
New York State Department of Health 2005 Guidance for HIV Counseling and Testing and New Laboratory Reporting Requirements

Increase HIV Testing

1. Streamline HIV counseling in all settings using a simplified written *Informed Consent* form for Pre-test Counseling

Streamlined counseling in medical and non-medical settings. Detailed, face-to-face counseling is not required by Public Health Law Article 27F. In many cases the provider may give the informational section (Part A) of the *Informed Consent* form to individuals for review, together with an explanation that he or she recommends testing for HIV. Individuals who have no questions may be asked to sign the signature page (Part B) of the *Informed Consent* form. Other ways to streamline counseling may include verbal review of the form and/or the use of print and/or audiovisual materials. More extensive counseling should be provided upon patient request or upon provider assessment that this is required.

Clients with limited reading proficiency or low health literacy skills might not inform providers that they are unable to read the form. If clients appear to be struggling with the information or are not able to read the document on their own, or the provider is not sure, providers may choose to read the document to them and explain each section. Providers should use translation services, as needed, to ensure that clients using consent forms in languages other than English truly understand the information provided.

Simplify and streamline written Informed Consent. To reduce barriers to HIV testing the NYSDOH is publishing a simplified English language version of the *Informed Consent to Perform an HIV Test* form on its web site and directing that all providers of HIV counseling and testing utilize this form, or a compatible version approved by the Department, effective June 1, 2005.

Part A, the informational section, contains all of the basic information that someone would need to know to make a decision about being tested. It is written in simple, easy-to-follow language. For many persons, this written document can be provided for review and, unless there are questions or other circumstances warranting further steps, individuals can be asked to sign Part B indicating their written consent. They should be encouraged to keep the informational section (Part A). The signature page, Part B of the new *Informed Consent* form, should be maintained by the provider.

The foreign language versions of the existing *Informed Consent* form may continue to be used until the new form is available in other languages. The new form, while easier to understand, maintains emphasis on important confidentiality and anti-discrimination provisions and penalties. Written informed consent is an essential component of HIV counseling in NYS.

The new *Informed Consent* form also includes authorization for HIV antibody testing and, if HIV-positive, the series of resistance testing and viral load testing as well as incidence testing to monitor the HIV epidemic. It also allows pregnant women to consent to more than one test during the same pregnancy, as has been the practice in NYS since 2004.

To maintain flexibility in changing forms in the future, NYSDOH is removing the approved *Informed Consent to Perform an HIV Test*, as well as the *Authorization for the Release of Confidential HIV Related Information*, from the Part 63 regulations. These forms will continue to be posted on the Department's web site to enable the widest possible dissemination. The Department will continue to approve provider-designed versions of the *Informed Consent* form on a case-by-case basis, as it has for many years.

2. Integrate routine HIV testing in medical care settings.

To encourage HIV testing more broadly, NYSDOH, consistent with the Centers for Disease Control and Prevention (CDC) Advancing HIV Prevention Initiative, urges HIV testing to be recommended as a routine part of medical care and other services. Even in areas of low seroprevalence, consideration should be given to testing individuals with no identified risk factors at least once. Recent data indicate that routine HIV testing at least once may be cost effective, even in areas with seroprevalence less than 1% (Bozette, NEJM, 2005; Sanders et al., NEJM, 2005; Paltiel et al, NEJM, 2005).

Health care providers in NYS are encouraged to routinely discuss HIV with their patients, regardless of their perceived risk, and to have a low threshold for recommending HIV testing since not all infected persons are aware of or willing to disclose their risk. Health care providers should recommend HIV testing, as appropriate, to all sexually active persons, persons with a history of substance abuse and persons in areas with high seroprevalence (i.e., at least 1%), including major urban areas.

Routine testing should be recommended through managed care and fee-for-service providers at primary care sites, community health centers/diagnostic and treatment centers, urgent care centers, Designated AIDS Centers and other hospitals, substance abuse treatment programs, public STD clinics, family planning programs, correctional facilities and other settings. Testing in emergency rooms is also encouraged, particularly in areas of high seroprevalence and for individuals at high risk.

Universal Recommendation for Testing of Pregnant Women New York State regulations require hospitals and diagnostic and treatment centers licensed under Article 28 of the Public Health Law and health maintenance organizations to provide HIV counseling and to **recommend** testing for all women in prenatal care without regard to risk. The Department recommends that HIV counseling and testing be provided early in pregnancy to ensure that women who test positive receive appropriate health care as well as therapy to reduce the risk of mother to child HIV transmission. These regulations also apply to private physicians participating in HMOs through independent practice associations (IPAs) and group and network arrangements. Private providers of prenatal care not practicing in regulated settings are not subject to Department regulations; however, the routine provision of HIV counseling with recommended voluntary testing is a standard of prenatal medical practice in New York State.

Repeat Testing in the Third Trimester of Pregnancy Recent Department studies have shown that infection during pregnancy, after an initial negative test early in pregnancy, is a leading cause of residual mother to child HIV transmission in New York State. Based on these findings, the Department joins the American College of Obstetricians and Gynecologists in strongly recommending that prenatal care providers repeat HIV testing in the third trimester of pregnancy. Ideally, third trimester testing should take place in the 35th-37th week of gestation. The *Informed Consent* has been changed to allow pregnant women to consent once for two tests during pregnancy.

3. Adopt rapid testing technology.

Rapid HIV tests are simple to use and require little or no specialized equipment. Rapid HIV antibody tests can provide a result during a single appointment. Individuals may be more likely to be tested for HIV if they know that the appointment, inclusive of counseling, consent and testing, will be relatively brief. Additional information about rapid testing is available at:

<http://www.health.state.ny.us/diseases/aids/testing/rapid/index.htm>

Ensure entry into care

4. Facilitate referrals and access to care and services.

Advances in treatment have made it possible for HIV-infected persons to live longer, healthier lives. Entry into care is critical and the improved health of HIV-infected persons on antiretroviral therapy has contributed to an improved understanding of the importance of referral to care. Services such as medical care, case management services, ongoing prevention counseling, services to help notify partners or spouses

regarding their exposure to HIV, substance or alcohol abuse prevention and treatment services, mental health services, legal services, STD screening and treatment, screening and treatment for viral hepatitis, and other HIV prevention and support services (e.g., assistance with housing, food, employment, transportation, child care, domestic violence, and legal services) can help clients access and accept medical services and adopt and maintain behaviors to reduce risk for HIV transmission and acquisition.

To facilitate referrals and access to care and services, the *Authorization for the Release of Confidential HIV Related Information* has also been improved. The new *HIPAA Compliant Authorization for the Release of Medical Information and Confidential HIV-Related Information* allows individuals to use a single form to authorize release of general medical information as well as HIV-related information to more than one provider and to authorize designated providers to share information between and among themselves.

Increase Laboratory Reporting

5. Increase laboratory reporting to include results of resistance, viral load tests and CD4 tests.

The recent case of multiple drug resistant HIV with apparent rapid progression to AIDS highlighted the need for better ways to track HIV drug resistance in the population. Although drug resistance is commonly seen among persons who have received prior antiretroviral therapy without complete suppression of viral load, population-based data are not available on the extent of resistance in the treated population, nor is it known to what extent resistant strains are transmitted from one person to another.

With amendments to Part 63 regulations, effective June 1, 2005, laboratories conducting tests on specimens from New York State residents are required to report HIV resistance test results, non-detectable viral load test results and CD4 test results. This reporting is necessary to monitor the suppression of HIV by antiretroviral therapy and, thus, the risk of drug resistance. Public health agencies will benefit from improved information for planning HIV/AIDS-related care, supportive services and prevention services. The examination of geographic differences and trends in resistance patterns may eventually be valuable to physicians, providing them with information that may help guide HIV treatment practices.

The "State Register" containing the emergency regulations may be found at the following web site: <http://www.dos.state.ny.us/info/register.htm>.

Resources

Revised Informed Consent and Release Forms

- New *Informed Consent to Perform an HIV Test*
<http://www.health.state.ny.us/diseases/aids/forms/>
- New *HIPAA Compliant Authorization for the Release of Medical Information and Confidential HIV-Related Information*
<http://www.health.state.ny.us/diseases/aids/forms/>

Key Messages

- “Key Message about the Importance of HIV Testing”
- <http://www.health.state.ny.us/diseases/aids/testing/rapid/keymessage.htm>

HIV Reporting and Partner Notification Law

- Information for Providers
- <http://www.health.state.ny.us/diseases/aids/regulations/>
- How Informed Consent for HIV Testing, HIV Partner Notification by PNAP/CNAP and Access to HIV Primary Care Are Handled When Minors Are Involved
- http://www.health.state.ny.us/diseases/aids/regulations/notification/hivpartner/minor_qa.htm
- Materials Regarding Screening for Domestic Violence
- <http://www.health.state.ny.us/diseases/aids/regulations/#domestic>

To Locate HIV Testing Programs

- “HIV Counseling & Testing Resource Directory - 2004 Edition”
<http://www.health.state.ny.us/diseases/aids/testing/directory/index.htm>
- How to Locate an Anonymous Testing Site
<http://www.health.state.ny.us/diseases/aids/testing/directory/anonct.htm>

Educational Materials about HIV/AIDS

Educational materials that are especially relevant to the new HIV counseling and testing guidance include:

- "100 Questions and Answers about HIV/AIDS"
<http://www.health.state.ny.us/diseases/aids/facts/questions/index.htm>
- Testing Q&A
<http://www.health.state.ny.us/diseases/aids/facts/questions/testing.htm>

- HIV/AIDS Educational Materials for Consumers
<http://www.health.state.ny.us/diseases/aids/publications/>

- "Two Good Reasons to Get an HIV Test - Brochure"
<http://www.health.state.ny.us/diseases/aids/docs/0232eng.pdf> (English)
<http://www.health.state.ny.us/diseases/aids/docs/0233span.pdf> (Spanish)