Standard Operating Procedures

Post-Exposure Prophylaxis (PEP) Protocol for HIV, Hepatitis B, and STIs

2023

AMPATH Consortium Post-Exposure Prophylaxis (PEP) Protocol for HIV, Hepatitis B, and STIs

HIV Exposure

Infectious vs Non-Infectious Exposures

1. Blood, visually bloody body fluids, semen, vaginal secretions, cerebrospinal fluid, peritoneal fluid, pleural fluid, pericardial fluid, synovial fluid, and amniotic fluid are all potentially infectious.
2. Feces, urine, vomitus, nasal secretions, saliva, sputum, sweat, tears, are NOT considered to be infectious unless they are visibly bloody.

Needle sticks, lacerations, or exposure of non-intact skin (i.e., open wounds, abrasions, chapped skin, or areas of dermatitis)

1. Allow wound to bleed but do not squeeze enough to bruise and do not suck wound
2. Wash the affected area gently with soap and water but do not scrub strongly or use nail brush
3. Inform team leader / supervisor to be evaluated for PEP as soon as exposure occurs (see below)

Mucous Membrane Exposure

1. Irrigate the affected area (eye, mouth, etc.) with clean water
2. Inform team leader / supervisor to be evaluated for PEP as soon as exposure occurs (see below)

Sexual Exposure

1. Inform team leader / supervisor to be evaluated for PEP as soon as exposure occurs (see below)

Who to Inform

1. The exposed person should immediately contact their Team Lead and/or immediate supervisor
2. The Team Lead should immediately contact the AMPATH Ghana Executive Field Director for expert consultation
3. In their absence, use the UCSF Clinical Consultation Center for PEP
   - http://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/
   - +1 888 448 4911
4. If the exposed is a trainee from a U.S. institution, the U.S. institutional lead should be informed about the exposure in general to ensure appropriate follow-up care back in the U.S
   - The nature or details of the exposure need not be shared to ensure privacy of the exposed person
   - This does not have to be done in real-time and should not delay PEP care. This can be done later prior to the trainee's return to the U.S.
5. It is the responsibility of the Executive Field Director to facilitate the evaluation, treatment, and follow-up care for the exposed person, with expert medical consultation from an infectious disease specialist.

Initial Evaluation for HIV PEP

Exposed Person

1. Exposed individuals should undergo rapid HIV testing immediately after exposure.
    a. It is the responsibility of the Executive Field Director to ensure there is a supply of non-expired HIV testing kits available.
2. A brief medical history, medication list, and allergies should be obtained from the exposed to ensure no contraindications to ARVs and to tailor the regimen appropriately should there be any potential interactions
3. A pregnancy test should be offered to all exposed females.
4. ARVs should be started as soon as possible, ideally within 2 hours of exposure, up to 72 hours post-exposure for any of the following exposures listed above.

Source Patient

1. Rapid HIV testing should be performed on all source patients unless they are known to be HIV positive
    a. If source patient is known to be HIV positive (regardless of viral load), and the exposed person is deemed to have an exposure necessitating PEP, then a full course of PEP should be offered
    b. Initiation of PEP should not be delayed while awaiting results of HIV testing on the source patient
2. If the source patient is HIV positive, further clinical history should be obtained regarding the latest VL and any potential ARV resistance which will guide PEP treatment decisions for the exposed

Clinical Management of HIV PEP

Anti-Retroviral Regimen

1. The standard regimen is tenofovir-emtricitabine (Truvada) PLUS dolutegravir
2. The regimen should be continued for a full 28 days if the source patient is confirmed positive or status remains unknown
    a. The full 28-day regimen should be continued even if the source patient is positive but has an undetectable viral load as transmission can still occur
    b. If rapid HIV testing on the source patient is negative, and there is no evidence of acute retroviral syndrome, then PEP can be discontinued
3. Expert consultation should be sought for an exposed person who is pregnant or breastfeeding, but initiation of PEP should not be delayed.
4. Alternate regimens due to medical contraindications or drug interactions among the exposed, or known source patient resistance patterns, should be tailored on a case-by-case basis after discussion with the Executive Field Director.

Monitoring and Follow-Up

1. The exposed person should be given a month (4-week) supply of ARVs, with monitoring visits at 72 hours post-exposure, at 2 weeks, and as needed.

2. If 4th generation HIV tests are done, then HIV tests should be done at baseline, at 6 weeks, and at 4 months post-exposure. If 3rd generation HIV tests are done, then HIV tests should be done at baseline, at 6 weeks, at 12 weeks, and at 6 months. (Of note, 4th generation HIV tests are generally the standard test in the US.)
3. Blood counts, renal function and liver enzymes should be checked at baseline and 2-week follow-up
    a. The Executive Field Director should facilitate this testing and retrieval of results
        i. Reliable private labs can be used on the weekends or at the request of the exposed person and the discretion of the Executive Field Director
    b. Awaiting results of baseline laboratory testing should not delay initiation of PEP
4. If there any adverse reactions or signs of toxicity, the exposed person should see the Executive Field Director immediately who can arrange expert consultation to decide what further monitoring is needed and whether a regimen change is necessary.
5. All health information regarding exposed person is kept confidential with the Executive Field Director and only necessary information is disclosed to other personnel (ID specialists, health transport, etc.) as needed for appropriate medical care and follow-up.
6. If the exposed person completes their 4-week course of ARVs while in Ghana, they should have a follow-up examination in Ghana, with the assistance of the Executive Field Director.
    a. If the exposed person returns to the US during or after their 4-week course, they are required to get follow-up examination in the U.S. Evidence of their doctor's visit should be given to their respective clinical lead in the US.

Documentation

1. Regardless of the HIV status of the source patient, an email should be written by the Executive Field Director, with input from the expert consultants as needed, detailing the following:
    a. Demographic details of the exposed
    b. Clinical history (PMH, medications, allergies) of the exposed
    c. Clinical history of the source patient
    d. Date, time, and nature of exposure
    e. Initial HIV testing results of the exposed
    f. Pregnancy status of the exposed (if female)
    g. Baseline laboratory results
    h. ARV regimen selected, date and time of initiation
    i. When PEP was discontinued, and for what reason.
    j. Clinical status of exposed at monitoring visits, including laboratory monitoring results
    k. Recommendations for future follow-up and testing
    l. Contact information of clinician(s) managing PEP in Ghana for follow-up provider in North America.
2. The email detailing the above should be sent to Rajesh Vedanthan, MD from an NYU Langone Health email to his NYU Langone Health email. Internal NYU Langone Health emails are HIPAA-compliant. Rajesh Vedanthan, MD will file the report in a HIPAA-compliant location.
3. A copy of the email should be given to the exposed person to take back home for follow-up care.

Sexual Exposure PEP

1. Follow Evaluation, Management, Monitoring, and Documentation procedures as outlined above for HIV PEP.
2. Consider use of sexual assault resources if sexual assault took place.
3. Emergency contraceptives ("Plan B") should be made readily available by the Executive Field Director and taken within 72 hours of the sexual contact.
    a. Plan B is readily available via most pharmacies within Tamale. It is not available at TTH.
4. Pregnancy testing should be offered.
5. Provide empiric treatment for STIs
    a. Ceftriaxone 250mg IM or cefixime 400mg PO once
    b. Azithromycin 1g PO once or Doxycycline 100mg PO BID for 7 days
    c. Benzathine Penicillin 2.4mill U IM

Hepatitis B PEP

1. Follow Evaluation, Management, Monitoring and Documentation procedures as outlined above for HIV PEP
2. The assumption is that all AMPATH consortium trainees here in a clinical capacity will be immunized against Hepatitis B as that is required for all health care workers in the United States
    a. Confirm Hepatitis B immunization status of the exposed person
        i. Contact the trainee's institutional lead to confidentially request immunization records of the exposed person
    b. If the exposed person has not received the full Hepatitis B vaccine series, or their status remains unknown, then the following should be done:
        i. The source patient should be tested for Hepatitis B with the HBsAg. If the source patient is HBsAg positive, or unknown, then the exposed should:
            1. Receive 1 dose of HBIG (Hepatitis B Immune Globulin) 0.06ml/kg IM
            2. One dose of the Hepatitis B vaccine as soon as possible after exposure

Cost

1. All costs of PEP will be paid for by the exposed person.
    a. Individuals are responsible for following up with their own insurance companies for reimbursement. AMPATH consortium care providers involved in the case can provide documentation and support as needed by the individual and insurance company
    b. Initiation of PEP will not be delayed due to financial considerations