Effect of Pre-exposure Prophylaxis for HIV Infection Integrated with Community Health Services

The rate of acquiring human immunodeficiency virus (HIV) was extremely low despite a high incidence of sexually transmitted infections (STIs) in a study where pre-exposure antiretroviral medication to prevent HIV infection was dispensed at clinics in three metropolitan areas heavily affected by HIV, according to an article published online by *JAMA Internal Medicine.*

Clinics that treat STIs and community-based clinics serving men who have sex with men (MSM) are promising sites to deliver preexposure prophylaxis (PrEP) for HIV. Men who have sex with men account for more than two-thirds of new HIV infections in the United States. Previous randomized clinical trials have demonstrated the efficacy of PrEP in preventing HIV infection. However, little is known about adherence to the PrEP regimen, sexual practices and overall effectiveness when PrEP is implemented at STI and community-based clinics serving MSM.

Albert Y. Liu, M.D., M.P.H., of the San Francisco Department of Public Health, and coauthors report on the results of a demonstration project that assessed PrEP adherence, sexual practices and incidence of STIs and HIV infection among MSM and transgender women in San Francisco, Miami and Washington, D.C.

The project enrolled participants from two municipal STI clinics in San Francisco and Miami and at a community health center in Washington from October 2012 through January 2014 with final follow-up in February 2015. PrEP was provided free of charge to participants for 48 weeks as a combination of daily, oral tenofovir disoproxil fumarate and emtricitabine. Patients also received HIV testing, brief client-centered counseling and clinical monitoring. Sexual behaviors were assessed by questionnaire.

Overall, 557 participants initiated PrEP and 437 of them (78.5 percent) were retained in the demonstration project through 48 weeks. Of the 294 participants who had their tenofovir diphosphate levels measured, 80 percent to 85.6 percent had protective levels at follow-up visits. Participants who were African American and those from the Miami clinic were less likely to have protective levels. Participants who had stable housing and those who reported at least two condomless anal sex partners in the past three months were more likely to have protective levels. The average number of anal sex partners declined during follow-up from 10.9 at baseline to 9.3 at week 48, while the proportion of participants engaging in condomless receptive anal sex remained stable from 65.5 percent at baseline, according to the results.

Overall, the incidence of STI was high (90 per 100 person-years) but did not increase over time. Two individuals became HIV infected during the follow-up for an HIV incidence of 0.43 infections per 100 person-years, the data indicate. The first infection was detected about 19 weeks after study enrollment and the second was detected about four weeks after the 48-week visit when the study drug was no longer dispensed. Both participants had tenofovir diphosphate levels consistent with taking fewer than two doses per week around the time of HIV infection, the authors explain.

Study limitations reported by the authors include under representation of the African American and transgender participants in the study, the results may not be generalizable to broader MSM populations, and the cost and lack of insurance coverage may be barriers to PrEP access outside of the study.

"Adherence was higher among those participants with more reported risk behaviors. These results provide support for expanding PrEP implementation in MSM in similar clinical settings and highlight the urgent need to increase PrEP awareness and engagement and to develop effective adherence support for highly affected African American and transgender populations," the authors conclude.

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