



Proposed
HIV Post Exposure Prophylaxis Guidelines and Emergency Kit Inclusions

I. Definition of Exposure:

The exchange of blood and/or body fluids between an HIV (Human Immunodeficiency Virus), infected individual and a non-HIV infected individual. Exposure may be caused by needle sticks of infected needles, sexual contact, or exposure to open sores/cuts on infected individuals.

II. Treatment Timing for Post Exposure Prophylaxis (PEP):

- **Initiation:** Administer first dose of HIV without delay, preferably within one hour of exposure
- **Window for Treatment:** Treat within 72 hours of an exposure (HIV PEP may be not be effective after this time-frame)
- **Duration:** 28 days of Uninterrupted therapy
- **Exposure Uncertainties:** Provide the highest level of HIV PEP if available information as to exposure specifics is unclear, adjust later if necessary.

III. Testing:

- **Baseline Testing:** Patients receiving HIV PEP should undergo baseline testing within 72 hours of receiving treatment. Testing should include: HIV, hepatitis B and C, chemistry panel, complete blood count testing for all patients, liver enzymes testing for those receiving protease inhibitors, and PREGNANCY testing for females of childbearing age(even if on oral contraceptives).
- **HIV Source testing:** Testing the source should occur whenever possible. Although, HIV PEP should not be delayed to accommodate source testing.

IV. Source Testing:

- HIV testing of a human source of unknown HIV status should occur as soon as possible following the exposure. HIV PEP may be discontinued if the source is HIV uninfected.

- HIV testing of the injecting paraphernalia is **NOT** recommended

V. Overview:

Step 1: Determine if the exposure meets criteria for an HIV PEP evaluation		
<p>HIV PEP may be indicated for:</p> <ul style="list-style-type: none"> • Needlestick and sharp injuries from sources that are HIV infected or at risk of HIV infection • Unprotected vaginal or anal intercourse with persons at risk or known to be infected with HIV (ie. Sexual assault) • Blood/body fluids exposures to injured/damaged (non-intact) skin or mucosae from sources that are HIV infected or at risk of HIV infection • Sharing or injecting drug paraphernalia with people who are HIV infected or at risk of HIV infection, and usage of shared drug paraphernalia with visible blood 	<p>HIV PEP is UNNECESSARY for:</p> <ul style="list-style-type: none"> • Anyone who is HIV infected or has acquired immunodeficiency syndrome (AIDS) • Any blood/body fluid exposures to intact skin • Needlestick and sharp injuries from sources that CANNOT be HIV infected (e.g., sterile needles) • Any body fluid exposures from saliva, urine, vomit, feces, or sputum unless visibly bloody • After any kissing or touching of another person, or after eating food or sharing utensils used by others • Any non-human bites/stings • Any human bites or scratches without blood exposure (unless severe and from a known HIV-infected person) • Discarded needles or sharps that have NOT been in contact with an HIV infected source or at-risk of HIV infection source 	
Step Two: Determine HIV serostatus or risk factors or source(s) (when known)		
<ul style="list-style-type: none"> • Known non-HIV-infected source (e.g., sterile needle) • Unknown HIV risk source (e.g., unknown sexual assailant or partner, discarded needle) <ul style="list-style-type: none"> • Sources at higher risk for HIV infection* 		

<ul style="list-style-type: none"> Sources at lower risk for HIV infection** Known HIV-infected source 	
<p>Step Three: Based upon the exposure and source's HIV status, determine if HIV PEP should be recommended, offered, or considered, and select an appropriate HIV PEP regimen</p>	
Exposure	Course of Action
Exposure to Known HIV-infected source(s)	<p>RECOMMEND HIV PEP</p> <p>A. Source's <i>medication history</i> is UNKNOWN or the source is known NOT to be on anti-HIV medications</p> <ul style="list-style-type: none"> ❖ Zidovudine (AZT/ZDV) or stavudine (d4T) + lamivudine (3TC/Epivir) AND nelfinavir (Viracept) OR indinavir (Crixivan) ❖ Efavirenz + Combivir (zidovudine and lamivudine) *note: not to be used in women of child-bearing age <p>B. Source's <i>medication history</i> is KNOWN:</p> <p>Under the advisement of a specialist knowledgeable in HIV PEP and HIV medications, choose a medication regimen that takes into account the source's medication history and drug resistance. If this advice and information is unavailable, a regimen that is different from the medications the source currently uses can be used for the initial dose. Choose two nucleoside reverse transcriptase inhibitors and a protease inhibitor, such as:</p> <ul style="list-style-type: none"> • Zidovudine or stavudine + lamivudine AND nelfinavir, indinavir, amprenavir, saquinavir OR lopinavir/ritonavir • Stavudine + didanosine AND nelfinavir, indinavir, amprenavir, saquinavir OR lopinavir/ritonavir • Abacavir + zalcitabine AND nelfinavir, indinavir, amprenavir, saquinavir OR lopinavir/ritonavir
Exposures to UNKNOWN HIV status sources at HIGHER risk	<p>OFFER HIV PEP</p> <p>Zidovudine or Stavudine + lamivudine + Efavirenz</p>

of HIV infection	A protease inhibitor can be added if the source has multiple high HIV risk factors for HIV infection.
Exposures to UNKNOWN HIV status sources at LOWER risk of HIV infection	CONSIDER HIV PEP HIV NPEP may be considered on a case-by-case basis. Zidovudine or stavudine + lamivudine may be offered when compelling circumstances exist.

VI. Body Fluids That Are Known to Harbor HIV:

- Blood
- Amniotic fluid
- Cerebrospinal fluid
- Exudative or other tissue fluid from burns or skin lesions
- Human breast milk
- Pericardial fluid
- Peritoneal fluid
- Pleural fluid
- Synovial fluid
- Unfixed human tissues and organs

VII. Exposure Course of Action (2)

1. Exposure to Known HIV-infected Source(s), Recommend HIV PEP If:
 - **If source’s medication history is unknown or source is known not to be on anti-HIV medications:** Recommend zidovudine (AZT/ZDV) or stavudine (d4T) + lamivudine (3TC/Epivir) and nelfinavir (Viracept) or indinavir (Crixivan)+Efavirenz.
 - **If source’s medication history is known:** Take into account source’s medication history and drug resistance. If this is unavailable, a regimen that is different from the medications the source currently uses can be used for the initial dose.
2. Exposure to Unknown HIV Status Source(s) at High Risk of HIV Infection:
 - Offer HIV PEP: Zidovudine or Stavudine + lamivudine+ Efavirenz. A protease inhibitor(nelfinavir (Viracept) or indinavir (Crixivan)), can be added if the source has multiple high-risk factors for HIV infection

3. Exposure to Unknown HIV Status Source(s) at low risk of HIV infection:

- Consider HIV PEP on case-by case basis. Zidovudine or Statudine + Lamivudine may be offered when compelling circumstances exist.

VIII. Initial Follow-up Visit Within 72 Hours:1.

1. Reevaluation of HIV PEP indications and medications
 - a. Determine if any new information about the exposure and source is available.
 - i. Attempt to delineate if the exposure qualified for HIV PEP. If HIV PEP was not indicated, discontinue HIV PEP.
 - ii. Determine if any information is available about the source and if the source can be tested or medical records obtained pertaining to HIV status:
 - a. Source is not HIV infected (per a confirmed HIV test): Discontinue HIV PEP.
 - b. Source is HIV infected: Adjust the medications as necessary.
 - c. Source can be tested: Initiate HIV testing and then re-evaluate the need for HIV PEP and the medications provided when the test results are available. Rapid HIV testing (within 24 hours) is preferable, if status unknown.
 - d. Evaluate the source's risk profile and adjust medication regimen as indicated.
 - b. If no new information is available and HIV PEP was indicated by exposure, re-evaluate the medications prescribed and adjust as necessary.
 - c. Determine if initial laboratory testing was performed. If not, obtain the appropriate tests. If the tests were performed, review the results and adjust the medication regimen as necessary
2. Risk reduction counseling
 - a. Needlestick or sharp injuries: Counsel and instruct patient on ways to avoid these injuries (e.g., wearing sharp-permeable gloves, not touching medical waste). Intervention may also involve consultation with occupational health advisors and the Rhode Island Department of Health (HEALTH).

- b. Sexual assault: In coordination with sexual assault counselors, attempt to provide instruction, support, and resources on preventing further sexual assault.
3. Medication provisions:
- a. HIV PEP course: A two-week supply of medications is recommended for initial treatment.
 - b. Anti-emetics: A short course may be prescribed.
 - c. Vaccinations: Hepatitis B vaccination should be given to those not already vaccinated. Hepatitis A vaccination is recommended for those who had a sexual exposure.

VIII. Two-Week Follow-Up Visit:1.

1. Reevaluation of medications: If any new information regarding the source's HIV status or HIV risk is available, adjust medications as necessary.
2. Assessment of adverse side effects
 - a. Evaluate the patient for the presence of any signs or symptoms attributable to adverse side effects of the medication. Instruct the patient that some of these symptoms may be due to the anxiety of taking HIV PEP or stress regarding the exposure.
 - b. Discontinue HIV PEP for any signs or symptoms of severe or life-threatening adverse side effects.
 - c. Encourage the use of anti-emetics, a change in eating habits (e.g., eating a small snack with medications, increased water intake), and a change of the time taking medications.
 - d. Reassure the patient that the unpleasant side effects of the medications will likely become less during their 28-day course.
 - e. Perform complete blood count, chemistry panel, and liver-associated enzymes (if a protease inhibitor was prescribed) testing to monitor toxicity, and pregnancy testing for females of childbearing age.
3. Analysis of laboratory testing
 - a. Discontinue HIV PEP if the patient is HIV infected. Treat/refer accordingly.
 - b. Discontinue HIV PEP if either renal failure (creatinine >2.0) or severe anemia (hemoglobin <7.0) are present.
 - c. Provide any treatment or referral as necessary for any STD or hepatitis infections. Treat and test partners as indicated.
 - d. Refer or treat for any other condition (e.g., diabetes, pregnancy) noted from the baseline testing.
 - e. Refer to a primary care provider any patient who is not HIV infected and whose HIV PEP was discontinued. Refer any pregnant patient to an

obstetrician-gynecologist knowledgeable in the care of patients taking HIV medications.

4. Evaluate for acute HIV infection.
5. Risk reduction counseling: Continue to reinforce HIV exposure risk reduction.
6. Medication provision: A two-week supply of HIV PEP is recommended. Other medications (e.g., STD treatment, anti-emetics) should also be provided.
7. Patient instructions: Review the patient instructions with the patient.

IX. Six Week Visit: 1.

1. Assess the patient for adverse side effects attributable to HIV PEP: Perform additional laboratory testing or evaluations as indicated.
2. Laboratory testing:
 - a. For all patients who took HIV PEP: complete blood count, chemistry panel, HIV antibody screening. Liver-associated enzyme testing should be performed for any patient who took at least a two-week course of a protease inhibitor. Follow up results with patients as soon as possible and treat/refer when indicated.
 - b. Additional testing: pregnancy testing for any female of childbearing age. Refer to an obstetrician-gynecologist knowledgeable in the care of patients taking HIV medications if the patient is pregnant.
3. Evaluate for acute HIV infection.
4. Risk reduction counseling: Continue to reinforce HIV risk reduction.
5. Hepatitis B vaccination: Second dose should be provided four weeks after the first dose.

X. Additional Visits: 1.

1. HIV testing: Recommended at three and six months postexposure.
2. Risk reduction counseling: Continue to reinforce HIV risk reduction.
3. Hepatitis B vaccination: Third dose should be provided six months after the first dose. Those receiving a Hepatitis A vaccination should receive their second dose six months after the first dose

XI. Included in the Emergency Post Exposure Prophylaxis kit (1 week supply): 3.

- Basic Regimen (two nucleoside reverse transcriptase inhibitors):
 - Combivir: one tablet twice daily (each tablet contains zidovudine(AZT) 300mg+ Lamivudine(3TC) 150mg) (total 6 tablets)

- Expanded Regimen (for significant exposures to a known HIV positive source (add protease inhibitor):
 - Combivir (one tablet twice daily, total 6 tablets) + Nelfinavir(Viracept) 5 tablets(total of 1250mg), twice daily with food(total 30 tablets)
 - *Combivir (one tablet twice daily, total 6 tablets) + Efavirenz(Sustiva) (1 tablet daily(600mg), with food(total 7 tablets))**
- Pregnancy test kit
- Biohazard bags and containers
- Needle disposal container

**note: Efavirenz not to be used in women of child-bearing age*

Works Cited

1. Rhode Island Department of Health. "Nonoccupational HIV Post Exposure Prophylaxis Guidelines for Rhode Island Healthcare Practitioners". DOH. 2002 Aug.
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<http://online.lexi.com/crlonline>
4. CDC. "Antiretroviral Post Exposure Prophylaxis After Sexual, Injection-Drug Use, or Non-occupational Exposure to HIV in the United States". U.S. Department of Health and Human Sciences. Jan. 21, 2005.