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Special Series: What's Next for HIV Treatment?

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What's in the HIV Treatment Pipeline for 2022 and 2023?

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When it comes to the HIV treatment landscape, 2021 wasn't exactly a seismic year. Not like, say, 1996, when the lifesaving protease-driven "cocktail" treatment broke through. The biggest treatment advance in 2021 was probably the U.S. Food and Drug Administration (FDA) approval of Cabenuva (cabotegravir/rilpivirine), the first long-

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Looking ahead, the key word remains "long-acting"—meaning the possibility of more options that can be taken orally, by injection, or even by implant no more than once every month. (Of course, how many people will desire these methods, and how affordable and accessible they are, remains another story.)

Here's our rundown of what's on the horizon—organized with help from Mark Harrington and Richard Jefferys at Treatment Action Group (TAG), whose indispensable annual "pipeline" report can take you on a deeper (and wonkier!) dive if you so choose.

Cabenuva Makes a Splash—But Who Is Using It?

Yes, Cabenuva was approved by the FDA in early 2021. The first long-acting injectable HIV treatment, it combines two drugs—cabotegravir and rilpivirine—and can be received monthly at one's clinic via two quick shots in the butt.

But Cabenuva is still kind of a "pipeline" drug in that it's yet to be seen just how popular it will be, how widely it will be covered by insurance in the U.S., or if and when it will be available in low-income countries.

As for its uptake so far among folks with HIV, "ViiV [one of the drug's manufacturers] has been pretty tight-lipped about this," says Tim Horn, director of health access at the HIV advocacy group NASTAD.

The ongoing LATITUDE study is looking at whether Cabenuva can be an effective option for folks who've had a hard time taking the typical daily oral HIV regimen. Says TAG's Harrington, "The jury is still out on where Cabenuva fits in the HIV treatment landscape."

The drug has also been shown in studies to be effective taken only every *other* month—an indication that the FDA may approve that less-frequent dosing at some near point. [Editor's note: Shortly after this article was published, the FDA did indeed reportedly approve Cabenuva for every-two-month dosing.]

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Also FDA-approved in 2021, Rukobia (fostemsavir) is indicated for folks with heavily treatment-resistant HIV—usually longtime survivors who were failed by several single-drug options before the 1996 treatment revolution. In studies leading to its approval, Rukobia, taken alongside the best possible preexisting HIV drugs, got (at best) about half of takers' viral loads to undetectable, and also modestly raised their CD4 count.

Rukobia, which prevents HIV from attaching to T cells, likely isn't a drug that will become a household name. But Horn puts it this way: "Ensuring that heavily treatment-experienced patients have access to novel classes of drugs, particularly for use in combination with each other, to maximize chances of achieving and maintaining viral suppression, is—and always will be—a very good thing."

Up-and-Coming HIV Medications: Islatravir and Lenacapavir

These two different kinds of drugs—the first an NRTTI, the second a capsid inhibitor—are being studied as an oral combination. Islatravir has already proven in phase 2 trials to have high anti-HIV potency alongside the NNRTI doravirine, and it is also being studied alongside another experimental NNRTI, the as-yet unnamed MK-8507.

However, clinical trials involving islatravir were halted in late November after certain patients saw drops in their white blood cell levels. Before going forward, scientists are trying to find out if the drop is due to the islatravir or the MK-8507 (or an effect of combining the two).

Meanwhile, lenacapavir is the first drug that targets HIV's crucial capsid protein, meaning that it could be a great option for folks resistant to drugs that work in other ways. In the CAPELLA trial of such folks, who got the drug orally for 14 days and then went to a twice-yearly injection, lenacapavir—in combination with older HIV drugs—showed power in pushing down viral loads, with three-quarters of those followed out to 26 weeks getting to undetectable.

Other HIV Treatment Possibilities on the Horizon

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make it past early trials, although occasionally some of them, such as MK-8507, are revived as scientists test them out alongside another investigational agent.

The big unknown, says Harrington, concerns the emerging field of long-acting meds. "Getting HIV treatment down to once every six months would be a game-changer," he says, "but those pills would probably be $25,000 to $40,000 each. Are they going to bring your meds to you in a Brinks truck? This could be transformative in the next decade, but the jury's still out on how accessible they'll be."

HIV Vaccine and Cure Research in 2022: More Hope Than Reality

Largely because HIV is a very wily and slippery virus (compared to, say, COVID-19) and because we still have nearly no clue about why a small handful of people seem to be able to control HIV with their own immune systems, there's nothing very ripe on the horizon when it comes to either HIV vaccines or cures.

Vaccine-wise, 2021 was yet another groaner, as the long-awaited results of the Imbokodo trial proved disappointing. On the cure side, although researchers discovered the second woman ever whose own immune system seems to have eradicated HIV completely, there's currently nothing we've extracted from such cases to chart a path toward an intervention that would help the rest of us get there.

So what's the take-home as we go into 2022? Says Harrington: "We continue to see exciting developments in prevention and treatment, but at the same time, we're failing grievously to get [existing] treatment and PrEP to the people who need it, both domestically and globally."

Does this mean we should consider halting new developments while we try to maximize use of the very good tools we already have? No, says Harrington: "A breakthrough technology can potentially drive a huge new amount of demand."

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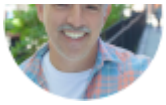

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