HPTN 067 demonstrates high-risk populations adhere well to daily PrEP regimen

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Results from HPTN 067, a Phase II, randomized, open-label study, demonstrate most study participants had higher coverage of sex events and better adherence when they were assigned to the daily dosing arm, investigators from the HIV Prevention Trials Network (HPTN) reported today at the 8th International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment and Prevention in Vancouver, Canada. HPTN 067, also known as the ADAPT Study, was designed to evaluate the feasibility of non-daily pre-exposure prophylaxis (PrEP) regimens. The study evaluated acceptability and use of three different oral PrEP regimens: daily, twice weekly with a dose after sex, and one dose before and another after sex. The study was not designed to assess the efficacy of the different regimens in preventing HIV, and participants were informed that only the daily regimen has been proven effective to prevent HIV infection.

The study of more than 500 participants included women in Cape Town, South Africa, and men who have sex with men (MSM) and transgender women (TGW) in Bangkok, Thailand, and Harlem, N.Y. The study was designed to assess whether non-daily use of oral FTC/TDF as PrEP, compared with daily use, would demonstrate equivalent coverage of sex acts, lower number of pills needed for coverage and decreased self-reported drug side effects over 24 weeks. The study also evaluated self-reported adherence and analyzed drug levels in the blood of participants.

Coverage of sex acts, that is taking pills around the time of sex acts, was defined as having taken one tablet within four days (96 hours) prior to sex and one tablet within one day (24 hours) after sex. The measure was used to assess pill taking around the time of sex, but this amount of drug is not known to be protective. Adherence was defined as the number of pills taken compared to the number of pills instructed to take based on self-reported sex acts.

"The ADAPT study was designed to see if participants assigned to a non-daily dosing schedule would take their pills as prescribed. If participants were able to take fewer pills at times when they were not having sex, there could be greater satisfaction with PrEP services and cost savings if these regimens later proved to be effective and were recommended," said Robert Grant, M.D., M.P.H., of the Gladstone Institutes, the University of California, San Francisco (UCSF) and principal investigator for HPTN 067. "Our overall goal was to learn more about people's experience with PrEP, and how different dosing recommendations affect that experience."

In HPTN 067, after a six-week period to determine individual blood levels including four weeks of once-a-week directly observed pill taking, participants were randomly assigned to oral FTC/TDF in three dosage groups: daily dosing, time-driven dosing, and event-driven dosing. In all three dosing groups, dosing was not to exceed two pills per day or seven pills per week.

Results from each group of participants were analyzed separately. Thai MSM in Bangkok had the highest levels of coverage and adherence to the daily and time-driven dosing regimens. These were both significantly higher compared to the event-driven arm (85% of all sex events were covered in the daily arm, 84% in the time-driven arm and 74% in the event-driven arm). These findings indicates that some MSM and TGW could adhere to these non-daily PrEP regimens, though coverage was

significantly lower in the event-driven arm.

In a cohort of young, predominantly black MSM in Harlem, N.Y., participants had a statistically significant higher level of coverage of sex acts in the daily arm (66% of all sex events were completely covered) compared to the non-daily arms (47% of all sex events were covered in the time-driven arm; 52% of all sex events were covered in the event-driven arm). Adherence was significantly higher among those assigned to the daily arm compared to those assigned to the non-daily arms.

HPTN 067 demonstrated that young, single, black women in South Africa can take and adhere to a daily regimen of PrEP. This study showed high levels of coverage of sex acts in the daily arm (75%) among study participants in Cape Town when they were aware that the product works and that they were receiving the active product (i.e., in the setting of an open label study, not a placebo-controlled trial).

"HPTN 067 ADAPT study provides encouraging findings that diverse populations are able to take PrEP in a manner to achieve high coverage of sex acts," said Myron Cohen, M.D., director of the Institute for Global Health and Infectious Diseases at the University of North Carolina at Chapel Hill and HPTN Principal Investigator. "The findings will motivate further exploration of ways to provide this important prevention intervention to populations."

Provided by The HIV Prevention Trials Network