



# CLINICAL GUIDELINES PROGRAM

NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE | HIV · HCV · SUBSTANCE USE · LGBT HEALTH

## PEP to Prevent HIV Infection

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## Guideline Information

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## Updates

- August 11, 2022:** The recommendation regarding discussion of the small risk of teratogenicity with DTG in the first trimester and the need for birth control while completing the 28-day PEP regimen *has been removed*. DTG has been shown to be safe throughout pregnancy. See the MCCC’s statement *Use of Dolutegravir in Individuals of Childbearing Capacity* for further discussion.
- November 4, 2021:**
  - 1. Cautions regarding prescription of dolutegravir for individuals of childbearing capacity were revised throughout the guideline: “For individuals of childbearing potential, discuss the small risk of teratogenicity in the first trimester and counsel about the need for birth control while completing the 28-day PEP regimen; there is no elevated risk for initiation beyond the first trimester during pregnancy.”
  - 2. Two new footnotes have been added to Table 3: Alternative Post-Exposure Prophylaxis Regimens for Patients Who Weigh ≥40 kg:
    - c. Cobicistat-containing regimens should not be used during pregnancy.
    - d. If DRV or ATV are prescribed during pregnancy, dose adjustments are required. See the guideline section *PEP During Pregnancy or Breastfeeding* or [Clinicalinfo.HIV.gov](http://Clinicalinfo.HIV.gov) > *Table 10. Antiretroviral Drug Use in Pregnant Women with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy*.
- June 2020:** This edition is a reorganization of the previous 4 PEP guidelines into 1 document that addresses management of occupational, non-occupational (e.g., consensual sexual exposure, exposure through needle sharing), sexual assault, and pediatric exposures to HIV and potential concomitant exposures to hepatitis B virus and hepatitis C virus. This edition reflects a unified approach to the recommendations for all exposure types, with differences between exposure scenarios highlighted throughout.



# PEP to Prevent HIV Infection

## Purpose and Use of This Guideline

This guideline was developed by the New York State Department of Health (NYSDOH) AIDS Institute (AI) for healthcare practitioners in any medical setting (e.g., emergency department, sexual health clinic, urgent care clinic, inpatient unit primary care practice) who manage the care of individuals who request post-exposure prophylaxis (PEP) after a possible exposure to HIV. Despite the availability of prevention measures, exposures occur that pose the risk of transmission. Fortunately, with rapid initiation of PEP, infection can be blocked. Preventing new HIV infections is crucial to the success of *New York State’s Ending the Epidemic Initiative*.

HIV transmission can be prevented through use of barrier protection during sex (e.g., latex condoms), safer drug injection techniques, and adherence to universal precautions in the healthcare setting. HIV infection can also be prevented with use of antiretroviral (ARV) medications taken as pre-exposure prophylaxis (PrEP). After an exposure has occurred, HIV infection can be prevented with rapid administration of ARV medications as PEP. The first dose of PEP should be administered within 2 hours of an exposure (ideal) and no later than 72 hours after an exposure.

### → KEY POINTS

- **EXPOSURE TO HIV IS A MEDICAL EMERGENCY:** PEP should be initiated immediately—ideally within 2 hours of an exposure but no later than 72 hours after an exposure—because the effectiveness of PEP decreases over time after 2 hours.
- Assessment of exposure, HIV and other baseline testing, and other related activities can proceed after the first dose of PEP is administered.

In addition to clinical recommendations, this guideline details selected good practices and highlights laws and legal considerations that are pertinent in delivering PEP care.

**Goals:** This guideline aims to achieve the following goals:

- Prevent HIV infection in individuals who experience a high-risk exposure.
- Reinforce that HIV exposure is an emergency that requires rapid response, with immediate administration of the first dose of PEP medications.
- Reduce under- and over-prescribing of PEP by describing the benefits of PEP and providing guidance for identifying high-risk HIV exposures for which PEP is indicated.
- Ensure prescription of PEP regimens that are effective and well tolerated.
- Assist clinicians in recognizing and addressing challenges to successful completion of a PEP regimen.
- Detail the baseline testing, monitoring, and follow-up that should accompany prescription of a 28-day course of PEP.
- Assist clinicians in managing potential concurrent exposures to hepatitis B virus (HBV) and hepatitis C virus (HCV).

**How to use this guideline:** This guideline is organized to support rapid location of key topics, such as when to initiate PEP, how to evaluate whether continuation of PEP is necessary based on specific risk factors, source testing, how to choose and prescribe a PEP regimen, and recommendations for follow-up care for exposed individuals.

The NYSDOH AI Medical Care Criteria Committee recommendations for prescribing PEP are based on a comprehensive review of available published evidence. In formulating recommendations for NYS, [this Committee](#) balanced the strength of published evidence regarding efficacy and timing of initiation of the PEP regimen. See the [Guideline Development and Recommendation Ratings](#) for a description of the development and ratings processes.

**Icon Key:** The following icons have been used throughout this document to highlight key information specific to one of the 4 types of exposure to HIV addressed in this guideline.

- |                                   |  |                                     |
|-----------------------------------|--|-------------------------------------|
| <b>A</b> All exposures            | <b>O</b> Occupational exposures                  | <b>N</b> Non-occupational exposures |
| <b>S</b> Sexual assault exposures | <b>C</b> Exposures in children 2 to 12 years old |                                     |

# Risk of Infection Following an Exposure to HIV

**Factors that increase the risk of transmission:** Many factors that contribute to HIV infection are shared by the 4 PEP scenarios outlined below. HIV transmission risk depends on the viral load of the source with HIV and the type of exposure [Sultan, et al. 2014]. Factors that increase the risk of HIV transmission include early- and late-stage untreated HIV infection and a high level of HIV RNA in the blood [Cardo, et al. 1997], the presence of genital or anorectal ulcers from sexually transmitted infections (STIs), and direct blood-to-blood exchange, such as syringe sharing during injection drug use [Wall, et al. 2017; Mayer and Venkatesh 2011; Johnson and Lewis 2008; Blank 2005; Kaplan and Heimer 1992].

**Factors that decrease the risk of HIV transmission:** Similarly, across the 4 PEP scenarios, there are shared factors that decrease the risk of HIV infection. HIV transmission risk is low and often negligible when the source of the exposure has a low or undetectable viral load [Rodger, et al. 2019; Rodger, et al. 2016] and is lower if the source is circumcised (if a cis-gender male and the circumcision is healed) [Bailey, et al. 2007; Gray, et al. 2007; Auvert, et al. 2005] or is taking antiretroviral medications as pre-exposure prophylaxis (PrEP) [Baeten, et al. 2012; Grant, et al. 2010]. In the context of sexual exposure, there is a robust body of evidence that individuals do not sexually transmit HIV if they are taking antiretroviral therapy (ART) and have an undetectable viral load (HIV RNA <200 copies/mL); see NYSDOH AI *U=U Guidance for Implementation in Clinical Settings*. Data are insufficient to make recommendations regarding HIV transmission via breastfeeding.

## Occupational Exposure Risk

The risk of HIV transmission in a healthcare setting has been reported as 0.3% through percutaneous exposure to the blood of a source with HIV [Cardo, et al. 1997] and 0.09% after a mucous membrane exposure [Kuhar, et al. 2013]. In the Centers for Disease Control and Prevention (CDC) Needlestick Surveillance Group study, use of zidovudine (as post-exposure prophylaxis [PEP]) by healthcare workers reduced the risk of HIV acquisition by 81% overall for percutaneous exposures [Cardo, et al. 1997]. With the use of potent antiretroviral (ARV) medications that have increased bioavailability, it is presumed the use of a 3-drug PEP regimen would significantly reduce this risk further.

In the current era of increasing viral suppression in patients with HIV, early and appropriate PEP initiation, and improved infection control protocols, these rates may be lower. In one cohort of 266 healthcare workers who had percutaneous or mucocutaneous injuries and exposure to HIV-contaminated body fluids, there were zero seroconversions over a 13-year period (seroconversion rate 0%). In addition to their internal findings, the authors compared their results to a calculated overall HIV seroconversion rate of 0.13% after a literature review conducted in October 2016 yielded 17 articles that documented 10 seroconversions among 7,652 healthcare-related exposures [Nwaiwu, et al. 2017].

The mean risk may be significantly higher in cases of percutaneous exposure in which more than 1 risk factor is present (e.g., in individuals who incur a deep injury with a hollow-bore needle from a source with HIV and a high viral load). Although the effect of viral load level has not been studied in the patients with occupational exposures, there is evidence that the probability of sexually transmitting HIV is correlated with the source’s HIV viral load [Attia, et al. 2009; Modjarrad, et al. 2008; Quinn, et al. 2000].

**Prevention of occupational exposure:** As part of the employer’s plan to prevent transmission of bloodborne pathogens, the following measures can be taken to avoid injuries:

- Eliminate unnecessary use of needles and other sharps.
- Ensure use of and compliance with devices with safety features.
- Eliminate needle recapping.
- Ensure safe handling and prompt disposal of needles in containers for sharps disposal.
- Provide ongoing education about and promote safe work practices for handling needles and other sharps.

For more information about prevention of needlestick injuries, refer to the NIOSH Alert: [Preventing Needlestick Injuries in Health Care Settings](#) [National Institute for Occupational Safety and Health 1999].

**RESOURCES**

- Occupational Safety and Health Administration (OSHA): [Needlestick Safety and Prevention Act FAQs](#).
- Legal basis and guidance regarding exposure: [Public Law 106-430 \(federal law\)](#).
- Centers for Disease Control and Prevention (CDC): [Preventing Needlestick Injuries in Health Care Settings](#).

Even when effective prevention measures are implemented, exposures to blood and bodily fluid still occur. Employers of personnel covered by the *OSHA Bloodborne Pathogen Standard* are obligated to provide post-exposure care, including prophylaxis, at no cost to the employee. The employer may subsequently attempt to obtain reimbursement from Workers' Compensation. See *Employer Responsibilities in Management of Post-Exposure Prophylaxis (PEP) to Prevent HIV Infection Following an Occupational Exposure* for more information.

## N Non-Occupational Exposure Risk

**Box 1: Risk per 10,000 Exposures of Acquiring HIV From an Infected Source and Factors That Increase Risk**  
 Modified from the Centers for Disease Control and Prevention [CDC 2015].

**Parenteral Exposure Risk:**

- Needle sharing during injection drug use: **63**
- Percutaneous (needlestick): **23**

**Factors that increase risk of transmission through parenteral exposure:**

- Hollow-bore needle
- Deep injury (penetration)
- Needle placed in an artery or vein [Cardo, et al. 1997]
- Presence of blood on needle; however, risk through exposure to dried blood on discarded needles is extremely low [Zamora, et al. 1998].

**Sexual Exposure Risk:**

- Receptive anal intercourse: **138**  
 [Patel, et al. 2014; Varghese, et al. 2002; European Study Group on Heterosexual Transmission of HIV 1992]
- Receptive penile-vaginal intercourse: **8**  
 [Varghese, et al. 2002; Leynaert, et al. 1998; European Study Group on Heterosexual Transmission of HIV 1992]
- Insertive anal intercourse: **11**  
 [Varghese, et al. 2002; European Study Group on Heterosexual Transmission of HIV 1992]
- Insertive penile-vaginal intercourse: **4**  
 [Varghese, et al. 2002; European Study Group on Heterosexual Transmission of HIV 1992]
- Oral sex: **Low.** HIV transmission has been documented, but rarely. Accurate estimates of risk are not available. It is prudent to consider non-occupational PEP for receptive oral sex with ejaculation, although discussion about the low risk should occur [Page-Shafer, et al. 2002; Varghese, et al. 2002].

**Factors that increase risk of transmission through sexual exposure:**

- Source with known HIV who is not taking ART or has incomplete viral suppression; risk of transmission increases with higher source HIV viral load levels [Tovanabutra, et al. 2002; Quinn, et al. 2000], most notably during acute HIV infection, when the probability of transmission is 8- to almost 12-fold higher than exposures that take place after the viral set point is established [Wawer, et al. 2005; Pilcher, et al. 2004].
- Absence of barrier protection, such as male/insertive or female/receptive condoms.
- Presence of genital ulcer disease or other STIs [CDC 2017; LeGoff, et al. 2007].
- Trauma at the site of exposure.
- Blood exposure, which can be minimal and therefore not recognized by the exposed individual; if the exposed individual reports frank blood exposure, PEP is indicated.
- Lack of male circumcision [Bailey, et al. 2007; Gray, et al. 2007].
- Non-intact oral mucosa (e.g., oral lesions, gingivitis, wounds) in oral sexual exposure.

**Other Exposure Types:**

- Biting: **Negligible**  
 [Cresswell, et al. 2018; Bartholomew and Jones 2006; Pretty, et al. 1999; Richman and Rickman 1993]
- Spitting: **Negligible**  
 [Cresswell, et al. 2018]
- Throwing bodily fluids, including semen or saliva: **Negligible**
- Sharing sex toys: **Negligible**

**Factors that increase risk of transmission through other exposures:**

- Source with high HIV viral load [Tovanabutra, et al. 2002; Quinn, et al. 2000].
- Activity involving exposure to blood.

**Sexual exposures (consensual):** Exposures that may prompt a request for non-occupational PEP include condom slippage or breakage; lapse in condom use by serodiscordant or unknown status partners; or other episodic exposure to blood or other potentially infectious body fluids, including semen, vaginal secretions, or body fluids with visible blood contamination. In addition to the viral load of a source with HIV, other factors that influence transmission and acquisition risk include [Sultan, et al. 2014]:

- Genitorectal trauma.
- Type of sexual exposure, i.e., receptive anal, receptive vaginal, insertive anal, insertive vaginal, receptive oral.
- Presence of STIs and genital/anal ulcers.
- Circumcision status.

Condomless receptive anal sex with and without ejaculation carries a risk of 1.43% and 0.65%, respectively. Condomless insertive anal intercourse carries a risk of 0.62% in uncircumcised men and 0.11% in circumcised men [Jin, et al. 2010]. In one European study, the risk associated with condomless receptive and insertive vaginal intercourse was 0.08% and 0.04%, respectively [Mastro and de Vincenzi 1996]. Information for patients is available about correct [male](#) (insertive) and [female](#) (receptive) condom use.

- The CDC's [HIV Risk Reduction Tool](#) can help identify an individual's risk of acquiring HIV.

**Needle sharing and needlestick injuries:** Needle sharing among injection drug users is a common reason to request PEP, as the associated risk has been estimated to be as high as 63 per 10,000 exposures based on a study among injection drug users in Thailand [Hudgens, et al. 2002; Hudgens, et al. 2001]. For this reason, PEP should always be considered in this scenario provided the potential exposure was within 72 hours.

Another route of exposure that prompts requests for PEP is needlestick injury in the community. Factors associated with risk from needlestick injuries include the potential source of the needle, type of needle, presence of blood, and skin penetration.

Individuals who incur needlestick injuries from discarded needles are often concerned about potential HIV exposure. Consideration of potential risk from discarded needles should include the prevalence of HIV in the community or facility where the exposure occurred and the prevalence of injection drug use in the surrounding area. However, the risk of HIV transmission through exposure to dried blood found on syringes is extremely low [Zamora, et al. 1998]. Discarded needles should not be tested for HIV because of low yield and the risk of injury to personnel involved in the testing.

Vaccination to prevent tetanus and administration of hepatitis B vaccine are indicated for needlestick injuries resulting in puncture wounds, based on immunization history and hepatitis B virus status of the source [Stobart-Gallagher 2017; Bader and McKinsey 2013]. Hepatitis B immunoglobulin may also be necessary (see the guideline sections [Management of Potential Exposure to Hepatitis B Virus](#) and [Management of Potential Exposure to Hepatitis C Virus](#)).

**Bite wounds:** An estimated 250,000 human bites occur annually in the United States in a variety of settings [American Academy of Pediatrics 1997]. Although possible, HIV transmission through bites is thought to be extremely rare. Though many reported instances of bites have occurred, few cases of associated HIV infection have been established. Cases of possible HIV transmission have been documented following bites in adults exposed to blood-tinged saliva [Pretty, et al. 1999; Vidmar, et al. 1996]. A systematic review found no cases of HIV transmission through spitting and 9 possible cases of HIV transmission through a bite (6 occurred between family members, and 2 involved untrained first responders who placed their fingers in the mouth of an individual who is experiencing a seizure). Only 4 of the 9 cases were confirmed or classified as highly plausible [Cresswell, et al. 2018].

A bite wound that results in blood exposure should prompt consideration of PEP. When a human bite occurs, it is possible for both the individual who was bitten and the biter to incur blood exposure (see scenarios listed below). Use of PEP in such a case may be indicated if there is significant exposure to deep, bloody wounds. A bite is not considered a risk exposure to either party when the integrity of the skin is not disrupted.

Scenarios in which bites may result in blood exposure:

- Blood exposure to the biter: When the biter inflicts a wound that breaks the skin and blood from the bitten individual enters the biter's mouth.
- Blood exposure to the bitten individual: When the biter has blood in his or her mouth (e.g., from bleeding gums or lesions) and inflicts a wound that breaks the skin of the individual bitten.
- Blood exposure to both parties: A break in the skin of the individual who was bitten and the biter has blood in his/her mouth (e.g., from bleeding gums or lesions).

**Prevention of non-occupational exposure:** Transmission of HIV can be prevented through use of condoms and safer drug injection techniques. HIV infection can be prevented with use of antiretroviral medications as PrEP to protect an individual who engages in behaviors that may result in exposure to HIV. See the NYSDOH AI guideline *PrEP to Prevent HIV and Promote Sexual Health > Candidates for PrEP*. “Treatment as prevention (TasP)” and “undetectable equals untransmittable (U=U)” are evidence-based strategies for greatly reducing the risk of HIV transmission through sexual exposure; see in NYSDOH AI *U=U Guidance for Implementation in Clinical Settings*.

## S Sexual Assault Exposure Risk

Statistics on sexual assault in the United States show high rates of attempted or completed rape among several populations, including cisgender women, men, children, and transgender individuals:

- 21.3% of women reported attempted or completed rape\* in their lifetime, with the first assault occurring [Smith SG, et al. 2018]:
  - Before age 18 years in 43.2% (~11 million)
  - Between the ages of 11 and 17 years in 30.5% (~7.8 million)
  - At age 10 or younger in 12.7% (~3.2 million)
- 1.4% of men reported attempted or completed rape in their lifetime, with their first experience<sup>1</sup> occurring [Smith SG, et al. 2018]:
  - Before age 18 years in 26% (~2 million)
  - Between the ages of 11 and 17 years in 19.2% (~1.5 million)
- 26% of women and 15% of men who were victims of sexual violence, physical violence, or stalking by an intimate partner in their lifetime first experienced these or other forms of violence by that partner before age 18 years [CDC 2019b].
- 10% of 27,715 respondents to the 2015 U.S. Transgender Survey reported that they had been sexually assaulted in the 12 months prior to survey completion; 47% reported that they had experienced sexual assault during the course of their lives [James, et al. 2016].

\*See *How NISVS Measured Sexual Violence* for definitions. Smith SG, Zhang X, Basile KC, et al. National Intimate Partner and Sexual Violence Survey: 2015 Data Brief – Updated Release. 2018 Nov. <https://www.cdc.gov/violenceprevention/pdf/2015data-brief508.pdf> [accessed 2019 Mar 11].

**Risk of HIV infection:** Increased risk of infection in cases of sexual assault has been associated with trauma at the site of exposure and absence of barrier protection:

- Genitorectal trauma has been documented in 50% to 85% of sexual assault patients [Sommers, et al. 2012; Jones, et al. 2009; Sachs and Chu 2002], and anogenital trauma has been observed in 20% to 85% [Larsen, et al. 2015; Laitinen, et al. 2013; Sugar, et al. 2004; Grossin, et al. 2003; Jones, et al. 2003; Riggs, et al. 2000].
- High rates of unprotected receptive anal intercourse (88%) and vaginal penetration (>60%) have been reported [Draughon Moret, et al. 2016]. Perpetrators of intimate partner violence are not likely to use condoms (or use condoms inconsistently), are likely to force sexual intercourse without a condom and to have sexual intercourse with other partners [Stephenson and Finneran 2017; Casey, et al. 2016; Raj, et al. 2006].

PEP is the only proven method of reducing HIV acquisition after exposure, and it should be offered in cases of sexual assault. There are published reports of HIV seroconversion following sexual assault [Myles, et al. 2000; Albert, et al. 1994; Claydon, et al. 1991; Murphy, et al. 1989].

## C Exposure Risk in Children

**Lead authors:** Aracelis Fernandez, MD, with Lisa-Gaye Robinson, MD, and Ruby Fayorsey, MD, with the *Medical Care Criteria Committee*; June 2020

Although there is evidence to support HIV prophylaxis for perinatal exposure, there are no randomized clinical trials of PEP in children beyond the perinatal period. Types of exposures that may be reported in children include sexual assault, needlesticks, or bite from a child who has HIV, but as noted below, this last type of exposure is no longer likely to occur.

**Biting:** Biting is a common occurrence among young children and in daycare settings. The levels of HIV detected in saliva alone are very low. The few documented cases of possible HIV transmission following bites occurred in adults exposed to blood-tinged saliva [Andreo, et al. 2004; Pretty, et al. 1999; Vidmar, et al. 1996]. As mentioned previously, a recent systematic review found no cases of HIV transmission through spitting and 9 possible cases of transmission through biting [Cresswell, et al. 2018]. A bite is not considered a risk exposure to either party when the integrity of the skin is not disrupted. Because there are so few children with HIV now, it is unlikely that a child would be the *source* of an HIV exposure.

**Sexual abuse:** HIV transmission has been described in children who have been sexually abused, and this abuse was identified as the only risk factor for infection [Lindgren, et al. 1998; Gellert, et al. 1993]. Children might be at increased risk of becoming infected with HIV due to the cervical ectopy in adolescent girls and to the thinness of the vaginal epithelium in prepubertal girls [Kleppa, et al. 2015]. In addition, children who experience abuse multiple times over an extended period by the same perpetrator are at increased risk due to mucosal trauma with bleeding [CDC 2016; Smith DK, et al. 2005; Dominguez 2000].

**Discarded needles:** Risk of transmission from discarded needles is thought to be low. In 2 cohorts of children (1 with 59 children and the other with 249) exposed to needlesticks from discarded needles, there was no HIV transmission [American Academy of Pediatrics 1999]. HIV could not be isolated from the washings of 28 discarded needles from public places and 10 needles collected from a needle exchange program [American Academy of Pediatrics 1999]. In a Canadian study evaluating 274 pediatric community-acquired needlestick injuries, only 30% of those exposed received PEP, but there were no seroconversions in 189 children tested for HIV after 6 months [Papenburg, et al. 2008]. These studies, as well as the intolerance of HIV to environmental conditions through exposure to air over time, provide reassuring data regarding the low risk of transmission from this type of exposure. (See [Table 1: Baseline Testing Based on Age of Exposed Individual and Type of Exposure](#) and [Table 6: Recommended Monitoring after Post-Exposure Prophylaxis Initiation](#) for recommendations regarding laboratory testing, including for hepatitis C virus, based on type of exposure.)

→ KEY POINTS

- **Exposures that DO NOT warrant PEP:** Kissing, spitting, oral-to-oral contact in the absence of mucosal damage (e.g., mouth-to-mouth resuscitation); human bites not involving blood; exposure to needles or sharps that have not been in contact with an individual with or at risk of HIV.
- **Exposures for which PEP should be considered (promptly):** Condomless vaginal or anal intercourse during sexual abuse; oral sex with ejaculation or blood exposure during sexual abuse; injuries with exposure to blood from a source known to have HIV; injuries with exposure to blood from a source of unknown HIV status (including needlesticks and human bites). See [Box 1: Risk per 10,000 Exposures of Acquiring HIV from an Infected Source and Factors That Increase Risk](#) for risk calculations for specific exposures.

## Rationale for PEP and Evidence of PEP Effectiveness

**Lead author:** Elliot DeHaan, MD, with the [Medical Care Criteria Committee](#); November 2021

**PEP in children material:** Aracelis Fernandez, MD, with Lisa-Gaye Robinson, MD, and Ruby Fayorsey, MD

Post-exposure prophylaxis (PEP) has been established to effectively prevent HIV infection in an exposed individual when initiated within 2 hours (ideal) and no later than 72 hours after an exposure. Rapid and effective response to a reported HIV exposure are key to the successful prevention of HIV infection.

**PEP blocks viral replication:** After percutaneous or mucosal exposure to HIV, local replication of virus occurs in tissue macrophages or dendritic cells (see [Figure 1](#), below). However, if infection cannot be contained at this stage, it is followed within 48 to 72 hours by replication of HIV in regional lymph nodes. Viremia then follows within 72 to 120 hours (3 to 5 days) of virus inoculation.

This sequence of events carries significant implications. Given the rapid appearance of productively-infected cells following the introduction of virus, PEP regimens with the most rapid onset of activity, multiple sites of antiviral action, and greatest potency are likely most effective.



→ KEY POINTS

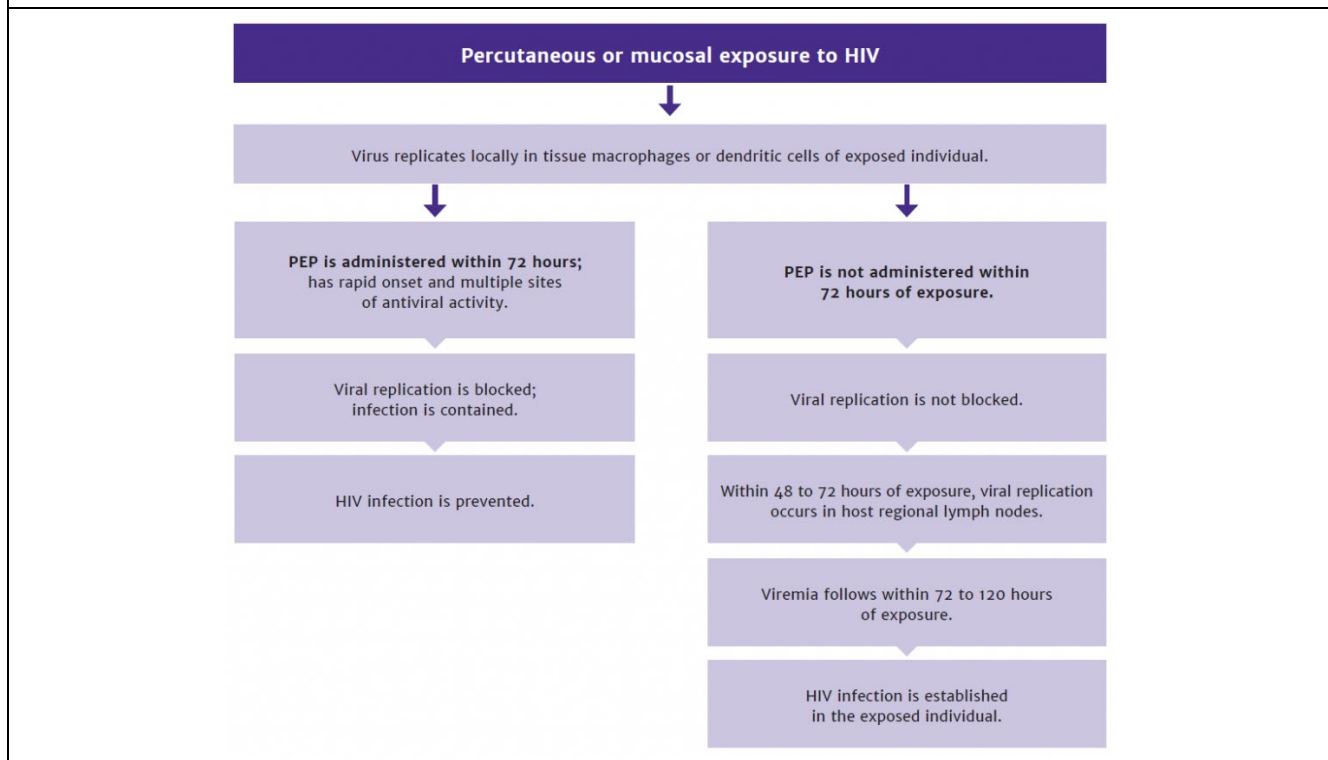
- PEP is effective in preventing HIV infection when it is administered rapidly—ideally within 2 hours and not later than 72 hours—after a high-risk exposure.
- ARV regimens currently recommended for PEP are safe in individuals who do not have HIV, as documented in published studies of observational cohorts [McAllister, et al. 2017; Mulka, et al. 2016; Ford, et al. 2015; McAllister, et al. 2014; Mayer, et al. 2012].
- ARV medications recommended for PEP have minimal adverse effects [McAllister, et al. 2017; Mulka, et al. 2016; Ford, et al. 2015; McAllister, et al. 2014; Mayer, et al. 2012].
- Antiretroviral therapy is recommended for pregnant individuals with HIV and has been used safely during pregnancy [DHHS 2021], providing reassurance for its safety profile in pregnant individuals who require PEP.

**Evidence of PEP effectiveness:** Evidence of PEP effectiveness has been derived primarily from animal model studies and extrapolated from clinical trials of ARV prophylaxis to prevent perinatal transmission of HIV.

**Evidence from animal models:** Animal studies demonstrate time-dependent efficacy of PEP within 72 hours of exposure, with excellent efficacy reported if initiated within 36 hours [Otten, et al. 2000; Tsai, et al. 1998].

- In a recent study, infected mice injected intraperitoneally with fluorescently labeled HIV-1 had no detectable plasma p24 or HIV-1 RNA when treated with raltegravir 1 day post infection. Ten mice that were not treated and became positive for plasma p24 and HIV-1 RNA and developed swollen lymph nodes in the peritoneal cavity [Ogata-Aoki, et al. 2018].
- A systematic review and meta-analysis identified 16 studies that specifically assessed the efficacy of PEP (N = 180) compared with controls (N = 103). A pooled analysis of all animal studies reported the risk of seroconversion was 89% lower among primates exposed to PEP than among controls [Irvine, et al. 2015].
- In macaques exposed to HIV intravaginally, PEP initiated at 12 and 36 hours post exposure prevented infection; however, breakthrough plasma viremia was observed in some animals when PEP was initiated 72 hours post exposure [Otten, et al. 2000].
- SIV infection was prevented in macaques treated 24 hours post exposure with ARV medications as PEP (short-term 9-[2-(R)-(phosphonomethoxy)propyl]adenine); half of the subjects that received PEP at 48 and 72 hours post exposure developed infection [Tsai, et al. 1998].

**Figure 1: Sequence of Events Following HIV Exposure, With and Without Administration of Post-Exposure Prophylaxis (PEP)**



**Evidence from human studies:** A limited number of case-control studies and clinical trials have established PEP effectiveness in humans.

- *Occupational exposure:* In a Centers for Disease Control and Prevention (CDC) retrospective case-control study of zidovudine (ZDV) use after occupational HIV exposure in healthcare workers, the risk of HIV infection was reduced by 81% in those who received ZDV [Cardo, et al. 1997]. In a 4-country study, 33 cases of occupationally acquired HIV were compared with 665 control subjects. Case patients were significantly less likely than control subjects to have taken ZDV prophylaxis after exposure, with an odds ratio of 0.19 [Cardo, et al. 1997].
- Since 1999, only 1 confirmed case of occupationally acquired HIV has been reported to the CDC [Joyce, et al. 2015]. In this case, a laboratory technician sustained a needle puncture while working with concentrated HIV cultures, which is a very high-risk scenario.
- *PEP following needle sharing and transfusion:* No specific studies currently address PEP use and its efficacy among individuals who inject drugs and share needles, and no data are currently available regarding HIV transmission via needle sharing when the source has an undetectable viral load.
  - Retrospective analyses of PEP do include small numbers of participants with injection drug use as a risk factor and did not report PEP failures among this group [McDougal, et al. 2014; Kahn, et al. 2001].
  - One case report demonstrated PEP effectiveness for a 12-year-old girl with sickle cell disease who received 4-drug PEP with tenofovir, emtricitabine, ritonavir-boosted darunavir, and raltegravir after a blood transfusion and exposure to the blood of a donor who had an HIV viral load of 9,740 copies/mL [Al-Hajjar, et al. 2014].

**Evidence from studies of seroconversion with PEP use after sexual exposure:** Observational cohorts have provided some data about seroconversion rates among PEP users and possible risk factors among seroconverters.

- A retrospective study analyzed all non-occupational PEP courses prompted by sexual exposure at a California health center to determine factors associated with seroconversion within 24 weeks of initiating PEP. The incidence rate of HIV infection was 2.3/100 person-years. Of note, 17 seroconversions occurred among 1,744 individuals who followed up within the 24-week period; of these 17 seroconversions, 7 had re-exposure risks, 8 had condom-protected sex only, and 2 reported abstinence from sex following the exposure for which they received PEP. In a multivariate analysis, significant predictors of seroconversion included methamphetamine use, incomplete PEP medication adherence, and time from initial exposure to PEP dose >48 hours but <72 hours [Beymer, et al. 2017].
- One systematic review analyzed completion rates among 15 studies (1,830 initiations) of 2-drug PEP regimens and 10 studies (1,755 initiations) of 3-drug PEP regimens. Although the failure rate as determined by HIV seroconversion could not be compared because events overall were rare and protocols for follow-up were not uniform, the data underscore the value and effectiveness of PEP initiation [Ford, et al. 2015].

**PEP following sexual assault of children and adolescents:** One study reported that in an inner-city pediatric emergency department in an area with high HIV prevalence, PEP was offered to 87 survivors of sexual assault who qualified for the intervention. Of those 87 children, only 5.7% were provided with PEP, but 69% were given antibiotic prophylaxis to prevent sexually transmitted infections other than HIV [Fajman and Wright 2006]. The reasons for such a low number (5 children) of PEP initiations were not provided. Among those who did receive PEP, there was no record of seroconversions, but 2 of those patients were lost to follow-up. The study had many limitations.

## First Dose of PEP and Management of the Exposure Site

**☑ RECOMMENDATIONS**

- **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; Truvada plus Tivicay) [a]

**RECOMMENDATIONS**

- Lamivudine (3TC; Epivir) may be substituted for FTC in either regimen.
- Raltegravir (RAL; Isentress) may be prescribed in the high-dose formulation, but the high-dose formulation should not be given to pregnant patients.
- **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)
- 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)

**Note:**

- a. The recommendation regarding discussion of the small risk of teratogenicity with DTG in the first trimester and the need for birth control while completing the 28-day PEP regimen has been removed. DTG has been shown to be safe throughout pregnancy. See the MCCC’s statement on *Use of Dolutegravir in Individuals of Childbearing Capacity* for further discussion [Zash, et al. 2022].

## A Exposure to HIV Is An Emergency

An HIV exposure is a medical emergency and rapid initiation of PEP—ideally within 2 hours and no later than 72 hours post exposure—is essential to prevent infection. Therefore, this Committee encourages emergency departments, outpatient clinics, and urgent care centers to train triage staff to assign high priority to patients who report a potential exposure. In deciding whether to continue PEP beyond the first emergency dose, care providers must balance the benefits and risks. PEP can be discontinued later in the evaluation process if indicated.

Because the efficacy of PEP in preventing an established HIV infection diminishes rapidly, initiation as soon as possible after exposure is best [CDC 2016; Kuhar, et al. 2013]. Animal models have consistently demonstrated improved outcomes at 12 to 36 hours post exposure compared with 72 hours [Otten, et al. 2000; Smith MS, et al. 2000; Van Rompay, et al. 2000; Tsai, et al. 1998; Van Rompay, et al. 1998; Black 1997]. Consistent with these findings, the virus can be detected in the regional lymph nodes of SIV-infected rhesus macaques within 2 days of intravaginal exposure [Spira, et al. 1996].

**PEP for an individual who is taking PrEP:** On occasion, an exposed individual who has been taking PrEP may insist on receiving a third ARV medication as PEP despite a clinician’s reassurance that it is not necessary. A clinician may reassure a patient who is taking PrEP with daily adherence that no current evidence can support adding an additional ARV after a potential exposure. However, if the exposed individual has only recently started taking PrEP, has been taking PrEP inconsistently, or has been taking the medications “on-demand,” it may be reasonable to consider a 28-day course of 3-drug PEP after a high-risk exposure. Similarly, if the source has virus with known underlying resistance to the components of a PrEP regimen (emtricitabine or tenofovir), offering 3-drug PEP to the exposed individual should be considered, particularly if the source’s viral load is not suppressed (i.e., <200 copies/mL). Lastly, there may be instances where the clinician may have to balance an exposed individual’s level of anxiety with maintaining the therapeutic alliance between the patient and care provider: offering 3-drug PEP in these scenarios may be appropriate to daily PrEP users in rare circumstances, such as high-risk needle sharing exposures or on a case-by-case basis. A request for PEP from a patient who is consistently using PrEP should not be accommodated following an exposure that is evaluated to be low or zero risk.

☆ NEW YORK STATE LAW

New York State law allows minors to consent to HIV-related prevention services, including PEP, just as they can consent to other reproductive or sexual health-related services. See *Sections 23.1 and 23.2 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York*.

→ KEY POINTS

- Time to protection is based on pharmacokinetic modeling studies and has not been clinically determined.
- For rectal exposure, protection against HIV acquisition is achieved after 7 days of TDF/FTC daily dosing and possibly earlier.
- For genital and blood exposure, protection against HIV acquisition is likely achieved after 7 days of TDF/FTC daily dosing, but optimal drug concentrations are achieved after 20 days of daily dosing.
- Taking 2 pills of TDF/FTC as PrEP on the day of initiation will decrease the time needed to achieve protective drug concentrations for all sites of exposure.
- Data are insufficient to make an estimate regarding time to protection for TAF/FTC. For more information and references, see the NYSDOH AI guideline *PrEP to Prevent HIV and Promote Sexual Health > Time to Protection*.

**Request for PEP later than 72 hours post exposure:** Because evidence indicates that PEP is not effective when initiated more than 72 hours post exposure, clinicians should not initiate PEP after this time point [Beymer, et al. 2017; Otten, et al. 2000; Smith MS, et al. 2000; Van Rompay, et al. 2000; Tsai, et al. 1998; Van Rompay, et al. 1998; Black 1997].

→ KEY POINT

- An *intentional decision* to wait until the 72-hour mark to initiate PEP could place an exposed individual at increased risk of seroconversion.

After 72 hours post exposure, HIV infection may have been established. If PEP is prescribed after 72 hours and then discontinued after 28 days, the risk of viral rebound with that inadvertent interruption in ART is significant, as is the associated risk of developing resistance to ART; therefore, this Committee stresses that PEP should not be initiated later than 72 hours post exposure.

In response to an exposure reported after 72 hours post exposure, follow-up that is appropriate to the type of exposure should be arranged (see *Table 1: Baseline Testing Based on Age of Exposed Individual and Type of Exposure*):

- O** **Occupational exposure:** Serial HIV testing, serial hepatitis C virus (HCV) testing, and hepatitis B virus (HBV) prophylaxis if indicated based on prior immunity status (e.g., records of HBV surface antibody titers).
- N** **Non-occupational exposure:** Serial HIV testing, serial HCV testing, HBV prophylaxis if indicated, and appropriate screening for STIs. Provide risk-reduction counseling and linkage to PrEP services if indicated.
- S** **Sexual assault exposure:** Serial HIV testing, serial HCV testing, HBV prophylaxis if indicated, empiric STI treatment, and linkage to appropriate services and support.
- C** **Exposure in a child aged 2 to 12 years:** Serial HIV testing, HCV antibody testing, HBV prophylaxis if indicated, empiric STI treatment if sexual assault exposure, and linkage to appropriate services and support.

**Note:** See the guideline section *Management of Potential Exposure to Hepatitis B Virus* for indications for HBV prophylaxis.

## Management of the Exposed Site

Care of the exposure site should prioritize appropriate cleansing and infection preventive measures and minimize further trauma and irritation to the exposed wound site. The site of a wound or needlestick injury should be cleaned with soap and water only. It is best to avoid use of alcohol, hydrogen peroxide, povidone-iodine, or other chemical cleansers. Squeezing the wound may promote hyperemia and inflammation at the wound site, potentially increasing systemic

exposure to HIV if present in the contaminating fluid. The use of surgical scrub brushes or other abrasive tools should be avoided, as they can cause further irritation and injury to the wound site. Eyes and other exposed mucous membranes should be flushed immediately with water or isotonic saline.

## When to Consult an Expert Regarding the First Dose of PEP

Examples of clinical scenarios that warrant consultation with an experienced HIV care provider include: a source with ARV-resistant HIV, an exposed individual with limited options for PEP medications due to potential drug-drug interactions or comorbidities, or an exposed individual who is pregnant or unconscious.

**Expert consultation for New York State clinicians:** In such circumstances, clinicians are advised to call the Clinical Education Initiative (CEI Line) to speak with an [experienced HIV care provider](#).

- Call 1-866-637-2342 and press “1” for HIV PEP. The CEI Line is available 24/7.

The **Clinical Consultation Center (CCC) for PEP** may be reached by calling 1-888-448-4911. The CCC is part of the AIDS Education and Training Centers and is located at the University of California, San Francisco/Zuckerberg San Francisco General Hospital. It is funded by the Health Resources and Services Administration and the Centers for Disease Control and Prevention. See [UCSF > PEP for more information](#), including hours.

### \* SELECTED GOOD PRACTICE REMINDERS

#### A ALL EXPOSURES

- *Communications:* Use clear and direct language when communicating with an exposed individual or with an adult accompanying an exposed child. Use age-appropriate language with children.
- *If PEP is refused:* Explain the timing requirement for initiation and provide instructions for acquiring PEP if that decision changes. Document refusal of PEP in the patient’s medical record.

## Exposure Risk Evaluation

### ☑ RECOMMENDATIONS

#### 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)

**RECOMMENDATIONS**

- 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)

**Box 3: Risk of HIV Transmission From a Source With HIV**

**Meaningful risk of transmission:**

- Blood
- Semen
- Vaginal secretions
- Breast milk
- Cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids

**No meaningful risk of transmission:**

- Nonbloody saliva
- Tears
- Sweat
- Nonbloody urine
- Nonbloody feces

**O Occupational Exposure Risk Evaluation**

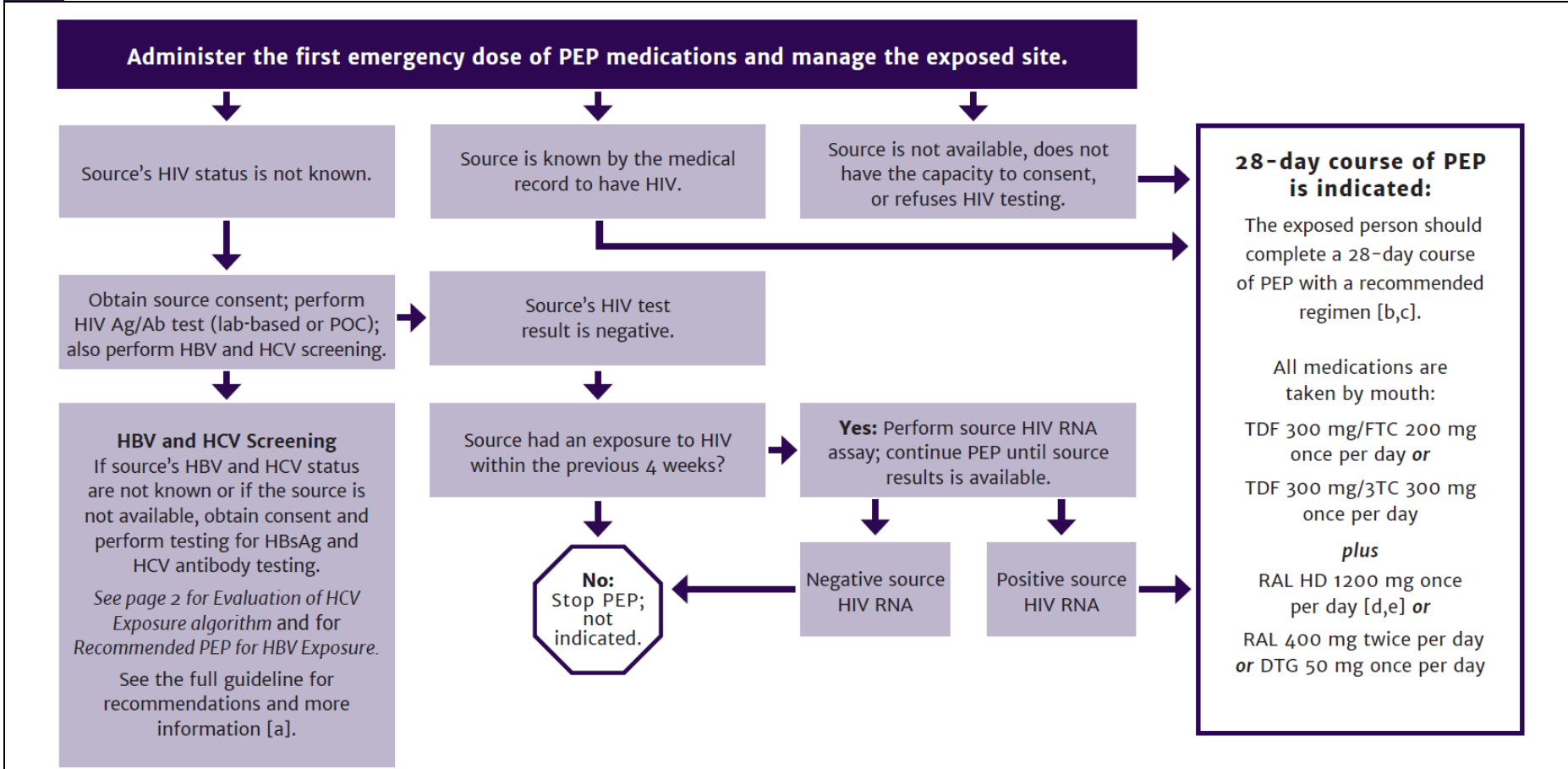
PEP is indicated whenever an occupational exposure to blood, visibly bloody fluids, or other potentially infectious material occurs through percutaneous or mucocutaneous routes or through non-intact skin. *Figure 2*, below, illustrates the steps in determining whether ongoing PEP is indicated after the first emergency dose.

**Occupational exposures for which PEP is indicated include the following:**

- Break in the skin by a sharp object (including hollow-bore, solid-bore, and cutting needles or broken glassware) that has been in the source’s blood vessel or is contaminated with blood, visibly bloody fluid, or other potentially infectious material.
- Bite from a patient with visible bleeding in the mouth that causes bleeding in the exposed individual.
  - PEP is *not* indicated for an exposure to saliva, including from being spat on, in the absence of visible blood.
- Splash of blood, visibly bloody fluid, or other potentially infectious material to the mouth, nose, or eyes.
- A non-intact skin (e.g., dermatitis, chapped skin, abrasion, or open wound) exposure to blood, visibly bloody fluid, or other potentially infectious material.

**Evaluation for other bloodborne pathogens:** See the following sections of this guideline: *Management of Potential Exposure to Hepatitis B Virus* and *Management of Potential Exposure to Hepatitis C Virus*.

**O** Figure 2: Occupational HIV Exposure: Post-Exposure Prophylaxis (PEP) and Exposure Management When Reported Within 72 Hours



**Abbreviation key:** Ag/Ab, antigen/antibody; CrCl, creatinine clearance; HBV, hepatitis B virus; HBsAg, hepatitis B surface antigen; HCV, hepatitis C virus; PEP, post-exposure prophylaxis; POC, point-of-care.

**Drug name abbreviations (brand name):** 3TC, lamivudine (Epivir); DTG, dolutegravir (Tivicay); FTC, emtricitabine (Emtriva); RAL, raltegravir (Isentress); TDF, tenofovir disoproxil fumarate (Viread); TDF/FTC (Truvada)

- Notes:**
- a. See *Management of Potential Exposure to Hepatitis B Virus and Management of Potential Exposure to Hepatitis C Virus*.
  - b. See *Table 2* for preferred PEP regimen and *Table 3* for alternative regimens.
  - c. Do not use fixed-dose combination tablet for patients who require dose adjustment for renal failure. Adjust dose of TDF/FTC or TDF/3TC for patients with CrCl <50 mL/min. See NYSDOH AI guideline *Recommended Dose Adjustments for Use of Selected Fixed-Dose Combination ARVs in Patients with Hepatic or Renal Impairment*.
  - d. RAL HD may be prescribed for patients who weight >40kg.
  - e. RAL HD should not be prescribed for pregnant individuals.

## N Non-Occupational Exposure Risk Evaluation

In many cases of non-occupational exposure, the source is not available for testing. The HIV status of the source should not be the focus of the initial evaluation; determination of whether the exposure warrants PEP and, when indicated, prompt initiation of PEP, should be the focus. *Figure 3*, below, illustrates the steps in determining whether ongoing PEP is indicated after the first emergency dose.

### → KEY POINTS

- The decision to recommend PEP is based on the nature of the exposure and not on the geographic location at which an assault occurred or the location of the source’s or the exposed individual’s residence.
- When an individual presents for PEP, evaluation and PEP services should be delivered in combination with patient education, with a strong emphasis on prevention of future exposures [Golub, et al. 2008].
  - For more information on pre-exposure prophylaxis (PrEP), see the NYSDOH AI guideline *PrEP to Prevent HIV and Promote Sexual Health*.

**Risk of transmission:** *Box 1: Risk per 10,000 Exposures of Acquiring HIV From an Infected Source and Factors That Increase Risk*, above, provides the risk of HIV infection following various types of non-occupational exposure to an individual known to have HIV and factors that may increase risk. HIV transmission occurs most frequently during sexual or drug use exposures; however, many factors can influence risk.

**Exposure to a source with acute HIV:** Due to the presence of high HIV viral load levels, the probability of transmission when the source is in the acute and early stage of HIV infection (first 6 months) is 8- to almost 12-fold higher than it is once a source’s viral set point has been established, typically about 6 months after infection [Wawer, et al. 2005; Pilcher, et al. 2004]. The presence of STIs in either the source or the exposed individual also increases risk of HIV transmission [CDC 2017; Johnson and Lewis 2008; Advisory Committee for HIV and STD Prevention 1998]. Conversely, transmission risk with sexual exposure is significantly decreased when a source is taking effective antiretroviral therapy (ART) and has an undetectable viral load [Cohen, et al. 2011] (see NYSDOH AI *U=U Guidance for Implementation in Clinical Settings*).

*Box 4*, below, lists non-occupational exposures that should prompt consideration of PEP and those that do not warrant PEP.

### N Box 4: Non-Occupational Exposure Risks and Indications for Post-Exposure Prophylaxis (PEP)

- **Higher-Risk: PEP is Recommended:**
  - Receptive and insertive vaginal or anal intercourse [a].
  - Needle sharing [a].
  - Penetrating injury, such as a needlestick with a hollow-bore needle, with exposure to blood or other potentially infected fluids [a].
  - Bite with visible bleeding in the mouth that causes bleeding in the exposed individual.
- **Lower-Risk: Assess Factors that Increase Need for PEP:**
  - Exposure: Oral-vaginal and oral-anal contact, receptive and insertive; receptive and insertive penile-oral contact, with or without ejaculation.
  - Factors that increase risk: 1) Source is known to have HIV with high viral load. 2) Non-intact oral mucosa, e.g., oral lesions, gingivitis, wounds. 3) Blood exposure—may be minimal and not recognized by the exposed individual; if frank blood exposure is reported, then PEP is indicated. 4) Presence of genital ulcer disease or other sexually transmitted infections.
- **PEP is Not Indicated [b]:**
  - Kissing: Remote risk associated with open-mouthed kissing if blood is exchanged due to sores or bleeding gums [Kaplan and Heimer 1992].
  - Oral-to-oral contact in the absence of mucosal damage, e.g., mouth-to-mouth resuscitation.
  - Human bites not involving blood.



<b>N</b>	<p><b>Box 4: Non-Occupational Exposure Risks and Indications for Post-Exposure Prophylaxis (PEP)</b></p> <ul style="list-style-type: none"> <li>– Exposure to solid-bore needles or sharps not in recent contact with blood: Examples of solid-bore needles include tattoo needles and lancets used to measure blood-sugar levels.</li> <li>– Mutual masturbation without skin breakdown or blood exposure.</li> <li>– Exposure to saliva, including if spat on, in the absence of visible blood.</li> </ul> <p>-----</p> <ol style="list-style-type: none"> <li>a. Source is known to have HIV or source’s HIV status is not known.</li> <li>b. See also NYSDOH AI <i>U=U Guidance for Implementation in Clinical Settings</i>.</li> </ol>
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A frank discussion between the clinician and an exposed individual regarding sexual activities, needle sharing, and other drug-using activities that have the potential for exposure to blood and other body fluids can help determine a patient’s need for PEP (see *Boxes 1 and 4*). The behaviors that confer the highest risk are needle sharing and receptive unprotected anal intercourse with an individual who has HIV [Varghese, et al. 2002; CDC 1997; DeGruttola, et al. 1989].

Clinicians should also assess factors that have been associated with increased risk of HIV infection, including:

- Trauma at the site of exposure, especially if there was contact with blood, semen, or vaginal fluids.
- Presence of genital ulcer disease or other STIs [CDC 2017; LeGoff, et al. 2007].
- High plasma viral load in a source with HIV [Patterson BK, et al. 2002; Tovanabutra, et al. 2002].
- Exposure in an uncircumcised male [Bailey, et al. 2007; Gray, et al. 2007; Patterson BK, et al. 2002].

Factors that may significantly decrease transmission of HIV include exposure to a source who is taking effective ART (see NYSDOH AI *U=U Guidance for Implementation in Clinical Settings*) or use of daily PrEP and use of condoms during sexual exposures [Weller and Davis 2002]. After consensual sexual exposures that meet NYSDOH U=U Guidance criteria in the source, there is no evidence to support the use of PEP by the exposed individual. Furthermore, there is no evidence that a 3-drug PEP regimen provides any additional benefit to an exposed individual who adheres to a daily PrEP regimen; consistent use of PrEP has been shown to be 99% effective when taken appropriately (see the NYSDOH AI guideline *PrEP to Prevent HIV and Promote Sexual Health > PrEP Efficacy*). Correct condom use is highly effective in preventing transmission of HIV; however, during the post-exposure evaluation, it often is not possible to reliably ascertain whether condoms were used correctly or whether breakage, slippage, or spillage occurred.

**Evaluation for exposure to STIs other than HIV:** Risk behaviors leading to HIV infection also confer risk or exposure to other STIs. Patients who present for PEP after a consensual sexual exposure should be evaluated for other STIs.

Baseline testing generally cannot detect STIs that were acquired as a result of the exposure, but it may detect infections present prior to the exposure that prompted the evaluation for PEP. Presentation for PEP provides an opportunity to screen individuals at risk of STIs and treat infections as indicated. High rates of concomitant STIs at the time of presentation for PEP have been found in men who have sex with men [Jamani, et al. 2013; Hamlyn, et al. 2006].

Routine empiric treatment for STIs is not recommended for consensual sexual exposures. Education about STI symptoms should be provided, and patients should be instructed to call their healthcare provider if symptoms occur. Follow-up STI screening should be considered at 2 weeks post exposure to definitively exclude STIs [Mayer, et al. 2017; McAllister, et al. 2017; Mulka, et al. 2016; Oldenburg, et al. 2015; Mayer, et al. 2012; Tosini, et al. 2010; Mayer, et al. 2008].

**Evaluation for other bloodborne pathogens:** See the following sections of this guideline: *Management of Potential Exposure to Hepatitis B Virus* and *Management of Potential Exposure to Hepatitis C Virus*.

**Emergency contraception:** For individuals who can but who do not desire to become pregnant, and who consent, emergency contraception should be initiated immediately. There are a range of methods (copper intrauterine device, levonorgestrel, and ulipristal acetate) that can be taken within 5 days of a sexual exposure. Of note, emergency contraception is not an abortifacient and will generally not disrupt an ongoing healthy pregnancy. For more information, see *Bedsider: Emergency Contraception*.

**N** Figure 3: Non-Occupational HIV Exposure: Post-Exposure Prophylaxis and Management When Reported Within 72 Hours

**STEP 1: Administer the first emergency dose of PEP and manage the exposed site.**

**STEP 2: Determine if ongoing PEP is required.**

**PEP is indicated within 72 hours of high- and higher-risk exposures:**

- Receptive or insertive anal or vaginal intercourse with an individual of unknown or positive HIV status.
- Needle sharing with an individual of unknown or positive HIV status.
- High-risk exposure to a source with documented HIV (i.e., in the source's medical record) or through HIV testing if the source is available.
- Mucosal contact through a sexual exposure: vaginal–penile, anal–penile, or oral–penile contact, with or without physical injury, tissue damage, or the presence of blood at the site of the exposure.
- Broken skin or mucous membranes in the exposed individual that have been in contact with the blood, semen, or vaginal fluids of the source.
- Source with broken skin or mucous membranes that have been in contact with the blood, semen, or vaginal fluids of the exposed individual.
- Receptive or insertive oral–vaginal or oral–anal contact and/or receptive or insertive penile–oral contact, with or without ejaculation, in the presence of any of the following risk-enhancing factors: 1) Source with a high HIV viral load; 2) Source or exposed individual with oral lesions; 3) Frank blood exposure.
- Source or exposed individual has genital ulcer disease or other STIs.
- An injury (e.g., bite, accident, stick with a hollow-bore needle) that results in exposure to blood or other potentially infectious fluids from an individual of unknown or positive HIV status.

**Ongoing PEP is not required if:**

**PEP is not indicated for negligible or lower-risk exposures:**

- Oral–oral contact (e.g., kissing, mouth-to-mouth resuscitation) if there is no mucosal damage in the source or exposed individual.
- Human bite if no blood is drawn.
- Mutual masturbation with intact skin and with no blood exposure.
- Needlestick with solid-bore needle or another sharp not in recent contact with blood.
- Receptive or insertive oral–vaginal, oral–anal, or penile–oral contact, with or without ejaculation, if no risk-enhancing factors (see above) are present.

**Next steps if ongoing PEP IS required:**

**STEP 3: Initiate 28-Day PEP with a preferred or alternative PEP regimen [1,2,3].**

**Preferred regimen (≥40 kg):**  
 TDF 300 mg/FTC 200 mg [4,5] once per day or  
 TDF 300 mg/3TC 300 mg [4,5] once per day  
**PLUS**  
 RAL HD 1200 mg once per day [6,7] or  
 RAL 400 mg twice per day or  
 DTG 50 mg once per day

**Notes:**

1. All medications are taken by mouth.
2. See Table 3 for alternative PEP regimens for individuals who weigh ≥40 kg.
3. See Table 4 for PEP regimens for individuals who weigh <40 kg.
4. Do not use fixed-dose combination medications for patients who require dose adjustment for renal failure.
5. Adjust dose [a] of TDF/FTC or TDF/3TC for patients with CrCl <50 mL/min.
6. RAL HD may be prescribed for patients who weigh >40 kg.
7. RAL HD should not be prescribed for pregnant patients.

**STEP 4: Perform baseline testing.**

**Exposed individual:**

- HIV test: Ag/Ab combination immunoassay.
- HBV and HCV screening [b].
- Pregnancy test if individual is of childbearing capacity; offer emergency contraception if indicated.
- Liver and renal function tests.

**Consensual sexual exposures:**

CT/GC NAAT, based on site of exposure; syphilis screening; trichomoniasis screening if symptoms are present.

**Available source who consents:**

- Rapid Ag/Ab combination immunoassay HIV test (result <1 hour).
- Negative result, but exposure to HIV may have occurred within previous 4 weeks: Obtain plasma HIV RNA assay.
- Definitive negative result: Discontinue PEP.
- Definitive positive result: Continue PEP.

**STEP 5: Perform follow-up care.**

- **Contact the exposed individual within 48 hours:** Provide in-person or telephone contact to assess medication tolerance and assist with adverse effect management, as indicated.
- Arrange for serial HIV test at weeks 4 and 12 post exposure.
- Repeat STI testing, if indicated.
- Ongoing adherence support, assessment of regimen tolerability, and adverse effect management, as indicated.
- Referral for HBV and/or HCV treatment, if indicated.
- Referral for substance use or mental health treatment, if indicated.
- Risk-reduction counseling and education, including referral for PrEP; see NYSDOH AI guideline *PrEP to Prevent HIV and Promote Sexual Health*.

**Next steps if ongoing PEP is not required:**

**STEP 3: Perform baseline testing.**

**Exposed individual:**

- Offer HIV test.
- Offer STI testing following sexual exposure.

**STEP 4: Perform risk-reduction counseling.**

- Provide counseling and education about risk-reduction actions and resources, including evaluation or referral for PrEP; see the NYSDOH AI guideline *PrEP to Prevent HIV and Promote Sexual Health*.

**STEP 5: Perform follow-up care.**

- Offer follow-up STI testing, if indicated.

**Abbreviations:** Ag/Ab, antigen/antibody; CrCl, creatinine clearance; CT/GC NAAT, chlamydia/gonorrhea nucleic acid amplification testing; HBV, hepatitis B virus; HCV, hepatitis C virus; PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection.

**Drug name abbreviations (brand name):** DTG, dolutegravir (Tivicay); RAL, raltegravir (Isentress); TDF/3TC, tenofovir disoproxil fumarate/lamivudine (Cimduo); TDF/FTC, tenofovir disoproxil fumarate/emtricitabine (Truvada).

**Notes:**  
 a. Do not use fixed-dose combination tablet if dose adjustment for renal failure is required. Adjust dose of TDF/FTC or TDF/3TC for patients with CrCl <50 ml/min. See *Recommended Dose Adjustments for Use of Selected Fixed-Dose Combination ARVs in Patients with Hepatic or Renal Impairment*.  
 b. For HBV and HCV post-exposure management, see guideline sections *Management of Potential Exposure to HBV* and *Management of Potential Exposure to HCV*.

## S Sexual Assault Exposure Risk Evaluation

The decision to recommend PEP to an individual who may have been exposed to HIV through sexual assault should not be based on the geographic location of the assault but rather on the nature of the exposure during the assault and the HIV status of the defendant, if known. Although the seroprevalence of HIV in different New York State communities may vary, the HIV status of an individual accused of sexual assault remains unknown until that individual has been tested.

### → KEY POINTS

- The decision to offer PEP should be based on evaluation of the exposure, not on the perceived or assumed risk behavior of a defendant or the geographical location.
- If a significant exposure has occurred during an assault, then PEP should be recommended.

**Risk of HIV transmission:** The risk of HIV transmission in sexual assault is greater due to the presence of genitorectal trauma, which may be present in as many as 50% to 85% of sexual assault patients [Sommers, et al. 2012; Jones, et al. 2009; Sachs and Chu 2002]. Studies on sexual assault document high rates of unprotected receptive anal intercourse (10% to 15%) and unprotected vaginal penetration (55% to 80%) [Draughon Moret, et al. 2016]. Studies also demonstrate a wide range (20% to 85%) of incidence of anogenital trauma [Larsen, et al. 2015; Laitinen, et al. 2013; Sugar, et al. 2004; Grossin, et al. 2003; Jones, et al. 2003; Riggs, et al. 2000]. In one study, 1% of men convicted of sexual assault in Rhode Island had HIV when entering prison [Di Giovanni, et al. 1991], higher than the general male population (0.3%).

The absence of visible trauma does not rule out sexual assault; microabrasions and bruising are common, and the appearance of these manifestations following sexual assault may be delayed. Oral trauma may also occur during sexual assault, with potential exposure to blood, semen, or vaginal fluids from the defendant, which may carry a potential risk for HIV exposure. Bites or trauma may be inflicted during an assault and are indications for prophylaxis if there is the possibility of contact with blood, semen, or vaginal fluids from the defendant. A bite from a source with visible bleeding in the mouth that causes bleeding in the exposed individual is an indication for PEP.

HIV testing of the sexual assault patient should be performed in the emergency department setting. HIV testing may be performed on excess blood specimens obtained in the emergency department for other reasons, but only if informed consent has been obtained. In the absence of a baseline HIV test result, it may not be possible to establish that the assault resulted in HIV infection if the patient is later confirmed to have HIV.

If PEP is initiated, then responsibility for monitoring and follow-up should be coordinated by the treating clinician. If the baseline screening HIV test is reactive, then the assault patient should continue the PEP regimen until the result is confirmed with an HIV-1/HIV-2 antibody differentiation immunoassay or HIV RNA test and linkage to care with an experienced HIV care provider has been made. If the patient is not under the care of a primary care clinician, the emergency department clinician who has obtained the HIV test is responsible for ensuring that the patient is informed of the result promptly. If HIV infection has been diagnosed, the PEP regimen may be altered by the HIV care provider or continued in this case as ART.

Every hospital that provides emergency treatment to a sexual assault patient must adhere to and fully document services provided, consistent with the following standards of professional practice and [Public Health Law 2805-P](#):

- Counsel sexual assault patients about options for emergency contraception to prevent pregnancy. Prompt access improves efficacy.
- Provide sexual assault patients with written information about emergency contraception that has been prepared or approved by the NYSDOH.
- Consider a urine pregnancy test to diagnose unplanned pregnancy, similar to STI screening in individuals who may be at risk. Inform the individual that a pregnancy test is being performed.

The following websites offer more information about the use of emergency contraception:

- [Bedsider: Emergency Contraception](#)
- [Emergency Contraception: What You Need to Know](#)

### ☆ NEW YORK STATE LAW

- If a sexual assault exposure is assessed as high-risk:
  - Provide a 7-day starter pack of medications if the patient is  $\geq 18$  years old.
  - Provide the full 28-day course of PEP medications if the patient is  $< 18$  years old.
  - Arrange a follow-up appointment with an experienced HIV care provider.
  - If the sexual assault patient is not able to make a timely decision about PEP, provide a starter pack and arrange for a follow-up appointment within 24 hours to review indications for PEP.
- Notify the sexual assault patient, verbally and in writing, of their right to decline to provide private health insurance information for billing for a forensic rape examination.

**STI prophylaxis:** Clinicians should *offer* all sexual assault patients prophylactic medication to prevent gonorrheal and chlamydial infections and trichomoniasis. Rates of STIs have increased in all populations in the United States through a combination of increased incidence of infection and changes in diagnostic, screening, and reporting practices. Surveillance data for the United States indicate that between 2014 and 2018, rates increased for chlamydia (by 19%), gonorrhea (by 64%), primary and secondary syphilis (by 71%) and congenital syphilis (by 185%) [CDC 2019a, 2018]. Trichomoniasis can be diagnosed or excluded in the emergency department if microscopy is available; otherwise, empiric treatment should be administered.

In cases of sexual assault, routine testing for gonorrhea, chlamydia, and syphilis is *not recommended* because test results would only determine whether the patient had an STI prior to the assault, and this information can be used to bias a jury against a survivor of sexual assault in court [NYSDOH 2020].

**Evaluation for exposure to HBV:** See guideline section *Management of Potential Exposure to Hepatitis B Virus*.

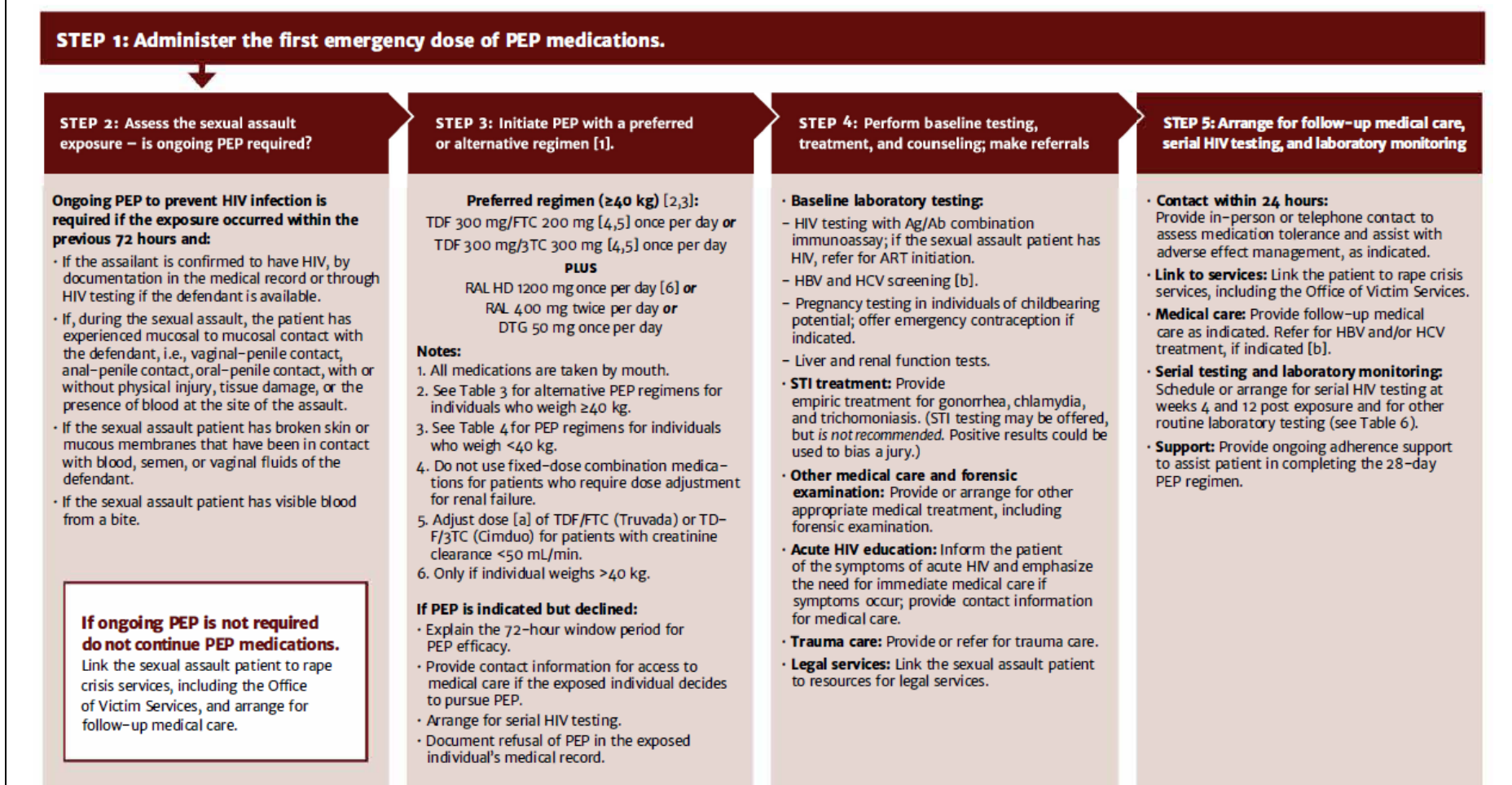
**Evaluation for exposure to HCV:** See guideline section *Management of Potential Exposure to Hepatitis C Virus*.

### RESOURCES

- *NYSDOH Sexual Violence Prevention Program*
- *NYSDOH Rape Crisis Programs by County*
- *Domestic and Other Violence Emergencies (DOVE) at New York-Presbyterian/Columbia University Medical Center*
- *NYC Anti-Violence Project*
- *New York State Coalition Against Sexual Assault and New York City Alliance Against Sexual Assault*
- *Sexual Assault Victim Bill of Rights*

Figure 4, below, illustrates the steps in determining whether ongoing PEP is indicated after the first emergency dose.

**S** Figure 4: Sexual Assault HIV Exposure: Post-Exposure Prophylaxis and Exposure Management When Reported Within 72 Hours



**Abbreviations:** Ag/Ab, antigen/antibody; ART, antiretroviral therapy; HBV, hepatitis B virus; HCV, hepatitis C virus; STI, sexually transmitted infection.

**Drug name abbreviations (brand name):** 3TC, lamivudine (Epivir); DTG, dolutegravir (Tivicay); FTC, emtricitabine (Emtriva); RAL, raltegravir (Isentress); TDF, tenofovir disoproxil fumarate (Viread).

- Notes:**
- Do not use fixed-dose combination tablet for patients who require dose adjustment for renal failure. Adjust dose of TDF/FTC or TDF/3TC for patients with creatinine clearance <50 ml/min. See NYSDOH AI guideline *Selecting an Initial ART Regimen > Table 9: Recommended Dose Adjustments for Use of Selected Fixed-Dose Combination ARVs in Patients with Hepatic or Renal Impairment*.
  - For HBV and HCV post-exposure management, see *Management of Potential Exposure to Hepatitis B Virus* and *Management of Potential Exposure to Hepatitis C Virus*.

## C Considerations for Sexual Assault in Children

**Lead authors:** *Aracelis Fernandez, MD, with Lisa-Gaye Robinson, MD, and Ruby Fayorsey, MD, with the Medical Care Criteria Committee; June 2020*

Care providers with experience in managing childhood sexual assault should assist in evaluating children who have been sexually assaulted to best assess the comprehensive needs of the child. Clinicians should assess children who are sexually assaulted for possible exposure to other STIs, including gonorrhea, syphilis, chlamydia, hepatitis B, hepatitis C, and trichomoniasis. Indications for laboratory evaluation and antimicrobial prophylaxis depend on the nature of the assault.

Once the initial, emergency dose of PEP has been administered, care for children exposed to HIV through sexual assault should be managed by a multidisciplinary team that includes the following:

- Clinicians with expertise in providing care for children who have been sexually assaulted.
- Child protective services, which are mandated by law to conduct an initial assessment and investigation of reported assault/abuse.
- Law enforcement officials to gather and evaluate evidence.
- Rape crisis counselors or advocates to provide support to the child and family.
- Mental health workers to provide immediate services as needed and who can provide long-term follow-up of the child and family, if appropriate.

For more information, see [The New York State Child Abuse Medical Provider Program > Education for Child Abuse Medical Providers](#).

Children who are sexually assaulted should be managed in an emergency department or other setting where appropriate resources are available to address the resulting medical, psychological, and legal issues. Children who present for care following sexual assault may have been victims of multiple exposures over time. PEP is indicated only for a sexual exposure that occurred within the 72 hours prior to the report of sexual assault. However, HIV testing may be indicated if a high-risk exposure occurred after the 72-hour cut-off for PEP efficacy.

For children who may have been exposed to HIV through sexual assault, the decision to continue PEP beyond the first emergency dose should be made based on the exposure evaluation; all sources of sexual exposure in children should be assumed to have HIV unless and until negative status can be confirmed. Clinicians should not delay initiating PEP in an exposed child pending results of the source’s HIV test.

→ **KEY POINTS**

- See [NYSDOH Requirements to Report Instances of Suspected Child Abuse or Maltreatment](#).
- Inquiries regarding child/adolescent sexual assault can be directed to: Child and Adolescent Sexual Assault Medical Protocol, Rape Crisis Program, NYSDOH, ESP Corning Tower, Albany, NY 12237. To request a copy of the protocol, call 518-474-3664.
- Clinicians should ensure that the evaluation of and treatment for sexual assault of a child is managed by a multidisciplinary team that is experienced in the care of children who have been sexually assaulted.
- Clinicians should ensure that a Sexual Assault Forensic Examiner who is trained to perform pediatric examinations is included on the team to assist in the medical examination, coordination of care, and discussions about treatment regimen. Clinicians should involve a rape crisis counselor and/or child advocacy team in all cases of sexual assault to assist the child and the family in dealing with the trauma and to assist with referrals.
  - See [NYSDOH Sexual Assault Forensic Examiner \(SAFE\) Program](#).

**\* SELECTED GOOD PRACTICE REMINDERS**

**A ALL EXPOSURES**

- *Bites:* If a bite exposure has been reported, evaluate the exposure in the biter and in the individual who was bitten. If an individual with bleeding in the mouth causes bleeding in someone who they have bitten, the bitten individual is a candidate for PEP.
- *If an exposure is assessed as high-risk:* Inform the patient of the need to complete a 28-day course of PEP, confirm the patient’s access to the PEP medications, and provide a starter pack of medications.
- *Describe the signs and symptoms of acute retroviral syndrome:* Stress the need for immediate medical attention if these symptoms occur, and provide the exposed individual with appropriate access to HIV testing that includes HIV RNA testing if indicated.
- *If an exposure is assessed as high-risk and completion of a 28-day PEP is indicated but declined:*
  - Inform the exposed individual of the results of the source’s HIV test.
  - Explain the 72-hour window period for PEP efficacy.
  - Describe the symptoms of acute retroviral syndrome.
  - Provide contact information for access to medical care if the exposed individual decides to pursue PEP.
  - Provide a referral for counseling and trauma care.
  - Arrange for serial HIV testing.
  - Document refusal of PEP in the exposed individual’s medical record.

**N NON-OCCUPATIONAL EXPOSURES**

- *Comprehensive evaluation:* Identify and assess all specific behaviors that may have resulted in exposure to HIV.
- *High-risk exposure:* Provide counseling and educating about risk reduction, including the availability of PrEP. Individuals who report a high-risk sexual exposure are candidates for PrEP, immediately if PEP is not indicated or upon completion of PEP once a negative HIV status is confirmed. Provide a referral for PrEP care if it is not available on site.

**S SEXUAL ASSAULT EXPOSURES**

- *HPV vaccine:* The Centers for Disease Control and Prevention recommend vaccination against HPV for sexual assault and sexual abuse patients aged 9 to 45 years. See also [Unger, et al. 2011].

## Source HIV Status and Management

In many cases of non-occupational exposure, the source is not available for testing. The HIV status of the source should not be the focus of the initial evaluation; determination of whether the exposure warrants PEP and, when indicated, prompt initiation of PEP, should be the focus.

**RECOMMENDATIONS**

**High-Risk Exposure**

- 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)

**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)

**RECOMMENDATIONS**

- 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 HIV-1/HIV-2 antibody (Ab) 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 Ab 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 complete 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 Ab differentiation immunoassay result is negative, consistent with a false-positive initial test. (A1)

**If the source is NOT available:** When the source of any potential exposure to HIV is not known, not available, or cannot be HIV tested for any reason, the care provider should assess the exposed individual's level of risk, assume the source has HIV until proven otherwise, and respond accordingly.

Determining whether the exposure warrants PEP and promptly initiating PEP when indicated should be the focus at initial presentation, rather than the HIV status of the source.

**If the source IS available—test for HIV:** When the source is available and consents to HIV testing, use of an HIV-1/2 antigen (Ag)/Ab combination immunoassay is recommended, preferably with a fast turn-around time. Results from point-of-care (POC) assays are available in less than 1 hour, and results from laboratory-based screening tests are often available within 1 to 2 hours. Rapid oral testing is *not recommended* due to lack of sensitivity to identify recent infection and requirements regarding food, drink, and tobacco use.



A <b>Box 5: Source HIV Testing</b>		
Available Source with Confirmed HIV	Available Source with Unknown HIV Status	Unknown or Unavailable Source
<ul style="list-style-type: none"> <li>Obtain the following:                             <ul style="list-style-type: none"> <li>Current viral load.</li> <li>Resistance test results.</li> <li>Current antiretroviral therapy (ART) regimen.</li> <li>Previous ART regimens.</li> <li>Contact information for prescriber(s).</li> </ul> </li> <li>Do not delay PEP initiation while waiting for test results.</li> </ul>	<ul style="list-style-type: none"> <li>Inform the source of the exposure incident.</li> <li>Perform HIV test using an antigen/antibody combination immunoassay.</li> <li>Assess the source patient for risk of HIV acquisition within the past 4 weeks (acute HIV infection).</li> </ul>	<ul style="list-style-type: none"> <li>Assess the exposure to identify the exposed individual’s risk of HIV infection.</li> <li>Assume the source has HIV until proven otherwise.</li> </ul>

→ KEY POINTS
<ul style="list-style-type: none"> <li>Do not discontinue PEP in an exposed individual until the source’s HIV serostatus is confirmed negative.</li> <li>Rapid oral HIV tests should not be used for source testing.</li> <li>Per the NYSDOH AI guideline <i>HIV Testing</i>, clinicians should use an HIV-1/2 Ag/Ab combination immunoassay to screen patients for HIV infection.</li> <li><b>Occupational exposure:</b> Facilities subject to <a href="#">Occupational Safety and Health Administration (OSHA) regulations</a> should choose the type of HIV test (laboratory-based or POC) that will return results most rapidly.</li> </ul>

When obtaining HIV testing in the source of a potential HIV exposure, consideration must be given to the source’s risk of HIV acquisition in the 4 weeks prior. During this period, often referred to as the “window period” of the HIV-1/2 Ag/Ab combination immunoassay, an initial HIV screening test may be nonreactive. If the source has engaged in condomless sexual intercourse (insertive or receptive anal, penile-vaginal) with or without pre-exposure prophylaxis (PrEP), or has shared intravenous needles or syringes with or without PrEP, then the source should also be tested for acute HIV infection with an HIV-1 RNA assay (qualitative or quantitative). Please note, only the qualitative HIV-1 RNA assay is U.S. Food and Drug Administration (FDA)-approved for aid in diagnosis of HIV.

PEP initiation should not be delayed; the first dose of PEP medications should be administered to the exposed individual before HIV testing and exposure evaluation. Only after the first dose of PEP has been administered should the source’s HIV serostatus, HIV exposure history, and other HIV-related information be evaluated to determine whether to continue PEP.

The most sensitive screening tests available should be used to allow for detection of early or acute HIV infection. The Centers for Disease Control and Prevention (CDC) and this Committee recommend screening with an FDA-approved Ag/Ab combination immunoassay, followed by confirmation with an FDA-approved HIV-1/HIV-2 Ab differentiation immunoassay (see the NYSDOH AI guideline *HIV Testing* and the CDC/American Public Health Laboratories [APHL] *Laboratory Testing Algorithm in Serum/Plasma*).

**Source with confirmed HIV:** If the source is known to have HIV, information about their viral load, ART medication history, and history of ART drug resistance should be obtained, when possible, to assist in the selection of a regimen if PEP is indicated [Beltrami, et al. 2003]. Administration of the exposed individual’s first emergency dose of PEP should not be delayed while awaiting this information.

When a sexual exposure to a source with HIV occurs, the exposed individual may discontinue PEP if the source is taking ART and has an undetectable viral load at the time of exposure. In that scenario, providing information about U=U to the exposed individual and may be reassuring. However, if an exposed individual requests PEP, it should not be denied (see NYSDOH AI *U=U Guidance for Implementation in Clinical Settings*).

**Informed consent:** If the source is available and has an unconfirmed HIV status, then consent for voluntary HIV testing should be sought as soon as possible after the exposure. Clinicians should follow individual institutional policies for

obtaining consent for HIV testing of the source. In New York State, when the source has the capacity to consent to HIV testing, that individual should be informed that HIV testing will be performed unless the source objects.

If the source objects, the care provider should inform the source that an HIV exposure may require the exposed individual to take medications to prevent infection, and the results of the source’s HIV test could help determine the duration of the exposed individual’s treatment. This information may encourage the source to agree to testing. However, if the source continues to refuse, then HIV testing cannot be performed.

<b>Box 6: Clinician-to-Clinician Communication</b>	
<b>O</b>	<i>Occupational exposure:</i> Communication between clinicians <i>is allowed</i> ; source information may be shared.
<b>N</b>	<i>Non-occupational exposure:</i> Source information may be shared <i>only</i> if the source signs an <i>Authorization for Release of Health Information and Confidential HIV-Related Information form DOH-2557</i> .
<b>S</b>	<i>Sexual assault exposure:</i> As of November 1, 2007, <i>New York State Criminal Procedure Law § 210.16</i> requires HIV testing of criminal defendants indicted for certain felony sex offenses when requested by the individual who was assaulted. For guidance on defendant testing, please see <i>New York State Court-Ordered HIV Testing of Defendants</i>
<b>C</b>	<i>Exposure in a child aged 2 to 12 years:</i> Source information may be shared <i>only</i> if the source signs an <i>Authorization for Release of Health Information and Confidential HIV-Related Information form DOH-2557</i> .

**HIV testing in the source of an occupational exposure:** If a source does not have the capacity to consent, consent may be obtained from a surrogate, or anonymous testing may be performed if a surrogate is not immediately available (see *Box 7*, below). Clinicians should follow individual institutional policies for obtaining consent.

<b>O</b>	<b>Box 7: HIV Testing When the Source of an Occupational Exposure Is Unable to Consent</b>
<ul style="list-style-type: none"> <li>• The <i>Family Health Care Decisions Act (FHCDA)</i> stipulates who is able to consent for care. If a source is unable to provide consent for HIV testing, then clinicians should follow institutional policies related to the FHCDA for obtaining consent for the source’s HIV test. If the source is deceased, then anonymous testing should be performed. Healthcare proxy and other surrogacy status ends with death.</li> <li>• <b>No surrogate is immediately available to consent on behalf of the source:</b> In cases of occupational exposures in which there is significant risk of contracting or transmitting HIV infection, an anonymous HIV test may be ordered without consent of the source if all 4 of the conditions listed below are met. Expeditious decisions regarding PEP for occupational exposures are essential. The decision to perform anonymous HIV testing of a source may be made immediately if no surrogate is present to provide consent.             <ol style="list-style-type: none"> <li>1. The source is comatose or is determined by an attending professional to lack the mental capacity to consent.</li> <li>2. The source is not expected to recover in time for the exposed individual to receive appropriate medical treatment.</li> <li>3. There is no individual immediately available who has the legal authority to consent in time for the exposed individual to receive appropriate medical treatment.</li> <li>4. The exposed individual will benefit medically by knowing the source’s HIV test results.</li> </ol> </li> <li>• <b>Anonymous testing of the source:</b> <i>New York State public health law</i> now allows healthcare providers to order anonymous testing in specific types of occupational exposures, and laboratories are no longer required to have a patient name to perform an HIV test in these cases. A clinician may order an anonymous HIV test only when an occupational exposure involves a source who is deceased, comatose, or otherwise unable to consent and there is no surrogate immediately available. The medical benefit of knowing the source’s test result must be documented in the exposed individual’s medical record. The result may not be documented in the source’s medical record. The result of the source’s anonymous HIV test is provided to the clinician providing care for the exposed worker for purposes of making decisions regarding PEP. Patient written authorization for release is not required.</li> </ul> <p><b>Source:</b> <i>NYSDOH AI Occupational Exposure and HIV Testing: Fact Sheet and Frequently Asked Questions</i></p>	

→ KEY POINT

- **In cases of occupational exposure:** Source information may be shared between treating clinicians. Healthcare facilities that supply occupational PEP to workers may be subjected to OSHA rules and have specific regulations regarding HIV testing of sources (see *Employer Responsibilities in Post-Exposure Prophylaxis (PEP) Management Prevent HIV Infection Following an Occupational Exposure*).

**HIV testing in the source of a non-occupational exposure when the source is taking PrEP:** If the source is taking PrEP, then plasma HIV RNA testing should be performed if the HIV-1/2 Ag/Ab combination immunoassay is negative, as is recommended for other groups at high risk (such as a source who reports possible exposure to HIV within the previous 4 weeks through sex or needle sharing). A negative viral load test will provide reassurance that the source is adherent to PrEP and allow the clinician and the exposed individual to rely on more than just the verbal report of the source.

**HIV testing in the source of a sexual assault exposure:** In most instances, the HIV status of the assailant will not be known and cannot be available in sufficient time to influence the decision to initiate PEP. If the HIV status of the defendant is established and confirmed, that knowledge should guide the decision to initiate or continue PEP; if the drug resistance data are available for a defendant with HIV, then that information can be used to tailor the PEP regimen. A negative HIV status of a defendant can determine whether the sexual assault patient should complete the 28-day PEP regimen; discontinuing unnecessary PEP has medical and psychological benefits. See *NYSDOH Guidance for HIV Testing of Sexual Assault Defendants* for more information.

As of November 1, 2007, New York State Criminal Procedure Law § 210.16 requires testing of criminal defendants indicted for certain felony sex offenses for HIV, upon the request of the victim. For guidance on defendant testing, please visit *NYS Court-Ordered HIV Testing of Defendants*. Information regarding interpretation of HIV tests can be found in the CDC/APHL *Laboratory Testing Algorithm in Serum/Plasma*.

The increased risk of HIV transmission can be attributed to risk behavior profiles of the defendant, who engage in high-risk behaviors [Klot, et al. 2013].

**Confirmed defendant HIV status:** If the defendant is confirmed to have HIV, then information about the defendant’s viral load, ART medication history, and history of ART drug resistance should be obtained, if possible, to assist in selection of a PEP regimen [Beltrami, et al. 2003]. Administration of the first emergency dose of PEP should not be delayed while awaiting this information.

**HIV status of defendant is unknown or unconfirmed:** Even if the individual reporting sexual assault knows the defendant, assumptions about HIV status or risk should have *limited* influence on the decision to initiate PEP. Familiarity with the defendant may influence the patient’s perception of risk and their decision to accept PEP. Because HIV risk behaviors and status may be hidden from close friends and family, decisions based on familiarity with the defendant should be made cautiously. It is not possible to know whether a defendant has HIV infection solely by risk behaviors. Categorical judgments should not be made on perceived risk. The decision to offer PEP should be based on whether significant exposure has occurred during the assault rather than on the risk behavior of the defendant.

\* SELECTED GOOD PRACTICE REMINDERS

**A ALL EXPOSURES**

- **Source testing:** Test the source with an FDA-approved laboratory or POC HIV-1/2 Ag/Ab combination immunoassay; do not use a rapid oral HIV test.
  - If the source’s screening test is reactive, provide the results and follow up with confirmatory testing.
  - Inform the exposed individual of the result, and explain the process for confirming HIV infection.
  - If source’s confirmatory testing is positive (Ab differentiation immunoassay or HIV-1 RNA test), provide linkage to an HIV-experienced care provider if the source is not already engaged in medical care.
- **If the source has drug-resistant HIV:** Consult an **experienced HIV care provider** for assistance in modifying the exposed individual’s PEP regimen.
- **Provide counseling and education to the exposed individual.**
- **If a 28-day course of PEP is indicated:** If the exposure is assessed to be high-risk and the exposed individual will complete a 28-day course of PEP, arrange for telephone follow-up within 48 hours to ensure the individual has the medications and to assess for adverse effects.

**\* SELECTED GOOD PRACTICE REMINDERS**

**N NON-OCCUPATIONAL EXPOSURES**

- *Undetectable equals untransmittable (U=U)*: Research has established that a source with HIV who is taking ART and has an undetectable viral load (HIV RNA <200 copies/mL) at the time of a consensual sexual (only) exposure will not transmit the virus through sex [Rodger, et al. 2019; Cohen, et al. 2016; Rodger, et al. 2016].
- *If the source’s viral load at the time of a sexual exposure is available*: Offer information about U=U as reassurance for the exposed individual.
- *U=U pertains only to consensual sexual exposure*: It does not apply to exposure through needle sharing, breastfeeding, or needlestick injury.

## Baseline Testing of the Exposed Individual

**Lead author:** Elliot DeHaan, MD, with the *Medical Care Criteria Committee*; June 2020

**Lead authors for material on PEP in children:** Aracelis Fernandez, MD, with Lisa-Gaye Robinson, MD, and Ruby Fayorsey, MD

**RECOMMENDATIONS: Baseline Testing of the Exposed Individual**

**All Exposures**

- Clinicians should perform baseline HIV testing of an exposed individual using a U.S. Food and Drug Administration (FDA)-approved HIV-1/2 antigen/antibody (Ag/Ab) combination immunoassay, preferably at the time of post-exposure prophylaxis (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)
- 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 HIV-1/2 Ag/Ab combination immunoassay is reactive, clinicians should recommend the continuation of PEP until the positive result is confirmed with an Ab differentiation immunoassay 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)
  - See the NYSDOH AI guideline *When to Initiate ART, With Protocol for Rapid Initiation*.
- 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)

Baseline HIV testing of the exposed individual identifies individuals who were already infected with HIV at the time of presentation (see *Table 1*, below). Results may inform decision-making regarding initiation of ART as treatment for established infection or initiation of 28 days of PEP to prevent HIV infection (see the NYSDOH AI guideline *When to Initiate ART, With Protocol for Rapid Initiation*).

An initial reactive screening result must be confirmed with an HIV Ab differentiation immunoassay, and the PEP regimen should be continued until that result is obtained. Furthermore, the PEP regimen should be continued as rapid ART initiation if the reactive result is confirmed with an Ab differentiation immunoassay or HIV-1 RNA test, and the exposed individual should be referred to an experienced HIV care provider.

→ KEY POINTS

- For initial HIV screening, this Committee and the Centers for Disease Control and Prevention (CDC) recommend using a laboratory-based Ag/Ab combination immunoassay. This type of HIV test can simultaneously detect both HIV-1/HIV-2 antibodies and HIV-1 p24 antigens and will generally be positive within a median of 17.8 days, with an interquartile range of 13 to 23.6 days of infection [Delaney, et al. 2017].
- A negative baseline HIV test only demonstrates that the exposed individual was not previously infected with HIV before the exposure occurred.

## O Exposed Workers

In cases of occupational exposure, exposed workers should be counseled that it is in their best interest to receive a baseline HIV test to document their HIV status at the time of the exposure. In the rare event of seroconversion following an occupational exposure, a negative baseline test is the only way to show that the exposed worker was infected as a result of the exposure.

Baseline HIV testing of the exposed worker is also used to identify individuals who were infected with HIV at the time of the exposure. This allows decisions to be made regarding the continuation of ART (see the NYSDOH AI guideline *When to Initiate ART, With Protocol for Rapid Initiation*). If the baseline screening HIV test is reactive, then the exposed worker should continue the PEP regimen until the result is confirmed with an HIV-1/HIV-2 Ab differentiation immunoassay or HIV-1 RNA test and linkage to an HIV care provider has been established.

Individuals who decline baseline HIV testing risk the possibility of treatment interruption should they initiate PEP and refuse HIV baseline testing. However, refusal of baseline testing should not be a reason to withhold PEP in the event that an exposed worker had a high-risk exposure that warrants a 28-day course of PEP. Furthermore, the clinician should allow for testing to be performed within 3 days of PEP initiation to allow the exposed worker the opportunity to make an informed decision and to accommodate any anxiety or stress related to a possible HIV exposure.

## A Baseline Testing of Exposed Individuals

**Table 1: Baseline Testing Based on Age of Exposed Individual and Type of Exposure**

Test	Age of Exposed Individual and Exposure Type
HIV-1/2 antigen/antibody combination immunoassay (HIV RNA testing may be required in some cases and within 72 hours in some cases)	<ul style="list-style-type: none"> <li>• ≥2 years: All exposures</li> </ul>
Serum liver enzymes, blood urea nitrogen, creatinine	<ul style="list-style-type: none"> <li>• ≥2 years: All exposures</li> </ul>
Complete blood count	<ul style="list-style-type: none"> <li>• 2 to 12 years: All exposures</li> </ul>
Pregnancy (individuals of childbearing capacity)	<ul style="list-style-type: none"> <li>• 2 to 12 years: Sexual exposure</li> <li>• ≥12 years: All exposures</li> </ul>
Hepatitis B serology panel (surface antigen, surface antibody)	<ul style="list-style-type: none"> <li>• ≥2 years: All exposures</li> </ul>
HCV antibody	<ul style="list-style-type: none"> <li>• ≥2 years: All exposures</li> </ul>
Rapid plasma reagin (RPR)	<ul style="list-style-type: none"> <li>• 2 to 12 years: Sexual exposure</li> <li>• ≥12 years: All exposures</li> </ul>
Gonorrhea/chlamydia nucleic acid amplification test (NAAT), by site	<ul style="list-style-type: none"> <li>• 2 to 12 years: Sexual exposure</li> <li>• ≥12 years, consensual sexual exposure</li> <li>• May offer for sexual assault exposure</li> </ul>
Trichomonas NAAT	<ul style="list-style-type: none"> <li>• 2 to 12 years: Sexual exposure</li> <li>• &gt;12 years: Consensual sexual exposure</li> <li>• May offer for sexual assault exposure</li> </ul>
<p><b>Note:</b> In cases of non-sexual exposure in children aged 2 to 12 years, the medical record should be checked for history of tetanus vaccination.</p> <ul style="list-style-type: none"> <li>• HIV RNA testing required in select cases (see guideline section <i>Sequential HIV Testing and Laboratory Monitoring</i>).</li> <li>• HCV RNA testing required in select cases (see guideline section <i>Management of Potential Exposure to Hepatitis C Virus</i>).</li> </ul>	

**\* SELECTED GOOD PRACTICE REMINDERS**

**A ALL EXPOSURES**

- *Test results:* Perform baseline HIV testing of the exposed individual. When results are available, explain them to the patient and ensure understanding.
- *If HIV infection is confirmed in the exposed individual:* Explain the benefits of rapid initiation of ART and provide a referral for HIV care.
- *ART initiation:* Rapid initiation of ART is recommended for all patients diagnosed with HIV. See the NYSDOH AI guideline *When to Initiate ART, With Protocol for Rapid Initiation*.
- *Arrange for HIV care:* If HIV infection is confirmed, or if seroconversion is suspected, or if HIV infection cannot be ruled out, then refer the exposed individual for HIV care and rapid initiation of ART.
- *Pregnancy testing:* Perform pregnancy testing in all individuals of childbearing capacity.
- *Sexually transmitted infections (STIs) other than HIV:* Provide counseling about the risk of acquiring other STIs through sexual exposure and information on signs and symptoms of STIs, and stress the need to seek medical attention if symptoms occur.
  - Sexual assault exposures: See U.S. Department of Justice. *A National Protocol for Sexual Assault Medical Forensic Examinations Adults/Adolescents Second Edition*. 2013. NCJ 228119.
  - See NYSDOH *Sexual Assault Victim Bill of Rights*.
- *Emergency contraception:* Offer emergency contraception to individuals of childbearing potential who report sexual exposure.

**S SEXUAL ASSAULT EXPOSURES**

- *Undetectable equals untransmittable (U=U):* Research has established that a source with HIV who is taking ART and has an undetectable viral load (HIV RNA <200 copies/mL) at the time of a consensual sexual (only) exposure will not transmit the virus through sex [Rodger, et al. 2019; Cohen, et al. 2016; Rodger, et al. 2016].
- *If the source’s viral load at the time of a sexual exposure is available:* Offer information about U=U as reassurance for the exposed individual.
- *U=U pertains only to consensual sexual exposure:* It does not apply to exposure through needle sharing, breastfeeding, or needlestick injury.

## Selecting and Initiating a 28-Day Course of PEP

**RECOMMENDATIONS**

**Preferred Regimens [a]**

- 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; brand name Truvada) or TDF/lamivudine (3TC; brand name 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) [CDC 2016; Günthard, et al. 2016; Ford and Mayer 2015; Kuhar, et al. 2013]. 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*
- 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)

**RECOMMENDATIONS**

**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.

**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)
- 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)

**Note:**

- a. The recommendation regarding discussion of the small risk of teratogenicity with DTG in the first trimester and the need for birth control while completing the 28-day PEP regimen has been removed. DTG has been shown to be safe throughout pregnancy. See the MCCC’s statement on [Use of Dolutegravir in Individuals of Childbearing Capacity](#) for further discussion [Zash, et al. 2022].

**A Considerations and Caveats**

**Suspected seroconversion:** If acute HIV infection is suspected at any time, immediate consultation with a clinician experienced in managing acute HIV infection is advised (see the NYSDOH AI guideline [Diagnosis and Management of Acute HIV](#)). Clinicians can call the Clinical Education Initiative (CEI Line) to speak with an [experienced HIV care provider](#): 1-866-637-2342 (press “1” for HIV PEP). The CEI Line is available 24/7.

**Source confirmed HIV negative:** If the source is confirmed to be HIV negative, the exposed individual’s PEP regimen should be discontinued.

**Use of a 3-drug PEP regimen:** This Committee recommends a 3-drug ARV regimen as the preferred option once the decision has been made to initiate PEP. When the source is known to have HIV, past and current ARV experience, viral load data, and genotypic or phenotypic resistance data (if available) may indicate the use of an alternative PEP regimen. Consult with an [experienced HIV care provider](#).

**Drug-drug interactions and adverse effects:** Care providers should advise patients not to take divalent cations (aluminum, calcium, magnesium) or iron supplements concurrently with DTG or RAL. Metformin dosing should be limited to 1 g by mouth per day when an individual is taking DTG concurrently.

Care providers should counsel patients about the low risk of gastrointestinal adverse effects with TDF/FTC, such as nausea, abdominal bloating, and vomiting, along with headache. A low risk of neuropsychiatric effects with DTG may also exist. RAL has been rarely associated with rhabdomyolysis [FDA 2013].

**RESOURCES**

- [University of Liverpool HIV Drug Interactions](#)
- [University of California, San Francisco HIV InSite Database of Antiretroviral Drug Interactions](#)
- [Prescribers’ Digital Reference Network](#)
- [Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV](#)

**Impaired renal function:** Exposed individuals who have impaired renal function may require dose adjustments of ARV medications used for PEP and may require additional monitoring while completing a 28-day course of PEP [DHHS 2021].

**Hepatitis B virus infection:** Additional monitoring is required for exposed individuals who have HBV infection.

**Tenofovir alafenamide (TAF):** Recommended and alternative regimens do not include TAF because evidence suggests decreased vaginal, cervical, and rectal tissue concentrations of the active form (tenofovir diphosphate) in healthy volunteers [Cottrell, et al. 2017]. This Committee does not recommend including TAF in PEP regimens until further research is completed.

**Adherence and completion requirements:** The recommended 28-day treatment duration is based on limited animal data and expert opinion [Tsai, et al. 1998]. Nonetheless, adherence to a full 28-day course of PEP and completion of therapy is important to prevent HIV seroconversion post exposure.

**Repeated requests for non-occupational PEP:** PEP should not be routinely dismissed solely based on repeated risk behavior or repeat presentation for PEP. See *Risk Reduction* section.

**PEP completion following sexual assault:** Limited data exist on the use of antiretroviral therapy (ART) to prevent HIV infection in sexual assault populations. One study demonstrated higher completion rates (66% vs. 42%) among individuals taking TDF/FTC in combination with DTG or RAL, as compared with those taking TDF/FTC plus darunavir (DRV) boosted with ritonavir (RTV) [Kumar, et al. 2017], suggesting these regimens are better tolerated in this population.

**\* SELECTED GOOD PRACTICE REMINDERS**

**A ALL EXPOSURES**

- *Avoid drug-drug interactions and medication-related adverse events:* Before prescribing a 28-day course of PEP, review the patient’s current medications and comorbidities to identify possible drug-drug interactions and to anticipate and prevent medication-related adverse events. See NYSDOH AI *ART Drug-Drug Interactions*.
- *Impaired renal function:* Review baseline laboratory test results to identify the need to adjust ARV medication dosing for renal insufficiency or choose an alternative regimen. Consult with an experienced HIV care provider or other resources, such as drug package insert(s), to determine dose adjustments for patients with baseline CrCl <50 mL/min.
- *If 28-day PEP is indicated:* Ensure the patient understands the need to complete the full 28 days of PEP and explain the adherence requirements.
  - Make sure the patient understands that if a dose of PEP is missed, a “double-up” dose is not necessary. Instead, if dose is missed at a specific time, it can be taken as soon as it is remembered within 24 hours of the scheduled time.
- *If possible, provide the 28-day supply of medications.* If the full course of medications cannot be provided, then supply a starter pack, as noted below, and a prescription for the medications required to complete 28 days of PEP.
  - Non-occupational exposures: Provide a 7-day starter pack.
  - Occupational exposures: Provide a 7-day (at least) starter pack.
  - Sexual assault exposures (per New York State law): Provide a 7-day starter pack if the patient is ≥18 years old; provide the full, 28-day course of PEP medications if the patient is <18 years old.
- *Ensure the patient’s ability to obtain the medication needed to complete 28 days of PEP.*
- *Discuss possible adverse effects of PEP medications.* Ensure the patient knows what to do if they experience those effects. If an individual who is completing 28 days of PEP does not have a primary care provider with whom to follow-up, the *NYSDOH PrEP/PEP Provider Directory* can be used to identify a care provider for a referral.

## A Preferred PEP Regimens for Patients Who Weigh ≥40 kg

The medications that comprise the recommended PEP regimens (and substitutions) listed in *Table 2: Preferred Post-Exposure Prophylaxis Regimen for Patients Who Weigh ≥40 kg*, below, have favorable adverse effect profiles, fewer potential drug-drug interactions, and expected efficacy similar to older PEP regimens that contained ZDV or PIs. Researchers have reported increased rates of adherence and regimen completion when TDF/FTC or TDF/3TC have been used as components of the PEP regimen [Tosini, et al. 2010; Mayer, et al. 2008]. Observational cohorts and 1 small



randomized study reported improved tolerability with TDF/FTC plus RAL [McAllister, et al. 2017; Mulka, et al. 2016; Mayer, et al. 2012]. Additionally, TDF/FTC has been highly successful in recent studies of pre-exposure prophylaxis [Baeten, et al. 2012; Thigpen, et al. 2012; Grant, et al. 2010]. One observational cohort demonstrated high completion rates with TDF/FTC plus DTG [McAllister, et al. 2017].

Unlike PIs, which block HIV replication after integration with cellular DNA, all currently recommended medications (TDF/FTC plus DTG or RAL) act before viral integration with cellular DNA, providing a theoretical advantage in preventing establishment of HIV infection.

→ KEY POINT

- **ZDV is not recommended for PEP in adults:** This committee no longer recommends the use of ZDV in PEP regimens for adults. ZDV confers no advantage in expected efficacy over TDF, and it has significantly higher rates of treatment-limiting adverse effects. Tolerability is one of the most important factors in completion of the 28-day PEP regimen. ZDV is still recommended for prevention of perinatal HIV transmission.

**Table 2: Preferred Post-Exposure Prophylaxis Regimens for Patients Who Weigh ≥40 kg [a,b]**

Preferred Regimen	Notes
<ul style="list-style-type: none"> <li>• Tenofovir disoproxil fumarate 300 mg/emtricitabine 200 mg (TDF/FTC; Truvada) once per day <b>or</b></li> <li>• TDF 300 mg/lamivudine (TDF/3TC; Cimduo) 300 mg once per day</li> </ul> <p><b>plus</b></p> <ul style="list-style-type: none"> <li>• Raltegravir (RAL; Isentress) 400 mg twice per day <b>or</b></li> <li>• RAL HD 1200 mg once per day [c] <b>or</b></li> <li>• Dolutegravir (DTG; Tivicay) 50 mg once per day</li> </ul>	<ul style="list-style-type: none"> <li>• <b>DTG:</b> <ul style="list-style-type: none"> <li>– Metformin dosing should be limited to 1 g by mouth per day when an individual is taking DTG concurrently.</li> <li>– Magnesium- or aluminum-containing antacids may be taken 2 hours before or 6 hours after DTG; calcium-containing antacids or iron supplements may be taken simultaneously if taken with food.</li> <li>– The recommendation regarding discussion of the small risk of teratogenicity with DTG in the first trimester and the need for birth control while completing the 28-day PEP regimen has been removed. DTG has been shown to be safe throughout pregnancy. See the MCCC’s statement on <i>Use of Dolutegravir in Individuals of Childbearing Capacity</i> for further discussion [Zash, et al. 2022].</li> </ul> </li> <li>• <b>RAL:</b> Magnesium- or aluminum-containing antacids are contraindicated; coadministration of calcium-containing antacids is not recommended with RAL HD.</li> <li>• <b>TDF:</b> Requires dose adjustment for creatinine clearance (CrCl) &lt;50 mL/min. Alternatively, another agent can be considered, in which case consultation with an experienced HIV care provider is advised.</li> <li>• <b>TDF/FTC and TDF/3TC:</b> Dosing should be adjusted in patients with baseline CrCl &lt;50 mL/min.</li> </ul>
<p><b>Notes:</b></p> <p>a. All medications are taken by mouth for 28 days.</p> <p>b. Available alternative formulations and methods of administration:</p> <ul style="list-style-type: none"> <li>– 3TC: Acceptable to crush or split. Available as an oral solution (10 mg/mL).</li> <li>– DTG: Acceptable to crush.</li> <li>– FTC: Acceptable to open and dissolve in water. Available as an oral solution (10 mg/mL).</li> <li>– RAL: Available as a chewable tablet (25 mg, 100 mg) and oral powder for suspension (100 mg/packet); neither is bioequivalent to the 400 mg adult dose.</li> <li>– TDF: Acceptable to dissolve in water. Available as an oral powder only (40 mg/1 g) that can be mixed with soft food.</li> <li>– TDF/FTC: Acceptable to crush and dissolve.</li> </ul> <p>c. RAL HD: May be prescribed for patients who weigh &gt;40 kg; RAL HD should <i>not</i> be prescribed for pregnant individuals.</p>	

## A Alternative PEP Regimens for Patients Who Weigh ≥40 kg

Table 3, below, lists 2 alternative PEP regimens that are acceptable options when a preferred regimen is not available. They are possibly less well tolerated than the preferred regimen of TDF/FTC plus RAL or DTG, but they are significantly

better tolerated than regimens containing ZDV or lopinavir/ritonavir (LPV/RTV). Observational studies have demonstrated excellent tolerability and completion rates [Mayer, et al. 2017; Fätkenheuer, et al. 2016; Valin, et al. 2016].

A single-tablet regimen for a patient with adequate kidney function (CrCl >70 mL/min) and no expected drug-drug interactions may be a good option for those who prefer a once-daily, single-tablet PEP regimen. It also allows use of medication assistance programs if a patient has limited medication coverage options.

**Drug-drug interactions:** The potential for drug-drug interactions in patients receiving PIs or cobicistat (COBI) is increased due to the extensive cytochrome P450 interactions. Clinicians should assess for potential interactions before prescribing a PEP regimen.

Table 3: Alternative Post-Exposure Prophylaxis Regimens for Patients Who Weigh ≥40 kg [a,b]	
Alternative Regimens	Notes
<ul style="list-style-type: none"> <li>Elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg (EVG/COBI/FTC/TDF) as a fixed-dose single tablet once per day (Stribild) [c]</li> </ul>	<ul style="list-style-type: none"> <li><b>For individuals with creatinine clearance (CrCl) &lt;70 mL/min:</b> Fixed-dose single tablet EVG/COBI/TDF/FTC is <i>contraindicated</i>.</li> </ul>
<ul style="list-style-type: none"> <li>TDF 300 mg/FTC 200 mg (Truvada) <i>plus</i> ritonavir (RTV; Norvir) 100 mg <i>plus</i> darunavir (DRV; Prezista) 800 mg once per day [d]</li> <li>Substitutions:                             <ul style="list-style-type: none"> <li>For FTC: Lamivudine (3TC; Epivir) 300 mg once per day.</li> <li>For DRV: Atazanavir (ATV; Reyataz) 300 mg once per day <i>or</i> fosamprenavir (FPV; Lexiva) 1400 mg once per day <i>plus</i> RTV 100 mg once per day.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li><b>For individuals with baseline CrCl &lt;50 mL/min:</b> Adjust dosing of 3TC/FTC plus TDF.</li> </ul>
<p><b>Notes:</b></p> <p>a. All medications are taken by mouth for 28 days.</p> <p>b. Available alternative formulations and methods of administration:</p> <ul style="list-style-type: none"> <li>3TC: Acceptable to crush or split. Available as an oral solution (10 mg/mL).</li> <li>ATV: Acceptable to open capsule and sprinkle contents. Oral dispersible powder (50 mg/packet).</li> <li>DRV: Probably acceptable to crush. Available as an oral suspension (100 mg/mL).</li> <li>DTG: Acceptable to crush.</li> <li>FTC: Acceptable to open and dissolve in water. Available as an oral solution (10 mg/mL).</li> <li>RAL: Available as a chewable tablet (25 mg, 100 mg) and oral powder for suspension (100 mg/packet); neither is bioequivalent to the 400 mg adult dose.</li> <li>RTV: Available as an oral solution (80 mg/mL).</li> <li>TDF: Can be dissolved in water. Available as an oral powder (40 mg/1 g) that can be mixed with soft food only.</li> <li>TDF/FTC: Acceptable to crush and dissolve.</li> </ul> <p>c. Cobicistat-containing regimens should not be used during pregnancy.</p> <p>d. If DRV or ATV are prescribed during pregnancy, dose adjustments are required. See the guideline section <i>PEP During Pregnancy or Breastfeeding</i> or <i>Clinicalinfo.HIV.gov &gt; Table 11. Antiretroviral Drug Use in Pregnant People with HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy</i>.</p>	

**→ KEY POINT**

- Call the Clinical Education Initiative (CEI Line) to speak with an [experienced HIV care provider](#) regarding PEP: 1-866-637-2342 (press “1” for HIV PEP). The CEI Line is available 24/7.

**Other alternative PEP regimens:** Other alternative PEP regimens may be acceptable in certain situations. Some clinicians continue to favor the use of ZDV in PEP regimens based on the results of a retrospective study supporting the efficacy of the agent [Cardo, et al. 1997] and from long-term experience in occupational PEP. Clinicians who continue to prescribe ZDV should recognize and inform patients that the drug is associated with significant adverse effects and that better tolerated agents are available.

Use of LPV/RTV has greater potential for drug-drug interactions and adverse effects than RAL, DTG, or DRV/r (the preferred alternative boosted PI), with little added efficacy benefit expected. Studies have demonstrated decreasing PI resistance among HIV strains [Paquet, et al. 2011], suggesting there may be a diminishing benefit to choosing LPV/RTV for

its activity against resistant HIV strains. DRV/r has excellent activity against many PI-resistant strains and is better tolerated than LPV/RTV.

This Committee recommends a 3-drug regimen because of the greater likelihood of enhanced effectiveness; however, if tolerability is a concern, use of a 2-drug regimen would be preferred to discontinuing the regimen completely. An early case-control study of occupational exposure demonstrated an 81% reduction in seroconversion with the use of ZDV monotherapy alone [Cardo, et al. 1997], suggesting that treatment with any active ARV agent is beneficial in reducing risk. Other studies have investigated 2-drug PEP regimens and found excellent tolerability [Kumar, et al. 2017; Mayer, et al. 2008].

## C PEP Regimens for Patients Who Weigh <40 kg

**Pediatric PEP lead author:** Aracelis Fernandez, MD, with Lisa-Gaye Robinson, MD, and Ruby Fayorsey, MD

No clinical studies are available to determine the best regimens for HIV PEP in children. The recommendations for drug choices and dosages presented here follow current U.S. Department of Health and Human Services recommendations in *Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection*, which are based on expert opinion. The recommended regimens reflect experience with ARV combinations that effectively suppress viral replication in children with HIV and with combinations that are well tolerated and increase adherence to PEP. The chosen preferred regimens have demonstrated good potency and tolerability.

The alternative PEP regimens for children are also based on expert opinion. They all have demonstrated potent antiviral activity. However, the PI-containing regimens are often more difficult to tolerate, secondary to gastrointestinal adverse effects. To improve adherence, clinicians can and should prescribe preemptive antiemetics for anticipated gastrointestinal adverse effects.

When choosing a PEP regimen, care providers should consider factors that may affect adherence, such as ARV drug intolerance, regimen complexity, expense, and drug availability.

Table 4: Post-Exposure Prophylaxis Regimens for Patients 2 to 12 Years Old Who Weigh <40 kg [a]
<p>See DHHS for dosing, administration, and additional information about each medication. Each medication name below is linked to a page about that medication.</p> <ul style="list-style-type: none"> <li>• <b>Preferred:</b> Tenofovir disoproxil fumarate (TDF; Viread) plus emtricitabine (FTC; Emtriva) plus raltegravir (RAL; Isentress). TDF/FTC is available as the fixed-dose combination (Truvada).</li> <li>• <b>Substitutions:</b> <ul style="list-style-type: none"> <li>– Lamivudine (3TC; Epivir) may be substituted for FTC.</li> <li>– Dolutegravir (DTG; Tivicay) may be substituted for RAL.</li> </ul> </li> <li>• <b>Alternatives:</b> <ul style="list-style-type: none"> <li>– <b>Age ≥2 years to 12 years:</b> Zidovudine (ZDV; Retrovir) plus 3TC (Epivir) plus RAL (Isentress) or lopinavir/ritonavir (LPV/RTV; Kaletra).</li> <li>– <b>Age ≥3 years to &lt;12 years:</b> TDF (Viread) plus FTC (Emtriva) plus darunavir (DRV/Prezista) plus ritonavir (RTV; Norvir).                             <ul style="list-style-type: none"> <li>○ <b>Substitution:</b> 3TC (Epivir) may be substituted for FTC.</li> </ul> </li> </ul> </li> </ul>

→ KEY POINTS
<ul style="list-style-type: none"> <li>• A systematic review of several studies that included ARV medications used as PEP in children exposed to HIV and of antiretroviral therapy (ART) for children with HIV reported a 4.5% rate of discontinuation due to adverse events [Penazzato, et al. 2015].</li> <li>• Limited data exist on dosing or safety for some ARV agents, including INSTIs, used in children.</li> <li>• Poor palatability of liquid medication preparations and high pill burden of some pediatric dose formulations can also affect adherence to the PEP regimen.</li> </ul>

## A ARV Medications to Avoid for PEP

Newer ARV medications have demonstrated significantly fewer adverse effects than older ARVs. The medications listed in *Table 5*, below, should be avoided.

Table 5: Antiretroviral (ARV) Medications to Avoid for Post-Exposure Prophylaxis				
ARV Class	Agent	<40 kg	≥40 kg	Comments
First-generation protease inhibitors	<ul style="list-style-type: none"> <li>Indinavir (IDV; Crixivan)</li> <li>Nelfinavir (NFV; Viracept)</li> </ul>	Avoid	Avoid	Poorly tolerated.
First-generation non-nucleoside reverse transcriptase inhibitors	<ul style="list-style-type: none"> <li>Efavirenz (EFV; Sustiva)</li> <li>Nevirapine (NVP; Viramune)</li> </ul>	Avoid	Avoid	<ul style="list-style-type: none"> <li><b>EFV:</b> Potential for neuropsychiatric adverse effects.</li> <li><b>NVP:</b> Associated with fulminant hepatic failure and risk of Stevens-Johnson syndrome [CDC 2001b].</li> </ul>
Nucleoside reverse transcriptase inhibitors	<ul style="list-style-type: none"> <li>Abacavir (ABC; Ziagen)</li> <li>Didanosine (ddl; Videx)</li> <li>Stavudine (d4T; Zerit)</li> <li>Tenofovir alafenamide (TAF)</li> <li>Zidovudine (ZDV, AZT; Retrovir)</li> </ul>	Avoid d4T, ddl, ABC, TAF	Avoid all	<ul style="list-style-type: none"> <li><b>ABC:</b> Potential for serious, sometimes fatal hypersensitivity reaction.</li> <li><b>d4T, ddl, ZDV:</b> Significant mitochondrial toxicities.</li> <li><b>TAF:</b> Decreased vaginal, cervical, and rectal tissue concentrations of the active moiety of (tenofovir diphosphate) in healthy volunteers [Cottrell, et al. 2017].</li> </ul>
CCR5 antagonist	Maraviroc (MVC; Selzentry)	Avoid	Avoid	Only shows activity against R5-tropic virus.

Consultation with an [experienced HIV care provider](#) is recommended before using any of the medications listed above for PEP, or before using etravirine or doravirine, for which limited data exist.

## A PEP During Pregnancy or Breastfeeding

Use of ARV prophylaxis in pregnancy generally does not increase the risk of birth defects [DHHS 2021]. ARV prophylaxis can prevent HIV transmission during acute infection in pregnancy, when viral loads are extremely high, which is associated with a high risk of infection to the infant [Patterson KB, et al. 2007]. No severe adverse effects or adverse pregnancy outcomes have been noted among women taking ART for PEP [CDC 2016]. However, no clinical trial data regarding PEP use in pregnant individuals are currently available [CDC 2016], and data are limited on the use of integrase inhibitors during pregnancy [DHHS 2021].

→ **KEY POINT**

- In addition to the risk of seroconversion for the exposed individual, the high viral load levels associated with early or acute HIV infection markedly increase the risk of transmission to the fetus or breastfeeding infant.

When screening for HIV in pregnant patients, care providers should be aware that detection of early/acute HIV infection requires HIV RNA testing in most instances and should repeat antibody testing as late as the third trimester [Wertz, et al. 2011] when screening for HIV infection in pregnant patients.

Current U.S. Department of Health and Human Services guidelines require dose adjustments for DRV and atazanavir (ATV) [DHHS 2021]:

- DRV (Prezista): 600 mg twice per day plus RTV (Norvir) 100 mg twice per day.
- ATV (Reyataz): 400 mg once per day plus RTV 100 mg once per day *in the third trimester*.

Although birth defects and adverse effects on human fetuses have generally not been associated with the ARV agents that are currently available, exposure of a fetus to ARV agents during pregnancy carries a theoretical risk of embryotoxicity.

**ARV medications to avoid as PEP during pregnancy:** The [ARV medications to be avoided for PEP](#) above also apply to pregnant individuals. Based on animal data, there has been a theoretical concern for teratogenicity of EFV in the first trimester; however, current federal perinatal guidelines do not preclude its use [DHHS 2021; Martinez de Tejada, et al. 2019]. ZDV is still recommended for prevention of perinatal HIV transmission.

**PEP during breastfeeding:** Initiation of PEP in exposed individuals who are breastfeeding requires careful discussion. Both HIV and ARV medications may be found in breast milk; therefore, breastfeeding should be avoided for 3 months after the exposure to prevent HIV transmission and potential drug toxicities [American Academy of Pediatrics 2013]. Clinicians should discuss the risks and benefits with the patient. The infant's pediatrician should be informed of any potential exposure to HIV or ARV medications.

## A Adherence and Completion of the 28-Day PEP Regimen

Reported adherence to a 28-day PEP regimen has historically been modest (40%-60%) [Lunding, et al. 2010; Day, et al. 2006; Parkin, et al. 2000]. However, increased rates of adherence have been reported in studies of PEP regimens that include TDF/FTC or TDF/3TC plus a third agent [Tosini, et al. 2010; Mayer, et al. 2008], and some have reported improved tolerability with use of TDF/FTC plus DTG or RAL [McAllister, et al. 2017; Mulka, et al. 2016; Mayer, et al. 2012].

**Single-tablet regimens:** With the availability of several single-tablet regimens, many clinicians prefer them for PEP to optimize adherence or to use commercial medication assistance programs that may be available to uninsured or under-insured individuals. Several recently published observational prospective cohort studies support this approach:

- Two recently published studies examined the use of fixed-dose TDF/FTC/elvitegravir (EVG)/COBI (Stribild) as PEP in observational prospective cohorts in France and Boston. In the French cohort, 92% of participants completed 28 days of PEP, and only 3 individuals switched to another regimen due to adverse effects [Valin, et al. 2016]. Lower rates of completion were noted in the Boston group, with 71% completing the 28-day course as prescribed (no missed doses), 15% stopping or modifying their dosing, and 14% lost to follow-up [Mayer, et al. 2017]. Both cohorts reported gastrointestinal adverse effects as the most common adverse events. Neither study documented HIV seroconversions.
- Results of a 2015 open-label, single-arm study conducted at 2 public sexual health clinics and 2 hospital emergency departments in Australia demonstrated high PEP completion rates (92%) and no HIV seroconversions with fixed-dose single tablet TDF/FTC/rilpivirine (RPV; Complera). Most participants (86%) reported taking all doses with food, and 95% of those who completed the full course endorsed taking the medication with food. The authors acknowledge that they studied TDF/FTC/RPV in a population with a low background of transmitted nucleoside reverse transcriptase inhibitor (NRTI) (4.1%) and non-NRTI (3.1%) resistance and that this combination should be used carefully in populations with higher rates of transmitted resistance [Foster, et al. 2015].

The Centers for Disease Control and Prevention (CDC) and this Committee recommend DTG as a third agent (and alternative to RAL). A recent open-label, single-arm study at 3 sexual health clinics and 2 emergency departments in Australia found completion rates of 90% and no seroconversions with use of DTG plus TDF/FTC as PEP. Adherence was 98%, measured by pill count and consistent with drug levels, and no unexpected adverse events or serious adverse events occurred [McAllister, et al. 2017].

Alternatively, a once-daily PI-based PEP regimen of DRV/r plus 2 NRTIs has demonstrated lower discontinuation rates compared with LPV/r or EFV plus 2 NRTIs, without significant adverse events [Fätkenheuer, et al. 2016]. Together, these study results demonstrate that once-daily PEP regimens with multiple pills can be well tolerated and have high completion rates.

Regimens containing ZDV and LPV/r had lower rates of completion and higher rates of discontinuation due to adverse effects [Leal, et al. 2016a; Ford, et al. 2015]. Many agency guidelines switched first-line recommendations to include RAL as a third agent because it had a more favorable adverse effect profile and fewer drug-drug interactions [McAllister, et al. 2014; Mayer, et al. 2012]. However, given the twice-daily dosing of RAL, nearly one-fourth of one cohort on PEP missed the afternoon dose [Mayer, et al. 2012], which suggests that adherence to a RAL-based regimen is challenging.

## A Extending PEP Beyond 28 Days

It is rare that PEP is extended beyond the standard 28-day regimen. The only circumstances under which PEP would be extended include the following:

- The exposed individual has an indeterminate HIV test result at 4 weeks post exposure or is experiencing acute retroviral syndrome at 4 weeks post exposure.
- The exposed individual is pregnant and there is a high probability of HIV exposure, given the risk of viral rebound in pregnancy.

In these cases, the care provider should consult with an [experienced HIV care provider](#). Otherwise, no data are available to support extending PEP beyond 28 days to prevent HIV infection following an exposure within the previous 28 days.

## Counseling and Patient Education

The checklist in *Box 8*, below, includes topics for patient education for an individual exposed to HIV who has presented for post-exposure prophylaxis (PEP) or for the parent(s) or guardian(s) accompanying a child who is being evaluated for or initiated on PEP.

<b>A</b>	<b>Box 8: PEP Patient Education Checklist</b>
<i>Address each item in clear, direct, easy-to-understand language and assess the individual’s comprehension of each topic before moving on.</i>	
<b>Addressed and Understood:</b>	
	Reason for administering the first dose of PEP immediately.
	Process for evaluating the likelihood that the individual was exposed to HIV and the risk of infection.
	Use of PEP to help prevent HIV infection: Benefits, effectiveness, timing, and duration.
	Purpose of the HIV test and interpretation of results.
	Other baseline laboratory testing requirements and their purpose.
	What will happen if the exposed individual’s first HIV test is positive.
	If the source is available, what will happen if the source’s HIV test is positive.
	Follow-up visit and testing schedule and purpose.
	Possible drug-drug interactions: Evaluate the individual’s current medication list (e.g., prescription, over-the-counter, herbals, vitamins, supplements).
	How and when to take the PEP medications, including timing and food requirements.
	Prescription for the additional 21 days of PEP: Where and when to get it filled and how to pay for the medications; provide information about sources of payment assistance if needed. See: <ul style="list-style-type: none"> <li>• <a href="#">NYSDOH Payment Options for Adults and Adolescents for PEP Following Sexual Assault</a>.</li> <li>• <a href="#">NYSDOH Payment Options for Adults and Adolescents for PEP for All Other Non-Occupational Exposures</a>.</li> <li>• For programs within New York City, see <a href="#">Where to Get PrEP and PEP in New York City</a>.</li> </ul>
	Possible adverse effects and what to do if they occur.
	Importance of adherence to the prescribed regimen: <ul style="list-style-type: none"> <li>• What “adherence” means.</li> <li>• How to achieve success with adherence.</li> </ul>
	What to do if a dose of PEP is missed.
	Signs and symptoms of acute HIV infection and what to do if they occur.

☆ NEW YORK STATE LAW

- [New York Consolidated Laws, Public Health Law – PBH Article 2305](#) has long established the legal capacity of minors to consent to treatment and preventive services for sexually transmitted diseases (STDs). Provisions in Article 2305 require that the Commissioner of Health promulgate a list of STDs. A 2017 amendment to Article 2305 added HIV to the list of STDs, thereby bringing the capacity of minors to consent to HIV treatment and preventive services on par with that for other STDs.
- In addition, under Article 2305, medical or billing records may not be released or made available to the parent or guardian without the minor patient’s permission. For more information, see [NYS Register/April 12, 2017: Rule Making Activities](#).

**Information about serial HIV testing:** Clinicians should educate the exposed individual about the “window period” of HIV infection and the importance of serial HIV testing to avoid a false-negative result during the early stages of infection. A negative baseline HIV test does not confirm negative status, so further testing at 4 and 12 weeks post exposure can determine seroconversion in any exposed individual, whether PEP is taken or not.

Clinicians should arrange appropriate medical follow-up for the exposed individual, particularly if an emergency department performed the initial evaluation and treatment. Appropriate medical follow-up includes access to a care provider in the event of possible PEP-related adverse effects or symptoms suggestive of acute retroviral syndrome (ARS). Toward that end, the exposed individual should be provided with a telephone number to reach an outpatient medical facility that can provide treatment within 24 hours to address adverse effects or to evaluate for ARS.

**Symptoms of acute HIV infection:** Inform exposed individuals about the possible symptoms of acute HIV:

- Influenza- or mononucleosis-like illness
- Fever and night sweats
- Lymphadenopathy
- Myalgias
- Arthralgias
- Sore throat
- Fatigue or malaise
- Headache
- Generalized rash
- Mucocutaneous ulcers
- Meningismus
- Oropharyngeal candidiasis

For additional information, see the NYSDOH AI guideline [Diagnosis and Management of Acute HIV Infection > Presentation and Diagnosis](#).

Because of the similarity of acute HIV infection to influenza- or mononucleosis-like illnesses, the exposed individual should be encouraged to seek medical attention if these symptoms develop, regardless of PEP use. The exposed individual should also be educated about the high risk of HIV transmission during acute HIV infection.

**Adherence to the PEP regimen:** Education about adherence should stress the need to take all doses of PEP medications as directed and to complete the 28 days of PEP unless otherwise directed. Make sure the patient understands that if a dose of PEP medications is missed, a “double-up” dose is not necessary. Instead, if dose is missed at a specific time, it can be taken as soon as it is remembered within 24 hours of the scheduled time.

**Risk reduction:** Individuals who present with potential HIV exposures as a result of ongoing engagement in risk behavior should be referred for pre-exposure prophylaxis (PrEP). See the NYSDOH AI guideline [PrEP to Prevent HIV and Promote Sexual Health](#).

An individual’s intent to change behavior should be assessed, and an individualized risk-reduction plan should be developed. After completion of the 28-day PEP regimen, initiation of PrEP should be considered.

**O Occupational risk reduction:** To decrease the risk of future exposures, employers are required to provide education regarding the prevention of needlestick injury at the time of hire and annually thereafter. Each institution should have internal protocols consistent with current state and federal laws.

**C Information for an exposed child and family:** A potential HIV exposure in a child is likely to be an emotionally challenging situation for the family. Care providers should assess the health literacy of the parent(s) or guardian(s) and provide information at the appropriate level of understanding. Information should include risk of HIV acquisition

based on type of exposure (see guideline section *Risk of Infection Following an Exposure to HIV*). This risk data may provide some reassuring perspective to the parent(s) or guardian(s). Emphasize that when PEP is initiated within the 72 hours following HIV exposure, failure is rare.

**RESOURCES**

- *A National Protocol for Sexual Abuse Medical Forensic Examinations – Pediatric*
- *CHAMP – Child Abuse Medical Provider Program*
- *New York State Children’s Alliance – Child Advocacy Centers*

**\* SELECTED GOOD PRACTICE REMINDERS**

**A ALL EXPOSURES**

- *If HIV infection is confirmed in the exposed individual:* Explain the benefits of rapid initiation of antiretroviral therapy and provide a referral for HIV care.
- *Trauma care:* Provide information and a referral if the exposed individual would benefit from counseling or trauma care that addresses, among other issues, fear of HIV infection, and candidacy for PEP.
- *Discuss signs and symptoms of acute retroviral syndrome (ARS):* Stress the need for immediate medical attention if symptoms of ARS occur and provide the exposed individual with appropriate access to HIV testing that includes HIV RNA testing if indicated.

**N NON-OCCUPATIONAL EXPOSURES**

- *Risk reduction:* Individuals who report ongoing high-risk sexual exposure are candidates for PrEP.
  - If PEP is not indicated for the current exposure, discuss initiation of PrEP immediately once negative HIV status is confirmed.
  - If PEP is indicated, upon completion of PEP, and once negative HIV status is confirmed, start PrEP.
- *Referrals:* If the clinical setting in which an individual presents for PEP does not support evaluation for and provision of PrEP, then the patient should be given a referral for PrEP care.

**C EXPOSURES IN CHILDREN**

- *Families of children exposed to HIV:* In addition to the child exposed to HIV, parent(s), guardian(s), and other family members may also benefit from trauma care.

## Providing PEP Medications and Other Services

**RECOMMENDATIONS**

**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)



**RECOMMENDATIONS**

- **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)

## PEP Starter Pack

Starter packs may reduce the time to PEP initiation and have been used in several PEP protocols, including emergency department visits following sexual assault [Kumar, et al. 2017; Muriuki, et al. 2017; Krause, et al. 2014]. If a 28-day supply of medications cannot be provided, then in most cases, a 7-day supply will allow an individual sufficient time to access the additional medications needed to complete the full course of treatment. Patients who receive a 7-day starter pack should be informed that it does not contain the full 28-day course of PEP medication and assisted in creating a plan to obtain the rest of the required medications.

**→ KEY POINTS**

- Clinicians have an ethical responsibility to ensure a timely, uninterrupted supply of PEP medications for the patient.
- If possible, provide 28 days of PEP medications to all patients. If it is not possible to provide the full course of medications, then a 7-day starter pack is recommended for patients all types of exposures. The exception is sexual assault exposure in an individual who is <18 years old. By law, all sexual assault patients <18 years old must be provided with the full 28-day course of PEP medications. See [The New York State Senate > The Laws of New York/Consolidated Laws/Public Health/Article 28: Hospitals Section 2805-l: Treatment of sexual offense victims and maintenance of evidence in a sexual offense.](#)

## O Payment For Occupational PEP

**Federal law requires covered employers to ensure that all medical evaluations and procedures, vaccines, and post-exposure prophylaxis are made available to the employee within a reasonable time, at a reasonable location, and at no cost to the employee** (OSHA, 1910.1030 Bloodborne Pathogens).

The *New York Public Employee Safety Health Act (PESH)* and Occupational Safety and Health Administration (OSHA)'s *Bloodborne Pathogen Standards* indicate that the covered employer is responsible for all costs associated with an exposure incident. An employer may not require any out-of-pocket expenditures on behalf of the employee, such as requiring the employee to utilize workers' compensation if prepayment is required or compelling an employee to use health insurance to cover these expenses unless the employer pays all premiums and deductible costs associated with the employees' health insurance.

**Federal law:** Federal law mandates that employers must ensure that all medical evaluations and procedures, vaccines, and PEP medications (7-day starter pack and access to the full 28-day course of medications) are made available to the employee within a reasonable time, at a reasonable location, and at no cost to the employee (OSHA, 1910.1030 Bloodborne Pathogens).

Employers should determine who will pay for PEP and establish policies for submitting claims to their workers' compensation plans. Employers should not expect exposed workers to pay out of pocket for PEP, including copays, even if they are reimbursed at a later date.

## N Payment Assistance For Non-Occupational PEP

Care providers should ensure that a patient can acquire the medications needed to continue PEP through 28 days regardless of insurance coverage status. Options for patients who are uninsured or under-insured include medication assistance programs (MAPs) and health centers specifically funded to provide PEP at no or low cost.

If an individual has prescription drug coverage, third-party reimbursement may cover PEP, depending on the plan's prescription drug policy. If a medication-dispensing facility does not receive reimbursement for these services, such

expenses may be included in their annual *Institutional Cost Report* as part of indigent care costs. For patients who are paying out of pocket, cost is a factor in selecting a regimen.

→ KEY POINT

- Patients who have no alternative means of coverage or payment for PEP medications may need assistance with enrolling in payment assistance programs.

**MAPs:** MAPs are available for individuals who do not have insurance coverage for PEP and who meet certain criteria and cover several drugs included in the recommended PEP regimens:

- Fixed-dose tenofovir disoproxil/emtricitabine (TDF/FTC; Truvada).
- Dolutegravir (DTG; Tivicay).
- Raltegravir (RAL; Isentress).
- Single-tablet, fixed-dose elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate (EVG/COBI/FTC/TDF; Stribild), a preferred alternative PEP regimen.

Clinicians should work with social workers and support staff to enroll patients in these programs, if indicated, to provide PEP to patients without alternative means of coverage or payment. These programs often provide 1 course of PEP. Obtaining future courses may be challenging, so clinicians should consider whether pre-exposure prophylaxis is appropriate for patients who receive PEP from a MAP.

## C Payment For PEP Medications for Exposed Children

In New York State, all children qualify for health insurance regardless of their immigration status. Payment difficulties may arise for patients who have private insurance with high medication copays.

### RESOURCES

- *NYSDOH Payment Options for Adults and Adolescents for Post-Exposure Prophylaxis (PEP) Following Sexual Assault*
- *NYSDOH Payment Options for Adults and Adolescents for Post-Exposure Prophylaxis for All Other Non-Occupational Exposures (nPEP)*
- For programs within New York City, see *Where to Get PrEP and PEP in New York City*.

## S Payment Methods For PEP Following Sexual Assault

Various methods of payment for PEP are available for victims of sexual assault, including Medicaid, Medicare, or the *New York State (NYS) Office of Victim Services (OVS)*.

- See *NYSDOH Payment Options for Adults and Adolescents for PEP Following Sexual Assault*.

**Medication starter pack:** Timely initiation of medication is crucial to the success of PEP, and amendments to *Public Health Law section 2805-i* and *Executive Law section 631* effective June 15, 2020, require hospitals providing treatment to survivors of sexual assault to:

- Offer and make available a 7-day starter pack of HIV PEP to survivors of sexual assault who are ≥18 years old *and*
- Offer and make available the full 28-day supply of HIV PEP to survivors of sexual assault who are <18 years old.

Additionally, there are changes to hospital reimbursement for HIV PEP and sexual assault forensic exams. See the NYSDOH letter *Dear Colleague HIV PEP Guidance Update* for additional details.

☆ NEW YORK STATE LAW

- **New York State law** mandates the provision of a 7-day starter pack of PEP medications to individuals >18 years old who have been sexually assaulted. If a sexual assault patient is <18 years old, then New York State Law mandates provision of the full, 28-day course of PEP medications. See the NYSDOH letter *Dear Colleague HIV PEP Guidance Update* for additional details.
- **Follow-up:** Effective November 27, 2012, hospitals providing treatment to victims of sexual assault are required to provide or schedule an appointment for medical follow-up related to PEP and other care as appropriate.
  - See **Letter: Chapter 39 of the Laws of 2012 amending Section 2805-i of PHL.**

**Right to decline provision of private health insurance:** Under New York State law, hospitals must notify sexual assault patients, orally and in writing, of their right to decline to provide private health insurance information for billing for a forensic rape examination (FRE). If a sexual assault patient declines to provide such information, the hospital is prohibited from billing the patient or their insurance company for the FRE. Instead, the hospital may bill the OVS for the FRE. A minor patient may sign the FRE claim form so the facility can seek reimbursement for the sexual assault examination through the FRE program; however, it must be reasonable to conclude that the minor understands what they are signing and why.

Hospitals are required to advise sexual assault patients orally and in writing that they may decline to provide information about private health insurance benefits if they believe that provision of such information will substantially interfere with their privacy or safety. If patients so decline, then with the patient’s consent, OVS will be billed directly.

Follow-up PEP costs beyond the initial 7-day period and the costs of follow-up medical treatment needed as a result of the sexual assault will, for insured patients, continue to be reimbursed through the survivor/patient’s insurance, Medicaid, or another insurance program because OVS is the payor of last resort; however, OVS may consider the patient’s out-of-pocket responsibility for reimbursement. If a sexual assault patient is not insured or is a minor, a full OVS claim application should be filed. Minors are permitted to sign only the FRE claim form.

## Follow-Up of the Exposed Individual

☑ RECOMMENDATIONS

- **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.*

### A Initial and Ongoing Follow-Up

**Initial follow-up within 48 hours:** Clinicians should follow up with the exposed individual within 48 hours, either by telephone call or in person, to assess PEP tolerability and adherence and to confirm access to the medications required to complete the full 28-day PEP regimen. If the patient has difficulty accessing the prescribed PEP medications, a social worker or patient navigator should be engaged to explore options and assist with medication access.

Follow-up care is necessary for patients taking PEP medications, to monitor for adverse effects and maximize adherence. Patients who report adverse effects by telephone should be evaluated in person if they require a physical examination (e.g., new rash or severe gastrointestinal symptoms such as abdominal pain, nausea, vomiting, and diarrhea). If the patient does not tolerate the recommended regimen well, an early switch to an alternative regimen is encouraged to improve adherence. Consultation with an **experienced HIV care provider** is advised when a patient’s PEP regimen must be changed.

Discuss the best method of contact for any adolescent or young adult who does not wish to disclose HIV exposure to parent(s) or guardian(s) and make sure to note the confidential phone number or method of contact.

**Adherence support:** Follow-up should also include discussions of daily adherence and reminders to complete the full 28 days of PEP. Clinicians should be aware of community resources for medical and supportive counseling/adherence services that a patient may need following non-occupational exposure.

- [Resources for PEP for providers and patients](#) can be found at the NYSDOH website.

**Ongoing follow-up:** After the initial follow-up within 48 hours, a care provider or member of the PEP care team (such as a registered nurse, social worker, or patient navigator) should follow up with the patient by telephone or in-person visit by week 2 to further assess for adverse effects and confirm access to the medications required to complete the full 28-day course of PEP.

Patients who experience intolerable adverse effects may require in-person evaluation by a healthcare provider. Consultation with an [experienced HIV care provider](#) is advised if a switch to an alternative PEP regimen is required.

Care providers should pay particular attention to any symptoms suggestive of [acute retroviral syndrome](#).

## N Risk Reduction

**Transition to PrEP:** Patients who remain at high risk of exposure after completing a course of non-occupational PEP and who are negative for HIV at the time of the 4-week HIV test should be offered PrEP, to begin immediately after the last dose of non-occupational PEP.

In a case-control study in Barcelona of possible predictors for HIV seroconversion among individuals using non-occupational PEP, independent factors associated with HIV seroconversion included being a man who has sex with men (MSM), having a known partner with HIV, taking a previous course of PEP, and having prior sexually transmitted infections (STIs) [Leal, et al. 2016b]. Several observational cohort studies have noted high rates of HIV seroconversion among PEP users beyond the initial 3-month period after a potential exposure to HIV. These seroconversions are likely due to ongoing risk behaviors that may have been prevented by repeated courses of PEP or, more suitably, use of PrEP. At a large sexual health clinic in London where PEP was prescribed to 530 MSM over a 6-month period in 2013, 183 men received repeat PEP, and the incidence of repeat PEP was 24 per 100 person-years. Among the 57 men who acquired HIV, 12 could not be ruled out as experiencing PEP failure, and HIV incidence was 7.6 per 100 person-years [Whitlock, et al. 2017]. High rates of incident HIV have also been seen among non-occupational PEP recipients in Amsterdam, Australia, and Boston [Jain, et al. 2015; Heuker, et al. 2012; Poynten, et al. 2009].

### RESOURCES

- [NYSDOH Syringe Access and Disposal, including Syringe Exchange Programs](#)
- [NYSDOH Expanded Syringe Access Program \(ESAP\)](#)
- [NYSDOH AI guideline: PrEP to Prevent HIV and Promote Sexual Health](#)
- [NYSDOH PrEP/PEP Voluntary Provider Directory](#)
- [Payment Options for Adults and Adolescents for PrEP](#)

## S Follow-Up of Sexual Assault Patients

If a sexual assault patient is too distraught to engage in discussion and decision-making about PEP, then the care provider should encourage the individual to take a single dose of PEP and revisit the discussion the following day. The risk of taking one dose is minimal, and the efficacy that would be lost if delayed a whole day may be salvaged. If the individual decides to defer the decision to initiate PEP, then a follow-up visit within 24 hours should be scheduled to ensure that PEP is started as soon as possible and no later than 72 hours post exposure.

**Resources and support for sexual assault patients:** Sexual assault patients may require additional resources and support to ensure adherence to the daily PEP regimen and completion of the 28-day course. In a retrospective cohort study in Nairobi, Kenya, PEP was initiated in only 54% of cases involving sexual assault, and victims had low overall rates of

completion of PEP (34%) and low rates (10%) of repeat HIV testing at 3 months [Muriuki, et al. 2017]. Similar low rates of PEP completion (27%) were noted in sexual assault patients at an academic medical center in Boston, MA [Krause, et al. 2014].

Specific factors in this population may influence the acceptance of PEP. For instance, an analysis of forensic nurse examinations in the Mid-Atlantic region of the United States found that patients with injuries to the anus or genitalia were more likely to initiate PEP than patients with injuries to the face or head [Draughon Moret, et al. 2016]. These data suggest that sexual assault patients may need additional in-person visits or follow-up telephone calls from patient navigators, and social workers, and medical monitoring for adverse effects.

The treating clinician, preferably a sexual assault forensic examiner (SAFE), must coordinate care to encourage medical follow-up and adherence to PEP. The rape crisis advocate may become the crucial link between the sexual assault patient and the care provider, clarifying communication and facilitating follow-up care for the patient. When the patient does not have a primary care provider or has difficulty arranging access to a clinician experienced in HIV PEP, this link is especially important. Support from the advocate increases the likelihood that the sexual assault patient will adhere to the PEP regimen and that the primary care provider, PEP prescriber, or SAFE will be notified of medical problems. The advocate can also ensure that problems are addressed expeditiously as they arise.

→ KEY POINT

- Sexual assault patients may need focused encouragement and support from clinicians and other care providers to initiate PEP and to adhere to the medication regimen for 28 days when it is indicated.

\* SELECTED GOOD PRACTICE REMINDERS

**A ALL EXPOSURES**

- *Discuss signs and symptoms of acute retroviral syndrome:* Stress the need for immediate medical attention if [these symptoms](#) occur, and provide appropriate access to HIV testing that includes HIV RNA testing if indicated.
- *Follow up in person or by telephone within 48 hours to accomplish the following:*
  - Assess for signs or symptoms of acute HIV.
  - Review and confirm the decision to complete the full 28-day course of PEP and confirm that the patient has access to required PEP medications.
  - Assess for and advise on the management of adverse effects associated with PEP medications as needed.
  - Encourage adherence to the PEP regimen.
- Make referrals or arrangements for follow-up care as needed, including referral to an experienced HIV care provider if needed.

**N NON-OCCUPATIONAL EXPOSURES**

- *STI testing:* Consider STI testing at week 2 in cases of sexual exposure.
- *If ongoing exposure risk is high:* Counsel and educate the patient about risk reduction, including the availability of PrEP.
- *Refer for PrEP:* If the clinical setting in which an individual presents for PEP does not support evaluation for and provision of PrEP, then the patient should be given a referral for PrEP care.

**S SEXUAL ASSAULT EXPOSURES**

- *Plan for follow-up care:* Review the plan for follow-up care with the patient and with a rape crisis counselor or outreach worker who will follow the patient after discharge from the emergency department or other healthcare setting.
- *Empiric STI treatment:* Confirm that empiric treatment for gonorrhea, chlamydia, and trichomonas was given at the initial presentation.
- *STI testing:* Baseline testing for STIs may be offered, along with syphilis testing at week 2.



# Sequential HIV Testing and Laboratory Monitoring

**Lead author:** Elliot DeHaan, MD, with the *Medical Care Criteria Committee*; November 2021

**Lead authors of material on PEP in children:** Aracelis Fernandez, MD, with Lisa-Gaye Robinson, MD, and Ruby Fayorsey, MD

## RECOMMENDATIONS

### 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 laboratory-based HIV-1/2 antigen/antibody (Ag/Ab) combination immunoassay screening test. (A2)
  - Point-of-care (POC) HIV tests can be used at 4 and 12 weeks only if they are Ag/Ab combination immunoassays; 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.
- If an exposed individual's HIV screening test result is reactive at any time, clinicians should perform an FDA-approved confirmatory HIV-1/HIV-2 Ab differentiation immunoassay. (A1)

### Sequential HIV Testing and Laboratory Monitoring: 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; an Ag/Ab combination immunoassay is the recommended serologic screening test.

During the 28-day PEP treatment period, laboratory tests may be indicated to monitor for adverse effects of treatment. The timing and specific testing indicated varies based on the PEP regimen used (see *Table 6: Recommended Monitoring After Post-Exposure Prophylaxis Initiation*, below).

Renal and liver function tests may be repeated during the 28-day follow-up period in the event of abnormal baseline renal or liver function tests (grade 1 abnormalities or higher). In one New York City PEP cohort, only 32 individuals (2.9%) and 95 individuals (8.5%) had abnormal renal function or liver function tests at baseline [Mikati, et al. 2019]. Follow-up testing found mostly grade 1 abnormalities, and no PEP regimens were changed because of renal function or liver function abnormalities. Repeat renal and liver function testing is advised for patients with decreased urine output, abdominal pain, nausea, vomiting, jaundice, or diarrhea.

Repeat sexually transmitted infection (STI) screening for non-occupational PEP following sexual exposure should also be considered at week 2 to assess for possible bacterial STI infection at the time of the potential HIV exposure, which would not have been detected with baseline testing. Screening should include chlamydia, gonorrhea, syphilis, and trichomoniasis if symptoms are present.

**Sequential HIV testing (beyond the baseline):** If HIV is transmitted during an exposure, seroconversion will generally occur within 2 to 4 weeks [Joyce, et al. 2015; Cardo, et al. 1997; Ciesielski and Metler 1997]. HIV testing at baseline, 4 weeks, and 12 weeks is recommended for all individuals who experience a high-risk exposure, even if PEP is declined.

**Recommended HIV test:** Point-of-care HIV tests in general are slightly less sensitive than laboratory-based HIV tests; therefore, exposed individuals should be tested with laboratory-based HIV tests whenever possible. An HIV-1/2 Ag/Ab combination immunoassay is the recommended serologic screening test. Point-of-care HIV tests that are Ag/Ab combination immunoassays are acceptable for follow-up testing.

**HIV testing at 6 months after exposure is no longer recommended:** Late seroconversion (i.e., after 3 months) is rare [Ciesielski and Metler 1997; Ridzon, et al. 1997] but has occurred after completion of PEP [Terzi, et al. 2007]. It is unclear whether these rare events were related to the original or subsequent exposures. This Committee believes that because of the infrequency of late seroconversion and the increased sensitivity of standard HIV tests to detect early infection and seroconversion, the benefit of routinely testing all exposed individuals for HIV at 6 months after exposure is outweighed by the added anxiety and significant consequences of an additional 3 months of precautions and testing for exposed individuals.

**Laboratory monitoring:** Table 6 includes recommended laboratory monitoring for patients who initiate a 28-day course of PEP. Serial HIV testing is recommended even if a patient declines PEP.

Table 6: Recommended Monitoring After Post-Exposure Prophylaxis Initiation		
Monitoring Test or Activity	Frequency	Notes
Clinic visit	<ul style="list-style-type: none"> <li>• Baseline</li> <li>• 48 hours</li> <li>• Week 2</li> <li>• Week 4</li> <li>• Week 12</li> </ul>	Follow-ups at 48 hours and 2 weeks may be conducted by telephone call.
HIV-1/2 antigen/antibody combination immunoassay (recommended even if the exposed individual declines PEP)	<ul style="list-style-type: none"> <li>• Baseline</li> <li>• Week 4</li> <li>• Week 12</li> </ul>	HIV specialist consultation: Immediate consultation with a <a href="#">clinician experienced in managing antiretroviral therapy</a> is advised to determine optimal treatment options if the exposed individual’s sequential test confirms HIV infection.
Serum liver enzymes, blood urea nitrogen, creatinine, complete blood count (CBC)	<ul style="list-style-type: none"> <li>• Baseline</li> <li>• Weeks 2 and 4 in patients ≥12 years if baseline test results are abnormal or if adverse effects are reported.</li> </ul>	<ul style="list-style-type: none"> <li>• Obtain CBC in children 2 to 12 years old if PEP regimen contains zidovudine.</li> <li>• Use a serum liver enzyme panel provided by laboratory.</li> <li>• Repeat laboratory testing after week 2 of PEP medications in the case of abnormal renal or liver function [Mikati, et al. 2019].</li> <li>• Repeat laboratory testing if the patient experiences signs or symptoms of drug-induced kidney or liver injury while taking PEP medications.</li> </ul>
Pregnancy test	<ul style="list-style-type: none"> <li>• Baseline</li> <li>• Week 4</li> </ul>	Only if exposed individual is of childbearing capacity.
Hepatitis B surface antigen (HBsAg) and surface antibody (anti-HBs)	<ul style="list-style-type: none"> <li>• Baseline: All patients</li> <li>• Week 12: If patient is ≥12 years old</li> </ul>	Patients with a reactive anti-HBs test result need not repeat an HB sAg test.
Hepatitis C virus (HCV) antibody	<ul style="list-style-type: none"> <li>• Baseline</li> <li>• Week 12</li> </ul>	<ul style="list-style-type: none"> <li>• HCV serology should be performed 6 months after an initial nonreactive test result.</li> <li>• Liver function panel and HCV antibody test should be performed 6 months after HCV exposure.</li> </ul>
Rapid plasma reagin (RPR) and 3-site screening for gonorrhea and chlamydia	Baseline	<ul style="list-style-type: none"> <li>• Consider repeat screening at week 2 for sexual exposures.</li> <li>• Repeat RPR at week 12 if the exposed individual is &lt;12 years old.</li> </ul>



# Management of Potential Exposure to Hepatitis B Virus

**Lead author:** Christine A. Kerr, MD, with the *Medical Care Criteria Committee*; June 2020

## RECOMMENDATIONS

- 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):

- 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).
- 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].

**Risk of HBV transmission:** The risk of HBV transmission from an occupational exposure is significantly greater than the risk of HIV transmission and ranges from 1% to 31% depending on the presence of hepatitis B e antigen (HBeAg), which is a marker of active replication [Schillie, et al. 2013].

Average risk of HBV transmission after needlestick (compared with HIV) [Schillie, et al. 2013; CDC 2001a]:

- HBV: 1.0% to 31.0%.
  - HBeAg+: 22% to 31%.
  - HBeAg-: 1.0% to 6.0%.
- HIV: 0.3%.

Factors that may increase the risk of sexual transmission include degree of viremia in the source, sex with multiple partners, history of sexually transmitted infections (including HIV), or any disruption of mucous membranes.

Any area exposed to blood or bodily fluid, including via needlestick, should be washed with soap and water as soon as possible after exposure. No data are available to suggest that the use of bleach or other antiseptic agents reduces transmission [Schillie, et al. 2013].

**HBV vaccine:** When considering PEP for HBV exposure, evaluation of both the source's HBsAg status and the exposed individual's vaccination status is necessary (see below). Even if the risk of exposure to HBV is not deemed significant, HBV vaccination is advised for all non-HBV-immune individuals. Household, sex, and needle sharing contacts of HBsAg-positive individuals should be identified and vaccinated according to the guidelines for patients exposed to known HBsAg-positive individuals, and the source should be referred for evaluation and treatment of HBV infection.

Both the first dose of the HBV vaccine and, if indicated, HBIG should be administered as soon as possible after HBV exposure. The HBV vaccine should be administered within 24 hours post exposure, and HBIG should be administered within 7 days (ideally) and not later than 14 days post exposure.

- The 3-dose vaccine (e.g., Recombivax-HB, Engerix-B) is administered at 0, 1 to 2, and 6 months.
- The 2-dose vaccine (e.g., HepHisav-B) is administered at day 0 and 1 month later.
- Hepatitis A vaccination can be combined with hepatitis B (e.g., Twinrix) in a 3-dose series.

Anti-HBs should be obtained within 1 to 2 months after completion of the last dose of the vaccine.

- See the Centers for Disease Control and Prevention (CDC) *Vaccine Recommendations on Hepatitis B* and American Academy of Pediatrics *Care of the Adolescent After an Acute Sexual Assault* [Crawford-Jakubiak, et al. 2017].

Initiation of the HBV vaccine series within 12 to 24 hours post exposure has been demonstrated to be 70% to 90% effective in preventing HBV infection [Schillie, et al. 2013]. The combination of vaccine and HBIG achieves a similar level of efficacy [Perrillo, et al. 1984; Redeker, et al. 1975]. Among known nonresponders to vaccination, one dose of HBIG is 70% to 90% effective in preventing HBV when administered within 7 days of percutaneous HBV exposure [Weinbaum, et al. 2003; Beasley, et al. 1983]. The maximum effective interval for prophylaxis is likely within 14 days for sexual exposure [Papaevelou, et al. 1988; Roumeliotou-Karayannis, et al. 1986; Perrillo, et al. 1984; Szmuness, et al. 1980; Redeker, et al. 1975]. It should be noted that a brief period of HBsAg positivity, reflecting a false-positive value, can be seen after vaccination [Rysgaard, et al. 2012].

Pregnant women can safely receive both the HBV 3-dose vaccine series and HBIG. However, to date, there are no data available on the use of the newer 2-dose vaccine in pregnant patients, children, or patients on hemodialysis. Both the standard 3-dose vaccine and immunoglobulin are thought to be safe for both adult and pediatric patients; the 2-dose vaccine is not approved for patients younger than 18 years [FDA 2017; CDC 2001a]. Adverse effects of the vaccines, also present at the same rate in placebo, include pain at the injection site and fever [CDC 2001a]. HBIG is also safe for administration; there is no history of transmission of viral hepatitis or HIV through HBIG because the viruses are screened, inactivated, and eliminated during production of HBIG. Although anaphylactic reactions to HBIG or other immunoglobulin preparations are rare, if a patient does have a history of anaphylaxis after receipt of immunoglobulin, HBIG should not be given.

**→ KEY POINT**

- Determination of antibody response of previously vaccinated exposed individuals should be based on information available at presentation. The decision to vaccinate should not be delayed while testing for anti-HBs.

*Table 7: Recommended Post-Exposure Prophylaxis for Hepatitis B Virus Exposure*, below, shows indicated treatment for individuals exposed to HBV, based on the status of the source. For the most current information regarding HBV post-exposure management, please refer to the CDC *Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices*.

<b>Table 7: Recommended Post-Exposure Prophylaxis for Hepatitis B Virus [a]</b>			
<b>Exposed Individual Vaccination Status</b>	<b>Source is HBsAg-Positive</b>	<b>Source is HBsAg Negative or Not Available</b>	<b>Source is Not Available; Known High-Risk [b]</b>
<b>Indicated treatment for EXPOSED individual:</b>			
Unvaccinated/non-immune	<ul style="list-style-type: none"> <li>• Administer HBIG 0.06 mL/kg IM.</li> <li>• Initiate HBV vaccine series.</li> </ul>	Initiate HBV vaccine series.	Treat as if source is HBsAg-positive.
Previously vaccinated with completed HBV series; known responder [c]	No treatment.		
Previously vaccinated with completed HBV series; known nonresponder [c]	<ul style="list-style-type: none"> <li>• Administer HBIG 0.06 mL/kg IM.</li> <li>• Initiate revaccination [d] or administer second dose of HBIG 1 month later.</li> </ul>	No treatment.	Treat as if source is HBsAg-positive.
Previously vaccinated with completed HBV series; unknown antibody response	<ul style="list-style-type: none"> <li>• Administer single dose of vaccine.</li> <li>• Check titer. If low, complete 3-dose vaccine series.</li> </ul>	No treatment.	Treat as if source is HBsAg-positive.

Table 7: Recommended Post-Exposure Prophylaxis for Hepatitis B Virus [a]			
Exposed Individual Vaccination Status	Source is HBsAg-Positive	Source is HBsAg Negative or Not Available	Source is Not Available; Known High-Risk [b]
	Indicated treatment for EXPOSED individual:		
Undergoing vaccination at time of exposure	<ul style="list-style-type: none"> <li>Administer HBIG 0.06 mL/kg IM.</li> <li>Complete 3-dose vaccine series.</li> </ul>	Complete vaccine series.	

**Abbreviations:** anti-HBs, hepatitis B surface antibody; HBIG, hepatitis B immune globulin; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; IM, intramuscular.

**Notes:**

- Individuals who have previously been infected with HBV with HBsAb positivity are immune to re-infection and do not require post-exposure prophylaxis.
- 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].
- Based on information available at presentation. Responder is defined as an individual with previously documented adequate levels of serum antibody to HBsAg (serum anti-HBs >10 mIU/mL); a nonresponder is an individual with previously documented inadequate response to vaccination (serum anti-HBs <10 mIU/mL). The decision to vaccinate should not be delayed while testing for anti-HBs at presentation.
- The option of giving 1 dose of HBIG and reinitiating the vaccine series is preferred for nonresponders who have not completed a second vaccine series. For individuals who previously completed a second vaccine series but failed to respond, 2 doses of HBIG are preferred, given 1 month apart.

## Management of Potential Exposure to Hepatitis C Virus

**Lead author:** Christine A. Kerr, MD, with the Medical Care Criteria Committee, September 2020

☑ RECOMMENDATIONS
<ul style="list-style-type: none"> <li>When an individual reports an exposure to HIV, clinicians should assess for concurrent exposure to hepatitis C virus (HCV). (A2)</li> <li>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 <i>Figure 5: Evaluation of Hepatitis C Virus (HCV) Exposure Risk and Recommended Follow-Up</i>): (A2)             <ul style="list-style-type: none"> <li><b>Exposed individual:</b> HCV antibody, and if positive, HCV RNA; liver function tests, including liver enzyme test.</li> <li><b>Source:</b> HCV antibody; if positive or the source has had recent HCV exposure, perform HCV RNA test.</li> </ul> </li> <li>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)             <ul style="list-style-type: none"> <li><b>Week 4:</b> HCV RNA and alanine aminotransferase (ALT).</li> <li><b>Week 12:</b> HCV RNA and ALT.</li> <li><b>Week 24:</b> HCV antibody and ALT with reflex to HCV RNA if either is abnormal.                 <ul style="list-style-type: none"> <li>See NYSDOH AI guideline <i>Treatment of Chronic HCV with Direct-Acting Antivirals</i>.</li> </ul> </li> </ul> </li> <li>If HCV infection is identified, the clinician should refer the exposed individual for medical management by a clinician with experience in treating HCV. (A2)</li> <li>Clinicians should not administer immunoglobulin or antiviral agents for HCV post-exposure prophylaxis (PEP). (A2)</li> <li>If at any time the serum ALT level is elevated, clinicians should repeat HCV RNA testing to evaluate for acute HCV infection. (A3)</li> </ul>

**Risk of HCV transmission:** The risk of transmission of HCV is significantly greater than the risk of HIV transmission after bloodborne exposure. In cases of occupational exposure, the risk of HCV infection following a needlestick is 1.8%, whereas the risk of HIV infection is 0.3% [Beltrami, et al. 2000]. The risk of HCV transmission from a single mucous membrane exposure is negligible, except when the potential exposure is through receptive anal intercourse.

Factors that may increase the risk of sexual transmission include sex with multiple partners, history of sexually transmitted infections (including HIV), or any other practice that might disrupt mucous membranes (e.g., fisting or use of sex toys).

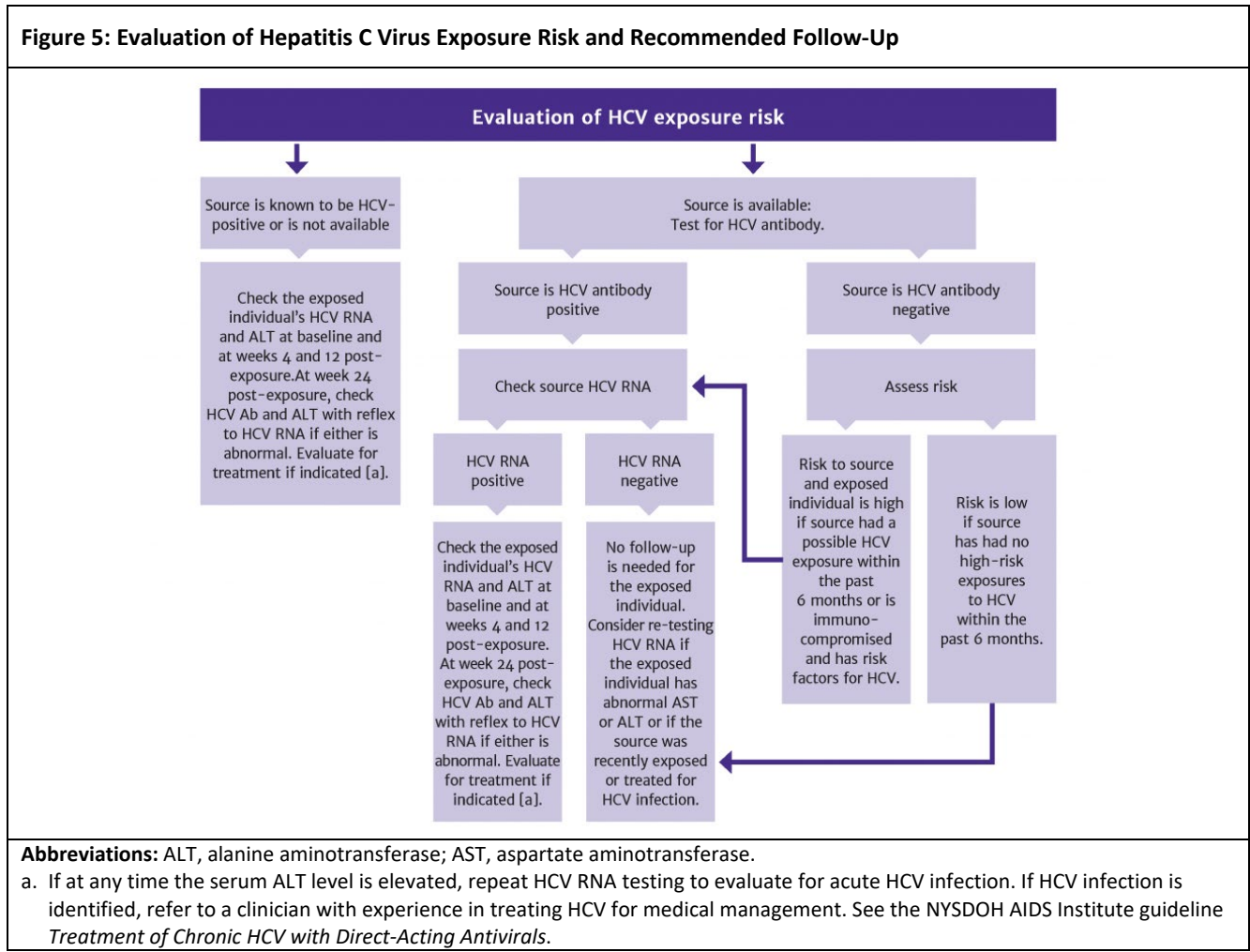
The following activities carry risk of HCV transmission:

- Blood-to-blood contact, including through sharing of personal care items, such as razors or toothbrushes, that may have been exposed to another individual’s blood; occupational needlestick injuries; and sharing needles, syringes, intranasal straws, or other equipment to inject or inhale drugs.
- Sexual activity, particularly anal receptive intercourse.
- Receipt of blood, plasma, organs, tissue, or semen.
- Perinatal transmission.

HCV is not spread via food or water and is not transmitted by:

- Sharing of eating utensils.
- Hugging, kissing, or holding hands.
- Coughing or sneezing.
- Breastfeeding: HCV is not transmitted by breastfeeding; however, HCV is spread by infected blood. Therefore, if the HCV-positive mother’s nipples and/or surrounding areola are cracked and bleeding, she should stop nursing temporarily.
  - Clinicians should advise women who may have been exposed to HIV to avoid breastfeeding for 3 months after the exposure (see guideline section *Selecting and Initiating a 28-Day PEP Regimen > PEP During Pregnancy or Breastfeeding*).

**HCV testing of source:** If the source is tested for HCV antibody and found to be positive, follow-up testing is necessary to confirm the source’s status. HCV RNA may be used as the confirmatory test. If the source tests positive with an HCV RNA test, the exposed individual should be managed as if the source has chronic HCV. If the source patient has recent risks for new HCV acquisition or the risk is unknown, consider nucleic acid amplification testing (NAAT) for HCV RNA as an initial test.



**PEP for HCV:** Currently, research has identified no effective prophylaxis for HCV infection. Immunoglobulin and antiviral agents are not recommended for HCV PEP. However, if an individual becomes acutely infected with HCV and is diagnosed at that time, immediate referral to a clinician experienced in the treatment of HCV is strongly recommended. Currently, the best regimen or duration of therapy for acute HCV is unknown, even with the availability of direct-acting HCV antiviral therapy. Patients should be managed according to genotype, liver disease progression, and history of previous HCV treatment, if any (see the NYSDOH AI guideline *Treatment of Chronic HCV with Direct-Acting Antivirals*).

Observation for a period of 8 to 12 weeks post infection is reasonable to assess for possible spontaneous resolution of acute HCV [Ghany, et al. 2009], and clinical trials are underway to assess the value of treatment with direct-acting antivirals for acute HCV infection. Whether treatment with direct-acting antiviral agents is appropriate will depend upon the individual scenario [Boerekamps, et al. 2019; Chromy, et al. 2019; Naggie, et al. 2019].

**Follow-up:** For individuals who are exposed to a source with HCV, regular follow-up with HCV RNA testing is recommended in addition to HCV antibody testing. HCV RNA testing can identify acute infection within 2 weeks of exposure, whereas the antibody test may not provide an accurate result for up to several months after acute infection (i.e., during the “window period”). Seroconversion with the enzyme-linked immunosorbent assay (ELISA) antibody test occurs in 50% of patients who are infected within 9 weeks of exposure, in 80% of patients within 15 weeks of exposure, and in at least 97% of patients within 6 months of exposure [CDC 2001a]. The ELISA test is highly sensitive but relatively nonspecific, resulting in a low positive predictive value in low-prevalence populations. Positive HCV ELISA antibody test results require confirmation by a quantitative viral load assay, such as an HCV polymerase chain reaction assay. This Committee recommends linking exposed patients to HCV care for monitoring and assessment for treatment (see the NYSDOH AI guideline *Treatment of Chronic HCV with Direct-Acting Antivirals*).

→ KEY POINT

- Educate exposed individuals about the natural history of HCV infection and provide counseling about transmission risks, avoidance of alcohol, and medications that may be toxic to the liver.

## All Recommendations

All RECOMMENDATIONS: PEP to Prevent HIV Infection

### First Dose of PEP and Management of the Exposure Site

- **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; Truvada plus Tivicay) [a]
  - Lamivudine (3TC; Epivir) may be substituted for FTC in either regimen.
  - Raltegravir (RAL; Isentress) may be prescribed in the high-dose formulation, but the high-dose formulation should not be given to pregnant patients.
- **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)

**☑ All RECOMMENDATIONS: PEP to Prevent HIV Infection**

- 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****High-Risk Exposure**

- 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)

**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)

**☑ All RECOMMENDATIONS: PEP to Prevent HIV Infection**

- 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 HIV-1/HIV-2 antibody (Ab) 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 Ab 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 complete 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 Ab differentiation immunoassay result is negative, consistent with a false-positive initial test. (A1)

**Baseline Testing of the Exposed Individual**

**All Exposures**

- Clinicians should perform baseline HIV testing of an exposed individual using a U.S. Food and Drug Administration (FDA)-approved HIV-1/2 antigen/antibody (Ag/Ab) combination immunoassay, preferably at the time of post-exposure prophylaxis (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)
- 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)

**☑ All RECOMMENDATIONS: PEP to Prevent HIV Infection**

- If the result of a baseline screening HIV-1/2 Ag/Ab combination immunoassay is reactive, clinicians should recommend the continuation of PEP until the positive result is confirmed with an Ab differentiation immunoassay 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)
  - See the NYSDOH AI guideline *When to Initiate ART, With Protocol for Rapid Initiation*.
- 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 [a]**

- 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; brand name Truvada) or TDF/lamivudine (3TC; brand name 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) [CDC 2016; Günthard, et al. 2016; Ford and Mayer 2015; Kuhar, et al. 2013]. 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*
- 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.

**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)
- 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.



**☑ All RECOMMENDATIONS: PEP to Prevent HIV Infection**

- **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  $\geq 18$  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**

- **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****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 laboratory-based HIV-1/2antigen/antibody (Ag/Ab) combination immunoassay screening test. (A2)
  - Point-of-care (POC) HIV tests can be used at 4 and 12 weeks only if they are Ag/Ab combination immunoassays; 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.
- If an exposed individual's HIV screening test result is reactive at any time, clinicians should perform an FDA-approved confirmatory HIV-1/HIV-2 Ab differentiation immunoassay. (A1)

**Sequential HIV Testing and Laboratory Monitoring: 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; an Ag/Ab combination immunoassay is the recommended serologic screening test.

**☑ All RECOMMENDATIONS: PEP to Prevent HIV Infection**

### 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.
- c. 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)
  - **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)

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**Note:**

- a. The recommendation regarding discussion of the small risk of teratogenicity with DTG in the first trimester and the need for birth control while completing the 28-day PEP regimen has been removed. DTG has been shown to be safe throughout pregnancy. See the MCCC’s statement on *Use of Dolutegravir in Individuals of Childbearing Capacity* for further discussion [Zash, et al. 2022].

# All Good Practices

## → ALL GOOD PRACTICES: PEP to Prevent HIV Infection

### First Dose of PEP and Management of the Exposure Site

#### All Exposures

- *Communications:* Use clear and direct language when communicating with an exposed individual or with an adult accompanying an exposed child. Use age-appropriate language with children.
- *If PEP is refused:* Explain the timing requirement for initiation and provide instructions for acquiring PEP if that decision changes. Document refusal of PEP in the patient's medical record.

### Exposure Risk Evaluation

#### All Exposures

- *Bites:* If a bite exposure has been reported, evaluate the exposure in the biter and in the individual who was bitten. If an individual with bleeding in the mouth causes bleeding in someone who they have bitten, the bitten individual is a candidate for PEP.
- *If an exposure is assessed as high-risk:* Inform the patient of the need to complete a 28-day course of PEP, confirm the patient's access to the PEP medications, and provide a starter pack of medications.
- *Describe the signs and symptoms of acute retroviral syndrome:* Stress the need for immediate medical attention if these symptoms occur, and provide the exposed individual with appropriate access to HIV testing that includes HIV RNA testing if indicated.
- *If an exposure is assessed as high-risk and completion of a 28-day PEP is indicated but declined:*
  - Inform the exposed individual of the results of the source's HIV test.
  - Explain the 72-hour window period for PEP efficacy.
  - Describe the symptoms of acute retroviral syndrome.
  - Provide contact information for access to medical care if the exposed individual decides to pursue PEP.
  - Provide a referral for counseling and trauma care.
  - Arrange for serial HIV testing.
  - Document refusal of PEP in the exposed individual's medical record.

#### Non-Occupational Exposures

- *Comprehensive evaluation:* Identify and assess all specific behaviors that may have resulted in exposure to HIV.
- *High-risk exposure:* Provide counseling and educating about risk reduction, including the availability of PrEP. Individuals who report a high-risk sexual exposure are candidates for PrEP, immediately if PEP is not indicated or upon completion of PEP once a negative HIV status is confirmed. Provide a referral for PrEP care if it is not available on site.

#### Sexual Assault Exposures

- *HPV vaccine:* The Centers for Disease Control and Prevention [recommend vaccination against HPV for sexual assault and sexual abuse patients](#) aged 9 to 45 years. See also [Unger, et al. 2011].

### Source HIV Status and Management

#### All Exposures

- *Source testing:* Test the source with an FDA-approved laboratory or POC HIV-1/2 Ag/Ab combination immunoassay; do not use a rapid oral HIV test.
  - If the source's screening test is reactive, provide the results and follow up with confirmatory testing.
  - Inform the exposed individual of the result, and explain the process for confirming HIV infection.
  - If source's confirmatory testing is positive (Ab differentiation immunoassay or HIV-1 RNA test), provide linkage to an HIV-experienced care provider if the source is not already engaged in medical care.
- *If the source has drug-resistant HIV:* Consult an [experienced HIV care provider](#) for assistance in modifying the exposed individual's PEP regimen.
- *Provide counseling and education to the exposed individual.*

→ ALL GOOD PRACTICES: PEP to Prevent HIV Infection

- *If a 28-day course of PEP is indicated:* If the exposure is assessed to be high-risk and the exposed individual will complete a 28-day course of PEP, arrange for telephone follow-up within 48 hours to ensure the individual has the medications and to assess for adverse effects.

**Non-Occupational Exposures**

- *Undetectable equals untransmittable (U=U):* Research has established that a source with HIV who is taking ART and has an undetectable viral load (HIV RNA <200 copies/mL) at the time of a consensual sexual (only) exposure will not transmit the virus through sex [Rodger, et al. 2019; Cohen, et al. 2016; Rodger, et al. 2016].
- *If the source’s viral load at the time of a sexual exposure is available:* Offer information about U=U as reassurance for the exposed individual.
- *U=U pertains only to consensual sexual exposure:* It does not apply to exposure through needle sharing, breastfeeding, or needlestick injury.

**Baseline Testing of the Exposed Individual**

**All Exposures**

- *Test results:* Perform baseline HIV testing of the exposed individual. When results are available, explain them to the patient and ensure understanding.
- *If HIV infection is confirmed in the exposed individual:* Explain the benefits of rapid initiation of ART and provide a referral for HIV care.
- *ART initiation:* Rapid initiation of ART is recommended for all patients diagnosed with HIV. See the NYSDOH AI guideline *When to Initiate ART, With Protocol for Rapid Initiation*.
- *Arrange for HIV care:* If HIV infection is confirmed, or if seroconversion is suspected, or if HIV infection cannot be ruled out, then refer the exposed individual for HIV care and rapid initiation of ART.
- *Pregnancy testing:* Perform pregnancy testing in all individuals of childbearing capacity.
- *Sexually transmitted infections (STIs) other than HIV:* Provide counseling about the risk of acquiring other STIs through sexual exposure and information on signs and symptoms of STIs, and stress the need to seek medical attention if symptoms occur.
  - Sexual assault exposures: See U.S. Department of Justice. *A National Protocol for Sexual Assault Medical Forensic Examinations Adults/Adolescents Second Edition*. 2013. NCJ 228119.
  - See NYSDOH *Sexual Assault Victim Bill of Rights*.
- *Emergency contraception:* Offer emergency contraception to individuals of childbearing potential who report sexual exposure.

**Sexual Assault Exposures**

- *Undetectable equals untransmittable (U=U):* Research has established that a source with HIV who is taking ART and has an undetectable viral load (HIV RNA <200 copies/mL) at the time of a consensual sexual (only) exposure will not transmit the virus through sex [Rodger, et al. 2019; Cohen, et al. 2016; Rodger, et al. 2016].
- *If the source’s viral load at the time of a sexual exposure is available:* Offer information about U=U as reassurance for the exposed individual.
- *U=U pertains only to consensual sexual exposure:* It does not apply to exposure through needle sharing, breastfeeding, or needlestick injury.

**Selecting and Initiating a 28-Day Course of PEP**

**All Exposures**

- *Avoid drug-drug interactions and medication-related adverse events:* Before prescribing a 28-day course of PEP, review the patient’s current medications and comorbidities to identify possible drug-drug interactions and to anticipate and prevent medication-related adverse events. See NYSDOH AI *ART Drug-Drug Interactions*.
- *Impaired renal function:* Review baseline laboratory test results to identify the need to adjust ARV medication dosing for renal insufficiency or choose an alternative regimen. Consult with an experienced HIV care provider or other resources, such as drug package insert(s), to determine dose adjustments for patients with baseline CrCl <50 mL/min.
- *If 28-day PEP is indicated:* Ensure the patient understands the need to complete the full 28 days of PEP and explain the adherence requirements.

→ **ALL GOOD PRACTICES: PEP to Prevent HIV Infection**

- Make sure the patient understands that if a dose of PEP is missed, a “double-up” dose is not necessary. Instead, if dose is missed at a specific time, it can be taken as soon as it is remembered within 24 hours of the scheduled time.
- *If possible, provide the 28-day supply of medications.* If the full course of medications cannot be provided, then supply a starter pack, as noted below, and a prescription for the medications required to complete 28 days of PEP.
  - Non-occupational exposures: Provide a 7-day starter pack.
  - Occupational exposures: Provide a 7-day (at least) starter pack.
  - Sexual assault exposures (per New York State law): Provide a 7-day starter pack if the patient is ≥18 years old; provide the full, 28-day course of PEP medications if the patient is <18 years old.
- *Ensure the patient’s ability to obtain the medication needed to complete 28 days of PEP.*
- *Discuss possible adverse effects of PEP medications.* Ensure the patient knows what to do if they experience those effects. If an individual who is completing 28 days of PEP does not have a primary care provider with whom to follow-up, the *NYSDOH PrEP/PEP Provider Directory* can be used to identify a care provider for a referral.

**Counseling and Patient Education**

**All Exposures**

- *If HIV infection is confirmed in the exposed individual:* Explain the benefits of rapid initiation of antiretroviral therapy and provide a referral for HIV care.
- *Trauma care:* Provide information and a referral if the exposed individual would benefit from counseling or trauma care that addresses, among other issues, fear of HIV infection, and candidacy for PEP.
- *Discuss signs and symptoms of acute retroviral syndrome (ARS):* Stress the need for immediate medical attention if symptoms of ARS occur and provide the exposed individual with appropriate access to HIV testing that includes HIV RNA testing if indicated.

**Non-Occupational Exposures**

- *Risk reduction:* Individuals who report ongoing high-risk sexual exposure are candidates for PrEP.
  - If PEP is not indicated for the current exposure, discuss initiation of PrEP immediately once negative HIV status is confirmed.
  - If PEP is indicated, upon completion of PEP, and once negative HIV status is confirmed, start PrEP.
- *Referrals:* If the clinical setting in which an individual presents for PEP does not support evaluation for and provision of PrEP, then the patient should be given a referral for PrEP care.

**Exposures in Children**

- *Families of children exposed to HIV:* In addition to the child exposed to HIV, parent(s), guardian(s), and other family members may also benefit from trauma care.

**Follow-Up of the Exposed Individual**

**All Exposures**

- *Discuss signs and symptoms of acute retroviral syndrome:* Stress the need for immediate medical attention if these symptoms occur, and provide appropriate access to HIV testing that includes HIV RNA testing if indicated.
- *Follow up in person or by telephone within 48 hours to accomplish the following:*
  - Assess for signs or symptoms of acute HIV.
  - Review and confirm the decision to complete the full 28-day course of PEP and confirm that the patient has access to required PEP medications.
  - Assess for and advise on the management of adverse effects associated with PEP medications as needed.
  - Encourage adherence to the PEP regimen.
- Make referrals or arrangements for follow-up care as needed, including referral to an experienced HIV care provider if needed.

**Non-Occupational Exposures**

- *STI testing:* Consider STI testing at week 2 in cases of sexual exposure.
- *If ongoing exposure risk is high:* Counsel and educate the patient about risk reduction, including the availability of PrEP.

## → ALL GOOD PRACTICES: PEP to Prevent HIV Infection

- *Refer for PrEP:* If the clinical setting in which an individual presents for PEP does not support evaluation for and provision of PrEP, then the patient should be given a referral for PrEP care.

**Sexual Assault Exposures**

- *Plan for follow-up care:* Review the plan for follow-up care with the patient and with a rape crisis counselor or outreach worker who will follow the patient after discharge from the emergency department or other healthcare setting.
- *Empiric STI treatment:* Confirm that empiric treatment for gonorrhea, chlamydia, and trichomonas was given at the initial presentation.
- *STI testing:* Baseline testing for STIs may be offered, along with syphilis testing at week 2.

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# Supplementary Materials

## Employer Responsibilities in PEP Management to Prevent HIV Infection Following an Occupational Exposure

*NYSDOH AIDS Institute, June 2020*

**Requirements:** Organizations that employ health professionals or others who are at risk for occupational exposure to blood, body fluids, or other potentially infectious materials are generally required to establish policies and procedures that guide the management of such exposures.

Employers must conform to the *OSHA Bloodborne Pathogens Standard* (OSHA Bloodborne Pathogens Standard 29 CFR § 1910.1030 and Compliance Directive CPL 02-02-069, 11/27/01, *Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens*), which are applicable to New York public employers under the *New York Public Employee Safety and Health (PESH) Act* (Labor Law § 27-a) and regulations (12 NYCRR Part 800). OSHA and PESH standards regarding occupational exposure to bloodborne pathogens are identical. These regulations require that a management plan is in place.

**Employee access to post-exposure services:** The employer should ensure that any employee who sustains an occupational exposure has access to post-exposure services within 1 to 2 hours of a reported event. Services must be available 24 hours per day, 7 days per week. Organizations that do not have onsite occupational health services are encouraged to form agreements or contracts with another facility, Emergency Department, or private practitioner for such services.

**Definition of individuals covered:** New York State regulations apply to staff, employees, or volunteers in the performance of employment or professional duties who work in:

- A medical or dental office.
- A facility regulated, authorized, or supervised by the Department of Health, Office of Mental Health, Office of Mental Retardation and Developmental Disabilities, Office of Children and Family Services, Office of Alcoholism and Substance Abuse Services, or the Department of Correctional Services.
- Emergency response employee (paid or volunteer, including an emergency medical technician, a firefighter, a law enforcement officer or local correctional officer, or medical staff).

**Post-exposure policies should define who is included as an “employee” for purposes of providing care.** In addition to staff who are employed by an organization (e.g., nurses, laboratory personnel, housekeepers), consideration must be given to whether other individuals (e.g., medical/nursing students, house staff, attending physicians, volunteers, and pre-hospital care personnel) will be covered by the institution’s policy. In addition, the **scope of services** that will be provided must be delineated (e.g., laboratory testing, occupational health services, prophylactic drugs or vaccines), including whether there are limitations within the categories of individuals covered, particularly regarding workers’ compensation benefits.

**Access to services:** Exposed workers who sustain an occupational exposure should be ensured access to post-exposure services within 1 or 2 hours of a reported event. This may require 24-hour and weekend coverage. Procedures should identify how workers access services during regular work hours and, if different, how they access services during evening, night, or weekend shifts. Organizations that do not have onsite occupational health services should consider forming agreements or contracts with another facility or private practitioner for such services.

Post-exposure services for exposures to all bloodborne pathogens include but are not limited to:

- Post-exposure evaluation and follow-up post-exposure vaccinations.
- Arrangements for a full course of PEP medications, at no cost to the employee.
- Care provided under the supervision of a licensed physician or other licensed healthcare professional.
- Availability of a rapid HIV test for source testing.
- Supportive counseling.

**Federal law requires covered employers to ensure that all medical evaluations and procedures, vaccines, and post-exposure prophylaxis are made available to the employee within a reasonable time and at a reasonable location and**



are made available at **no cost to the employee** (OSHA, 29 CFR, Part 1910.2030, CPL 2-02.069, 11/27/01, *Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens*).

PESH and OSHA's Bloodborne Pathogens Standards indicate that the covered employer is responsible for all costs associated with an exposure incident. An employer may not require any out-of-pocket expenditures on behalf of the employee, such as requiring the employee to utilize workers' compensation if prepayment is required or compelling an employee to use health insurance to cover these expenses unless the employer pays all premiums and deductible costs associated with the employees' health insurance. In addition to services listed above, the NYSDOH AI guideline *Post-Exposure Prophylaxis (PEP) to Prevent HIV Infection* states that the following should be considered by the employer when establishing plans for providing PEP for HIV exposure:

- Who will perform the post-exposure evaluation.
- Who will provide counseling to the exposed worker regarding the exposure and indications for PEP (for off-hour exposures as well).
- How PEP will be made available within 2 hours of an exposure.
- How a 7-day supply of PEP will be made available for urgent use.
- Who will be given authority for releasing drugs for this purpose.
- How the exposed worker will obtain PEP medications to complete the 28-day regimen.

**Determining the HIV status of the exposure source:** Procedures to facilitate rapid evaluation and voluntary testing for HIV, hepatitis B virus (HBV), hepatitis C virus (HCV), and other bloodborne pathogens and disclosure of related information of the source individual should be in place.

The employer is responsible for establishing and implementing policies to protect the confidentiality of both the exposed employee and the exposure source (New York Public Health Law §§ 2135, 2782; 10 NYCRR § 63.6).

**Access to source HIV-related information:** New York law and regulations (Public Health Law § 2781(6)(e); 10 NYCRR § 63.8(m)) authorize disclosure of existing HIV-related information to healthcare providers of those who have been exposed in the workplace when significant risk exposure has occurred.

When the source is already known to be infected with HBV, HCV, or HIV, testing for the source individual's known HBV, HCV, or HIV status does not need to be repeated. Testing for other bloodborne pathogens should still occur.

If the exposed worker is part of the healthcare team, he/she may have access to the medical record and know the HIV status of the source, as well as information about drug resistance. Information related to drug regimens, and, if available, resistance information should be made available to the exposed employee's healthcare provider to determine the best regimen for the employee. However, initiation of PEP should not be delayed while awaiting this information.

**HIV testing of the source:** Consistent with recommendations by the Centers for Disease Control and Prevention (CDC), and the U.S. Department of Labor, OSHA mandates that medical facilities subject to OSHA authority use rapid HIV antibody tests when testing the source after potential exposure to a bloodborne pathogen. The CDC recommends testing with an HIV-1/2 antibody/antigen combination immunoassay.

- The source should be tested as soon as possible to determine HIV infectivity.
- Results of the source individual's HIV testing should be made available to the exposed worker's healthcare provider. Patient authorization for the release of this information is not required for necessary communication of information between care providers for timely treatment of the exposed worker.

**Source has the capacity to consent for HIV testing:** Informed consent from the source should be obtained. If consent is not obtained for HIV testing, the employer should document that consent cannot be obtained and testing cannot be performed. See *Box 7: HIV Testing When the Source of an Occupational Exposure Is Unable to Consent*.

**Source does not have the capacity to consent for HIV testing:** If the source is comatose or is determined by his or her attending professional to lack the mental capacity to consent, and the source is not expected to recover in time for the exposed individual to receive appropriate medical treatment, the Health Care Proxy Law and Family Health Care Decisions Act (FHCDA) give healthcare providers the ability to locate someone who has the legal authority to consent to HIV testing (the healthcare agent or FHCDA Surrogate).

New York regulations [§§ 63.3(d)(7), 63.8(n)] also authorize anonymous testing when no individual authorized to consent on behalf of the source is immediately available.

**An anonymous test\* may be performed if:** The healthcare agent or FHCDAs Surrogate, who has the legal authority to consent, is not available or reasonably likely to become available in time for the exposed individual to receive appropriate medical treatment **and** the exposed individual will benefit medically by knowing the source's HIV test results **or** the source is deceased.

\*The law requires that results of anonymous source testing are given only to the healthcare provider of the exposed individual solely for assisting the exposed individual in making appropriate decisions regarding post-exposure medical treatment. The results of the test cannot be disclosed to the source or placed in the source's medical record. The source may be told that the exposure occurred and that an HIV test was performed. The source should be offered confidential testing so that they may have access to information about his/her own HIV status.

**Worker's compensation program:** The Workers' Compensation Law has specific implications for employees exposed to HIV, as well as those rare cases that result in seroconversion. Individuals who manage such exposures should be familiar with these implications because they should be able to counsel employees and refer them for legal and medical assistance accordingly. The organization's workers' compensation provider should be contacted as situations arise.

**NYS Worker's Compensation Board:**

- Website: <http://www.wcb.ny.gov/>
- Worker benefits and information regarding how to file a claim: <http://www.wcb.ny.gov/content/main/Workers/Workers.jsp>
- Advocate for Injured Workers, for questions related to injured workers:  
(877) 632-4996  
(800) 580-6665  
Email: [advinjwkr@wcb.ny.gov](mailto:advinjwkr@wcb.ny.gov)

**Preventing transmission of bloodborne pathogens:** As part of the employer's plan to prevent transmission of bloodborne pathogens, the following measures can be taken to avoid injuries:

- Elimination of unnecessary use of needles or other sharps.
- Use of devices with safety features.
- Verification of training and compliance with safety features.
- Avoidance of needle recapping.
- Planning before beginning any procedure using needles or other sharps for safe handling and prompt disposal in sharps disposal containers.
- Promotion of education and safe work practices for handling needles and other sharps.

For more information about prevention of needlestick injuries, refer to the National Institute for Occupational Safety and Health Alert: *Preventing Needlestick Injuries in Health Care Settings*.

Even when effective prevention measures are implemented, exposures to blood and bodily fluid still occur. Employers of personnel covered by the OSHA Bloodborne Pathogens Standard are obligated to provide post-exposure care, including prophylaxis, at no cost to the employee. The employer may subsequently attempt to obtain reimbursement from workers' compensation.

**Documentation:** Information that should be recorded after an occupational exposure to HIV has occurred includes the following, which the clinician should record in the exposed worker's confidential medical record:

- Date and time of the exposure.
- Details of the procedure being performed and the use of protective equipment at the time of the exposure.
- Type, severity, and amount of fluid to which the worker was exposed.
- Details about the source individual.
- Whether HIV testing of the source was performed.
- Medical documentation that provides details about post-exposure management.
- If the occupationally exposed individual declines PEP, the clinician should document this decision in the individual's medical record.

Specific OSHA requirements regarding documentation may be found at *Safety and Health Topics: Bloodborne Pathogens and Needlestick Prevention*.

## Services for Sexual Assault Patients

*NYSDOH AIDS Institute, June 2020*

New York State (NYS) Public Health Law 2805-i requires that hospitals providing treatment to survivors of sexual assault advise the patient of the availability of services provided by the local rape crisis or victim assistance organization and secure such services as requested by the patient.

**Role of the rape crisis advocate:** The primary role of the rape crisis advocate is to provide the patient with emotional support, advocacy, information, counseling, and accompaniment services, and to facilitate informed decision-making at a time when the patient may be in crisis. Advocates do not provide healthcare or collect evidence; however, they can enhance the efforts of healthcare staff through the provision of information regarding medical and legal options. For information about rape crisis services, see NYSDOH *Sexual Violence Prevention Program*. The NYSDOH, with other State agencies, healthcare facilities, and professional organizations, provides technical assistance on sexual assault issues.

**Sexual Assault Forensic Examiner (SAFE):** The initial response that a survivor of rape or sexual assault receives when seeking healthcare or reporting the crime has a profound influence on that individual’s subsequent recovery. Engagement of healthcare practitioners from the SAFE program helps improve the care that survivors of sexual assault receive. The NYSDOH certifies all appropriately qualified individuals as SAFEs. A SAFE is a specially trained registered nurse, nurse practitioner, physician, or physician’s assistant.

NYS public health law requires that the NYSDOH establish standards for and certify SAFE hospital programs. All **SAFE Designated Hospitals** have a SAFE available either on site or on-call within 60 minutes of the sexual assault patient’s arrival at the hospital, except under exigent circumstances (*NYS Public Health Law 2805-i*). In NYS, the standard of care for survivors of rape and sexual assault presenting at healthcare settings includes comprehensive high-quality medical care, collection of forensic evidence, and respectful and sensitive treatment. The NYSDOH recommends the use of SAFEs in all hospitals to assist in meeting this standard. The SAFE should be an active participant in the discussion regarding initiation of HIV post-exposure prophylaxis (PEP). SAFEs help to ensure the best medical, legal, and psychological outcomes for the adult survivor of sexual assault and provide compassionate emotional support. They are trained to provide care to survivors of sexual assault and to collect and preserve forensic evidence to support prosecution if the patient decides to report the crime to law enforcement.

### RESOURCES

- *Requirements Regarding Emergency Services for Victims of Sexual Offense*
- *NYS Rape Crisis and Sexual Violence Prevention Program*
- *New York State Sexual Assault Victim Bill of Rights*

**Reimbursement for SAFE services:** Provider reimbursement under the Office of Victim Services (OVS) *FRE Direct Reimbursement Program* is intended to cover the forensic examiner’s services, including pharmaceuticals related to a sexual assault forensic examination. This reimbursement includes the cost of the initial 7-day starter pack of PEP if the care provider determines a risk of HIV exposure. Claim forms for reimbursement under the Direct Reimbursement Program can be found in each Sexual Offense Evidence Collection Kit and be downloaded from the OVS website.

Documentation of a visit to a facility that provides a forensic medical examination satisfies the OVS reporting requirement, thereby providing survivors who are either unwilling or unable to report the crime to the police the opportunity to file a regular compensation claim. Survivors of sexual assault may also contact a Rape Crisis Center or Victim Advocate Program in their county or region for assistance in filing regular compensation claims with OVS, particularly when an emergency award is needed from the OVS (see below). Many of these agencies have 24-hour hotlines. For more information and a list of Victim Advocate Programs and other resources, consult the OVS website.

The OVS has an “emergency award” procedure in addition to its normal compensation process to ensure continued availability of PEP for survivors of sexual assault beyond the initial 7-day starter pack supply. Advocates who know the community connections and procedures to expedite the process should work with the exposed individual. The process for requesting an emergency award is as follows: 1) Claimant files a regular claim application with the OVS, indicating that medication for HIV PEP is necessary, and requests an emergency award. 2) OVS makes an expedited determination for the purposes of the emergency award. 3) If the OVS determines it can grant an emergency award, up to \$2,500, then OVS directly reimburses pharmacy providers on behalf of the claimant.

# Supplement: Guideline Development and Recommendation Ratings

Guideline Development: New York State Department of Health AIDS Institute Clinical Guidelines Program	
<b>Developer</b>	<i>New York State Department of Health AIDS Institute (NYS DOH AI) Clinical Guidelines Program</i>
<b>Funding Source</b>	NYSDOH AI
<b>Program Manager</b>	Clinical Guidelines Program, Johns Hopkins University School of Medicine, Division of Infectious Diseases. See <i>Program Leadership and Staff</i> .
<b>Mission</b>	To produce and disseminate evidence-based, state-of-the-art clinical practice guidelines that establish uniform standards of care for practitioners who provide prevention or treatment of HIV, viral hepatitis, other sexually transmitted infections, and substance use disorders for adults throughout New York State in the wide array of settings in which those services are delivered.
<b>Expert Committees</b>	The NYSDOH AI Medical Director invites and appoints committees of clinical and public health experts from throughout NYS to ensure that the guidelines are practical, immediately applicable, and meet the needs of care providers and stakeholders in all major regions of NYS, all relevant clinical practice settings, key NYS agencies, and community service organizations. <ul style="list-style-type: none"> <li>See <i>Expert Committees</i></li> </ul>
<b>Committee Structure</b>	<ul style="list-style-type: none"> <li>Leadership: AI-appointed chair, vice chair(s), chair emeritus, clinical specialist(s), JHU Guidelines Program Director, AI Medical Director, AI Clinical Consultant, AVAC community advisor</li> <li>Contributing members</li> <li>Guideline writing groups: Lead author, coauthors if applicable, and all committee leaders</li> </ul>
<b>Conflicts of Interest Disclosure and Management</b>	<ul style="list-style-type: none"> <li>Annual disclosure of financial relationships with commercial entities for the 12 months prior and upcoming is required of all individuals who work with the guidelines program, and includes disclosure for partners or spouses and primary professional affiliation.</li> <li>The NYSDOH AI assesses all reported financial relationships to determine the potential for undue influence on guideline recommendations and, when indicated, denies participation in the program or formulates a plan to manage potential conflicts.</li> <li>Disclosures are listed for each committee member.</li> </ul>
<b>Evidence Collection and Review</b>	<ul style="list-style-type: none"> <li>Literature search and review strategy is defined by the guideline lead author based on the defined scope of a new guideline or update.</li> <li>A comprehensive literature search and review is conducted for a new guideline or an extensive update using PubMed, other pertinent databases of peer-reviewed literature, and relevant conference abstracts to establish the evidence base for guideline recommendations.</li> <li>A targeted search and review to identify recently published evidence is conducted for guidelines published within the previous 3 years.</li> <li>Title, abstract, and article reviews are performed by the lead author. The JHU editorial team collates evidence and creates and maintains an evidence table for each guideline.</li> </ul>
<b>Recommendation Development</b>	<ul style="list-style-type: none"> <li>The lead author drafts recommendations to address the defined scope of the guideline based on available published data.</li> <li>Writing group members review the draft recommendations and evidence and deliberate to revise, refine, and reach consensus on all recommendations.</li> <li>When published data are not available, support for a recommendation may be based on the committee’s expert opinion.</li> <li>The writing group assigns a 2-part rating to each recommendation to indicate the strength of the recommendation and quality of the supporting evidence. The group reviews the evidence, deliberates, and may revise recommendations when required to reach consensus.</li> </ul>

**Guideline Development: New York State Department of Health AIDS Institute Clinical Guidelines Program**

<b>Review and Approval Process</b>	<ul style="list-style-type: none"> <li>▪ Following writing group approval, draft guidelines are reviewed by all contributors, <a href="#">program liaisons</a>, and a volunteer reviewer from the AI Community Advisory Committee.</li> <li>▪ Recommendations must be approved by two-thirds of the full committee. If necessary to achieve consensus, the full committee is invited to deliberate, review the evidence, and revise recommendations when required.</li> <li>▪ Final approval by the committee chair and the NYSDOH AI Medical Director is required for publication.</li> </ul>
<b>External Reviewers</b>	<ul style="list-style-type: none"> <li>▪ External peer reviewers recognized for their experience and expertise review guidelines for accuracy, balance, clarity, and practicality and provide feedback.</li> <li>▪ Peer reviewers may include nationally known experts from outside of New York State.</li> </ul>
<b>Update Process</b>	<ul style="list-style-type: none"> <li>▪ JHU editorial staff ensure that each guideline is reviewed and determined to be current upon the 3-year anniversary of publication; guidelines that provide clinical recommendations in rapidly changing areas of practice may be reviewed annually. Published literature is surveilled to identify new evidence that may prompt changes to existing recommendations or development of new recommendations.</li> <li>▪ If changes in the standard of care, newly published studies, new drug approval, new drug-related warning, or a public health emergency indicate the need for immediate change to published guidelines, committee leadership will make recommendations and immediate updates.</li> <li>▪ All contributing committee members review and approve substantive changes to, additions to, or deletions of recommendations; JHU editorial staff track, summarize, and publish ongoing guideline changes.</li> </ul>

<b>AIDS Institute HIV Clinical Guidelines Program Recommendations Rating Scheme</b>	
<b>Strength of Recommendation</b>	<b>Quality of Supporting Evidence</b>
A = Strong	1 = At least 1 randomized trial with clinical outcomes and/or validated laboratory endpoints
B = Moderate	2 = One or more well-designed, nonrandomized trial or observational cohort study with long-term clinical outcomes
C = Optional	3 = Expert opinion

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