

Continued Progress Toward Eliminating the HIV Epidemic



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Objectives

- Define the current state of the HIV epidemic and trends in HIV diagnosis
- Evaluate the new data on Undetectable = Untransmittable
- Examine the CDC recommendations for routine HIV testing
- Illustrate the importance of routine HIV testing in the POL setting and clinics

Current Epidemiology of HIV disease

The background features a blue-to-purple gradient. Several stylized virus particles are scattered across the frame, including a large one in the top right, a smaller one in the middle right, and a large one in the bottom right. On the left side, there are faint, purple-tinted virus-like structures.

What does the U.S. HIV/AIDS epidemic look like in 2023?



Image source, CDC

HIV Disease is Not a Thing of the Past

Current U.S. Epidemiology

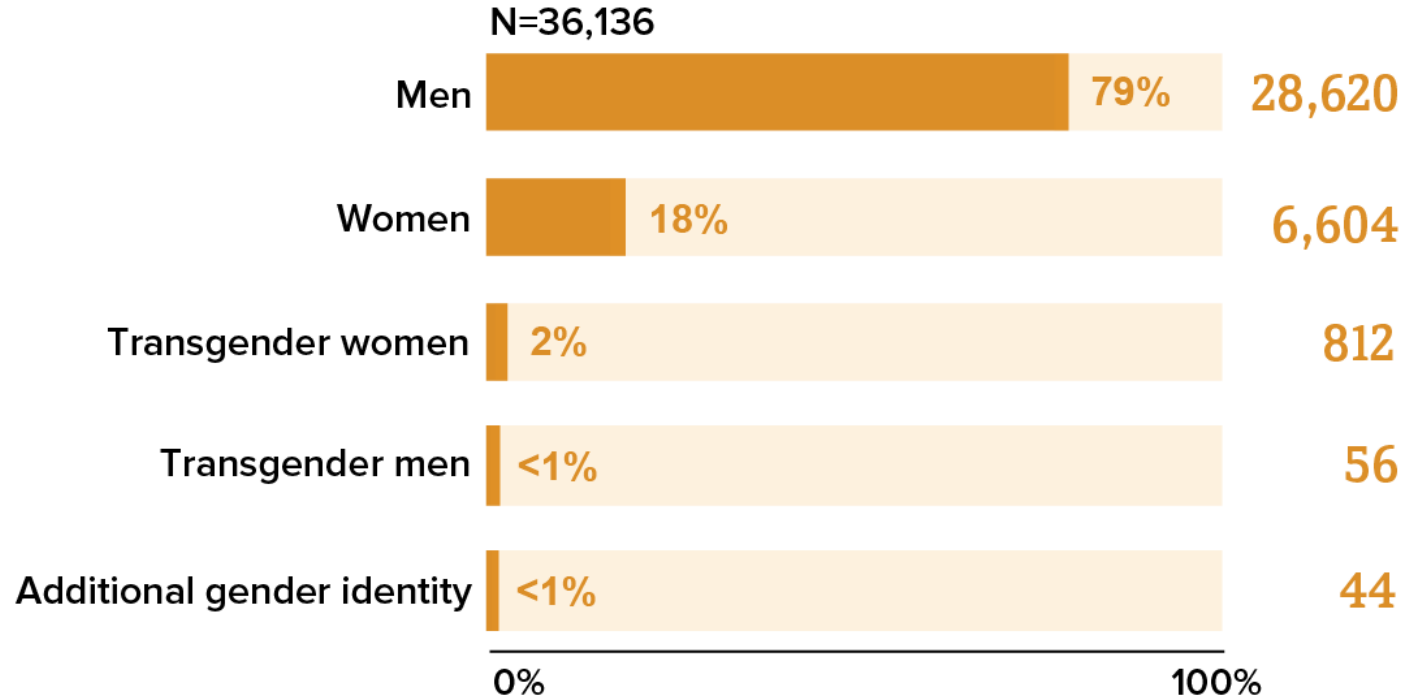
1.2 million persons in the U.S. living with HIV ¹

- 58%, aged 13 - 34 years ¹
- 1 in 8 are unaware of their HIV serostatus ¹
 - Generate 40% of new infections

In 2021: 36,136 new infections in the U.S.¹

Differences in New HIV Diagnoses by Gender*

Men continue to be heavily affected by HIV, accounting for 79% of new HIV diagnoses in 2021.



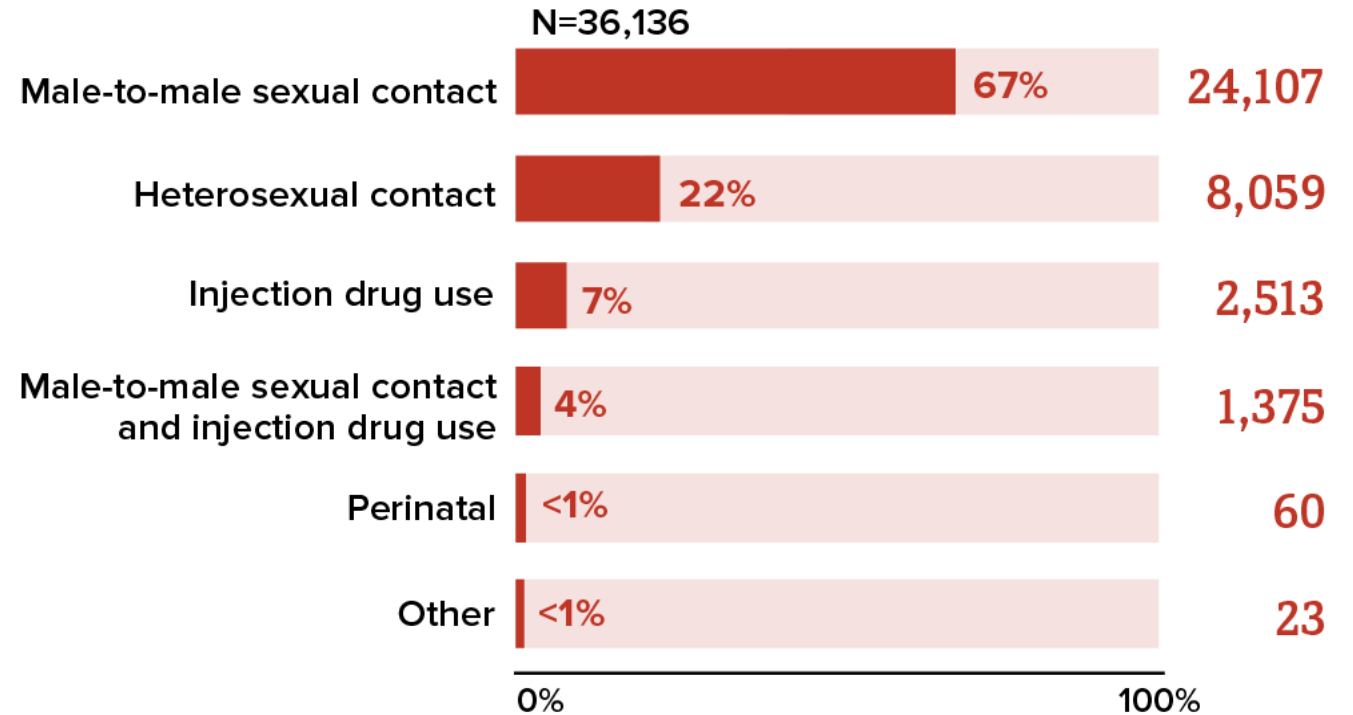
* Among people aged 13 and older.

Source: CDC. Diagnoses of HIV Infection in the United States and Dependent Areas, 2021. *HIV Surveillance Report* 2023;34.



Differences in New HIV Diagnoses by Transmission Category[†]

Gay, bisexual, and other men who reported male-to-male sexual contact are the population most affected by HIV.



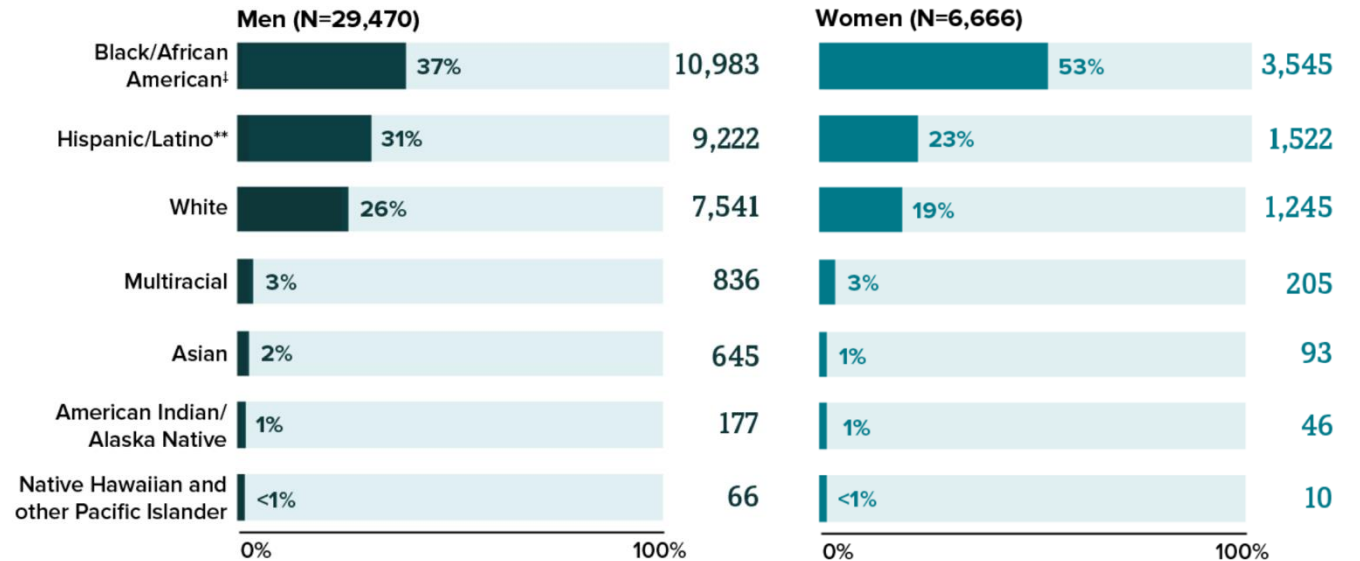
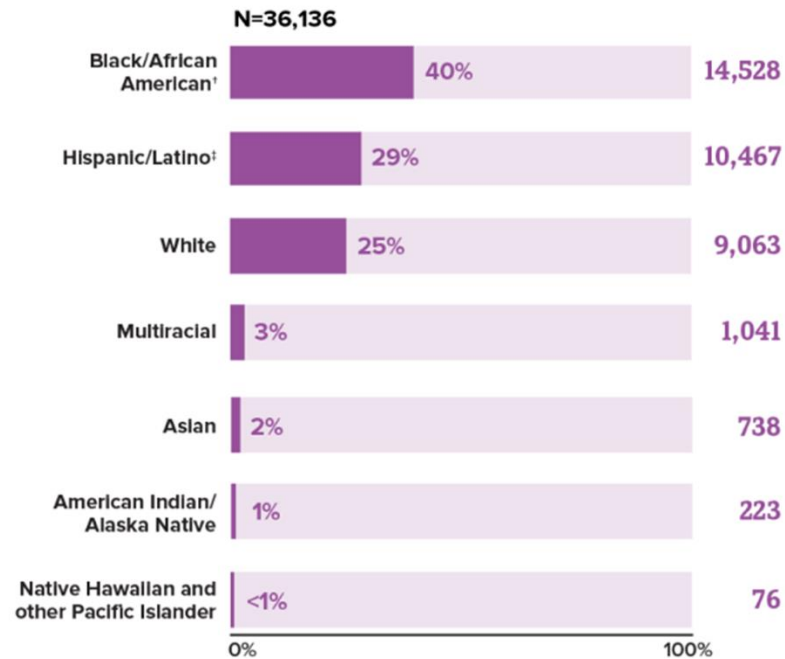
* Among people aged 13 and older.

[†] Transmission category is classified based on a hierarchy of risk factors most likely responsible for HIV transmission. Classification is determined based on the person's assigned sex at birth. Data have been statistically adjusted to account for missing transmission category.

Source: CDC. Diagnoses of HIV Infection in the United States and Dependent Areas, 2021. *HIV Surveillance Report* 2023;34.



Differences in New HIV Diagnoses by Race/Ethnicity^{†,‡} and by Gender



Among people aged 13 and older.

[†] Black refers to people having origins in any of the Black racial groups of Africa. African American refers to people of African descent with ancestry in North America.

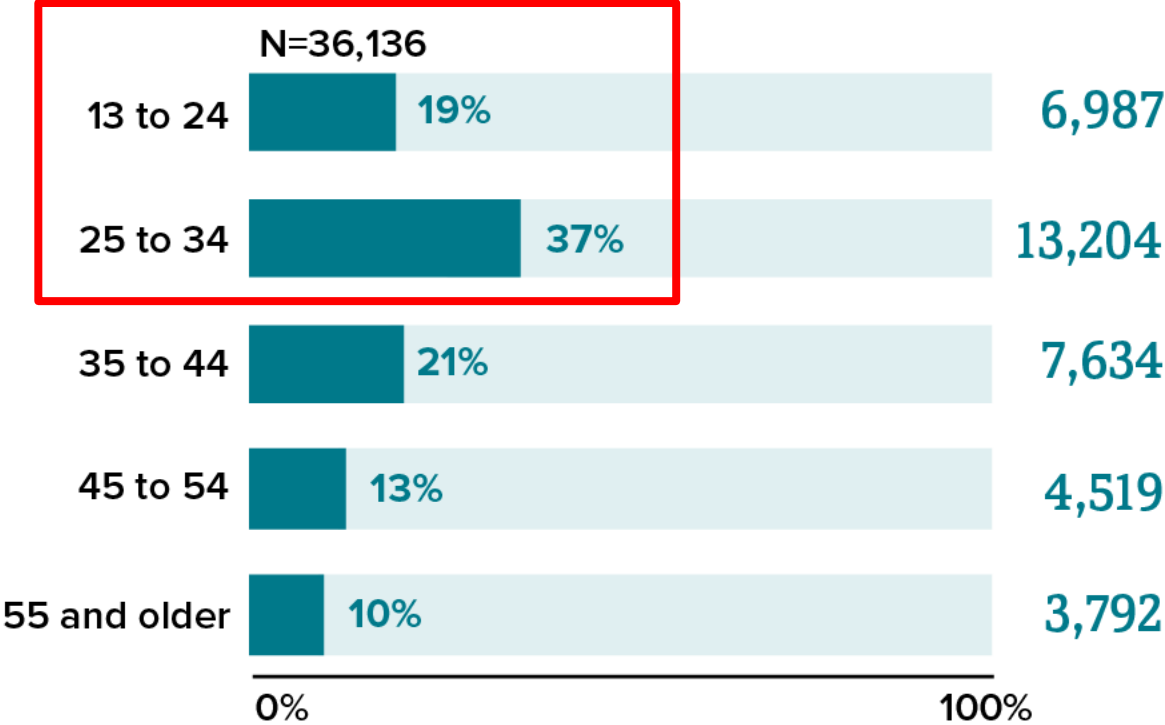
[‡] Hispanic/Latino people can be of any race.

1. CDC. Diagnoses of HIV infection in the United States and dependent areas, 2021. HIV Surveillance Report 2023;34.

2. CDC. HIV in the United States by Race and Ethnicity: HIV Diagnoses. <https://www.cdc.gov/hiv/group/raciaethnic/other-races/diagnoses.html>, updated June 26, 2023.

Differences in New HIV Diagnoses by Age

People aged 13 to 34 accounted for more than half (56%) of new HIV diagnoses in 2021.

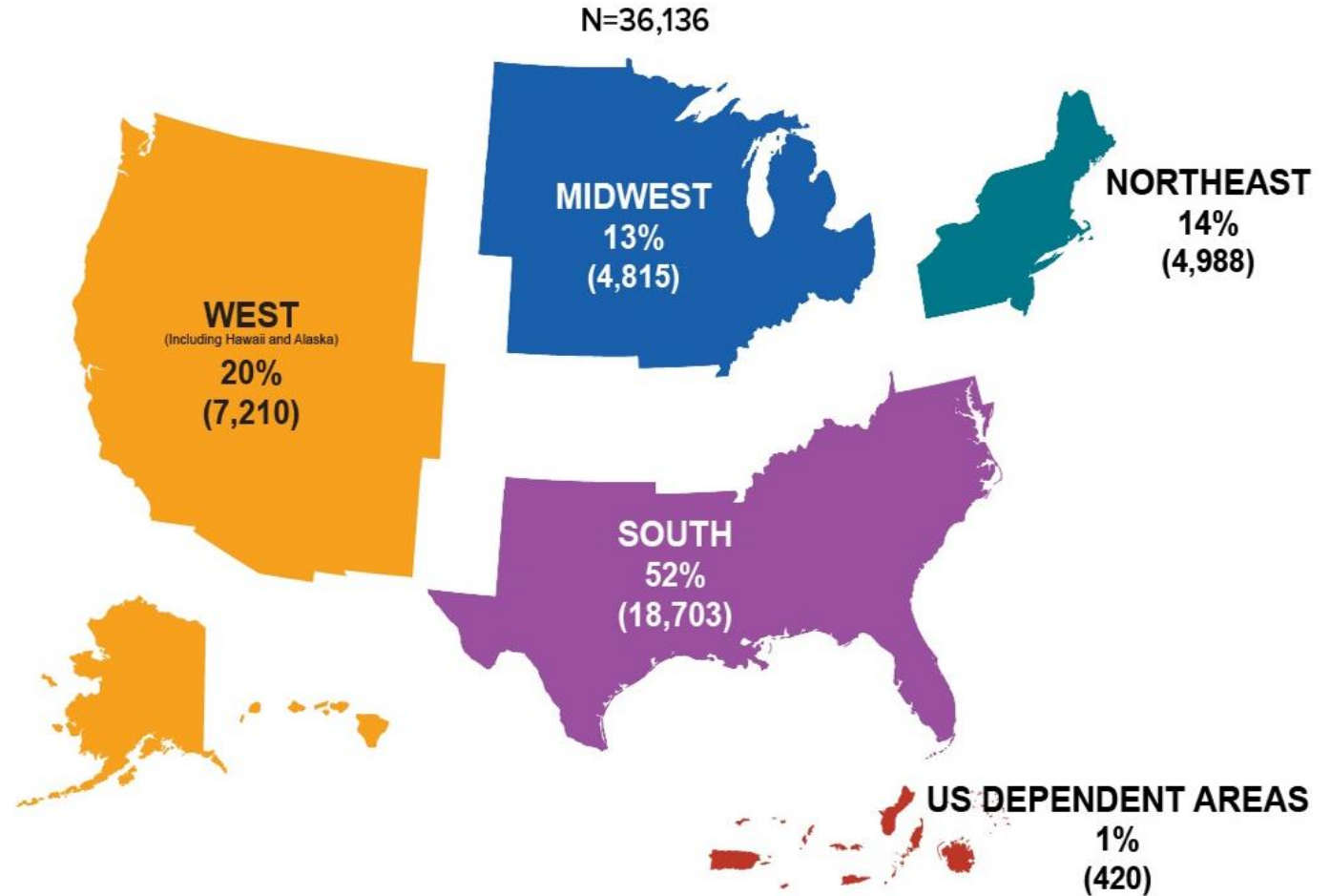


Source: CDC. Diagnoses of HIV Infection in the United States and Dependent Areas, 2021. *HIV Surveillance Report* 2023;34.



Differences in New HIV Diagnoses by Region of the U.S.*

The South accounted for more than half (52%) of new HIV diagnoses in 2021.



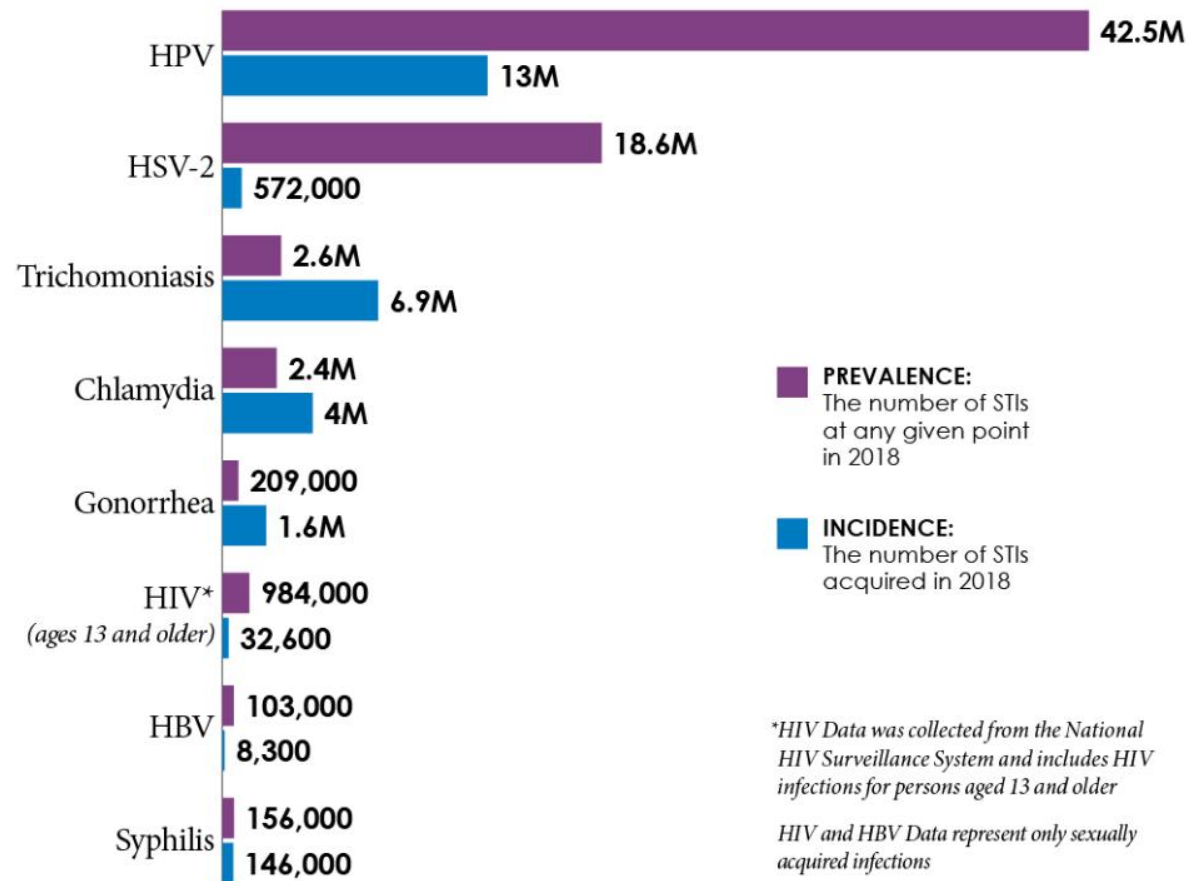
* Among people aged 13 and older.

Source: CDC. Diagnoses of HIV Infection in the United States and Dependent Areas, 2021. *HIV Surveillance Report* 2023;34.



LATEST CDC ESTIMATES REVEAL NEARLY 68 MILLION STIs IN THE U.S., AND MORE THAN 26 MILLION NEW INFECTIONS

Estimated number of new and existing sexually transmitted infections

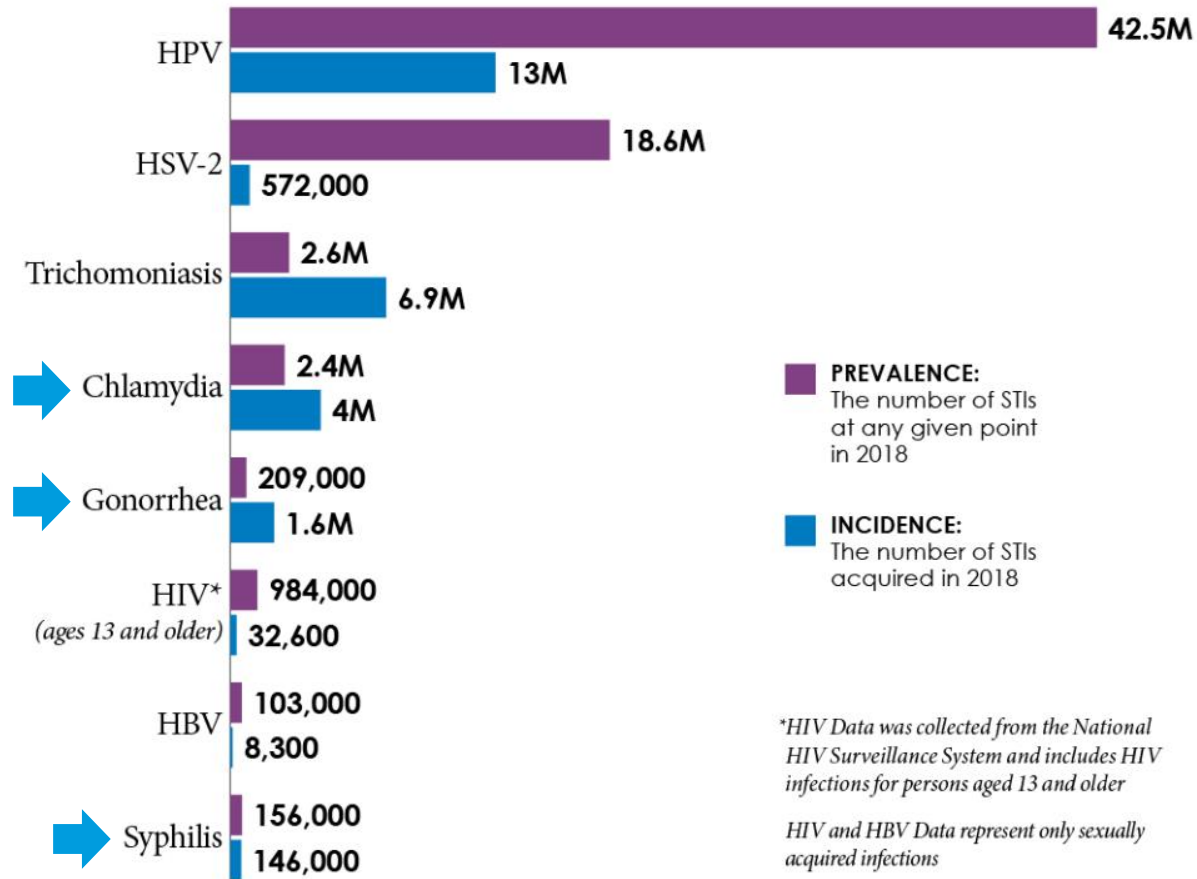


STIs in the U.S.

- 1 in 5 people have an STI
- 46% of STI infections occur between ages 15-24 years

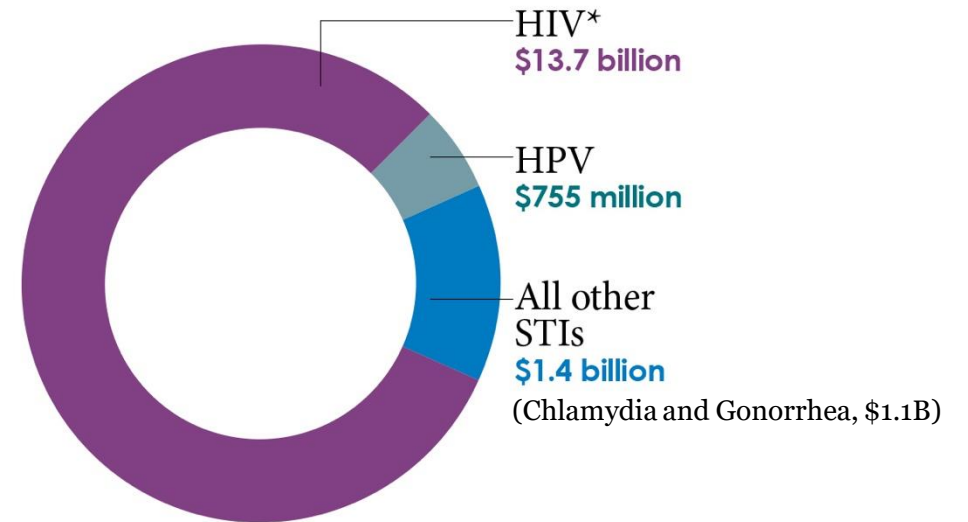
LATEST CDC ESTIMATES REVEAL NEARLY 68 MILLION STIs IN THE U.S., AND MORE THAN 26 MILLION NEW INFECTIONS

Estimated number of new and existing sexually transmitted infections



STIs in the U.S.

- 1 in 5 people have an STI
- 46% of STI infections occur between ages 15-24 years
- ~ \$16 billion in medical costs



**HIV Data represent only sexually acquired infections*

Cases of Sexually Transmitted Infections (STIs) are on the Rise

April 2023, most recent national data from CDC (2021)

≥ 2.5 MILLION STIs ¹

7% INCREASE OVER PRIOR YEAR²

Chlamydia (≤50%) 4% increase

Gonorrhea 5% increase

Syphilis 32% increase

Significant number of congenital (newborn) infections

NEW CASES OF STIS PARALLEL RISKS
OF NEW HIV INFECTIONS

1. CDC. U.S. STI Epidemic Showed No Signs of Slowing in 2021 – Cases Continued to Escalate. <https://www.cdc.gov/media/releases/2023/s0411-sti.html>, last reviewed May 25, 2023.

2. AAFP. [CDC Report Shows STI Cases Nearing Pre-Pandemic Levels](#). Apr 26, 2023.

Syphilis and HIV

GENITAL ULCERS CAN BLEED EASILY

There is a $\geq 10x$ increased risk of HIV transmission if a person has a genital ulcer

CDC HIV Goals

**Progress Toward Achieving,
But Don't Let Foot Off the Gas**

Ending
the
HIV
Epidemic

The time is now.

Investments to Ending HIV Epidemic (EHE) in the U.S. is “...vital to regain momentum, advance innovation, and achieve health equity.”

*“...four science-based strategies that can end the epidemic: **Diagnose, Treat, Prevent, and Respond.**”*



DIAGNOSE



TREAT



PREVENT

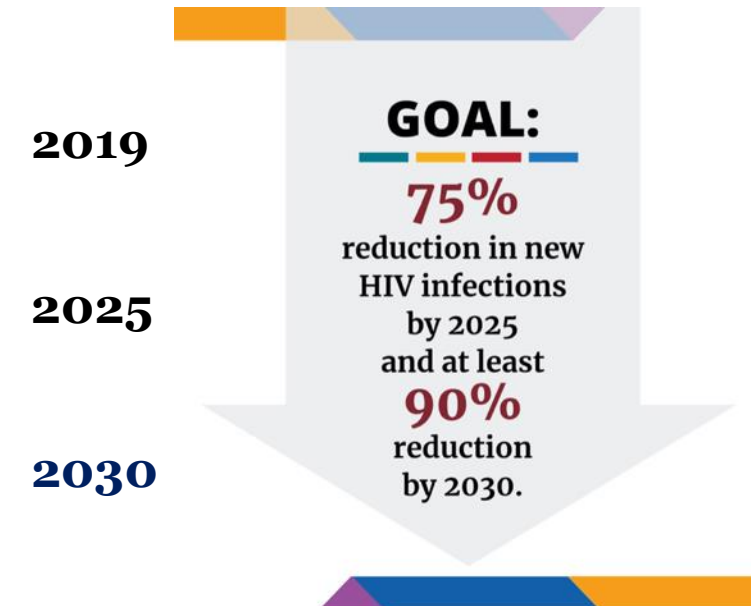


RESPOND

CDC's Ending the HIV Epidemic (EHE) in the U.S. 2019 → 2025 → 2030

The time is now. Ending the HIV Epidemic

- Diagnose** all people with HIV as early as possible.
- Treat** people with HIV rapidly and effectively to reach sustained viral suppression.
- Prevent** new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs).
- Respond** quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.

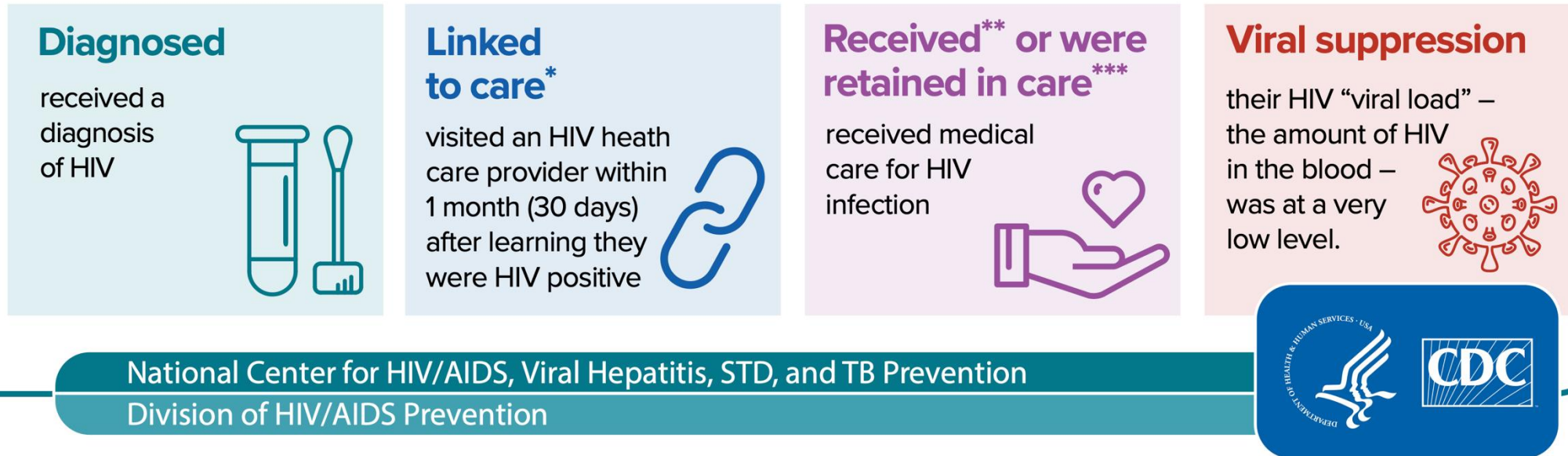


STILL SIGNIFICANT GAPS TO REACH GOAL, NEED ALL HEALTHCARE AND COMMUNITY CENTERS TO GET ON BOARD WITH CDC INITIATIVE

1. HIV.gov. What is 'Ending the HIV Epidemic: A Plan for America'? <https://www.hiv.gov/ending-hiv-epidemic/>, Sept 3, 2019.

HIV Care Continuum

Consists of several steps to achieve viral suppression



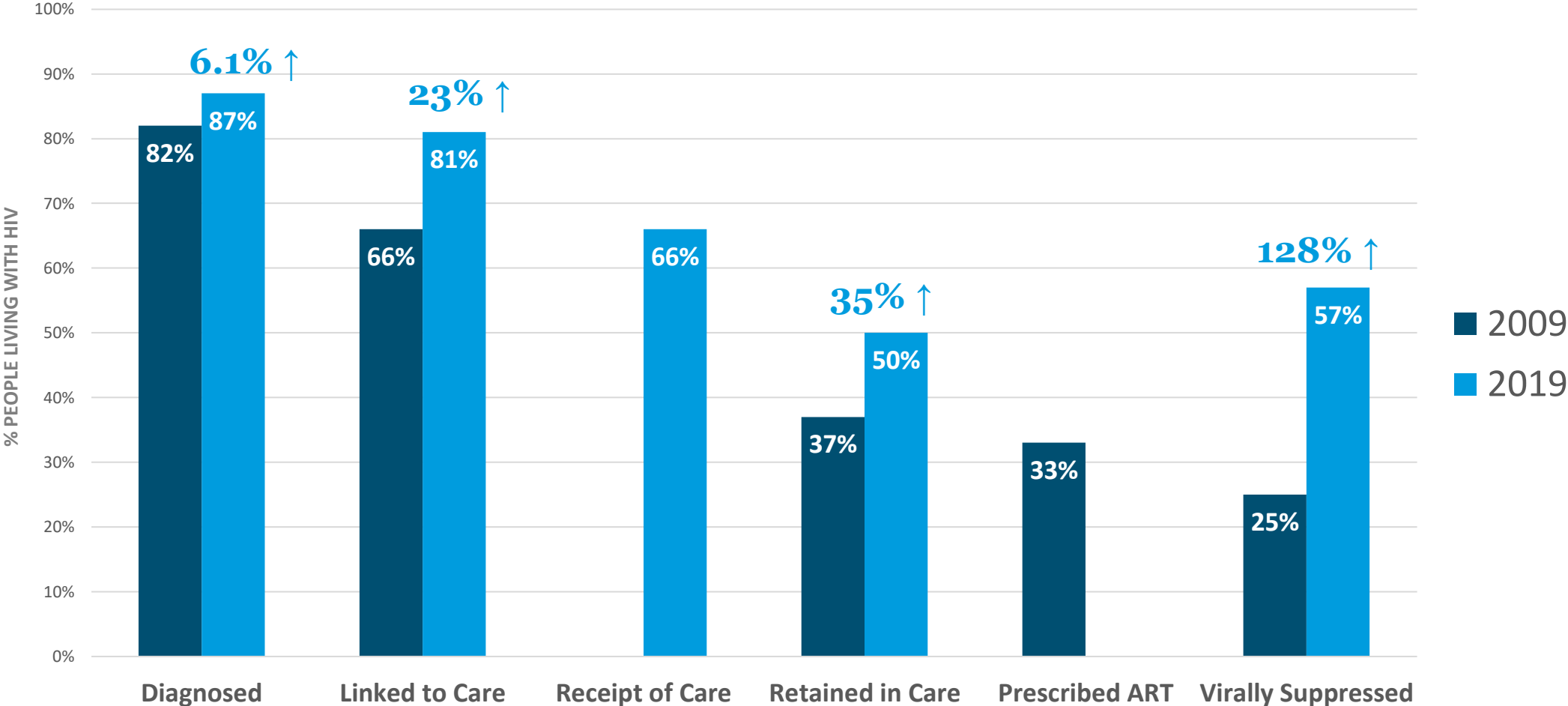
* Linked to care is calculated differently from other steps in the continuum, and cannot be directly compared to other steps. See Table 1 on page 5 for details.

** Receipt of medical care was defined as ≥ 1 test (CD4 or viral load [VL]) in 2016.

*** Retained in continuous medical care was defined as ≥ 2 tests (CD4 or VL) ≥ 3 months apart in 2016. Viral suppression was defined as < 200 copies/mL on the most recent VL test in 2016. See Table 1 on page 5 for details.

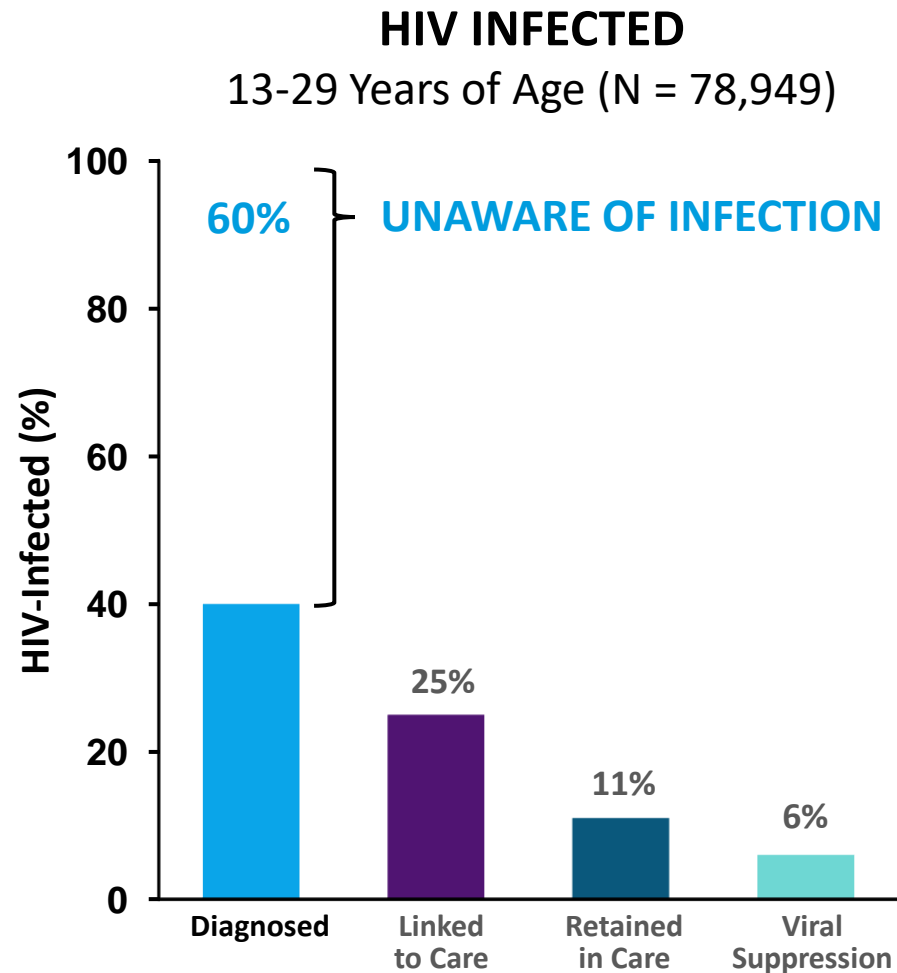
HIV Progress: From Diagnosis to Viral Suppression

2009¹ - 2019²

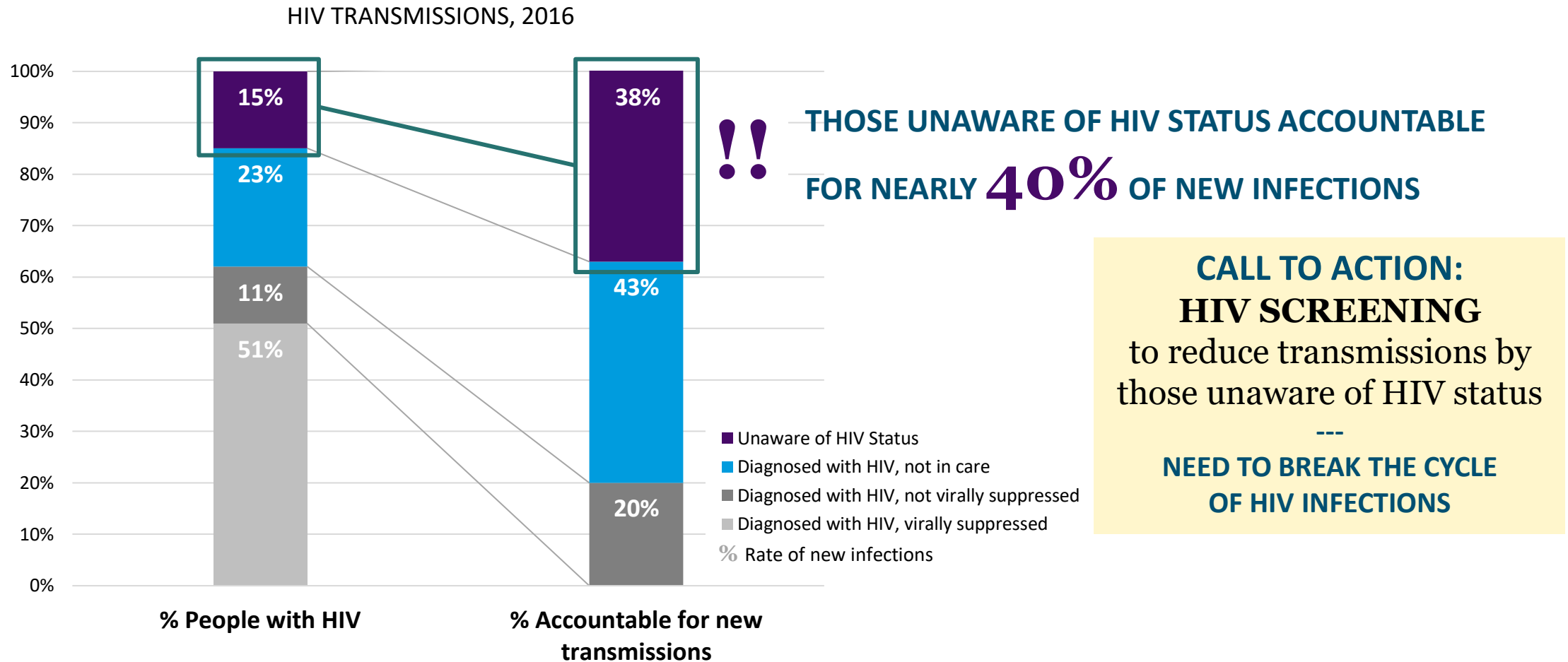


1. Hall HI, et al. Differences in human immunodeficiency virus care and treatment among subpopulations in the United States. JAMA Intern Med. 2013 Jul 22;173(14):1337-44.
2. HIV.gov. What Does the HIV Care Continuum Show? <https://www.hiv.gov/federal-response/policies-issues/hiv-aids-care-continuum>, updated Oct 28, 2022.

Unaware of HIV Status is Greatest Among Adolescents and Young Adults



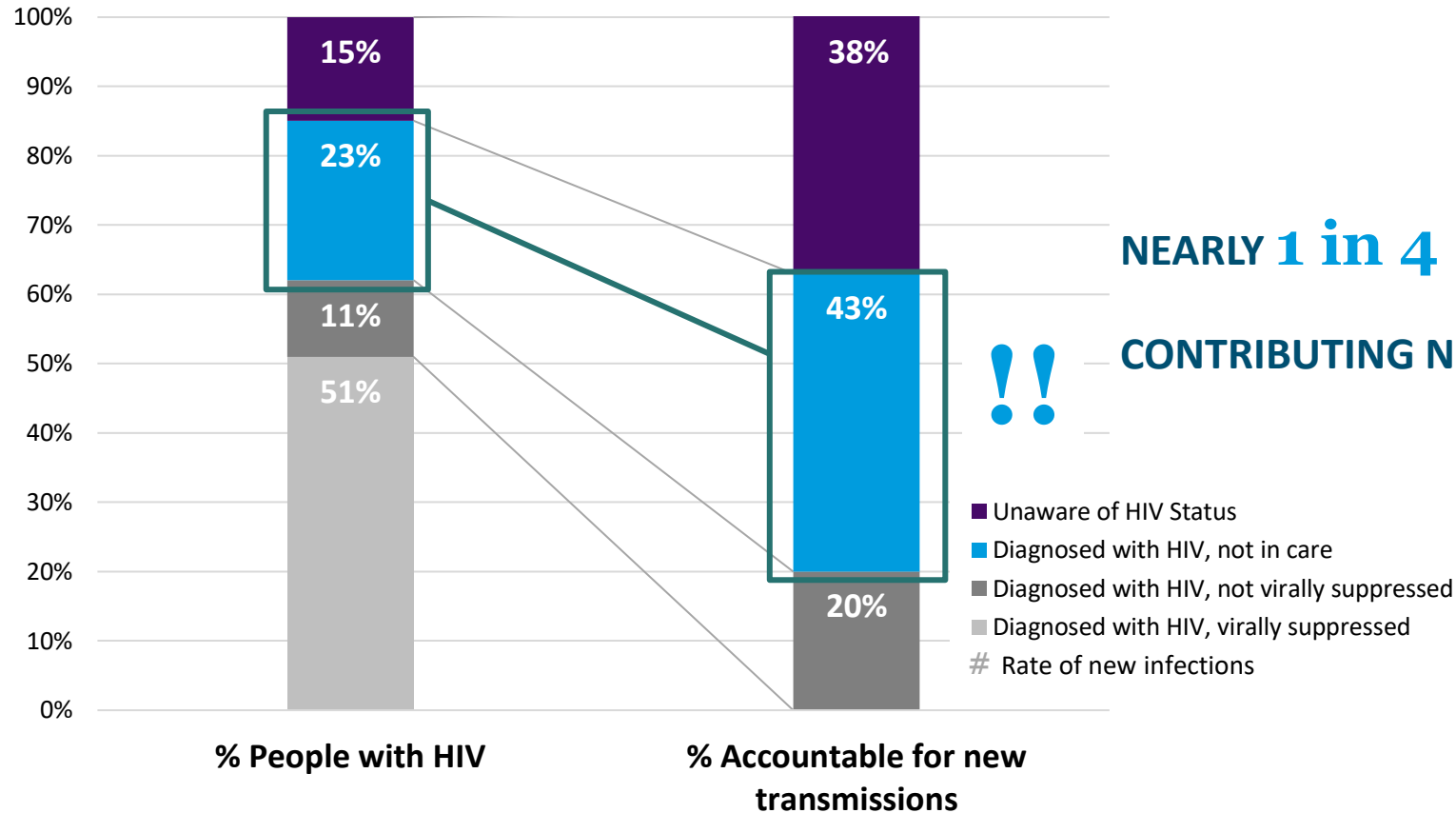
Alarming HIV Transmission Stats



1. CDC. [Vital Signs – Ending the HIV Epidemic- HIV Treatment is Prevention](#). Updated March 18, 2019
2. Dailey AF, et al. Vital Signs: Human Immunodeficiency Virus Testing and Diagnosis Delays — United States. MMWR Morb Mortal Wkly Rep 2017;66:1300–1306.

Alarming HIV Transmission Stats

HIV TRANSMISSIONS, 2016



NEARLY **1 in 4** PEOPLE WITH HIV ARE NOT IN CARE

CONTRIBUTING NEARLY **43%** OF NEW INFECTIONS



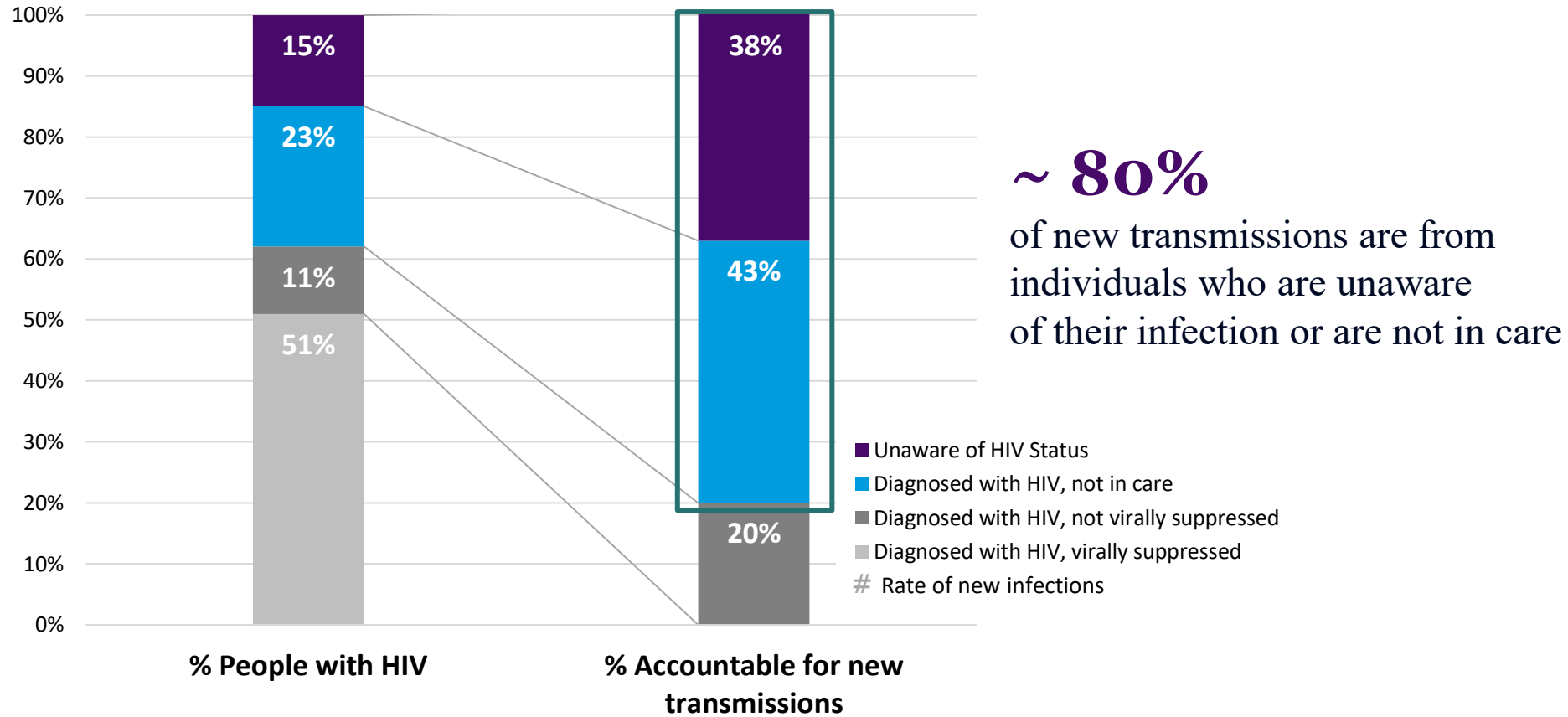
CALL TO ACTION:
LINK TO CARE
to reduce new infections

**NEED TO BREAK THE CYCLE
OF HIV INFECTIONS**

1. CDC. [Vital Signs – Ending the HIV Epidemic- HIV Treatment is Prevention](#). Updated March 18, 2019
2. Dailey AF, et al. Vital Signs: Human Immunodeficiency Virus Testing and Diagnosis Delays — United States. MMWR Morb Mortal Wkly Rep 2017;66:1300–1306.

Alarming HIV Transmission Stats

HIV TRANSMISSIONS, 2016



1. CDC. [Vital Signs – Ending the HIV Epidemic- HIV Treatment is Prevention](#). Updated March 18, 2019
2. Dailey AF, et al. Vital Signs: Human Immunodeficiency Virus Testing and Diagnosis Delays — United States. MMWR Morb Mortal Wkly Rep 2017;66:1300–1306.

Other Initiatives Focused on “Ending the Epidemic”

HIV “CURES”

- Only a few confirmed to date
 - Bone marrow transplant, cord blood stem cells^{1,2}

HIV VACCINES

- Continued to be studied ^{3,4}
- No major success / One recent failure (Mosaico Trial⁵)

1. Hsu J, et al; International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT) P1107 Team. HIV-1 remission and possible cure in a woman after haplo-cord blood transplant. Cell. 2023 Mar 16;186(6):1115-1126.e8.
2. Jensen, BE.O., et al. In-depth virological and immunological characterization of HIV-1 cure after CCR5Δ32/Δ32 allogeneic hematopoietic stem cell transplantation. Nat Med 29, 583–587 (2023)
3. Phase 1 Study to Evaluate the Safety and Immunogenicity of eOD-GT8 60mer mRNA vaccine and Core-g28v2 60mer mRNA Vaccine - recently launched at 4 sites in the U.S. ClinicalTrials.gov Identifier: NCT05001373.
4. Clinical Trial to Evaluate Safety and Immunogenicity of BG505 and BG505 MD39.3 gp151 CD4KO HIV Trimer mRNA Vaccines in Healthy, HIV-uninfected Adults. ClinicalTrials.gov Identifier: NCT05217641.
5. NIH Press release, January 18, 2023. Experimental HIV vaccine regimen safe but ineffective, study finds. <https://www.nih.gov/news-events/news-releases/experimental-hiv-vaccine-regimen-safe-ineffective-study-finds>

TREATING HIV IN 2023



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

HIV Treatment as Prevention

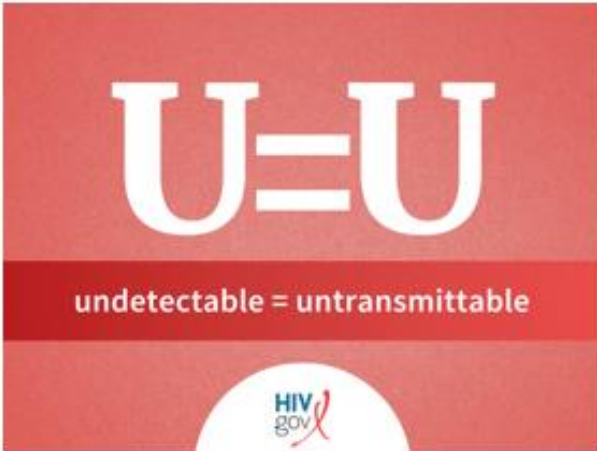


U=U **UNDETECTABLE = UNTRANSMITTABLE**

HIV medicine can help you get and keep an **undetectable viral load**.

This means you can stay healthy and **will not transmit HIV** to HIV-negative partners through sex.

OASH Office of Infectious Disease and HIV/AIDS Policy **HIV.gov**



U=U

undetectable = untransmittable

HIV.gov



Must take ART to achieve and maintain undetectable viral load

With an undetectable HIV count, there is no risk of transmitting HIV to sexual partner

The Remarkable Evolution of Antiretroviral Therapy (ART)



Photo: HRSA, Ryan White HIV/AIDS Program.

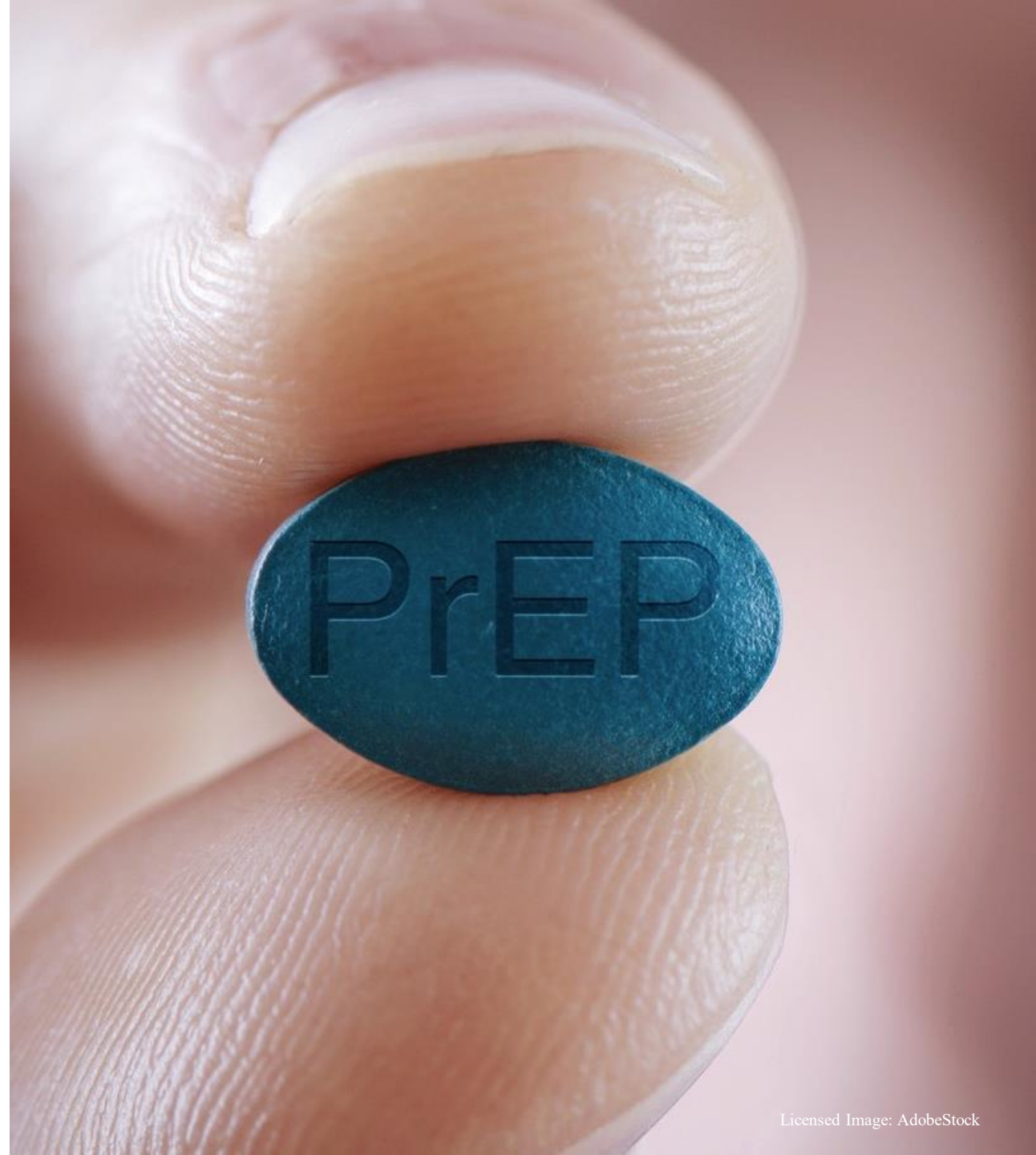
“AIDS Cocktail”



Photos: Licensed,
AdobeStock

**Single-tablet regimen
(STR)**

Pre-Exposure Prophylaxis (PrEP) for HIV Prevention



Efficacy and Support for PrEP is Well-Established

Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial



Sheena McCormack*, David T Dunn*, Monica Desai, David I Dolling, Mitzy Gafos, Richard Gilson, Ann K Sullivan, Amanda Clarke, Iain Reeves, Gabriel Schembri, Nicola Mackie, Christine Bowman, Charles J Lacey, Vanessa Apea, Michael Brady, Julie Fox, Stephen Taylor, Simone Antonucci, Saye H Khoo, James Rooney, Anthony Nardone, Martin Fisher, Alan McOwan, Andrew N Phillips, Anne M Johnson, Brian Gazzard, Owen N Gill



1

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



Kenneth H Mayer, Jean-Michel Molina, Melanie A Thompson, Peter L Anderson, Karam C Mounzer, Joss J De Wet, Edwin DeJesus, Heiko Jessen, Robert M Grant, Peter J Ruane, Pamela Wong, Ramin Ebrahimi, Lijie Zhong, Anita Mathias, Christian Callebaut, Sean E Collins, Moupali Das, Scott McCallister, Diana M Brainard, Cynthia Brinson, Amanda Clarke, Pep Coll, Frank A Post, C Bradley Hare

3

The NEW ENGLAND JOURNAL of MEDICINE

2

ORIGINAL ARTICLE

On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-1 Infection

J.-M. Molina, C. Capitant, B. Spire, G. Pialoux, L. Cotte, I. Charreau, C. Tremblay, J.-M. Le Gall, E. Cua, A. Pasquet, F. Raffi, C. Pintado, C. Chidiac, J. Chas, P. Charbonneau, C. Delaugerre, M. Suzan-Monti, B. Loze, J. Fonsart, G. Peytavin, A. Cheret, J. Timsit, G. Girard, N. Lorente, M. Préau, J.F. Rooney, M.A. Wainberg, D. Thompson, W. Rozenbaum, V. Doré, L. Marchand, M.-C. Simon, N. Etien, J.-P. Aboulker, L. Meyer, and J.-F. Delfraissy, for the ANRS IPERGAY Study Group*

1. McCormack S, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial. *Lancet*. 2016 Jan 2;387(10013):53-60. doi: 10.1016/S0140-6736(15)00056-2. Epub 2015 Sep 9.
2. Molina J-M, et al. On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-1 Infection. *N Engl J Med* 2015; 373:2237-2246.
3. Mayer KH, 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 Jul 25;396(10246):239-254.

PrEP Adherence Important to Reinforce in Young MSM

- 48-Week Assessment (Doses/Week)

- A. Self-reported adherence
- B. Wisepill bottle opening monitoring
- C. Hair concentrations
- D. Dried blood spot testing

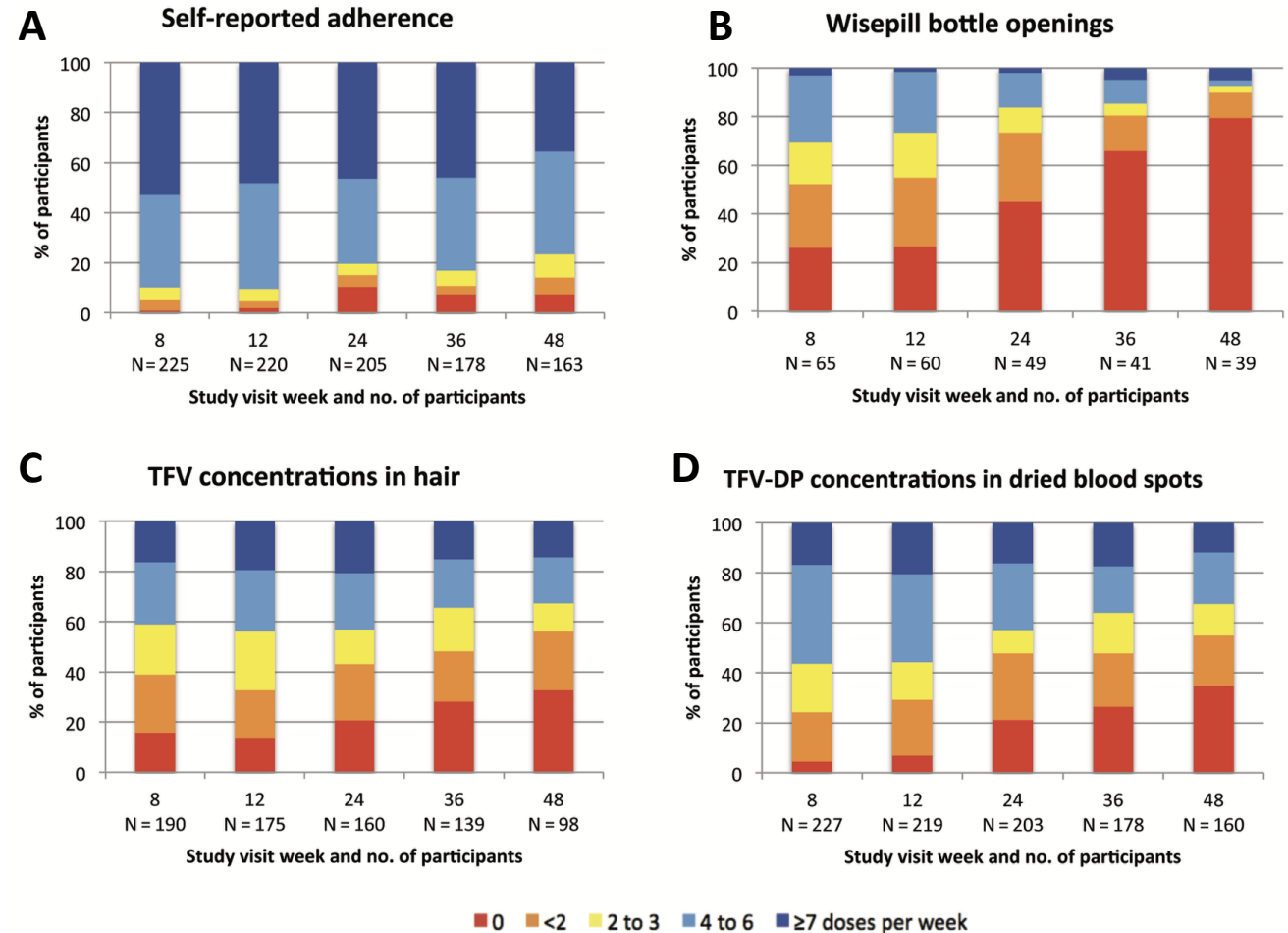
- Self-Reporting (“A”)

- overestimated adherence

- Measures/Tests (“B-D”)

- PrEP adherence waned over time
- PrEP use inadequate by 48 weeks

”...strategies to bolster adherence such as text message reminders, financial incentives, and peer support will be needed to ensure that young people on PrEP consistently achieve adequate levels of protection from HIV.”



TFV, tenofovir; TFV-DP, tenofovir diphosphate.

Koss CA, Hosek SG, Pachetti P, et al. Comparison of measures of adherence to HIV pre-exposure prophylaxis among adolescent and young men who have sex with men in the U.S.. CID. 2018; 66(2): 213-9.

Include STI Screening with PrEP Testing



1. CDC. Incidence of Gonorrhea and Chlamydia Following Human Immunodeficiency Virus Preexposure Prophylaxis Among Men Who Have Sex With Men: A Modeling Study. <https://www.cdc.gov/nchstp/neema/successstories/sti-and-prep-modeling.html#:~:text=As%20part%20of%20clinical%20follow,STI%20screening%20after%20PrEP%20initiation> updated Mar 30, 2023.
2. Jenness SM, Weiss KM, Goodreau SM, et al. Incidence of Gonorrhea and Chlamydia Following Human Immunodeficiency Virus Preexposure Prophylaxis Among Men Who Have Sex With Men: A Modeling Study. Clin Infect Dis. 2017 Sep 1;65(5):712-718.

HIV: When Should You Be SCREENING and Testing



Diagnose all people with HIV as early as possible.

Noted Concerns Related to Screening



Screening / Testing

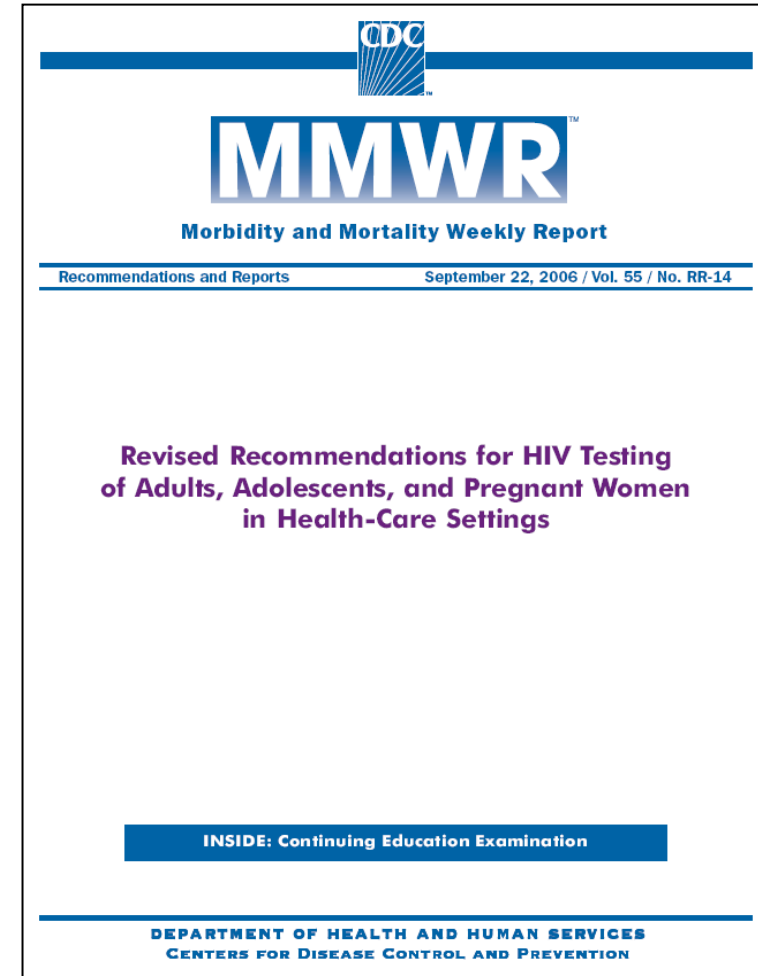
- Access remains inadequate
- Median HIV diagnosis delay - **3 years**¹
- **2/3** individuals with HIV risk factors **had not been tested** but had been seen by a **healthcare provider**¹

Latest Guidance for HIV Testing

- Effective therapies and preventative treatments available
- Many HIV-infected persons access health care but are not tested for HIV until symptomatic
- Knowledge of HIV infection leads to substantial reductions in high-risk sexual behavior
- Increased experience with HIV testing, including rapid tests

NEW GUIDANCE:

- Not based on patient risk
- Opt-out testing
- No separate consent for HIV
- No prevention counseling required
- Repeat HIV testing at discretion of provider (based on patient risk)



Who Should be Tested for HIV ?



Image source, CDC

Who Should be Tested for HIV Infection?

CDC RECOMMENDS SCREENING ALL PATIENTS AGED 13 - 64 ¹

Screening should be:

- Routine, voluntary; at least once as part of routine health check-up
- Irrespective of individual risk
- Discontinued if yield is < 1/1000

..... **ADDITIONAL HIV TESTING CONSIDERATIONS BY RISK GROUPS**

Asymptomatic sexually active men who have sex with men (MSM) ^{1,2}

At least annually; consider every 3 or 6 months in those with risk factors

Ages 13-29 ³

Routine check-up

People who inject drugs (PWID) ¹

At least annually

Sex workers ⁴

Test regularly

Pregnant ¹

Routine prenatal care; and 3rd trimester in jurisdictions with elevated rates of HIV in pregnant women

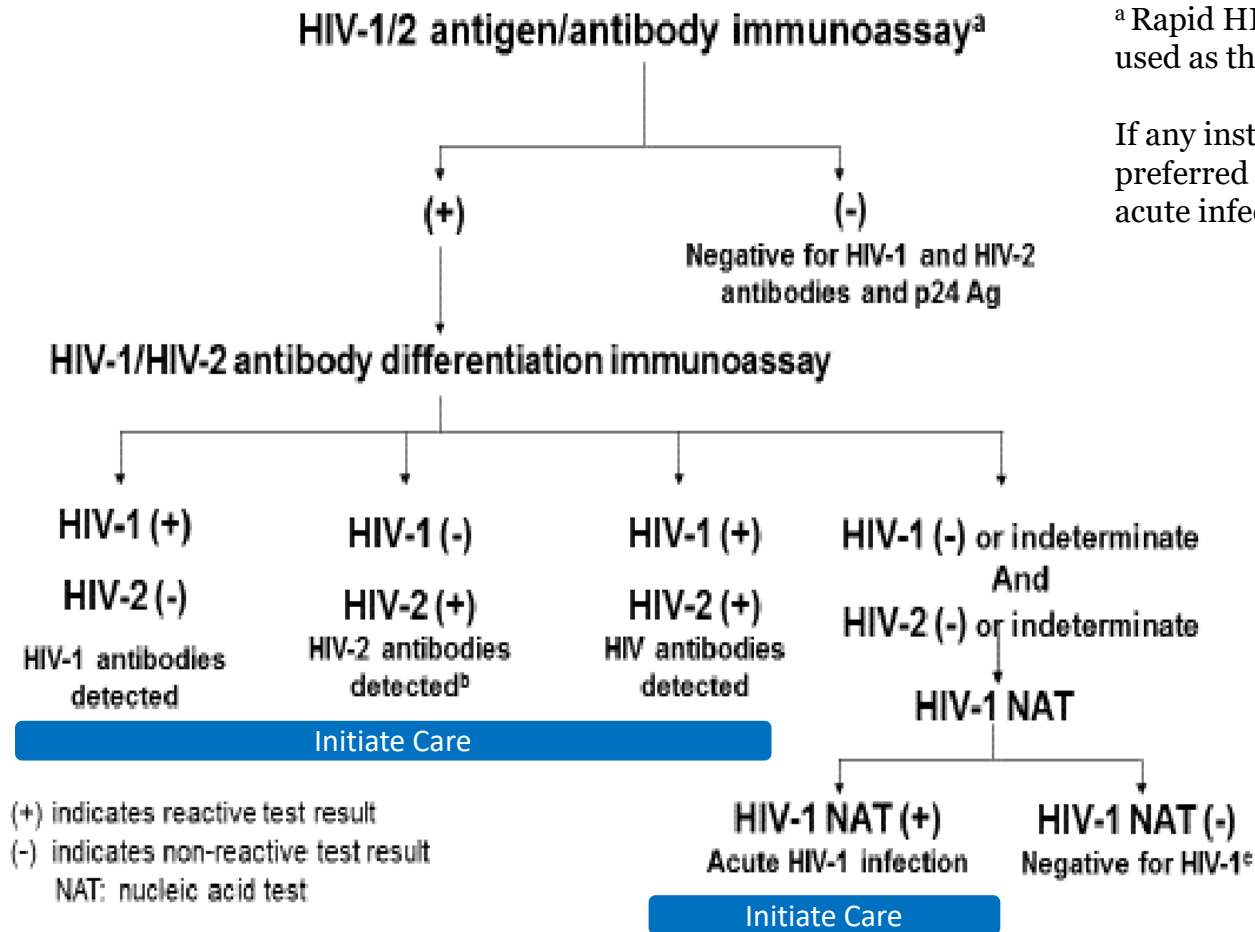
On Preexposure prophylaxis (PrEP) ⁵

At least every 3 months

Clinical Indications for HIV Testing

- Unexplained weight loss
- Recurrent infections (pneumonia, skin and soft tissue)
- Persistent fevers
- Neurological symptoms
- Unusual or recurrent skin rashes

Recommended HIV Lab Testing Algorithm: Serum/Plasma ¹

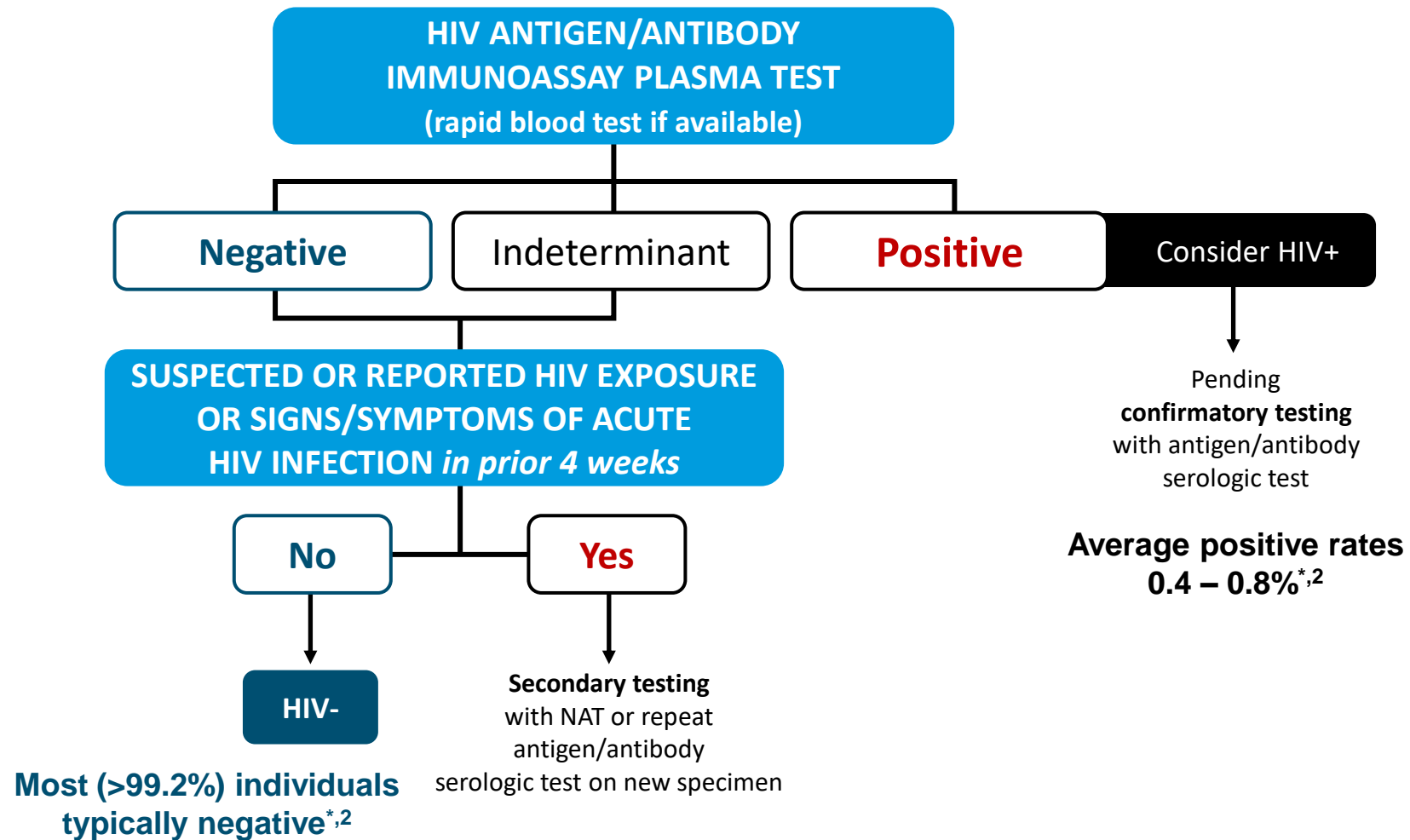


^a Rapid HIV-1/HIV-2 antigen/antibody immunoassay can be used as the initial assay.

If any instrumented antigen/antibody test is available, it is preferred due to its superior sensitivity for detecting HIV during acute infection (1,2).

Updated: January, 2018

Current Algorithm: HIV Testing before Initiation of PrEP¹



*Based on typical positivity rates in CDC-funded HIV Testing centers.

1. CDC. US Public Health Service: PrEP for the prevention of HIV infection in the U.S. — 2021 Update: a Clinical Practice Guideline. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Adapted Fig. 4a: Partial algorithm of initial testing, only.
2. CDC. CDC-Funded HIV Testing in the U.S., Puerto Rico, USVI 2020 Annual HIV Testing Report. <https://www.cdc.gov/hiv/pdf/library/reports/cdc-hiv-annual-hiv-testing-report-2020.pdf>, updated Sept 15, 2021.

CDC Screening Guidelines: No Consent or Counseling Required ¹

PRIOR CDC REQUIREMENTS

“**OPT-IN**” = CONSENT,
PREVENTION COUNSELING

Patients **ASKED** if they want to be tested
and provide prevention counseling.
DOCUMENTATION required ¹

This policy
missed identifying individuals
positive for HIV whose risk factors
were less obvious ¹

CURRENT CDC RECOMMENDATION

“**OPT-OUT**” = NO CONSENT,
NO HIV COUNSELING

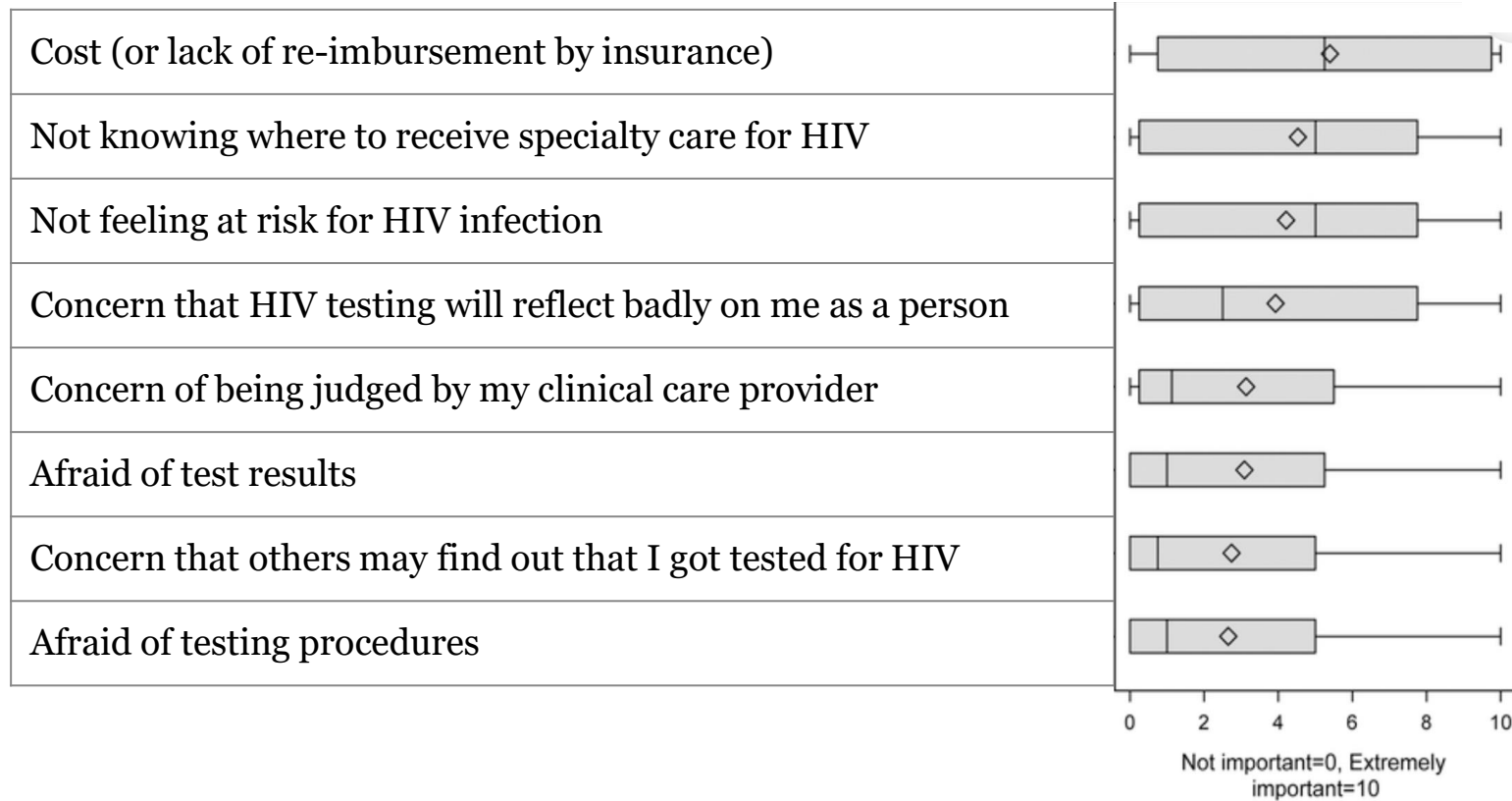
Patients **INFORMED** they are being tested,
now considered part of routine preventive
care during the visit unless they object. ¹

73.4%
increase in HIV testing
after OPT-OUT HIV screening
was implemented ²

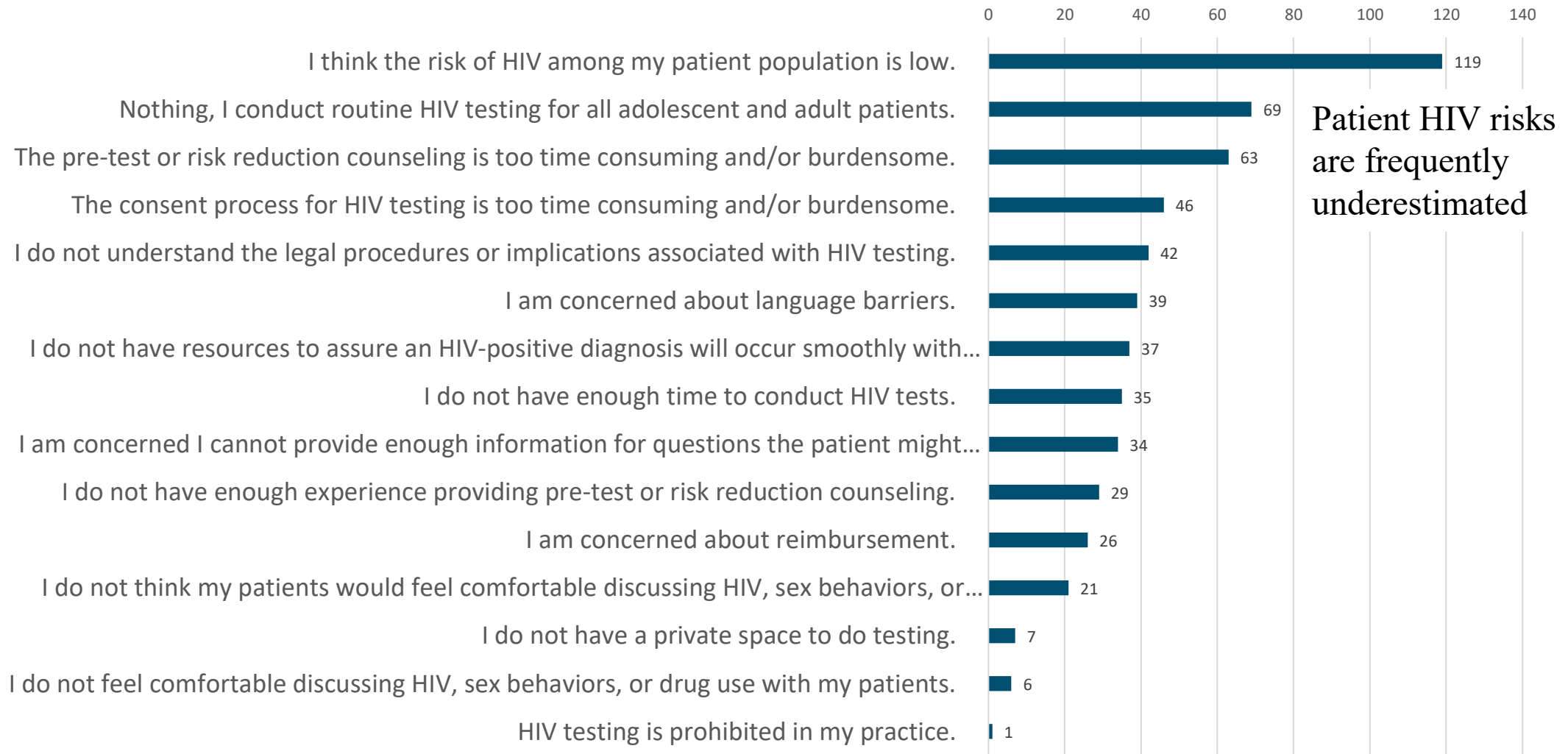
1. Branson BM, Handsfield HH, Lampe MA, et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *MMWR Recomm Rep* 2006;55(RR-14):1-17; quiz CE1-4.

2. Montoy JC, Dow WH, Kaplan BC. Patient choice in opt-in, active choice, and opt-out HIV screening: randomized clinical trial. *BMJ* 2016;532:h6895.

Patient Specified Barriers to HIV Testing



Provider Specified Barriers to HIV Testing



Screening Needs to be a Higher Priority

>2/3

of patients at increased risk of HIV were not offered HIV testing during office visit ¹

Study that diagnosed MSM and PWID with HIV,

~50% reported having a healthcare encounter in prior year without being offered HIV testing ²

CALL TO ACTION:

SCREEN

during health check-ups and rely on opt-out vs. opt-in to improve test acceptance rates

Settings of frequently missed opportunities for HIV diagnosis:

- ED and Specialty clinics ³
- Dental offices ⁴
- Pharmacies ⁵

1. Dailey AF, et al. Vital Signs: Human Immunodeficiency Virus Testing and Diagnosis Delays — United States. MMWR Morb Mortal Wkly Rep 2017;66:1300–1306.
2. Wejnert C, Prejean J, Hoots B, et al. Prevalence of missed opportunities for HIV testing among persons unaware of their infection. JAMA. 26 2018(June 26);319(24):2555-2557.)
3. DeRose J, Zucker J, Cennimo D, et al. Missed testing opportunities for HIV screening and early diagnosis in an urban tertiary care center. AIDS Res Treat. 2017:5708620.
4. Parish CL, Siegel K, Liguori T, et al. HIV testing in the dental setting: Perspectives and practices of experienced dental professionals. AIDS Care. 2018(March);30(3):347-352.
5. Weidle PJ, Lecher S, Botts LW, et al. HIV testing in community pharmacies and retail clinics: a model to expand access to screening for HIV infection. J Am Pharm Assoc (2003). 2014(Sept-Oct);54(5):486-492.

Screening Needs to be a Higher Priority

>2/3

of patients at increased risk of HIV were not offered HIV testing during office visit ¹

Study that diagnosed MSM and PWID with HIV, **~50%** reported having a healthcare encounter in prior year without being offered HIV testing ²

1/3

tested individuals do not return for test results ⁶

CALL TO ACTION:

SCREEN

during health check-ups and rely on opt-out vs. opt-in to improve test acceptance rates

Settings of frequently missed opportunities for HIV diagnosis:

- ED and Specialty clinics ³
- Dental offices ⁴
- Pharmacies ⁵

CALL TO ACTION:

SCREEN WITH RAPID TESTS

if individual unlikely to return for results, especially in those with risk factors

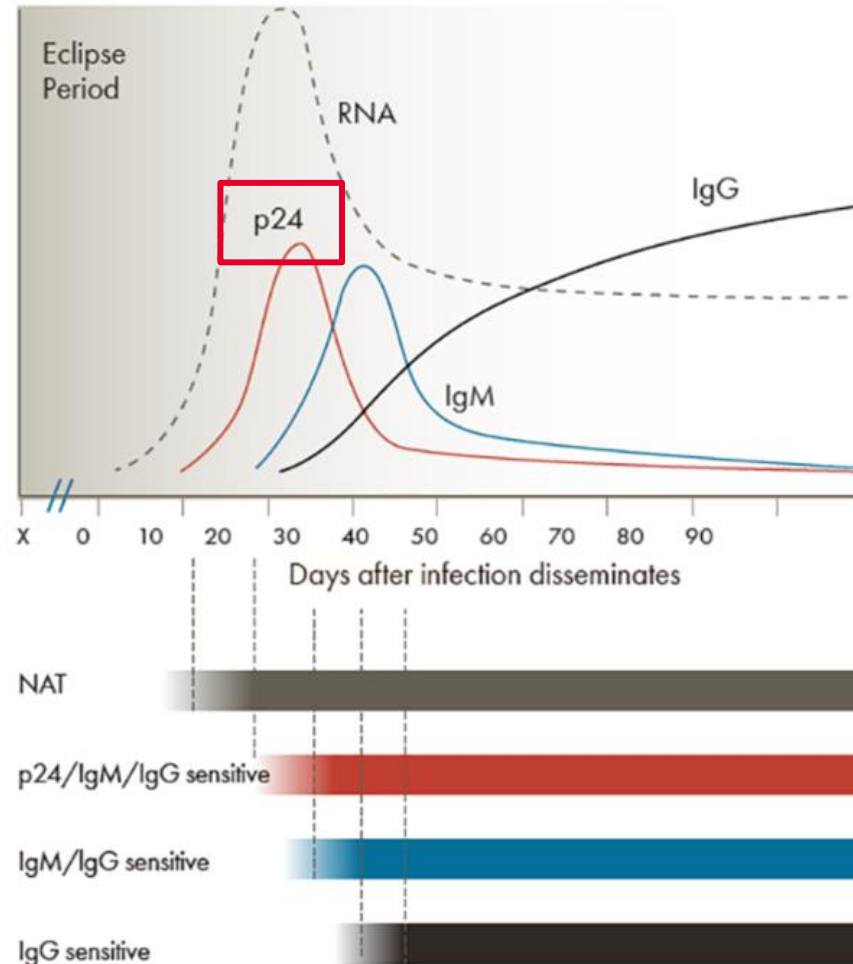
1. Dailey AF, et al. Vital Signs: Human Immunodeficiency Virus Testing and Diagnosis Delays — United States. MMWR Morb Mortal Wkly Rep 2017;66:1300–1306.
2. Wejnert C, Prejean J, Hoots B, et al. Prevalence of missed opportunities for HIV testing among persons unaware of their infection. JAMA. 26 2018(June 26);319(24):2555-2557.)
3. DeRose J, Zucker J, Cennimo D, et al. Missed testing opportunities for HIV screening and early diagnosis in an urban tertiary care center. AIDS Res Treat. 2017:5708620.
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6. Greenwald JL, Burstein GR, Pincus J, Branson B. A rapid review of rapid HIV antibody tests. Curr Infect Dis Rep. 2006 Mar;8(2):125-31.

HOW TO TEST FOR HIV

The background features a blue-to-purple gradient. Several stylized virus particles are scattered across the scene, rendered in a light, semi-transparent white or light blue. These particles have a spherical core with various protrusions and spikes extending from their surfaces, resembling the structure of a coronavirus or a similar enveloped virus. The overall aesthetic is clean and scientific.

Early HIV Detection Depends on the Test

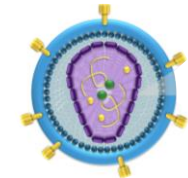
Acutely infected individuals
up to **26x**
more infectious than
chronically infected.³



< 2 weeks

people may test negative or
indeterminate post-infection¹

p24 antigen

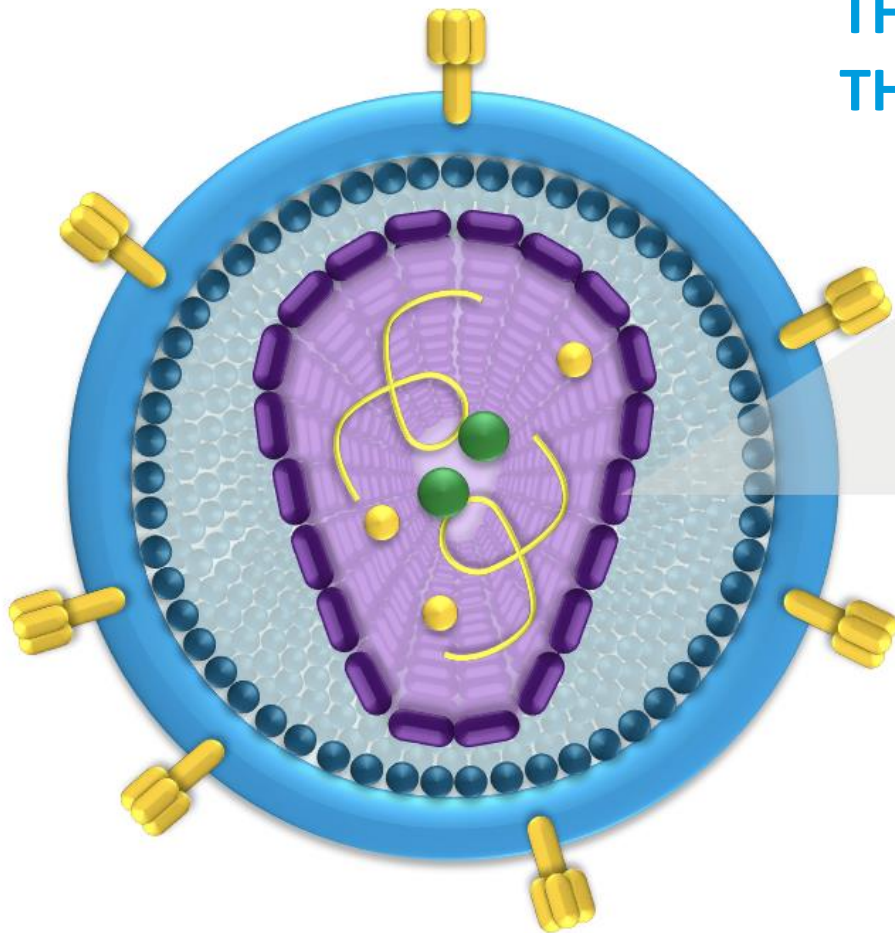


enhances detection during acute phase
of infection to help reduce of risk
missing recently infected individuals /
unrecognized acute infections.^{1,2}

1. CDC. Which HIV Tests Should I Use? <https://www.cdc.gov/hiv/clinicians/screening/tests.html>, updated June 1, 2023. Adapted, removed Western blot.
2. Tang S, Zhao J, Wang A, et al. Characterization of immune responses to capsid protein p24 of human immunodeficiency virus type 1 and implications for detection. *Clin Vaccine Immunol.* 2010 Aug;17(8):1244-51.
3. Miller WC, Rosenberg NE, Rutstein SE, Powers KA. Role of acute and early HIV infection in the sexual transmission of HIV. *Curr Opin HIV AIDS.* 2010;5(4):277-282.

HIV-1 Capsid Protein (p24 Antigen) for Early HIV Detection

**THE HIV VIRAL CORE PRIMARILY CONSISTS OF
THE P24 VIRAL PROTEIN ANTIGEN**



p24 antigens are an essential marker to detect acute HIV infections.

Including p24 antigen detection in initial testing helps diagnose individuals with an acute infection up to 30 days earlier than antibody-only tests.

Early detection reduces the risk of missing highly infectious individuals.

Multiple Rapid HIV Tests

TESTS VARY VARIOUS FACTORS, INCLUDING CLIA WAIVED SAMPLE TYPE AND DETECTED PROTEINS (ANTIBODY ONLY OR ANTIBODY/ANTIGEN)



**Determine™ HIV-1/2
AG/AB Combo**



**OraQuick ADVANCE® Rapid HIV-1/2
Antibody Test**



**SURE CHECK®
HIV 1/2 Assay**



**HIV 1/2 STAT-PAK® Infectious Disease
Immunoassay Rapid Test Kit**

Clinic Advantages: Point-of-Care HIV Testing



Alternate test method

- When need rapid test result
- Automated platforms not available on site

Ease of use for tester and recipient

- Fingerstick whole blood or oral fluid¹, although oral fluid is less sensitive²
 - Eliminates need for venipuncture, processing, handling, storage of blood
- Allows for simple “walk-in” encounter
- Reduces follow-up of lab-based test results
- Reduces follow-up with the individual (notified while on-site)

Often fewer issues with reimbursement

- Many sites offer free testing

“ Absence of easy to use, rapid tests that reliably detect AHI may represent the greatest limitation, **as loss to follow up remains a major concern in these settings.**”³

AHI, acute HIV infection

1. Hurt CB, Nelson JAE, Hightow-Weidman LB, Miller WC. Selecting an HIV Test: A Narrative Review for Clinicians and Researchers. *Sex Transm Dis.* 2017;44(12):739-746.
2. CDC. US Public Health Service: PrEP for the prevention of HIV infection in the U.S. —2017 Update: a clinical practice guideline. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>. Published March 2018.
3. Hoenigl M, Little SJ. How can we detect HIV during the acute or primary stage of infection?. *Expert Rev Mol Diagn.* 2016;16(10):1049-1051.

Patient Advantages: Point-of-Care HIV Testing

Rapid results in ≤ 20 minutes



- Greatly increases likelihood patient receives result¹
- Permit an all-in-one encounter¹
 - If test (preliminary) positive, can be immediately linked to care and possibly started on ART
 - Increases continuum of care (linkage to care) and support
 - Reduces delays of initiating ART
 - If HIV test negative, increases ability to educate on prevention/PrEP discussion
 - Better patient experience

Recommendations to Increase Routine HIV Screening

RECOMMENDATION

SOCIOECOLOGICAL

Emphasize the public health and individual benefits of knowing one's HIV status

Public policy and **interpersonal**

Provide enhanced reimbursement for HIV screening

Public policy

Develop quality indicators for HIV screening for use in primary care

Public policy

Ensure compatibility between state and federal guidelines

Public policy and **institutional**

Enhance systems of referrals between primary and HIV specialty care (including behavioral health services)

Community

Invest in campaigns to address HIV-related stigma

Community and institutional

Integrate HIV screening into clinical workflows

Institutional and intrapersonal

Educate patients and providers on the importance of routine HIV screening

Institutional, interpersonal, and interpersonal

SUMMARY

The background features a vertical gradient from dark purple on the left to bright blue on the right. Scattered across the image are several faint, stylized representations of virus particles, some with surface proteins and spikes, rendered in light blue and white tones.

Summary

- 1 in 8 with HIV in the U.S. are unaware of their status and account for 40% of new HIV transmissions
- 2/3 persons with risks for HIV were not tested in the prior 12 months but had been seen by a healthcare provider
 - Median HIV diagnosis delay: 3 years
- Current data are a reminder that ALL healthcare providers should recommend HIV testing
 - Not just Primary Care: Ob/Gyn, Neurology, Oncology, Dermatology, ENT, Surgery, ER
 - All persons 13 to 65 years of age should be screened at least once for HIV, regardless of risk
 - All pre-natal patients should be screened at baseline (and again in 3rd TM if at-risk)
 - Patients with risk factors for HIV should ideally be tested every 3 - 6 months or at least annually
- Rapid testing provides opportunity for a single visit test and educate to increase awareness to HIV infections and to initiate treatments or other preventative measures

Appendix: Additional Citations

Screening Guidelines, Slide 36

1. Branson BM, Handsfield HH, Lampe MA, et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. MMWR Recomm Rep 2006;55(RR-14):1-17; quiz CE1-4.
2. CDC. Sexually Transmitted Infections Treatment Guidelines, 2021. Men Who Have Sex with Men (MSM). <https://www.cdc.gov/std/treatment-guidelines/msm.htm>, updated July 22, 2021.
3. Zanoni BC, Mayer KH. The Adolescent and Young Adult HIV Cascade of Care in the United States: Exaggerated Health Disparities. AIDS Patient Care STDS. 2014;28:128-35.
4. CDC. HIV, Sex Workers. <https://www.cdc.gov/hiv/group/sexworkers.html>, updated March 16, 2022.
5. CDC. US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. December-2021 (<https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>).