All Recommendations: Post-Exposure Prophylaxis (PEP) to Prevent HIV Infection

All Recommendations

☑ ALL RECOMMENDATIONS: POST-EXPOSURE PROPHYLAXIS (PEP) TO PREVENT HIV INFECTION

FIRST DOSE OF PEP AND MANAGEMENT OF THE EXPOSED SITE

All Exposures

EXPOSURE TO HIV IS AN EMERGENCY

- When an individual reports a sexual exposure or an exposure to blood, visibly bloody fluids, or other potentially infectious material from an individual known to have HIV or whose HIV status is not known, clinicians should administer the first dose of post-exposure prophylaxis (PEP) immediately—ideally within 2 hours and no later than 72 hours post-exposure (A2). The following recommended regimens also have activity in the rare *possibility of an exposure to known HIV-2 or a source patient at risk for HIV-2 infection (see the NYSDOH AI guideline Diagnosis and Management of HIV-2 in Adults*).
  - Tenofovir disoproxil fumarate/emtricitabine plus raltegravir (TDF/FTC plus RAL; Truvada plus Isentress) or
  - TDF/FTC plus dolutegravir (TDF/FTC plus DTG; brand names Truvada plus Tivicay); see *Box 2: Use of Dolutegravir in Individuals of Childbearing Capacity*.
  - Lamivudine (3TC; Epivir) may be substituted for FTC in either regimen.
  - Raltegravir (RAL, Isentress) may be prescribed in the HD formulation, but the HD formulation should not be given to pregnant patients.
- Clinicians should advise all individuals of childbearing potential of the small risk of teratogenicity with DTG in the first trimester of pregnancy and that contraception should be used while taking DTG. (A2) See *Box 2: Use of Dolutegravir in Individuals of Childbearing Capacity*.
  - RAL, which has been used safely in pregnancy, may be used instead of DTG as the preferred integrase strand transfer inhibitor in this population; see *Table 2: Preferred Post-Exposure Prophylaxis Regimen for Patients Who Weigh ≥40 kg*.
- **First dose of PEP for an individual who weighs <40 kg (88 lb):** *See Table 4: Post-Exposure Prophylaxis Regimens for Patients 2 to 12 Years Old Who Weigh <40 kg*.
- If the initial emergency dose of PEP is declined, clinicians should inform the exposed individual of the results of the source's HIV test if and when available. (A3)
- If the exposed individual's baseline HIV test result indicates HIV infection before the reported exposure, then clinicians should recommend initiation of antiretroviral therapy (ART) and refer the patient to an experienced HIV care provider (see the NYSDOH AI guideline *Selecting an Initial ART Regimen*). (A1)
- Clinicians should not provide PEP later than 72 hours after a potential exposure to HIV. (A2)
  - If an individual presents for PEP past 72 hours post exposure, clinicians should perform baseline HIV testing and recommend serial HIV testing at 4 and 12 weeks post exposure. (A2)

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- When an individual who has been taking pre-exposure prophylaxis (PrEP) with **daily adherence** requests PEP following a sexual exposure, clinicians should advise that additional antiretroviral (ARV) medication for PEP is not warranted in most situations (see below for discussion of scenarios in which PEP may be appropriate). (B1)
- **If the source is not available:** When the source of a high-risk exposure is not available for HIV testing, clinicians should recommend that the exposed individual complete the 28-day PEP regimen. (A2)

EXPOSURE RISK EVALUATION

All Exposures

- Clinicians should complete an expeditious and comprehensive evaluation of the potential HIV exposure to determine the need for post-exposure prophylaxis (PEP). (A2)

Sexual Assault Exposure

- Clinicians should recommend PEP to individuals reporting sexual assault as follows (A2):
  - When the exposed individual has experienced direct contact of the vagina, penis, anus, or mouth with the semen, vaginal fluids, or blood of a source, with or without physical injury, tissue damage, or presence of blood.
  - When the exposed individual's broken skin or mucous membranes have been in contact with the blood, semen, or vaginal fluids of an assailant.
  - When an exposed individual has visible blood, i.e., a bite has drawn blood.
- Clinicians should administer the first dose of the human papillomavirus (HPV) vaccine for individuals aged 18 to 45 years who have not yet been vaccinated. (A3)
- Clinicians should not routinely perform baseline STI testing of individuals exposed through sexual assault; testing may be offered on a case-by-case basis. Clinicians should provide empiric treatment for gonococcal, chlamydial, and trichomonal infections. (A3)

Exposures in Children

- Clinicians should recommend PEP to children reporting sexual assault as follows: (A2)
  - When the exposed child has experienced direct contact of the vagina, penis, anus, or mouth with the semen, vaginal fluids, or blood of an assailant, with or without physical injury, tissue damage, or presence of blood at the site of the assault.
  - When the exposed child's broken skin or mucous membranes have been in contact with the blood, semen, or vaginal fluids of an assailant.
  - When the assaulted child has physical evidence of sexual abuse, even if the child is unable to report the details of the abuse.
- Clinicians should recommend PEP for children who have visible blood from trauma, i.e., a bite has drawn blood. (A2)
- Clinicians should perform baseline STI testing for children who may have been sexually assaulted because they may have experienced long-term, repetitive abuse. (A3)
- Clinicians should provide empiric treatment for gonococcal, chlamydial, and trichomoniasis infections. (A3)
- Clinicians should administer the first dose of the human papillomavirus (HPV) vaccine for children aged 9 to 17 years who have not yet been vaccinated. (A3)
- Clinicians should provide prophylaxis for hepatitis B virus (HBV) exposure in a child if indicated (see the guideline section *Management of Potential Exposure to HBV*). (A1)

SOURCE HIV STATUS AND MANAGEMENT

All Exposures

- If, after counseling, the patient indicates that the exposure was high risk for HIV transmission, clinicians should administer the first dose of post-exposure prophylaxis (PEP) if that has not already been done (A2) and recommend completion of the 28-day PEP regimen. (A2)

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Continue PEP Until Source's HIV Status Is Confirmed

- Clinicians should recommend that the exposed individual continue PEP for up to 28 days until the source's HIV serostatus is confirmed negative. (A2)
- Clinicians should perform plasma HIV RNA testing in the source if:
  - The screening test result is nonreactive, but the source reports possible exposure to HIV within the previous 4 weeks (e.g., through unprotected sex or needle sharing). (A2)
  - The screening test result is reactive and the confirmatory assay is indeterminate. (A2)
- If a source's confirmatory antibody-differentiation immunoassay is positive or plasma RNA test results are positive, then clinicians should recommend that the exposed individual complete the 28-day PEP regimen. (A2)
- Clinicians should discontinue PEP if the source of an exposure has no evidence of plasma HIV RNA (i.e., undetectable viral load, defined as <200 copies/mL) and the confirmatory antibody-differentiation immunoassay result is negative, consistent with a false-positive initial test. (A1)

If the Source Is Known to Have HIV

- If the source is known to have HIV, clinicians should recommend that the exposed individual continue PEP if the source is not taking antiretroviral therapy (ART) or if the source's viral load is not known, is detectable, or, in the case of a consensual sexual exposure, cannot be confirmed to be undetectable at the time of exposure. (A2)
- If the source is known to have HIV, and if the medical record is available, clinicians should obtain the source's viral load, ART history, and antiretroviral (ARV) drug resistance profile to inform decisions regarding formulation or completion of the 28-day PEP regimen. (A3)
  - If this information is available, the clinician should consult with an experienced HIV care provider to select a 28-day PEP regimen that will have maximal effectiveness against the source's strain of HIV. Initiation of PEP should not be delayed while acquiring this information. The regimen can be adjusted later, once the medical record is available. (A3)
  - If the medical record is not available, clinicians should query the source for this information. (B3)
- If the exposure is evaluated as high-risk and the source's viral load cannot be confirmed as undetectable at the time of a consensual exposure, clinicians should recommend completion of the PEP regimen. (A2)
- Consensual sexual exposure only: If the source is known to have HIV and an undetectable viral load (<200 copies/mL) at the time of the exposure and is taking ART, the clinician should explain that an individual with an undetectable viral load will not transmit HIV through sex. (A1)
  - See NYSDOH AI *U=U Guidance for Implementation in Clinical Settings*.

Nonreactive HIV Test Result in Source

- Clinicians should perform plasma HIV RNA testing in the source if the screening test result is negative, but the source reports possible exposure to HIV within the previous 4 weeks (e.g., through unprotected sex or needle sharing). (A2)
  - If a source's plasma RNA test result is positive, then clinicians should recommend that the exposed individual compete the 28-day PEP regimen. (A2)
  - Clinicians should discontinue PEP if the source has no evidence of plasma HIV RNA (i.e., undetectable viral load) and the confirmatory antibody-differentiation immunoassay result is negative, consistent with a false-positive initial test. (A1)

BASELINE TESTING OF AN EXPOSED INDIVIDUAL

All Exposures

- Clinicians should perform baseline HIV testing of an exposed individual using a U.S. Food and Drug Administration (FDA)-approved 4th-generation HIV antigen/antibody (Ag/Ab) combination immunoassay, preferably at the time of PEP initiation, but no later than 72 hours after exposure. (A1)
  - Rapid oral HIV tests are not recommended due to lack of sensitivity to identify recent infections and requirements regarding food, drink, and tobacco use. (A2)
- Clinicians should recommend baseline testing even if the exposed individual declines PEP. (A3)

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- If an exposed individual refuses baseline testing following any type of potential exposure to HIV, clinicians should document the refusal in the patient's medical record. (A3)
- If the result of a baseline screening 4th-generation HIV test is reactive, clinicians should recommend the continuation of PEP until the positive result is confirmed with a differentiation assay or HIV-1 RNA test. (A3)
- Clinicians should continue PEP in any individual who is suspected to be seroconverting (A1) or for whom HIV has not been ruled out at week 4 (A2) and should refer the patient to an experienced HIV care provider.
- If the exposed individual is confirmed to have HIV, clinicians should refer the individual to HIV care immediately for rapid initiation of antiretroviral therapy (ART) and continue the 3-drug PEP regimen as ART. (A1)
- Clinicians should perform additional baseline laboratory testing specified in *Table 1: Baseline Testing Based on Age of Exposed Individual and Type of Exposure.* (A2)
- If the exposed individual declines to complete the 28-day PEP regimen, the clinician should recommend HIV testing at weeks 4 and 12 post exposure. (A2)

Baseline STI Testing in Children

- Clinicians should perform baseline STI testing for children who may have been sexually assaulted because they may have experienced long-term, repetitive abuse. (A3)
- Clinicians should provide empiric treatment for gonococcal, chlamydial, and trichomoniasis infections. (A3)

SELECTING AND INITIATING A 28-DAY COURSE OF PEP: PREFERRED REGIMENS

All Exposures

Preferred Regimens

- Because of potential toxicities associated with PEP (and older ARV medications in particular), this Committee, along with the *CDC* and the *World Health Organization*, recommends inclusion of tenofovir disoproxil fumarate/emtricitabine (TDF/FTC; Truvada) or TDF/lamivudine (3TC; Epivir) as the preferred backbone of a PEP regimen, combined with a third agent, usually an integrase strand transfer inhibitor (INSTI) or a protease inhibitor (PI) [Kuhar, et al. 2013; Ford and Mayer 2015; CDC 2016; Günthard, et al. 2016]. See the following tables:
  - *Table 2: Preferred Post-Exposure Prophylaxis Regimen for Patients Who Weigh ≥40 kg*
  - *Table 3: Alternative Post-Exposure Prophylaxis Regimens for Patients Who Weigh ≥40 kg*
  - *Table 4: Post-Exposure Prophylaxis Regimens for Patients 2 to 12 Years Old Who Weigh <40 kg*

Cautions

- Clinicians should advise all individuals of childbearing potential of the risk of teratogenicity with dolutegravir (DTG) in the first trimester of pregnancy and recommend the use of contraception while taking this medication. (A2)
  - Raltegravir (RAL) 400 mg twice per day, which has been used safely in pregnancy, may be used instead of DTG as the preferred INSTI.
- For an exposed individual whose baseline laboratory testing indicates a creatinine clearance (CrCl) <50 mL/min, clinicians should not prescribe fixed-dose combination tenofovir disoproxil fumarate/emtricitabine (TDF/FTC; brand name Truvada) or tenofovir disoproxil fumarate/lamivudine (TDF/3TC; brand name Cimduo). (A1)

Antiretroviral (ARV) Medications to Avoid for PEP

- Clinicians should not prescribe the following for PEP: Abacavir (ABC; brand name Ziagen), efavirenz (EFV; brand name Sustiva), indinavir (IDV; brand name Crixivan), maraviroc (MVC; brand name Selzentry), nelfinavir (NFV; brand name Viracept), nevirapine (NVP; brand name Viramune), and zidovudine (ZDV; brand name Retrovir). (A2)
  - ZDV remains a recommended medication for the prevention of perinatal transmission of HIV and for pediatric PEP (see NYSDOH AI guideline *Prevention of Mother-to-Child HIV Transmission*).

PEP During Pregnancy or Breastfeeding

- When a significant exposure to HIV has occurred at any time during an exposed individual's pregnancy or while that individual is breastfeeding a baby, clinicians should initiate PEP with a preferred or alternative regimen (see *Table 2: Preferred Post-Exposure Prophylaxis Regimen for Patients Who Weigh ≥40 kg* and *Table 3: Alternative Post-Exposure Prophylaxis Regimens for Patients Who Weigh ≥40 kg*). (A2)

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- Clinicians should advise individuals who may have been exposed to HIV to avoid breastfeeding for 3 months after the exposure. (A2)
  - Individuals confirmed to be HIV negative may breastfeed. (A1)

PROVIDING PEP MEDICATIONS AND OTHER SERVICES

All Exposures: If possible, clinicians should provide patients with a 28-day supply of post-exposure prophylaxis (PEP) medications. (A3) If a 28-day supply cannot be provided and if the patient does not have immediate access to a 28-day supply, then clinicians should provide a starter pack as indicated below.

Occupational Exposure: Clinicians should provide at least a 7-day starter pack of PEP medications to a worker assessed as having a high-risk exposure to HIV. (A3)

Non-occupational exposure: Clinicians should provide a 7-day starter pack of PEP medications to an individual assessed as having a high-risk exposure to HIV. (A3)

Sexual assault exposure: Clinicians are required by New York State law to provide a 7-day starter pack of PEP medications to sexual assault patients who are ≥18 years old and the full, 28-day course of PEP medications to those who are <18 years old.

Sexual assault exposure in a child: Clinicians should provide 28 days of PEP medications to children (any individual <18 years old) who have been sexually assaulted and are assessed as having a high-risk exposure to HIV. (A3)

Other types of high-risk exposures in children: Clinicians should provide a 7-day starter pack of PEP medications to a child assessed as having a high-risk exposure to HIV. If a child can take only liquid medications, then a 28-day supply should be provided. (A3)

- Clinicians should include antiemetics in the starter packs for children. (Good Practice)

FOLLOW-UP OF THE EXPOSED INDIVIDUAL

All Exposures

- **Acute HIV:** Clinicians should assess patients for signs or symptoms of acute HIV during all follow-up encounters. (A2)
- **Candidates for pre-exposure prophylaxis (PrEP):** Clinicians should recommend or refer for PrEP any individual reporting a non-occupational exposure who: (A1)
  - Reported an exposure for which post-exposure prophylaxis (PEP) was not indicated following assessment of risk.
  - Engages in risk-taking behaviors, such as unprotected sexual intercourse or intravenous drug use.
  - Will continue to engage in risk-taking behaviors after completing the 28-day PEP regimen.
    - See the NYSDOH AI guideline *PrEP to Prevent HIV and Promote Sexual Health.*

SEQUENTIAL HIV TESTING AND LABORATORY MONITORING

All Exposures

HIV Testing at 4 and 12 Weeks Post Exposure

- Clinicians should follow up with an in-person visit (preferred) at 4 weeks post exposure to perform HIV testing and other laboratory testing specified in *Table 6: Recommended Monitoring After Post-Exposure Prophylaxis Initiation*. (A3)
- After obtaining a baseline HIV test within 72 hours of exposure, clinicians should obtain sequential confidential HIV testing of the exposed individual at 4 and 12 weeks post exposure, using a U.S. Food and Drug Administration (FDA)-approved 4th-generation laboratory-based antigen/antibody (Ag/Ab) HIV screening test (A2).
  - Point-of-care (POC) HIV tests can be used at 4 and 12 weeks only if they are antigen/antibody tests; any other type of POC test is not recommended.
  - Sequential testing at 4 and 12 weeks is recommended even if an exposed individual refuses PEP.
  - Sequential HIV testing beyond 12 weeks post exposure is not recommended.

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- If an exposed individual's HIV screening test result is reactive at any time, clinicians should perform an FDA-approved confirmatory HIV differentiation immunoassay. (A1)

If Acute HIV Is Suspected

- If the exposed individual presents with signs or symptoms of acute HIV seroconversion, clinicians should perform an HIV serologic screening test in conjunction with a plasma HIV RNA assay to diagnose acute HIV infection. (A1)

Routine Laboratory Testing

- Clinicians should perform routine laboratory monitoring as detailed in *Table 6: Recommended Monitoring After Post-Exposure Prophylaxis Initiation*. (A2)

Serial HIV Testing in Children

- If an exposed child >2 years old has a reactive HIV screening test result at any time, clinicians should perform an FDA-approved confirmatory assay; a 4th-generation HIV antigen/antibody combination test is the recommended serologic screening test.

MANAGEMENT OF POTENTIAL EXPOSURE TO HEPATITIS B VIRUS

- Clinicians should evaluate the source for hepatitis B virus (HBV) by testing for hepatitis B surface antigen (HBsAg). (A2)
- Clinicians should initiate the HBV vaccine series in non–HBV-immune individuals who are exposed to HBV in blood or bodily fluid, with the first dose administered during the initial evaluation. Clinicians should not delay the decision to vaccinate while testing for hepatitis B surface antibody (anti-HBs) for patients who are known to be non-immune or whose serostatus is unknown. (A1)
- Clinicians should administer prophylactic hepatitis B immune globulin (HBIG) and initiate the HBV vaccine series in an individual exposed to blood or bodily fluid from a source with known acute or chronic HBV infection if the immune status of the exposed individual is unknown or non-immune. (A1)
- Ideally, clinicians should administer the first dose of the HBV vaccine [a, b] within 24 hours of exposure, and HBIG should be administered [b] as soon as possible, ideally within 7 days. (A2)
- Clinicians should initiate the HBV vaccine series if the source is not available for testing and the exposed individual's status is unknown or not immune. (A3)
- If the source is at high risk of HBV infection [c], then clinicians should proceed as if the source is HBsAg-positive (A3); if the source is negative, then no further action is necessary. (A2)
  - **Notes (HBV Exposure Management):**
    a. If the HBV vaccine series has been initiated in an exposed individual, the clinician should administer the second and third doses 1 to 2 months and 6 months, respectively, after the first dose for the standard vaccine or 1 month later for the recombinant vaccine (see guideline text for more information).
    b. HBIG should be administered as soon as possible post exposure, ideally within 7 days and not later than 14 days, and the HBIG and HBV vaccines should be administered at different sites in the exposed individual.
- Individuals at high risk are those who engage in needle sharing or high-risk sexual behaviors or were born in geographic areas with HBsAg prevalence of >2% [Weinbaum, et al. 2008].

MANAGEMENT OF POTENTIAL EXPOSURE TO HEPATITIS C VIRUS

- When an individual reports an exposure to HIV, clinicians should assess for concurrent exposure to hepatitis C virus (HCV). (A2)
- Once the clinician has determined that exposure to blood or bodily fluid has occurred, the following baseline tests should be obtained, preferably within 48 hours (see *Figure 5: Evaluation of Hepatitis C Virus (HCV) Exposure Risk and Recommended Follow-Up*): (A2)
  - **Exposed individual:** HCV antibody, and if positive, HCV RNA; liver function tests, including liver enzyme test.
  - **Source:** HCV antibody; if positive or the source has had recent HCV exposure, perform HCV RNA test.
- If the source is unavailable for testing or is known to be positive for HCV antibody or HCV RNA, clinicians should follow up with the exposed individual as follows: (A2)

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- **Week 4:** HCV RNA and alanine aminotransferase (ALT).
- **Week 12:** HCV RNA and ALT.
- **Week 24:** HCV antibody and ALT with reflex to HCV RNA if either is abnormal.
  - See NYSDOH AI guideline *Treatment of Chronic HCV with Direct-Acting Antivirals*.

- If HCV infection is identified, the clinician should refer the exposed individual for medical management by a clinician with experience in treating HCV. (A2)
- Clinicians should not administer immunoglobulin or antiviral agents for HCV post-exposure prophylaxis (PEP). (A2)
- If at any time the serum ALT level is elevated, clinicians should repeat HCV RNA testing to evaluate for acute HCV infection. (A3)