Nonoccupational Post-exposure Prophylaxis (nPEP) for HIV (sexual, injection drug use, or other substantial nonoccupational HIV exposure). For ID Physicians.

June 3, 2019

Assessment for nPEP

Assess for three key risk factors, all three must be present for an exposure to qualify as "high risk":

- 1. High-risk anatomic site of exposure
 - a. Vagina
 - b. Rectum
 - c. Eye
 - d. Mouth or other mucous membrane
 - e. Nonintact skin
 - f. Percutaneous contact
- 2. High-risk type of fluid
 - a. Blood
 - b. Semen
 - c. Vaginal secretions
 - d. Rectal secretions
 - e. Breast milk
 - f. Any body fluid visibly contaminated with blood
- 3. Known (or strongly suspected) HIV-positive source

Eligibility for nPEP requires both (i) high risk for acquisition (all three factors above) and (ii) < 72h since exposure.

 A case-by-case determination about nPEP is recommended when the HIV infection status of the source of the body fluids is unknown and the reported exposure presents a substantial risk for transmission if the source did have HIV infection

Estimated per-act risk for acquiring human immunodeficiency virus (HIV) from an infected source, by exposure act

| Exposure type | Rate for HIV acquisition per 10,000 exposures | | | | |
|--|---|--|--|--|--|
| Parenteral | | | | | |
| Blood transfusion | 9,250 | | | | |
| Needle sharing during injection drug use | 63 | | | | |
| Percutaneous (needlestick) | 23 | | | | |
| Sexual | | | | | |
| Receptive anal intercourse | 138 | | | | |
| Receptive penile-vaginal intercourse | 8 | | | | |
| Insertive anal intercourse | 11 | | | | |
| Insertive penile-vaginal intercourse | 4 | | | | |
| Receptive oral intercourse | Low | | | | |
| Insertive oral intercourse Low | | | | | |
| Other ^b | | | | | |
| Biting | Negligible | | | | |
| Spitting | Negligible | | | | |
| Throwing body fluids (including semen or saliva) | Negligible | | | | |
| Sharing sex toys | Negligible | | | | |

Tests that should be obtained on the EXPOSED patient if nPEP is indicated

- HIV with a rapid HIV test (rapid HIV test turn around is 30 minutes, and the usual HIV Ag/Ab test is up to 4 hours). Patients with baseline rapid tests indicating existing HIV infection should NOT be started on nPEP. (See below for HIV lab testing and interpretation)
- Hepatitis B and C serologies, other STIs as indicated, CBC and comprehensive metabolic profile.
- For females of child-bearing age also check a Urine Pregnancy test. See included chart below.

B) HIV Testing

Order HIV Rapid Test to assess status for all persons:

Next steps in assessment depends on if Rapid HIV test is positive or negative.

10 Labs: HIV Rapid Test (results in ~60 minutes).

NEGATIVE Rapid HIV Test:

IF Rapid HIV Test is NEGATIVE, continue with assessment for nPEP.

POSITIVE Rapid HIV Test:

IF Rapid HIV Test is POSITIVE, order a confirmatory HIV test.

Patients with baseline rapid tests indicating existing HIV infection.

should NOT be started on nPEP.

Next steps in assessment depends on if Confirmatory HIV test is positive

or negative.

12 Labs: HIV Ag/Ab confirmatory test (results ~4hours)

NEGATIVE Confirmatory HIV Test:

IF Confirmatory HIV Test is NEGATIVE, continue with assessment for nPEP.

POSITIVE Confirmatory HIV Test:

IF Confirmatory HIV Test is POSITIVE, consult ID. Do not start nPEP.

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nPEP regimens

• All persons offered nPEP should be prescribed a 28-day course of a 3-drug antiretroviral regimen

• For non-pregnant individuals with intact renal function

- Emtricitabine 200mg PO qdaily + Tenofovir 300mg PO qdaily (available as a combination pill(Truvada)), needs dose adjustment for renal function AND Dolutegravir 50mg PO qdaily
 - It is important to give the first dose as soon as possible after exposure, then once daily.
 - The medications can be taken with or without food.
 - Possible side effects are infrequent but may include: nausea, vomiting, diarrhea, rash, fever, headaches, insomnia, arthralgias, fatigue, abdominal pain/hepatitis, renal dysfunction, rare lactic acidosis.

Special Situations for nPEP regimens

- For pregnant females/females who may become pregnant while on PEP (not on effective contraception), there is a risk of neural tube defects associated with exposure to Dolutegravir at conception, so please prescribe:
 - Emtricitabine 200mg PO qdaily + Tenofovir 300mg PO qdaily (available as a combination pill Truvada), needs dose adjustment for renal function AND Raltegravir 400 mg PO BID

- For women of reproductive capacity who have had genital exposure to semen and a negative
 pregnancy test when evaluated for possible nPEP, current contraception use should be
 assessed, and if a risk for pregnancy exists, emergency contraception should be discussed with
 the patient.
- For adults with renal dysfunction (creatinine clearance<59 ml/min), prescribe:
 - 3-drug regimen Emtricitabine + Tenofovir (BOTH need dose adjustment for renal function (both need to be adjusted for renal function) AND Dolutegravir 50 mg PO Qday.

Follow-up after starting nPEP

(Tess has offered that you can flag her to your note after starting nPEP and she can help take over follow-up)

• If risk factors for HIV persist, please place a consult to MRTC clinic for consideration of PrEP prior to the 28 days of nPEP ending.

Table 2. Recommended schedule of laboratory evaluations of source and exposed persons for providing nPEP with preferred regimens

| | Source | Exposed persons | | | | |
|---|----------|---|----------------|----------------|----------------|--|
| | Jource | | 4–6 weeks | 3 months | 6 months | |
| | Baseline | Baseline | after exposure | after exposure | after exposure | |
| Test | Daseille | | | • | | |
| HIV Ag/Ab testing ^a | | For all persons considered for or prescribed nPEP for any exposure | | | | |
| (or antibody testing if Ag/Ab test | 1 | 1 | ./ | | √b | |
| unavailable) | · • | , | * | * | ¥ - | |
| | | | | | | |
| Hepatitis B serology, including: | | | | | | |
| hepatitis B surface antigen | ✓ | ✓ | _ | _ | √c | |
| hepatitis B surface antibody | | | | | | |
| hepatitis B core antibody | / | | | | √d | |
| Hepatitis C antibody test | · · | • | | | • | |
| 0 | | For all persons considered for or prescribed nPEP for sexual exposure | | | | |
| Syphilis serologye | ✓ | ✓ | ✓ | _ | ✓ | |
| Gonorrheaf | ✓ | ✓ | √9 | _ | _ | |
| Chlamydia ^f | ✓ | ✓ | √ 9 | _ | _ | |
| Pregnancy ^h | _ | ✓ | ✓ | _ | _ | |
| | | For persons prescribed | | | | |
| | | tenofovir DF+ emtricitabine + raltegravir | | | | |
| | | Or | | | | |
| | | tenofovir DF+ emtricitabine + dolutegravir | | | | |
| Serum creatinine (for calculating estimated creatinine clearance) | | ✓ | ✓ | | <u> </u> | |
| | | | | | _ | |
| Alanine transaminase, aspartate | | 1 | √ | | | |
| aminotranferase | | ¥ | • | _ | | |
| | | For all persons with HIV infection confirmed at any visit | | | | |
| HIV viral load | ✓ | √i | | | | |
| HIV genotypic resistance | ✓ | √i | | | | |
| Abbreviations: Ad/Ab antigen/antibody combination test: HIV human immunodeficiency virus: nPEP propoculational postavnosure | | | | | | |

Abbreviations: Ag/Ab, antigen/antibody combination test; HIV, human immunodeficiency virus; nPEP, nonoccupational postexposure prophylaxis; tenofovir DF, tenofovir disoproxil fumarate.

Reference: CDC guidelines 2016