Safety, feasibility of PrEP for adolescent men who have sex with men

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Human immunodeficiency virus (HIV) preexposure prophylaxis (PrEP) was safe and well-tolerated in a study of adolescent men who have sex with men, although adherence to the daily medication waned and some HIV infections occurred among those with poor adherence, according to an article published by *JAMA Pediatrics*.

The U.S. Food and Drug Administration approved tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) for HIV PrEP in 2012. Since then, clinical trials and demonstration projects have supported the effectiveness of PrEP. But trials did not include adolescents younger than 18 so regulatory agencies were precluded from considering the approval of using TDF/FTC for minors.

Sybil G. Hosek, Ph.D., of the Cook County Health & Hospitals System's Stroger Hospital, Chicago, and coauthors designed Adolescent Medicine Trials Network for HIV/AIDS Interventions113 as an open-label demonstration project and phase 2 safety study for adolescent men who have sex with men who are ages 15 to 17 in the United States.

Study participants were recruited from adolescent medicine clinics and community partners in six U.S. cities. They had negative HIV test results but were at high risk for infection and were willing to participate in a behavioral intervention and to accept TDF/FTC as PrEP, which they were provided daily for 48 weeks.

The study enrolled 78 participants with an average age of 16, of whom 29 percent were black, 14 percent were white and 21 percent were white Hispanic.

Over the 48 weeks, 23 sexually transmitted infections were diagnosed in 12 participants and three participants acquired an HIV infection during the study for an HIV seroconversion rate of 6.4 per 100 person-years, according to the results. Among those with seroconversion, tenofovir diphosphate levels were consistent with taking less than an average of two doses per week of the PrEP at the likely time of HIV infection.

Most of the participants had detectable PrEP drug levels throughout the study, with more than 95 percent of participants having detectable levels over the first 12 weeks of treatment with declining levels thereafter, the authors report, noting that challenges to medication adherence among adolescents are commonplace.

Study limitations include its small sample size.

"The waning adherence, especially with quarterly visits, demonstrates that more time, attention and resources may need to be allocated to adolescents who are seeking prevention services," the article concludes.

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