Defendant Testing Guide

NYS DOH AIDS Institute
November 1, 2007

I. Background

As of November 1, 2007, New York Criminal Procedure Law § 210.16 requires the testing of criminal defendants, indicted for certain sex offenses, for human immunodeficiency virus (HIV), upon the request of the survivor.

The NYS Department of Health (NYS DOH) is responsible for issuing guidance for the Court on the following:

- Medical and psychological benefit to the survivor
- The appropriate HIV test to be ordered for the defendant
- When follow-up testing for the defendant is recommended
- When it is appropriate to discontinue post-exposure prophylaxis (PEP)

The NYS DOH AIDS Institute's Medical Care Criteria Committee and the Mental Health Guidelines Committee carefully reviewed the issues involved and developed this guidance through a consensus-based process. As requested, the committees specifically addressed HIV risk; however, the survivor's healthcare provider should also consider risk of transmission of hepatitis B, hepatitis C, and other sexually transmitted infections (STIs). The guidelines on the care of sexual assault survivors, *HIV Prophylaxis Following Non-Occupational Exposure Including Sexual Assault*, developed by the Medical Care Criteria Committee of the NYS DOH AIDS Institute, include recommendations for the post-exposure management of HIV, hepatitis B, and hepatitis C. The NYS DOH The Protocol for the Acute Care of the Adult Patient Reporting Sexual Assault includes guidelines for prophylaxis against other STIs.

II. Definitions

The defendant testing law refers to "significant exposure" as defined by 10 NYCRR § 63.10. *HIV Prophylaxis Following Non-Occupational Exposure Including Sexual Assault* offers a definition of sexual assault that is pertinent to the assessment of a significant exposure. Both definitions are listed below.

Table 1. Definitions of Significant Risk and Sexual Assault Exposure

Significant Risk, as defined by 10 NYCRR § 63.10:
The three factors necessary to create a significant risk of contracting or transmitting HIV infection are:

(1) the presence of a significant-risk body substance;
(2) a circumstance which constitutes significant risk for transmitting or contracting HIV infection; and
(3) the presence of an infectious source and a non-infected person.

Significant risk body substances are blood, semen, vaginal secretions, breast milk, tissue, and the following body fluids: cerebrospinal, amniotic, peritoneal, synovial, pericardial, and pleural.

Circumstances which constitute "significant risk of transmitting or contracting HIV infection" are:

(1) sexual intercourse (e.g., vaginal, anal, oral) that exposes a non-infected individual to blood, semen, or vaginal secretions of an HIV-infected individual;
(2) sharing of needles and other paraphernalia used for preparing and injecting drugs between HIV-infected and non-infected individuals;
(3) the gestation, birthing, or breastfeeding of an infant when the mother is HIV-infected;
(4) transfusion or transplantation of blood, organs, or other tissues from an HIV-infected individual to a non-infected individual, provided such blood, organs or other tissues have not tested conclusively [negatively] for antibody or antigen and have not been rendered non-infective by heat or chemical treatment;
(5) other circumstances not identified in paragraphs (1) through (4) during which a significant risk body substance (other than breast milk) of an infected individual contacts mucous membranes (e.g., eyes, nose, mouth), non-intact skin (e.g., open wound, skin with a dermatitis condition, abraded areas), or the vascular system of a non-infected person. Such circumstances include, but are not limited to, needlestick or puncture wound injuries and direct saturation or permeation of these body surfaces by the infectious body substance.

Circumstances that do **not** *involve "significant risk" include:*

(1) exposure to urine, feces, sputum, nasal secretions, saliva, sweat, tears, or vomitus that does not contain blood that is visible to the naked eye;
(2) human bites where there is no direct blood to blood, or blood to mucous membrane contact;
(3) exposure of intact skin to blood or any other body substance;
(4) occupational settings where individuals use scientifically accepted preventive practices and barrier techniques in circumstances that would otherwise pose a significant risk, provided that such barriers are not breached and remain intact.

Sexual Assault Exposure, as defined by the NYS AI *HIV Prophylaxis Following Non-Occupational Exposure Including Sexual Assault* guidelines:
Direct contact of vagina, anus, or mouth with semen or blood of the alleged assailant, with or without evidence of physical injury, tissue damage, or presence of blood at the site of the assault.

III. GUIDANCE FOR MAXIMIZING THE MEDICAL AND PSYCHOLOGICAL BENEFIT TO THE SURVIVOR

The guidelines for initiation of PEP for the sexual assault survivor DO NOT change from that which is currently recommended in HIV Prophylaxis Following Non-Occupational Exposure Including Sexual Assault. The sexual assault survivor should be evaluated in an emergency department (ED) as soon as possible for treatment and discussion of PEP. If a significant exposure, as defined in Table 1, did occur and the decision is made to initiate PEP, it should be initiated ideally within 2 hours and generally no later than 36 hours from the time of the exposure. Studies have shown that the sooner PEP is initiated, the more likely it is to be effective. A 28-day course of a 3-drug regimen, as outlined in HIV Prophylaxis Following Non-Occupational Exposure Including Sexual Assault should be used for PEP. The survivor should receive a baseline HIV test within 72 hours of the exposure, and at 1 month, 3 months, and 6 months post-exposure, even if PEP is declined.

A. Court-Ordered HIV Testing of Defendants: 7 to 30 Days from the Time of the Exposure

Rationale for 7- to 30-Day Timeframe:

HIV can be detected as early as 7 days when using both a plasma HIV RNA assay and a standard HIV-1 ELISA antibody test. After 30 days from the time of exposure, the survivor will have completed the 28-day PEP regimen; therefore, the testing recommendations change because the use of a plasma HIV RNA assay in addition to the antibody test is not medically beneficial. See Section B. *Court-Ordered HIV Testing of Defendants: 30 Days to 6 Months From the Time of the Exposure* for the psychological benefit that may be gained from defendant testing after 30 days.

Medical Benefit of Defendant Testing for the Survivor:

- The only clear medical benefit for the survivor of HIV testing the defendant would be the discontinuation of PEP to avoid potential toxicity and side effects; for this benefit to be realized, the defendant's test results would need to be available within the 28-day period for which the PEP regimen is prescribed
- The medical decision to discontinue PEP on the part of the survivor should be made only in full consultation with the survivor's clinician. The survivor's clinician should consult with an HIV Specialist before discontinuing the regimen. The NYS PEP Line can be used for phone consultation.

Psychological Benefit of Defendant Testing for the Survivor:

Defendant testing for HIV may have the following psychological benefits for the survivor:

- Providing information that may help the survivor understand the degree of risk for acquiring HIV
- The comfort of knowing that exposure to HIV is unlikely in those instances when the defendant tests HIV negative on both the antibody test and plasma HIV RNA assay
- Allowing the survivor to participate more fully in the decision of whether to continue or discontinue post-exposure prophylaxis regimen

Recommendations:

The Medical Care Criteria Committee recommends that a plasma HIV RNA assay should be used in conjunction with a standard HIV-1 ELISA antibody test when the defendant is tested 7 to 30 days from the time of the survivor's exposure. Because the results of the defendant's test may be the only criterion used to decide to terminate the survivor's PEP regimen, the Committee concluded that it was necessary to exclude the possibility of the defendant being in the "window period." The window period is the length of time after infection (usually 2 to 6 weeks) that it takes a person to develop enough specific antibodies to be detected by an antibody test. The HIV RNA assay would, however, detect HIV viral load as soon as 7 days after infection and would establish a diagnosis; therefore, it is important to use both a plasma HIV RNA assay and antibody testing when the completion of the survivor's PEP regimen hinges on the defendant's test results.

Negative test results from both the antibody test and the HIV RNA assay would indicate that the defendant is *not* infectious with HIV and would permit discontinuation of the survivor's PEP regimen. Positive test results from **either** the HIV antibody test or the HIV RNA assay would indicate that the defendant is likely to be infected with HIV and that the survivor's PEP regimen should be completed. When making decisions regarding the management of the survivor, the defendant should be considered to be HIV-infected until proven negative. Table 2 outlines the different possibilities of test results, how each result would affect the survivor's PEP regimen, and the necessary follow-up.

<table>
<tr><th colspan="4">Table 2
Defendant Testing Recommendations:
7 to 30 Days From Time of Assault</th></tr>
<tr><th>Tests to Obtain</th><th>Defendant Test Results</th><th>Survivor PEP</th><th>Defendant Retesting and Follow-Up</th></tr>
<tr><td rowspan="5">HIV Antibody Test (with standard HIV ELISA antibody test)

and

HIV Viral Load Test (with either qualitative or quantitative plasma HIV RNA assay)

Positive antibody tests should be confirmed by Western blot</td><td>Both the antibody and viral load test results are negative</td><td>PEP may be discontinued after consultation with physician</td><td>No follow-up testing of defendant recommended for benefit of survivor. As a standard of care for defendant, repeat antibody test in 3 months.</td></tr>
<tr><td>Both the antibody and viral load test results are positive</td><td>PEP should be continued</td><td>Antibody test requires confirmation by Western blot to establish diagnosis. No other follow-up testing required. Defendant should be referred for care.</td></tr>
<tr><td>RNA test positive, and
Antibody negative</td><td>PEP should be continued</td><td>Repeat both tests as soon as possible. A positive antibody test requires confirmation by Western blot to establish diagnosis.</td></tr>
<tr><td>RNA test negative, and
Antibody positive</td><td>PEP should be continued</td><td>Antibody test requires confirmation by Western blot to establish diagnosis. Defendant should be referred for care or continue care if already receiving it.</td></tr>
<tr><td>Indeterminate results from either the antibody or viral load test</td><td>PEP should be continued</td><td>Repeat both tests as soon as possible with consultation from an HIV Specialist.</td></tr>
</table>

B. Court-Ordered HIV Testing of Defendants: 30 Days to 6 Months From the Time of the Exposure

Rationale for 30-Day to 6-Month Timeframe:
By 30 days, survivors who received PEP will have completed the PEP regimen. During the 30 day to 6-month time period, the clinician cannot say with certainty whether HIV was transmitted by exposure through the assault; therefore, defendant testing may still have psychological benefit for the survivor. At the end of 6 months, if the survivor tests negative, then HIV transmission by exposure from the assault can be excluded.

Medical Benefit of Defendant Testing for the Survivor:

- There is no medical benefit to the survivor of testing the defendant for HIV during this time period. If the survivor chose to receive PEP, the 4-week PEP regimen will have been completed at this point.

Psychological Benefit of Defendant Testing for the Survivor:

Defendant testing for HIV may have the following psychological benefits for the survivor:

- Providing information that may help the survivor understand the degree of risk for acquiring HIV
- The comfort of knowing that exposure to HIV is unlikely in those instances when the defendant tests HIV negative

Recommendations:

The Medical Care Criteria Committee recommends that an HIV-1 antibody test is obtained when the defendant is tested 30 days to 6 months from the time of the assault (see Table 3)**.**

When HIV testing is ordered within 30 to 42 days from the time of exposure, a standard HIV ELISA should be used for antibody testing. When HIV testing is ordered 42 days to 6 months from the time of exposure, either a rapid HIV antibody test or standard HIV ELISA can be used.

Positive antibody test results require confirmation by Western blot.

Table 3
Defendant Testing Recommendations:
30 Days to 6 Months From Time of Assault

Test to Obtain	Defendant Test Results	Survivor PEP	Defendant Retesting and Follow-Up
<u>HIV Antibody Test</u> • When testing *30 days to 42 days* from the time of the assault: use a standard HIV ELISA antibody test* • When testing *42 days to 6 months* from the time of the assault: use either a rapid HIV antibody test or standard HIV ELISA antibody test	Negative	PEP should be completed	No follow-up testing of the defendant is recommended for benefit of survivor. As a standard of care for defendant, repeat antibody test in 3 months.
	Positive	PEP should be completed	Positive test results require confirmation by Western blot. Defendant should be referred for care.

* According to the manufacturer package inserts, the window period for rapid tests is up to 42 days; therefore, the standard ELISA antibody test should be used for defendant testing between 30 and 42 days from the time of the assault.

IV. Responsibilities of Public Health Officer (County or State)

Responsibilities to the Defendant:

- Provide pre-test counseling
- Obtain appropriate HIV test/s, depending on the timing of testing in relation to when the exposure occurred
- Provide post-test counseling

Responsibilities to the Survivor:

- Notify the survivor of the defendant's test results
- Instruct the survivor to inform his/her healthcare provider of the results and discuss how to proceed with post-exposure prophylaxis

Responsibilities to the Court:

- Notify the Court in writing that the test(s) was performed and the results were shared with survivor

REMINDER:
Disclosure of confidential HIV-related information shall be made to the defendant upon his or her request, and disclosure to a person other than the defendant will be limited to the person making the application; further disclosure shall be permitted only to the survivor, the survivor's immediate family, guardian, physicians, attorneys, medical or mental health providers, and to his or her past and future contacts to whom there is a reasonable risk of HIV transmission. Disclosure shall not be permitted to any other person or the court.

Website Resources:

HIV Prophylaxis Following Non-Occupational Exposure Including Sexual Assault. Available at: http://www.hivguidelines.org

The Protocol for the Acute Care of the Adult Patient Reporting Sexual Assault. Available at: http://www.health.state.ny.us/professionals/protocols_and_guidelines/sexual_assault/index.htm