Overview & Objectives

Occupational Exposures
- Resources & Definitions
- Classifying types of exposures (HBV and HIV)
- Best estimates for transmission

HIV PEP
- Practical management considerations
  - Timing & Duration of PEP
  - Choosing a regimen
  - Laboratory Monitoring

HBV PEP
- Use of HBIG and HBV vaccine
Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis

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
Postexposure Prophylaxis for Occupational Bloodborne Exposure

A MANUAL FOR HEALTH CARE PROVIDERS

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Christopher Behrens, MD
David H. Spach, MD
and
The Northwest AIDS Education and Training Center

Last Updated: June 30, 2009

Instructions for Health Care Workers

1. In the Event of An Exposure
   In the event of a possible exposure to a bloodborne pathogen, the health care worker (HCW) should act promptly to carry out the steps listed below.

2. Decontaminate the Area of the Exposure

72 Hour Follow-up Visit

Instructions for the Managing Clinician

1. Address HCW Questions or Concerns
   At this visit address any questions or concerns the exposed HCW may have about the exposure or PEP recommendations to date. Form 9: 72 Hour Follow-up Visit provides a template that can be used to record details of this and subsequent follow-up visits. Offer psychological counseling referral if indicated.

Two Week Follow-up Visit
(For HCWs Who Initiated Antiretroviral PEP)

1. Address HCW Questions or Concerns
   Address any questions or concerns the exposed HCW may have about the exposure or PEP recommendations to date. Use Form 11: Two Week Follow-up Visit: Recommendations for HCW to record details of this and subsequent steps. Offer psychological counseling referral if indicated.

Six Week Follow-up Visit

1. Address HCW Questions or Concerns
   Address any questions or concerns the exposed HCW may have about the exposure. Offer psychological counseling referral if indicated.
Post-Exposure Prophylaxis (PEP)

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

• For health-care workers, PEP commonly considered for exposures to HIV and Hepatitis B
Exposures...What Counts?

Exposures:
- Transfusions
- IV, IM, SQ needle injury w/ potentially infectious fluid*
- Mucus Membrane/skin break splash w/ potentially infectious fluid*
- Human Bites (if bleeding present in mouth & at bite)

Non-Exposures
- Intact Skin splash w/ potentially infectious fluid*
- IV, IM, SQ needle injury w/ no infectious fluid
- Mucus Membrane/skin break splash w/ no infectious fluid
- Human Bites (non-bloody)

SEX!
*Potentially Infectious Fluid (HIV/HCV)*

**YES**
- Blood
- Semen
- Vaginal Fluid
- Pus
- Amniotic Fluid
- Spinal, Pleural, Synovial, Peritoneal Fluid
- Breastmilk

**NO**
- Saliva/Sputum
- Urine
- Feces
- Vomit
- Sweat
- Tears
- Nasal Secretions (unless visibly bloody)
### Potentially Infectious Fluid (HBV)

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- Feces
- Vomit
- Sweat
- Tears
- Nasal Secretions (unless visibly bloody)
Hepatitis/HIV – Relative Risk of transmission

- ‘The rule of three’
- Needlestick transmission rates:
  - HBV – 30 of every 100
  - HCV – 3 of every 100
  - HIV – 0.3 of every 100

<table>
<thead>
<tr>
<th>Method</th>
<th>Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percutaneous (blood)</td>
<td>0.3%</td>
</tr>
<tr>
<td>Mucocutaneous (blood)</td>
<td>0.09%</td>
</tr>
<tr>
<td>Receptive anal intercourse</td>
<td>1 - 2%</td>
</tr>
<tr>
<td>Receptive vaginal intercourse</td>
<td>0.1 – 0.2%</td>
</tr>
<tr>
<td>Insertive vaginal intercourse</td>
<td>0.03 – 0.14%</td>
</tr>
</tbody>
</table>

MMWR Sept 30, 2005 54(RR-9):1-17
HIV PEP
Evidence of Efficacy of HIV-PEP

- Animal models: high level of protection when started within 24 hours\(^1\), 28 days more effective than 3 days or 10 days
- OR = 0.19 for zidovudine (AZT) use in case-control study\(^2\) (81% decrease in risk of HIV acquisition)
- Two drugs vs. three drugs:
  - no direct evidence that more drug = more effective
  - cases of seroconversion despite 3-drug PEP imply efficacy less than 100%\(^3,4\)

4. MMWR June 29, 2001 / 50(RR11);1-42
When should PEP be started?

- Efficacy of PEP thought to wane with time
- at what point is PEP “no longer worth it”?

CDC language:
“…as soon as possible, preferably within hours rather than days…”
“Interval after which there is no benefit for humans is not known”
“Obtain expert advice when interval has exceeded 24-36 hours”
### CDC PEP Guidelines: Known HIV+ Source

<table>
<thead>
<tr>
<th>Exposure Type</th>
<th>Source Infection Status</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HIV+ Class 1</td>
</tr>
<tr>
<td>Less Severe*</td>
<td>Basic (2 Drugs)</td>
</tr>
<tr>
<td>More SevereΔ</td>
<td>Expanded (≥ 3 Drugs)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exposure Type</th>
<th>Source Infection Status</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HIV+ Class 1</td>
</tr>
<tr>
<td>Small Volume*</td>
<td>Consider Basic (2 Drugs)</td>
</tr>
<tr>
<td>Large VolumeΔ</td>
<td>Recommend Basic (2 Drugs)</td>
</tr>
</tbody>
</table>

### CDC-Recommended PEP regimens

#### Basic:

<table>
<thead>
<tr>
<th>Drug Combination</th>
<th>Dose</th>
</tr>
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<tbody>
<tr>
<td>Zidovudine + Lamivudine</td>
<td>AZT 300 mg/3TC 150 mg</td>
</tr>
<tr>
<td>Truvada®</td>
<td>TDF 300 mg/FTC 200 mg</td>
</tr>
</tbody>
</table>

#### Expanded = Basic PLUS:

1. **Lopinavir/ Ritonavir (LPV/r) Kaletra®**
   - LPV 200 mg/RTV 50 mg

2. **Atazanavir (ATV) Reyataz®**
   - 300 mg

3. **Fosamprenavir (FPV) Lexiva®**
   - 700 mg

4. **Indinavir (IDV) Crixivan®**
   - 400 mg

5. **Saquinavir (SQV) Invirase®**
   - 500 mg

6. **Ritonavir (RTV) Norvir®**
   - 100 mg
‘Modern’ PEP regimens

Basic:

<table>
<thead>
<tr>
<th>Tenofovir + Emtricitabine</th>
<th>Truvada®</th>
</tr>
</thead>
<tbody>
<tr>
<td>701</td>
<td>TDF 300 mg/FTC 200 mg</td>
</tr>
</tbody>
</table>

i tab PO QD

Expanded = Basic PLUS:

ii tabs PO QD

iii tabs PO QD

i tab BID

Source: NW-AETC PEPManual
NCCC: Non-Guideline PEP Regimens

N = 465 exposures, 638 HIV PEP regimens

<table>
<thead>
<tr>
<th>Non-Preferred Drugs</th>
<th>Number of Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Darunavir/Ritonavir (boosted)</td>
<td>37 (36%)</td>
</tr>
<tr>
<td>Raltegravir</td>
<td>32 (31%)</td>
</tr>
<tr>
<td>Atazanavir/Ritonavir (boosted)</td>
<td>19 (18%)</td>
</tr>
<tr>
<td>Maraviroc</td>
<td>6 (6%)</td>
</tr>
<tr>
<td>Atazanavir (unboosted)</td>
<td>2 (2%)</td>
</tr>
<tr>
<td>Etravirine</td>
<td>2 (2%)</td>
</tr>
<tr>
<td>Fosamprenavir (unboosted)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Indinavir (unboosted)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Nevirapine</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Efavirenz</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Atripla (Efavirenz/Tenofovir/Emtricitabine)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Total</td>
<td>88 (100%)</td>
</tr>
</tbody>
</table>

Predictor Variables for Non-Guideline PEP Regimen Recommendation

<table>
<thead>
<tr>
<th>Predictor Variables</th>
<th>Odds Ratio</th>
<th>P value</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Known ARV Resistance</td>
<td>20.88</td>
<td>0.015</td>
<td>1.80 – 242.0</td>
</tr>
<tr>
<td>Viral Load &gt;1500 copies/mL</td>
<td>12.04</td>
<td>0.14</td>
<td>0.43 – 337.2</td>
</tr>
<tr>
<td>SP Clinical Status</td>
<td>4.67</td>
<td>0.38</td>
<td>0.15 – 143.1</td>
</tr>
<tr>
<td>NCCC PEPline</td>
<td>1.03</td>
<td>0.98</td>
<td>0.12 – 8.54</td>
</tr>
<tr>
<td>Clinician Degree</td>
<td>0.074</td>
<td>0.068</td>
<td>0.0045 – 1.21</td>
</tr>
<tr>
<td>SP Currently On ARVs</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Follow-up of HCW exposed to HIV

<table>
<thead>
<tr>
<th>Test</th>
<th>Time Elapsed Since the Exposure Occurred</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
</tr>
<tr>
<td>HIV antibody test</td>
<td>✓</td>
</tr>
<tr>
<td>CBC with differential</td>
<td>✓</td>
</tr>
<tr>
<td>Serum liver enzymes</td>
<td>✓</td>
</tr>
<tr>
<td>Blood Urea Nitrogen</td>
<td>✓</td>
</tr>
<tr>
<td>Pregnancy Test#</td>
<td>✓</td>
</tr>
</tbody>
</table>

* HIV antibody testing should be performed at 12 months if the health care worker acquires hepatitis C virus from the occupational exposure

^ Only necessary to obtain these studies for health care workers who will receive postexposure prophylaxis to monitor for antiretroviral therapy toxicity

# For women of reproductive age, especially if they will receive post-exposure prophylaxis

Adapted from: MMWR 2005; 54(No. RR-9) and reproduced from www.hivwebstudy.org
HEPATITIS B PEP
Hepatitis B PEP

- HBV prevalence in U.S. is low (0.1-2%)

- Most HCW are vaccinated against HBV

- Hepatitis B PEP: immunization + HBIG (HBV Immune Globulin – effective up to 1 week post exposure)
PEP: Summary

• HIV-PEP should be offered within **hours** from exposure and for 28 day duration
• Counseling is crucial to discuss true risks and benefits of PEP
• Providers should choose 2- or 3-drug HIV-PEP regimen based on exposure & source
• HBV PEP involves HBIG and HBV vaccination
Help is Available!!!

- **PEPLine**: 888-448-4911
  - [www.ucsf.edu/hivcntr/Hotlines/PEPline](http://www.ucsf.edu/hivcntr/Hotlines/PEPline)
  - 9AM – 2 AM EST

- **CDC/DHHS**: 800-893-0485
  - [http://depts.washington.edu/nwaetc/resources/pep.html](http://depts.washington.edu/nwaetc/resources/pep.html)