



State of New Jersey
Department of Human Services
Division of Medical Assistance & Health Services
New Jersey Drug Utilization Review Board

NEWSLETTER

Volume 26 No. 16

December 2016

TO: Physicians, Nurse Practitioners, Clinics and Federally Qualified Health Centers- **For Action**
Providers of Pharmaceutical Services and Health Maintenance Organizations – **For Information Only**

SUBJECT: HIV Pre-Exposure Prophylaxis (PrEP)

PURPOSE: To provide practitioners useful clinical information regarding Truvada® and its use for HIV Pre-Exposure Prophylaxis

BACKGROUND: The New Jersey Drug Utilization Review Board (Board) serves as an advisory board to the New Jersey Department of Human Services and the New Jersey Department of Health. The Board's responsibilities include recommending clinical standards based, in part, on the evaluation of prescription drug use by participants in the State's prescription drug programs. The Board is also responsible for disseminating information that the Board has determined would encourage appropriate drug utilization. This includes raising concerns about under-utilization as well as over-utilization. The attached bulletin raises a concern about low utilization of Truvada® and its use for HIV Pre-Exposure Prophylaxis.

ACTION: Attached is a bulletin regarding the **risk of HIV and the benefits of PrEP**. This bulletin may also be viewed online at: <http://www.state.nj.us/humanservices/dmahs/boards/durb/newsletters/>. The Board welcomes your comments regarding the information shared in the bulletin. These comments may be sent to:

New Jersey DURB
Division of Medical Assistance and Health Services
Office of the Medical Director
P.O. Box 712
Trenton, New Jersey 08625
Attn: DURB Secretary

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HIV Pre-Exposure Prophylaxis

October 2016

Introduction:

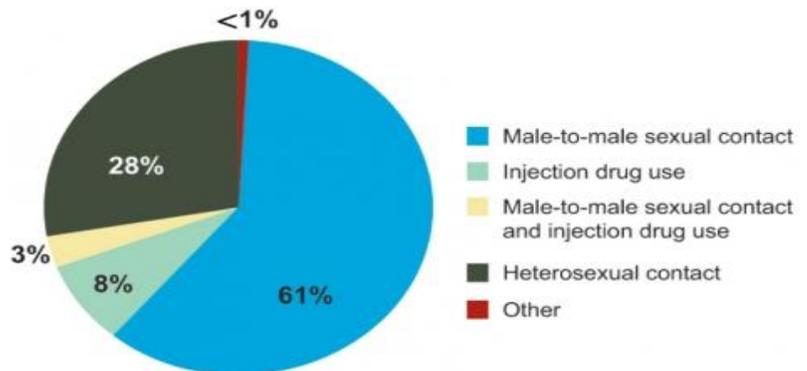
After many years of trying to find a cure or vaccine for human immunodeficiency virus (HIV), many experts and researchers are turning their attention to prevention. Studies have shown the economic value of prevention considering the high cost of HIV/AIDS treatment. Pre-Exposure prophylaxis is a promising approach in this effort.

Who is at high risk for HIV infection?

Anyone can contract HIV, and while intravenous drug users (IDUs) are at great risk because of practices related to their drug use, anyone who engages in unsafe sex (e.g., unprotected sex with an infected partner) may be exposed to HIV infection. It is still true that, gay or bisexual men having sex with men (MSM) are the most likely individuals to acquire HIV. MSM accounts for just a small fraction (2 percent) of the total U.S. population, yet nearly two-thirds of all new infections occurred within this group in 2009, and one-half of all people living with HIV in 2008 were MSM.

Key Principles for Prescribing Pre-Exposure Prophylaxis (PrEP):

- PrEP should not be offered as a sole intervention for human immunodeficiency virus (HIV) prevention. PrEP should only be prescribed as part of a comprehensive prevention plan.
- Efficacy of PrEP is dependent on adherence. PrEP should only be prescribed to those who are able to adhere to the regimen and express a willingness to do so.
- PrEP is indicated for individuals who have a documented negative HIV test result and are at ongoing high risk for HIV infection



Diagnosis of HIV Infection among Adults and Adolescents, by Transmission Category (2010)

Source: Centers for Disease Control and Prevention

Prevention:

Early detection and treatment prevents transmission of HIV. Research indicates that routine HIV screening among populations with a prevalence rate as low as one percent is as cost effective as screening for other conditions as breast cancer and high blood pressure. In addition, scientists have demonstrated that providing early Highly Active Anti-Retroviral Therapy (HAART) therapy to the HIV-infected partner of a heterosexual couple is 96% successful in preventing the spread of the virus to the uninfected partner. Also, consistent and

correct use of the male latex condom reduces the risk of sexually transmitted disease (STD) and human immunodeficiency virus (HIV) transmission. Of course, condom use cannot provide absolute protection against any STD, but according to the Center for Disease Control and Prevention (CDC), among the MSM population, those who use condoms have a 70% lower risk of HIV than those who don't.

Pre-Exposure prophylaxis:

Pre-Exposure Prophylaxis, or PrEP, is a way for people who do not have HIV but who are at substantial risk of getting it can prevent HIV infection by taking a medication every day. The medication, tenofovir/emtricitabine or Truvada is an option for the MSM population or for anyone in a discordant relationship (one partner with HIV, one without). A study published in the February 2015 edition of Sexually Transmitted Diseases showed that in an MSM population, those who always used condoms and who adhered to the daily regimen of tenofovir/emtricitabine (or at least an adherence rate of 90% had an estimated 92% lower HIV risk than those who never used condoms or PrEP. In consequence, it is recommended that people who use PrEP should commit to taking the drug every day (and be available for follow-up with their healthcare provider every 3 months for tests). This should include tests for HIV and other sexually transmitted diseases.

Educating the healthcare provider:

In June 2016, the American Medical Association (AMA) adopted new policies recognizing the need for improved education of physicians on the effective use of PrEP to prevent HIV acquisition in high-risk individuals. Although the FDA approved PrEP in July 2012, a 2015 survey by the CDC found that 34% of primary care doctors and nurses had never heard of PrEP. Also, more discouraging, it's estimated that only 5% of high-risk individuals are currently taking it. AMA also adopted two additional policies: to advocate that all insurers be required to cover the costs associated with administration of PrEP; and to work with government officials to study the feasibility of providing PrEP free of charge to high-risk individuals.

Summary of Guidance for PrEP Use

	Men Who Have Sex With Men	Heterosexual Women and Men	Injection Drug Users
Detecting substantial risk of acquiring HIV infection:	<ul style="list-style-type: none"> Sexual partner with HIV Recent bacterial STD High number of sex partners History of inconsistent or no condom use Commercial sex work 	<ul style="list-style-type: none"> Sexual partners with HIV Recent bacterial STD High number of sex partners History of inconsistent or no condom use Commercial sex work Lives in high-prevalence area or network 	<ul style="list-style-type: none"> HIV-positive injecting partner Sharing injection equipment Recent drug treatment (but currently injecting)
Clinically eligible:	<ul style="list-style-type: none"> Documented negative HIV test before prescribing PrEP No signs/symptoms of acute HIV infection Normal renal function, no contraindicated medications Documented hepatitis B virus infection and vaccination status 		
Prescription	Daily continuing oral doses of TDF/FTC (Truvada), ≤90 day supply		
Other services:	Follow-up visits at least every 3 months to provide: <ul style="list-style-type: none"> HIV test, medication adherence counseling, behavioral risk reduction support, side effects assessment, STD symptom assessment At 3 months and every 6 months after, assess renal function Every 6 months test for bacterial STDs 		
	<ul style="list-style-type: none"> Do oral/rectal STD testing 	<ul style="list-style-type: none"> Assess pregnancy intent Pregnancy test every 3 months 	<ul style="list-style-type: none"> Access to clean needles/syringes and drug treatment services

Adapted from: US Public Health Service. Prophylaxis for the prevention of HIV infection in the United States – 2014: a clinical practice guideline.

References:

1. National Institute on Drug Abuse: Who Is at Risk for HIV Infection and Which Populations Are Most Affected?
<https://www.drugabuse.gov/publications/research-reports/hivaids/who-risk-hiv-infection-which-populations-are-most-affected> Accessed July 29, 2016
2. National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention: Pre-Exposure Prophylaxis (PrEP) for HIV Prevention.
http://www.cdc.gov/hiv/pdf/prep_fact_sheet_final.pdf Accessed July 29, 2016
3. American Medical Association: AMA Urges Greater Physician Education on Effective Use of Once-A-Day HIV Prevention Option; 2016 AMA Press Releases and Statements: June 15, 2016

Other Sources:

<http://www.cdc.gov/hiv/basics/prep.html>

<http://www.fda.gov/ForPatients/Illness/HIVAIDS/ucm126372.htm>

<http://www.hivguidelines.org/clinical-guidelines/pre-exposure-prophylaxis/guidance-for-the-use-of-pre-exposure-prophylaxis-prep-to-prevent-hiv-transmission/>