Researchers Report Rare PrEP Failure in San Francisco

Experts emphasize that Truvada for HIV prevention remains highly effective.

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A San Francisco man contracted HIV despite consistent use of Truvada for pre-exposure prophylaxis (PrEP), researchers reported at the IDWeek 2018 meeting last week in San Francisco.

This case involves a 21-year-old bisexual Latino man who tested positive for HIV RNA after a year on PrEP with apparently good adherence. He contracted a strain of HIV that is resistant to one but not both of the drugs in the Truvada combination pill.

This is the sixth confirmed or suspected case of PrEP failure among hundreds of thousands of users, and experts emphasize that the intervention is highly effective at preventing HIV infection.

“By far the most common reason for PrEP to not ’work’ is because it isn’t used,” said Stephanie Cohen, MD, MPH, medical director of San Francisco City Clinic, the city’s largest sexually transmitted infection (STI) clinic. “In other words, our biggest challenge in HIV prevention is not figuring out why in these extremely rare circumstances PrEP is ineffective, but rather how can we make sure those who can benefit from PrEP know about it? How can we make it as acceptable, accessible and affordable as possible? And how do we support individuals who choose to take PrEP so that they can stay on it throughout periods of risk?”

In July 2012, the Food and Drug Administration approved Truvada (tenofovir disoproxil fumarate/emtricitabine) for HIV prevention based on data from the iPrEx trial, which showed that once-daily Truvada reduced the risk of HIV infection by 92 percent among mostly gay and bisexual men with blood drug levels indicating consistent use. Across several other studies and demonstration projects, no one who took Truvada at least four times a week has contracted HIV.

Nonetheless, a handful of apparent or confirmed cases of PrEP failure in real-world use have been reported at conferences and in medical journals.

In early 2016, researchers in Toronto reported the first such case, which involved a man who had good adherence to PrEP but had an HIV strain that was resistant to both tenofovir and emtricitabine. A similar case from New York City was presented later that year. In 2017, researchers in Amsterdam reported the first case of a breakthrough infection with non-resistant

HIV. Another probable case, from North Carolina, was presented earlier this year. That was the first time drug levels in hair were used to assess adherence over time. An analysis of hair segments showed that the man had adequate tenofovir levels during the three months before he tested HIV positive, but because he had short hair, that was as far back as the tests could go.

The San Francisco Case

The latest case was described in a poster by Cohen and colleagues at the San Francisco Department of Public Health and the University of California at San Francisco (UCSF).

The young man, who reported having sex with men, transgender women and cisgender (non-trans) women, tested negative for HIV antibodies and HIV RNA at City Clinic. He was prescribed a 30-day supply of Truvada with two refills and asked to come back in three months for follow-up monitoring. He again tested HIV negative at three, six and 10 months after starting PrEP. He was treated for gonorrhea at 12 months but had no other STIs.

At his 13-month visit, a rapid HIV antibody test was negative and his PrEP prescription was renewed. But five days later, his HIV RNA test came back positive with a viral load of 559 copies per milliliter.

The man reported excellent adherence to PrEP and various tests supported this. He had adequate levels of tenofovir and emtricitabine before the visit and over the preceding six weeks, according to blood plasma and dried blood spot tests. He also had tenofovir levels measured in a hair sample, and because he had longer hair than the North Carolina man, tests were able to show consistent good adherence going back six months.

Genotypic and phenotypic testing showed that the man's HIV was resistant to emtricitabine but remained susceptible to tenofovir. The genetic diversity of his virus suggested he had an acute infection, probably acquired within the past few weeks, the researchers surmised.

The man was immediately notified and started a complete antiretroviral treatment regimen that included Tivicay (dolutegravir) and boosted Prezista (darunavir). In addition, one of the man's sexual partners was found to be HIV positive with a viral load of 15,000 copies/ml; he was relinked to care.

Based on these findings, Cohen's team concluded that HIV acquisition could occur in a person taking Truvada as PrEP when the virus is resistant to emtricitabine, even if adherence is high and it remains susceptible to tenofovir.

"Individuals taking PrEP and health care providers should be aware that PrEP failure is very rare, but not impossible, even with consistent adherence," they wrote.

"We've always said that PrEP is not 100 percent efficacious. It's an important reminder that PrEP is not a golden bullet," said Charlene Flash, MD, of Baylor College of Medicine in Houston. "It's part of a prevention package and one element of a prevention tool kit, so we still have to encourage

our patients to consider other things like partner selection, positioning, condom use and harm reduction."

But Robert Grant, MD, of the UCSF Gladstone Center for AIDS Research, who was lead investigator for the iPrEx trial, questioned the media's emphasis on such rare cases.

"HIV infections during PrEP use are extremely rare. There are only a few cases reported worldwide after hundreds of thousands of people have used PREP and tens of thousands of HIV infections have been prevented," he said. "Almost all people who use PrEP stay free of HIV, and a handful of others are diagnosed early and promptly and successfully treated. Once virally suppressed on treatment, their infection is non-transmissible. These cases call us to reconsider our stigmatizing way of regarding people with HIV."

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