HIV Post Exposure Prophylaxis Update

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PEP Hotline – 1-888-448-4911
www.aidscenterecmc.org
www.ceitraining.org
www.hivguidelines.org

Needlestick Injuries

- Hospital–based Healthcare personnel
  - 385,000 needlesticks and other sharps related injuries
  - Average of 1,000 per day
  - ½ go unreported
- OSHA estimates between 600,000 and 800,000 in US
New York State Guidelines

- Occupational Exposures
  - October, 2012
- Non-occupational exposures
  - July, 2013

www.hivguidelines.org

Support for PEP Treatment Guidelines

- ACTG 076 Study
  - Decreased transmission by 67%
- NYS PCR Study
- CDC International Case Control Study
  - Use of AZT by HCW decreased risk of HIV acquisition by 81%
- Laboratory and animal models
  - No adequate human data on nPEP efficacy
Macaques and PMPA (Tenofovir)

- Macaques injected with SIV
- 28 days PMPA protective if initiated within 24 hours post-exposure
  - Infections seen:
    - initiation delayed 48–72 hours post-exposure
    - treatment duration shortened to 10 days
    - No efficacy if treatment duration 3 days


Case Study

21 yo male admitted to inpatient rehab center. Using IV drugs up to admission. Nurse drawing blood on day 3 of admission is bumped from behind while withdrawing phlebotomy needle. Needle punctures palm. The nurse washes puncture wound with soap and water and remembers not to squeeze (milk) wound.
**What should the nurse do next?**

1. Finish shift and report to ED
2. Wait till next day when supervisor is at work to tell her about exposure
3. Go to emergency room immediately
4. Go home and think about it

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**Rationale for PEP: Role of Pathogenesis**

- **“Window of opportunity”** – during which PEP may prevent viral replication
- **First 24 hours** – dendritic cells in the mucosa and skin are initial targets of HIV
- **24–48 hours** – migration of these cells to regional lymph nodes
- **5 days** – virus detectable in peripheral blood
Timing of PEP Initiation

- When a potential occupational exposure to HIV occurs, every effort should be made to initiate PEP as soon as possible, **ideally within 2 hours**. (AII)
  - A first dose of PEP should be offered to the exposed worker while the evaluation is underway.

- Decisions regarding initiation of PEP **beyond 36 hours post exposure** should be made on a case–by–case basis with the realization of diminished efficacy when timing of initiation is prolonged. (AII)
Indications for PEP

- Exposure to blood, or visibly bloody fluid:
  - break in skin with sharp object visibly contaminated with blood or was in source’s blood vessel
  - splash of blood or bloody fluid to mucosal surface (mouth, nose, eye)
  - non-intact skin exposure to blood or bloody fluid (e.g. dermatitis, chapped skin, abrasions, etc.)

Factors that influence blood-borne transmission risk

“Significant Exposure”

- Device visibly contaminated with the patient’s blood
- Procedure that involved a needle placed directly in a vein or artery
- Deep injury
- Patients with terminal illness (high titer of HIV in blood)
What medications should be used for PEP?

1. Zidovudine (AZT) 300 mg po bid + lamivudine (3TC) 150 mg po bid (Combivir 1 po bid) PLUS tenofovir 300 mg po qd

2. Tenofovir 300 mg + emtricitabine (FTC) 200 mg (one tablet daily) PLUS raltegravir 400 mg bid

3. Zidovudine (AZT) 300 mg po bid + lamivudine (3TC) 150 mg po bid

4. Tenofovir 300 mg + emtricitabine (FTC) 200 mg (one tablet daily) PLUS nevirapine 200 mg bid

Preferred PEP Regimen

Truvada [TRV] (tenofovir [TDF] 300 mg/emtricitabine [FTC] 200 mg) one tablet daily

+ Isentress (raltegravir [RAL]) 400 mg BID

Duration X 28 days (or until SP ruled out for HIV)
Alternative PEP Regimens

TRV one tab
+ Darunavir (DRV) 800 mg
OR Atazanavir (ATV) 300 mg
OR Fosamprenavir (FPV) 1400 mg
+ Ritonavir (RTV) 100 mg
All once daily

TDF + FTC + ZDV
or
TRV + Lopinavir/ritonavir (LPVr)
or
ZDV/3TC (Combivir) +
one of the following RTV–boosted PIs:
DRV, ATV, FPV, or LPV

PEP in Pregnancy

- The recommended PEP regimen is the same for pregnant women as for non-pregnant adults. (AII)
  - Before administering PEP to a pregnant woman, the clinician should discuss the potential benefits and risks to her and to the fetus.
  - In addition to risk of seroconversion in EW, high viral loads in acute HIV infection markedly increase risk of transmission to the fetus or breast-feeding infant.

- Drugs to avoid in pregnancy
  - Efavirenz, combinations of stavudine and didanosine, nevirapine and unboosted indinavir in the 2nd or 3rd trimester
Both HIV and antiretroviral drugs may be found in breast milk.

Initiation of PEP in exposed workers who are breastfeeding requires careful discussion.
- Clinicians should discuss the risks and benefits with the exposed worker.

Clinicians should advise women who may have been exposed to HIV through occupational exposure to avoid breastfeeding for 3 months after the exposure.
- If HIV infection is definitively excluded in SP at any time prior to 3 months post-exposure, the woman may resume breastfeeding.

### PEP in Lactating EW

- **Initiation of PEP in exposed workers who are breastfeeding requires careful discussion.**

- **Clinicians should discuss the risks and benefits with the exposed worker.**

- **Clinicians should advise women who may have been exposed to HIV through occupational exposure to avoid breastfeeding for 3 months after the exposure.**

- If HIV infection is definitively excluded in SP at any time prior to 3 months post-exposure, the woman may resume breastfeeding.

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**Diagram:**

1. Source partner HIV STATUS UNKNOWN
2. Clinician contact to rapid HIV testing of source patient
3. Source test POSITIVE
4. Source partner HIV status in custody
5. Source partner refuses HIV testing
6. Source test NEGATIVE
7. Obtain HIV RNA assay from source patient to confirm HIV positive
8. STOP PEP
9. END

---

**Table:**

<table>
<thead>
<tr>
<th>28-DAY REGIMEN:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommended PEP Regimen:</td>
</tr>
<tr>
<td>1. Tenofovir 300 mg, lamivudine 300 mg, efavirenz 600 mg once daily for 28 days.</td>
</tr>
<tr>
<td>2. Tenofovir 300 mg, lamivudine 300 mg, nevirapine 400 mg once daily for 28 days.</td>
</tr>
</tbody>
</table>

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**Notes:**

1. **STOP PEP** after PEP has been successfully administered.
2. **END** if HIV infection is definitively excluded in SP at any time prior to 3 months post-exposure.
3. **See Table for details on laboratory testing.**
Management: Exposure Report

- Record in the confidential medical record
  - Date and time of exposure
  - Details of the procedure being performed and the use of protective equipment at time of exposure
  - The type, severity, and amount of fluid to which the person was exposed
  - Details about the exposure source
  - Medical documentation that provided details about post-exposure management


Education and Counseling

- Relative risk of transmission by the exposure
- Risks and benefits of PEP including side effects
- Need to report any signs and symptoms of acute (primary) HIV infection
- Need to prevent secondary transmission
- Acknowledge the fear/anxiety that commonly occur in exposed HCWs
  - Counseling should be made available
Repeat HIV testing for the nurse should occur at:

1. 4 weeks, 12 weeks, 24 weeks
2. 4 weeks, 12 weeks
3. 4 weeks, 24 weeks
4. 4 weeks, 24 weeks, 52 weeks

Sequential HIV Testing

- HIV testing at 6 months post-exposure is no longer recommended
- HIV testing of the exposed worker at 4 weeks and 12 weeks should be performed with laboratory-based HIV tests rather than rapid point-of-care HIV tests
- If the post-exposure evaluation determined that PEP was indicated, but the exposed worker declines PEP, serial testing should still be obtained
## PEP Follow-Up Schedule

Table 6: Monitoring Recommendations After Initiation of PEP Regimens Following Occupational Exposure

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
<th>Week 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinic Visit</td>
<td>✓</td>
<td>✓ Or by telephone</td>
<td>✓ Or by telephone</td>
<td>✓ Or by telephone</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Pregnancy Test</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serum liver enzymes, BUN, creatinine, CBC*</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>HIV test c</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

*For post-exposure management for hepatitis B and C, see Section XI: Occupational Exposures to Hepatitis B and C.

\* CBC should be obtained for all exposed workers at baseline. Follow-up CBC is indicated only for those receiving a zidovudine-containing regimen.

\c Recommended even if PEP is declined.

## Exposure Source: Evaluation and Testing

- Inform source of incident
- HIV testing is voluntary
- Has the source patient been at risk in the last six weeks?
What test would you order for source patient?

1. Rapid antibody test with oral consent 56%
2. Anonymous antibody testing 4%
3. Rapid antibody test, no consent needed 4%
4. Standard antibody test with oral consent 35%

Health Advisory: OSHA Requirement for Rapid HIV Antibody Testing

- NYS DOH Memo – June 14, 2007

“Consistent with CDC’s recommendations, US Department of Labor, Occupational Safety and Health Administration (OSHA) has issued an interpretation that it is a violation of 29CFR 1910.1030 for a medical facility subject to OSHA authority not to perform rapid HIV antibody testing on a source individual after an exposure to blood borne pathogens”
Anonymous HIV Testing in Certain Cases of Occupational Exposure

Source Patient
Deceased, comatose, unable to consent, not expected to recover in time
• Family Health Care Decision Act

Health Care Worker
• At significant risk
• Medical benefit
• Result used to make appropriate decisions

1. HIV test result, but not source patient’s identity, provided to exposed person’s attending provider
2. Medical benefit documented in exposed person’s chart
3. Result not disclosed to source patient or recorded in his/her chart

The source patient’s antibody test is negative. What do you do next?

1. Stop PEP
2. Continue PEP, order viral load
3. Continue PEP, order Western Blot
Source Patient (SP) Testing

- If HIV Ab test is positive, assume true positive and *utilize* in decision-making regarding PEP for EW.
  - Inform SP of preliminary positive result and send for confirmatory testing

- If HIV Ab test is negative BUT SP may have had HIV exposure in the last 6 weeks, obtain HIV VL on SP and continue PEP until results are available.
  - SP evaluation of risk for HIV exposure is key

Average Risk for Transmission of Hepatitis B and C Viruses After a Needlestick (compared to HIV)

Table 8

<table>
<thead>
<tr>
<th>Source</th>
<th>Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBV</td>
<td></td>
</tr>
<tr>
<td>HBeAg+</td>
<td>22.0% - 30.0%</td>
</tr>
<tr>
<td>HBeAg-</td>
<td>1.0% - 6.0%</td>
</tr>
<tr>
<td>HCV+</td>
<td>1.8%</td>
</tr>
<tr>
<td>HIV+</td>
<td>0.3%</td>
</tr>
</tbody>
</table>
Hepatitis B

- Approximately 800 HCW infected each year following occupational exposure
- HBV vaccine available since 1982
- Decision to treat:
  - Source hepatitis B surface antigen positive
  - HCW vaccinated
  - Vaccine provided immunity

### Recommended PEP for Hepatitis B Virus

<table>
<thead>
<tr>
<th>Vaccination/Ab response status of exposed patient</th>
<th>Treatment when source patient is:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HBsAg positive</td>
</tr>
<tr>
<td>Unvaccinated/non-immune</td>
<td>HBIG ×1; initiate HB vaccine series</td>
</tr>
<tr>
<td>Previously vaccinated, known responder</td>
<td>No treatment</td>
</tr>
<tr>
<td>Previously vaccinated, known non-responder</td>
<td>HBIG ×1 and initiate revaccination or HBIG ×2</td>
</tr>
<tr>
<td>Previously vaccinated, response unknown</td>
<td>Single vaccine booster dose</td>
</tr>
<tr>
<td>Still undergoing vaccinated</td>
<td>HBIG ×1; complete series</td>
</tr>
</tbody>
</table>
Hepatitis C

- 1% of HCW have evidence of HCV
- No estimates of numbers occupationally infected
- No vaccine and no treatment that will prevent infection
- Immune globulin not recommended

### HCV Exposures

**Table 10: Hepatitis C Post-Exposure Management According to Baseline Test Results**

<table>
<thead>
<tr>
<th>Clinical Scenario</th>
<th>Follow-Up*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source patient is HCV-antibody negative</td>
<td>No further testing or follow-up is necessary for source patient or the exposed worker&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Source patient is unavailable or refuses testing</td>
<td>Exposed worker: Follow-up HCV antibody at 3 and 6 months&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Source patient is HCV-antibody positive and HCV RNA negative</td>
<td>Manage the exposed worker as if the source patient has chronic hepatitis C (see Section 2: Post-Exposure Follow-Up for HCV)&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>Source patient is positive for both HCV antibody and HCV RNA and Exposed worker is HCV-antibody negative</td>
<td>Source patient: Counsel and manage as chronic hepatitis C regardless of status of exposed worker Exposed worker: Follow up as outlined in Section 2: Post-Exposure Follow-Up for HCV</td>
</tr>
<tr>
<td>Exposed worker tests positive for both HCV antibody and HCV RNA</td>
<td>Counsel and manage as chronic hepatitis C</td>
</tr>
</tbody>
</table>

* Refer to Appendix E for information about HCV tests and how to interpret results.

<sup>a</sup> If at any time the serum ALT level is elevated in the exposed worker, the clinician should test for HCV RNA to assess for acute HCV infection.

<sup>b</sup> A single negative HCV RNA result does not exclude active infection.
Sexual Assault

- Candidates for HIV PEP include survivors exposed by direct contact (to semen or blood of the alleged assailant) to the:
  - Vagina
  - Anus
  - Mouth
  - Broken skin
  - Mucous membranes
- PEP should be offered in cases of bites resulting in visible blood

Sexual Assault Follow-up

- If survivor too distraught to discuss or decide about PEP, offer first dose and follow-up within 24 hours
- If PEP initiated, follow-up within 24 hours is also recommended to review understanding, tolerance, & adherence, and to ensure subsequent follow-up
Bill –A669C  11/27/12

Public Health Law mandates
- 7 day starter pack of HIV post exposure prophylaxis
- ER department must provide or arrange for an appointment for PEP follow-up

Payment Methods
- Medicaid/Medicare
- Private insurance, if prescription drug plan
- If no coverage, facility can include in annual Institutional Cost Report for indigent care
- Office of Victim’s Services (OVS)
  - Documentation of a medical visit for a forensic physical exam satisfies CVB reporting requirement
  - Will directly reimburse pharmacy
  - www.cvb.state.ny.us
Rape Crisis Counselor

- Should be active participant in the discussion regarding HIV PEP
- Follow-up with rape crisis counselor or outreach worker who will work with the survivor critical
- May be part of the multidisciplinary team, but if not, HIV release necessary to communicate with outside counselor

Non–Occupational Exposure

- PEP recommended in situations of:
  - Isolated exposure (sexual, needle, trauma)
  - Lapse in previous risk–reduction practices
  - When patients express interest in behavioral change
- Repeated high–risk behavior or presentation for repeat courses of PEP
  - Opportunity for intensification of education & prevention
  - Attempt behavioral change
### Table 1: Consideration of nPEP According to the Type of Risk Exposure

<table>
<thead>
<tr>
<th>Types of Exposures for Which nPEP Should Be Recommended (higher-risk exposures)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Receptive and insertive vaginal or anal intercourse</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Needle sharing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injuries with exposure to blood or other potentially infected fluids from a source known to be HIV-infected or HIV status is unknown (including needlesticks with a hollow-bore needle, human bites, accidents)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Types of Exposures That Require Case-by-Case Evaluation for nPEP (lower-risk exposures: assess for factors that increase risk before recommending initiation of nPEP)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral-vaginal contact (receptive and insertive)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral-anal contact (receptive and insertive)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Receptive penile-oral contact with or without ejaculation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insertive penile-oral contact with or without ejaculation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Factors that increase risk:**

- Source person is known to be HIV-infected with high viral load
- An oral mucosa that is not intact (e.g., oral lesions, gingivitis, wounds)
- Blood exposure — it is important to note that blood exposure can be minimal and therefore not recognized by the exposed person. If the exposed person reports frank blood exposure, PEP would be indicated
- Presence of genital ulcer disease or other STIs
- Kissing
- Oral-to-oral contact without mucosal damage (mouth-to-mouth resuscitation)
- Human bites not involving blood
- Exposure to solid-bore needles or sharps not in recent contact with blood

### Estimated Transmission Risk

<table>
<thead>
<tr>
<th>Exposure Type if Source HIV infected</th>
<th>Estimated Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needle-sharing exposure</td>
<td>0.67% (1/150)(^1)</td>
</tr>
<tr>
<td>Receptive anal intercourse</td>
<td>0.5% (1/200) to 3% (6/200)(^2,3)</td>
</tr>
<tr>
<td>Receptive vaginal intercourse</td>
<td>0.1% (1/1000)(^3,4)</td>
</tr>
<tr>
<td>Insertive anal intercourse</td>
<td>0.065% (1/1500)(^3,4)</td>
</tr>
<tr>
<td>Insertive vaginal intercourse</td>
<td>0.05% (1/2000)(^3,4)</td>
</tr>
<tr>
<td>Oral sex with ejaculation</td>
<td>Conflicting data, but felt to be low-risk. PEP recommended for receiver(^5,6)</td>
</tr>
</tbody>
</table>
Occupational Exposure / Sexual Assault

1-888-448-4911
Available 24/7

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