

Pre-Exposure Prophylaxis (PrEP): A New Tool for Primary Care Providers to Help Prevent HIV Infection

Ryan Nall, MD, and Viraj Patel, MD, MPH

Dr. Nall is assistant professor of medicine at the University of Florida College of Medicine, and Dr. Patel is assistant professor at Montefiore Medical Center, Albert Einstein College of Medicine, in New York City.

Primarily care providers are critical to the reduction of new HIV infections in all populations, including men who have sex with men (MSM) and transgender individuals. Despite advances in HIV prevention and treatment, the number of new HIV infections has remained around 50,000 annually for the past decade. While most groups have experienced declines in new infections, MSM and transgender communities disproportionately account for new HIV infections, particularly in those under age 30.¹ To reduce rates of HIV transmission, primary care must play a central role and is the ideal setting for HIV risk assessment, risk reduction counseling, HIV screening, treatment of sexually transmitted infections (STIs), post-exposure prophylaxis (anti-retrovirals *after* potential exposure), and now pre-exposure prophylaxis (PrEP) with anti-retrovirals (given *prior* to potential exposure).

PrEP is an important tool primary care physicians have at their disposal to reduce the risk of HIV infection. Two large prospective randomized controlled trials of PrEP have shown it to be effective in reducing rates of HIV transmission when paired with risk reduction counseling. First, the iPrEX study group evaluated the use of PrEP among HIV-seronegative men and transgender women who have sex with men;² 2,499 participants were randomized to daily tenofovir-emtricitabine (TDF-FTC) or placebo. All subjects received HIV testing, risk reduction counseling, condoms, and management of STIs. Participants were followed for 1.2 to 2.8 years, and 100 new cases of HIV infection (36 in the FTC-TDF group

and 64 in the placebo group) were identified, indicating a 44% reduction in the incidence of HIV transmission (95% confidence interval [CI], 15% to 63%; $P=0.005$). Second, the Partners PrEP study group evaluated the use of PrEP in HIV serodiscordant heterosexual couples in Kenya and Uganda.³ The HIV-seronegative partner in this study was randomized to daily tenofovir (TDF), TDF-FTC, or placebo. The HIV-seropositive partners in this study were not eligible for antiretroviral therapy according to national guidelines. Couples received standard HIV treatment and prevention counseling. Among the 4,747 couples who were followed, 82 new HIV infections occurred in the 36-month study period—17 in the TDF group, 13 in the TDF-FTC group, and 52 in the placebo group—indicating a relative reduction in the incidence of new HIV infection of 67% with TDF (95% CI, 44% to 81%; $P<0.001$) and 75% with TDF-FTC (95% CI, 55% to 87%; $P<0.001$). Most recently, PrEP was also proven efficacious in IV drug users in Thailand. In all of these studies, efficacy was directly related to adherence, with those individuals who were more than 90% adherent showing no linked transmissions.

PrEP has been found to be safe, well tolerated, and cost effective if given to high-risk individuals. Based on these and other studies of PrEP, in 2012 the FDA approved daily oral TDF-FTC for use as PrEP as part of a comprehensive prevention plan in at-risk individuals. The CDC has also released formal guidelines on the provision of PrEP,⁴ and the governor of New York most recently included PrEP as one of the three main components to end the AIDS epidemic

in New York State. Further, commercial insurers and other payers, including state Medicaid programs, are increasingly providing coverage for PrEP. For the uninsured and those whose insurances do not currently cover PrEP, a patient assistance program exists to provide coverage.

Key Points About Prescribing PrEP

PrEP is not meant to be offered as a sole intervention for HIV prevention but prescribed as part of a comprehensive prevention plan. PrEP is indicated for individuals who have a documented negative HIV test result and are at ongoing high risk for acquiring HIV. A negative HIV test result needs to be confirmed as close to initiation of PrEP as possible. Because efficacy of PrEP is dependent on adherence, PrEP should be prescribed to those who are able to adhere to the regimen. While consistent condom use is a critical part of prevention, lack of use of condoms is *not a contraindication* to PrEP. PrEP is contraindicated in individuals with HIV infection, creatinine clearance less than 60 mL/min, and those who are not ready to adhere to daily PrEP. The first prescription of PrEP (TDF-FTC, 1 tablet PO daily) should only be provided for 30 days to allow for a follow-up visit to assess adherence, tolerance, and commitment. Patients receiving PrEP need regular visits—at least every three months—to monitor HIV status, adherence, and side effects. Follow-up of patients on PrEP should include risk-reduction counseling, ensuring access to condoms, STI screening, and mental health and

continued on page 2

CLINICAL UPDATE I

continued from page 1

substance use screening, when indicated. PrEP should be immediately discontinued when patients receive a positive HIV test result and link to HIV care.

Primary care providers are most likely to encounter HIV-negative individuals and are most appropriately situated to help patients stay HIV negative. This now includes consideration of PrEP in at-risk individuals. Primary care physicians must maintain a non-judgmental approach, take careful ongoing sexual histories, and assess risk of new HIV/STI infections in all patients.

PrEP is an effective new tool to augment behavior change in at-risk populations, help patients stay HIV negative, and reduce HIV transmission and related health disparities experienced by MSM and transgender communities. For comprehensive guidelines on assessing risk, counseling, and prescribing PrEP, visit www.hivclinicalguidelines.org or consult the CDC's clinical guidelines.⁴

References

1. <http://www.cdc.gov/hiv/statistics/reports/index.html> (accessed on July 31, 2014)
2. Grant RM, Lama JR, Anderson PL, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med* 2010; 363(27):2587.
3. Baeten JM, Donnell D, Ndase P, et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *N Engl J Med* 2012; 367(5):399.
4. <http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf> (accessed on August 2, 2014)

SGIM