CAN COMMUNITY HEALTH

Test And Inject, Rapid Protect: Delivering Same-Day Injectable PrEP Access

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Introduction

HIV prevention in the United States has been strengthened by biomedical advances, yet gaps remain in timely PrEP initiation and sustained adherence, (Sullivan et al., 2020). Despite the proven efficacy of daily oral PrEP, many at-risk individuals face barriers such as stigma, pill fatigue, and healthcare system delays, limiting the full potential to reduce new HIV infections (Karris et al., 2014).

"Timely access to patient-centered prevention strategies is essential to optimizing health outcomes and reducing barriers to care. This initiative was about getting individuals the right PrEP at the right time for them."

Katy Wendel, Chief Nursing Officer
CAN Community Health

This white paper introduces the **Test and Inject: Rapid Protect initiative, a same-day PrEP delivery model** that integrates rapid diagnostic testing with immediate initiation of injectable PrEP samples for eligible patients.

This protocol aims to strengthen adherence, reduce drop-off between testing and treatment, and improve outcomes within community and outpatient settings by expediting the pathway from risk identification to protection.

Long-acting injectable PrEP, specifically cabotegravir (Apretude), offers a promising solution by reducing the reliance on daily adherence and expanding prevention options. However, optimizing the delivery of injectable PrEP requires innovative models that address clinical and operational challenges.

By advancing a pragmatic, patient-centered strategy, this protocol supports broader efforts to accelerate progress toward ending the HIV epidemic while addressing persistent structural and behavioral barriers to prevention.

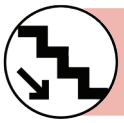
US HIV Prevention Landscape

The United States (US) employs a comprehensive approach to HIV prevention, integrating biomedical, behavioral, and structural interventions aimed at reducing new infections (CDC, 2024). Supported by initiatives such as the Ending the HIV Epidemic plan, these strategies focus on addressing both individual and population-level risk. Key components of this multifaceted approach include:

Pre-Exposure Prophylaxis (PrEP): PrEP involves the use of antiretroviral medication by HIV-negative individuals to prevent HIV acquisition.

Post-Exposure Prophylaxis (PEP): PEP is an emergency antiretroviral intervention initiated within 72 hours following potential HIV exposure.

Condom Use: The correct and consistent use of condoms remains a cornerstone of HIV and STI prevention.



Harm Reduction for People Who Inject Drugs: Interventions such as syringe service programs and access to substance use treatment reduce HIV transmission in populations at elevated risk.

Educational and Behavioral Interventions: Comprehensive sex education and targeted risk-reduction counseling address behavioral drivers of HIV transmission.

Treatment as Prevention (TasP): Initiation and maintenance of effective antiretroviral therapy (ART) for people living with HIV reduces community-level transmission risk, a concept captured in "Undetectable = Untransmittable" (U=U).

Voluntary Medical Male Circumcision (VMMC): While more prominent in high-prevalence regions outside the U.S., VMMC has been shown to reduce heterosexual men's risk of acquiring HIV and is considered in certain contexts.

Importantly, biomedical interventions such as PrEP are supported by federal policy, such as the "*Ending the HIV Epidemic*" plan, which focuses on diagnosing, treating, and responding to HIV in the most affected communities. The U.S. Preventative Services Task Force (USPSTF) Grade A recommendation and coverage ensures insurance coverage through the preventive care requirement under the Affordable Care Act (US Preventive Services Task Force et al., 2023).

However, PrEP remains underutilized. In 2018, only 18% of those who could benefit from PrEP were accessing it (CDC, 2024). Moreover, retention in PrEP care is suboptimal, with average duration of daily oral PrEP use lasting less than eight months. This under use is not a reflection of the efficacy or safety of PrEP; both oral and long-acting injectable formulations are highly effective and well-tolerated when taken as prescribed.

Daily oral PrEP has been shown to Reduce the risk of acquiring HIV by more than 90% when used as prescribed.

Additionally, long-acting injectable PrEP options, such as cabotegravir, administered every two months, offer alternatives to daily pills.

The persistent gap between clinical effectiveness and real-world uptake highlights the need for innovative, responsive delivery systems that can provide immediate access and improve retention in PrEP care.

Adherence Challenges

While daily oral PrEP regimens, such as emtricitabine/tenofovir disoproxil fumarate (Truvada) and emtricitabine/tenofovir alafenamide (Descovy), have been shown to reduce HIV acquisition risk by over 90% when taken as prescribed, real-world adherence to these regimens presents multifactorial challenges (Chou et al., 2019). Despite their clinical efficacy, traditional PrEP regimens require a high level of engagement from patients and seamless navigation of healthcare systems, both of which are frequently compromised by social, structural, and behavioral barriers (Mayer & Allan-Blitz, 2019).

Medication Adherence Barriers

Daily PrEP requires a consistent dosing schedule, and missed doses can significantly reduce its protective effect. Pill fatigue, or the reluctance to maintain a daily regimen over extended periods, is a frequently cited contributor to suboptimal adherence, especially in asymptomatic individuals who may perceive limited immediate benefit from daily medication.

Stigma and Perceived Judgment

PrEP use may be associated with concerns about being labeled as promiscuous, HIV-positive, or engaging in behaviors considered high-risk, such as sex work or injection drug use. This stigma is compounded in marginalized populations, including men who have sex with men (MSM), people who inject drugs (PWID), and sex workers, who often report discriminatory experiences in healthcare settings (Calabrese et al., 2014). Anticipated or actual stigma from healthcare providers further deters engagement in preventive services.

Side Effects And Tolerability

Although generally well-tolerated, oral PrEP can cause side effects such as gastrointestinal discomfort, headaches, or fatigue, which may influence individuals to discontinue or inconsistently use the medication.

Access And Financial Constraints

While PrEP is covered by many insurance plans due to its USPSTF Grade A recommendation, cost-related factors including copayments, lack of insurance, and transportation challenges can present substantial barriers. Structural inequities, such as living in rural or under served areas with limited PrEP access, exacerbate these challenges.

Knowledge Gaps And Risk Perception

Misconceptions about the efficacy, safety, and purpose of PrEP contribute to its under use. Additionally, shifts in perceived HIV risk, such as entering a monogamous relationship, or changes in life circumstances, including travel or disruptions to routine, often lead to interruptions or discontinuation of PrEP use.

Healthcare System Barriers

Access to PrEP-prescribing providers remains inconsistent across geographic regions. States that restrict Nurse Practitioners (NPs) and Physician Associates (PAs) from practicing independently or limit pharmacists' scope of practice are associated with lower PrEP prescription rates. In contrast, jurisdictions that authorize broader prescribing rights for NPs, PAs, and pharmacists demonstrate higher uptake of PrEP services.

Delays in treatment initiation due to provider shortages, fragmented care pathways, and prolonged insurance authorization processes limit the potential for timely PrEP initiation, which is critical in preventing HIV seroconversion following identified risk.

Psychosocial And Structural Determinants

Mental health conditions such as anxiety, depression, or low self-esteem may interfere with preventive health behaviors, including PrEP adherence. Fear of judgment or distrust in healthcare institutions may also contribute to the avoidance of regular medical follow-up. Furthermore, systemic inequities, including racism, homophobia, transphobia, and other forms of discrimination, create additional access barriers for racial and ethnic minorities, LGBTQ+ populations, and individuals in stigmatized occupation (Calabrese, 2020).

Collectively, these barriers illustrate the need for alternative PrEP delivery models that reduce reliance on daily adherence, minimize stigma, and address structural barriers to access. Innovations such as long-acting injectable PrEP, delivered at the point of care, represent a promising approach to overcoming these challenges.

Injectable PrEP Benefits

Long-acting injectable PrEP, such as cabotegravir (Apretude), offers sustained protection with a single administration, providing continuous drug levels superior to the peaks and troughs of oral regimens (Landovitz et al., 2021). This extended coverage, lasting at least two months per injection, assures both patients and providers of protection without daily adherence challenges.

Adherence is inherently improved, as patients are guaranteed therapeutic drug levels until the next scheduled injection. This reduces the need for intensive monitoring and minimizes opportunities for missed doses (Koss & Parikh, 2025).

Patients interested in Apretude often face insurance delays of a month or more, leading many to continue oral PrEP. However, patients frequently discontinue oral PrEP on their own due to perceived lower risk, pill fatigue, or forgetfulness. Immediate initiation of injectable PrEP when requested could significantly reduce HIV risk by improving adherence, states CAN Community Health's Chief Medical Officer, Steven Barnett.

Injectable PrEP also mitigates stigma by eliminating the need for daily pill storage or use, allowing patients to maintain discretion. This is particularly valuable for individuals in relationships or cultural contexts where PrEP use may be difficult to negotiate. Finally, injectable PrEP expands access to a broader patient population, including those engaging in vaginal sex and those who are pregnant, where oral PrEP options like Descovy are not indicated.

Test And Inject, Rapid Protect

Given the limitations of traditional PrEP delivery and the demonstrated benefits of long-acting injectable options, there is a critical need to implement models that can operationalize rapid access to injectable PrEP. The Test and Inject: Rapid Protect protocol is designed to streamline the process from risk identification to same-day initiation, ensuring timely protection and addressing many of the adherence and access barriers inherent in traditional approaches. The following section outlines the key components of this protocol and its integration into clinical workflows.

Pre-Implementation Setup

Successful same-day injectable PrEP initiation requires deliberate pre-implementation planning to ensure seamless integration into clinical workflows. The implementation process began with securing on-site availability of fourth-generation rapid HIV testing to allow for same-day HIV status confirmation. Simultaneously, collaboration with the pharmaceutical partner, ViiV Healthcare, was essential in facilitating access to starter doses of cabotegravir (Apretude) for clinic-based use. This partnership included working closely with the ViiV pharmaceutical representative and reimbursement specialist to coordinate the provision of medication samples and assess insurance-related barriers.

> The coordinated efforts of partners, ViiV and CAN were critical in ensuring same-day access, inventory readiness, and efficient navigation of billing workflows.

To further support efficiency, an assessment of common payer policies was conducted to identify insurance plans that consistently approve long-acting injectable PrEP. These payer-specific protocols were integrated into the Electronic Medical Record (EMR) system through a customized alert. When a patient with a qualifying insurance plan is scheduled for a “new PrEP” appointment type, the system generates an automatic notification flagging the patient as eligible for the Rapid Protect same-day injectable protocol.

Administrative Framework

The launch of the Rapid Protect protocol was supported by existing administrative systems, allowing for efficient and seamless integration.

By leveraging existing administrative infrastructure and established partnerships, the clinic seamlessly integrated a same-day injectable PrEP process into current operations, enabling rapid implementation with minimal disruption.

Medication Procurement
Injectable medication procurement processes were established within the organization. These included both buy-and -bill model and pharamcy-delivered injectable PrEP. This allowed for seamless transition from sample-based administration to standard procurement channels, ensuring uninterrupted access to medication.

Inventory and Sample Management
Current inventory management systems, including sample tracking, were easily extended to include injectable PrEP. Existing partnerships with ViiV and reimbursement specialists ensured uninterrupted supply and oversight.

EMR Documentation and Billing
The EMR contained pre-existing templates and workflows for medication administration, prior authorizations, and billing. Minor documentation adjustements were necessary to document an injectable sample administration.

Same Day Injectable PrEP Process

STEP 1: Rapid Testing

The patient receives rapid HIV and STI testing using on-site fourth-generation HIV tests and appropriate STI screens.

STEP 2: Risk Identification

If the HIV test is negative and the patient is at-risk status, the patient is identified as a candidate for PrEP initiation.

STEP 3: HIV/STI and PrEP Counseling

The patient is counseled on HIV prevention, STI treatment, and the benefits of PrEP.

STEP 4: Same-Day Appointment Scheduling

A same-day appointment is made with a provider to discuss PrEP options and initiate treatment.

STEP 5: Insurance Eligibility Review

The patient's insurance is reviewed to confirm it is on the approved payor list for same-day injectable PrEP initiation (EHR Alert).

STEP 6: PrEP Counseling

The provider delivers counseling on both oral and injectable PrEP options, including benefits, dosing intervals, and follow-up.

STEP 7: Clinical Evaluation

If Apretude is the best option for the patient, the provider assesses readiness for same-day injectable Apretude.

STEP 8: Patient Agreement

Upon counseling and clinical review, the patient agrees to initiate injectable PrEP.

STEP 9: Sample Administration and Buy & Bill Initiation

The healthcare team provides a same-day Apretude sample and initiates the buy-and-bill or pharmacy fill process within the EMR system.

STEP 10: Approval for Future Injections

Insurance authorization is completed for ongoing injectable PrEP delivery via clinic or pharmacy benefits for all subsequent doses.

Clinical Appropriateness

- No restrictions based on age, gender, or other demographics.
- Contraindication: allergy to injection components.
- Consider patient comfort with IM injections.

Ideal Candidate:

- Motivated and understands adherence to dosing windows.
- Commits to follow-up testing and appointment schedule.
- Engages in injection site discussions (e.g., buttock implants, ISR risk).
- Informed that no PrEP option is 100% effective; seroconversion risk is addressed.

Social Factors

- Reliable transportation or support.
- Confirmed insurance coverage or ability to pay.
- Availability for clinic visits at least every two months.
- Ability to maintain communication (phone/internet access)

Adherence Potential

- Past non-adherence to daily oral PrEP may indicate injectable suitability.
- History of consistent attendance at medical appointments.
- No known aversion or adverse reactions to injections.

Monitoring Systems

Follow-Up Protocols

- Nurse visits scheduled every 1-2 months (Apretude).
- Provider visits scheduled every 2, 4, or 6 months.
- Labs drawn at each nurse/provider visit during injection.
- Integrated workflows including same-day SOP, status-neutral approach, and STI testing.

Compliance Tracking

- Coordinated tracking via designated staff.
- Real-time alerts are used to flag delayed or missed injections to ensure timely follow-up.

Outcome Measurement

- Retention in care (oral vs. injectable patients).
- Adherence:
  - Oral: self-reported dosing.
  - Injectable: on-time injections.
- Seroconversion rates post-discontinuation (3 months for oral, 6 months for injectable).
- Patient satisfaction comparison (oral versus injectable).

Best Practices and Recommendations

Clinical Guidelines

- U.S. Public Health Service PrEP Guidelines (2021 Update).

Administrative Procedures

- Standard Operating Procedure development.
- Adherence tracking systems to monitor treatment windows.

Quality Metrics

- HIV positivity rate while on PrEP.
- Retention in care (percentage and duration) for oral versus injectable PrEP.
- Patient satisfaction rates (oral versus injectable).
- Number of patients educated on PrEP versus number initiating PrEP.

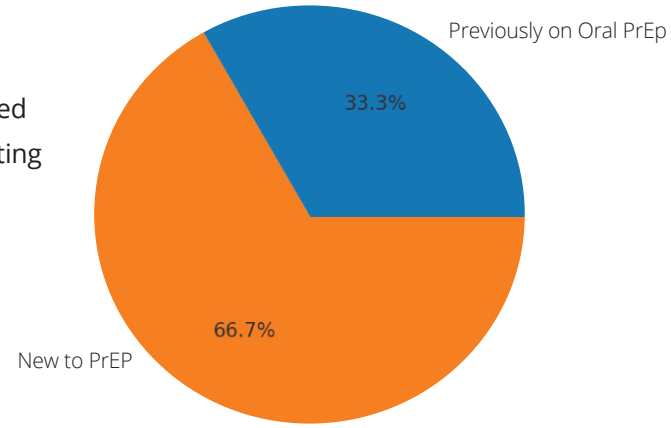
Outcomes

Between October 2024 and March 2025, CAN Community Health implemented the **Test and Inject: Rapid Protect** protocol across its owned and operated locations. A total of 75 patients initiated same-day injectable PrEP (Apretude) under this model. The following key insights were observed from the patient cohort:

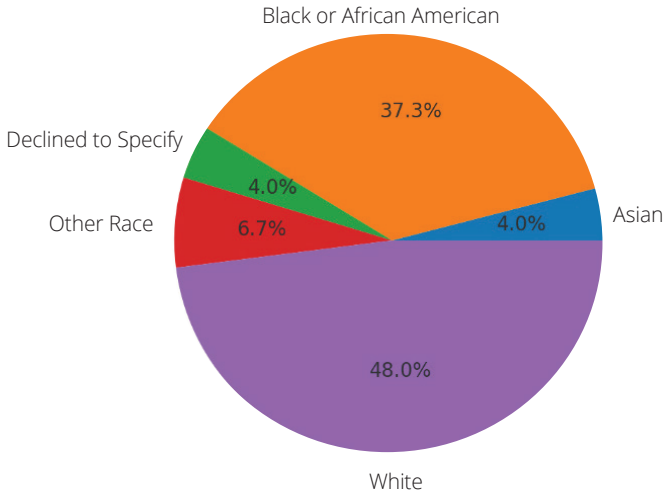
Prior PrEP Experience

One-third of patients (33%) were already engaged in PrEP through oral formulations prior to initiating Apretude, while the majority (67%) were new to PrEP at CAN Community Health.

PrEP History



Race Group



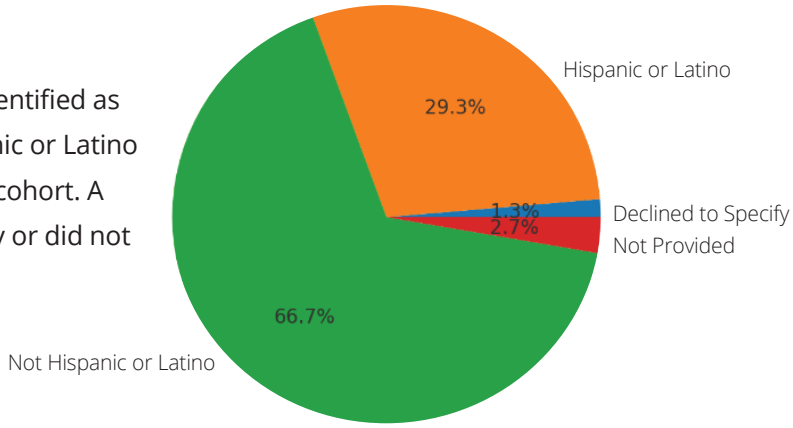
Race

White patients made up the largest racial group (48%), followed by Black or African American patients (37%). Smaller proportions of patients identified as Asian or Other Race, with a minimal number declining to specify.

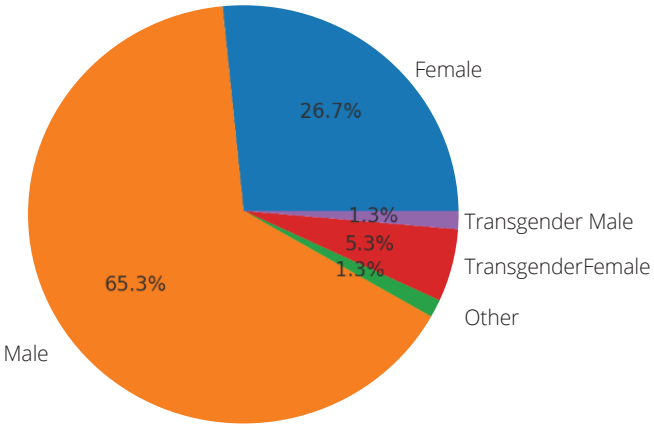
Ethnicity

Over two-thirds (67%) of patients identified as Not Hispanic or Latino, while Hispanic or Latino individuals represented 29% of the cohort. A small percentage declined to specify or did not provide information.

Ethnicity Group



Gender Identity



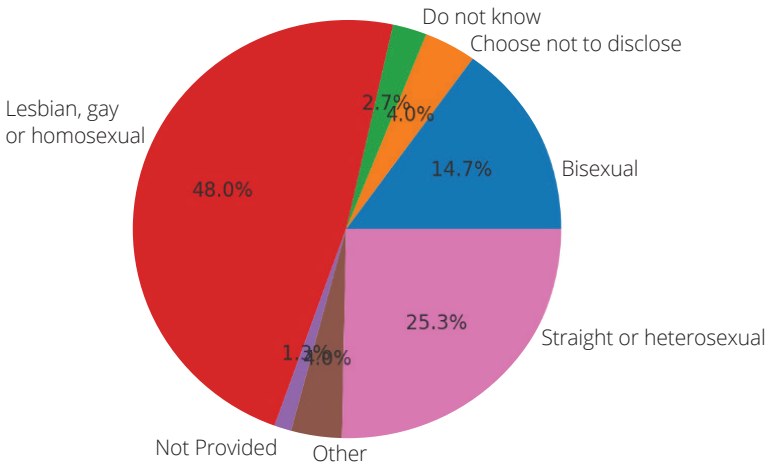
Gender Identity

Most patients identified as male (65%), with females representing 27% of the group. Transgender identities accounted for approximately 7%, while a small proportion identified as Other.

Sexual Orientation

Many patients identified as lesbian, gay, or homosexual (48%), while heterosexual individuals accounted for 25%. Bisexual and other orientations comprised the remaining distribution.

Sexual Orientation



Conclusion And Future Plans

These findings demonstrate the program's effectiveness in engaging both new and previously established PrEP users, while reflecting broad representation across communities. The data reinforces the potential for same-day injectable PrEP to reduce adherence barriers and expand access among priority populations.

Future directions include adapting the model for other long-acting injectable medications and embedding it within comprehensive HIV prevention strategies. Sustained evaluation efforts will promote long-term adherence, optimize clinical and operational workflows, and address implementation challenges.

As injectable PrEP becomes more widely adopted, insurance coverage and reimbursement pathways will continue to be critical. Further research is warranted to assess long-term clinical outcomes, economic impact, and strategies to enhance equitable access, particularly for under served and marginalized communities.

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