



Department of Health

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Commissioner

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Executive Deputy Commissioner

April, 2015

Dear Colleague,

The New York State Department of Health (NYSDOH) AIDS Institute supports the use of Pre-exposure Prophylaxis (PrEP) as a first line intervention for individuals at high risk of acquiring HIV. This biomedical prevention measure may prove to be the key in New York State's effort to end the epidemic.

I invite you to read and share the attached letter written by Demetre Daskalakis, MD, MPH, Assistant Commissioner of the New York City Department of Health and Mental Hygiene. Dr. Daskalakis summarizes three recent studies on PrEP that were presented at the February 2015 Conference on Retroviruses and Opportunistic Infections (CROI). The results of the studies may raise some questions about the frequency of administration of PrEP and this letter assists with interpreting the findings and addressing patient concerns.

At this time, the NYSDOH Guidelines committee continues to recommend daily dosing of PrEP to protect against HIV.

We are committed to providing the tools clinicians need to feel confident when prescribing PrEP to their patients.

- [Guidance for the Use of Pre-Exposure Prophylaxis \(PrEP\) to Prevent HIV Transmission](#), developed by the NYSDOH [HIV Clinical Guidelines Program](#), provides detailed prescribing information and easy to follow checklists for PrEP management
- The [Clinical Education Initiative \(CEI\)](#) provides online access to clinical information and continuing medical education (CME) on a variety of topics related to HIV including PrEP
- The CEI Clinical Consultation Line for consultation with a clinician experienced in managing PrEP and PEP (post exposure prophylaxis): **866-637-2342**

Sincerely,

Bruce D. Agins, MD

Bruce Agins, MD, MPH
Medical Director
AIDS Institute



NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Mary T. Bassett, MD, MPH
Commissioner

Demetre C. Daskalakis, MD, MPH March 27, 2015

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Dear NYC PrEP Providers,

Several studies presented at the 2015 Conference on Retroviruses and Opportunistic Infections augment the already strong support for the important role of Pre-Exposure Prophylaxis (PrEP) as a safe and efficacious method to prevent HIV infection. Three of these studies are presented in brief below.

The NYC Department of Health and Mental Hygiene's Bureau of HIV/AIDS Prevention and Control continues to support once-daily dosing of fixed-dose combination tenofovir and emtricitabine (TDF/FTC, or Truvada®) for individuals at risk of HIV infection.

IPERGAY: This study evaluated an event-driven, or on-demand, strategy for PrEP use among men in France and Canada. Men enrolled in this study, all of whom were men who have sex with men (MSM), were directed to take 2 doses of TDF/FTC at 2-24 hours before sex and then once daily for 2 days after sex. This strategy was associated with an 86% relative reduction in HIV acquisition when compared to placebo (0.94 vs. 6.6 per 100 person-years) and the number of people needed to treat to avert an HIV infection was 18. Some important details of the study:

- ***The average number of pills taken per month by participants was 16, mirroring an adherence level of approximately 4 pills per week.*** In analyses of the open label extension of a daily oral PrEP study, iPrEx, drug levels consistent with patients taking 4 tablets per week were associated with a very high level of protection from HIV. Therefore, the reported frequency of use of on-demand PrEP in IPERGAY may have been high enough to approximate near daily use of PrEP.
- ***Nearly 60% of men in this study did not use on-demand PrEP, or reported suboptimal use, at last intercourse.*** One benefit of daily dosing of PrEP is the lack of decision-making or planning required immediately prior to sexual activity, and other data support that MSM are unable to successfully predict when future sexual acts will occur. The need to initiate PrEP in advance of intercourse, and thus have some planning involved, is an important factor in the optimal use of an on-demand dosing strategy and may lead to occasions of intercourse unprotected by PrEP.
- ***This study was in men only.*** Differential pharmacokinetics in women taking TDF/FTC for PrEP caution against extending these findings to women without further study.

PROUD: This study evaluated a real-world PrEP implementation by comparing immediate versus deferred PrEP initiation among MSM in sexual health clinics in the United Kingdom. The study demonstrated both high levels of adherence to, and efficacy of, daily use of PrEP. Comparing the incidence in the immediate start arm to the deferred group (1.3 vs. 8.9 per 100 person-years), the efficacy of PrEP was 86% and the number of people needed to treat to avert an HIV infection was only 13. There were no significant differences in diagnoses of sexually transmitted infections (STI) between the two arms, though rates were high in both.

Partners Demonstration Project: Interim data from a trial among higher-risk heterosexual serodifferent couples in Kenya and Uganda demonstrated that a strategy that combines PrEP with initiation of treatment was associated with a large and significant reduction in HIV transmission. Specifically, in this study, HIV-negative partners started and continued PrEP while their HIV-positive partners initiated ART for the goal of viral load suppression (VLS). Some important details of this study:

- ***The majority of observations analyzed at this stage of the study represented time when the HIV-negative partners were on PrEP.*** Additional time-points will evaluate the effect of stopping PrEP after VLS has been achieved by the HIV positive partner. Current data mainly reflect the impact of PrEP on HIV prevention.
- ***The study population was heterosexual.*** Extrapolation of this strategy to MSM or transgender women who have sex with men should be done with caution.

How do these findings impact my practice and my patients starting or consistently taking PrEP?

1. Should I encourage my patients to use “on-demand” PrEP?

We currently recommend that patients be encouraged to take daily PrEP as outlined [in previous guidance](#). On-demand PrEP may be right for a very small group of individuals; that decision should be made on a case-by-case basis. The complexity of the dosing schedule for “on-demand” use of PrEP and the need to initiate PrEP based on forecasted sexual activity make this strategy less than optimal. ***Daily use of TDF/FTC for PrEP is the preferred strategy. Continue to encourage patients on PrEP to maintain this schedule.***

2. High levels of sexually transmitted infections (STI) have been reported in many PrEP studies. What should my strategy be to help prevent these infections?

PrEP studies recruit people at high risk for HIV and STI and, accordingly, report higher rates of these infections. The studies also include frequent and rigorous screening for STIs and, thus, may identify more infections in under-tested populations at risk.

Providers of PrEP should continue to offer genital and extragenital screening for gonorrhea and chlamydia, syphilis testing, and Hepatitis C screening; they should also provide vaccination for Hepatitis A and B and Human papillomavirus (HPV) as indicated. PrEP users should be encouraged to use condoms as much as possible given the associated reduction in both HIV and STI, including Hepatitis C.

3. Acute Hepatitis C has been sporadically reported in people on PrEP. What should I do?

Guidelines encourage screening people on PrEP for Hepatitis. Patients, especially MSM, should be counseled about the risk of sexually transmitted Hepatitis C infection and the potential role of condoms in preventing this infection. Injection drug users should be encouraged to use syringe access programs and avoid sharing any drug use paraphernalia. Providers of PrEP should be vigilant for acute Hepatitis C and have a low threshold to screen for this infection. If cost allows, we recommend ordering a Comprehensive Metabolic profile (or panel) when patients are due for their semi-annual check for tenofovir-associated nephrotoxicity. Such testing includes both kidney function testing and liver enzymes. Any abnormality in liver enzymes should be pursued with further testing for Hepatitis C in all, and Hepatitis A and B in non-immune patients. Routine screening for Hepatitis C should be undertaken at least annually for injection drug users, MSM, and those with multiple sexual partners.

* * *

Taken together, data from recent studies, such as PROUD, IPERGAY, and Partners Demonstration Project, strongly support the use of PrEP in populations at risk as defined by local and national guidance. We are enthusiastic about the exploration of new strategies to use PrEP, but the limitations of these studies should be taken into account when making decisions for individual patients.

The NYC Health Department encourages you to continue your work in supporting your patients' commitment to "[Be HIV sure.](#)" To end the HIV epidemic in NYC, it is critical to use all of the tools in the ever-expanding HIV treatment and prevention toolbox.

Sincerely,

A handwritten signature in black ink, appearing to read "Demetre C. Daskalakis". The signature is fluid and cursive, with a large initial "D" and "C".

Demetre C. Daskalakis, MD, MPH
Assistant Commissioner