

QUICK TAKE

NEW OPTIONS FOR HIV TREATMENT AND PREVENTION ARE HERE

OVER THE PAST TWO DECADES, HIV treatment has drastically reduced illness and death related to HIV, and it is possible to live a long, high-quality life. People living with HIV have a large number of medication options that are highly effective, and for prevention, there is a small, but growing number of options for pre-exposure prophylaxis (PrEP). HIV treatment must be taken continually over one’s life and typically involves taking medicine at least once daily, usually an oral pill(s).

Many of the communities most heavily impacted by HIV face a variety of challenges in taking medication daily. Indeed, one-third of people living with HIV in the US are not virally suppressed and even fewer maintain viral suppression over longer periods of time. While viral suppression is improving across all groups, improvement is needed for everyone. Large disparities persist across race, age, and gender. More convenient regimens that do not require daily pill taking could improve adherence to HIV treatment and PrEP. In addition to recently approved longer-acting (LA) injectable products, the HIV prevention research pipeline currently includes a variety of innovative modalities that give users more choices, including post-exposure prophylaxis (PEP), rectal douches, and multipurpose prevention technologies (MPT) that prevent unwanted pregnancy and STIs, in addition to HIV.

LONGER-ACTING MEDICATIONS: WHY THEY MATTER

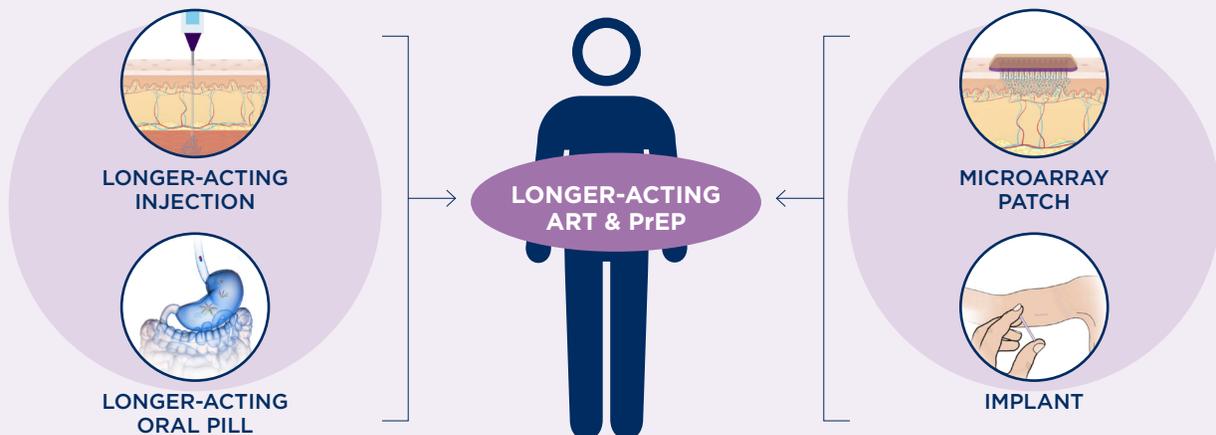
For a variety of reasons, many individuals with acute and chronic health concerns do not take their medications daily, including people living with HIV on antiretroviral therapy (ART) and people who are using pre-exposure prophylaxis (PrEP). Longer-acting (LA) medications do not require daily pill taking and are generally effective for a month or longer, requiring less frequent administration. These types of products are widely available for contraception and mental health conditions. LA options are becoming available for ART as treatment and for prevention as PrEP.

WHAT IS LONGER-ACTING HIV TREATMENT AND PREP?

Longer-acting products provide more choices for consumers.

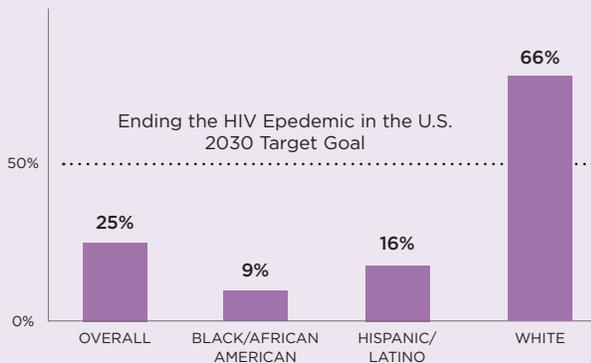
Longer-acting (LA) medications are those that are effective for a month or longer, requiring less frequent administration. So far, a LA injection is approved for HIV treatment and another for PrEP that both require administration once every two months. There are many LA products currently in development, including injections and oral formulations, some of which would only need to be administered once or twice a year. Other LA products are in development as implants (which are small devices inserted under the skin, often in the arm), and microarray patches (also known as microneedle patches) that are applied like a small bandage.

TECHNOLOGIES FOR DRUG DELIVERY



TEN YEARS IN, PrEP'S PROMISE HAS YET TO BE REALIZED

PrEP COVERAGE IN THE U.S. BY RACE/ETHNICITY, 2020



It has been ten years since the FDA approved Truvada as PrEP, yet some of the most impacted communities, such as Black and Latinx gay and bisexual men, are still vastly underrepresented among PrEP users. Among people for whom PrEP is recommended, stark disparities exist across age and gender as well. For example, young people ages 16-24 are the least likely to be using PrEP compared to other age groups; only about 16% of this population for whom PrEP is recommended were prescribed it. Cisgender women represented about 1 in 5 new HIV diagnoses in 2019, but their use of PrEP is far below that of men, even when accounting for the smaller share of women for whom PrEP is indicated.

Source: PrEP for HIV Prevention in the U.S., CTRS. FOR DISEASE CONTROL AND PREVENTION (Nov. 23, 2021).

ARE THESE PRODUCTS SAFE AND EFFECTIVE?

In the US, the Food and Drug Administration (FDA) must first determine that a product is both safe and effective. To obtain FDA approval, researchers must conduct laboratory, animal, and clinical testing with people on the product's safety and effectiveness and submit that information to the FDA. To date, there are two FDA approved LA medications for HIV treatment and prevention. These two products were proven to be safe and effective in clinical trials.

WHAT WILL IT TAKE TO ENSURE THAT INNOVATIVE PRODUCTS SERVE COMMUNITIES IN NEED?

LA products have the potential to transform HIV treatment and prevention. Technological innovations are not a remedy, however, for structural barriers to care. As we embrace the potential for LA products to give individuals more options and improve adherence, we

also need to adopt innovations in how treatment and prevention services are delivered, including expanding access to make it easier for people to stay in care and increasing access in rural and underserved areas. Existing HIV prevention and treatment sites will need to adapt as providing LA products will require staff training, changes to workflow, medication stocking and ongoing clinical education. New and existing treatment and prevention services offerings must be patient-centered and stigma-free, promoting sexual health for all communities. Proactive strategies are needed to understand consumer questions, concerns, and potential barriers to adoption. While some of these barriers are pre-existing and relate to HIV treatment and PrEP use more generally, there are likely questions and concerns that researchers and providers have not considered. Further, LA products pose additional challenges. Self-administered oral formulations (traditional and LA) maintain autonomy and may be preferred by patients versus increased visits required for injectables. More frequent diagnostics required by these new modalities may exacerbate disparities related to access, requiring consumers to spend more time and other resources getting to and from appointments, as well as increase cost and insurance reimbursement considerations.

POLICY REFORM IS NEEDED TO ENSURE EQUITABLE ACCESS

Specific efforts are needed to ensure that innovations in LA treatment and PrEP do not lead to even greater disparities across groups. Some states have already mandated that all payers must cover LA-ART, which can be part of such a response. We also need more implementation research and an increased evidence base for real world rollout, use, and expanded access. The excitement for these innovative products must match our commitment to ensuring they improve the lives of communities impacted by HIV.

TO LEARN MORE

See other 2022 Quick Takes from the Longer-Acting HIV Treatment and Prevention Policy Project, and for additional background information, please see our 2018 series of briefs prepared for amfAR, *Long-Acting HIV Treatment and Prevention are Coming: Preparing for Potential Game-Changers*, all found at the link below.

See various longer-acting materials produced by AVAC at <https://www.avac.org>.