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GLOBAL HEALTH

The drug lenacapavir is a mighty weapon against HIV. Its rollout gets mixed reviews

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Michal Ruprecht



An injection of the new drug lenacapavir provides six months of protection against infection by HIV.

Osodi Emmanuel/Reuters

Kalisizo, Uganda — Along the deeply rutted red dirt roads of central Uganda's Lake Victoria coast, there is little for miles beyond banana groves and bustling markets. The landscape is unassuming — and very dusty. Yet few places have done more to shape HIV care.

Irene knows this well. For the past three years, the soft-spoken 22-year-old, who is HIV-negative, has been a participant in one of the most influential HIV clinical trials. She asked NPR to only use her first name for fear of discrimination within her community, where participating in an HIV trial can lead others to assume she has HIV.

She was motivated to participate by her uncle, who lives with HIV. "I can see that his life is so hard. Like he gets strong illnesses and even right now he's so slim," she says. "Once you get it, your life changes for the worse."

But HIV is now in the rearview mirror for Irene and her baby, due in three weeks. Thanks to a medication called lenacapavir, she no longer worries about acquiring HIV, which affects 13% of people in her district.

The drug is currently only approved for HIV-negative individuals to prevent them from getting the disease. In the medical world that's called pre-exposure prophylaxis, or PrEP. Unlike other PrEP, lenacapavir tackles two major barriers: adherence and efficacy.

Lenacapavir takes the place of a daily pill. It's injected into the abdomen, releasing into the body slowly over time. The best part? Patients receive the jab only twice a year at the trial site (an oral version of the drug exists but it requires more frequent dosing).

And the promise of this drug is extraordinary. Two years ago, the clinical trials examining lenacapavir — called PURPOSE 1 and 2 — delivered unprecedented results. An independent monitoring committee concluded that lenacapavir was so effective that the randomized phase of both trials should be stopped early. Researchers then offered lenacapavir to participants in the placebo arm of the study because it was no longer ethical to withhold the drug.



HEALTH

Amid U.S. funding cuts, the International AIDS Conference faces an uncertain future

New data presented at the International AIDS Conference in July showed that protection remained just as strong one year after participants were offered lenacapavir. In PURPOSE 1 — the trial Irene participated in — none of the nearly 4,200 women acquired HIV during the period after everyone was offered the drug.

The proportion of people who adhered to treatment was equally impressive: more than 96% of women received the drug on time. Those findings come from a trial that only included women — who make up the majority of all new HIV infections in sub-Saharan Africa.



Dr. Flavia Matovu Kiweewa, the director of research at the Makerere University-Johns Hopkins University Research Collaboration, led the PURPOSE 1 clinical trial in Uganda. Her team of more than two dozen, which includes a makeup artist and hair stylist to encourage participants to keep coming back, administers lenacapavir in Mityana.

Michal Ruprecht for NPR

However, lenacapavir works on both men and women. The companion trial, PURPOSE 2, recruited men and gender-diverse people who have sex with men. In that trial, adherence was slightly lower, and one participant acquired HIV.

Dr. Flavia Matovu Kiweewa, the director of research at the Makerere University-Johns Hopkins University Research Collaboration who led PURPOSE 1 in Uganda, says results like these have "not happened before in history." That's because a core problem in HIV prevention is that a pill has to be taken every day. That can be a challenge for those who fear the stigma if a partner knows they are taking the

drug or who have trouble filling prescriptions. Missing even a few doses every week can dramatically reduce the efficacy of PrEP.

Lenacapavir's infrequent dose makes it much easier for people to stay protected. Another advantage is its mechanism of action, which targets multiple stages of the HIV lifecycle.

Matovu Kiweewa says this can be best understood by comparing HIV to a robber trying to enter a house. Lenacapavir is like having security guards stationed throughout the building, ready to "catch" an intruder at various points. Other HIV prevention drugs, she says, are more like guards who man just one entrance.

A rocky rollout



A health worker gives an injection of lenacapavir, a long-acting HIV prevention drug, in Epworth, outside Harare, the capital Harare of Zimbabwe.

Philimon Bulawayo/REUTERS

Countries began to adopt the drug for PrEP after it was approved by the United States Food and Drug Administration last year. The agency also granted access for

people with multi-drug-resistant HIV because the drug works at different points in the HIV replication cycle.

Despite all of the fanfare, the initial rollout of the drug has faced mixed reviews.

When oral PrEP was first approved in the U.S. in 2012, it took 3 years to reach sub-Saharan Africa — and another 5 years before it was widely available. That drug was introduced by Gilead Sciences, the same company behind lenacapavir. So when lenacapavir was introduced simultaneously in low- and high-income countries, many in the world of public health hailed it as a historic milestone.

Others have criticized the launch, citing concerns about distribution and pricing. While trial participants like Irene will continue to receive the drug, access remains limited for communities around the world who could benefit from it. Uganda received its first batch of nearly 20,000 doses of lenacapavir in February and began distributing it in April, one month behind schedule.

Although Ministry of Health officials say they prioritized areas at greatest risk, Kalangala — another district selected for the PURPOSE 1 trial because of its high HIV burden — wasn't included in the initial distribution plans, according to a Ministry of Health planning document shared with NPR by an organization involved in the rollout. The document states that additional sites will be "onboarded in November 2026 when additional stock is delivered to health facilities."

The Ministry of Health did not respond to NPR's questions about the document or the district's exclusion from the initial rollout.

Government health officials in Mityana district told NPR the rollout has been plagued by confusion and uncertainty about how many doses would arrive at each health facility.



Amiri Kabuye, a nurse who helps oversee HIV care in Kasensero, sits in his office inside the town's only health clinic. While his contracts previously ran for a full year, they have been reduced to short-term periods of 3 to 5 months due to budget uncertainties. The work, which he began in 2019, now carries added strain for the nurse originally from western Uganda. One of his responsibilities will be to distribute lenacapavir, the new injectable drug that prevents HIV infection.

Michal Ruprecht for NPR

Amiri Kabuye, a nurse who helps oversee HIV care in Kasensero, says just 60 people received 6 months of protection at the town's only health clinic. Kasensero, home to a highly mobile population of about 15,000, received enough lenacapavir to cover those patients, but has already run out. The town is in Kyotera district, where Irene lives, and has one of the highest rates of HIV in Uganda. Sending doses to its clinic — the only one in the district to receive any — is a nod to the community's role in shaping HIV care in the country.

During interviews with NPR, government health officials at times gave conflicting accounts of the rollout. Many like Matovu Kiweewa and Kabuye were visibly excited about the rollout but also skeptical about continued supply, citing

concerns about long-term funding stability. The next batch of doses is scheduled to arrive at Kabuye's clinic this month.

Asia Russell, the executive director of Health Global Access Project, compares the rollout to a "drip feed." She adds that the "unambitious" strategy means people will get "exposed to HIV unnecessarily."

The Ministry of Health did not respond to requests for comment.

The critique of the drug rollout comes as no surprise to Goldiano Kiganda, the son of Uganda's first reported HIV patient, Goldiano Kivumbi.

Orphaned in the early 1980s after both of his parents died of AIDS, the 47-year-old lives in Kasensero, where researchers recruited participants for the lenacapavir trial. He says the unfolding scenario reminds him of his own experiences with the Ugandan government.

"I am really fed up with speaking to people," Kiganda says, standing in his yard by his father's unmarked grave, a small pile of moss-covered rocks overgrown with weeds and dried leaves. He says he was promised a marked headstone by the government nearly half a century ago.

For years, Kiganda channeled his grief into advocacy, participating in World AIDS Day to raise awareness about HIV. But over time, repeated disappointments have left him disillusioned and skeptical that speaking out would lead to any change — with his father's grave serving as a constant reminder of an unmet pledge.



Goldiano Kiganda, the son of Uganda's first reported HIV patient, stands at his father's grave in Kasensero. The town of 15,000 was one of the lenacapavir clinical trial sites. During the rollout, the town received 60 doses of the drug.

Michal Ruprecht for NPR

Kiganda draws a parallel between that unfulfilled promise and what he sees as the promises made about lenacapavir, saying his community has yet to benefit from the drug. He adds: "It feels like we have been abandoned and it is really harmful."

Another sticking point is the price of the drug, Russell says. The current list price is about \$28,000 for two doses — much higher than the roughly \$45 annual cost of daily oral PrEP.

Others have criticized Gilead for its control over distribution. In March, Doctors Without Borders alleged that Gilead had refused to allow the nonprofit to purchase the drug directly for its own programs. In a statement sent to NPR about the charge, Gilead encouraged organizations interested in procuring the drug to work with the Global Fund to Fight AIDS, Tuberculosis and Malaria, the world's largest financier of HIV, tuberculosis and malaria programs.

"Using a centralized procurement pathway helps align forecasting, ordering and distribution and avoids fragmentation across multiple bilateral arrangements," Gilead wrote in the statement.

According to the company, lenacapavir is currently available in 10 countries and expected to reach 24 low- and middle-income countries by the end of 2026.

In response to criticism over pricing, Gilead issued a statement that says the company has taken steps to make the drug cheaper. For one, they've signed agreements with manufacturers to produce and sell generics of the drug, which are estimated to hit the market in 2027 and may lead to more competitive prices. Gilead has also promised to sell the drug at no profit until generics hit the market.

"Gilead shares the urgency of expanding access to twice-yearly lenacapavir for HIV prevention and has moved faster than with any previous HIV prevention medicine to help make that possible," Gilead wrote in a statement to NPR. "Our focus remains on working with governments, communities and global health partners to help ensure this innovation reaches as many people as possible, as quickly as possible."

Unitaid, a United Nations agency that helps reduce the cost of treatments for HIV, TB and malaria, announced last year it had reached an agreement with an Indian pharmaceutical company to produce a generic version of lenacapavir at \$40 per patient for the twice-yearly injection.

U.S. funding cuts dampen future plans

Even as questions are raised about the potential for lenacapavir in Uganda, the country is facing other challenges in its campaign to quash HIV.

After the U.S. cut back on foreign aid funding in 2025, Uganda's well-oiled HIV treatment program began to fall apart. According to Emax Kintu, who oversees HIV programs in Kyotera district, programs and services that people had come to rely on were scaled back or eliminated.

Kintu's district has lost staff in various areas of the HIV treatment and prevention system: counselors, data clerks, drug specialists, contact tracing workers, among others. Even if the country had all the lenacapavir it needed, he says, getting it to communities, identifying those most at risk and HIV-negative, administering the

injections and then tracking recipients would require a workforce that has been significantly depleted.

The first hurdle — delivering the drug to communities — has already proven difficult to clear. Kabuye, Kintu's colleague in Kasensero, waited about four months after the doses arrived in Uganda before receiving just 60.

In a statement to NPR, the U.S. State Department wrote that Uganda will receive "thousands" of doses of the drug by 2028, adding that the initiative will "save lives in Uganda while helping establish this breakthrough treatment in emerging markets."

"We are working with strategic local partners to help ensure people at high risk for HIV receive focused attention and that prevention services reach those who need them most," the State Department statement read. "We are confident the Government of Uganda will make the most of this period of mutual memorandum of understanding co-investments to match resources with the services that will provide the greatest positive impact on the health and wealth of its people."

Despite the challenges, an estimated 980 Ugandans have started lenacapavir since April. That same month, the State Department signaled that it will increase access to the drug, promising to provide 3 million people worldwide with injectable lenacapavir. But the gap between supply and need remains vast: an estimated 20 million people could benefit from the drug, according to the Clinton Health Access Initiative.

Oral PrEP is still the backbone of prevention

While lenacapavir is the new shiny breakthrough, oral PrEP remains the mainstay of prevention. Forecasters view the future through a Swiss knife model: prevention of HIV spread can only happen if multiple tools are available.

But even oral PrEP is facing its own challenges. A memo released in June by the Clinton Health Access Initiative estimated that the proportion of people starting on oral PrEP for the first time fell 42% across 10 countries in 2025 compared with the previous year, amounting to about 677,000 fewer people starting the preventive medication.

"I acted as the bridge between patients and health workers," Martin Matovu says. The 21-year-old used to work as a peer educator at an unmarked oral PrEP

distribution center in Mityana district, where the building's discreet appearance was intended to protect patients' privacy and reduce stigma. The center closed last September because of aid cuts. Though many factors contributed to the decline in the number of people starting oral PrEP, Matovu says centers like these made it easier for people to seek services.

For some districts like Kalangala — a PURPOSE 1 trial site that wasn't included in the country's initial rollout — the oral route remains but long-standing hurdles persist. The district is made up of an archipelago of 65 inhabited islands with some of the highest rates of HIV in Uganda.

Currently, health workers deliver oral PrEP to several nearby island communities by boat — with each trip costing at least \$100. The price can double for the district's most remote islands. The doses typically arrive every 3 months because Uganda's supply chain is designed to maintain a 3- to 6-month supply rather than a long-term stockpile.

After aid cuts reduced available funding, community members have had to pool money to cover those transportation costs, according to Ronald Musiitwa, the village health team supervisor on Kitobo island. Injectable lenacapavir could cut those visits down to just twice a year.

Uganda's PrEP journey now resembles a puzzle with a few new lenacapavir pieces in place but many surrounding pieces missing. Health workers are determined to stave off the spread of HIV — though they're keenly aware that without those missing pieces, the picture can never be complete.

"I see my sisters in big trouble and big risks of getting AIDS," Irene says as she rests her hand on her pregnant belly. "If we are not getting any support, I see a Uganda full of AIDS patients."

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