Non-Occupational Post-Exposure HIV Prophylaxis nPEP

Why?
When?
Who?
How?

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Callen-Lorde Community Health Center
Objectives - at the end of the session participants will be able to:

- Review efficacy & safety data regarding nPEP
- Apply national and state guidelines for nPEP
- Understand evaluation and monitoring required for prescribing nPEP
- List the challenges of applying these guidelines in the real world of a community health center and consider solutions
FQHC, Article 31
2013: 14,875 patients, 77,500 encounters,
36% uninsured, 1,200 Transgender, 3,700 PLWHA
Agenda nPEP

nPEP and PrEP: Controlling the epidemic?
nPEP guidelines
Cascade of PEP provision data
Applying nPEP guidelines
CL nPEP delivery model
Evidence for PEP:

ANIMAL TRANSMISSION MODELS
PERINATAL CLINICAL TRIALS
OCCUPATIONAL PEP
OBSERVATIONAL STUDIES
What Possible Negative Consequences of nPEP?
Considered Possible Negative Consequences of nPEP

Impact on Risk Reduction
Side effects
Selection of resistant virus
Cost
  Cost effectiveness
Access
Considered Possible Negative Consequences of nPEP

Impact on Risk Reduction
Side effects
Selection of resistant virus
Cost
  Cost effectiveness
  Access

40,000 new HIV infections annually in US
Strategy for epidemic control: Patient Care & Public Health - nPEP and PrEP

Preventing malaria
Mind before Madness

YOUR ABCD AGAINST MALARIA

A: Awareness: Recognizing Malaria!
B: Bite prevention: Controlling Mosquitoes!
C: Chemoprophylaxis: Use Preventive Medication!
D: Diagnosis: Early Recognition!

SOURCE: DIETSMANN
(HTTPS://WWW.DIETSMANN.COM/PREVENTINGMALARIA)
nPEP Evaluation

Clinical Assessment and Plan
  Substantial risk?
  Timing?
  Patient acceptance, adherence, follow-up?

Administrative Assessment and Plan
  Insurance?
  Ability to pay?
  Immigration status?

24/7 PEPline 1-866-637-2342
Timing is critical
Blood transfusion
Receptive penile-vaginal intercourse
Receptive anal intercourse

What's the risk?
<table>
<thead>
<tr>
<th>Exposure Route</th>
<th>Risk per 10,000 exposures to an infected source</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Transfusion</td>
<td>9,000</td>
<td>74</td>
</tr>
<tr>
<td>Needle-sharing injection-drug use</td>
<td>67</td>
<td>75</td>
</tr>
<tr>
<td>Receptive anal intercourse</td>
<td>50</td>
<td>76, 77</td>
</tr>
<tr>
<td>Percutaneous needle stick</td>
<td>30</td>
<td>78</td>
</tr>
<tr>
<td>Receptive penile-vaginal intercourse</td>
<td>10</td>
<td>76, 77, 79</td>
</tr>
<tr>
<td>Insertive anal intercourse</td>
<td>6.5</td>
<td>76, 77</td>
</tr>
<tr>
<td>Insertive penile-vaginal intercourse</td>
<td>5</td>
<td>76, 77</td>
</tr>
<tr>
<td>Receptive oral intercourse</td>
<td>1</td>
<td>77</td>
</tr>
<tr>
<td>Insertive oral intercourse</td>
<td>0.5</td>
<td>77</td>
</tr>
</tbody>
</table>

* Estimates of risk for transmission from sexual exposures assume no condom use.

† Source refers to oral intercourse performed on a man.
Table 1: Consideration of nPEP According to the Type of Risk Exposure

<table>
<thead>
<tr>
<th>nPEP recommended</th>
<th>penile-anal sex</th>
<th>penile-vaginal sex</th>
<th>needle sharing</th>
</tr>
</thead>
<tbody>
<tr>
<td>nPEP considered</td>
<td>oral-vaginal sex</td>
<td>oral-anal sex</td>
<td>penile-oral sex</td>
</tr>
<tr>
<td>nPEP not</td>
<td>oral-oral contact</td>
<td>human bites</td>
<td>recommended</td>
</tr>
</tbody>
</table>

(edited from) NYSDOH AIDS Institute
www.hivguidelines.org
Consider HIV VL test in source patient
Baseline STI Screening
Post exposure HIV test at 4 & 12 weeks
Consideration for PrEP
Choice of nPEP Rx
Figure. Algorithm for evaluation and treatment of possible HIV exposures. [DHHS 2005; USPHS 2013]

Substantial Risk for HIV Exposure
- Exposure of... vagina, rectum, eye, mouth, or other mucous membrane, non-intact skin, or percutaneous contact
- With... blood, semen, vaginal secretions, rectal secretions, breast milk, or any body fluid that is visibly contaminated with blood
- When... source is known to be HIV-infected

Negligible Risk for HIV Exposure
- Exposure of... vagina, rectum, eye, mouth, or other mucous membrane, intact or non-intact skin, or percutaneous contact
- With... urine, nasal secretions, saliva, sweat, or tears if not visibly contaminated with blood
- Regardless... of the known or suspected HIV status of the source
33 YEAR WOMAN
WORRIED SHE’S BEEN EXPOSED TO HIV
IT IS NOW SUNDAY 3:00 PM
33 YEAR WOMAN
WORRIED SHE’S BEEN EXPOSED TO HIV
IT IS NOW SUNDAY 3:00 PM

WHEN?  WEDNESDAY 11:00 PM
HOW?
CONTEXT?

Scenario 1
33 YEAR WOMAN
WORRIED SHE’S BEEN EXPOSED TO HIV
IT IS NOW SUNDAY 3:00 PM

WHEN?            WEDNESDAY 11:00 PM
HOW?
CONTEXT?

ARRANGE FOR COMPREHENSIVE STD SCREENING, CONTRACEPTIVE COUNSELING, PRIMARY CARE & CONSIDERATION OF PREP

Scenario 1
33 YEAR WOMAN
WORRIED SHE’S BEEN EXPOSED TO HIV
IT IS NOW SUNDAY 3:00 PM

WHEN?
SUNDAY 8:00 AM

HOW?
RECEPTIVE ORAL SEX

CONTEXT?

Scenario 2
33 YEAR WOMAN
WORRIED SHE’S BEEN EXPOSED TO HIV
IT IS NOW SUNDAY 3:00 PM

WHEN? SUNDAY 8:00 AM
HOW? RECEPTIVE ORAL SEX
CONTEXT? 

ARRANGE FOR COMPREHENSIVE STD SCREENING, CONTRACEPTIVE COUNSELING (IF WARRANTED), PRIMARY CARE

Scenario 2
25 YEAR OLD MAN
WORRIED HE’S BEEN EXPOSED TO HIV
IT IS SUNDAY 3:00 PM

WHEN?  SUNDAY 8:00 AM
HOW?  RECEPTIVE ANAL SEX WITHOUT CONDOM, WITH EJACULATION, UNKNOWN STATUS OF PARTNER
CONTEXT?  USUALLY HAS ORAL SEX OR ANAL SEX WITH CONDOM

Scenario 3
25 YEAR OLD MAN
WORRIED HE’S BEEN EXPOSED
TO HIV
IT IS SUNDAY 3:00 PM

WHEN?  SUNDAY 8:00 AM
HOW?  RECEPTIVE ANAL SEX WITHOUT
CONDOM, WITH EJACULATION,
UNKNOWN STATUS OF PARTNER
CONTEXT?  USUALLY HAS ORAL SEX OR ANAL
SEX WITH CONDOM

NEEDS URGENT NPEP (COMPREHENSIVE STD
SCREENING, PRIMARY CARE & CONSIDERATION OF
PREP)

Scenario 3
What tests to do & when?
### Monitoring Recommendations After Initiation of PEP Regimens Following Non-occupational Exposures

<table>
<thead>
<tr>
<th>Week</th>
<th>Baseline</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinic Visit</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnancy Test</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serum liver enzymes, BUN, creatinine, CBC</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>HIV test</strong> - Recommended even if PEP is declined</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>STI Screening</strong> - Recommended even if PEP is declined</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis B and C</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**See separate document**

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**SOURCE: HIV CLINICAL RESOURCE**

Remember to consider Hep C
nPEP Evaluation

Clinical Assessment and Plan
- Substantial risk?
- Timing?
- Patient acceptance, adherence, follow-up?

Administrative Assessment and Plan
- Insurance?
- Ability to pay?
- Immigration status?
nPEP Flow sheet(s)

- PPEP (private insurance)
- PAP-PEP (pharmacy assistance program)
- SPEP (self pay)
- FPEP (funded PEP)
### Payment Options for Post-Exposure Prophylaxis Following Non-Occupational Exposures Including Sexual Assault (nPEP)

#### Sexual Assault

Chapter 39 of the Laws of 2012 amending Section 2805-i of Public Health Law requires hospitals to provide the first seven days of medication to victims of sexual assault. Prescriptions must be given for the remaining 21 days.

<table>
<thead>
<tr>
<th>Insurance Status</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medicaid</strong></td>
<td>PEP is covered.</td>
</tr>
<tr>
<td><strong>Private Insurance</strong></td>
<td>PEP coverage is based on plan. Large co-pay may be a consideration. NYS Office of Victim Services (OVS) may reimburse co-pays of a victim who submits an eligible application with the agency. Co-payment cards are available from the manufacturers. Gilead - 1-877-505-6986 Merck - 1-855-834-3467 or <a href="http://www.isentress.com">www.isentress.com</a></td>
</tr>
<tr>
<td><strong>Insured, but does not use insurance</strong></td>
<td>A victim may decline to provide insurance information if he/she believes provision of that information would substantially interfere with his or her personal privacy or safety. A victim may ask the provider to directly bill the OVS for the Forensic Rape Exam (FRE), including the first seven days of medication.</td>
</tr>
<tr>
<td><strong>No Insurance</strong></td>
<td>OVS may be directly billed as above and the victim may apply to OVS for expenses beyond the FRE, including a prescription for the remaining 21 days.</td>
</tr>
<tr>
<td><strong>NYS Office of Victim Services (formerly the Crime Victims Board)</strong></td>
<td>OVS has an Emergency Award Procedure designed to pay the pharmacy in 1-4 days. It is important that the forms be filled out correctly and submitted with the supporting information requested. Emergency awards are available for up to $2,500. It is best to work with Victim Advocates in your community to pursue this process; they know the community connections and the procedure to expedite this process. Call 1-800-247-8035 or go to <a href="http://www.ovs.ny.gov">www.ovs.ny.gov</a> for more information.</td>
</tr>
</tbody>
</table>

**Source:** New York State Department of Health

## Payment Options for Post-Exposure Prophylaxis Following Non-Occupational Exposures Including Sexual Assault (nPEP)

### For All Other Non-Occupational Exposures in any Health Care Setting

<table>
<thead>
<tr>
<th>Medicaid</th>
<th>PEP is covered.</th>
</tr>
</thead>
</table>
| Private Insurance | PEP coverage is based on plan. Co-payment cards are available from the manufacturers.  
Gilead - 1-877-505-6986  
Merck - 1-855-834-3467 or www.isentress.com |
| Insured, but does not use insurance | • Treating institution provides immediate access to drugs.  
• Begin application process for Medicaid, if appropriate. (Coverage is not guaranteed).  
• Explore the Patient Assistance Programs from pharmaceutical companies.  
• Contact your human service/social work department for special funds. |
| Patient Assistance Programs | Common Patient Assistance Program Application (HIV)  
http://hab.hrsa.gov/patientassistance/index.html  
HIV meds are listed by company with instructions on how to submit the application. You may need to apply to more than one company depending on regimen chosen.  
*Please see specific application process on next page for Gilead and Merck.* |
**Patient Assistance Programs**

**Gilead Patient Assistance**
1. Fax a letter of medical necessity to 1-800-226-2056.
   Include:
   - Patient’s name
   - Therapy needed
   - Date of exposure
   - Provider’s signature
2. Call 1-800-226-2056 and notify them you have a patient who needs PEP.
   - Tell them you faxed in a letter of medical necessity.
     - Give them time of fax
     - Number of pages
     - Your fax number
   - Have this information available:
     - Name
     - Address
     - Phone number
     - Date of birth
     - Social security number
     - Number of people claimed as dependents
     - Household income
     - Any insurance coverage
     - Provider name
     - Provider address
     - Provider phone number
   - Will take 5-10 minutes
   - Hours: Monday - Friday 9am-8pm EST
3. They will give you a voucher number to place on the prescription. The patient may go to the pharmacy to have the prescription filled with no out-of-pocket expenses.
4. **Co-payment Assistance:** Call 1-877-505-6986. Hours: Monday - Friday 8am- 8pm EST. Patient is given an authorization number to present with the prescription and other insurance at the pharmacy.

**Source:** New York State Department of Health

(https://www.health.ny.gov/diseases/aids/providers/standards/docs/payment_options_npep.pdf)
Patient Assistance Programs

1. **Merck Patient Assistance Program**
   2. Locate form at www.needymeds.org
      - Support enrollment form
      - Print and fill out
      - **Indicate prescribing PEP** - this will expedite processing.
      - Fax to 1-866-410-1913. You may send fax any time. Hours of operation: 6am - 3pm PST Monday - Friday.
   3. Call 1-800-850-3430 1-2 hours after sending fax.
   4. Will send medications to provider or patient as indicated on form
      - If received by 12:30 PST, will have overnight delivery. (about 24 hours)
      - If received after 12:30 PST, will have next day delivery. (about 48 hours)
   5. **Co-payment Assistance:** Call 1-855-834-3467 or www.isentress.com
      - For online application and coupon redemption
      - For presentation with the prescription and insurance coverage at the pharmacy.

**SOURCE:** NEW YORK STATE DEPARTMENT OF HEALTH
(HTTPS://WWW.HEALTH.NY.GOV/DISEASES/AIDS/PROVIDERS/STANDARDS/DOCS/PAYMENTOPTIONS_NPEP.PDF)
PEP Cascade

100

85 initiate nPEP

25 incomplete nPEP

30 complete and follow up*

15 decline nPEP

60 complete nPEP