Surveillance Report* 2021;32.

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.

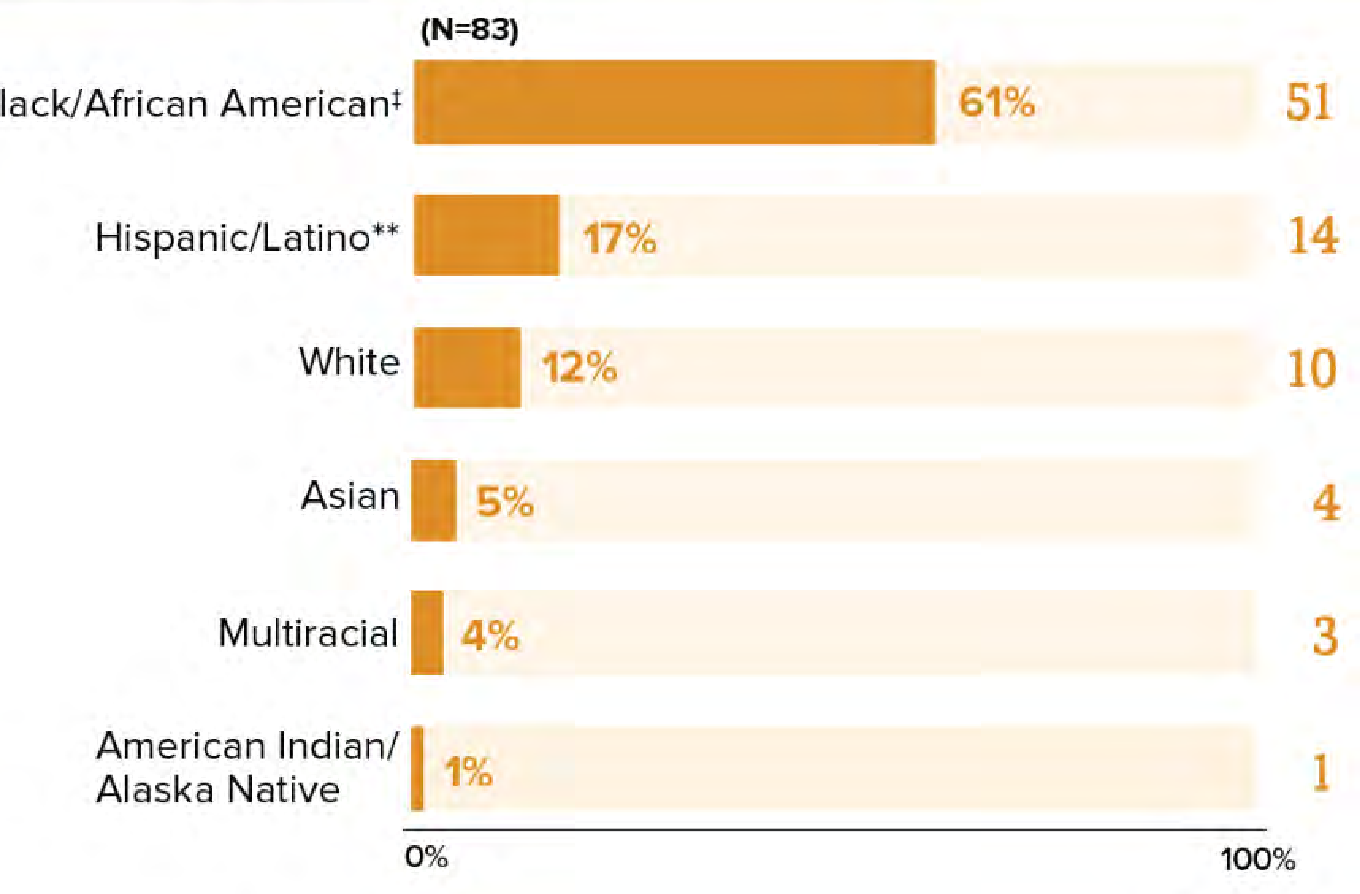




Of the **36,801 new HIV diagnoses** in the US and dependent areas in 2019, <1% (84) were due to perinatal transmission.*

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.

HIV Diagnoses by Region, 2020

- Midwest 13% (4,118)
- Northeast 14% (4,262)
- Dependent Areas 1% (289)
- West 21% (6,305)
- South 51% (15,661)

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.

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

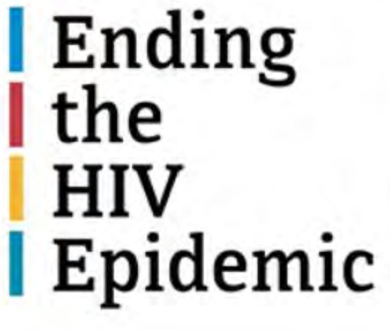
Health Resources & Services Administration

HIV.gov

Indian Health Service

Substance Abuse and Mental Health Services Administration

The time is now.



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
the
HIV
Epidemic

GOAL:

75% (2025)
reduction in new HIV infections in 5 years

and at least
90% (2030)
reduction in 10 years.

www.hiv.gov

CS302517B

The time is now.

Ending the HIV Epidemic

Ending the HIV Epidemic

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

Ending the HIV Epidemic

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.

Ending the HIV Epidemic

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.

Ending the HIV Epidemic

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	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. See the Practice Considerations section for more information about identification of persons at increased risk and about effective antiretroviral therapy.	A

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

WA 28%
MT 17%
ND 16%
MN 24%
VT 45%
NH 27%
ME 23%
OR 24%
ID 18%
WY 16%
SD 24%
WI 22%
MI 20%
NY 54%
MA 41%
RI 39%
CT 32%
NJ 29%
DE 15%
MD 21%
D.C. 52%
NE 46%
IA 41%
PA 36%
IL 33%
IN 19%
OH 21%
WV 14%
VA 20%
NV 43%
UT 48%
CO 25%
KS 25%
MO 23%
KY 17%
CA 30%
OK 21%
AR 25%
TN 32%
NC 25%
AZ 26%
NM 23%
SC 28%
MS 35%
AL 25%
GA 31%
TX 28%
LA 26%
FL 34%
AK 17%
HI 26%
PR 6%

PrEP Coverage (Percentage)
4% - 16%
17% - 20%
21% - 25%
26% and above

* 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.**

AIDSVu.ORG | @AIDSVu SOURCE: AIDSVu AIDSVu

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.

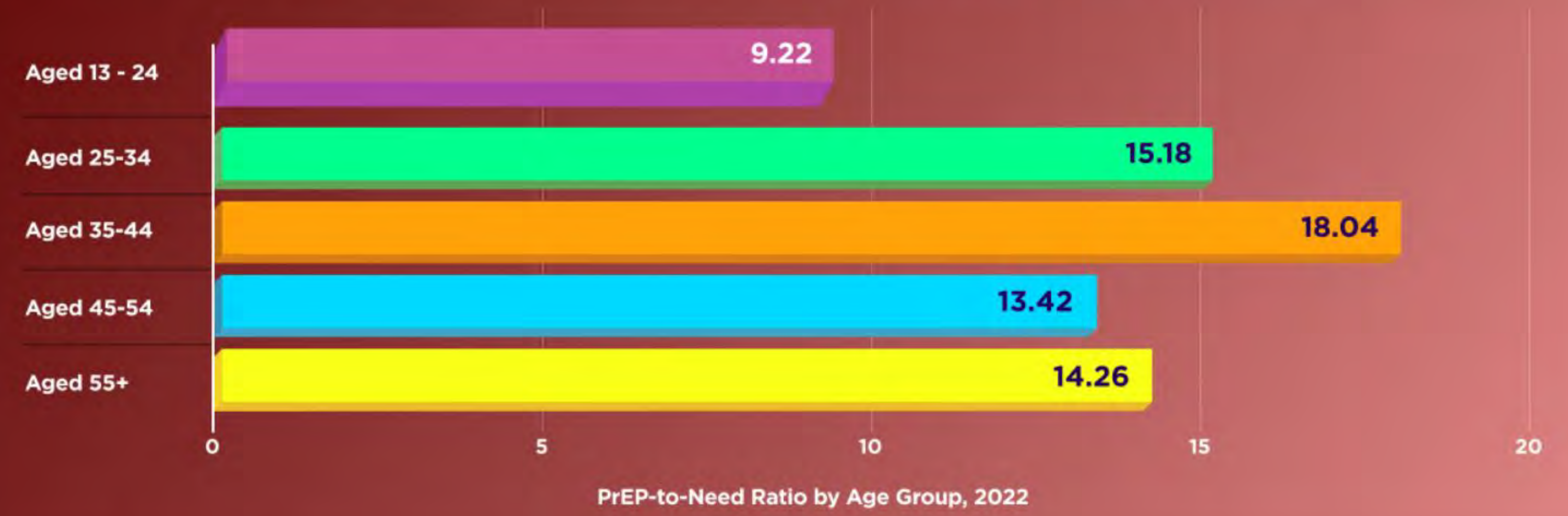
There were **6 female PrEP users** for every new HIV diagnosis among women.

AIDSVu.ORG | @AIDSVu

SOURCE: AIDSVu

AIDSVu

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


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.
Aged 13 - 24
9.22
Aged 25-34
15.18
Aged 35-44
18.04
Aged 45-54
13.42
Aged 55+
14.26
0
5
10
15
20
PrEP-to-Need Ratio by Age Group, 2022
*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.
AIDSVu.ORG | @AIDSVu
SOURCE: AIDSVu
AIDSVu

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

Pleuhs et al. 2020. AIDS Patient Care and STDs

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)?

Do you have health insurance?

Yes

Medication	Lab Test	Clinic Visits
• Use Your Insurance	• Use Your Insurance	• Use Your Insurance

If you still have a copay, apply for copay assistance from the manufacturer or Patient Advocate Foundation.

No

Apply

www.healthcare.gov

Are you eligible for Medicaid or ACA plans?

Yes (Use your insurance)

No

Household Income Below 500% of Federal Poverty Level: Apply for manufacturer's Medication Assistance Program.

Medication	Lab Test	Clinic Visits
• Medication cost covered	• Care at Community Health Center with sliding scale fee*	• Care at Community Health Center with sliding scale fee*

Any Income Level: Apply for Ready, Set, PrEP.

Medication	Lab Test	Clinic Visits
• Medication cost covered	• Care at Community Health Center with sliding scale fee*	• Care at Community Health Center with sliding scale fee*

Check to see if your state provides PrEP assistance. Costs for lab tests and clinic visits may be reduced or eliminated.
Check your state PrEP Assistance Program at: www.nastad.org/prepcost-resources/prep-assistance-programs

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

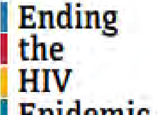


Table 9 NASTAD Table of State PrEP Financial Assistance Programs (as of August 2022)

STATE	DRUG ASSISTANCE		CLINICAL VISITS AND LAB TEST ASSISTANCE	PATIENT INCOME LIMIT
	COPAY 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 clinicst	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

JAMA August 16, 2022 Volume 328, Number 7

The time is now.

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

WELCOME to the

Get PrEP'd ECHO: HIV Pre-Exposure Prophylaxis

Session 2, Sexual history Taking, September 19, 2023

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

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

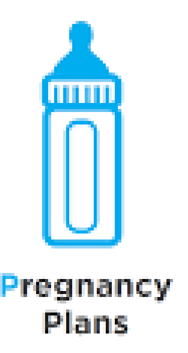
CDC’s 5P model

Partners

Practices

Past History of STDs

Protection from STDs



Pregnancy Plans

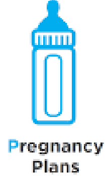
To learn more about taking a sexual history, visit:
cdc.gov/HIVNexus

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

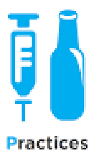
Practices



- 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

Thank you!
Questions?

Bobby Kelly, MD, MPH, FAAFP

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267-250-9848

WELCOME to the

Get PrEP'd ECHO:
HIV Pre-Exposure Prophylaxis

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

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

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	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. See the Practice Considerations section for more information about identification of persons at increased risk and about effective antiretroviral therapy.	A

Figure 1 Populations and HIV Acquisition Risk

General Population

Persons in high prevalence groups or communities

Persons with identified PrEP indications

Persons with virally-unsuppressed partners with HIV

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.

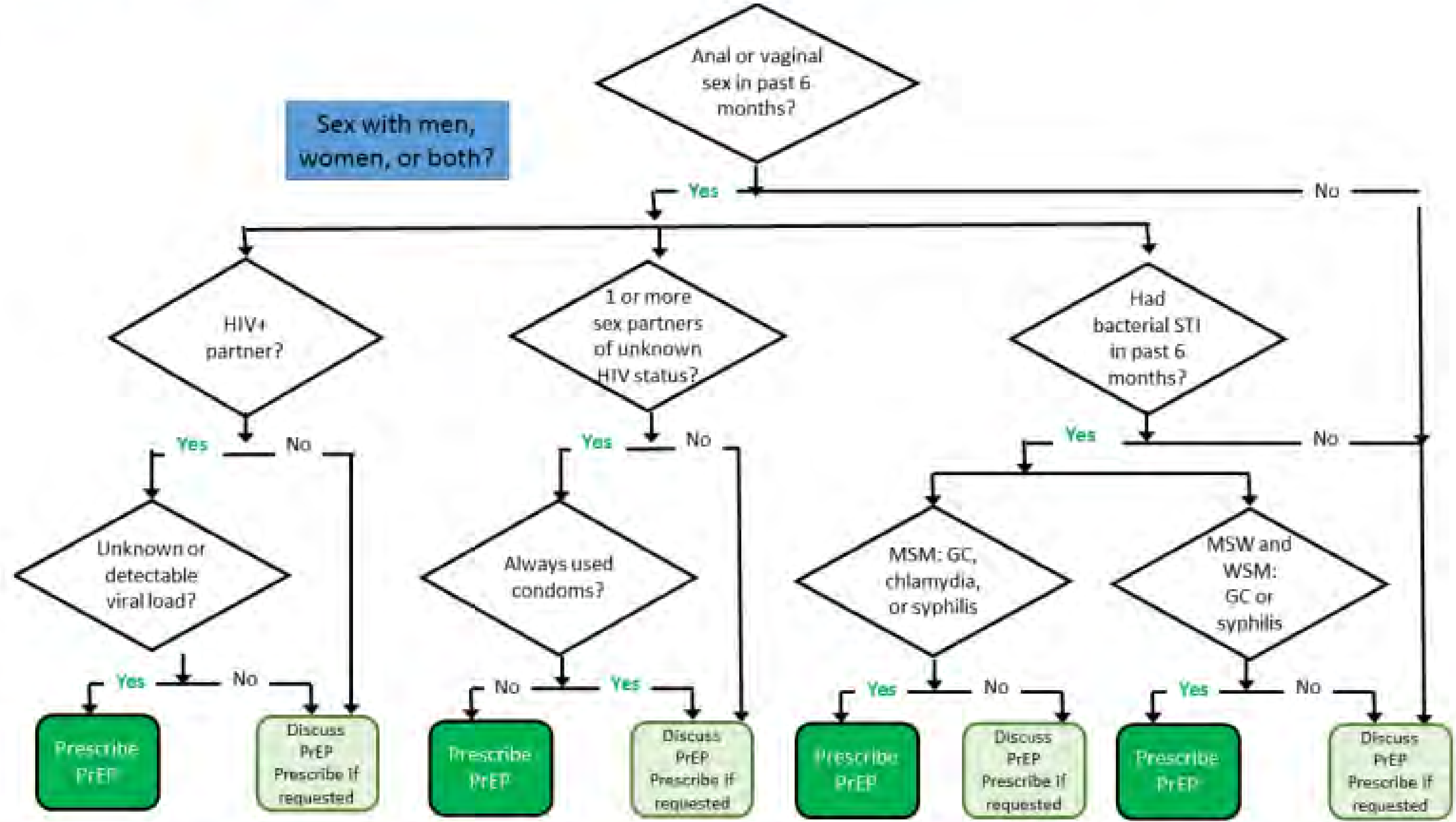
Source:

- 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

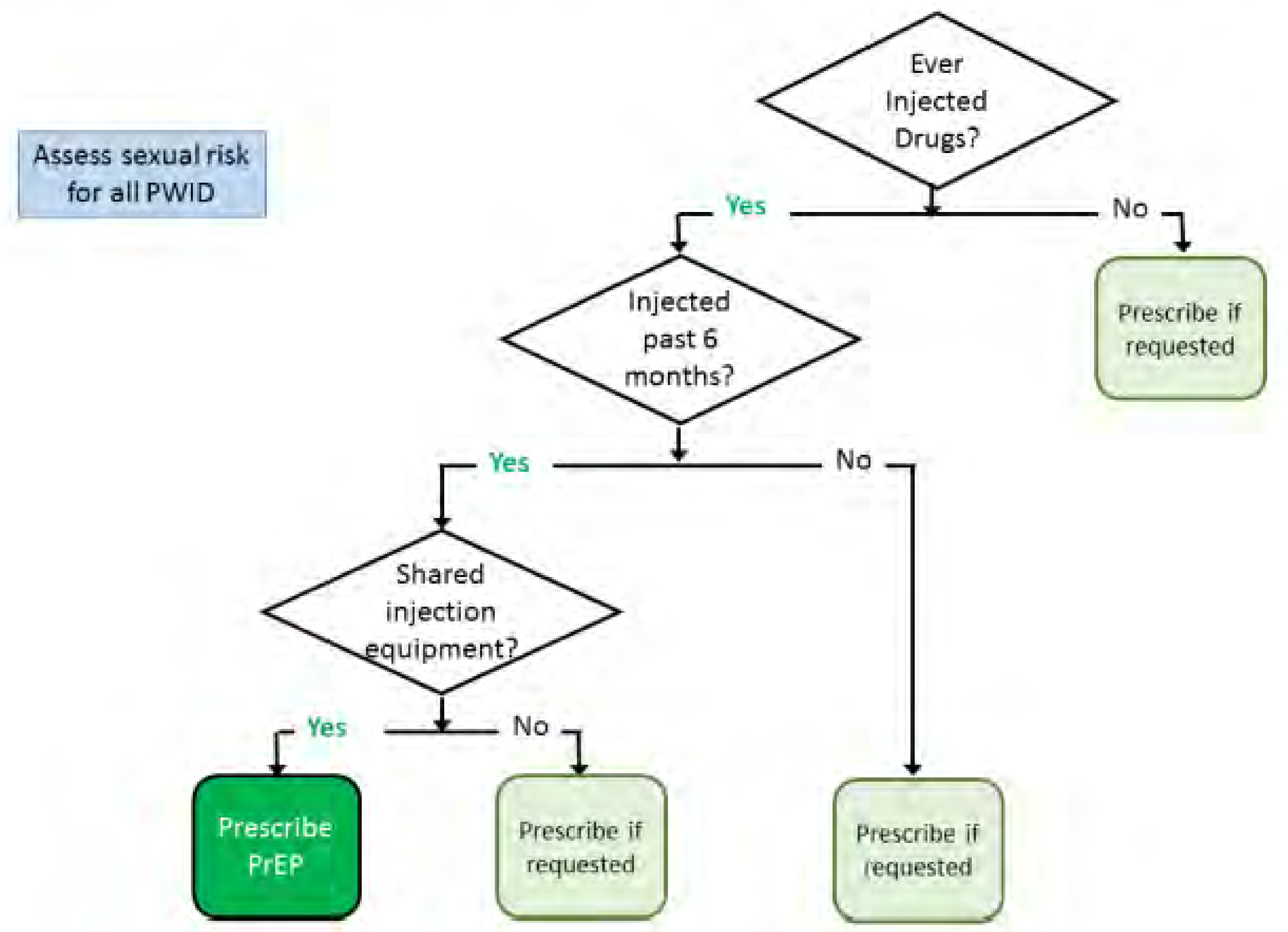


MSM Risk Index [13]			
1	How old are you today?	If <18 years, score 0 If 18-28 years, score 8 If 29-40 years, score 5 If 41-48 years, score 2 If 49 years or more, score 0	______
2	In the last 6 months, how many men have you had sex with?	If >10 male partners, score 7 If 6-10 male partners, score 4 If 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	______

4	In the last 6 months, how many of your male sex partners were HIV-positive?	If >1 positive partner, score 8 If 1 positive partner, score 4 If <1 positive partner, score 0	________
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?	If 5 or more times, score 6 If 0-4 times, score 0	________
6	In the last 6 months, have you used methamphetamines such as crystal or speed?	If yes, score 6 If no, score 0	________
		Add down entries in right column to calculate total score	________ TOTAL SCORE*

* 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]

#	Question	Response		Score
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, If 0 times,	Injection sub-score 1 Injection sub-score 0	________
	In the last 6 months, how often did you inject cocaine?	If 1 or more times, If 0 times,	Injection sub-score 1 Injection sub-score 0	________
	In the last 6 months, how often did you share a cooker?	If 1 or more times, If 0 times,	Injection sub-score 1 Injection sub-score 0	________
	In the last 6 months, how often did you share needles?	If 1 or more times, If 0 times,	Injection sub-score 1 Injection sub-score 0	________
	In the last 6 months, how often did you visit a shooting gallery?	If 1 or more times, If 0 times,	Injection sub-score 1 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			________ 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 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	

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

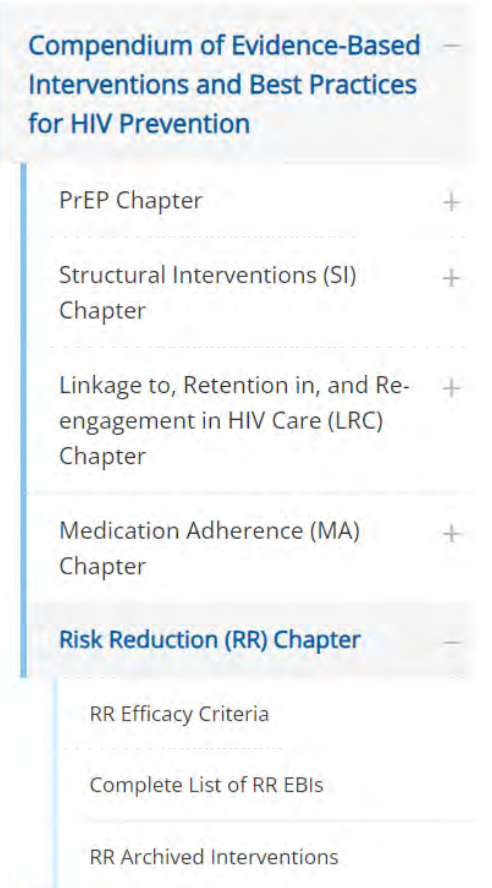
	Sexually-Active Adults	Persons Who Inject Drugs[1]
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: • HIV-positive sexual partner (especially if partner has an unknown or detectable viral load) • Bacterial STI in past 6 months[2] • 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	

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).



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

Compendium | Intervention Research | Research | HIV | CDC

WELCOME to the

Get PrEP'd ECHO: HIV Pre-Exposure Prophylaxis

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

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

HIV Diagnostics

Bryan J. Marsh, MD

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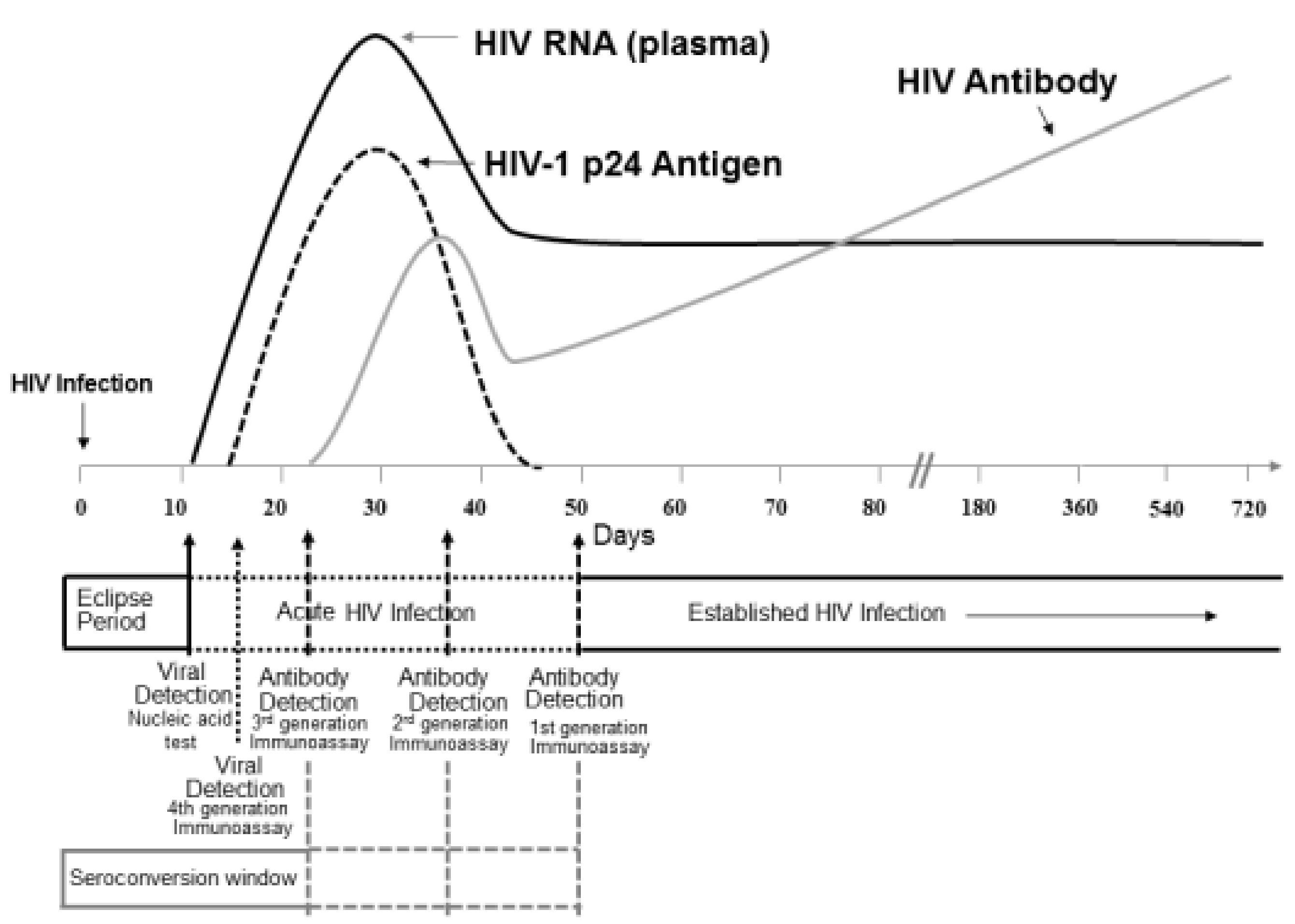
Co-program Director the HOPE Program, Dartmouth Health

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

The Window is Shrinking



HIV-1/2 antigen/antibody combination immunoassay

(+)

(-)
Negative for HIV-1 and HIV-2 antibodies and p24 Ag

HIV-1/HIV-2 antibody differentiation immunoassay

HIV-1 (+) HIV-2 (-)	HIV-1 (-) HIV-2 (+)	HIV-1 (+) HIV-2 (+)	HIV-1 (-) or indeterminate HIV-2 (-)
HIV-1 antibodies detected	HIV-2 antibodies detected	HIV antibodies detected	HIV-1 NAT

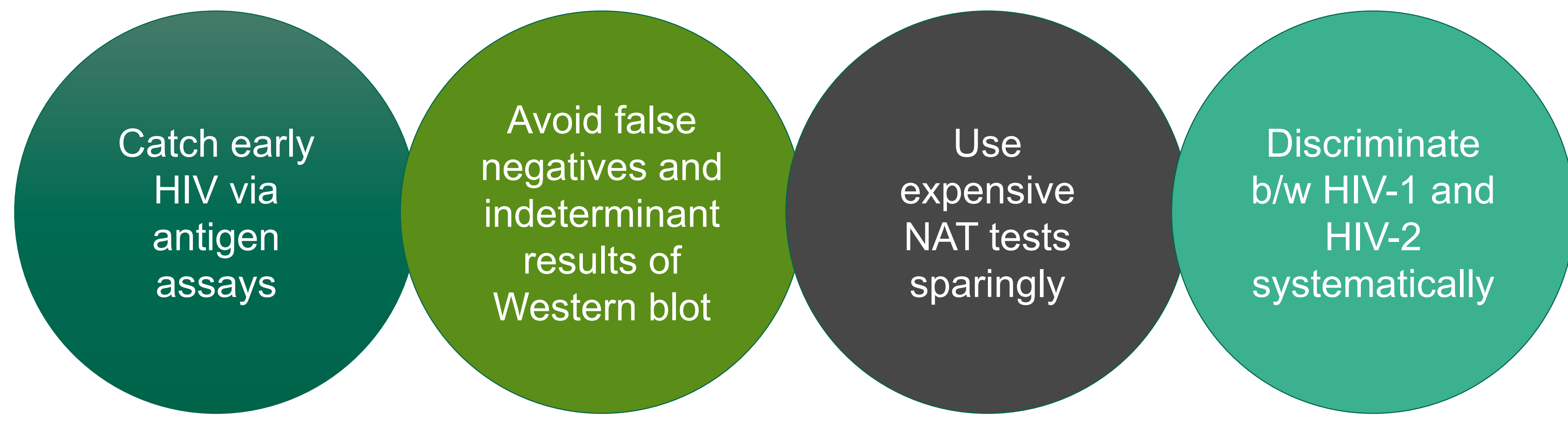
HIV-1 NAT (+)
Acute HIV-1 infection

HIV-1 NAT (-)
Negative for HIV-1

(+) indicates reactive test result
(-) indicates nonreactive test result
NAT: nucleic acid test

http://www.cdc.gov/hiv/pdf/HIVtestingAlgorithmRecommendation-Final.pdf

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



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

If the patient has not taken oral PrEP or PEP medication in the past 3 months
AND
has not received a cabotegravir injection in the past 12 months

HIV antibody/antigen plasma test laboratory (preferred) with reflex confirmation
OR blood rapid test

Nonreactive (negative)

Indeterminate Differentiation Assay

Reactive (positive)

HIV + (if laboratory test)

(pending supplemental confirmatory testing (if non-laboratory rapid test)

Reported HIV exposure-prone event in prior 4 weeks
AND
Signs/symptoms of acute HIV infection anytime in prior 4 weeks

HIV - No

Yes

Send plasma for HIV antibody/antigen assay

±

Send plasma for quantitative or qualitative HIV-1 RNA assay

Reactive (positive) HIV +

Nonreactive (negative) HIV -

HIV-1 RNA ≥200 copies/ml HIV +

HIV-1 RNA detectable but <200 copies/ml

Draw new plasma specimen
Defer PrEP decision until false positive ruled out

HIV-1 RNA < level of detection
no signs/symptoms on day of blood draw HIV -

HIV-1 RNA < level of detection with signs/symptoms on day of blood draw
Retest in 2-4 weeks
Defer PrEP decision, consider nPEP

Legend

- HIV - Eligible for PrEP
- HIV + Not Eligible for PrEP
- HIV Status Unclear Defer PrEP decision

Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update Clinical Practice Guideline
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Figure 4b Clinician Determination of HIV Status for PrEP Provision to Persons with Recent or Ongoing Antiretroviral Prophylaxis Use

If the patient has taken oral PrEP or PEP medication in the past 3 months
OR
has received a cabotegravir injection in the past 12 months

Send plasma for

HIV antibody/antigen assay
AND
qualitative or quantitative
HIV-1 RNA assay

Reactive Ab/Ag test (positive)
AND
HIV-1 RNA detected (positive)
→ **HIV +**

Non-reactive Ab/Ag test (negative)
AND
HIV-1 RNA not detected (negative)
→ **HIV -**

Reactive Ab/Ag test (positive)
AND
HIV-1 RNA not detected (negative)

Non-reactive Ab/Ag test (negative)
AND
HIV-1 RNA detected (positive)

Send new plasma specimen for
qualitative or quantitative
HIV-1 RNA assay

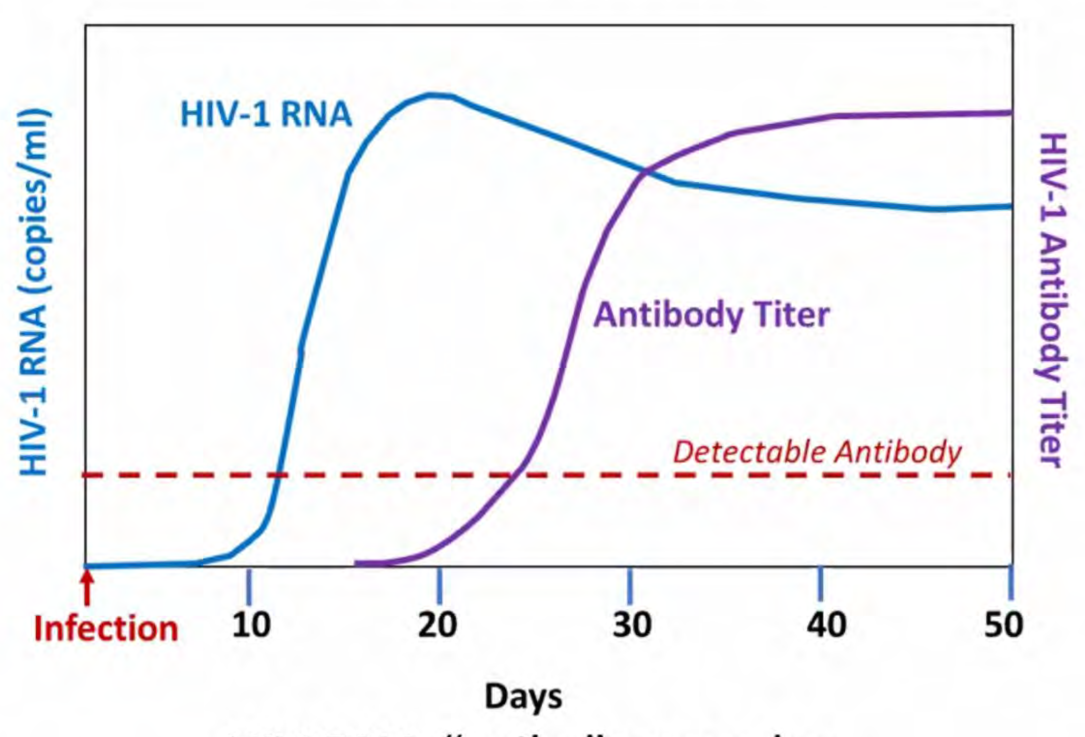
HIV-1 RNA > level of detection → **HIV +**

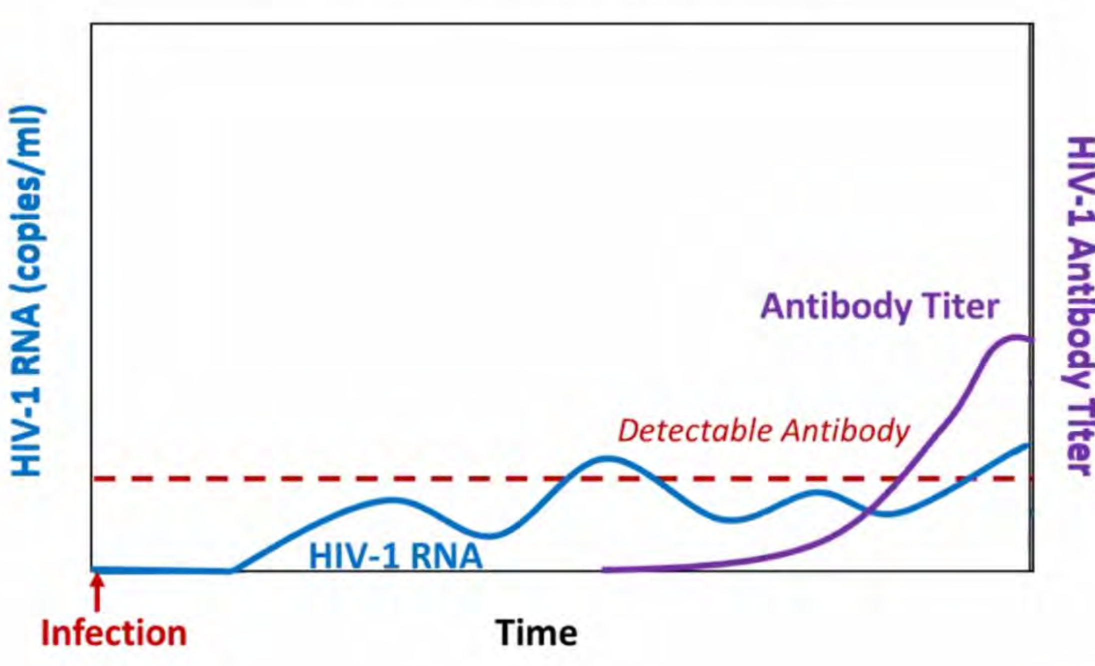
HIV-1 RNA < level of detection → **HIV -**

Legend

- HIV – assay result
- HIV + assay result
- HIV Status Unclear

Diagnosing Acute HIV Infection





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)**

Extract from: Marzinke MA et al. JID. 2021:224(9):1581-1592

Table 2: Clinical Signs and Symptoms of Acute (Primary) HIV Infection[71]

Features	Overall (n = 375) %	Sex: Male (n = 355) %	Sex: Female (n = 23) %	Route of transmission: Sexual (n = 324) %	Route of transmission: 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	

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¶ 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.