PAMC Guideline for HIV Post-Exposure Prophylaxis After Sexual Assault

Last Updated: 5/2015

Scope of Guideline/Pathway:
- This guideline is intended for use in older adolescent and adult patients (ages 16 years and above) seeking preventative care for human immunodeficiency virus (HIV) after sexual assault.
- A formal referral to a clinician with expertise in the management of HIV should be made for follow-up of ALL patients initiated on post-exposure prophylaxis after initial evaluation and during initial evaluation of complicated cases (as determined at the discretion of the evaluating healthcare professional).
- All doses listed below assume normal renal/hepatic function. Doses should be modified as appropriate for patients with renal/hepatic impairment.

Initial Assessment:
All of the following factors need be evaluated for and considered during the initial assessment of a victim of sexual assault and evaluation of the need for HIV post-exposure prophylaxis (PEP).
- PEP should ALWAYS be recommended if any ONE of the below criteria is met:
  - Direct contact of the vagina, penis, anus, or mouth with the semen, vaginal fluid, or blood of the alleged assailant with or without physical injury, tissue damage, or the presence of blood at the site of the assault
  - Broken Skin or mucous Membranes of the victim have been in contact with blood, semen, or vaginal fluids of the alleged assailant
  - Bites that result in visible blood
- HIV Status of the assailant:
  - Unless the identity and HIV status of the assailant has been clearly established to assist with decision making, PEP should be promptly initiated.
    - Therapy should NOT be delayed while awaiting the HIV test results from the alleged assailant
  - PEP may be discontinued, prior to completion of a standard 28-day course, if ALL of the following criteria are met:
    - The identity of the alleged assailant is known
    - The rapid HIV test results from the alleged assailant are negative
    - The 3rd or 4th generation EIA or HIV RNA assay from the alleged assailant is negative.
  - Even if the assailant is known to be HIV-infected, the nature of the sexual assault (above criteria) should be taken into consideration prior to the initiation of PEP.
- Victim readiness/willingness to complete the PEP regimen:
  - Efficacy of PEP is highly dependent on compliance with the regimen with regards to both frequency of administration and duration of therapy. A victim’s readiness and willingness to complete a course of PEP needs to be assessed prior to initiation of therapy.

Necessary HIV Testing:
- Initial Evaluation:
  - ALL victims being initially evaluated after sexual assault meeting the above criteria for PEP should have a baseline rapid HIV test performed.
    - NOTE: PEP should not be delayed while waiting for test results.
- Follow-up Evaluation:
  - ALL patients initiated on PEP should be formally referred to a clinician with expertise in the management of HIV for follow-up care.
  - If PEP is determined appropriate, in addition to the baseline rapid HIV test, repeat HIV tests should be performed at the below intervals.
    - 4 weeks post-exposure
    - 12 weeks post-exposure
    - A negative HIV test at 12 weeks post-exposure reasonably excludes HIV infection related to the isolated exposure event.
**PEP Regimen:**

- **HIV Post-Exposure Prophylaxis Medication Regimen:**

  Tenofovir 300 mg PO daily + Emtricitabine 200 mg PO daily (Truvada 300 mg/200 mg PO daily) + Raltegravir 400 mg PO bid

  Total Duration of Therapy = 28 Days

- **General Principles:**
  - When indicated, PEP should be initiated **AS SOON AS POSSIBLE** after the assault.
    - Ideally PEP would be initiated within 2 hours of the assault.
  - Decisions regarding PEP initiation beyond 36 hours after the assault should be made on a case-by-case basis understanding that the efficacy diminishes as a result of delay in initiation.
  - The absolute elapsed time after which PEP should not be given is unknown; some experts would initiate PEP up to 7 days after exposure.
  - If the victim is too distraught to engage in discussion regarding PEP then a "starter pack" should be provided with clear instructions/recommendations for follow-up within 24 hours to discuss further indication for prophylaxis.
  - If the decision to initiate therapy is made then clear instructions/recommendations for follow-up with a clinician with expertise in the management of HIV within 24-72 hours of starting PEP should be made in order to assess:
    - Tolerability
    - Adherence to the regimen
    - Appropriate follow-up care
  - PEP regimen during pregnancy is the same as listed above.
  - Important patient education aspects surrounding PEP to be discussed at the time of initiation of therapy include:
    - Potential benefit of prophylaxis vs. unproven efficacy
    - Potential toxicities of therapy
    - Appropriate duration of therapy
    - Importance of adherence to regimen in order to prevent failure or development of resistance should infection occur
    - Need to reduce risk and prevent exposure to others
    - Clinical laboratory monitoring/follow-up schedule
    - Signs and symptoms of acute HIV infection
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Reported Sexual Assault

Does patient meet any ONE of the following criteria?
- Direct contact of the vagina, penis, anus, or mouth with the semen, vaginal fluid, or blood of the alleged assailant with or without physical injury, tissue damage, or the presence of blood at the site of the assault
- Broken skin or mucous membranes of the victim have been in contact with blood, semen, or vaginal fluids of the alleged assailant
- Bites that result in visible blood

No Post-Exposure Prophylaxis Indicated

Time Between Assault and Presentation

< 72 Hours

Send Rapid HIV test

**Begin PEP:**
Truvada 300 mg/200 mg PO daily x 28 days*,**
+ Raltegravir 400 mg PO bid x 28 days*

Provide Patient with appropriate PEP patient education

72 Hours – 7 Days

Assess risk vs. benefit of PEP given prolonged time to presentation.
Does risk outweigh benefit?

Yes

Send rapid HIV test
PEP not indicated given time to presentation.α

No

Provide formal referral to clinician with expertise in management of HIV

7 Days

Repeat HIV test at 4 and 12 weeks post-exposure

* - To be provided initially as “starter pack” supplied by PAMC and then future supply to be prescribed by Infectious Diseases Physician
** - Dose adjusted to q48hrs for patients with estimated CrCl is <50 ml/min.
α - Available data suggests that the utility of PEP when initiated >72 hours after the exposure is substantially decreased.
References:


