



Action Guide for PrEP Adherence and Retention Management in Health Centers

 HEALTH CENTER



INFRASTRUCTURE



CARE DELIVERY



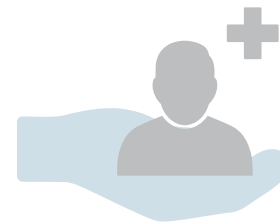
PEOPLE



PrEP ADHERENCE AND RETENTION MANAGEMENT

WHY

is attention to PrEP adherence and retention so important?



HIV remains a significant public health crisis in the United States, especially for traditionally-marginalized populations, including people of color, men who have sex with men (MSM), transgender women (TGW), people who inject drugs (PWID), among others. There are currently 1.1 million Americans living with HIV, and annual new HIV infections have stagnated at 39,000-40,000 since 2011, underscoring the need to rejuvenate HIV prevention efforts.^{i, ii}

In 2018, MSM accounted for 69% of the new HIV infectionsⁱⁱⁱ. African American and Latinx MSM represent the two highest risk sub-populations with 9,499 and 7,543 new HIV infections in 2018, respectively, accounting for roughly 44% of all new HIV infections in the US^{iv}. African American MSM and Latinx MSM have a 1 in 2 and 1 in 5 chance of acquiring HIV in their lifetime, respectively^v. Moreover, HIV incidence has decreased the fastest for white MSM (19%), but has plateaued or increased for African American and Latinx MSM from 2010-2016.^{vi}

New biomedical tools, including pre-exposure prophylaxis (PrEP), to prevent HIV acquisition offer tremendous potential to bolster HIV prevention efforts. PrEP is highly effective at preventing new HIV infections when taken consistently^{vii}. But suboptimal medication adherence is pervasive, undermining PrEP's utility. Clinical implementation data indicates PrEP adherence is generally low and wanes over time.^{viii, ix, x} Likewise, PrEP adherence is worse among people of color, thereby exacerbating HIV incidence and PrEP uptake inequities.^{xi, xii}

Similarly, poor retention in care, or "PrEP persistence," precludes providers from addressing barriers to adherence and supporting at-risk patients to stay HIV-negative. Several PrEP studies demonstrate PrEP persistence is suboptimal across sub-populations.^{xiv, xv, xvi} One important study shows that HIV incidence is higher among those not retained on PrEP versus those never initiated on PrEP^{xvii}, highlighting the importance of supporting individuals to stay in care over time, even months or years after PrEP initiation.

One key study demonstrates that poor PrEP adherence among African American MSM led to a 32% prevalence of HIV among those on PrEP, compared to 20% of those not initiated on PrEP.^{xviii}



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Community health centers are uniquely positioned to ensure that PrEP works effectively for those at the greatest risk of HIV acquisition. Approximately 29 million people receive services at community health centers, 82% of whom are uninsured or publicly insured and 63% of whom are members of racial/ethnic minorities.^{xviii} By emphasizing PrEP adherence and persistence, health centers can ensure that PrEP works effectively for those at highest risk of infection and contribute to national HIV prevention efforts. This is further supported by the “Ending the HIV Epidemic: A Plan for America (EHE)” initiative that specifically identifies community health centers as one of the main delivery sites of the four pillars of action to end HIV in the United States.^{xix}

WHAT

are the current clinical guidelines for managing PrEP adherence and retention?



The United States Preventive Services Task Force (USPSTF) recommends with “Grade A certainty” that providers offer PrEP to all individuals at high risk of HIV acquisition.^{xx} Moreover, they stress the importance of adherence in determining PrEP effectiveness. Upon review of the evidence, the USPSTF concluded that:

PrEP is of substantial benefit for decreasing the risk of HIV infection in persons at high risk of HIV infection, either via sexual acquisition or through injection drug use. The USPSTF also found convincing evidence that adherence to PrEP is highly correlated with its efficacy in preventing the acquisition of HIV infection.

The Centers for Disease Control and Prevention (CDC) also emphasizes the importance of adherence and retention in maximizing PrEP outcomes. In the [PrEP for Prevention of HIV Infection in the United States – 2017 Clinical Practice Guidelines](#) the CDC recommends daily PrEP in conjunction with follow up visits at least every 3 months.^{xxi} For patients newly initiating PrEP, providers should educate patients regarding the importance of high adherence. Side effects can lead to non-adherence, so clinicians should discuss potential side effects with newly initiating patients and describe methods to mitigate them to ensure consistent PrEP adherence. At follow-up visits, clinicians should provide medication adherence counseling and behavioral risk reduction support, in conjunction with HIV, sexually transmitted infection (STI) testing, and other health services.

Key Components of Medication Adherence Counseling

Establish trust and bidirectional communication

Provide simple explanations and education

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

Support adherence

- Tailor daily dose to patient's daily routine
- Identify reminders and devices to minimize forgetting doses
- Identify and address barriers to adherence

Monitor medication adherence in a non-judgmental manner

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



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While self-reporting (asking the patient how often he or she is taking their medicine) is the most widely used method of assessing medication adherence, it is subject to bias and several studies note a discrepancy between self-reported PrEP adherence and actual PrEP adherence.^{xxii} Alternatively, objective adherence monitoring with biomarkers of adherence (i.e., urine or blood concentrations of PrEP drug components) can play a key role in targeting adherence support to those who need it most. Numerous scientific studies have been published noting a protective effect of certain drug concentrations in plasma, urine, hair, and dried blood spot.^{xxiii} Likewise, several innovations have led to the commercialization and utilization of biomarker-based objective adherence monitoring, especially urine-based methods, that are routinely used at PrEP clinics nationwide.

HOW

can health centers impact PrEP adherence and retention?



Health centers play an integral role in ensuring that PrEP works effectively for those at the greatest risk of HIV acquisition. Nevertheless, supporting patients to sustain medication and appointment adherence requires buy-in from stakeholders at all levels of the organization. Holistic support services are needed to ensure patients remain adherent and retained in care.

Health centers can use the following 5 action steps to optimize the efficacy of their PrEP program.

5 STEP ACTION GUIDE

- STEP 1 ENGAGE leadership:** Make adherence and retention an organizational priority and focal point of the health center's PrEP program with buy-in from leadership.
- STEP 2 ADOPT and implement an objective adherence monitoring and adherence support protocol:** Use the protocol to facilitate the allocation of patient-level adherence support services.
- STEP 3 USE adherence data to identify patients at risk of future non-retention (patient level):** Segment your patient population into target groups in need of PrEP retention support services.
- STEP 4 MONITOR trends in adherence across patients and demographics (clinic-level):** Use data generated by adherence testing to improve the quality of PrEP services.
- STEP 5 MAXIMIZE reimbursement for adherence and retention support services:** Identify the billing codes that correspond with testing and support services provided to PrEP patients and train staff on how to utilize them.

**The CDC does not explicitly recommend using objective adherence monitoring to assess PrEP adherence, in part because very few methods were available at the time that the PrEP guidelines were written. In their PrEP guidelines, the CDC cites (1) a lack of established drug concentrations that correspond to prevention of HIV acquisition and (2) limited availability of laboratories that can measure drug concentrations for PrEP patients.*



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STEP 1 ENGAGE leadership

The first step in improving PrEP outcomes across your health center's PrEP population is building consensus within the organization regarding the importance of PrEP adherence and retention. Name a clinical lead who is responsible for managing activities related to PrEP adherence and retention. Ensure that leadership supports this staff member through messaging, dedicated time, and additional resources to carry out necessary activities.

In conjunction with leadership, set short-term and long-term targets for PrEP adherence and retention. Short-term targets could include training staff and updating PrEP care protocols. Long-term targets could include 6-month and 12-month adherence and retention metrics across PrEP patients.



Action Item: Leadership acknowledges PrEP adherence and retention as an explicit priority and updates broader health center strategy to include this new priority. Appoint a PrEP adherence and retention clinical lead and work with leadership to set benchmarks for success.

STEP 2 ADOPT and implement an objective adherence monitoring and adherence support protocol

Identifying patients in need of enhanced adherence and retention support services is a requisite first step to intervening and improving PrEP outcomes. This can be achieved by adopting and integrating routine objective adherence testing into your health center's standard PrEP clinical workflow.

Biomarker-based methods of assessing adherence to PrEP (e.g., urine-based adherence testing or dried blood spot) can be utilized to objectively identify non-adherent patients and link them to adherence support services. Urine-based objective adherence testing – an indicator of recent PrEP adherence – is noninvasive and easy to implement, as urine samples are already routinely collected for STI testing. Dried blood spot adherence testing – an indicator of long-term PrEP adherence – only requires a fingerstick and can be quickly collected at routine appointments.

For patients identified as “non-adherent,” clinicians can employ integrated motivational interviewing, and informed choice counseling. For example, Next Steps Counseling (iNSC) is an evidence-based intervention to improve adherence, which entails:

- Share adherence test results in a non-judgmental manner
- Discuss barriers to adherence
- Brainstorm solutions to improve adherence

iNSC paired with a biomarker-based method of assessing PrEP adherence generated a 50% improvement in PrEP adherence in a 2017 study.^{xxiv}



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Utilize a patient portal available through your existing electronic medical record or through an external patient centric and PrEP-specific vendor (e.g., Healthvana, PlushCare, or MISTR) to provide diagnostic results directly to your patients. These tools can be effective at increasing patient engagement in care and also improving adherence and retention.



Action Item: Leadership and PrEP leads should update clinical protocols or standard operating procedures to include routine objective adherence monitoring and support services for all patients on PrEP. Once updated, train staff on how to conduct adherence testing and provide iNSC to non-adherent patients.

STEP 3

USE adherence data to identify patients at risk of future non-retention (patient level)

In addition to identifying patients who are not consistently taking PrEP, objective adherence testing can be used to identify patients at risk of dropping out of care. Research shows that non-adherent patients are more likely to drop out of care than adherent patients. As objective adherence testing is rolled out to PrEP patients, ensure that non-adherent patients receive support services to bolster both adherence and PrEP retention.

Create patient tracking and outreach systems to monitor and improve PrEP retention. Update databases and electronic medical records to track previous adherence status and appointment attendance performance. Create automated registries of patients at higher-risk for non-retention and target outreach efforts to minimize loss-to-follow-up. Targeted outreach activities can include:

- Send monthly appointment reminders
- Call patients the week before appointment
- Ensure staff are available to communicate with patients in between appointments

An app-based portal that provides direct contact between staff and patient can facilitate communication around retention support and increase the likelihood of keeping individuals in care.



Action Item: Create a registry of previously non-adherent patients and allocate additional support services to ensure they present for their quarterly clinic visit.



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STEP 4 MONITOR trends in adherence across patients and demographics (clinic-level)

By implementing routine adherence testing, your clinic is generating a wealth of behavioral data that was previously undetectable. Your center can now track patient- and clinic-level adherence and retention metrics, including but not limited to:

- Overall adherence rates across the health center, disaggregated by race, ethnicity, sexual orientation, sex assigned at birth, and gender
- Patient-level adherence trends since PrEP initiation
 - Proportion of non-adherent patients who demonstrate adherence at their next appointment after receiving adherence support services
 - Appointment attendance rates
 - 3-, 6-, and 12-month retention in care rates

This data can be used to run reports for leadership and refine benchmarks based on organizational performance.



Action Item: Regularly monitor adherence and retention trends, identify patients and sub-populations at greater risk, and adjust support services to improve performance across the health center.

STEP 5 MAXIMIZE reimbursement for adherence and retention support services

Insurers will generally reimburse your health center for routine PrEP adherence testing and counseling. The following reimbursement codes have been identified by the "[Billing Coding Guide for HIV Prevention](#)"^{xxv} compiled by NASTAD (National Alliance of State and Territorial AIDS Directors) as potentially useful for adherence and retention counseling:

Z51.81	Encounter for therapeutic drug level monitoring. Use for PrEP monitoring.
Z79.899	Other long term (current) drug therapy. Use for PrEP monitoring.
99401-99404	Preventive medicine counseling and/or risk factor reduction interventions provided to an individual.
99411-99412	Preventive medicine counseling and/or risk factor reduction interventions provided in a group setting.
98960-98962	Self management education and training face-to-face for 1-8 patients. In certain states, can be performed by a non-licensed peer provider (e.g., Community Health Worker).



Action Item: Identify sources of reimbursement for HIV prevention, PrEP adherence testing, and support services; train staff on how to incorporate these billing codes into the electronic medical record and billing systems.



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