



AMERICAN ACADEMY OF  
**HIV MEDICINE**

# Challenges in Improving PrEP Uptake: Systemic Barriers & Resilient Strategies

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This activity is jointly provided by the Partners for Advancing Clinical Education (Partners) and the American Academy of HIV Medicine.



**Partners for Advancing  
Clinical Education**

This activity is supported by independent educational grants from Gilead Sciences.

## Target Audience

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

## Statement of Need/Program Overview

# Joint Accreditation Statement

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



# Physician Continuing Medical Education

## CREDIT DESIGNATION

- Partners designates this live activity for a maximum of 1.0 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

# Pharmacist Continuing Education

## CREDIT DESIGNATION

- Partners designates this continuing education activity for 1.0 contact hour(s) (0.1 CEUs) of the Accrediting Council for Pharmacy Education.  
(Universal Activity Number JA4008073-9999-26-074-L01-P)
- Type of Activity: Application

Upon completion of the online evaluation, your credit will be submitted to CPE Monitor. Pharmacists have up to thirty (30) days to complete the evaluation and claim credit. Please check your NABP account within thirty (30) days to make sure the credit has posted.

# Nursing Continuing Professional Development

## CREDIT DESIGNATION

- The maximum number of hours awarded for this Nursing Continuing Professional Development Activity is 1.0 contact hours.
- Designated for 0.5 contact hours of pharmacotherapy credit for Advanced Practice Registered Nurses.

# Disclosure Information

## Disclosure of Conflicts of Interest

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All relevant financial relationships for anyone with the ability to control the content of this educational activity are listed below and have been mitigated according to Partners' policies. Others involved in the planning of this activity have no relevant financial relationships.



# Faculty Disclosures:

Dr. Bernardo, faculty for this educational activity, has no relevant financial relationships.

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The opinions expressed in the educational activity are those of the faculty and do not necessarily represent the views of the planners. Please refer to the official prescribing information for each product for discussion of approved indications, contraindications, and warnings.

# Disclaimer

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

# Fee Information

There is no fee for this educational activity.

# Educational Objectives

*Upon completion of this activity, participants should be able to:*

- Navigate systemic barriers to PrEP delivery in real-time.
- Identify nuanced challenges in adherence and persistence.
- Discuss management of marginalized communities.
- Highlight implementation in underfunded/restrictive environments.
- Address policy changes and hostile attitudes harming the workforce.

# The Epidemiology of Need: Lifetime Risk

## Black Populations



Men:  
**1 in 27**



Women:  
**1 in 75**

## Hispanic/Latine Populations



Men:  
**1 in 50**



Women:  
**1 in 287**



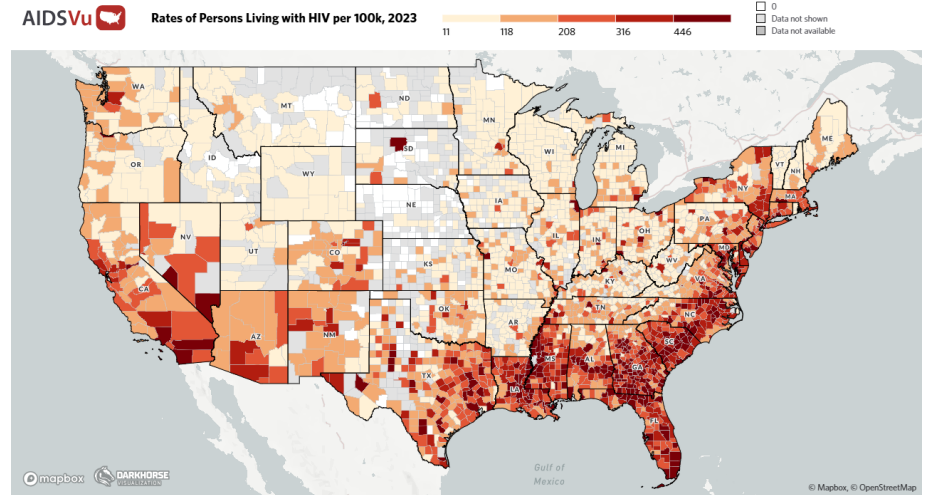
Overall US  
Lifetime Risk:  
**1 in 120**



National  
PrEP-to-Need Ratio  
(PNR):  
**15.6**↑

# Geographic Inequity: The US South

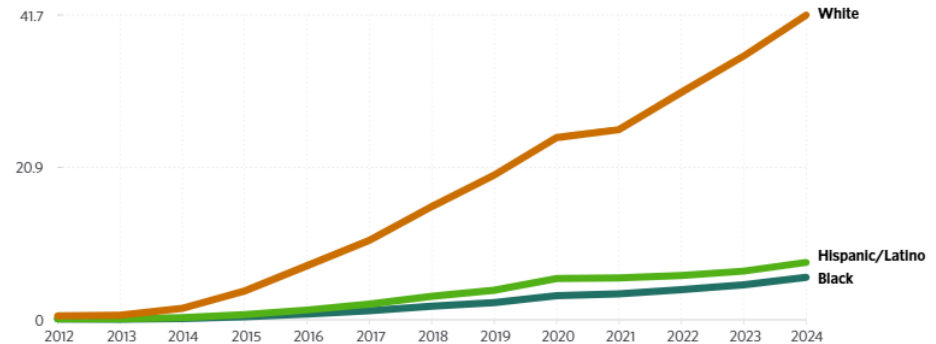
- The South accounts for 52% of new HIV diagnoses.
- Only 39% of total US PrEP users reside in the South.
- PNR in the South (12.0) remains the lowest in the nation.



# Demographic Inequity: Racial Disparities

- Black Populations: 38% of new diagnoses / 14% of PrEP users.
- Hispanic/Latine: 32% of new diagnoses / 18% of PrEP users.
- White Populations: 24% of new diagnoses / 63% of PrEP users.

PREP-TO-NEED RATIO (PNR) BY RACE/ETHNICITY, 2012-2024



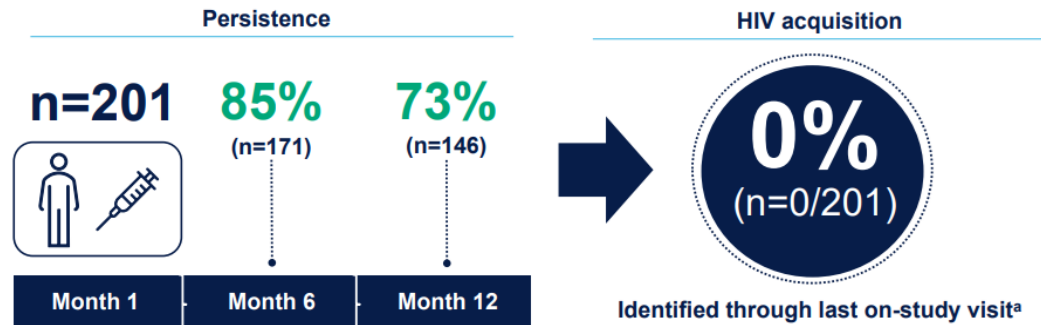
PnR reflects the number of PrEP users in a group for every new HIV diagnosis in that group. A lower PnR indicates more unmet need for PrEP.



# The Persistence Problem: PILLAR

- Phase IV Implementation Trial.
- Month 12 Persistence: 73% retention in care.
- No HIV acquisitions observed over 12 months with CAB-LA.

Figure 3. Persistence and HIV Acquisition Through Month 12



# Systemic Barriers & “The Churn”



## ‘The Churn’

Frequent insurance interruptions causing medication gaps.



## Administrative Burden

Prior authorizations as “soft barriers” to entry.



## Medical Mistrust

The impact of structural racism on engagement.

# Hostile Policy & Healthcare Workforce



## Rescinded Prevention Funds

Loss of local HIV infrastructure.



## Political Backlash

Legislative threats create 'chilling effects'.



## Moral Injury

Provider burnout and attrition in hostile jurisdictions.

# Transgender Population Challenges

- TGW HIV Prevalence: 14.1% (up to 44% in Black TGW).
- Integration with GAHT is essential for trust and uptake.

## Myth-Busting: GAHT & PrEP

- iBrEATHe Study: GAHT (Estrogen/Testosterone) does NOT reduce PrEP drug levels.
- Tenofovir-DP concentrations remain in therapeutic ranges.
- Conclusion: GAHT is NOT a contraindication for any PrEP modality.



# Cisgender Women: The Gender Gap

## PrEP Usage Disparity



Men account for 91% of PrEP users;  
Women represent only 9%.

## HIV Burden & Racial Disparities



**1 in 5 (19%)**

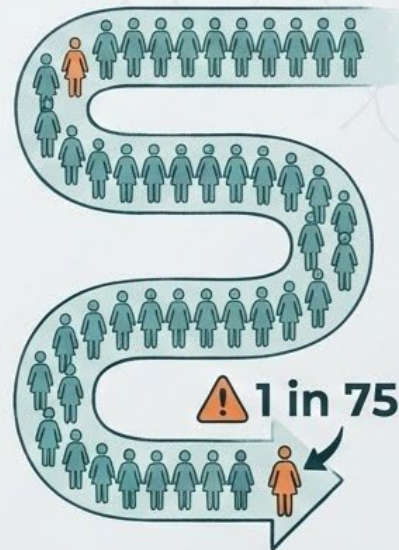
Of new US HIV diagnoses  
occur in women



**50%**  
Black  
Women

Black women account for 50%  
of diagnoses among all  
cisgender women.

## Lifetime Risk

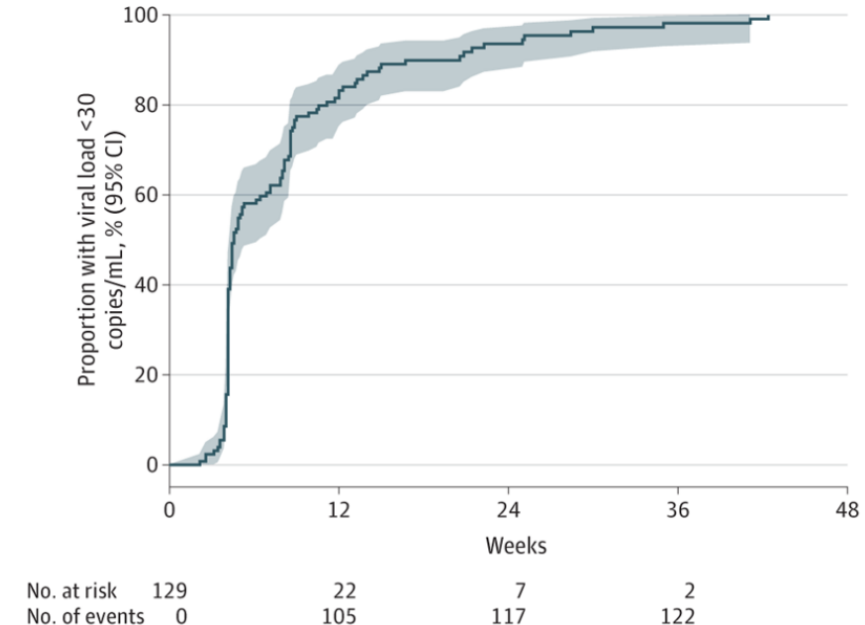


Lifetime Risk for  
Black Women

# Innovative Implementation: Ward 86

- Safety-net model in San Francisco.
- 83% retention using CAB-LA in unstable housing or substance use.
- Success through low-barrier and 'on-demand' clinical access.

Figure. Time to Achieve a Viral Load Less Than 30 Copies/mL for People With HIV Starting Cabotegravir/Rilpivirine With Viremia



# The Injectable Revolution: CAB-LA

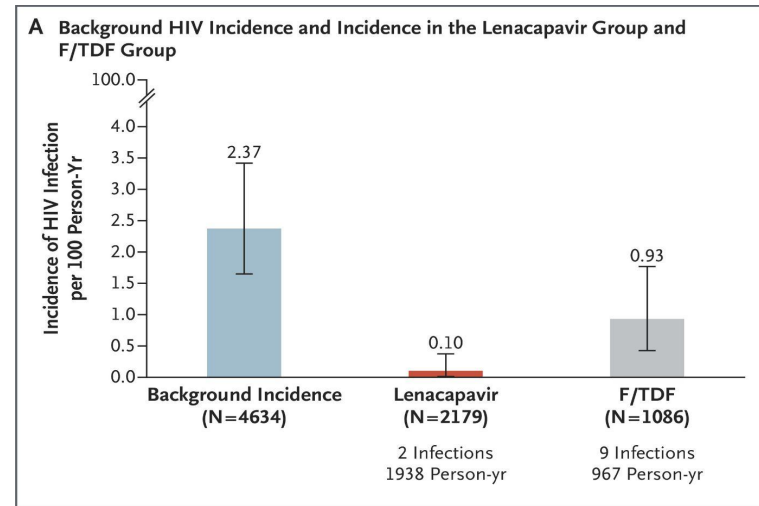
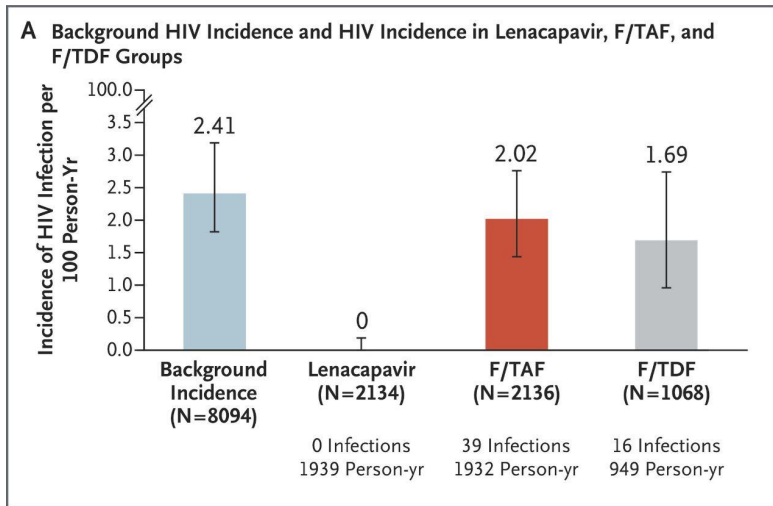
- HPTN 083 (MSM/Transwomen): Superior to daily, oral TDF/FTC. HR 0.34 (66% reduction in HIV acquisition).
- HPTN 084 (Women): Superior to daily, oral TDF/FTC . HR 0.12 (88% reduction in HIV acquisition).
- Why it works: Removes the daily pill burden, reducing stigma and privacy concerns.



# The Breakthrough: Lenacapavir (LEN)

- First-in-class HIV capsid inhibitor.
- Targets nuclear transport, virus assembly/release, and capsid core formation.
- Twice-Yearly Injections: Two once-daily oral doses, and two subcutaneous doses every 6 months.
- PURPOSE-1: 100% Efficacy (0 infections) in cisgender women; two incident HIV infections occurred among participants in the LEN arm after the time of the primary analysis.
- PURPOSE-2: 96% Relative Risk Reduction (99.9% HIV-free).
- Impact: Aligning PrEP visits with standard 6-month checkups de-medicalizes the process.

# The Breakthrough: Lenacapavir (LEN)



# De-Medicalizing: Pharmacy-Led PrEP

- Task-shifting from clinics to community pharmacists.
- Data: 81% retention at 26 weeks; 94% on-time injections.
- Strategy: Utilizing pharmacists expands the workforce and access points.
- Overcomes white-coat anxiety and transportation barriers.

# Tele-PrEP & Digital Health



## Overcomes 'Geographic Deserts'

Expands access in underfunded and restrictive states.



## Virtual Visits & Mail-in Labs

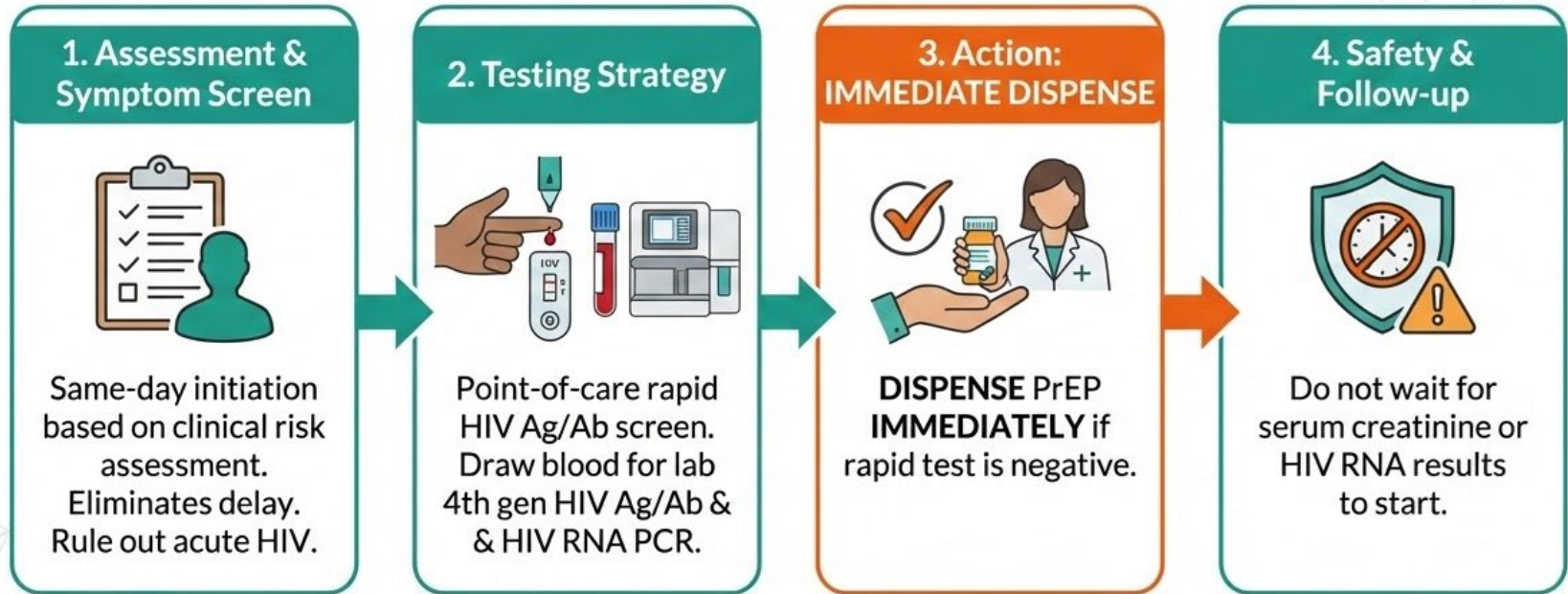
Increases uptake, especially among younger populations.



## Ensures Continuity of Care

Maintains access regardless of local provider availability.

# Clinical Protocol: Rapid Start

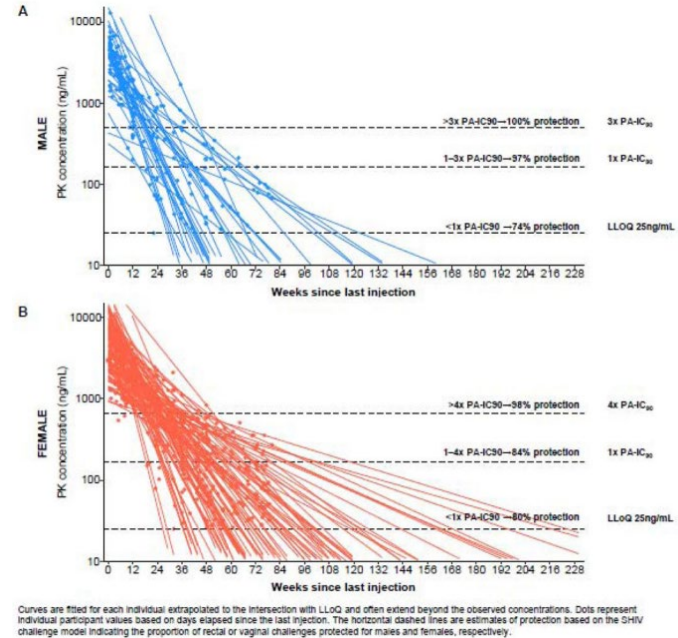


# Clinical Challenge: Acute HIV & 'LEVI' Syndrome

- LEVI (Long-Acting Early Viral Inhibition): Long-acting agents can blunt HIV antibody response to early HIV infection, masking detection of new, acute HIV infection.
- Risk: Delayed HIV diagnosis leads to resistance.
- Detection: 7 participants in HPTN 083 receiving on-time CAB-LA injections acquired new HIV infection; 5 of these developed INSTI resistance.
- Strategy: Diagnosis requires careful questioning for high risk exposures; standard Ag/Ab tests may be delayed or non-reactive. HIV RNA PCR test is needed to diagnose.

# LEVI Syndrome

- Long-Acting Early Viral Inhibition (LEVI).
- Masked HIV infection can result in delayed diagnosis for 6-12 months.
- Risk of high-level INSTI resistance (G140/Q148 mutations).

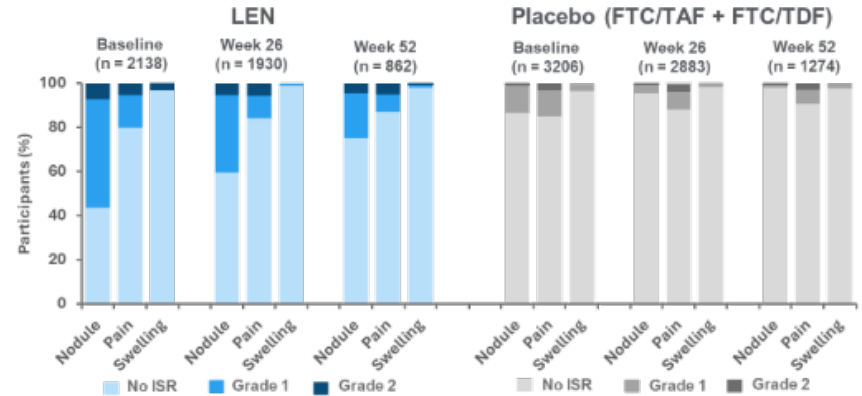


**Figure 1.**  
Individual participant log-linear regression curves of plasma CAB concentration over time since Cmax to Clast after the last injection by sex



# Managing Side Effects: ISRs

- Prevalence: About 70% to 80% of patients experience ISRs initially; <5% discontinue.
- Technique: Slow injection (10-15 seconds) of room-temperature medication.
- Comfort: Use of cold packs pre- and post-injection.
- Counseling: 'Grade 1-2' soreness is expected; severity decreases over time.



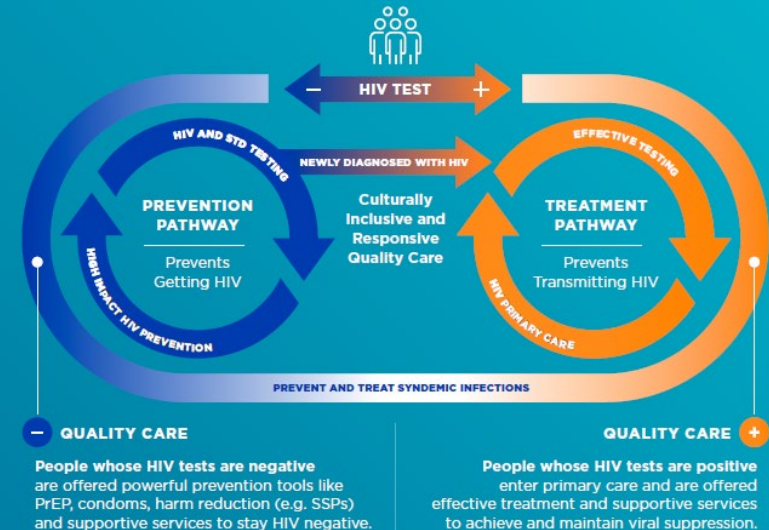


# Status-Neutral Care Continuum

- Engaging every patient in sexual health, regardless of status.
- HIV Testing -> PrEP (if negative) or ART (if positive).
- Removes the 'Moral Judge' from the encounter.
- Status-Neutral Care is patient centered not disease centered.

## The Status Neutral HIV Continuum of Care

Status Neutral HIV Prevention and Care, or Status Neutrality, is a *whole person approach* to HIV prevention and care that emphasizes **high-quality care** to engage and retain people in services **regardless** of if the services are for HIV treatment or prevention.



Find a testing site near you at [aidsvu.org/services](https://aidsvu.org/services).

Regardless of HIV status, **quality care** is the foundation of HIV prevention and effective treatment. Both pathways provide people with the tools they need to stay healthy and end the HIV epidemic.

# Gate-Opener vs. Gatekeeper

- Reframing PrEP from a reward to a routine health option.
- Eliminating intrusive behavior questions in favor of autonomy.
- De-medicalizing' the eligibility process.

# Conclusion

- Scientific Breakthrough: Transitioning from daily oral to 6-month dosing.
- Dismantling Myths: Instability is an indication for long-acting PrEP, not a barrier.
- Addressing Inequity: Overcoming the social policing of sexuality and the gender gap.
- Systemic Evolution: Utilizing pharmacy-led and Status-Neutral care models.
- Call to Action: Move from Gatekeeper to Gate-opener to ensure health autonomy.

# References

1. AIDSvu. (2025). Local Data: United States. Emory University, Rollins School of Public Health.
2. Becasen, J. S., et al. (2019). Estimating the Prevalence of HIV and Sexual Risk Behaviors Among Transgender Women in the United States. *American Journal of Public Health*, 109(1), 206–214.
3. Bekker, L. G., et al. (2024). Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in Cisgender Women. *New England Journal of Medicine*, 391(11), 977-989.
4. Centers for Disease Control and Prevention. (2025). HIV Surveillance Report, 2023; vol. 35.
5. Dawson, L., et al. (2023). Policy Hostility and the HIV Care Workforce. *Journal of Acquired Immune Deficiency Syndromes*, 94(2), 112-119.
6. Delany-Moretlwe, S., et al. (2022). CAB-LA for HIV prevention in cisgender women (HPTN 084). *The Lancet*, 399(10337), 1779-1789.
7. Grant, R. M., et al. (2020). Gender-Affirming Hormones and TDF/FTC Concentrations in TGNC Populations (iBrEATHe). *Clinical Infectious Diseases*, 71(10), 2549-2556.

# References

8. Kelley, C. F., et al. (2024). Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in MSM and TGNB Persons. *New England Journal of Medicine*, 391(11), 990-1002.
9. Landovitz, R. J., et al. (2021). Cabotegravir for HIV Prevention in MSM and Transgender Women. *New England Journal of Medicine*, 385(7), 595-608.
10. Landovitz, R. J., et al. (2020). Tail-phase safety, tolerability, and pharmacokinetics of long-acting injectable cabotegravir in HIV-uninfected adults: A secondary analysis of the HPTN 077 trial. *The Lancet HIV*, 7(7), e472–e481
11. Spinelli, M. A., et al. (2024). Low-barrier long-acting PrEP for individuals with unstable housing and substance use. *Clinical Infectious Diseases*, 78(4), 1012-1019.
12. Touger, R., et al. (2022). Telemedicine and HIV Prevention. *Current HIV/AIDS Reports*, 19(5), 371-382.
13. Tung, E., et al. (2022). Feasibility of a community pharmacy-based PrEP program. *BMC Infectious Diseases*, 22(1), 669.