HIV, Hepatitis B & C
Postexposure Prophylaxis
for Sexual Assault Victims

Update for Case Managers

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10/17/11
Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States

Recommendations from the U.S. Department of Health and Human Services

January 21, 2005 MMWR Vol. 54, No. RR-2
Objectives

1. List the estimated rates of HIV transmission following nonoccupational exposures.

2. Review risks and benefits of antiretroviral postexposure prophylaxis after sexual, injection-drug use or other nonoccupational exposure to HIV.

3. Discuss the evaluation and treatment of persons seeking care after potential nonoccupational exposure to HIV.
A traumatic sexual assault of a child in 2005 motivated teams to improve the quality of care for sexual assault victims.

The 3 teams worked together to establish clinical care guidelines for initial and ongoing screening and preventative treatment of HIV, Hepatitis B & C.
I. Rationale for nonoccupational postexposure prophylaxis (nPEP)

Since some HIV exposures are impossible to eliminate, postexposure prophylaxis has emerged as a strategy to reduce the risk of transmitting HIV infection.
I. Rationale for nPEP

Use of antiretroviral drugs (ARVs) to prevent HIV infection after unanticipated sexual or injection-drug use, or other nonoccupational exposure, may be beneficial.
I. Rationale for nPEP

Scientific evidence for potential benefit of nPEP is based upon cumulative data from:
- Animal transmission model studies
- Perinatal clinical trials
- Studies of health care workers receiving PEP
- Observational studies
# I. Rationale for nPEP

<table>
<thead>
<tr>
<th>Type of Study</th>
<th>Overview</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animals Models</td>
<td>Inoculation of animals with HIV and administering PEP</td>
<td>PEP most effective when started w/i 24 hours and for 28 days</td>
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<tr>
<td>Perinatal Studies</td>
<td>Administering PEP to perinatally exposed infants</td>
<td>ACTG 076: 67% decrease in transmission (25.5% to 8.3%)</td>
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## I. Rationale for nPEP

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<tr>
<td>Occupational Health Exposures</td>
<td>PEP offered to health care workers after needlestick injury</td>
<td>81% decrease in risk for acquiring HIV</td>
</tr>
<tr>
<td></td>
<td>Example: sexual assault survivors in Sao Paolo Brazil</td>
<td>PEP – 0/180</td>
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<tr>
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<td>No PEP – 4/145 (2.75%)</td>
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I. Rationale for nPEP

Most-direct evidence: Case-control study of postexposure prophylaxis provided to health care workers following needlestick injuries

- Prompt initiation of AZT, taken for 4 weeks following exposure, was associated with an 81% reduction in risk of acquiring HIV
II. Possible Risks of nPEP

A. Decrease use of risk reduction behaviors “since” PEP available

B. Toxicity and side effects (SE) of ARV
   – ~10% initiating nPEP stop because of SE
   – Retrospective review of 492 HCP who received at least 3 medications for nPEP, 57% reported nausea and 38% reported fatigue or malaise

C. Resistance - In rare instances, when HIV infection occurs despite nPEP, the virus may have developed resistance to medications in the nPEP regimen
II. Possible Risks of nPEP

D. Cost-effectiveness:
Questionable when compared to behavioral interventions focused on avoiding exposure to HIV

Not cost effective when the HIV exposure involves low transmission risk.
III. Consideration for use of nPEP

- **Timing:**
  - Time and frequency of exposure
  - Duration of time since exposure

- **Exposure Risk:**
  - Risk of transmission
  - Type of exposure

- Likelihood that source is HIV infected:
A. Timing-Time and Frequency of Exposure

- nPEP only indicated for infrequent exposures, NOT for recurrent high-risk exposures
- Individuals with recurrent risk require intensive risk reduction interventions
A. Timing – Duration of time since exposure

- nPEP should be started as soon as possible after exposure
  - “Ideally” within 2 to 4 hours of exposure
  - Many experts do not recommend nPEP if > 72 hours has elapsed since exposure
  - If initiation of nPEP is delayed, decreased likelihood of benefit must be weighed against risks of exposure to ARV medications
B. Exposure Risk

Types of Exposures That Should Prompt Consideration of nPEP:

- Unprotected receptive and insertive vaginal or anal intercourse with a source that is HIV infected or with a source of unknown HIV status

[www.hivguidelines.org #2]
B. Exposure Risk

Types of Exposures That Should Prompt Consideration of nPEP:

- Needle sharing with a source known to be HIV infected or at risk for HIV
- Injuries with exposure to blood from a source known to be HIV infected or at risk for HIV (including needlesticks, human bites, accidents)

www.hivguidelines.org #2
## Estimated Risk of HIV Transmission Following Different Types of Exposure

<table>
<thead>
<tr>
<th>Type of Exposure</th>
<th>Risk Event</th>
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<tr>
<td>Needle-sharing exposure with an infected source</td>
<td>0.67%</td>
</tr>
<tr>
<td>Receptive anal intercourse with an infected source</td>
<td>0.5%-3%</td>
</tr>
<tr>
<td>Receptive vaginal intercourse with an infected source</td>
<td>0.1%</td>
</tr>
<tr>
<td>Insertive anal intercourse with an infected source</td>
<td>0.065%</td>
</tr>
<tr>
<td>Insertive vaginal intercourse with an infected source</td>
<td>0.05%</td>
</tr>
<tr>
<td>Oral sex with ejaculation with an infected source</td>
<td>Low Risk</td>
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*Sources: [www.hivguidelines.org](http://www.hivguidelines.org)*
B. Exposure Risk

Situations which should prompt consideration of nPEP:

- Consensual unprotected sexual intercourse
  - Can occur in the absence of ejaculation
  - Can occur through oral sex
- Sexual assault
- Sharing or injury by equipment used by intravenous drug users
- Accidental exposure in caregivers of HIV infected individuals
C. Likelihood that Source is HIV infected

- If source person available
  - Known HIV infected: obtain detailed hx of ARV use, viral load, any available resistance testing
  - Unknown HIV status: Rapid testing

- HIV status of source is often not known and source is often not available particularly in cases of sexual assault
Whenever possible, risk assessment and initiation of nPEP should occur in clinical settings where HIV prevention counseling services, as well as HIV clinical expertise, are readily available.

Weighing the risks and benefits of nPEP should be individualized
Algorithm for evaluation and treatment of possible nonoccupational HIV exposure

Substantial Exposure Risk

<72 hours Since Exposure
- Source HIV +
  - nPEP recommended

Source HIV status Unknown

>72 hours Since Exposure
- nPEP not recommended
  - Case by Case determination

Negligible Exposure Risk
Evaluation of an Individual Seeking nPEP

1. Determination of HIV status of potentially exposed person
2. Timing and characteristics of most recent exposure
3. Frequency of exposures to HIV
4. HIV status of the source
5. Need for postexposure prophylaxis for other infections
Baseline Testing at Initiation of nPEP

- Baseline HIV testing
  - Best done with a FDA-approved rapid test
  - If rapid testing not available, initiate nPEP based on assumption that patient is not infected
  - Appropriate pre and post test counseling
Baseline Testing at Initiation of nPEP

- Baseline testing should include: CBC, Chemistry, LFTs & Hepatitis B & C serology
- Pregnancy testing for any women of child-bearing age
- Assessment for other STD’s (GC, Chlamydia & Syphilis)
- Consider prophylaxis for STDs in sexually exposed patients
Assessing HIV Exposure

Clinician should consider:

– Behavioral factors and circumstances that led to HIV exposure – time, frequency, duration

– Patient’s risk of HIV acquisition based on the type of exposure – elicit very detailed history of exposure and rate risk accordingly

– Possibility that the source is HIV infected – known vs. unknown HIV status of source
Clinical Care

- Provide risk reduction counseling and primary prevention to all clients.
- nPEP should not be prescribed when there is negligible risk of HIV transmission.
- nPEP should not be used as prophylaxis for someone planning on engaging in high risk behavior.
Selecting an ARV regimen for nPEP

- 28 day course of nPEP recommended
  - Consider likelihood of adherence, potential toxicities and cost
Selecting an ARV regimen for nPEP

Preferred regimens

- Nonnucleoside based
  - Efavirenz and FTC/3TC with AZT or tenofovir (Atripla once daily)
- Protease inhibitor based
  - Lopinivir/ritonovir (Kaletra) with AZT and FTC/3TC

Two drug regimen (AZT and 3TC/FTC) option (Combivir (AZT/3TC) bid)

- Consider especially when source person of unknown HIV status and unavailable for testing
Patient Counseling related to nPEP

- Patient should be counseled about:
  - Potential benefits of nPEP
  - Associated SEs and adverse events
  - Need for adherence to prescribed regimen
  - Need to initiate/resume risk reduction and preventive behaviors
  - Signs and symptoms of primary HIV infection
  - Need and schedule for clinical and laboratory monitoring
Tips when prescribing nPEP

- Provide medications to treat common side effects (antiemetics/antimotility agents)

- Use of starter packs
  - Dispense initial doses (ER setting)
  - Assure availability of coverage for prescriptions or alternative source of entire 28 day course of ARVs
Tips when prescribing nPEP

- Expert consultation, especially for pregnant women and children – (should not delay initiation of nPEP)
- Adherence support
- If source found to be HIV negative, nPEP should be discontinued
Follow-up Testing and Care

- Monitor CBC, liver/renal function at baseline nPEP and 2 weeks after starting nPEP
- HIV testing at baseline, 4-6 weeks, 3 months and 6 months after exposure
- Offer testing for sexually transmitted diseases (Chlamydia, Gonorrhea, Syphilis) and pregnancy as indicated
- Testing for Hepatitis B (or immunization status) and C at baseline, 4-6 weeks and 3 months
- Review symptoms of acute retroviral syndrome: indication for immediate evaluation
V. Sexual Assault

Characteristics of Sexual Assault that may increase risk for HIV transmission

– Associated trauma, bleeding and tissue injury
– Characteristics of sexual assaults
  - Multiple assailants (20%)
  - Assault by stranger (39%)
  - Vaginal penetration, if female (83%)
  - Sodomized (39%)
  - Genital trauma (53%)
  - Sperm or semen detectable (48%)
Sexual Assault

Decision to initiate nPEP should **not** be based on likelihood that perpetrator is infected

- Every perpetrator should be considered at risk until his/her HIV status determined

nPEP should be recommended when a significant exposure has occurred

- Vaginal or anal penetration (unprotected)

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Clinicians should consider initiation of nPEP within 72 hours when the source is known to be HIV positive and the exposure event presents a substantial risk for transmission of HIV.

Clinicians should carefully weigh the risks and benefits on a case by case basis when the exposure is negligible or ongoing, > 72 hours after exposure, HIV status of source is unknown, or completion of nPEP unlikely or impossible.
1. CDC. Recommendations from the U.S. Department of Health and Human Services on Antiretroviral Postexposure Prophylaxis After Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the U.S. MMWR 2005; 54 (no RR-2).