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HIV-1 PrEP drug can be part of strategy to prevent infection in at-risk adolescents

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The Food and Drug Administration (FDA) recently expanded the indication for Truvada (emtricitabine/tenofovir disoproxil fumarate, 200 mg/300 mg) for pre-exposure prophylaxis (PrEP) of human immunodeficiency virus-1 (HIV-1) infection in at-risk adolescents, along with safer sex practices.

This combination antiretroviral is a single tablet dosed orally once daily in HIV-uninfected adolescents and adults weighing at least 35 kilograms (kg) to reduce the risk of sexually acquired HIV-1 infection. Comprehensive HIV prevention measures in addition to HIV-1 PrEP include monthly HIV testing, screening and treatment of other sexually transmitted infections, risk reduction counseling (consistent and correct condom use and safer sex practices), and provision of condoms.

Truvada is the only product approved by the FDA for HIV-1 PrEP. It also is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 17 kg.

The FDA approved Truvada for HIV-1 PrEP in adults in 2012. The adult efficacy findings, safety data from treatment trials in HIV-infected adolescents and an open-label trial in uninfected adolescents supported expansion of the PrEP indication to adolescents.

Initiating HIV-1 PrEP in at-risk youths may help avert the increase in HIV diagnoses seen in adolescents and young adults (http://dx.doi.org/10.15585/mmwr.mm6707a2). Clinical trials demonstrated that the effectiveness of Truvada for HIV-1 PrEP is strongly correlated with adherence to the dosing regimen. In all PrEP trials, Truvada was offered as part of a comprehensive HIV prevention strategy (see table).

HIV serostatus should be monitored at least every three months while on Truvada for HIV-1 PrEP due to the risk of developing HIV-resistant strains when used in individuals with an undetected acute HIV infection. Truvada has been associated with decreases in bone mineral density, renal laboratory abnormalities and infrequently with renal impairment. Renal and bone adverse events usually do not cause clinical symptoms and are reversible.

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HIV-1 PrEP trials	Population	Mean [range] age (years)	Number of participants	Duration of follow-up	Results
iPrEx	Adult men who have sex with men (MSM) and transgender women (TGW)	27 [18-67]	2,499	4,237 person-years	42% reduction in risk of acquiring HIV-1 compared to placebo
PrEP Partners	Adult HIV-serodiscordant heterosexual couples	34 [18-64]	4,747	7,827 person-years compared to placebo	62% reduction in risk of acquiring HIV-1
ATN113	Young MSM	17 [15-18]	67	48 weeks	HIV seroconversion occurred in three adolescents with drug levels reflecting poor adherence. Overall, adherence declined markedly when adolescents switched from monthly to quarterly clinic visits, suggesting adolescents may benefit from more frequent visits/counseling.

Resources

- More information on Truvada