

PrEP use high but wanes after three months among young African women

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In a study of open-label Truvada as daily pre-exposure prophylaxis (PrEP) to prevent HIV among 427 young African women and adolescent girls, 95% initiated the HIV prevention strategy, and most used PrEP for the first three months. However, PrEP use fell among participants in this critical population during a year of follow-up clinic visits, although HIV incidence at 12 months was low. The preliminary results suggest that tailored, evidence-based adherence support strategies may be needed to durably engage young African women in consistent PrEP use. The study, known as HPTN 082, was supported by the National Institute of Allergy and Infectious Diseases (NIAID) and the National Institute of Mental Health (NIMH), both parts of the National Institutes of Health. The data were presented at the 10th International AIDS Society Conference on HIV Science.

Young women and girls in sub-Saharan Africa account for 3 million of the 4 million people aged 15-26 with HIV in the region. The NIH-sponsored HIV Prevention Trials Network (HPTN) reports that recent clinical trials had unacceptably high HIV incidence rates of 5-6% per year among young African women in this age group.

"Young women and girls in sub-Saharan Africa must be empowered to make informed choices about HIV prevention methods, including PrEP, that have the potential to protect individuals' health as well as turn the tide of the HIV epidemic," said NIAID Director Anthony S. Fauci, M.D. "The new data suggest that we need to do more to help this population use PrEP every day as prescribed to effectively prevent HIV

acquisition."

HPTN investigators conducted the Phase 4 clinical trial, known as "Evaluation of Daily Oral PrEP as a Primary Prevention Strategy for Young African Women: A Vanguard Study." At clinic visits three months after initiating PrEP, 84% of 371 [study participants](#) who returned for follow-up had detectable levels of tenofovir diphosphate (TFV-DP)—a metabolite of one of the antiretrovirals in Truvada—in their blood according to dried blood spot analyses. Among these participants, 25% had TFV-DP levels suggesting "high adherence." At six- and 12-month follow-up visits, investigators found that participants with detectable levels of TFV-DP declined to 57% and 31%, respectively. Only 9% of [young women](#) had TFV-DP levels associated with high adherence at 12 months. Overall, four women acquired HIV during the study, all of whom had undetectable drug levels in their blood, suggesting limited adherence to PrEP.

"Multiple efficacy studies have shown that taking PrEP consistently every day provides high levels of protection against the acquisition of HIV," said Connie Celum, M.D., M.P.H., HPTN 082 protocol chair at the University of Washington in Seattle. "Unfortunately, as with all routine medication—especially for prevention purposes—daily adherence can be a challenge. Our findings suggest that our participants initially adhered well to PrEP. We need to develop effective ways to support young African women who still desire PrEP after this initial period to maintain their adherence and optimize their protection."

In the study, HIV-negative women and girls—ages 16 to 25—received HIV prevention counseling at an initial visit and were offered daily oral Truvada as PrEP. Participants who accepted PrEP as well as those who initially declined PrEP were followed for up to a year at clinics in Cape Town and Johannesburg, South Africa, and Harare, Zimbabwe. All participants who accepted PrEP received standard adherence support

services, including counseling, information about peer clubs and SMS text messaging reminders. Approximately half of participants who accepted PrEP were randomized to also receive counseling that included information about their drug-level results throughout the clinical trial. Investigators saw no difference in drug levels between the two groups at three, six or 12 months, indicating that drug level feedback did not improve PrEP adherence.

The HPTN 082 team plans to conduct further analyses, including qualitative interviews with up to 75 study participants, to assess why some women chose to accept or decline PrEP, and to identify specific adherence challenges. Interviews also may illuminate whether a participant's risk behavior or perception of personal HIV risk changed throughout the study, informing a potential choice to continue or discontinue PrEP use.

"Our data offer useful insights into the lives of our study participants," said Sinead Delany-Moretlwe, M.B.Ch.B., Ph.D., HPTN 082 protocol co-chair at the University of Witwatersrand in Johannesburg, South Africa. "In our future analyses, we have an opportunity to capture more complete information about the lives, sexual behavior and adherence support needs of these young [women](#) in order to better provide services and strategies that work for them."

In addition to indicating the need for more effective adherence support services, the findings also suggest that HIV prevention methods that do not rely on daily [adherence](#) may be advantageous in this population.

More information: C Celum et al. PrEP Adherence and Effect of Drug Level Feedback Among Young African Women in HPTN 082. 10th IAS Conference on HIV Science, Mexico City (2019).

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