After 2.5 Years, No One in Large SF PrEP Group Contracts HIV

September 2, 2015 By Benjamin Ryan

Two and a half years into a large Truvada (tenofovir/emtricitabine) as pre-exposure prophylaxis (PrEP) program in San Francisco, none of the more than 600 men who have sex with men (MSM) taking the HIV prevention medication have contracted the virus. At the same time, many of these individuals are using condoms less since starting PrEP, and during their first year on Truvada half of them had contracted at least one sexually transmitted infection (STI). Those at higher risk of the virus were more likely to opt to start PrEP after their initial consultation.

Researchers at Kaiser Permanente published their findings in Clinical Infectious Diseases. The paper represents a powerful endorsement of PrEP's ability, in a real-world setting, to prevent HIV infection among those at very high risk of contracting the virus. The lack of new HIV infections among these men challenges the stance of AIDS Healthcare Foundation president Michael Weinstein, who has vigorously campaigned that PrEP should not be used as a widescale public health intervention.

On the flip side, the Kaiser findings challenge the received wisdom from PrEP clinical trials that those taking Truvada as HIV prevention do not increase sexual risk-taking while on the medication.

"Our study is the first to extend the understanding of the use of PrEP in a real-world setting and suggests that the treatment may prevent new HIV infections even in a high-risk setting," reports lead author Jonathan Volk, MD, MPH, a physician and epidemiologist at Kaiser Permanente San Francisco Medical Center. "Until now, evidence supporting the efficacy of PrEP to prevent HIV infection had come from clinical trials and a demonstration project."

Kaiser released preliminary data about the PrEP-taking group in December 2014, stating at the time that two of them had contracted hepatitis C virus (HCV), most likely through sex. Since then there have been no new hep C infections.

Over a 32-month period, 1,045 individuals were referred to Kaiser Permanente San Francisco Medical Center's PrEP program. A total of 835 (80 percent) of them had an in-person evaluation for PrEP at the clinic, and 657 of that group (82 percent) then began Truvada. Starting in September 2013, when media attention to PrEP suddenly surged, the Kaiser group saw interest in PrEP begin to rise.

The average age of those taking PrEP was 37 (they ranged between 20 and 68 years of age), and 99 percent of them were MSM. The group included three heterosexual women and one transgender man who has sex with men. Three reported injection drug use and 15 of them had taken post-exposure prophylaxis (PEP) during the three-month period before staring PrEP.

Those who ultimately went on PrEP were more likely to say that they had multiple sex partners than those who chose not to take Truvada (84 percent vs. 69 percent). Among those who did not start PrEP, 35 percent opted out because they felt they were at low risk for HIV, 15 percent were concerned about cost, 10 percent did not want to have make the required quarterly clinic visits, 6.3 percent preferred PEP as an HIV prevention method, 2.8 percent were worried about side effects, and 1.4 percent were concerned that PrEP might influence them to increase their sexual risk-taking.

Among the group taking Truvada, the average time on PrEP has been 7.2 months, which adds up to 388 person-years. (Person-years represent the cumulative time spent on Truvada among the group. So if one person took PrEP for one year and another for two years, that would represent three person years.)

After six months, the clinicians at Kaiser surveyed 143 of the cohort about their sexual risk-taking. At that time, 74 percent reported that their number of recent sexual partners had not changed since starting PrEP, while 15 percent said they had fewer sexual partners and 11 percent said they had more. Regarding condom use, 56 percent said they used them at the same rate after starting Truvada, 41 percent used them less and 3 percent used them more.

Because these individuals were not engaged in a clinical trial, there is no control group to measure the change in these men's sexual risk-taking against. So there is no way to tell if the group would have changed their risk-taking in a similar pattern if they had not been taking PrEP.

One thing is clear, however: These men would have been at very high risk of contracting HIV had they not been taking PrEP while engaging in the same level of sexual risk-taking. The evidence is in their very high rate of STIs. Six months into taking PrEP, 30 percent of the PrEP users had been diagnosed with at least one STI. During their first year on PrEP (or partial first year), half of them contracted one or more STIs, with 33 percent diagnosed with a rectal STI, 33 percent with chlamydia, 28 percent with gonorrhea, and 5.5 percent with syphilis. As noted, two of them contracted hep C.

"Without a control group, we don't know if these STI rates were higher than what we would have seen without PrEP," stressed the paper's co-author Julia Marcus, PhD, MPH, postdoctoral fellow at the Kaiser Permanente Division of Research. "Ongoing screening and treatments for STIs, including hepatitis C, are an essential component of a PrEP treatment program."

No one in the group has been diagnosed with HIV.

In an accompanying editorial in Clinical Infectious Diseases, Kimberly A. Koester, MA, and Robert

M. Grant, MD, MPH, of the University of California, San Francisco, called the lack of HIV infections among the group “tremendously good news.” They wrote that the paper’s findings demonstrate “meaningful progress towards the goal of halting infections” of HIV.

Koester and Grant also called for “a vigorous conversation about sexually transmitted infections, too long eclipsed by fear of HIV infection,” and stressed the need for routine STI testing in primary care practices. “If the STI burden in the context of PrEP use become[s] too great, communities can and will make course corrections,” they wrote, while noting that rising rates of STIs among MSM predates the advent of PrEP.

At this time Kaiser has no data to report about the group’s adherence to the daily Truvada regimen. Such information is forthcoming.

The researchers said that demand for PrEP is growing in San Francisco. They also pushed for increased outreach to offer Truvada to other high-risk individuals, including transgender women, heterosexual men and women, and injection drug users.

To read the study abstract, click here.

To read the accompanying commentary, click here.

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