Long-acting antiretroviral therapy suppresses HIV among people with unstable housing, mental illnesses, SUD

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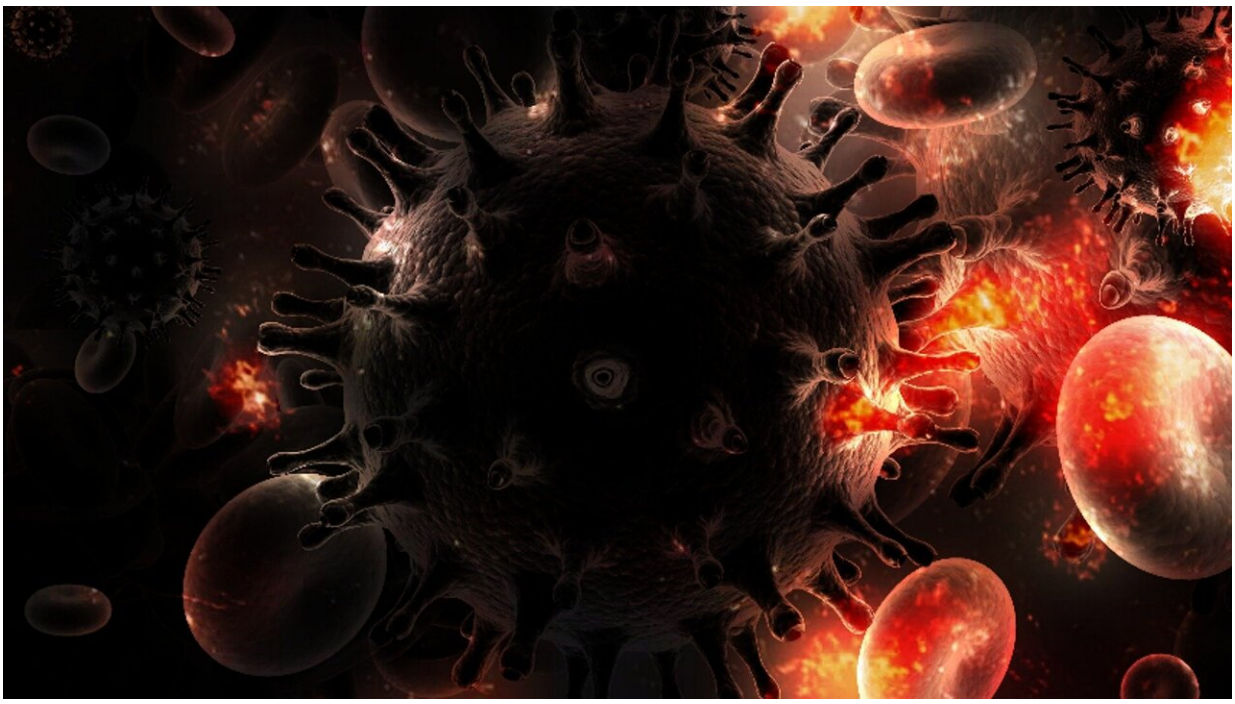

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A long-acting antiretroviral treatment (LA-ART) given every four to eight weeks, and delivered with comprehensive support services, suppressed HIV in people who were previously not virologically suppressed. This is according to an ongoing demonstration study of 133

people with HIV in San Francisco, funded by the National Institutes of Health. The study focused on reaching people who have historically had decreased access to antiretroviral therapy (ART), including people experiencing housing insecurity, mental illnesses, and substance use disorders. The study findings indicate that long-acting injectable ART can benefit people who face many treatment barriers and are historically underserved.

The findings were presented at the Conference on Retroviruses and Opportunistic Infections (CROI) by Monica Gandhi, M.D., M.P.H., professor of medicine and associate division chief at the University of California, San Francisco, and medical director of the Ward 86 HIV clinic at San Francisco General Hospital. The research was supported in part by the National Institute of Allergy and Infectious Diseases (NIAID) and the National Institute of Mental Health (NIMH), both part of the National Institutes of Health.

"ART has been a medical gamechanger for saving lives as treatment and as a potent prevention tool with Undetectable=Untransmittable, or U=U. Yet, we have substantial gaps that remain for people who face co-occurring health, housing, and other socio-economic challenges," said Carl W. Dieffenbach, Ph.D., director of the NIAID Division of AIDS. "Making progress against the HIV pandemic necessitates that societies prioritize reaching those who have historically been left behind, yet stand to benefit the most from making newer, easier formulations of ART available."

Although there are highly effective options for daily oral ART to treat HIV, there are many barriers to adherence, including housing or food insecurity, untreated mental illnesses, substance use disorders, transportation challenges, legal system involvement, and other factors.

Long-acting injectable medications, which are given every four or eight

weeks, could help people overcome some of these day-to-day treatment barriers. However, the only LA-ART combination regimen approved by the U.S. Food and Drug Administration for people with HIV, injectable intramuscular cabotegravir and rilpivirine, is approved only for patients who have already achieved viral suppression and are currently on oral ART. As such, people who face challenges adhering to daily oral ART also face barriers to accessing LA-ART.

To address this gap, Dr. Gandhi and her team sought to enroll patients in their study who have historically been underserved, including those with high rates of unstable housing, mental illnesses, and substance use disorders. Participants did not have to be on daily oral ART or have viral suppression to be eligible for the study and to start treatment with the long-acting injectable.

Between June 2021 and November 2022, 133 study participants with HIV started on LA-ART, including 57 people (43%) with untreated or unsuppressed HIV and 76 people (57%) who were virologically suppressed on oral ART. The researchers performed biweekly review of each participant's health status, and pharmacy staff conducted regular outreach to remind patients of their injection appointments.

Among participants who began the study with virologic suppression, all (100%) remained suppressed over the period of follow-up. Among participants who did not begin the study with virologic suppression, at a median of 33 days, 55 out of 57 (96.5%) had achieved virologic suppression. Only two of the 133 study participants did not achieve or maintain viral suppression, a rate of 1.5%, in line with findings from previous clinical trials that studied LA-ART in people with HIV who had achieved viral suppression on daily oral ART.

Participants had a median age of 45, and 88% identified as cisgender men, 68% identified as non-white, 58% reported having unstable

housing, 8% reported experiencing homelessness, 38% reported having a mental illness, and 33% reported substance use.

"Our patient population does not look like the patient population that got enrolled in the clinical trials to determine the approval criteria for long-acting ART," said Dr. Gandhi. "It is the role of researchers to help address disparities through intentionally and proactively including diverse groups in our studies, and for this population to have the same successful outcomes as those in the other clinical trials was very important and exciting. We want to have the ability to offer these drugs to patients who stand to benefit the most, including those who face challenges adhering to daily treatment."

Together, results from three landmark NIAID-funded clinical trials—START, SMART, and HPTN 052—conclusively demonstrated that starting antiretroviral treatment promptly after HIV diagnosis, and continuing it without interruption, protects the health of the person living with HIV while preventing transmission of the virus to sexual partners. Yet persistent barriers, including stigma, often delay the start of ART and reduce adherence among people who face significant health and social challenges.

Further clinical trial data on the effectiveness of LA-ART in achieving and sustaining virologic suppression among people who face treatment barriers is needed. An ongoing NIAID-supported clinical trial (The LATITUDE Study) conducted in the AIDS Clinical Trials Group network is using a randomized design to directly compare the efficacy of LA-ART and oral ART regimens among people experiencing adherence challenges.

The study authors also note that reaching patients and following up with them requires intensive resources, a limitation that should be addressed to make LA-ART more widely available.

"The most effective treatments are those that fit into the lives of people who need them. These findings show that with the right support, long-acting ART can make it easier for people with HIV who face barriers in adhering to daily oral treatment to keep the virus under control," said NIMH Director Joshua A. Gordon, M.D., Ph.D.

"Dr. Gandhi and her team have made state-of-the-art HIV treatment finally available to people with unique challenges, like those who use drugs, and have found success," said Nora Volkow, M.D., director of the National Institute on Drug Abuse. "This is the sweet spot for addressing HIV—thinking outside the box to deliver care in a way that meets people's needs, even when that means it happens outside the clinic walls, by phone, or on neighborhood streets. This can be done—but it requires creativity and resolve."

More information: M Gandhi, et al. "High Virologic Suppression Rates on Long-Acting ART in a Safety-Net Clinical Population" (Presentation #518). Abstract from the 2023 Conference on Retroviruses and Opportunistic Infections, 2023.

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