

Improving Access to HIV Prevention to End the Epidemic in Rhode Island

PHILIP A. CHAN, MD; AMY S. NUNN, ScD; MICHAELA MAYNARD, NP

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The HIV epidemic continues to cause a significant amount of morbidity and mortality. Globally, over 38 million people were living with HIV and 1.5 million acquired HIV in 2021.¹ In the United States, there were over 36,000 cases of HIV diagnosed in 2021.² Additionally, significant disparities persist among gay, bisexual, and other men who have sex with men (MSM). In the United States, MSM have a one in six lifetime risk of acquiring HIV, which increases to as high as a one in five lifetime risk among Hispanic/Latino MSM, and a one in two lifetime risk among Black/African American MSM.³ In Rhode Island, remarkable progress has been made across the last couple of decades in addressing HIV.⁴ Advances and improved approaches in HIV testing and treatment have led to these significant declines. The United States Preventative Services Task Force (USPSTF) and the Centers for Disease Control and Prevention (CDC) all recommend routine HIV testing.⁵

PRE-EXPOSURE PROPHYLAXIS (PrEP)

Pre-exposure prophylaxis (PrEP) is a medication used by HIV-negative persons to prevent HIV acquisition.⁶ Multiple studies have demonstrated the efficacy of PrEP.⁷ There are now three medications approved as PrEP. Tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) was the first fixed-combination oral medication approved in the United States in 2012. TDF/FTC is approved as a single pill once a day in all people for the prevention of HIV due to sex or injection drug use. The CDC also supports “event-driven” PrEP for HIV prevention around the time of sex. In this approach, two pills of TDF/FTC are taken before sex, one pill 24 hours after sex, and a fourth and final pill 48 hours after sex (i.e., referred to as 2-1-1 dosing).⁸ TDF/FTC has been approved for HIV treatment since 2004 and has a favorable safety profile. Side effects are minimal for most people. TDF can affect renal function as well as bone mineral density, which should be considered in people who are

at risk of these conditions or have pre-existing disease (i.e., renal disease, osteopenia, etc.). For the treatment of HIV, the standard of care is still generally “three active medications”. A fully active treatment for HIV would include TDF/FTC in addition to another medication (recent regimens can include two medications in certain circumstances).

Tenofovir alafenamide and emtricitabine (TAF/FTC) was approved in 2019 as the second PrEP medication to prevent HIV. TAF/FTC has not been studied in cisgender women and is not recommended for people assigned female at birth who are at risk for HIV through receptive vaginal sex.⁸ TAF/FTC is also not recommended for people who inject drugs or for event-driven PrEP because it has not been studied in these cases. TAF/FTC may have fewer renal and bone mineral density side effects than TDF/FTC, but both prevent HIV at similarly high rates. TAF/FTC is associated with slightly more weight gain.⁸ In people on both medications, baseline laboratory testing for creatinine, hepatitis B serologies, HIV, and other sexually transmitted infections (STIs) such as syphilis, gonorrhea and chlamydia is recommended. People should generally follow up every 3–6 months.

In 2021, the first injectable PrEP medication was approved, called cabotegravir. Cabotegravir is administered as an intramuscular injection in the gluteus muscle at baseline, one month, and then every two months thereafter. This new formulation has a favorable safety profile and may be useful for populations with concerns about non-adherence or for patients who prefer not to take a daily medication. Routine monitoring for HIV and other STIs should occur every 3-6 months.⁸ Individuals who are at risk for HIV may prefer injectable PrEP for several reasons, including not having to remember to take a daily pill, less potential side effects, and less stigma due to not having an “HIV medication” bottle around.⁹ In contrast with oral PrEP, there are no renal contraindications to this medication. The clinical trials comparing injectable PrEP to oral PrEP demonstrated increased efficacy of injectable PrEP due to improved adherence.^{10,11} However, significant real-world challenges have limited injectable PrEP in the United States.

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BARRIERS

Costs continue to be a challenge

One of the foremost challenges to scaling PrEP has been the significant out-of-pocket costs associated with taking the medication. Our team and others have demonstrated the consequential impact this has on PrEP use.^{6,12} Importantly, out-of-pocket costs associated with PrEP include not just the medication, but also costs associated with laboratory testing and clinic visits. Out-of-pocket costs related to co-pays and deductibles associated with these three components of care can be in excess of thousands of dollars each year. TDF/FTC is now generic with a cost of approximately \$30–60 and is covered by most insurers. Brand name TDF/FTC (i.e., Truvada) costs \$1,949 for a 30-day supply compared with \$2,283 for brand name TAF/FTC (i.e., Descovy) and \$3,964 for brand name cabotegravir (i.e., Apretude).¹³ In addition, the cost for STI testing and laboratory monitoring can be significant. Current recommendations support extragenital gonorrhea and chlamydia testing. Historically, nucleic acid amplification testing (NAAT) of urine samples has been used for detection of gonorrhea and chlamydia of the urogenital tract. However, in people who perform oral sex or have receptive anal sex, gonorrhea and chlamydia infection can occur at these sites that isn't detected by the urine NAAT. Therefore, testing of oral and rectal specimens for gonorrhea and chlamydia is routine in most sexual health clinics. From a cost perspective, a single NAAT test for chlamydia (or gonorrhea) is typically >\$100. Costs associated with oral, rectal, and urogenital gonorrhea and chlamydia testing in addition to HIV and syphilis testing can be prohibitively expensive, even in patients with insurance. In addition to high out-of-pocket costs, prior authorizations for many types of medication and specifically PrEP can consume considerable time and resources of clinical staff. At this time, prior authorization for injectable PrEP has limited implementation of this PrEP modality.

In March of 2023, a Texas judge issued a decision which prevented the government from enforcing a requirement of the Affordable Care Act (ACA) that insurers need to cover specific preventative care services without out-of-pocket costs.¹⁴ PrEP should be covered under current ACA mandates. In practice, a significant number of patients experience out-of-pocket costs associated with PrEP care.¹⁵ Given that PrEP is part of the national cornerstone of HIV prevention and Ending the HIV Epidemic (i.e., the federal initiative to address HIV in the United States) as well as here in Rhode Island, efforts need to focus on reducing the burden of out-of-pocket costs for people that are at risk of HIV, many of whom come from underserved communities. This is also important as we work to achieve health equity for different communities who are disproportionately impacted by HIV.

RI ADVANCES

New law limits PrEP costs, allows pharmacists to dispense

Rhode Island now has fewer than 100 new HIV cases per year. One reason is that the state has been a leader in expanding PrEP to people who need it most. According to CDC estimates, Rhode Island ranks third (tied with Vermont and behind NY and MA) for PrEP coverage at 30% for those indicated.¹⁶ In 2023, the Rhode Island state legislature also passed a bill that would further improve HIV preventative care in the state.¹⁷ The bill requires insurers to cover all PrEP modalities without cost-sharing and limited prior authorizations.¹⁸ This is a major advance that should remove a commonly cited barrier for PrEP care in Rhode Island and fully cover this important preventative service. In addition, the bill allows pharmacists to dispense PrEP without a prescription by a physician, which will improve access across the state.

To end the HIV epidemic in Rhode Island, we will need to continue to expand access to PrEP. Out-of-pocket costs associated with the medication as well as laboratory testing and clinic visits can be a significant barrier to PrEP use among people at highest risk for HIV acquisition. Rhode Island has been a leader in PrEP implementation and recent legislative bills have the potential to enhance access. Oral PrEP can easily be administered by primary care physicians in outpatient settings, or at sexual health specialty centers such as Open Door Health, The Miriam Hospital Infectious Diseases Clinic, Planned Parenthood, Thundermist, and Providence Community Health Centers, among others. Open Door Health and The Miriam Hospital Infectious Diseases Clinic are also offering injectable formulations. Expanding access to these HIV-prevention technologies has the potential to eliminate HIV in the state of Rhode Island. ❖

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Authors

Philip A. Chan, MD, Brown University; Open Door Health, Rhode Island Public Health Institute; Rhode Island Department of Health, Providence, RI.

Amy S. Nunn, ScD, Open Door Health, Rhode Island Public Health Institute; Rhode Island Department of Health, Providence, RI.

Michaela Maynard, NP, Open Door Health, Rhode Island Public Health Institute; Rhode Island Department of Health, Providence, RI.

Disclosures

All authors report no conflicts of interest.

Correspondence

Philip A. Chan, MD

7 Central Street, Providence, RI, 02907

Philip_chan@brown.edu