NON-OCCUPATIONAL POST EXPOSURE PROPHYLAXIS FOR SEXUAL ASSAULT SURVIVORS

Carl LeBuhn, MD
Post-Exposure Prophylaxis (PEP)

- The use of therapeutic agents to prevent infection following exposure to a pathogen

- Types of exposures include percutaneous (needle stick), splash, bite, sexual

- For health-care workers, PEP commonly considered for exposures to HIV and Hepatitis B
Evaluation of Persons Seeking nPEP

- HIV status of person seeking nPEP
  - Perform HIV baseline testing on persons seeking nPEP; use rapid test if possible

- Time and frequency of exposure
  - nPEP is less likely to be effective >72 hours postexposure
  - nPEP should be used infrequently
Evaluation of Persons Seeking nPEP: HIV Status of Source

- HIV status of source: HIV positive
  - Consider nPEP if within 72 hours of exposure
  - When possible, interview source to determine ARV use and most recent viral load

- HIV status of source: Unknown
  - Determine whether source is available for testing
  - If source is from group with high prevalence of HIV infection, risk of transmission might be increased

- Do not delay initiation of nPEP for source testing
When should nPEP be started?

• Efficacy of PEP thought to wane with time
• At what point is PEP “no longer worth it”? 
Leone P UNC
Timing of PEP: CDC Guidelines

• “PEP should be initiated as soon as possible, preferably within hours rather than days of exposure.”

• Interval after which there is no benefit for humans is not known

• Obtain expert advice when interval has exceeded 24-36 hours

MMWR 2005;54(No. RR-9).
Evidence of Possible Benefits from nPEP

- Animal studies
- Postnatal (mother-to-child) prophylaxis
- Occupational PEP
- Observational studies of nPEP
Evidence of Efficacy of PEP

- Animal models: high level of protection when started within 24 hours\textsuperscript{1}

Evidence from occupational PEP

- Retrospective case-control study:
  - Use of AZT monotherapy >81% reduction in the risk of acquiring HIV infection (controlled for other HIV transmission risk factors)

- Two drugs, three drugs:
  - Cases of seroconversion despite 3-drug PEP imply efficacy less than 100%\(^2,3\)

3. MMWR June 29, 2001 / 50(RR11);1-42
Patients might be under considerable emotional stress when seeking care after a potential HIV exposure and might not attend to, or retain, all the information relevant to making a decision about nPEP. Clinicians should give an initial prescription for 3–5 days of medication and schedule a follow-up visit.

MMWR. 2005: Vol. 54;No. RR-2
## Preferred ARV Regimens for nPEP

<table>
<thead>
<tr>
<th>Regimen Type</th>
<th>Regimen Details</th>
</tr>
</thead>
</table>
| NNRTI based  | EFV + (3TC or FTC) + (ZDV or TDF) for 28 days  
*Do not administer EFV to pregnant women* |
| PI based     | LPV/RTV (Kaletra) + (3TC or FTC) + ZDV for 28 days  
(3TC and ZDV coformulated as Combivir) |

March 2008  
AETC National Resource Center,  
www.aidsetc.org
Abbreviations

- NNRTI- non nucleoside reverse transcriptase inhibitor
- PI- protease inhibitor
- EFV- efavirenz
- 3TC- lamivudine
- FTC- emtricitabine
- ZDV- zidovudine
- TDF- tenofovir
- LPV/RTV- lopinavir/ritonavir
Evidence from Animal Studies

- N = 24 macaques inoculated with SIV intravenously
- PEP initiated 24 hours post-inoculation
- PEP administered for 3, 10, or 28 days

Recommendations for Use of ARVs for nPEP

- **Substantial exposure risk**
  - ≤ 72 hours since exposure
    - **Source patient known to be HIV+**
      - nPEP recommended
  - >72 hours since exposure
    - **Source patient of unknown HIV status**
      - Case-by-case determination
- **Negligible exposure risk**
  - nPEP not recommended

Source patient known to be HIV+ and ≤ 72 hours since exposure:
- nPEP recommended

Source patient of unknown HIV status and >72 hours since exposure:
- Case-by-case determination

The source didn’t look sick, so I’m not at risk for HIV am I?
Considerations in the Setting of Sexual Assault

- Rhode Island Study found 1% of inmates convicted of sexual assault were HIV infected, higher than the 0.3% in the general population.
- Injury to tissue during sexual assault - study using toluidine blue dye to determine lacerations:
  - 40% if all assaulted, 70% nulliparous assaulted had lacerations.
  - 5% of women who had consensual sex.

Tolerability of HIV PEP in Health Care Workers

Incidence of Common Side Effects

## Adverse effects comparison

<table>
<thead>
<tr>
<th></th>
<th>Lopinavir/Ritonavir (Kaletra)</th>
<th>Levofloxacin</th>
<th>Azithromycin (single 1g dose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea</td>
<td>15</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>Nausea</td>
<td>5</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Vomiting</td>
<td>4</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

From package inserts
Adverse Effects: Basic vs Expanded Regimens

Puro V et al. 9th CROI, February 2002, Abstract 478-M
Important Things to Remember

- Adherence is important
- Side effects will happen - manage by anticipation, education, and treatment
Testing and Follow up
PHI: Diagnostic Testing

HIV RNA

1,000
100,000
1 mil

Exposure

0

Days

Symptoms

20 30 40 50

HIV-1 Antibodies

Ab

+ -
HIV Positive
HIV +

- Patient’s tests are ELISA positive
- ELISA test is repeated and is positive
- Test is confirmed by western blot
- Patient is now said to be “HIV positive”
Recommended lab evaluation for nPEP

<table>
<thead>
<tr>
<th>Test</th>
<th>Baseline</th>
<th>During nPEP</th>
<th>4-6 wks after exposure</th>
<th>3 months after exposure</th>
<th>6 months after exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV antibody testing</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>CBC w/ diff</td>
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<tr>
<td>CMP</td>
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<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Hep B serology</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Hep C serology</td>
<td>X</td>
<td></td>
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<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
Follow up Education/Counseling

- Adherence
- HIV Prevention
- Mental Health
Follow up appointments

- Uncomplicated cases can be managed by primary care in consult with ID specialist or national PEP hotline
- Arrangements should be made with local ID clinics on a case by case basis
- Bluegrass Care Clinic can accept limited referrals on a case by case basis
Consultation

- Expanded regimens and expert advice indicated for severe exposures or when resistance is suspected

- UK MD Clinical Consult:
  Toll free: 1-800-888-5533

- National Clinicians’ Post-Exposure Prophylaxis Hotline (PEPline)
  † (888) HIV-4911