French Man With HIV Transmits Virus While Off Meds During Cure Trial

Many HIV cure trials take participants off antiretrovirals for a period in order to see how well the investigational treatment works.

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French researchers have reported a case of an HIV-positive man who was taken off antiretroviral (ARV) treatment during an HIV cure trial—specifically a therapeutic vaccine study—and who during that time transmitted the virus to his female partner.

Many HIV cure trials will put participants through what is known as an analytical treatment interruption (ATI), during which time ARVs are temporarily discontinued and individuals are closely monitored. If the virus rebounds from undetectable levels, it can become transmissible during this time. Fully suppressing HIV renders the virus intransmissible.

The new case report was published in The Journal of Infectious Diseases and focused on a 59-year-old heterosexual man who participated in the ANRS LIGHT VRI02 trial, a randomized, multicenter double-blinded placebo-controlled Phase II therapeutic vaccine trial in France. The trial enrolled 103 people with HIV between September 2013 and May 2015. They were randomized 2 to 1 to receive injections of a pair of experimental vaccines or a placebo. Ninety-eight people received at least one injection and 93 received all injections, which were given over a 24-week period.

The study enrolled people who were on ARVs and had had an undetectable viral load for at least 18 months. Participants also needed to have been free of any history of AIDS-defining health events; have had a lowest-ever CD4 count of 300 or higher; have a CD4 count of at least 600 according to all tests taken during the six months before their week three screening visit; and have a viral load below 40 according to all tests taken within the previous six months.

The study's protocol put participants through an ATI between week 36 and 48 of the trial—meaning this period started 12 weeks after the last vaccine injection. During this time, the participants were monitored every two weeks, a process that included routine viral load testing. There were various criteria that, if met, would prompt researchers to put a participant back on ARVs before the end of the 12-week ATI period.

At each study visit, the participants received safer-sex counseling during which they were advised to use condoms and informed about the risks of transmission during the ATI. Truvada (tenofovir

disoproxil fumarate/emtricitabine) was not yet approved for use as pre-exposure prophylaxis (PrEP) in France at the time, so it was not recommended for use by participants' sexual partners.

The participant who transmitted the virus during his ATI had been diagnosed with HIV in 2005, shortly after contracting the virus. He began ARVs that same year and achieved a fully suppressed viral load. He subsequently became an HIV activist and routinely attended activist meetings. Consequently, the study investigators considered him "someone who is very familiar with HIV infection."

The man also experienced chronic depression for which he declined to take treatment. He also had diabetes, which he managed poorly.

Upon enrollment in the study, the man had been with a new female partner for one year, having previously separated from his wife. The new partner was 44 years old and had no notable medical history but also suffered from untreated depression. The couple reported that they were monogamous.

After enrolling in the trial in mid-2014, the man received five injections—whether of the vaccine or the placebo, the case study did not report. On the study visit that began his ATI, the physician consulting with him noted that the man, who attended the visit with his partner, was "perfectly informed of the need to protect all sexual intercourse by a physical means (condom) and the possible risk of primary-infection-like syndrome in case of resumption of viral replication."

One month into the ATI, the man developed a viral load of 2,000, a figure that ultimately peaked at 16,000 before spontaneously plateauing at 1,000 after two months.

During this time, the participant's partner developed symptoms that suggested she was experiencing seroconversion illness, including fever, pain in the joints and a rash on her neckline. Three weeks after these symptoms began, she received a rapid HIV antibody test. The positive result was ultimately confirmed with both an ELISA and Western blot test. The researchers confirmed through genetic testing of the partners' viruses that the man had transmitted to the woman.

The man went back on ARVs while his partner began taking them to treat her own HIV.

The couple reported that the only unprotected sex they had engaged in during the ATI was two or three acts of oral sex, in which the man performed cunnilingus on the woman. Such an act is not considered risky where HIV transmission is concerned. Consequently, the researchers stated in their case report that they cannot rule out other sexual acts as the route of transmission. They did not think this case warranted a reconsideration of the HIV risks associated with cunnilingus.

"This case highlights the risk of secondary transmission of HIV infection during treatment interruption," the researchers wrote, "including among participants who have a good understanding of their HIV infection and its effects and whose level of viral rebound is low. This risk is undoubtedly in part enhanced by a lack of protective sexual practices among participants

who have become accustomed to no longer needing them while receiving effective treatment and viral suppression."

The authors continued: "It is, therefore, essential to continuously reinforce the risk of secondary transmission [of HIV] during clinical trials that include a treatment interruption in conversations with all study participants and to propose, whenever possible, the prescription of PrEP to study participants' partners. However, preventive treatment is associated with potential side effects and the PrEP offer may be difficult to manage in practice if partners are multiple and casual."

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To read a POZ feature on the future of cure research, click here.

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