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QUICK TAKE

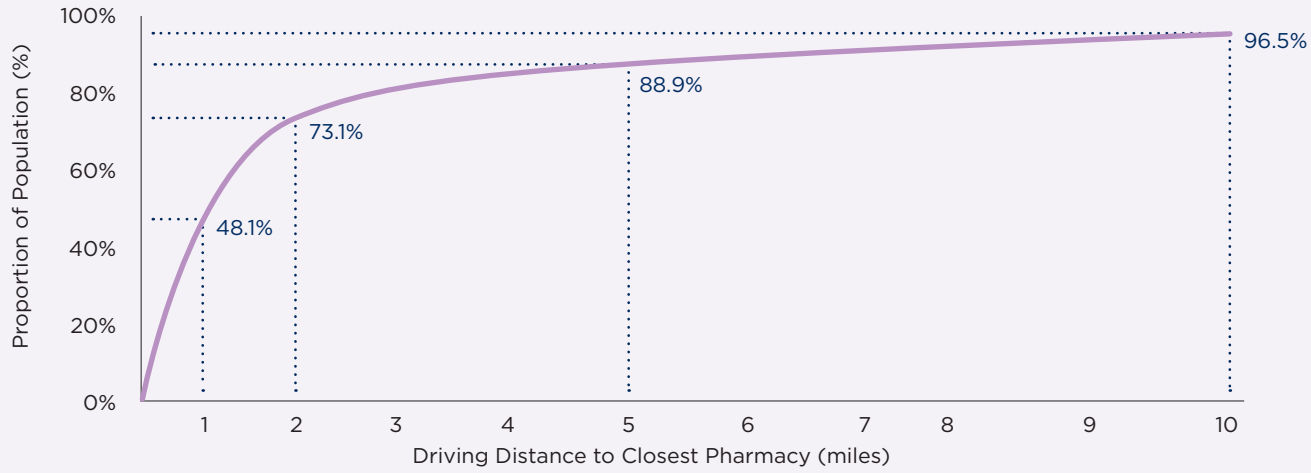
BARRIERS TO PHARMACIST-ADMINISTERED LONGER-ACTING INJECTABLE PREP

ANTIRETROVIRAL THERAPY (ART) FOR THE TREATMENT OF HIV has allowed for improved health and quality of life, and reduced HIV-related mortality along with reduced transmission of HIV. Since 2012, antiretrovirals also have been available as pre-exposure prophylaxis (PrEP). HIV treatment and prevention regimens, however, have depended on adherence to daily oral pills. While highly effective, some people struggle with daily pill taking. Further, uptake and persistence of oral PrEP has been suboptimal to achieve public health impact. In 2021, the Food and Drug Administration (FDA) approved a longer-acting (LA) injectable form of ART and PrEP. Numerous additional forms of LA products for HIV treatment and PrEP are in the research pipeline.

While not intending to replace oral regimens, the existence of alternative forms of administration can give users more options that may support adherence and persistence to PrEP. Too few people with a clinical indication for PrEP ever begin using it, and for those who do, taking medication as prescribed or consistently using PrEP over time can prove challenging. A recent study found that half of individuals discontinued PrEP within the first year. (McCormick C et al. Adherence and persistence of HIV pre-exposure prophylaxis use in the United States. 2024). If users are able to obtain financial access to LA injectable medication through insurance or other programs, it could help make PrEP use more consistent and sustainable. LA injectables could prove especially beneficial to some individuals experiencing homelessness, individuals who use drugs, young people, and others who may find it difficult to adhere to a daily oral medication regimen.

The only LA PrEP medication currently approved by the FDA (cabotegravir), is administered through a gluteal intramuscular injection, and is administered every two months after initial doses. Currently, this product is primarily administered in clinical settings, typically by a nurse or physician. Beyond financing barriers, uptake of LA PrEP often has been limited, due in some cases, to constrained clinical capacity and workflow challenges. Introducing LA

NEARLY 9 IN 10 AMERICANS LIVE WITHIN 5 MILES OF A PHARMACY



Source: Source: NASTAD, Pharmacist Initiated PrEP and PEP, available at https://nastad.org/sites/default/files/2021-11/PDF-Pharmacist-Initiated-PrEP-PEP.pdf
Source: https://www.japha.org/article/S1544-3191(22)00233-3/fulltext

ADEQUATE ACCESS TO LONGER-ACTING PRODUCTS FOR HIV PREVENTION IS A PROBLEM. WHILE COVERAGE BY INSURANCE AND GOVERNMENTAL HEALTH CARE PROGRAMS FOR LA PRODUCTS IS A SIGNIFICANT BARRIER, EXPANDING THE ROLE OF PHARMACIES IN ADMINISTERING THESE PRODUCTS OFFERS AN IMPORTANT PARTIAL SOLUTION TO IMPROVE ACCESS

PrEP in new settings and expanding scope of practice to allow a broader range of health professionals to administer it could help to address current gaps and barriers to access.

PHARMACIST SCOPE OF PRACTICE

Pharmacies are an important venue that can narrow gaps in access to PrEP. Patients visit pharmacies more often than their primary care providers, and nearly 90% of Americans live within 5 miles of a pharmacy. For pharmacies to administer PrEP, this must be authorized under state law. State laws, however, are not always clear on pharmacists' authority to administer LA injectable medications, or on authority to administer PrEP more broadly. In several states the practice of pharmacy includes the authority to administer injections. Some states explicitly authorize pharmacists to administer LA medication, but limit which medication can be administered (i.e., only antipsychotic medications). Where states are clear on authority to administer PrEP, they remain unclear on authority to administer LA PrEP. In recent years, however, many states have extended pharmacists' scope of practice through legislation or collaborative practice agreements.

As it stands, at least ten states have enacted legislation that either:

1) modifies scope of practice laws to expand pharmacist authority to prescribe PrEP
2) implements statewide standing orders allowing pharmacists to prescribe PrEP, or
3) gives authority to medical directors of local health departments to grant standing orders allowing pharmacists to prescribe in their jurisdiction.

These states offer a pathway for expanding on the ability of pharmacies and pharmacists to fulfill this critical role.

PHARMACIST REIMBURSEMENT

State and federal laws that determine how health services are billed state that "healthcare providers" can be reimbursed for services they perform, but tend to exclude pharmacists from the definition of "healthcare providers." Because of this, in most states pharmacists are not assured of reimbursement for services provided that would otherwise be reimbursed to other health providers. In some cases, pharmacists are not being paid for services that already fall within their scope of practice. This uncertainty around reimbursement poses a significant barrier to utilizing pharmacies to increase access to HIV prevention. Pharmacist administered LA would allow additional points of contact through which individuals could access HIV prevention. This, however, would require pharmacists to engage in additional services, such as testing and counseling, for which they would not be assured of reimbursement. Additionally, providing HIV prevention services requires training and education, and pharmacists may be hesitant to invest in such training when reimbursement is uncertain.

Several states, including Kentucky, New Mexico, Ohio, Oklahoma, Texas, Washington, and West Virginia, have passed legislation calling for payment parity for pharmacists. The various bills require insurers to reimburse pharmacists no less than other healthcare professionals providing similar services, as long as the services are within the pharmacist's scope of practice. Ensuring pharmacist payment parity would encourage pharmacists to engage in HIV prevention, potentially making LA products more accessible. Adequate access to longer-acting products for HIV prevention is a problem. While coverage by insurance and governmental health care programs for LA products is a significant barrier, expanding the role of pharmacies in administering these products offers an important partial solution to improve access. Building on the work of these initial states, policymakers should consider updates to laws and policies to seize the opportunity that pharmacies offer.

TO LEARN MORE

See *Big Ideas Brief: Effective Implementation of Longer-Acting HIV Treatment and PrEP Requires Delivery System Innovation*, May 2023, available at the link below.

NASTAD, Pharmacist Initiated PrEP and PEP, available at https://nastad.org/sites/default/files/2021-11/PDF-Pharmacist-Initiated-PrEP-PEP.pdf.

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This Quick Take is a product of the Longer-Acting HIV Treatment and Prevention Policy Project of the **O'Neill Institute for National and Global Health Law** and was developed with support from ***Gilead Sciences***, ***Merck***, and ***ViiV Healthcare***. It was authored by **Aiseosa Osaghae** with input from community stakeholders. The views expressed are solely those of the author.

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QUICK TAKE

EXPANDING ACCESS TO LONG ACTING HIV PREVENTION AND TREATMENT THROUGH MOBILE PHARMACIES

WHILE THERE IS NOW A WIDE ARRAY OF PRODUCTS available for the treatment of HIV, as well as a growing number of products for prevention, there remains a need to expand access so that the populations most vulnerable to HIV have their treatment and prevention needs met. Both HIV treatment and PrEP typically involve daily oral pills. Many people from communities most impacted by HIV, however, face challenges in taking medication daily. Innovative longer-acting (LA) products have been developed that give users alternatives to daily pill taking that offer the potential to increase adherence and persistence to medication regimens. To date, the FDA has approved LA products that only need to be administered every two months, but more products are on the horizon with likely different dosing schedules. While potentially transformative, uptake of these new LA products has been slow and efforts are needed to expand access.

Insurance and financing barriers often pose significant obstacles to accessing these products that require policy attention and likely consumer advocacy. At the same time, delivery of LA products often requires significant clinical transformation that can impede adoption of these new LA modalities. Supporting this transformation, however, may create new opportunities to innovate in how services are delivered to better meet the needs of people with or at risk for HIV.

MOBILE PHARMACIES MAY OFFER A WAY TO EXPAND ACCESS

One solution may lie in expanded use of mobile health (often called mobile vans). Mobile health has long been used to fill gaps in access to healthcare. Mobile health provides hope for those who face transportation barriers and can address cost barriers as well. Mobile pharmacies could prove to be effective in narrowing health disparities by broadening access to the medications necessary to prevent and treat HIV.

In November, Yale researchers established Connecticut's first mobile pharmacy.[1] Sandra Springer, a professor of medicine and HIV/AIDS researcher, established the mobile pharmacy as part of an effort to find innovative ways to treat people with HIV, Hepatitis C, and substance use disorders (SUD). The van offers a promising model for increasing access while offering well-rounded HIV care, as it links patients to community health workers, telehealth clinicians, and provides a means to prescribe and dispense treatment medications.

1 Erin Hu, *Yale Researchers Help Create State's First Mobile Pharmacy*, Yale Daily News, Oct. 13, 2023.

HOW ARE MOBILE HEALTH UNITS REGULATED?

State legislation around regulation of and limitations on operation of mobile health units is varied. Some states set limits based on the types of clinics that are authorized, and only provide express authority for mobile operation of specific types of facilities, such as mental health or behavioral health clinics. In some states, only

LONGER-ACTING MEDICATIONS: KEY STEPS IN EXPANDING ACCESS VIA MOBILE PHARMACIES

- **Establish state regulations** granting clear authority for mobile pharmacies to operate flexibly
- **Minimize geographical limitations** on mobile pharmacy operations
- **Expand scope of providers** who can provide care within mobile clinics
- **Broaden scope** of practice for pharmacists
- **Provide clear authority** for pharmacists to administer long acting injectable medications, particularly intramuscular injections
- **Facilitate adequate billing** for pharmacists' services

MOBILE CLINICS ARE A PROMISING DELIVERY MODEL FOR LA TREATMENT AND PREVENTION, AND INCORPORATING LA MODALITIES INTO MOBILE DELIVERY MODELS SHOULD BE A PRIORITY.

specific types of providers are authorized to provide health services within a mobile health clinic, while others regulate types of providers as well as the types of services that can be offered in a mobile health clinic.

HOW CAN STATES SUPPORT EXPANSION OF LA INTO MOBILE PHARMACIES?

Most mobile health clinics have limited authority to provide pharmaceutical services. In Connecticut, legislation was passed to allow pharmacies to operate outside of the storefronts for which they were initially licensed, which helped pave the way for Yale's mobile pharmacy to operate. The Connecticut bill, SB1102 , authorizes pharmacists to order and administer HIV related testing. It also provides authority for pharmacists to administer HIV related prophylaxis as needed, as long as training requirements are met, and expressly provides authority for mobile pharmacies to operate in temporary locations to meet the needs of communities with inadequate access to pharmacy services. Similar legislation in other states can significantly narrow disparities in access.

Connecticut's legislation, however, comes with limitations on the location from which the mobile pharmacy can operate, which may prove to be a hindrance. Mobile pharmacies in the state cannot operate for longer than seven consecutive days in one location, or more than fourteen days within a five-mile radius of a prior location. Additionally, it is unclear whether the legislation permits pharmacists to administer intramuscular injections other than vaccinations. Clarity around pharmacist authority to administer LA products will support efforts to expand access to LA treatment and prevention via mobile pharmacies.

CURRENT LIMITATIONS OF MOBILE CLINICS FOR LONGER ACTING TREATMENT AND PREVENTION

Mobile clinics offer promise for delivering existing and future longer-acting products. Yet currently available longer-acting treatment may not be suited for mobile delivery because the only available LA formulation for treatment (cabotegravir/ripilvirine) requires cold-storage. Many other LA products are in the pipeline, however, and currently available LA PrEP (cabotegravir) does not require cold storage. While it is not known whether future LA modalities for treatment and prevention will have similar constraints, mobile clinics are a promising delivery model for LA treatment and prevention, and incorporating LA modalities into mobile delivery models should be a priority.

Another challenge is the business case for operating mobile health services. Some standalone for-profit pharmacies may find that the operating costs do not justify the investment. Mobile health allows for the provision of services often at lower costs than traditional healthcare models, however, and health centers and safety net clinics might find that this is a tailored way to reach vulnerable populations and better meet the specific needs of some clients.

THE TIME IS NOW

Ensuring that mobile pharmacies can not only provide medication, but facilitate access to other services such as testing and counseling, will allow mobile pharmacies to efficiently address gaps in access to HIV treatment and prevention. Expanding pharmacists' scope of practice, broadening the types of services and providers authorized to prescribe and administer medication within a mobile pharmacy, and ensuring that pharmacists can be billed and paid for their services will allow mobile pharmacies to play an impactful role in bringing much-needed access to LA products to the populations that need it most.

TO LEARN MORE

See *The scope and impact of mobile health clinics in the United States: a literature review*, found at the link below, to learn more about the role of mobile health care in the United States.

Stephanie W. Y. Yu et.al, The Scope and Impact of Mobile Health Clinics in the United States: a Literature Review, 16 Int. J Equity Health 178 (2017).

2 https://www.cga.ct.gov/2023/ba/pdf/2023SB-01102-R000221-BA.pdf

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