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Long-Acting HIV Medicines and the Pandemic Inequality Cycle — Rethinking Access

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The world may look back on 2024 as a pivotal time in the fight against AIDS — the start of a revolution in the global biomedical response to HIV using long-acting antiretroviral medicines. Young women in southern Africa have described new prevention options as empowering, allowing them to "own their own sexual destiny" for the first time. Young people with HIV, many of whom have lived their lives dependent on daily pills, long to be free of the daily reminder of their stigmatizing infection. Members of criminalized groups, such as gay men in Uganda and Malaysia, are seeking HIV options they can leave at the clinic. New long-acting prevention and treatment innovations have the potential to change the HIV narrative — from dependency and stigma to empowerment and healthy lives. Whether they will do so depends on whether policymakers and pharmaceutical companies avoid repeating past mistakes in the few years that remain before 2030, the target date set by United Nations member states for ending the AIDS pandemic.

A similar opportunity presented itself in 1996, when it was announced at the International AIDS Conference in Vancouver, Canada, that triple-combination antiretroviral (ARV) treatment had proved effective in preventing deaths from AIDS.[1,2] The HIV-treatment era had begun. But in the ensuing decade, as AIDS-related deaths plummeted in the United States and Europe, they increased dramatically in low- and middle-income countries (LMICs).[3] UNAIDS estimates that 12 million people in Africa died of AIDS between 1997 and 2006 because pharmaceutical monopolies kept prices of life-saving medicines high and supplies low.[4-6]

Now that we know that treatment blocks HIV transmission,[7,8] it's clear that millions of avoidable HIV infections can also be traced to this unequal access. As the HIV/AIDS community looks ahead to a new era of long-acting antiretrovirals, it must interrupt that cycle. Doing so will require a new, nonlinear approach to global access to ARVs that combines far more rapid sharing of technology, decentralized global production, and research and development of products that meet the needs in Africa, Asia, Latin America, and the Caribbean, even if those needs are not the priorities of high-income countries.

THE LONG-ACTING ARV ERA

The science of long-acting ARVs for prevention and treatment is advancing quickly.[9] In the PURPOSE 1 study of lenacapavir (in which one of us was a national principal investigator), this HIV-prevention technology afforded 100% protection.[10] That study included thousands of young women in South Africa and Uganda, who received the medication as a subcutaneous injection just two times a year — which many experts see as potentially transformative. A follow-up study, PURPOSE 2 — conducted in Argentina, Brazil, Mexico, Peru, South Africa, Thailand, and the United States and involving cisgender men, transgender men, transgender women, and people of nonbinary gender who have sex with men — found an HIV-acquisition rate 96% lower than the expected background incidence rate.[11]

These results followed those of two studies, HPTN 083 and HPTN 084, showing that injectable cabotegravir administered every 2 months was also highly effective in preventing HIV infection and significantly more so than daily use of the current oral formulation.[12] Cabotegravir for long-acting preexposure prophylaxis (PrEP) has now been rolled out in the United States, where about 11,000 people had been prescribed

long-acting PrEP by January 2024.[13] A visitor to Washington, DC, might notice advertisements for long-acting PrEP on bus stalls and subway stations throughout the city. Longer-acting oral PrEP taken monthly may move into phase 3 trials in 2025, potentially demonstrating that a year of PrEP could require just 12 pills.

Meanwhile, long-acting HIV treatment is emerging. A combination of cabotegravir and rilpivirine was proven effective as treatment, with viral suppression rates equivalent to those achieved with daily oral medication.[14,15] People with HIV, albeit a limited number of them, are using this injectable treatment effectively in high-income countries,[16-22] where guidelines are shifting to include long-acting treatment.[21,22] Lenacapavir has shown efficacy and been approved in several countries for use, in combination with other antiretrovirals, in treating adults with multidrug-resistant HIV.[23] An even longer-acting cabotegravir, to be administered every 4 months, is under development and could make treatment even less burdensome.[24] Another option involving a regimen of lenacapavir and islatravir as a once-weekly oral pill has shown promise in phase 2 trials.[25]

INEQUITY IN ACCESS

But the world does not start the long-acting–antiretroviral era from a position of equity. Access has been a continuing problem (Fig. 1). Oral PrEP first received U.S. marketing approval in December 2012, but three and a half years passed before the drugmaker submitted for, and received, its first regulatory approval in an African country.[26] Scale-up has been deeply uneven. It took 10 years for as many people to be started on oral PrEP in South Africa as in the United States, where risk of HIV is far lower.[26] Regulatory approval of long-acting PrEP (cabotegravir), which came in the United States in 2021, has been quicker, though the delay is still considerable: as of September 2024, drug approval had been secured in 13 African countries.

More than 7 million people currently need PrEP but lack access, as compared with current global targets of 10.6 million using PrEP consistently.[27] There is expected to be only enough cabotegravir in LMICs for a few hundred thousand people through 2025, and rollout of what's available will be difficult.[28] Both price and supply are barriers. The U.S. President's Emergency Plan for AIDS Relief (PEPFAR) has purchased some doses to support programs in Zambia, Zimbabwe, Malawi, Ukraine, and Eswatini and hopes to scale up to 12 countries to reach at least 100,000 people by 2025 — an important contribution, but small compared with the need.[29] South Africa hopes to purchase cabotegravir, but the "noncommercial" price set by the only current producer, Viiv, is about U.S.$30 per injection (U.S.$180 per year), which is 2.5 times the rate that would make it cost-effective, according to an analysis by the South African government, and the quantity available to South Africa is unclear.[30] Meanwhile, countries in Latin America and Asia facing high rates of HIV infection — even some, such as Brazil and Peru, that hosted clinical trials — are not eligible for the "noncommercial" price. Generic versions are badly needed but may still be years away.

For treatment, long-acting medicines are in use in high-income countries but unavailable in LMICs. Research has shown that cabotegravir–rilpivirine can be used in African settings despite clinical and operational shortcomings.[31] But the makers of those drugs (Viiv and Johnson & Johnson, respectively) are not selling the combination in LMICs, and no generic version exists.[32] The combination product for treatment is not currently included in World Health Organization (WHO) guidelines.

NONLINEAR MODEL NEEDED

For decades, new HIV medicines have come out first in the United States and Europe and only years (often more than a decade) later reached wide circulation in the communities with the highest HIV rates in Africa, Asia, Latin America, the Caribbean, and Eastern Europe. Multiple factors contribute to these long delays, including the necessity of bringing down prices, boosting supply, securing financing, and overcoming regulatory and programmatic barriers. The lag time has been shrinking, but substantial inequality persists.

For each important new medicine with global utility, the AIDS community of clinicians, government officials, international organizations, and activists has secured production by generics manufacturers. LMIC governments have exercised flexibilities in intellectual property law to enable generic production of medicines, and originator companies have been pressured to license their

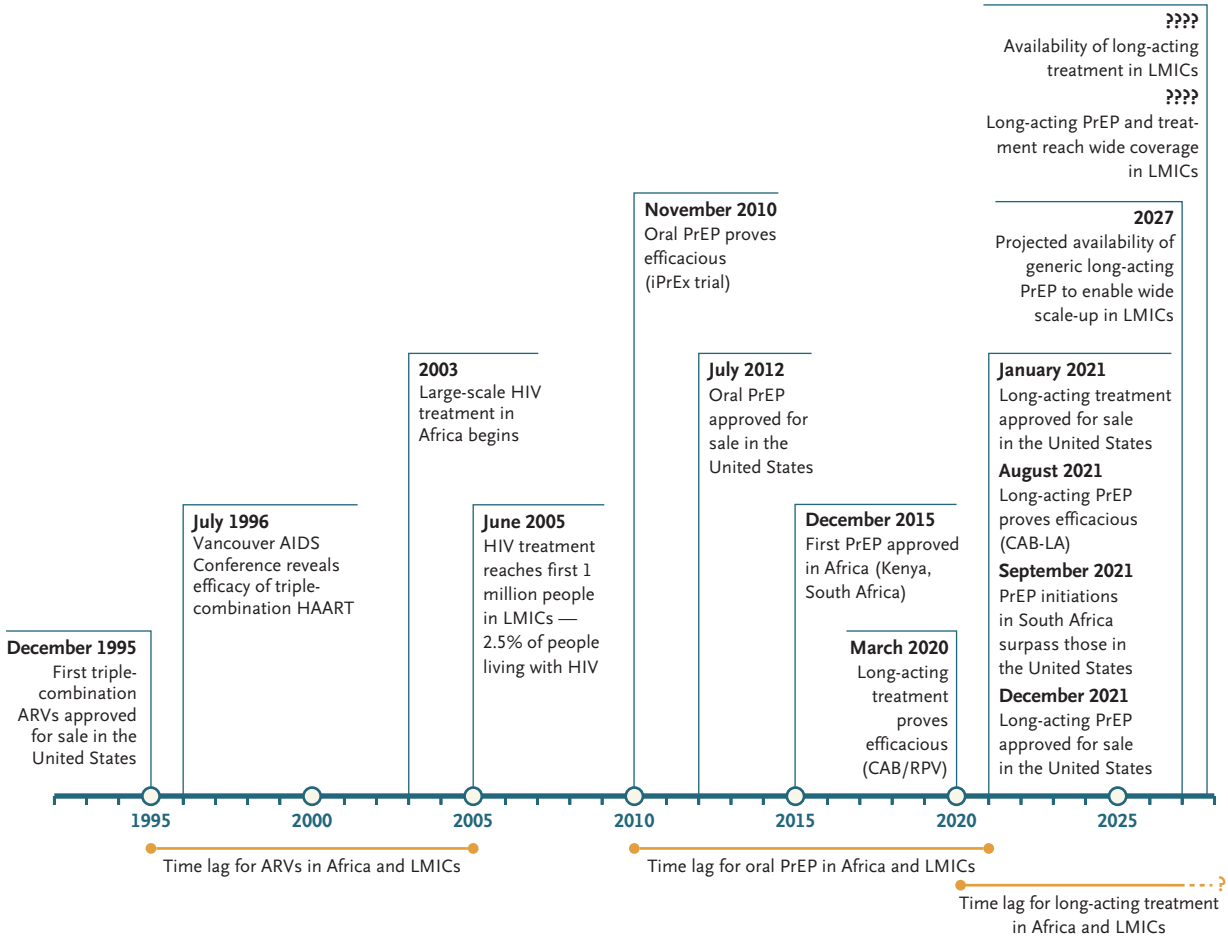

Figure 1. Time Lags in Access to HIV Treatment and Prevention Technology in Africa and LMICs.

ARV denotes antiretroviral, CAB-LA cabotegravir–lenacapavir, CAB/RPV cabotegravir–rilpivirine, HAART highly active antiretroviral therapy, LMICs low- and middle-income countries, and PrEP preexposure prophylaxis.

medicines voluntarily.[33,34] As a result, the price for a WHO-recommended first-line treatment involving tenofovir, lamivudine, and dolutegravir has fallen by more than 99%, to less than $45 per patient per year for eligible countries. This regimen is now used by millions of people worldwide.[35]

This combination of national legal action, voluntary licensing, decentralized production for generic competition, and financing has achieved treatment coverage levels that many observers thought were impossible. But the process continues to be too slow, too restricted to AIDS and a few other diseases, and too linear in that it doesn't start until originator companies decide to license their products to generic-drug producers. When governments of countries excluded from voluntary licenses try to use their rights under international law to access affordable generics, governments of high-income countries often pressure them not to do so.[36,37] If the AIDS pandemic is to end, all players must work to make new technologies available at the same time in countries with the highest HIV rates as they are in countries with the highest gross domestic products.

FASTER, WIDER LICENSING AND DECENTRALIZED PRODUCTION

Studies have shown that both generic cabotegravir and generic lenacapavir could be produced for $40 or less per person per year. This cost

would make them about as affordable as current oral PrEP and treatment products and cost-effective for LMICs.[38] Specifically, it's estimated that lenacapavir could be introduced at a price of less than $100, which could drop to $35 to $40 as volumes grew.[39] The cost of raw materials for cabotegravir has been estimated to be $30 to $40 at introduction and $14 to $18 once the number of users reaches 800,000 per year, plus a margin for the up-front investment in production equipment, unless this cost is supported by global health funding agencies.[40] But the prices charged by originator companies are far higher — $25,000 to $45,000 per patient per year in high-income settings and a lowest price for cabotegravir of $180 per patient per year in selected lower-income countries. As experience with previous HIV medications has shown, prices fall by orders of magnitude when generics are introduced.[41]

Long-acting medications may be revolutionary, but for an actual revolution to happen they need to be licensed in a way that recognizes that the Global South is as important as the Global North. ViiV granted licenses for generic production of cabotegravir to the U.N.-backed Medicines Patent Pool in July 2022, nearly 2 years after clinical trials proved its efficacy for treatment and 7 months after it was approved for prevention in the United States. Since licensing is only the first step toward generic production, there will probably be no generics on the market until 2027.[42,43] Gilead licensed lenacapavir before receiving regulatory approval for its use as PrEP and a few months after the PURPOSE 1 trial was completed, but that was still more than 2 years after it was proven effective for treatment.[23]

We believe that manufacturers can and should license these products as soon as they are deemed efficacious, if not before. Access planning should start well before the end of a trial. Licensing simply grants rights for a company or agency to use a technology or product without infringing on intellectual property (IP). It is the beginning of a time-consuming process of technology transfer, building production lines, training staff, and other actions. There is no reason to wait for marketing approval in wealthy countries before beginning the process by licensing to generics producers in the Global South. The National Institutes of Health, for example, has licensed key early-stage medicines, vaccines, and diagnostics so that IP would not be a barrier if products proved efficacious.[44] Regulatory approval is still required regardless of what manufacturer is involved. But just as originator companies prepare for production long before a medicine is approved, generics manufacturers require adequate lead time to avoid years-long delays.

Furthermore, now that antiretroviral agents have proven effective for treatment and prevention, we believe that licenses granting permission to produce a medicine should not limit how the medications can be used. A harmful precedent was set when ViiV licensed cabotegravir only for prevention: making the drug to prevent infection is no different from making it to prevent illness and death.

Licensing should also be widened. Many middle-income countries in Asia, Latin America, the Caribbean, and Eastern Europe are excluded from current licensing agreements, yet the majority of new HIV infections are occurring in middle-income countries, many of which have stark internal inequalities and health systems that are struggling to afford medicines for their populations.[27] Particularly for prevention, we have seen that health systems cannot afford to pay the prices set by originator companies.

Finally, pharmaceutical production should be diversified. In particular, long-acting medications need to be produced in Africa, which has by far the greatest need. Such a shift will require investment in capacity and commitments by governments and global health financing agencies to purchase from these producers, whose products may not be the least expensive at the start but could become less expensive with support.

Coverage is a key component of impact, and it is vital that governments and donors act together to purchase these products at scale. If the volumes purchased are small, then prices will stay high, impact will remain low, and a sustainable, affordable market for multiple manufacturers will not come to fruition. Coordinated work by UNAIDS; the Global Fund to Fight AIDS, Tuberculosis, and Malaria; PEPFAR; Unitaid; the WHO; and AVAC is building momentum, but more is needed.[45]

PRIORITIZING LONG-ACTING TREATMENT FOR LMICS

Meanwhile, long-acting treatment options for the 30 million people in LMICs receiving treatment for

HIV, and especially the nearly 10 million people with HIV who lack access, must become a priority for the international community.[27] The opportunity to move from a pill every day to an injection every few months could be as transformative for people living with HIV as it is for those seeking to avoid infection. Many people living with HIV say they want long-acting options.[46-49]

Long-acting treatment could also prove more sustainable in the long term for national AIDS programs, if structured well. The long-acting combination of cabotegravir and rilpivirine has been in use for 3 to 4 years in the United States, Canada, and the European Union,[50] and lenacapavir is approved as a treatment, in combination with oral therapy, for people with extensive drug resistance. But these medications have not been rolled out in the Global South. High cost and limited supply are important factors. Though there are operational concerns, such as the need for cold-chain storage and frequent clinic visits and the potential for resistance, that may make cabotegravir–rilpivirine less than ideal for LMICs, recent studies suggest that these challenges may be navigable.[31,46]

Better options should also be studied — some leading researchers and clinicians, for example, believe that a cabotegravir–lenacapavir combination could prove more effective as treatment in the Global South.[9] A regimen could combine cabotegravir every 2 months and lenacapavir every 6 months (with promising longer-acting cabotegravir formulations in development that may even allow more synchronous dosing).[24] But ViiV and Gilead compete for markets in the Global North and are not yet cooperating with researchers to robustly explore this possibility. We believe that global health agencies and funders should support researchers in the Global South now to conduct the needed trials and then continue backing them to innovate on this front in the years ahead.

GAME CHANGERS, NOT SILVER BULLETS

There is still no cure and no preventive vaccine for HIV. But long-acting ARVs are the closest thing to a vaccine that the world has today, and they could support long and healthy lives for people living with HIV. Perhaps most important, they could be a tool for putting the lives of people living with or at risk for HIV at the center of the AIDS response. Whether for adolescent girls in Nairobi or men who have sex with men in Manila, for people who inject drugs in Kiev or sex workers in São Paulo, for the millions of migrants on the move worldwide or people facing precarious employment or housing, the option of receiving HIV treatment or preventive interventions just a few times a year could be game changing.

It's essential to remember that inequality in access to technology is just one of the inequalities driving the AIDS pandemic, so continued work toward securing human rights, building equitable health systems, and supporting communities must also be prioritized. There are no silver bullets. But the HIV/AIDS community now has an opportunity to break the long-standing pattern of failing to get HIV technologies to the people who need them most, to stop playing catch-up, stop accepting that innovations must reach people in the Global South years late, and use long-acting medicines to help end the pandemic.

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