Guidance for HIV Testing of Sexual Assault Defendants

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Purpose of This Guidance

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

The NYSDOH is responsible for issuing guidance for the court on the following:

- Medical and psychological benefits to the survivor.
- Appropriate HIV test to be ordered for the defendant.
- Circumstances when follow-up testing for the defendant is recommended.
- Indications for discontinuation of post-exposure prophylaxis (PEP).

The NYSDOH Al's Medical Care Criteria Committee (MCCC) and the Mental Health Guidelines Committee carefully reviewed the issues involved and developed this guidance in 2007 through a consensus-based process, and updated it as needed, most recently in January 2024. As requested, the Committee specifically addressed HIV risk; however, care providers should also consider the risk of transmission of hepatitis B, hepatitis C, and other sexually transmitted infections in any sexual assault patient. The guideline PEP to Prevent HIV Infection, developed by the MCCC of the NYSDOH AI, includes recommendations for the post-exposure management of HIV, hepatitis B virus, and hepatitis C virus in sexual assault patients.

Definitions of Significant Risk of HIV Through Sexual Assault Exposure

The defendant testing law refers to "significant exposure" as defined by 10 NYCRR § 63.10. The NYSDOH AI guideline <u>PEP to Prevent HIV Infection</u> offers a definition of significant exposure during sexual assault that warrants assessment of the survivor. Both definitions are listed below.

- "Significant risk" as defined by 10 NYCRR § 63.10: Three factors are necessary to create a significant risk of contracting or transmitting HIV infection:
 - The presence of a significant-risk body substance, and
 - A circumstance that constitutes significant risk for transmitting or contracting HIV infection, and
 - The presence of an infectious source and a noninfected person.
- Significant risk body substances: Blood, semen, vaginal secretions, breast milk, tissue, and the following body fluids: cerebrospinal, amniotic, peritoneal, synovial, pericardial, and pleural.
- Circumstances that constitute "significant risk of transmitting or contracting HIV infection" for sexual assault survivors:
 - Sexual intercourse (e.g., vaginal, anal, oral) that exposes a noninfected individual to blood, semen, or vaginal secretions
 of an individual with HIV.
 - Sharing of needles and other paraphernalia used for preparing and injecting drugs between individuals with and without HIV.



- Penetrating injuries (such as needlesticks with a hollow-bore needle) with exposure to blood or other potentially infected fluids from a source known to have HIV or whose HIV status is unknown.
- Bite from a person known to have HIV or whose HIV status is unknown with visible bleeding in the mouth that causes bleeding in the exposed person.
- Other circumstances not identified during which a significant-risk body substance (other than breast milk) of an individual with HIV contacts mucous membranes (e.g., eyes, nose, mouth), nonintact skin (e.g., open wound, skin with a dermatitis condition, abraded areas), or the vascular system of an individual without HIV.
- Circumstances that do not involve "significant risk":
 - Kissing if no blood is exchanged due to sores or bleeding gums.
 - Exposure to urine, feces, sputum, nasal secretions, saliva, sweat, tears, or vomitus that does not contain blood that is visible to the naked eye.
 - Human bites where there is no direct blood-to-blood or blood-to-mucous membrane contact.
 - Exposure of intact skin to blood or any other bodily substance.

The NYSDOH AI guideline PEP to Prevent HIV Infection defines a significant exposure during "sexual assault" as follows:

- When the exposed individual has experienced direct contact of the vagina, penis, anus, or mouth with the semen, vaginal fluids, or blood of a defendant, with or without physical injury, tissue damage, or presence of blood at the site of the assault
- When the exposed individual's broken skin or mucous membranes have been in contact with the blood, semen, or vaginal fluids of a defendant.
- When an exposed person has visible blood as a result of bites, i.e., a bite has drawn blood.

Maximizing Medical and Psychological Benefit to the Survivor

Exposure to HIV is an emergency. The sexual assault survivor should be evaluated in an emergency department as soon as possible for treatment and evaluation for PEP. The first dose of PEP medications should be administered as soon as possible—ideally within 2 hours of exposure and no later than 72 hours post-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 PEP regimen, as outlined in the NYSDOH AI guideline PEP to Prevent HIV Infection, should be prescribed if a sexual assault patient experienced a significant exposure to HIV. Clinicians are required by law to offer and make available a 7-day starter pack of HIV PEP to survivors of sexual assault who are ≥18 years old and offer and make available the full 28-day supply of HIV PEP to survivors of sexual assault who are <18 years old. Sexual assault patients should receive HIV testing at baseline (within 72 hours of the exposure) and at 4 weeks and 12 weeks post-exposure, even if PEP is declined, as detailed in the guideline (see Figure 4: Sexual Assault HIV Exposure: PEP and Exposure Management When Reported Within 72 Hours).

☆ NEW YORK STATE LAW

• New York Public Health Law § 2805-I(1)(c): "Every hospital providing treatment to alleged victims of a sexual offense shall be responsible for offering and making available appropriate HIV post-exposure treatment therapies; including a seven day starter pack of HIV post-exposure prophylaxis for a person eighteen years of age or older, or the full regimen of HIV post-exposure prophylaxis for a person less than eighteen years of age, in cases where it has been determined, in accordance with guidelines issued by the commissioner, that a significant exposure to HIV has occurred, and informing the victim that payment assistance for such therapies and other crime related expenses may be available from the office of victim services pursuant to the provisions of article twenty-two of the executive law. With the consent of the victim of a sexual assault, the hospital emergency room department shall provide or arrange for an appointment for medical follow-up related to HIV post-exposure prophylaxis and other care as appropriate."



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

☑ PEP GUIDELINE RECOMMENDATION

• In the NYSDOH AI guideline <u>PEP to Prevent HIV Infection</u>, the MCCC recommends an FDA-approved HIV-1/2 antigen (Ag)/antibody (Ab) combination immunoassay followed by an HIV RNA assay, either qualitative or quantitative plasma HIV-1 RNA assay, when the defendant is tested 7 to 30 days from the time of the sexual assault survivor's exposure.

Rationale for the 7- to 30-day time frame: HIV can be detected as early as 7 days with an FDA-approved HIV-1/2 Ag/Ab combination 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 the HIV-1/2 Ag/Ab combination test in addition to the HIV RNA assay is not medically beneficial. See the section Court-Ordered HIV Testing of Defendants: 30 Days to 6 Months from the Time of the Exposure, below, for the psychological benefit that may be gained from defendant testing after 30 days.

Medical benefit for the survivor when testing the defendant between 7 and 30 days: The only clear medical benefit for the survivor of testing the defendant for HIV would be the discontinuation of PEP to avoid potential toxicity and adverse 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 a clinician experienced in managing PEP before discontinuing the regimen.

Psychological benefits of defendant testing for the sexual assault 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 negative on both the HIV-1/2 Ag/Ab combination test and Ab differentiation assay.
- Allowing the survivor to participate more fully in the decision of whether to continue or discontinue the PEP regimen.

Expert consultation for New York State clinicians: Clinicians are advised to call the Clinical Education Initiative (CEI Line) to speak with an experienced HIV care provider.

- Call 1-866-637-2342, and press "2" for HIV.
- The CEI Line is available from 9 AM to 5 PM, Monday through Friday.

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 acute stage of HIV-1 infection. The acute stage is the stage in which the virus and viral RNA are present in the blood but the person has not developed enough specific antibodies to be detected by an antibody test. An HIV-1/2 Ag/Ab combination immunoassay may detect HIV-1 p24 antigen as early as 14 days and will also detect HIV-1 and HIV-2 antibodies produced once seroconversion has occurred. An HIV-1 RNA assay is capable of detecting HIV-1 as soon as 7 days after infection and would establish a diagnosis; therefore, it is important to use both an HIV-1/2 Ag/Ab combination immunoassay and a plasma HIV-1 RNA assay when the completion of the victim's PEP regimen is contingent on the defendant test results. If the HIV antigen/antibody immunoassay is positive, the laboratory should complete the recommended HIV testing algorithm, which includes supplemental testing using an HIV-1/HIV-2 Ab differentiation test (see NYSDOH AI guideline HIV Testing). There is a robust body of evidence that individuals do not sexually transmit HIV if they are taking antiretroviral therapy (ART) and have an undetectable viral load (HIV RNA <200 copies/mL); see NYSDOH AI U=U Guidance for Implementation in Clinical Settings.

Negative test results from both the HIV-1/2 Ag/Ab combination immunoassay and the HIV-1 RNA assay would indicate that the defendant is not infected with HIV and would permit discontinuation of the survivor's PEP regimen. Positive test results for *either* the HIV antibodies or HIV-1 RNA assay, or both, would indicate that the defendant has HIV and that the survivor's PEP regimen should be completed. When making decisions regarding the management of the sexual assault survivor, the defendant should be considered to have HIV until proven otherwise. Table 1, below, outlines the different possibilities of test results, how each result would affect the survivor's PEP regimen, and the necessary follow up.



Table 1: Follow-Up Based on Results of Defendant HIV Testing [a] Performed 7 to 30 Days Post-Sexual Assault			
Defendant Test Results	Survivor PEP	Defendant Retesting and Follow-Up	
• RNA assay: Negative (-) • Ag/Ab assay: Negative (-)	PEP may be discontinued after consultation with physician.	 No follow-up testing of defendant recommended for benefit of survivor. As a standard of care for defendant, repeat Ag/Ab testing in 3 months if at ongoing risk for infection. 	
 RNA assay: Positive (+) Ag/Ab assay: Positive (+) 	PEP should be continued.	 An HIV-1/HIV-2 supplemental antibody test should be performed. If test does not confirm antibodies, HIV-1 infection is still present but may be in the acute or early stage. No other follow-up testing is required. Defendant should be referred for care. 	
 RNA assay: Positive (+) Ag/Ab assay: Negative (-) 	PEP should be continued.	 Repeat both tests as soon as possible. There is a very brief window within the acute stage of infection when RNA is detectable but HIV-1 p24 antigen has not reached detectable levels. 	
 RNA assay: Negative (-) Ag/Ab assay: Positive (+) 	PEP should be continued.	 To confirm antibodies, an HIV-1/HIV-2 supplemental antibody test should be performed. Defendant should be referred for care or continue care if already receiving it. 	
Inconclusive or invalid results from either the Ag/Ab or RNA assay.	PEP should be continued.	Repeat both tests as soon as possible in consultation with an HIV specialist.	

Abbreviations: Ab, antibody; Ag, antigen; PEP, post-exposure prophylaxis.

Note:

a. Tests to obtain: FDA-approved HIV-1/2 Ag/Ab combination immunoassay *and* either qualitative or quantitative plasma HIV RNA assay. If antibodies are not confirmed, but the differentiation assay is positive, the defendant is considered positive for HIV and is likely to be in the acute stage of infection.

Court-Ordered HIV Testing of Defendants 30 Days to 6 Months from Time of Exposure

Recommended testing: When performing HIV testing of a defendant, clinicians should use the type of HIV test noted in Table 2, below, based on the amount of time that has passed since the assault:

- 30 days to 6 months post-assault: FDA-approved HIV-1/2 Ag/Ab combination immunoassay is recommended.
- 30 days to 42 days post-assault: Laboratory-based HIV-1/2 Ag/Ab combination immunoassay is recommended.
- 42 days to 6 months post-assault: Point-of-care rapid HIV test or a laboratory-based HIV-1/2 Ag/Ab combination immunoassay can be used.

Reactive results on any type of HIV screening assay should be confirmed in a laboratory using the <u>recommended HIV testing</u> <u>algorithm</u> (see the NYSDOH AI guideline <u>HIV Testing</u>).

Medical benefit for the survivor when testing the defendant between 30 days and 6 months: There is no medical benefit for the sexual assault survivor when testing the defendant for HIV during the 30-day to 6-month period. If the survivor chose to receive PEP, the 28-day PEP regimen will have been completed at this point. If the survivor tests negative at 12 weeks, then HIV transmission by exposure from the assault can be excluded.

Psychological benefits for the survivor when testing the defendant between 30 days and 6 months: Defendant testing for HIV that may be mandated by the court for up to 6 months after the assault can 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.

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Table 2: Follow-Up Based on Results of Defendant HIV Testing [a] Performed 30 Days to 6 Months Post-Sexual Assault			
Defendant Test Results	Defendant Retesting and Follow-Up		
Negative	 No follow-up testing of the defendant is recommended for the benefit of survivor. As a standard of care for the defendant, repeat Ag/Ab test in 12 weeks if at ongoing risk for infection. 		
Positive	 If positive, continue testing sample using the recommended HIV testing algorithm. The defendant should be referred for care. 		

Abbreviations: Ab, antibody; Ag, antigen.

Note

a. According to the manufacturer package inserts, the window period for some rapid tests is up to 42 days; therefore, a laboratory-based HIV-1/2 Ag/Ab combination immunoassay should be used for defendant testing between 30 and 42 days from the time of the assault. If testing 42 days to 6 months post-sexual assault, use either a rapid HIV antibody test or a laboratory-based HIV-1/2 Ag/Ab combination immunoassay.

Responsibilities of the County or State Public Health Officer

If testing the defendant would provide medical benefit to the victim or a psychological benefit to the victim, then the testing is to be conducted by a state, county, or local public health officer designated by the order.

Responsibilities to the defendant:

- Provide pre-test information.
- 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 sexual assault 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 PEP.

Responsibility to the court: Notify the court in writing that the test(s) was performed and the results were shared with the sexual assault survivor.

Disclosure: Disclosure of confidential HIV-related information shall be made to the defendant upon his or her request.

- Disclosure to a person other than the defendant will be limited to the person making the application (i.e., the sexual assault survivor). The survivor may then disclose the defendant's HIV test results to the survivor's medical care provider, legal representative, and close family members or legal guardian. The survivor may also share the HIV-related information with his or her sex or needle-sharing partners if it is believed that these individuals were exposed to HIV.
- Survivors cannot disclose the defendant's name during these discussions.
- Disclosure shall not be permitted to any other person or to the court.

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