Thanks for Nothing: iPrEX Volunteers Shut Out of PrEP's Success

Most foreign volunteers who participated in the clinical trial that first proved Truvada prevents HIV no longer have access to the drug.

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Proving for the first time that Truvada (emtricitabine/tenofovir) reduces the risk of contracting HIV was a global effort. The landmark iPrEX study, which ran between 2007 and 2009 and which examined the drug's use in 2,500 high-risk HIV-negative MSM and transgender women who have sex with men, had sites in the United States, Peru, Ecuador, Brazil, Thailand and South Africa.

The benefits of the trial, however, have been more localized. After the drug was approved as pre-exposure prophylaxis (PrEP) in the United States in 2012, American iPrEX volunteers who wanted to keep taking the daily pill enjoyed the benefits of a cohesive system that referred them to various means of obtaining affordable or even free Truvada, as well as follow-up care. Meanwhile, the volunteers in the remaining iPrEX countries have largely been left out in the cold.

South Africa is the only other country in the world in which Gilead Sciences, which manufactures Truvada, has even applied for approval for the drug's use as a preventative measure. South African MSM also have something of a leg up because, as they await approval of PrEP, they can seek out an off-label prescription (since Truvada is approved as a treatment for HIV) for about $20 a month, a cost sometimes covered by insurance.

Mitchell Warren, executive director of the global HIV advocacy group AVAC, says, "One of the top priorities has got to be—and we've raised this over and over again—that Gilead should be applying, at least for registration [of Truvada as PrEP], in each of the countries where any of the PrEP trials took place. As with most things in ethics, reasonable people disagree in terms of where the ethical requirement is. But as a matter of good conduct, we believe that those communities and countries that supported the trials should be prioritized."

Juan Guanira, executive director of Investigaciones Medicas En Salud in Lince, Peru, is indignant that his countrymen have received the brush where access to PrEP is concerned. "It is really frustrating what is happening in my country," he says, "because we were by far the largest [iPrEX study] site. The advocacy process to introduce the concept of PrEP on the local agenda looks worthless when we see that even the combination of emtricitabine and tenofovir is not available in

the country for HIV prevention and not even for HIV treatment."

After the iPrEX study came to a close, each trial site eventually moved into what is known as an open-label extension (OLE—pronounced "olé"). This was an extended period during which volunteers could opt to continue participating in research of Truvada as PrEP, but receive active drug if they so chose, without the chance that their daily pill might be a placebo. According to Warren, about 85 percent of all the iPrEX participants opted to transition into an OLE; some actually preferred not to receive Truvada—they just liked the chance to participate in purposeful research.

But after the last OLE came to a close in December 2013, the lion's share of the iPrEX volunteers outside of the United States haven't been given the chance to share in the spoils of their own participation. (Additional ongoing studies around the world have been researching Truvada in other risk groups, such as serodiscordant heterosexual couples. IPrEX, however, was the first to prove PrEP's efficacy.)

"It really pissed me off to know that all the volunteers from the countries who participated in the trial, that their government failed to provide them with the medication," says Emmanuel Trenado, director of international programs at AIDES, a leading French HIV community-based organization.

Trenado also notes that the OLE periods were not necessarily seamless with each study site's initial trial phase: There was, for example, about a nine- to 12-month gap between the two phases in Ecuador, interrupting the chance participants had to significantly lower their risk of contracting HIV.

Wagering as to who ultimately has failed these volunteers, a fired-up Trenado wonders, "Is it the study itself, not having planned enough, or not being sure that the governments would provide drugs for the volunteers? Or is it only the governments of those countries who couldn't care less about prevention issues, and who aren't ready to provide Truvada to any gay men in the near future?"

Beatriz Grinsztejn, the director for clinical research on STDs and AIDS at Instituto de Pesquisa Clinica Evandro Chagas-Fiocruz in Rio de Janeiro, Brazil, grants that Gilead fulfilled its end of the initial stated bargain by supplying Truvada at no cost during iPrEX, and that the company went further in its pledge by participating in the OLE as well.

"Up front, it was very clear that there was no commitment from Gilead to provide drugs after the study was over, including during the OLE phase," she says. "We can't say that they behaved badly, because they did just what was [contracted]."

Gilead is continuing to provide free Truvada to further access programs. Both South Africa and Brazil have what are known as demonstration projects for PrEP in the works, and there are several such programs up and running in the United States. In these projects, data is collected to observe PrEP's use in a real-world setting, with the ultimate purpose of educating clinical researchers about

issues concerning uptake, adherence, sexual behaviors and side effects.

Mitchell Warren expresses worry about the bigger research picture where demonstration projects are concerned. Calling the projects “random acts of goodness,” he says they need to be better organized in order to more cohesively study how to effectively target at-risk populations with PrEP. “That to me is one of the top priorities for 2014,” he says.

Warren sees a connection between slow uptake of PrEP in the United States and a lack of preparation in designing and funding cohesive demonstration projects. If such effective study into real-world use of PrEP had gotten underway without delay, he argues, the U.S. public health system might have already developed the tools better encourage the drug’s use.

“Frankly, we’re not prepared for success,” Warren said.

As new biomedical interventions make their way through the HIV prevention research pipeline—including microbicides and vaginal rings in addition to long-term injectable PrEP requiring monthly or quarterly dosing—Warren hopes that forthcoming research of Truvada can help establish a better model for introducing such scientific advancements to the public.

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