



BIG IDEAS

ENDING THE HIV EPIDEMIC —
SUPPORTING ALL PEOPLE LIVING WITH HIV AND REDUCING NEW TRANSMISSIONS

EFFECTIVE IMPLEMENTATION OF LONGER-ACTING HIV TREATMENT AND PrEP REQUIRES DELIVERY SYSTEM INNOVATION

SCIENTIFIC ADVANCEMENTS RESULTING FROM OUR LONG-TERM NATIONAL COMMITMENT TO HIV RESEARCH have begun producing new products both for HIV treatment and prevention that do not require daily dosing. The first standalone longer-acting (LA) FDA-approved products are delivered by intramuscular injection every 1-2 months, but future products may require far less frequent injections or could come in other forms such as small implants under the skin or oral medications. These products represent exciting advances because they give users more options to stay engaged in the HIV treatment or prevention continuum. While many patients and providers speak of how transformative these products can be, access to these products is limited and a myriad of barriers prevent individuals from accessing them. Deliberate policy actions are needed to ensure that these innovations do not bypass the individuals and communities that stand to benefit the most from them.

Effectively integrating LA treatment and prevention modalities into our existing HIV services system will require significant adaptations and innovation. Focusing attention on four key issues can offer a pathway for expanding access to innovative products and improving equity:

1. HELPING CLINICS TO SCALE-UP ACCESS TO LONGER-ACTING PRODUCTS

Administering antiretrovirals in the clinic every 1-2 months is a fundamental change from the current standard practice for delivering most medications wherein a provider writes a prescription for oral regimens that an individual fills at a pharmacy or

POLICY NEEDS TO MATCH RESEARCH PROGRESS

Giving individuals new options to access longer-acting HIV treatment and PrEP has the potential to greatly improve outcomes and satisfaction with care. Key policy actions to increase equity and improve population-level outcomes include:

Helping Clinics to Scale-Up Access to Longer-Acting Products

Create new opportunities for communities of practice and implementation science.

Overcoming Finance and Insurance Barriers

Encourage professional organizations to develop prescriber guidance and support monitoring and advocacy in support of user access to longer-acting products. And, encourage all AIDS Drug Assistance Programs (ADAPs) to add longer-acting products to their formularies.

Breaking Out of the Box: Longer-Acting Delivery Outside of the Clinic

Assess regulatory and financing barriers to permit greater use of alternative delivery sites, including pharmacies, mobile clinics, and home administration.

Keeping the Focus on Equity and Population-Level Impacts

Establish metrics and goals and develop strategies for improving outcomes among priority populations.

receives via mail-order. This has implications for managing clinic workflow, the level and type of staffing and training needed, and new budgetary and space management issues to stock and maintain an inventory of highly expensive products (which could carry risks if excess product is ordered that expires, insufficient stock leads to service interruptions, or payor reimbursements are less than the medication acquisition costs).

POLICY ACTION: Create new opportunities for communities of practice and implementation science

These challenges are real and have contributed to the sluggish implementation of LA products. While not insurmountable, the changes involved in adapting service delivery models are complex and exacerbated by differences in clinic size, structure, financing arrangements, and geographic location, among other factors. There is a need for expanded opportunities for shared learning among clinics. New dialogues may be needed with pharmaceutical manufacturers, suppliers, and payors to minimize financial risk with purchasing product that may be associated with demand that is difficult to forecast and potentially result in acquisition and administration costs that exceed payor reimbursement.

Multiple partners must be engaged to foster this kind of innovation. The Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau (HAB) oversees Ryan White HIV/AIDS Program funded initiatives that support clinical leadership and adaptation. This includes the AIDS Education and Training Centers (AETCs) that provide regional networks of training and technical assistance to HIV health care providers, Target HIV, a technical assistance platform supported by HAB, as well as the Special Projects of National Significance (SPNS) program, which supports demonstration projects that can test and evaluate new service delivery models, including their current LA-ART demonstration project, the ALAI UP Project,¹ which seeks to help clinics across the United States develop injectable HIV treatment programs with the goal of addressing inequity in health outcomes. Associations of clinical providers, as well as partnerships with pharmaceutical manufacturers and payors can support shared learning to overcome clinic-level barriers and achieve greater access to LA medications. In addition to the surveillance of LA medications, the Centers for Disease Control and Prevention (CDC) is currently providing technical assistance to support LA-PrEP implementation, as well as funding a LA-ART demonstration project for formerly incarcerated persons on release from prison. The National Institutes of Health (NIH) through its support for HIV implementation science research also can also contribute to program innovation and evaluation.

2. OVERCOMING FINANCING AND INSURANCE BARRIERS

In our complicated health system, people living with and vulnerable to HIV rely on various types of insurance and other health care programs to access services. Each of these has their own rules, limitations, and consumer protections. As we saw with the implementation of PrEP, early access was (and remains) uneven by payor, and due to cost avoidance pressures, many private insurers have created opaque, burdensome and sometimes insurmountable prior authorization processes. Overcoming such barriers to longer-acting HIV treatment and PrEP will require a range of resources for users seeking access to these products. Community advocates, prescribers and clinics must take the time to engage with payors to overcome overly burdensome prior authorizations that are not evidence based.

POLICY ACTION: Encourage professional organizations to develop prescriber guidance and support monitoring and advocacy in support of user access to longer-acting products. And, encourage all AIDS Drug Assistance Programs (ADAPs) to add longer-acting products to their formularies

PROCUREMENT AND DELIVERY BARRIERS

Longer-acting prevention and treatment products introduce novel barriers to already complex and uneven healthcare systems. These relate to clinical, delivery system, medication procurement and other barriers.

In March 2022, NASTAD produced a brief, *Cabenuva (cabotegravir & rilpivirine extended-release injections) Considerations for AIDS Drug Assistance Programs*, that provides a helpful overview of relevant clinical, delivery system, medication procurement and other issues, see https://nastad.org/sites/default/files/2022-04/PDF_Cabenuva_ADAP_NASTAD_March%202022.pdf.

Given the diverse ways that HIV services are financed and delivered, there is no single best procurement model, but it will be important for clinics and providers to consider the relative benefits and drawbacks of current models, including Buy-and-Bill, White Bagging, and Clear Bagging in order to overcome some of the procurement related barriers to greater access to longer-acting products.

SAN FRANCISCO GENERAL'S WARD 86 OFFERS EARLY LESSONS

Ward 86 is a large HIV clinic based at San Francisco General Hospital at the University of California, San Francisco (USCF) that was established early in the HIV epidemic. It serves publicly insured patients who often have high levels of housing instability and stimulant use. Since 2021, the clinic has been providing longer-acting treatment both to people who are virally suppressed and those who are not, alongside wraparound services to address unmet needs for housing, substance use and mental health. They recently published findings from this demonstration project that highlight two individuals who had been living with HIV for more than a decade and had never reached sustainable viral suppression, but who became virally suppressed as a result of longer-acting injections.

It will take time to replicate these findings in other settings with fewer resources and in other parts of the country, but they demonstrate the tantalizing potential for emerging treatment (and prevention) modalities.

For more details, see *Clin Infect Dis.* 2023 Feb 1; 76(3): e645-

Whenever new products are approved, it can take time for the delivery system to integrate them, especially when innovative provider-administered products come with higher costs and more complex procurement and payment processes compared with existing products. Therefore, as we saw with PrEP, often local-level user monitoring and advocacy is needed to push payors to remove barriers to access. Given the range of safe and effective existing products, it is also not necessary for every person on treatment or PrEP to switch to a longer-acting product. Clinical providers have an important role to play in defining when access should be prioritized. Therefore, evidence-based policy must be developed that ensures that individuals and priority populations that are not presently benefitting from oral medicines and existing care systems will have access to longer-acting products. The National HIV/

AIDS Strategy for the United States identifies five priority populations—gay, bisexual, and other men who have sex with men (in particular Black, Latino, and American Indian/Alaska Native men), Black women, transgender women, young people aged 13–24 years, and people who inject drugs. While all should be considered priorities for expanded access to HIV treatment and PrEP, including longer acting options, available evidence suggests that challenges for daily pill adherence are particularly acute among young people, and this group overlaps with the other priority populations. Programs that specifically seek to use longer-acting products as a way to increase adherence to treatment and PrEP should offer a motivating opportunity to greatly improve outcomes.

3. BREAKING OUT OF THE BOX: LONGER-ACTING DELIVERY OUTSIDE OF THE CLINIC

The COVID-19 pandemic demonstrated that new approaches to service delivery can maintain engagement in care and support the initiation of PrEP. For example, removing longstanding barriers to telehealth and creating incentives for its adoption is one of the permanent outcomes of the pandemic. Concurrently, researchers have been developing new self-testing modalities for HIV and other sexually transmitted infections (STIs) and creating and evaluating new models for integrating self-sample collection and self-testing into clinical practice. These innovations help address previously identified challenges with clinic workflow and remove barriers to ongoing engagement in care. Developing new models that expand the range of venues for receiving longer-acting products should be an important innovation.

POLICY ACTION: Assess regulatory and financing barriers to permit greater use of alternative delivery sites, including pharmacies, mobile clinics, and home administration.

Health care is regulated primarily at the state level, subject to overlapping federal rules and funding requirements, and sometimes local ordinances also can come into play that create barriers to adopting new models of care. While the impetus for some of these regulations is to protect health and safety, some

PROGRAMS THAT SPECIFICALLY SEEK TO USE LONGER-ACTING PRODUCTS AS A WAY TO INCREASE ADHERENCE TO TREATMENT AND PrEP SHOULD OFFER A MOTIVATING OPPORTUNITY TO GREATLY IMPROVE OUTCOMES.

are outdated, largely protect entrenched interests, and create unnecessary barriers to innovation. A first step is to better understand the range of laws and policies that allow or prohibit health care services, including HIV treatment and PrEP to be delivered outside of a clinic and by nontraditional providers. Since many in the HIV community are interested in specific models that include expanded use of pharmacies, mobile clinics, as well as either home-delivered services or self-administered services that can be used in the home, it is important to systematically examine these policies to understand barriers and facilitators of new ways of providing services.

4. KEEPING THE FOCUS ON EQUITY AND POPULATION-LEVEL IMPACTS

Without deliberate policy action to overcome many of the structural barriers that produce health inequities, new innovations often exacerbate rather than reduce inequities. Thus, the people who benefit the most from existing service systems are the ones who have the best and earliest access to new approaches. The promise of longer-acting products, however, is not in giving people more options if the currently available treatment and PrEP options work for them. The promise comes in using innovation to reach chronically underserved communities. One of the disheartening aspects of early implementation of longer-acting HIV treatment is that FDA approval limited access to well suppressed individuals, due to clinical trials not prioritizing persons who have struggled to achieve and maintain viral suppression. Early experience, however, demonstrates that longer-acting products can help individuals that previously were unable to achieve and maintain viral suppression to do so.²

POLICY ACTION: Establish metrics and goals and develop strategies for improving outcomes among priority populations

To ensure that improving equity is a central outcome of expanded access to LA products, metrics and goals for improving outcomes among priority

populations must be established and used to drive accountability and progress. This includes the aforementioned priority populations, as well as persons who have not achieved viral suppression using daily oral medications. These and other metrics that measure drivers of inequities can be used at the national, state, local, and clinic levels to guide our response to addressing unmet HIV treatment and prevention needs using LA products. Further, federal programs and other payors must fund demonstration projects that improve delivery models that pair provision of LA medications with services for substance use, mental health, and housing, which will advance equity of access and use. For the most impacted populations, equity should be a fundamental criterion for identifying implementation models and site selection.

THE TIME IS NOW

In a world with a broad array of safe and effective products to treat and prevent HIV, the opportunity provided by innovative longer-acting products is not simply to give users more options. Rather, it is to use these innovations to provide a leap forward toward fewer inequities, better outcomes, and more sustainable services delivery models. Realizing this promise requires a commitment to implementation science and adaptation by policymakers, clinical providers, researchers, and community stakeholders. Done right, these products can be transformative.

ENDNOTES

- 1 Accelerating Implementation of Multilevel-strategies to Advance Long Acting Injectables for Underserved Populations <https://www.alai-up.org/>.
- 2 Christopoulos KA et al. First demonstration project of long-acting injectable antiretroviral therapy for persons with and without detectable human immunodeficiency virus (HIV) viremia in an urban HIV clinic. *Clinical Infectious Diseases*. 2023 Feb 1;76(3):e645-51.