



MARY TRAVIS BASSETT, MD, MPH, COMMISSIONER



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Dear Colleague:

The New York City Department of Health and Mental Hygiene issued the attached Health Alert on October 27, 2016 to inform health care providers of a case of HIV infection with a multidrug resistant strain of HIV in a man who reported adherence to PrEP. In this case, adherence was confirmed by detection of protective levels of tenofovir, one of the medications in PrEP, in hair and blood samples. This is the second reported case of multidrug resistant HIV diagnosed in a person who was apparently adherent to PrEP; the other [case](#) was diagnosed in Toronto, Canada earlier this year. In this letter, we provide context for understanding these cases, share resources for patients (see attached), and describe how public health and clinical providers can work together to ensure rapid identification of similar cases.

Background

PrEP clinical trials demonstrate [92-99%](#) efficacy when patients adhere to the medication. While cases of HIV infection among people adherent to PrEP are unsettling, no prophylactic medication is 100% effective, and breakthrough infections are expected to occur, albeit very rarely. Estimates indicate that there are approximately 15,000 people in NYS taking PrEP at this time. We are currently aware of only one such infection having occurred in New York. This is consistent with what we know about tenofovir resistant mutations, which occur across different HIV-1 subtypes in the United States at an estimated prevalence of [0.1%](#) or [0.3%](#).

Key recommendations

The State and City Health Departments recommend that clinical providers (and other support providers):

- Routinely discuss condom use and other harm reduction strategies, which, in conjunction with PrEP medication, can further reduce the risk of HIV infection, even if a person is exposed to resistant strains of HIV.
- **Promote** combination HIV prevention strategies to patients in a non-judgmental and evidence-based fashion.
- **Adhere to** general clinical guidance about PrEP prescribing and follow-up ([see below](#)).
- **Manage** suspected seroconversion according to best practices proposed herein ([see below](#)).
- **Report** suspected seroconversion to the appropriate public health authority ([see below](#)).
- **Continue** to promote PrEP and HIV treatment as prevention (TasP), both powerful HIV prevention tools that are central to the progress we are making to end the epidemic of HIV in New York by the end of 2020.

General Clinical Guidance about PrEP Prescribing and Follow-Up

Close adherence to NYS PrEP guidelines is important to identify and intervene on future breakthrough events. HIV testing every three months for all patients on PrEP is critical for early identification of any cases of breakthrough HIV infection. Providers who are managing patients on PrEP should ensure regular HIV testing is conducted using a lab-based fourth generation (combination antibody-antigen) test. Providers and patients should maintain a high level of vigilance about the signs and symptoms of [acute HIV infection](#). Additional testing, including HIV-1 RNA testing, should be conducted if acute HIV infection is suspected. Routine testing and early treatment for sexually transmitted infections are also critical components of PrEP care that help reduce the likelihood of HIV infection.

Management of Suspected Seroconversion

If a seroconversion is suspected, resistance testing should be conducted and immediate antiretroviral therapy for treatment initiated. Therapy should ideally be started on the day of diagnosis; it is *not* necessary to await results of resistance testing.

Pending both resistance testing and consultation with an experienced HIV provider, the following empiric medications should be prescribed:

- Continuation of the PrEP prescription [tenofovir 300mg/emtricitabine 200mg (Truvada), once daily]
- Dolutegravir (Tivicay) (50mg daily)

Plus one of the following:

- Darunavir (Prezista) (800mg daily) boosted with ritonavir (Norvir) (100mg daily)
- Darunavir boosted with cobicistat (co-formulated as Prezcoxib, one tablet daily)

Once resistance testing results are available, regimens can subsequently be adjusted as clinically indicated.

Reporting of Suspected Seroconversion

Providers who manage patients on PrEP are strongly encouraged to immediately report any cases of suspected PrEP/PEP breakthrough HIV infection as follows:

1. NYC: Report cases to the New York City Department of Health and Mental Hygiene by calling 212-442-3388 and following the directions detailed in the attached Health Alert, or
2. Rest of State: Report cases to New York State Department of Health by calling 518-474-4284 or using [DOH-4189](#) and contacting their local [Partner Services Program](#) to discuss the case.

State law requires that providers report all cases of HIV infection as soon as possible but no later than 14 days after diagnosis. Rapid case reporting is critical, because it allows health departments to investigate the case and engage field staff to:

1. Conduct outreach to the patient's social network;
2. Make HIV testing available to exposed partners; and,
3. Reduce secondary transmission by expediting linkage to care and PrEP/PEP referrals.

Summary

PrEP is highly effective at preventing HIV infection, but effectiveness is not 100%. The State and City Health Departments will continue to partner with clinical providers and community leaders to ensure maximal use of PrEP, PEP, TasP, condoms, and other forms of HIV prevention to prevent new cases of HIV infection. We remain committed to helping New Yorkers understand their risk of HIV infection and adopt the prevention strategies using methods that are both effective and acceptable. If you have questions or comments about the topics covered in this letter, please address them to Lyn Stevens at lyn.stevens@health.ny.gov or Demetre Daskalakis at ddaskalakis@health.nyc.gov.

Sincerely,



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