

Effect of pre-exposure prophylaxis for HIV infection integrated with community health services

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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

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 the 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.

In a related commentary, Raphael J. Landovitz, M.D., M.Sc., of the David Geffen School of Medicine at UCLA, Los Angeles, writes: "Overall, the news concerning PrEP dissemination is good, but there are sobering lessons. ... Realizing the benefits of PrEP requires an optimal cascade of events that is remarkably similar to the Gardner Cascade of engagement in care for those infected with HIV. The so-called PrEP cascade requires identification of at-risk individuals, promotion of interest and knowledge of PrEP, linkage to PrEP-knowledgeable clinics, and PrEP initiation, persistence and adherence. The benefits of PrEP will only fully be realized when we can identify ways of successfully moving persons at a high risk of HIV infection through this cascade."

PrEP Awareness, Use Among Young Black Men Who Have Sex with Men

A study of young black men in Chicago who have sex with men suggests that real-world PrEP use by those with the highest HIV incidence faces major implementation challenges, according to a research letter published online by *JAMA Internal Medicine*.

Young black men who have sex with men (YBMSM) are the only group in the United States where HIV incidence has increased over the past

decade with effective clinic-based HIV preventions that target YBMSM virtually nonexistent. The U.S. Food and Drug Administration approved PrEP in 2012.

John A. Schneider, M.D., M.P.H., of the University of Chicago, and coauthors used interviews to examine the relationship between PrEP awareness and use among 622 YBMSM with a set of sociodemographic, health care engagement, behavioral and social factors. The men were an average age of nearly 23; 39 percent of them had a high school or general education development (GED) education; and 79 percent of them reported income of less than \$20,000 per year. Nearly half of the HIV-negative (PrEP-eligible) men reported having some health coverage.

At baseline, PrEP awareness among the participants was 40.5 percent, while 12.1 percent knew of others who had used PrEP. About 72 percent of the participants were not infected with HIV, 3.6 percent of whom had used PrEP, according to the results.

Factors associated with PrEP awareness were having a primary care provider, participating in an HIV prevention program or research study, having had an anorectal sexually transmitted infection test and membership in the House and Ball community, a national network of socially organized "houses" largely comprised of YBMSM and transgender women that has existed in Chicago since the 1930s.

"Ongoing work should include scientific assessment of strategies to mobilize networks of YBMSM around PrEP as part of a comprehensive health care program. Concomitantly, efforts to mitigate the structural barriers that prevent PrEP uptake among YBMSM may greatly improve the public health effect potential of this promising HIV prevention intervention," the authors conclude.

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