CLINICAL GUIDELINES PROGRAM
NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE | HIV • HCV • STIs • SUBSTANCE USE • LGBTQ+ HEALTH

Post-Exposure Prophylaxis (PEP) to Prevent HIV Infection

Updates, Authorship, and Related Resources

Date of current publication	December 5, 2025
Highlights of changes, additions, and updates in the December 5, 2025 edition	• Management of Potential Exposure to Hepatitis B Virus section: Comprehensive update • Management of Potential Exposure to Hepatitis C Virus section: Comprehensive update • Supplementary Materials section: Comprehensive update • Providing PEP Medications and Other Services section: Text added on amendments to Public Health Law section 2805-I requiring hospitals to provide a full 28-day PEP regimen to survivors of sexual assault, regardless of age (effective February 3, 2026).
Intended users	New York State clinicians who provide PEP for individuals who report a potential exposure to HIV with a potential concomitant exposure to hepatitis B virus or hepatitis C virus
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Purpose of This Guideline

This guideline was developed by the New York State Department of Health AIDS Institute (NYSDOH 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. 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 pertinent to delivering PEP care.

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 and C viruses

Note on "experienced" HIV care providers: The NYSDOH AI Clinical Guidelines Program defines an "experienced HIV care provider" as a practitioner who has been accorded HIV Specialist status by the American Academy of HIV Medicine. Nurse practitioners (NPs) and licensed midwives who provide clinical care to individuals with HIV in collaboration with a physician may be considered experienced HIV care providers if all other practice agreements are met; NPs with more than 3,600 hours of qualifying experience do not require collaboration with a physician (8 NYCRR 79-5:1; 10 NYCRR 85.36; 8 NYCRR 139-6900).

Physician assistants who provide clinical care to individuals with HIV under the supervision of an HIV Specialist physician may also be considered experienced HIV care providers (10 NYCRR 94.2).

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 post-exposure prophylaxis (PEP) scenarios outlined below (see guideline sections Occupational Exposure, Non-Occupational Exposure, Sexual Assault Exposure, and Exposure Risk in Children). 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; PRN Notebook 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 cisgender 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[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 and have an undetectable viral load (HIV RNA <200 copies/mL). Achieving and maintaining viral suppression through ART during pregnancy and postpartum decreases breast/chestfeeding transmission risk to less than 1%, but not zero. In a shift from prior guidance, the U.S. Department of Health and Human Services (DHHS), American Academy of Pediatrics (AAP), and others now recommend that individuals with HIV who are on ART with a sustained undetectable viral load and who choose to breast/chestfeed should be supported in this decision. The AAP notes that “pediatricians should be prepared to offer a family-centered, nonjudgmental, harm reduction approach to support people with HIV on ART with sustained viral suppression below 50 copies per mL who desire to breastfeed”[Abuogi, et al. 2024]. Discuss both replacement feeding and breastfeeding with patients and address additional risk mitigation strategies, including possibly extending ARV prophylaxis (i.e., nevirapine or lamivudine) during breastfeeding after the initial period of ARV prophylaxis recommended for all infants with perinatal HIV exposure (i.e., zidovudine). Counseling should also address issues related to breast health (e.g., mastitis), mixed feeding, and slow weaning[DHHS 2024].

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 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 medications that have increased bioavailability, it is presumed the use of a 3-drug PEP regimen would further reduce this risk.

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 a cohort of 266 healthcare workers who had percutaneous or mucocutaneous injuries and exposure to HIV-contaminated body fluids, there were no seroconversions over a 13-year period (seroconversion rate 0%). In addition to their internal findings, the investigators compared their results to a calculated overall HIV seroconversion rate of 0.13% after a literature review conducted in October 2016 yielded 17 articles documenting 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 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.

◊ RESOURCES

- National Institute for Occupational Safety and Health: Preventing Needlestick Injuries in Health Care Settings [NIOSH 2014]
- Occupational Safety and Health Administration (OSHA): Needlestick Safety and Prevention Act FAQs
- Legal basis and guidance regarding exposure: Public Law 106-430 (federal law)
- 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 OSHA Bloodborne Pathogens and Needlestick Prevention 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. For more information, see Employer Responsibilities in PEP Management to Prevent HIV Infection Following an Occupational Exposure.

Non-Occupational Exposure Risk

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 (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 a 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 use of male (insertive) and female (receptive) condoms. The CDC 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 injures resulting in puncture wounds, based on immunization history and hepatitis B virus status of the source[Medscape 2021; Bader and

McKinsey 2013]. Hepatitis B immunoglobulin may also be necessary (see 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 experiencing a seizure); only 4 of the 9 cases were confirmed or classified as highly plausible[Cresswell, et al. 2018].

A bite wound resulting 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 their mouth (e.g., from bleeding gums or lesions)

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(a) 2019].

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 antiretroviral therapy 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

Box 1: Risk per 10,000 Exposures of Acquiring HIV From an Infected Source and Factors That Increase Risk
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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 sexually transmitted infections [CDC(b) 2024; 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]
- Nonintact 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

Prevention of non-occupational exposure: HIV transmission 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. "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.

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:

- 26.8% of women reported attempted or completed rape* in their lifetime, with the first assault occurring[CDC 2022]:
  - Before age 18 years in 49.0% (~16.4 million)
  - Between the ages of 11 and 17 years in 34.9% (~11.7 million)
  - At age 10 years or younger in 14.0% (~4.7 million)
- 3.8% of men reported attempted or completed rape in their lifetime, with the first assault occurring[CDC 2022]:
  - Before age 18 years in 56.6% (~2.5 million)
  - Between the ages of 11 and 17 years in 29.8% (~1.3 million)
  - At age 10 years or younger in 26.8% (~1.2 million)
- About 16 million women and 11 million 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(a) 2024].
- 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.

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 unlikely to use condoms (or they use condoms inconsistently), and 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].

Exposure Risk in Children

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[Lindegren, et al. 1998; Gellert, et al. 1993]. Children might be at increased risk of becoming infected with HIV because of the cervical ectopy in adolescent girls and the thinness of the vaginal epithelium in prepubertal girls[Kleppa, et al. 2015]. Additionally, children who experience abuse multiple times over an extended period by the same perpetrator are at increased risk because of mucosal trauma with bleeding[CDC 2016; Smith, et al. 2005; Dominguez 2000].

Discarded needles: Risk of transmission from discarded needles is low. In 2 cohorts of children (59 children and 249 children, respectively) 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]. Similarly, in a 2018 update to the Canadian study, a review of 14 studies of children exposed to needlesticks in the community documented no transmissions among 613 children followed for HIV, 575 children followed for hepatitis B virus, and 394 children followed for hepatitis C virus[Moore 2018]. Of the 613 children followed for HIV exposure, only 181 (29.5%) received antiretroviral prophylaxis. 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 of Exposed Individuals and Table 6: Recommended Laboratory Monitoring After PEP 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 promptly considered:** 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 or of **unknown** HIV status (including high-risk needlestick injuries, and human bites that result in blood exposure); high-risk sexual exposures (including source with known HIV who is not taking ART or has incomplete viral

→ KEY POINTS

suppression, trauma at the site of exposure, blood exposure, and nonintact oral mucosa, such as oral lesions, gingivitis, or open wounds in oral sexual exposures). See Non-Occupational Exposure Risk, above, for more high-risk scenarios.

- See Box 1: Risk per 10,000 Exposures of Acquiring HIV from an Infected Source and Factors That Increase Risk, above, for risk calculations for specific exposures.

Rationale for PEP and Evidence of PEP Effectiveness

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 is 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

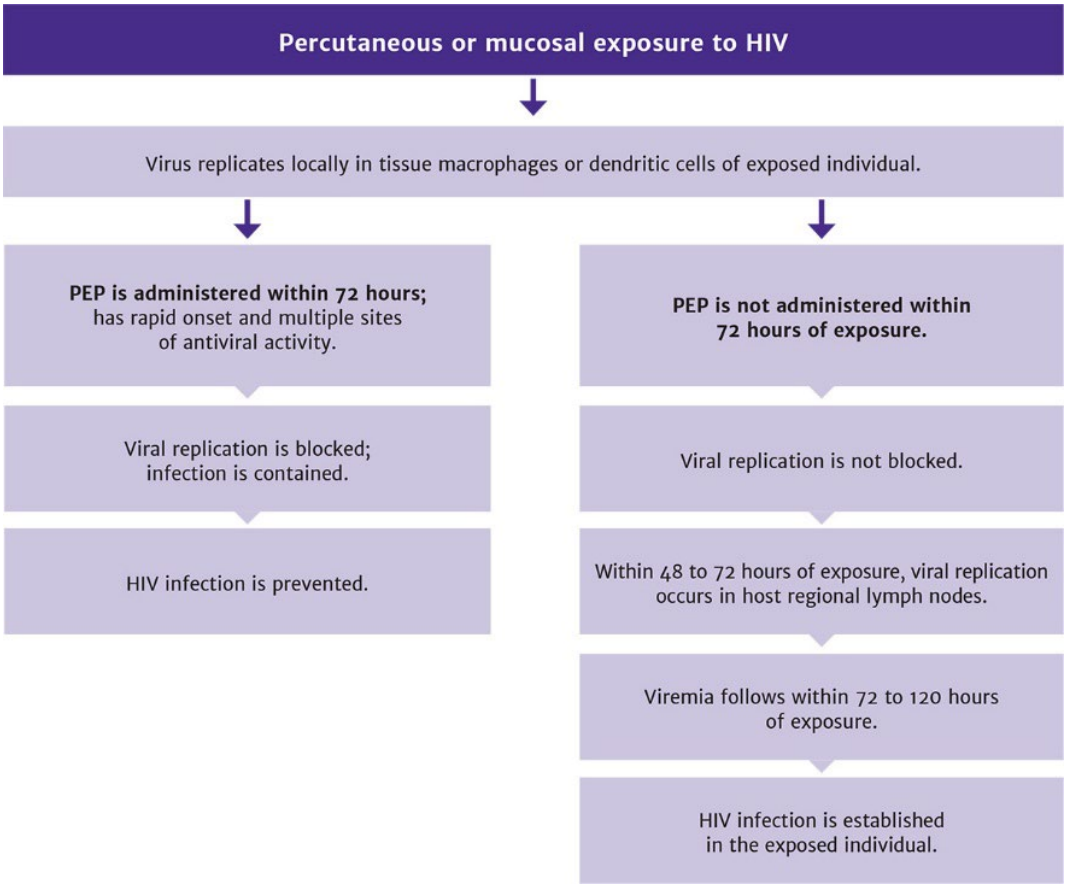
- PEP is effective in preventing HIV infection when administered rapidly—ideally within 2 hours and no later than 72 hours—after a high-risk exposure.
- Antiretroviral (ARV) regimens currently recommended for PEP are safe in individuals who do not have HIV, as documented in published studies of observational cohorts[McAllister, et al. 2017; Mulka, et al. 2016; Ford(a), 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(a), 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 2024], 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 after infection. Ten mice that were not treated and became positive for plasma p24 and HIV-1 RNA 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 that 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 after exposure prevented infection; however, breakthrough plasma viremia was observed in some animals when PEP was initiated 72 hours after exposure[Otten, et al. 2000].
- SIV infection was prevented in macaques treated 24 hours after exposure with ARV medications as PEP (short-term 9-[2-(R)-(phosphonomethoxy)propyl]adenine); half of the macaques that received PEP at 48 and 72 hours after exposure developed infection[Tsai, et al. 1998].
- SIV was prevented in 4 of 6 macaques treated with 2 doses of bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) given at 12 and 36 hours after exposure and in 5 of 6 macaques when given at 6 and 30 hours after exposure[Bekerman, et al. 2021].

Figure 1: Sequence of Events Following HIV Exposure, With and Without Administration of PEP



Abbreviation: PEP, post-exposure prophylaxis.

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 controls. Case patients were significantly less likely than controls to have taken ZDV prophylaxis after exposure (odds ratio, 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 girl aged 12 years with sickle cell disease who received 4-drug PEP with tenofovir, emtricitabine, ritonavir-boosted darunavir, and raltegravir after a blood transfusion and was exposed 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 per 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 abstaining 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 of more than 48 hours but less than 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(a), et al. 2015].
- Three studies examined the safety and tolerability of coformulated BIC/FTC/TAF among 280 total participants in China, the United States, and Canada. The once-daily dose of BIC/FTC/TAF was well tolerated with minimal adverse effects and very low discontinuation rates; of the 280 participants, only 4 discontinued the drug, and no seroconversions were reported[Tan, et al. 2024; Liu, et al. 2022; Mayer, et al. 2022].

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.

In an Australian study that examined adherence to 28-day PEP regimens in children younger than 16 years, 62 (12%) of 511 alleged child sexual assault events were assessed by the treating clinician as requiring PEP[Combs, et al. 2024]. However, PEP was not prescribed in 8 events (13%), with a reason documented for 6 of these cases (75%). Only 23 of the 54 children who were eligible for PEP (43%) were adherent to the 28-day regimen. Gastrointestinal upset contributed to early cessation in 5 of the children eligible for PEP (9%).

First Dose of PEP and Management of the Exposure Site

☑ RECOMMENDATIONS

First Dose of PEP: Exposure to HIV is an emergency

- Clinicians should administer the first dose of PEP immediately—ideally within 2 hours of and no later than 72 hours after exposure—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 unknown. (A2)
- Clinicians should administer a preferred or alternative PEP regimen (the following recommended regimens also have activity in the rare possibility of an exposure to known HIV-2 or a source patient at risk of HIV-2 infection): (A2)
  - Preferred single-tablet regimen: BIC/TAF/FTC by mouth once daily (preferred because of the lower discontinuation rates and minimal adverse effects)
  - Preferred multi-tablet regimen [a,b]: TDF/FTC plus either DTG or RAL; 3TC may be substituted for FTC in either regimen
  - See Table 2: Preferred PEP Regimens for Patients Who Weigh ≥40 kg.
  - For alternative regimens, see Table 3: Alternative PEP Regimens for Patients Who Weigh ≥40 kg.
- **First dose of PEP for an individual who weighs <40 kg (88 lb):** Clinicians should administer a preferred or alternative PEP regimen; see Table 4: PEP Regimens for Pediatric Patients Who Weigh <40 kg. (A2)
- **If the patient is pregnant or trying to conceive [a,b]:** Clinicians should recommend TDF/FTC plus either DTG or RAL (A2); or BIC/TAF/FTC (A3).
- **Patients with impaired renal function:** Clinicians should not initiate TDF/FTC as PEP for any individual with a confirmed CrCl <60 mL/min and should discontinue it in patients with a confirmed CrCl <50 mL/min; in such cases, initiate or switch to a TAF-containing regimen. (A1)
- 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)

☑ RECOMMENDATIONS

- If the exposed individual's baseline HIV test result indicates HIV infection before the reported exposure, clinicians should recommend initiation of ART and refer the patient to an experienced HIV care provider. (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 after exposure, clinicians should perform baseline HIV testing and recommend serial HIV testing at 4 and 12 weeks after exposure. (A2)
- When an individual who has been taking PrEP with **daily adherence** requests PEP following a sexual exposure, clinicians should advise that additional ARVs for PEP are not warranted in most situations (see guideline text 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)

Abbreviations: 3TC, lamivudine (brand name Epivir); ART, antiretroviral therapy; ARV, antiretroviral medication; BIC/TAF/FTC, bictegravir/tenofovir alafenamide/emtricitabine (brand name Biktarvy); CrCl, creatinine clearance; DTG, dolutegravir (brand name Tivicay); PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis; RAL, raltegravir (brand name Isentress); TDF/FTC, tenofovir disoproxil fumarate/emtricitabine (brand name Truvada).

Notes:

a. The high-dose formulation of RAL (RAL HD) should not be given to pregnant patients.
b. 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[Zash, et al. 2022].

Exposure to HIV Is An Emergency

An HIV exposure is a medical emergency and rapid initiation of PEP—ideally within 2 hours of and no later than 72 hours after 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. Given the urgency of PEP initiation, prescribing PEP by telehealth is reasonable when cooperative agreements are in place for PEP recipients to pursue recommended testing and follow-up. 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 after exposure compared with 72 hours[Otten, et al. 2000; Smith, 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-in-pocket (PIP): Studies of PIP, which entails giving individuals with an anticipated low frequency of high-risk HIV exposures a prescription for PEP to be used in the event of an HIV exposure, demonstrated that participants could initiate PEP appropriately on their own, often within a much shorter period between exposure and first PEP dose[Billick, et al. 2023; Alghamdi, et al. 2020; Tumarkin, et al. 2018]. Advise patients who receive PIP to store the medication so it remains clean and dry.

PEP for an individual who is taking PrEP: Occasionally, an HIV-exposed individual who has been taking PrEP insists on receiving a third ARV medication as PEP despite a clinician's reassurance that it is unnecessary. A clinician may reassure a patient who is taking PrEP with daily adherence that no current evidence supports 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 (FTC or tenofovir), offering 3-drug PEP to the exposed individual should be considered, particularly if the source's viral load is unsuppressed (HIV RNA >200 copies/mL). Lastly, there may be instances in which 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 WITH PrEP

- Time to protection of PrEP 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 exposures, 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.

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

→ KEY POINT

- Intentionally waiting until the 72-hour mark to initiate PEP could place an exposed individual at increased risk of seroconversion.

By 72 hours after 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 after exposure.

In response to an exposure reported 72 hours after exposure, follow-up appropriate to the type of exposure should be arranged as detailed in Table 1: Baseline Testing of Exposed Individuals.

Managing the Exposure Site

Care of the exposure site should prioritize appropriate cleansing and infection prevention 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 because of potential drug-drug interactions or comorbidities, or an exposed individual who is pregnant or unconscious. In such circumstances, New York State clinicians are advised to call the Clinical Education Initiative (CEI Line) to speak with an experienced HIV care provider. Call 866-637-2342 and press “1” for HIV PEP. The CEI Line is available 24/7.

The National Clinical Consultation Center (NCCC) for PEP (part of the AIDS Education and Training Centers and located at the University of California, San Francisco/Zuckerberg San Francisco General Hospital) may be reached by calling 888-448-4911. The NCCC is funded by the Health Resources and Services Administration and the Centers for Disease Control and Prevention.

→ SELECTED GOOD PRACTICE REMINDERS

First Dose of PEP and Management of the Exposure Site

- **All exposures:** 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.

Evaluating Exposure Risk

☑ RECOMMENDATIONS

All Exposures

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

Sexual Assault Exposures

- 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 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 gonorrhea, chlamydia, and trichomoniasis. (A3)

Exposures in Children

- Clinicians should recommend PEP—ideally within 2 hours of and no later than 72 hours after an exposure—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 are known or suspected to 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 gonorrhea, chlamydia, and trichomoniasis. (A3)
- Clinicians should administer the first dose of the HPV vaccine for children aged 9 to 17 years who have not yet been vaccinated. (A3)
- Clinicians should provide prophylaxis for HBV exposure in a child if indicated (see guideline section Management of Potential Exposure to Hepatitis B Virus). (A1)

Abbreviations: HBV, hepatitis B virus; HPV, human papillomavirus; PEP, post-exposure prophylaxis; STI, sexually transmitted infection.

Box 2: Risk of HIV Transmission From a Source With HIV	
Meaningful risk of transmission: • Blood • Semen • Vaginal secretions • Human milk • Cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids	**No meaningful risk of transmission:** • Nonbloody saliva • Nonbloody nasal secretions • Tears • Sweat • Nonbloody urine • Nonbloody feces

Evaluating Occupational Exposure Risk

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 nonintact skin. Figure 2, below, illustrates the steps in determining whether ongoing PEP is indicated after the first emergency dose.

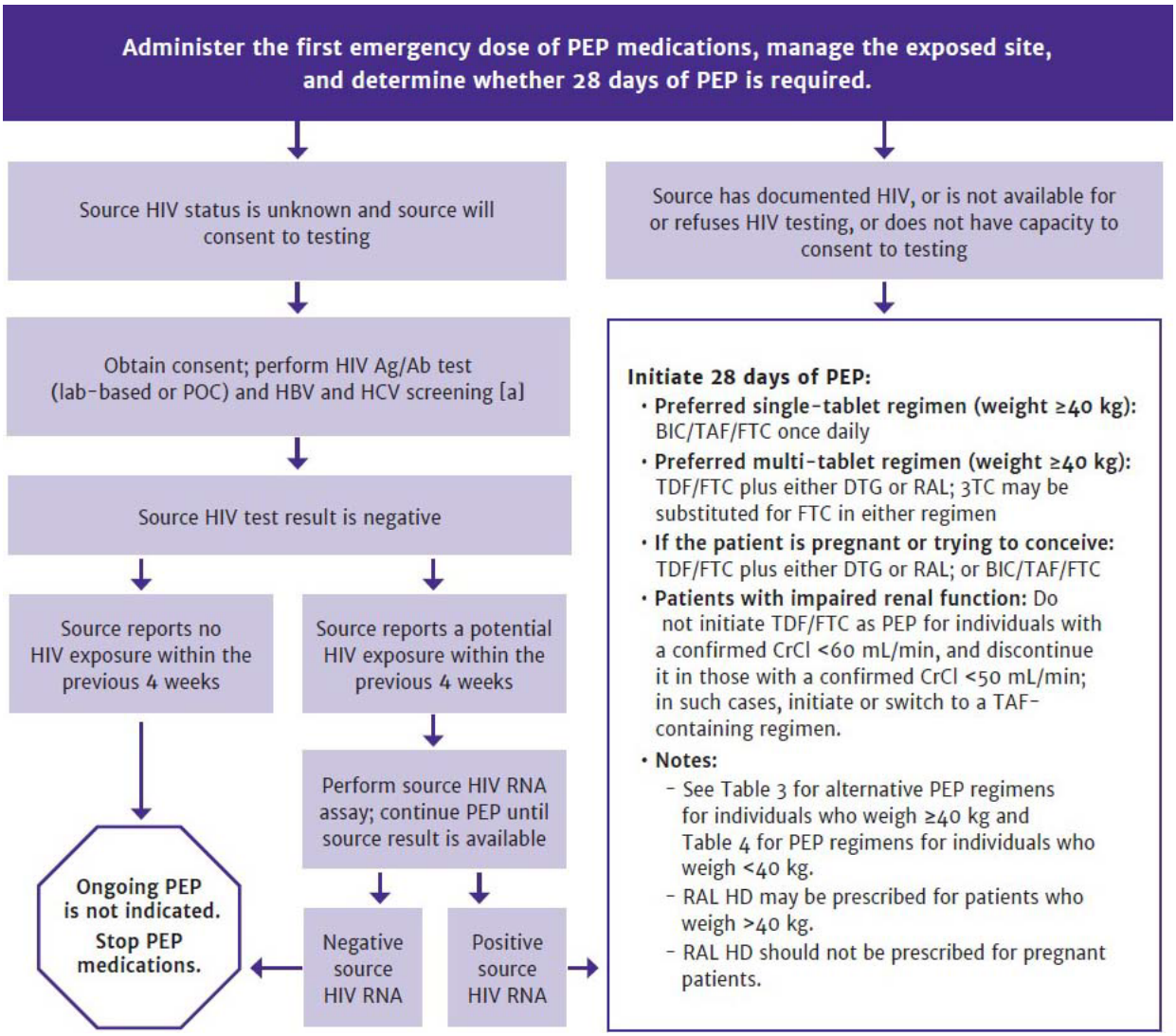
Occupational exposures for which PEP is indicated include the following:

- 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
- Splash of blood, visibly bloody fluid, or other potentially infectious material to the mouth, nose, or eyes
- A nonintact skin (e.g., dermatitis, chapped skin, abrasion, or open wound) exposure to blood, visibly bloody fluid, or other potentially infectious material

PEP is *not* indicated for an exposure to saliva, including from being spat on, in the absence of visible blood.

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

Figure 2: Occupational HIV Exposure: PEP and Exposure Management When Reported Within 72 Hours



Abbreviations: Ag/Ab, antigen/antibody; BIC/TAF/FTC, bictegravir/tenofovir alafenamide/emtricitabine (brand name Biktarvy); CrCl, creatinine clearance; DTG, dolutegravir (brand name Tivicay); HBV, hepatitis B virus; HBsAg, hepatitis B surface antigen; HCV, hepatitis C virus; PEP, post-exposure prophylaxis; POC, point-of-care; RAL, raltegravir (brand name Isentress); RAL HD, high-dose raltegravir (brand name Isentress HD); TAF, tenofovir alafenamide; TDF/FTC, tenofovir disoproxil fumarate/emtricitabine (brand name Truvada).

Note:

a. HBV and HCV screening: If source's HBV and HCV status are unknown or if the source is unavailable, obtain consent and perform testing for HBsAg and HCV antibody testing. See the full guideline for recommendations and more information.

Evaluating Non-Occupational Exposure Risk

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; determining 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.

→ KEY POINTS

- 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 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 outlines 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: Because of 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(b) 2024; 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].

Box 3, below, lists non-occupational exposures that should prompt consideration of PEP and those that do not warrant PEP.

Box 3: Non-Occupational Exposure Risks and Indications for Post-Exposure Prophylaxis

Higher Risk: Post-exposure Prophylaxis (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) Nonintact oral mucosa, for example, oral lesions, gingivitis, or wounds. 3) Blood exposure—may be minimal and not recognized by the exposed individual; if frank blood exposure is reported, 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 through 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
- Exposure to solid-bore needles (e.g., tattoo needles and lancets used to measure blood-sugar levels) or other sharps not in recent contact with blood
- Mutual masturbation without skin breakdown or blood exposure
- Exposure to saliva, including if spat on, in the absence of visible blood

Notes:

a. Source is known to have HIV or source's HIV status is unknown.
b. See NYSDOH AI U=U Guidance for Implementation in Clinical Settings.

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 Box 1: Risk per 10,000 Exposures of Acquiring HIV From an Infected Source and Factors That Increase Risk and Box 3,

above). 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(b) 2024; LeGoff, et al. 2007]
- High plasma viral load in a source with HIV [Patterson, et al. 2002; Tovanabutra, et al. 2002]
- Exposure in an uncircumcised male [Bailey, et al. 2007; Gray, et al. 2007; Patterson, et al. 2002]

Factors that may significantly decrease transmission of HIV include exposure to a source who is taking effective ART, 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. 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.

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

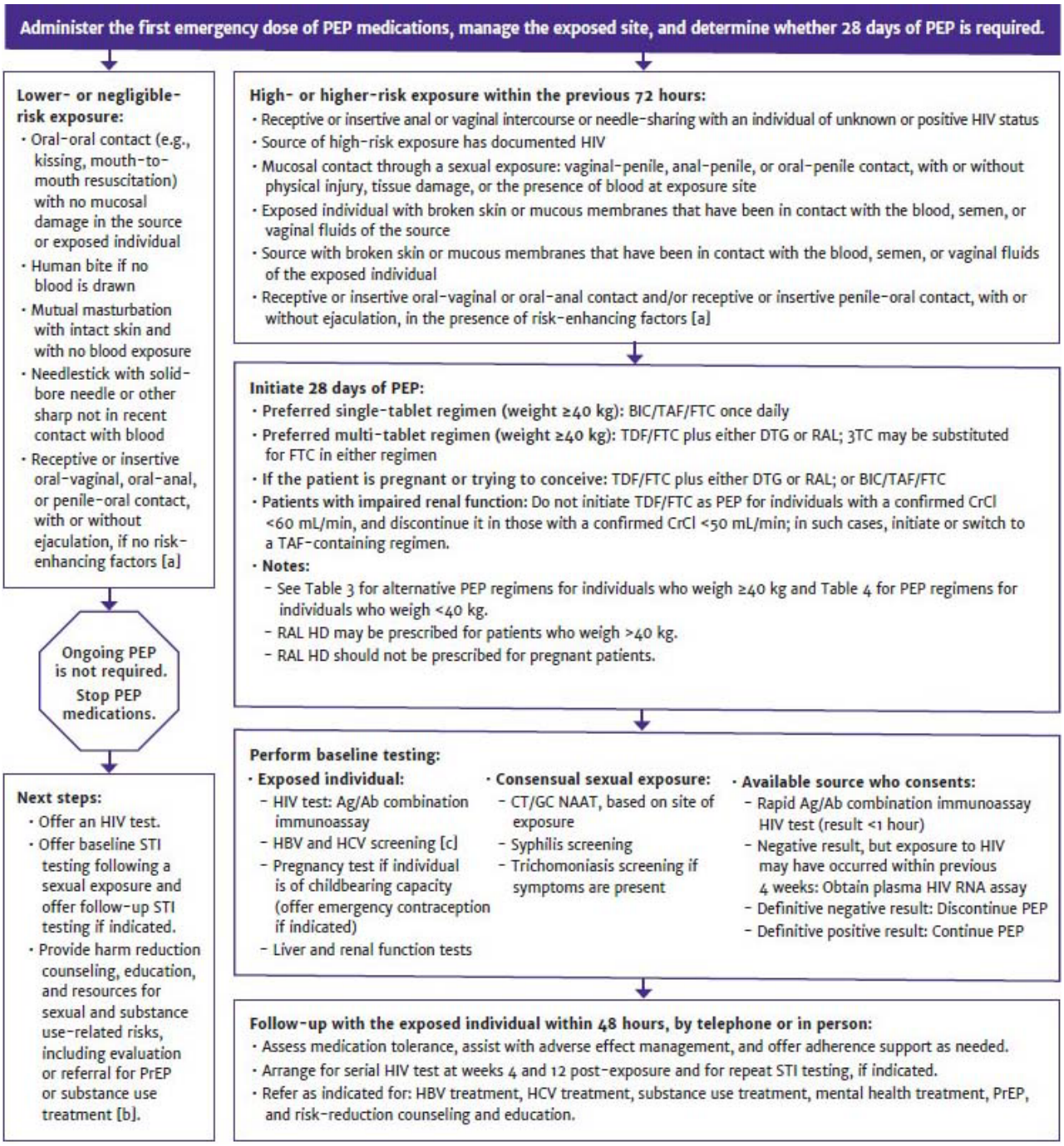
Baseline testing generally cannot detect STIs that were acquired as a result of the exposure, but may detect infections present before the exposure that prompted the evaluation for PEP. Presentation for PEP is an opportunity to screen individuals at risk of STIs and treat infections as indicated. High 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 after 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].

Exposure to other bloodborne pathogens: See guideline sections Management of Potential Exposure to Hepatitis B Virus and Management of Potential Exposure to Hepatitis C Virus.

Emergency contraception: For individuals who can but do not wish 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.

Figure 3: Non-Occupational HIV Exposure in Adults: PEP and Exposure Management When Reported Within 72 Hours



Abbreviations: 3TC, lamivudine (brand name Epivir); Ag/Ab, antigen/antibody; BIC/TAF/FTC, bictegravir/tenofovir alafenamide/emtricitabine (brand name Biktarvy); CrCl, creatinine clearance; CT/GC NAAT, chlamydia/gonorrhea nucleic acid amplification testing; DTG, dolutegravir (brand name Tivicay); HBV, hepatitis B virus; HCV, hepatitis C virus; PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis; RAL, raltegravir (brand name Isentress); RAL HD, high-dose raltegravir (brand name Isentress HD); STI, sexually transmitted infection; TAF, tenofovir alafenamide; TDF/FTC, tenofovir disoproxil fumarate/emtricitabine (brand name Truvada).

Notes:

a. Risk-enhancing factors: Source with a high HIV viral load; source or exposed individual with oral lesions; frank blood exposure; source or exposed individual has genital ulcer disease or other STIs; 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.
b. See NYSDOH AI guidelines PrEP to Prevent HIV and Promote Sexual Health and Substance Use Harm Reduction in Medical Care.
c. See guideline sections Management of Potential Exposure to Hepatitis B Virus and Management of Potential Exposure to Hepatitis C Virus.

Evaluating Sexual Assault Exposure Risk

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, PEP should be recommended.

Risk of HIV transmission: The risk of HIV transmission in sexual assault is greater with 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 carries a risk of 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, monitoring and follow-up should be coordinated by the treating clinician. If the baseline screening HIV test is reactive, 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 promptly informed of the result. If HIV infection has been diagnosed, the PEP regimen may be altered by the HIV care provider or continued 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.

More information about the use of emergency contraception is available at Bedsider: Emergency Contraception and Emergency Contraception: What You Need to Know.

★ NEW YORK STATE LAW

- If a sexual assault exposure is assessed as high risk:
  - Hospital clinicians are required by New York State law to provide a full 28-day PEP regimen to sexual assault patients, regardless of age (effective February 3, 2026). 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.
- See New York State Public Health Law 2805-I: Chapter 45, Article 28.

STI prophylaxis: Clinicians should *offer* all sexual assault patients prophylactic medication to prevent gonorrhea, chlamydia, and trichomoniasis. STI rates 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(b) 2019; CDC 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, trichomoniasis, and syphilis is *not recommended* for adults 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 2024].

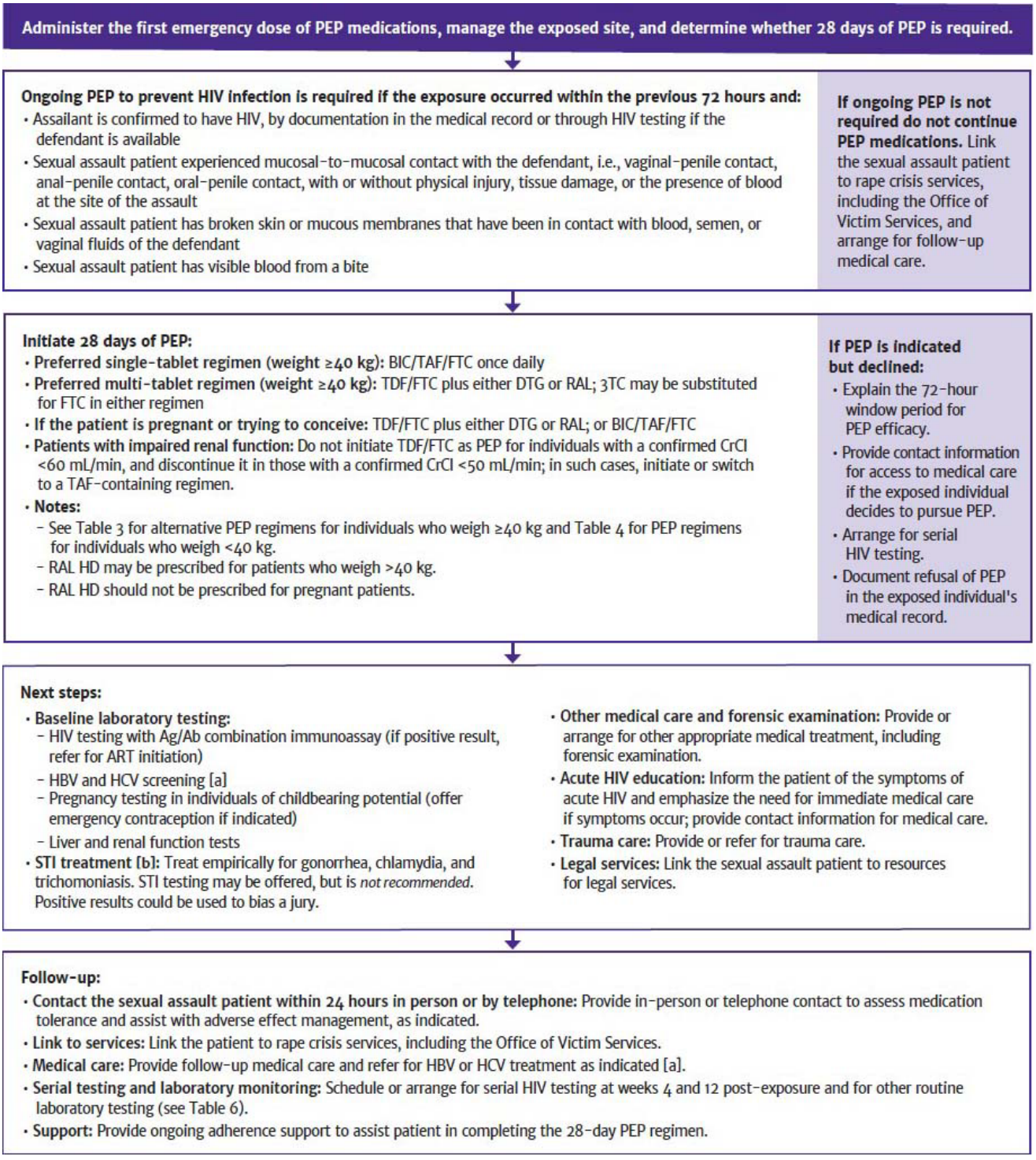
Evaluation for exposure to other bloodborne pathogens: See guideline sections Management of Potential Exposure to Hepatitis B Virus and Management of Potential Exposure to Hepatitis C Virus.

◊ RESOURCES

- NYSDOH Sexual Violence Prevention Unit
- NYSDOH Rape Crisis Programs by County
- Domestic and Other Violence Emergencies (DOVE) at New York-Presbyterian/Columbia University Irving 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.

Figure 4: Sexual Assault HIV Exposure in Adults: Post-Exposure Prophylaxis and Exposure Management



Abbreviations: 3TC, lamivudine (brand name Epivir); Ag/Ab, antigen/antibody; ART, antiretroviral therapy; BIC/TAF/FTC, bictegravir/tenofovir alafenamide/emtricitabine (brand name Biktarvy); CrCl, creatinine clearance; DTG, dolutegravir (brand name Tivicay); HBV, hepatitis B virus; HCV, hepatitis C virus; PEP, post-exposure prophylaxis; RAL, raltegravir (brand name Isentress); RAL HD, high-dose raltegravir (brand name Isentress HD); STI, sexually transmitted infection; TAF, tenofovir alafenamide; TDF/FTC, tenofovir disoproxil fumarate/emtricitabine (brand name Truvada).

Notes:

a. See guideline sections Management of Potential Exposure to Hepatitis B Virus and Management of Potential Exposure to Hepatitis C Virus.
b. For children ages 2 to 12 years with sexual exposure, perform baseline gonorrhea, chlamydia, and trichomoniasis testing and provide empiric treatment.

Considerations for Sexual Assault in Children

Care providers with experience 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 have been 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 or 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 treated 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 assault that occurred within 72 hours before the clinical evaluation. 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 policy statement Requirements to Report Instances of Suspected Child Abuse or Maltreatment.
- 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.
- Ensure that a Sexual Assault Forensic Examiner trained to perform pediatric examinations is included on the team to assist in the medical examination, coordination of care, and discussions about treatment regimen.
- 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 > Care for Suspected Child Abuse Patients.

→ SELECTED GOOD PRACTICE REMINDERS

Evaluating Exposure Risk

- **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 (ARS):** 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.

→ SELECTED GOOD PRACTICE REMINDERS

- **If PEP is declined:** 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 ARS.
  - 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:** Identify and assess all specific behaviors that may have resulted in exposure to HIV.
- **PrEP:** 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:** The Centers for Disease Control and Prevention recommends 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

☑ 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 PEP if not already 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)
- 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 Ab differentiation immunoassay or plasma HIV RNA test results are positive, 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 an undetectable viral load (HIV RNA <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 ART or if the source's viral load is unknown, 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 their medical record is available, clinicians should obtain the source's viral load, ART history, and 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. PEP initiation 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)

☑ RECOMMENDATIONS

- 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 (HIV RNA <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)

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 HIV RNA test result is positive, clinicians should recommend that the exposed individual compete the 28-day PEP regimen. (A2)
  - Clinicians should discontinue PEP if the source has an undetectable viral load (HIV RNA <200 copies/mL) and the confirmatory Ab differentiation immunoassay result is negative, consistent with a false-positive initial test. (A1)

Abbreviations: Ab, antibody; ART, antiretroviral therapy; ARV, antiretroviral; PEP, post-exposure prophylaxis.

Source HIV testing: In many cases of non-occupational exposure, the source is not available for testing. 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.

When the source of any potential exposure to HIV is unknown, unavailable, or cannot be HIV tested for any reason, the clinician should assess the exposed individual's level of risk, assume the source has HIV until proven otherwise, and respond accordingly.

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* because of its lack of sensitivity to identify recent infection and requirements regarding food, drink, and tobacco use.

See Box 4, below, for more on source HIV testing.

Box 4: Source HIV Testing

Available Source With Confirmed HIV	Available Source With Unknown HIV Status	Unknown or Unavailable Source
• Obtain the following: – Current viral load – Resistance test results – Current ART regimen – Previous ART regimens – Contact information for prescriber(s) • Do not delay PEP initiation while waiting for test results.	• Inform the source of the exposure incident. • Perform HIV test using an antigen/antibody combination immunoassay. • Assess the source patient for risk of HIV acquisition within the past 4 weeks (acute HIV infection).	• Assess the exposure to identify the exposed individual's risk of HIV infection. • Assume the source has HIV until proven otherwise.

Abbreviations: ART, antiretroviral therapy; PEP, post-exposure prophylaxis.

→ KEY POINTS

- Do not discontinue PEP in an exposed individual until the source's HIV serostatus is confirmed negative.
- Rapid oral HIV tests should not be used for source testing.
- Per the NYSDOH AI guideline HIV Testing, clinicians should use an HIV-1/2 Ag/Ab combination immunoassay to screen patients for HIV infection.
- **Occupational exposure:** Facilities subject to Occupational Safety and Health Administration (OSHA) regulations should choose the type of HIV test (laboratory-based or POC) that will return results most rapidly.

When obtaining HIV testing in the source of a potential HIV exposure, the source's risk of HIV acquisition in the 4 weeks prior must be considered. During this period, often referred to as the "window period" of the HIV-1/2 Ag/Ab combination immunoassay, an initial HIV screening test result may be nonreactive. The source should also be tested for acute HIV infection with an HIV-1 RNA assay (qualitative or quantitative) if they have engaged in condomless sexual intercourse (insertive or receptive anal, penile-vaginal) with or without pre-exposure prophylaxis (PrEP), or shared intravenous needles or syringes with or without PrEP.

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 a U.S. Food and Drug Administration (FDA)-approved HIV-1/2 Ag/Ab combination immunoassay, followed by confirmation with an FDA-approved HIV-1/HIV-2 Ab differentiation immunoassay. For more information, see the NYSDOH AI guideline HIV Testing and 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]. The exposed individual's first emergency dose of PEP should not be delayed while awaiting this information.

In the case of a sexual exposure to a source with HIV, the exposed individual may discontinue PEP if the source is taking ART and has an undetectable viral load at the time of exposure; providing information about U=U (undetectable = untransmittable) to the exposed individual may be reassuring. However, if an exposed individual requests PEP, it should not be denied.

Informed consent: If the source is available and has an unconfirmed HIV status, 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, HIV testing cannot be performed.

Box 5: Clinician-to-Clinician Communication

- **Occupational exposure:** Communication between clinicians *is allowed*; source information may be shared.
- **Non-occupational exposure:** Source information may be shared *only* if the source signs an Authorization for Release of Health Information and Confidential HIV-Related Information form DOH-2557.
- **Sexual assault exposure:** As of November 1, 2007, New York State Criminal Procedure Law § 210.16 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, see New York State Court-Ordered HIV Testing of Defendants.
- **Exposure in a child aged 2 to 12 years:** Source information may be shared *only* if the source signs an Authorization for Release of Health Information and Confidential HIV-Related Information form DOH-2557.

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 6, below). Clinicians should follow individual institutional policies for obtaining consent.

Box 6: HIV Testing When the Source of an Occupational Exposure Is Unable to Consent

- The Family Health Care Decisions Act (FHCDA) stipulates who is able to consent for care. If a source is unable to provide consent for HIV testing, clinicians should follow institutional policies related to the FHCDA for obtaining consent for the source's HIV test. If the source is deceased, anonymous testing should be performed. Healthcare proxy and other surrogacy status ends with death.
- **No surrogate is immediately available to consent on behalf of the source:** 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.
  1. The source is comatose or is determined by an attending professional to lack the mental capacity to consent
  2. The source is not expected to recover in time for the exposed individual to receive appropriate medical treatment
  3. No surrogate with the legal authority to consent is available in time for the exposed individual to receive appropriate medical treatment
  4. The exposed individual will benefit medically by knowing the source's HIV test results
- **Anonymous testing of the source:** New York State public health law 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.

Source: NYSDOH AI Occupational Exposure and HIV Testing: Fact Sheet and Frequently Asked Questions

→ 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 PEP Management to 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 and their HIV-1/2 Ag/Ab combination immunoassay result is negative, plasma HIV RNA testing should be performed, 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 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. For more information, see NYSDOH Guidance for HIV Testing of Sexual Assault Defendants.

As of November 1, 2007, New York State Criminal Procedure Law § 210.16 requires HIV testing of criminal defendants indicted for certain felony sex offenses, upon the request of the victim. For guidance on defendant testing, see New York State 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 the risk behavior profiles of defendants who engage in high-risk behaviors[Klot, et al. 2013].

Confirmed defendant HIV status: If the defendant is confirmed to have HIV, 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]. 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

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 the source's confirmatory testing is positive (HIV-1/HIV-2 Ab differentiation immunoassay or HIV-1 RNA test), link 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.
- **Counseling:** Provide counseling and education to the exposed individual.
- **Follow-up:** 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.
- **If the source's viral load at the time of a sexual exposure is available:** Offer information about U=U to reassure the exposed individual. 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 exposure will not transmit the virus through sex[Rodger, et al. 2019; Cohen, et al. 2016; Rodger, et al. 2016]. U=U does not apply to exposure through needle sharing, breast/chestfeeding, or needlestick injury.

Baseline Testing of the Exposed Individual

☑ RECOMMENDATIONS

All Exposures

- Clinicians should perform baseline HIV testing of an exposed individual using an FDA-approved HIV-1/2 Ag/Ab combination immunoassay, preferably at the time of PEP initiation, but no later than 72 hours after exposure. (A1)
  - Rapid oral HIV tests are not recommended because of the 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 HIV exposure, clinicians should document the refusal in the patient's medical record. (A3)
- If the result of a baseline HIV-1/2 Ag/Ab combination immunoassay is reactive, clinicians should recommend the continuation of PEP until the positive result is confirmed with an HIV-1/HIV-2 Ab differentiation immunoassay or HIV-1 RNA test. (A3)
- Clinicians should continue PEP in any individual 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.

☑ RECOMMENDATIONS

- If the exposed individual is confirmed to have HIV, clinicians should refer the individual to HIV care immediately for rapid initiation of ART and continue the 3-drug PEP regimen as ART. (A1)
- Clinicians should perform additional baseline laboratory testing specified in Table 1: Baseline Testing of Exposed Individuals. (A2)
- If the exposed individual declines to complete the 28-day PEP regimen, the clinician should recommend HIV testing at weeks 4 and 12 after 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 gonorrhea, chlamydia, and trichomoniasis. (A3)

Abbreviations: Ab, antibody; Ag, antigen; ART, antiretroviral therapy; FDA, U.S. Food and Drug Administration; PEP, post-exposure prophylaxis; STI, sexually transmitted infection.

Baseline HIV testing of the exposed individual identifies those 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.

An initial reactive screening test result must be confirmed with an HIV-1/HIV-2 Ab differentiation immunoassay, and the PEP regimen should be continued until that result is obtained. The PEP regimen should be continued as ART if the reactive test result is confirmed with an HIV-1/2 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 HIV-1/2 Ag/Ab combination immunoassay, which can simultaneously detect both HIV-1 and -2 antibodies and HIV-1 p24 antigens and will generally be positive within a median of 17.8 days, with an interquartile range of 13.0 to 23.6 days of infection[Delaney, et al. 2017].
- A negative baseline HIV test result only demonstrates that the exposed individual was not infected with HIV before the exposure occurred.

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 HIV seroconversion following an occupational exposure, a negative baseline HIV 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 infected with HIV at the time of the exposure, allowing decisions to be made regarding the continuation of ART. If the baseline screening HIV test result is reactive, 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.

Baseline Testing of Exposed Individuals

Table 1: Baseline Testing of Exposed Individuals [a]	
Test [b]	**Exposure Type**
HIV-1/2 antigen/antibody combination immunoassay (HIV RNA testing may be required in some cases [c])	All exposures
Serum liver enzymes, blood urea nitrogen, creatinine	All exposures
Complete blood count (if zidovudine is part of the regimen)	All exposures
Pregnancy (individuals of childbearing capacity)	All exposures
Hepatitis B serology panel (surface antigen, surface antibody)	All exposures
HCV antibody (HCV RNA testing may be required in some cases [d])	All exposures
Rapid plasma reagin	Sexual exposure [e]
Gonorrhea/chlamydia NAAT, by site	Sexual exposure [e]
Trichomoniasis NAAT	Sexual exposure [e]

Abbreviations: HCV, hepatitis C virus; NAAT, nucleic acid amplification test.

Notes:

a. For individuals who have been sexually assaulted, all baseline testing should be offered, not presented as mandatory or required, to avoid additional trauma.
b. In cases of nonsexual exposure, the medical record should be checked for history of tetanus vaccination.
c. See guideline section Sequential HIV Testing and Laboratory Monitoring.
d. See guideline section Management of Potential Exposure to Hepatitis C Virus.
e. For children ages 2 to 12 years with sexual exposure, perform baseline gonorrhea, chlamydia, and trichomoniasis testing and provide empiric treatment. For adults who have been sexually assaulted, *do not* perform baseline gonorrhea, chlamydia, trichomoniasis, and syphilis testing because this information can be used to bias a jury[NYSDOH 2024]; provide empiric gonorrhea, chlamydia, and trichomoniasis treatment to these patients.

→ SELECTED GOOD PRACTICE REMINDERS

Baseline Testing of the Exposed Individual

- **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 ART initiation and provide a referral for HIV care.
- **ART initiation:** Rapid ART initiation is recommended for all patients diagnosed with HIV.
- **Arrange for HIV care:** If HIV infection is confirmed, seroconversion is suspected, or HIV infection cannot be ruled out, refer the exposed individual for HIV care and rapid ART initiation.
- **Pregnancy testing:** Perform pregnancy testing in all individuals of childbearing capacity.
- **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.

Selecting and Initiating a 28-Day Course of PEP

☑ RECOMMENDATIONS

Preferred Regimens

- Clinicians should administer a preferred or alternative PEP regimen (the following recommended regimens also have activity in the rare possibility of an exposure to known HIV-2 or a source patient at risk of HIV-2 infection): (A2)
  - Preferred single-tablet regimen: BIC/TAF/FTC by mouth once daily (preferred because of the lower discontinuation rates and minimal adverse effects).
  - Preferred multi-tablet regimen [a,b]: TDF/FTC plus either RAL *or* DTG; 3TC may be substituted for FTC in either regimen.
  - For alternative regimens, see Table 3: Alternative PEP Regimens for Patients Who Weigh ≥40 kg.

ARV Medications to Avoid for PEP

- Clinicians should not initiate TDF/FTC as PEP for any individual with a confirmed CrCl <60 mL/min and should discontinue it in patients with a confirmed CrCl <50 mL/min; in such cases, initiate or switch to a TAF-containing regimen. (A1)
- Clinicians should not prescribe the following medications for PEP: ABC, EFV, IDV, MVC, NFV, NVP, and ZDV. (A2)
  - ZDV remains a recommended medication for the prevention of perinatal transmission of HIV and for pediatric PEP.

PEP During Pregnancy or Breast/Chestfeeding

- When a significant exposure to HIV occurs at any time during an exposed individual's pregnancy or while that individual is breast/chestfeeding a baby, clinicians should initiate PEP with a preferred or alternative regimen (see Tables 2 and 3 for preferred and alternative PEP regimens). (A2)
- Clinicians should advise individuals who may have been exposed to HIV to avoid breast/chestfeeding for 3 months after the exposure. (A2)
  - Individuals confirmed to be HIV negative may breast/chestfeed. (A1)

Abbreviations: ABC, abacavir (brand name Ziagen); ARV, antiretroviral; BIC/TAF/FTC, bictegravir/tenofovir alafenamide/emtricitabine (brand name Biktarvy); CrCl, creatinine clearance; EFV, efavirenz (brand name Sustiva); IDV, indinavir (brand name Crixivan); INSTI, integrase strand transfer inhibitor; MVC, maraviroc (brand name Selzentry); NFV, nelfinavir (brand name Viracept); NVP, nevirapine (brand name Viramune); PEP, post-exposure prophylaxis; PI, protease inhibitor; TDF/3TC, tenofovir disoproxil fumarate/lamivudine (brand name Cimduo); TDF/FTC, tenofovir disoproxil fumarate/emtricitabine (brand name Truvada); ZDV, zidovudine (brand name Retrovir).

Notes:

a. RAL may be prescribed in its high-dose formulation (RAL HD), but RAL HD should not be given to pregnant patients.
b. 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[Zash, et al. 2022].

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. Clinicians can call the Clinical Education Initiative (CEI Line) to speak with an experienced HIV care provider: 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 2021].

◊ RESOURCES

- University of Liverpool HIV Drug Interactions
- Prescribers' Digital Reference Network
- Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV

Impaired renal function: Do not initiate TDF/FTC as PEP for any individual with a confirmed CrCl <60 mL/min, and discontinue it in patients with a confirmed CrCl <50 mL/min; in such cases, initiate or switch to a TAF-containing regimen and continue monitoring while completing a 28-day course of PEP[DHHS 2024].

Hepatitis B virus infection: Additional monitoring is required for exposed individuals with HBV infection.

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 after exposure.

Repeated requests for non-occupational PEP: PEP should not be routinely dismissed based on repeated risk behavior or repeat presentation for PEP (see guideline section Counseling and Patient Education > Risk reduction), but clinicians should strongly encourage use of pre-exposure prophylaxis (PrEP) for individuals who repeatedly request PEP.

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 than those taking TDF/FTC plus darunavir (DRV) boosted with ritonavir (RTV)[Kumar, et al. 2017], suggesting TDF/FTC in combination with DTG or RAL is better tolerated in this population.

→ SELECTED GOOD PRACTICE REMINDERS

Selecting and Initiating a 28-Day Course of PEP

- **Avoid drug-drug interactions and medication-related adverse effects:** 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 effects.
- **Impaired renal function:** Do not initiate TDF/FTC as PEP for any individual with a confirmed CrCl <60 mL/min, and discontinue it in patients with a confirmed CrCl <50 mL/min; in such cases, initiate or switch to a TAF-containing regimen and continue monitoring while completing a 28-day course of PEP.
- **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 a 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, 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)**:** Hospital clinicians are required by New York State law to provide a full 28-day PEP regimen to sexual assault patients, regardless of age (effective February 3, 2026).
- **Medication access:** Ensure the patient can 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 adverse 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.

Preferred PEP Regimens for Patients Who Weigh ≥40 kg

The medications that comprise the recommended PEP regimens (and substitutions) listed in Table 2, 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 reported increased rates of adherence and regimen completion when the single-tablet regimen of BIC/TAF/FTC was used[Liu, et al. 2022; Mayer, et al. 2022]. For multi-tablet regimens TDF/FTC or TDF/3TC have been used as components of the PEP regimen [Tosini, et al. 2010; Mayer, et al. 2008] with high rates of adherence and low rates of discontinuation. Observational cohorts and a small randomized study reported improved tolerability with TDF/FTC plus RAL[McAllister, et al. 2017; Mulka, et al. 2016; Mayer, et al. 2012], and an observational cohort demonstrated high completion rates with TDF/FTC plus DTG[McAllister, et al. 2017]. Additionally, TDF/FTC has been highly successful in studies of PrEP[Baeten, et al. 2012; Thigpen, et al. 2012; Grant, et al. 2010].

Unlike PIs, which block HIV replication after integration with cellular DNA, all currently recommended PEP medications 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 PEP Regimens for Patients Who Weigh ≥40 kg [a,b]

Preferred Regimens	Notes
• Bictegravir 50 mg/tenofovir alafenamide 25 mg/emtricitabine 200 mg (BIC/TAF/FTC; Biktarvy) as a fixed-dose single tablet once per day	—
• Tenofovir disoproxil fumarate 300 mg/emtricitabine 200 mg (TDF/FTC; Truvada) once per day ***or*** • TDF 300 mg/lamivudine 300 mg (TDF/3TC; Cimduo) once per day ***plus*** • Raltegravir 400 mg (RAL; Isentress) twice per day ***or*** • RAL HD 1200 mg (Isentress HD) once per day [c] ***or*** • Dolutegravir 50 mg (DTG; Tivicay) once per day	• **DTG:** – Metformin dosing should be limited to 1 g by mouth per day when an individual is taking DTG concurrently. – 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. • **RAL:** Magnesium- or aluminum-containing antacids are contraindicated; coadministration of calcium-containing antacids is not recommended with RAL HD. • **TDF/FTC:** Do not initiate TDF/FTC as PEP for any individual with a confirmed CrCl <60 mL/min, and discontinue it in patients with a confirmed CrCl <50 mL/min; in such cases, initiate or switch to a TAF-containing regimen.

Abbreviations: CrCl, creatinine clearance; HD, high-dose; PEP, post-exposure prophylaxis.

Notes:

a. All medications are taken by mouth for 28 days.
b. Available alternative formulations and methods of administration:
   – 3TC: Acceptable to crush or split. Available as an oral solution (10 mg/mL).
   – DTG: Acceptable to crush.
   – FTC: Acceptable to open and dissolve in water. Available as an oral solution (10 mg/mL).
   – 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.
   – TDF: Acceptable to dissolve in water. Available as an oral powder only (40 mg/1 g) that can be mixed with soft food.
   – TDF/FTC: Acceptable to crush and dissolve.
c. RAL HD should *not* be prescribed for pregnant individuals.

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. Observational studies have demonstrated excellent tolerability and completion rates with these regimens[Mayer, et al. 2017; Fätkenheuer, et al. 2016; Valin, et al. 2016]. They are possibly less well tolerated than the preferred regimens of BIC/TAF/FTC and TDF/FTC plus either RAL or DTG, but they are significantly better tolerated than regimens containing ZDV or lopinavir/ritonavir (LPV/RTV).

In most cases, a single-tablet regimen for a patient with adequate kidney function (CrCl >70 mL/min) and no expected drug-drug interactions is preferred. In addition to low discontinuation rates, this option also allows for 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 by the extensive cytochrome P450 interactions. Clinicians should assess for potential interactions before prescribing a PEP regimen.

Table 3: Alternative PEP Regimens for Patients Who Weigh ≥40 kg [a,b]

Alternative Regimens	Notes
• Elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg (EVG/COBI/FTC/TDF; Stribild) as a fixed-dose single tablet once per day [c]	**For individuals with CrCl <70 mL/min:** Fixed-dose single tablet EVG/COBI/TDF/FTC is *contraindicated*.
• TDF 300 mg/FTC 200 mg (Truvada) ***plus*** ritonavir (RTV; Norvir) 100 mg ***plus*** darunavir (DRV; Prezista) 800 mg once per day [d] • Substitutions: – For FTC: Lamivudine (3TC; Epivir) 300 mg once per day – For DRV: Atazanavir (ATV; Reyataz) 300 mg once per day ***or*** fosamprenavir (FPV; Lexiva) 1400 mg once per day ***plus*** RTV 100 mg once per day	**For individuals with baseline CrCl <50 mL/min:** Adjust dosing of 3TC/FTC plus TDF.

Abbreviations: CrCl, creatinine clearance; PEP, post-exposure prophylaxis..

Notes:

a. All medications are taken by mouth for 28 days.
b. Available alternative formulations and methods of administration:
   – 3TC: Acceptable to crush or split. Available as an oral solution (10 mg/mL).
   – ATV: Acceptable to open capsule and sprinkle contents. Oral dispersible powder (50 mg/packet).
   – DRV: Probably acceptable to crush. Available as an oral suspension (100 mg/mL).
   – DTG: Acceptable to crush.
   – FTC: Acceptable to open and dissolve in water. Available as an oral solution (10 mg/mL).
   – 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.
   – RTV: Available as an oral solution (80 mg/mL).
   – TDF: Acceptable to dissolve in water. Available as an oral powder only (40 mg/1 g) that can be mixed with soft food.
   – TDF/FTC: Acceptable to crush and dissolve.
c. COBI-containing regimens should not be used during pregnancy.
d. If DRV or ATV are prescribed during pregnancy, dose adjustments are required. See guideline section PEP During Pregnancy or Breast/Chestfeeding, below, or Clinicalinfo.HIV.gov > Table 14. Antiretroviral Drug Use in Pregnant People With HIV: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy.

→ KEY POINT

- Call the Clinical Education Initiative (CEI Line) to speak with an experienced HIV care provider regarding PEP: 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/RTV (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/RTV 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 preferable 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[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].

PEP Regimens for Patients Who Weigh <40 kg

No clinical studies are available to determine the best regimens for HIV PEP in children. There are dosing and tolerability considerations unique to pediatric populations, namely poor palatability of liquid medication preparations and high pill burden of some pediatric dose formulations, which can affect adherence to PEP regimens. A simplified dosing regimen for PEP in pediatric populations would likely contribute to greater adherence and tolerance. Published data regarding the use of BIC/TAF/FTC as PEP in pediatric patients are limited, but the 3 aforementioned studies from China, Canada, and the United States from 2022 and 2024 in adults provide promising evidence from which to extrapolate[Tan, et al. 2024; Liu, et al. 2022; Mayer, et al. 2022]. Some institutions have implemented BIC/TAF/FTC for pediatric PEP, with early results showing promising improvements in adherence and tolerability without evidence of seroconversions[Combs, et al. 2024; Smith-Anderson, et al. 2024].

BIC/TAF/FTC is currently approved by the U.S. Food and Drug Administration for HIV treatment in children aged 2 years or older who weigh at least 14 kg. BIC/TAF/FTC is associated with minimal adverse effects and low discontinuation rates given its once-daily dosing[Natukunda, et al. 2021]. Because it is a relatively small pill, BIC/TAF/FTC may be easier for children and adolescents to swallow, and for children who are unable to swallow a whole tablet, it can be split with each part taken separately within 10 minutes[FDA 2022]. Alternatively, the tablets may be dissolved, but crushing tablets is not recommended.

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 because of potential 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. All PEP regimens should ideally be initiated within 2 hours of and no later than 72 hours after exposure and are 4 weeks (28 days) in duration. Clinicians may consider prescribing 7 days of ondansetron (Zofran) with PEP medications to ensure tolerability.

For more on PEP regimens in patients who weigh <40 kg, see Table 4, below, and Table A1 in the appendix.

Table 4: PEP Regimens for Pediatric Patients Who Weigh <40 kg [a,b]	
Regimen	**Administration**
Preferred	
Bictegravir 30 mg/tenofovir alafenamide 15 mg/emtricitabine 120 mg (BIC/TAF/FTC; Biktarvy) **For children who weigh ≥14 kg to <25 kg**	• 1 tablet by mouth once daily • If needed, tablet can be split and each part taken separately within 10 minutes. Alternatively, tablets may be dissolved, but crushing is not recommended.
Bictegravir 50 mg/tenofovir alafenamide 25 mg/emtricitabine 200 mg (BIC/TAF/FTC; Biktarvy) **For children who weigh ≥25 kg**	• 1 tablet by mouth once daily • If needed, tablet can be split and each part taken separately within 10 minutes. Alternatively, tablets may be dissolved, but crushing is not recommended.
Tenofovir disoproxil (TDF; Viread) *plus* emtricitabine (FTC; Emtriva) *plus* raltegravir (RAL; Isentress) **For children aged ≥2 years and/or who cannot swallow tablets**	• See Table A1: Dosing of nPEP Medications for Pediatric Patients Who Weigh <40 kg and/or Cannot Swallow Tablets for specific dosing information. • TDF/FTC is available as a fixed-dose combination (Truvada), approved for nPEP in adolescents only.
Zidovudine (ZDV; Retrovir) oral solution *plus* lamivudine (3TC; Epivir) oral solution *plus* raltegravir (RAL; Isentress) *or* lopinavir/ritonavir (Kaletra) oral solution **For infants and children aged 4 weeks to <2 years**	See Table A1: Dosing of nPEP Medications for Pediatric Patients Who Weigh <40 kg and/or Cannot Swallow Tablets for specific dosing information.
Alternative	
Zidovudine (ZDV; Retrovir) *plus* lamivudine (3TC; Epivir) *plus* raltegravir (RAL; Isentress) *or* lopinavir/ritonavir (LPV/RTV; Kaletra) **For children aged ≥2 years to 12 years**	See Table A1: Dosing of nPEP Medications for Pediatric Patients Who Weigh <40 kg and/or Cannot Swallow Tablets for specific dosing information.
Tenofovir disoproxil fumarate (TDF; Viread) *plus* emtricitabine (FTC; Emtriva) *plus* lopinavir/ritonavir (Kaletra) **For children aged ≥2 years to 12 years**	See Table A1: Dosing of nPEP Medications for Pediatric Patients Who Weigh <40 kg and/or Cannot Swallow Tablets for specific dosing information.
Tenofovir disoproxil fumarate (TDF; Viread) *plus* emtricitabine (FTC; Emtriva) *plus* darunavir (DRV; Prezista) *plus* ritonavir (RTV; Norvir) **For children aged ≥3 years to 12 years**	See Table A1: Dosing of nPEP Medications for Pediatric Patients Who Weigh <40 kg and/or Cannot Swallow Tablets for specific dosing information.
Zidovudine (ZDV; Retrovir) *plus* emtricitabine (FTC; Emtriva) *plus* raltegravir (RAL; Isentress) *or* lopinavir/ritonavir (LPV/RTV; Kaletra) **For infants and children aged 4 weeks to <2 years**	See Table A1: Dosing of nPEP Medications for Pediatric Patients Who Weigh <40 kg and/or Cannot Swallow Tablets for specific dosing information.

Abbreviations: CDC, Centers for Disease Control and Prevention; DHHS, U.S. Department of Health and Human Services; nPEP, non-occupational pre-exposure prophylaxis.

Notes:

a. Adapted from Lexidrug.
b. See also DHHS: Recommendations for the Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States > Table 14 or CDC: Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV — CDC Recommendations, United States, 2025.

→ KEY POINTS

- A systematic review of several studies that included ARV medications used as PEP in children exposed to HIV and as ART for children with HIV reported a 4.5% discontinuation rate due to adverse effects[Penazzato, et al. 2015].
- Limited data exist on dosing or safety for some ARV agents, including INSTIs, used in children[Tanner, et al. 2025; Smith-Anderson, et al. 2024].

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 Medications to Avoid for PEP

Drug Class	Agent	<40 kg	≥40 kg	Comments
First-generation protease inhibitors	• Indinavir (IDV; Crixivan) • Nelfinavir (NFV; Viracept)	Avoid	Avoid	Poorly tolerated
First-generation non-nucleoside reverse transcriptase inhibitors	• Efavirenz (EFV; Sustiva) • Nevirapine (NVP; Viramune)	Avoid	Avoid	• **EFV:** Potential for neuropsychiatric adverse effects • **NVP:** Associated with fulminant hepatic failure and risk of Stevens-Johnson syndrome [CDC(b) 2001]
Nucleoside reverse transcriptase inhibitors	• Abacavir (ABC; Ziagen) • Didanosine (ddI; Videx) • Stavudine (d4T; Zerit) • Zidovudine (ZDV, AZT; Retrovir)	Avoid d4T, ddI, ABC, TAF	Avoid all	• **ABC:** Potential for serious, sometimes fatal hypersensitivity reaction • **d4T, ddI, ZDV:** Significant mitochondrial toxicities
CCR5 antagonist	Maraviroc (MVC; Selzentry)	Avoid	Avoid	Only shows activity against R5-tropic virus

Abbreviation: PEP, post-exposure prophylaxis.

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.

PEP During Pregnancy or Breast/Chestfeeding

Use of ARV prophylaxis in pregnancy generally does not increase the risk of birth defects[DHHS 2024]. 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, 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 INSTIs during pregnancy[DHHS 2024].

→ 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 breast/chestfeeding infant.

The single-tablet ART regimen of BIC/TAF/FTC has been shown to be safe and effective when used during pregnancy and was associated with high levels of viral suppression and similar perinatal outcomes to those among pregnant individuals without HIV[Holt, et al. 2024; Olivero, et al. 2024; Powis, et al. 2024; Zhang, et al. 2024].

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 2024]:

- DRV: 600 mg twice per day plus RTV (Norvir) 100 mg twice per day
- ATV: 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 2024; Martinez de Tejada, et al. 2019]. ZDV is still recommended for prevention of perinatal HIV transmission.

PEP during breast/chestfeeding: Initiating PEP in individuals newly exposed to HIV who are breast/chestfeeding requires careful discussion. Both HIV medications may be found in human milk; therefore, breast/chestfeeding 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 medications. This scenario is different from an individual living with known HIV before pregnancy who has been adherent to ART with sustained virologic suppression, who, as per updated U.S. Department of Health and Human Services guidelines, can safely breast/chestfeed their infant with close monitoring and ARV prophylaxis for the baby under the care of a pediatric infectious disease specialist[DHHS 2024].

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[Inciarte, et al. 2023; 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 published observational prospective cohort studies support this approach:

- In the 3 studies in China, the United States, and Canada discussed above (total 280 participants), once-daily single-tablet BIC/FTC/TAF as PEP was well tolerated, adverse effects were minimal, and discontinuation rates were low. Only 4 participants discontinued the drug, and there were no seroconversions[Tan, et al. 2024; Liu, et al. 2022; Mayer, et al. 2022].
- Three published studies examined the use of fixed-dose TDF/FTC/elvitegravir (EVG)/COBI as PEP in observational prospective cohorts in France, Boston, and Spain. In the French cohort, 92% of participants completed 28 days of PEP, and only 3 individuals switched to another regimen because of 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]. In both cohorts, gastrointestinal adverse effects were the most common. In the study from Spain, 422 participants received TDF/FTC/EVG/COBI following sexual assault; 52% had documented completion of the 28 days of treatment and 71% attended a follow-up clinic appointment[Malinverni, et al. 2021], better rates than those observed in a similar group treated with alternative regimens. There were no documented HIV seroconversions in any of the 3 studies.
- 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). 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 investigators acknowledged 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].
- Results of a 2023 open-label, single-arm study conducted at a single emergency department in Barcelona, Spain, demonstrated high PEP completion rates (71%) and no HIV seroconversions with fixed-dose single-tablet doravirine (DOR)/3TC/TDF. Among participants who completed the full 28-day course, adherence was 96% and adverse effects were minimal and self-limited. There were no seroconversions[Inciarte, et al. 2023].

The Centers for Disease Control and Prevention 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 or serious adverse effects occurred[McAllister, et al. 2017].

Alternatively, a once-daily PI-based PEP regimen of DRV/RTV plus 2 NRTIs demonstrated lower discontinuation rates than with LPV/RTV or EFV plus 2 NRTIs, without significant adverse effects[Fätkenheuer, et al. 2016]. Together, these study results demonstrate that once-daily PEP regimens (single or multi-tablet) can be well tolerated and have high completion rates.

Regimens containing ZDV and LPV/RTV had lower rates of completion and higher rates of discontinuation because of adverse effects[Leal(a), et al. 2016; Ford(a), 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 a cohort on PEP missed the afternoon dose[Mayer, et al. 2012], which suggests that adherence to a RAL-based regimen is challenging.

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

In such cases, the clinician 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 7, below, includes topics for patient education for an individual exposed to HIV who presents 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.

Box 7: PEP Patient Education Checklist	
Address each item in clear, direct, easy-to-understand language and assess the individual's comprehension of each topic before moving on.	
Addressed and understood:	
	Reason for administering the first dose of HIV post-exposure prophylaxis (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: • NYSDOH Payment Options for Adults and Adolescents for PEP Following Sexual Assault • NYSDOH Payment Options for Adults and Adolescents for PEP for All Other Non-Occupational Exposures • For programs within New York City: Emergency Post-Exposure Prophylaxis (PEP)

Box 7: PEP Patient Education Checklist	
	Possible adverse effects and what to do if they occur
	Importance of adherence to the prescribed regimen: • What "adherence" means • How to achieve success with adherence
	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 after 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

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 a 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 behaviors should be referred for pre-exposure prophylaxis (PrEP).

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.

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.

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). These 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

Counseling and Patient Education

- **If HIV infection is confirmed in the exposed individual:** Explain the benefits of rapid ART initiation 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 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.
- **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, initiate 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:** 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

- **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:** Hospital clinicians are required by New York State law to provide a full 28-day PEP regimen to sexual assault patients, regardless of age (effective February 3, 2026).

☑ 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 medications and assisted in creating a plan to obtain the rest of the required medications. A systematic review of starter packs versus full prescriptions of PEP suggested that completion rates and adherence to PEP may be lower in individuals receiving starter packs; thus, it is essential that individuals receiving starter packs be counseled on the importance of following up with a clinician to receive a prescription for the remaining PEP course and for follow-up testing[Ford(b), et al. 2015].

→ 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, a 7-day starter pack is recommended. However, hospital clinicians are required by New York State law to provide a full 28-day PEP regimen to sexual assault patients, regardless of age (effective February 3, 2026).
  - See The New York State Senate > The Laws of New York/Consolidated Laws/Public Health/Article 28: Hospitals Section 2805-I: Treatment of sexual offense victims and maintenance of evidence in a sexual offense.

Payment For Occupational PEP

Federal law requires covered employers to ensure that all medical evaluations and procedures, vaccines, and PEP medications (7-day starter pack and access to the full 28-day course) are made available to the employee within a reasonable time, at a reasonable location, and at *no cost to the employee* (Occupational Safety and Health Administration [OSHA], 1910.1030 Bloodborne Pathogens).

The New York Public Employee Safety Health Act (PESH) and OSHA 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 use 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.

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.

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 help enrolling in payment assistance programs.

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

- Single-tablet, fixed-dose bictegravir/tenofovir alafenamide/emtricitabine (brand name Biktarvy)
- Fixed-dose tenofovir disoproxil/emtricitabine (brand name Truvada)
- Dolutegravir (brand name Tivicay)
- Raltegravir (brand name Isentress)
- Single-tablet, fixed-dose elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate (brand name Stribild), an alternative PEP regimen

Clinicians should work with social workers and support staff to enroll patients without alternative means of coverage or payment for PEP in MAPs. 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.

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.

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 Office of Victim Services (OVS).

★ NEW YORK STATE LAW

- Timely initiation of medication is crucial to the success of PEP, and amendments to Public Health Law section 2805-I require hospitals to provide a full 28-day PEP regimen to survivors of sexual assault, regardless of age (effective February 3, 2026).
- 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 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.

◊ 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)
- NYC Health Emergency PEP

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 PrEP:** Clinicians should recommend or refer for PrEP any individual reporting a non-occupational exposure who: (A1)
  - Reports an exposure for which PEP is not indicated following assessment of risk
  - Engages in risk behaviors such as condomless sex or intravenous drug use
  - Continues to engage in risk behaviors after completing the 28-day PEP regimen

Abbreviations: PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis.

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 any medical and supportive counseling and adherence services a patient may need following non-occupational exposure.

- PEP resources for care providers and patients can be found on 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. Care providers should pay particular attention to any symptoms suggestive of acute retroviral syndrome.

Risk Reduction

Transition to PrEP: Patients who remain at high risk of HIV 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 of 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

sex partner with HIV, taking a previous course of PEP, and having prior sexually transmitted infections (STIs)[Leal(b), et al. 2016]. Several observational cohort studies 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, Boston, and Switzerland[Hovaguimian, et al. 2021; 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

Follow-Up of Sexual Assault Patients

If a sexual assault patient is too distraught to engage in discussion and decision-making about PEP, 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, 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 after 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 of repeat HIV testing at 3 months (10%)[Muriuki, et al. 2017]. Similarly low rates of PEP completion (27%) were noted in sexual assault patients at an academic medical center in Boston, Massachusetts[Krause, et al. 2014].

Specific factors in this population may influence the acceptance of PEP. 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

Follow-Up of the Exposed Individual

- **Discuss signs and symptoms of ARS:** 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:**
  - 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.
- **Refer for follow-up care:** Refer or arrange for follow-up care as needed, including referral to an experienced HIV care provider if needed.

Follow-Up for 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, the patient should be given a referral for PrEP care.
- **Plan for follow-up care:** Review the plan for follow-up care with the patient and 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 trichomoniasis was given at the initial presentation.

Follow-Up for Sexual Assault Exposures

- **Plan for follow-up care:** Review the plan for follow-up care with the patient and 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 trichomoniasis 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

☑ RECOMMENDATIONS

All Exposures

HIV Testing at 4 and 12 Weeks After Exposure

- Clinicians should follow up with an in-person visit (preferred) at 4 weeks after exposure to perform HIV testing and other laboratory testing specified in Table 6: Recommended Laboratory Monitoring After PEP 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 after exposure, using an FDA-approved laboratory-based HIV-1/2 Ag/Ab combination immunoassay. (A2)
  - 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 after 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)

☑ RECOMMENDATIONS

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 Laboratory Monitoring After PEP Initiation. (A2)

Serial HIV Testing in Children

- If an exposed child older than 2 years 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.

Abbreviations: Ab, antibody; Ag, antigen; FDA, U.S. Food and Drug Administration; PEP, post-exposure prophylaxis; POC, point-of-care.

During the 28-day course of PEP, laboratory tests may be indicated to monitor for adverse effects. The timing and specific testing indicated varies based on the PEP regimen used (see Table 6, 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 a New York City PEP cohort, only 32 individuals (2.9%) and 95 individuals (8.5%) had abnormal renal function and liver function test results, respectively, 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 (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, below, 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 Laboratory Monitoring After PEP Initiation		
Monitoring Test or Activity	**Frequency**	**Notes**
Clinic visit	• Baseline • 48 hours • Week 2 • Week 4 • Week 12	Follow-ups at 48 hours and 2 weeks may be conducted by telephone call.
HIV-1/2 Ag/Ab combination immunoassay (recommended even if the exposed individual declines PEP)	• Baseline • Week 4 • Week 12	Immediate consultation with a clinician experienced in managing ART is advised to determine optimal treatment options if the exposed individual's sequential test confirms HIV infection.
Serum liver enzymes, blood urea nitrogen, creatinine, CBC	• Baseline • Weeks 12 and 24 in patients aged 12 years or older	• Obtain CBC in children aged 2 to 12 years if PEP regimen contains zidovudine. • Use a serum liver enzyme panel provided by the laboratory. • Repeat laboratory testing after week 2 of PEP medications in the case of abnormal renal or liver function[Mikati, et al. 2019]. • Repeat laboratory testing if the patient experiences signs or symptoms of drug-induced kidney or liver injury while taking PEP medications.
Pregnancy test	• Baseline • Week 4	Perform only if exposed individual is of childbearing capacity.
HBsAg, anti-HBs	• Baseline: All patients • Week 12 in patients aged 12 years or older	Patients with a reactive anti-HBs test result need not repeat an HBsAg test.
HCV antibody	• Baseline • Week 24	If source patient has known HCV viremia or unknown status, HCV antibody testing should be performed at baseline as well as 24 weeks after an initial nonreactive test result.
HCV RNA	• Week 4 • Week 12	If source patient has known HCV viremia or unknown status, HCV RNA should be performed during HIV testing at weeks 4 and 12.
RPR, 3-site screening for gonorrhea and chlamydia	Baseline	• Repeat screening at week 4 for sexual exposures. • Repeat RPR at week 12 if the exposed individual is younger than 12 years.
Abbreviations: Ab, antibody; Ag, antigen; anti-HBs, hepatitis B surface antibody; ART, antiretroviral therapy; CBC, complete blood count; HBsAg, hepatitis B surface antigen; HCV, hepatitis C virus; PEP, post-exposure prophylaxis; RPR, rapid plasma reagin.		

Management of Potential Exposure to Hepatitis B Virus

☑ RECOMMENDATIONS

Initial Testing After Potential HBV Exposure

- When an individual reports a potential exposure to HIV or other STIs, clinicians should assess for concurrent exposure to HBV. (A2)
- 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 HBV or whose HBV status is unknown, the clinician should obtain HBV vaccination history and the following baseline tests, preferably within 48 hours (A1):
  - **Exposed individual:** Triple panel testing for HBsAg, anti-HBc, and anti-HBs (if the exposed individual has known anti-HBs ≥10 mIU/mL or chronic HBV infection, no further intervention is needed)
  - **Source:** Triple panel testing for HBsAg, anti-HBc, and anti-HBs when possible

HBV Vaccination as PEP

- Clinicians should recommend HBV vaccination for all individuals who may have been exposed to HBV except those with known anti-HBs ≥10 mIU/mL, chronic HBV infection, or HBV vaccine nonresponse [a]. (A1)
- Clinicians should administer the first dose of the HBV vaccine series during the initial evaluation, ideally within 24 hours of exposure [b]; vaccination should not be delayed for triple panel testing results. (A1)
- Clinicians should complete the HBV vaccine series for exposed individuals with anti-HBs <10 mIU/mL on triple panel testing or who did not previously receive the full vaccine series. (A1)
- Clinicians should obtain anti-HBs testing within 1 to 2 months after the exposed individual's completion of the last dose of the HBV vaccine if there is ongoing risk for HBV exposure (test at 6 months if given HBIG). (A3)

Hepatitis B Immune Globulin as PEP

- If the exposed individual is unvaccinated, did not complete the HBV vaccine series, or is known to be nonimmune to HBV, and if the source has known acute or chronic HBV (HBsAg positive), the clinician should administer prophylactic HBIG; for occupational exposures, HBIG can also be administered if the source's HBV status is unknown. (A1)
- Clinicians should administer HBIG as soon as possible after HBV exposure, ideally within 7 days and no later than 14 days, and should be administered at a different site from the HBV vaccine in the exposed individual. (A2)

Abbreviations: anti-HBs, hepatitis B surface antibody; HBIG, hepatitis B immune globulin; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; PEP, post-exposure prophylaxis.

Notes:

a. Nonresponse defined as documented inadequate response (serum anti-HBs <10 mIU/mL) to 2 vaccine series. Adults with nonresponse who received only a nonadjuvanted HBV vaccine series should initiate a recombinant adjuvanted HBV vaccine series (approved by the U.S. Food and Drug Administration in 2017).
b. 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 adjuvanted vaccine (see guideline text for more information).

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

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

- 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 HBV 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].

Initial HBV testing for exposed and source individual: When an individual reports a potential HBV exposure, obtain an HBV vaccination history and, preferably within 48 hours, triple panel testing for HBsAg, anti-HBc, and anti-HBs; if the individual has known anti-HBs ≥10 mIU/mL or chronic HBV infection, no further intervention is needed. Triple panel testing for HBsAg, anti-HBc, and anti-HBs should also be performed for the source, preferably within 48 hours, when possible. Refer sources who test positive for HBsAg for evaluation for HBV treatment and advise that their household, sex, and needle-sharing contacts be identified, tested, and when indicated, vaccinated.

HBV PEP: For individuals at risk of acquiring HBV after a potential exposure, the HBV vaccine and HBIG may be used as PEP. When considering HBV PEP, evaluate the exposed individual's vaccination status and the source's HBsAg status (see Table 7, below). Even if the risk of exposure to HBV is not deemed significant, HBV vaccination is advised for all non–HBV-immune individuals.

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 of exposure, and HBIG should ideally be administered within 7 days (and no later than 14 days) of exposure.

- The 2-dose Toll-like receptor 9 (TLR-9) agonist adjuvanted HBV vaccine (e.g., Heplisav-B) is administered at day 0 and 1 month later. This vaccine is preferred for patients with prior HBV vaccine nonresponse.
- The 3-dose recombinant HBsAg vaccine (e.g., Recombivax-HB, Engerix-B) is administered at 0, 1 to 2, and 6 months.
- Hepatitis A vaccination can be combined with hepatitis B (e.g., Twinrix) in a 3-dose series.

Anti-HBs testing should be performed within 1 to 2 months after completion of the last dose of the vaccine if there is ongoing risk for HBV exposure.

See the Centers for Disease Control and Prevention (CDC) Hepatitis B Vaccination: Information for Healthcare Providers and American Academy of Pediatrics Care of the Adolescent After an Acute Sexual Assault [Crawford-Jakubiak, et al. 2017] for additional information.

Efficacy and safety of HBV PEP: When initiated within 12 to 24 hours of HBV exposure, the HBV vaccine series has been shown to be 70% to 90% effective in preventing HBV infection[Schillie, et al. 2013]. Combining the HBV vaccine with HBIG achieves a similar level of efficacy[Perrillo, et al. 1984; Redeker, et al. 1975]. Among individuals with known nonresponse to the HBV vaccine, 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[Papaevangelou, et al. 1987; Roumeliotou-Karayannis, et al. 1986; Perrillo, et al. 1984; Szmuness, et al. 1980; Redeker, et al. 1975]. A brief period of HBsAg positivity, reflecting a false-positive value, can be seen after HBV vaccination[Rysgaard, et al. 2012].

Pregnant individuals can safely receive a 3- or 2-dose HBV vaccine series and HBIG. Both the 3-dose HBV vaccine and HBIG are thought to be safe for adult and pediatric patients; however, the 2-dose vaccine is not approved for individuals younger than 18 years[FDA 2024; CDC(a) 2001]. Adverse effects of the vaccines include pain at the injection site and fever.

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. HBIG may impact the response to live virus vaccines; live virus vaccines should be deferred until approximately 3 months after HBIG administration (see HBIG prescribing information).

→ KEY POINT

- In previously vaccinated individuals who may have been exposed to HBV, determination of antibody response is based on the information available at presentation. The decision to vaccinate should not be delayed while testing for anti-HBs.

Table 7, below, shows indicated PEP for individuals who may have been exposed to HBV, based on their HBV vaccination status and the HBV status of the source. For additional information, see the following CDC guidance:

- Responding to HBV Exposures in Health Care Settings (includes nonoccupational settings)
- Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices [Schillie, et al. 2018]
- Updated Recommendation for Universal Hepatitis B Vaccination in Adults Aged 19-59 Years - United States, 2024 [Sandul, et al. 2024]

Table 7: PEP After Hepatitis B Virus Exposure [a]

Exposed Individual HBV Vaccination Status	Post-Exposure Testing [b]		PEP for Exposed Individual		Post-Vaccination Serologic Testing [d]
	Source Status (By History or Post-Exposure Testing)	Exposed Individual	HBIG	Vaccination [c]	
Documented response after complete HBV vaccine series [e]	No action needed				
Documented nonresponse after prior vaccine series [e]	Source is positive for HBV or status unknown	—	Administer 2 doses of HBIG 0.06 mL/kg IM separated by 1 month [f]	Revaccinate with CpG-adjuvanted vaccine unless 2 vaccine series, including at least 1 CpG-adjuvanted series, have been documented	N/A
	Source is negative for HBV	No action needed			
Response unknown after complete HBV vaccine series	Source is positive for HBV or status unknown	Exposed individual anti-HBs <10 mIU/mL	Administer 1 dose of HBIG 0.06 mL/kg IM [f]	Revaccinate [g]	Yes
	Source is negative for HBV	Exposed individual anti-HBs <10 mIU/mL	—	Revaccinate [g]	Yes
	Source is positive or negative for HBV, or status unknown	Exposed individual anti-HBs ≥10 mIU/mL	—	—	—
Have not received, did not complete, or refused HBV vaccine, or vaccination status unknown	Source is positive for HBV or status unknown	—	Administer 1 dose of HBIG 0.06 mL/kg IM [f]	Complete vaccination	Yes
	Source is negative for HBV	—	None	Complete vaccination	Yes

Abbreviations: anti-HBc, hepatitis B core antigen; anti-HBs, hepatitis B surface antibody; CpG, cytosine phosphoguanine; HBIG, hepatitis B immune globulin; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; IM, intramuscular; PEP, post-exposure prophylaxis.

Notes:

a. Adapted from Centers for Disease Control and Prevention Hepatitis B > Table 1: Treatment for HBV Exposures in Health Care Settings.
b. Triple panel test, which includes HBsAg, anti-HBs, and anti-HBc.
c. If never vaccinated receive as soon as possible and preferably within 24 hours.
d. Anti-HBs testing should be performed 1 to 2 months after the final dose of vaccine.
e. Based on information available at presentation. Response defined as previously documented adequate levels of serum antibody to HBsAg (serum anti-HBs ≥10 mIU/mL); nonresponse defined as 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.
f. For nonoccupational exposure, only give HBIG if source is known to have HBV infection.
g. CpG-adjuvanted vaccine series is preferred for individuals with documented nonresponse to prior vaccination.

Management of Potential Exposure to Hepatitis C Virus

☑ RECOMMENDATIONS

Initial Testing After Potential HCV Exposure

- When an individual reports a potential exposure to HIV or other STIs, clinicians should assess for concurrent exposure to HCV. (A2)
- 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 HCV or whose HCV status is unknown, the clinician should obtain the following baseline tests, preferably within 48 hours (A2):
  - **Exposed individual:** HCV antibody test, with reflex to NAT for HCV RNA if positive; liver function tests, including liver enzyme test
  - **Source:** HCV RNA test (an HCV antibody test, with reflex to NAT for HCV RNA if positive, is an alternative if no concern for acute HCV)

No PEP for Potential HCV Exposure

- Clinicians should not administer immunoglobulin or antiviral agents for HCV PEP. (A2)

Follow-Up Testing After Potential HCV Exposure

- If the source is unavailable for testing or tested positive for HCV antibody or RNA, clinicians should follow up with the exposed individual as follows (A2):
  - 3 to 6 weeks later [a]: HCV RNA test
  - 4 to 6 months later [a]: HCV antibody test, with reflex HCV RNA test if positive (if the exposed individual is immunocompromised, an HCV RNA test is recommended)
- If HCV infection is identified, the clinician should offer or refer for HCV treatment. (A2)
  - See the NYSDOH AI guideline Treatment of Chronic Hepatitis C Infection in Adults.

Abbreviations: ALT, alanine aminotransferase; HCV, hepatitis C virus; NAT, nucleic acid test; PEP, post-exposure prophylaxis; STI, sexually transmitted infection.

Note:

a. Weeks 6 and 24 coincide with HIV PEP testing.

For more information on HCV, see the following NYSDOH AI guidelines:

- Hepatitis C Screening, Testing, and Diagnosis in Adults
- Pretreatment Assessment in Adults With Chronic Hepatitis C Infection
- Treatment of Chronic Hepatitis C Infection in Adults

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, 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
- Breast/chestfeeding: HCV is not transmitted by breast/chestfeeding; however, HCV is spread by infected blood. Therefore, if the nipples and/or surrounding areola are cracked and bleeding, the individual with HCV should temporarily stop nursing.

HCV testing of source: If the source's HCV antibody test result is positive, follow-up testing is necessary to confirm the source's status. HCV RNA may be used as the confirmatory test. If the source's HCV RNA test result is positive, 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 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 is diagnosed with acute HCV, 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 treated according to genotype, liver disease progression, and history of previous HCV treatment, if any.

Observation for a period of 8 to 12 weeks after 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 depends on the individual scenario[Boerekamps, et al. 2019; Chromy, et al. 2019; Naggie, et al. 2019].

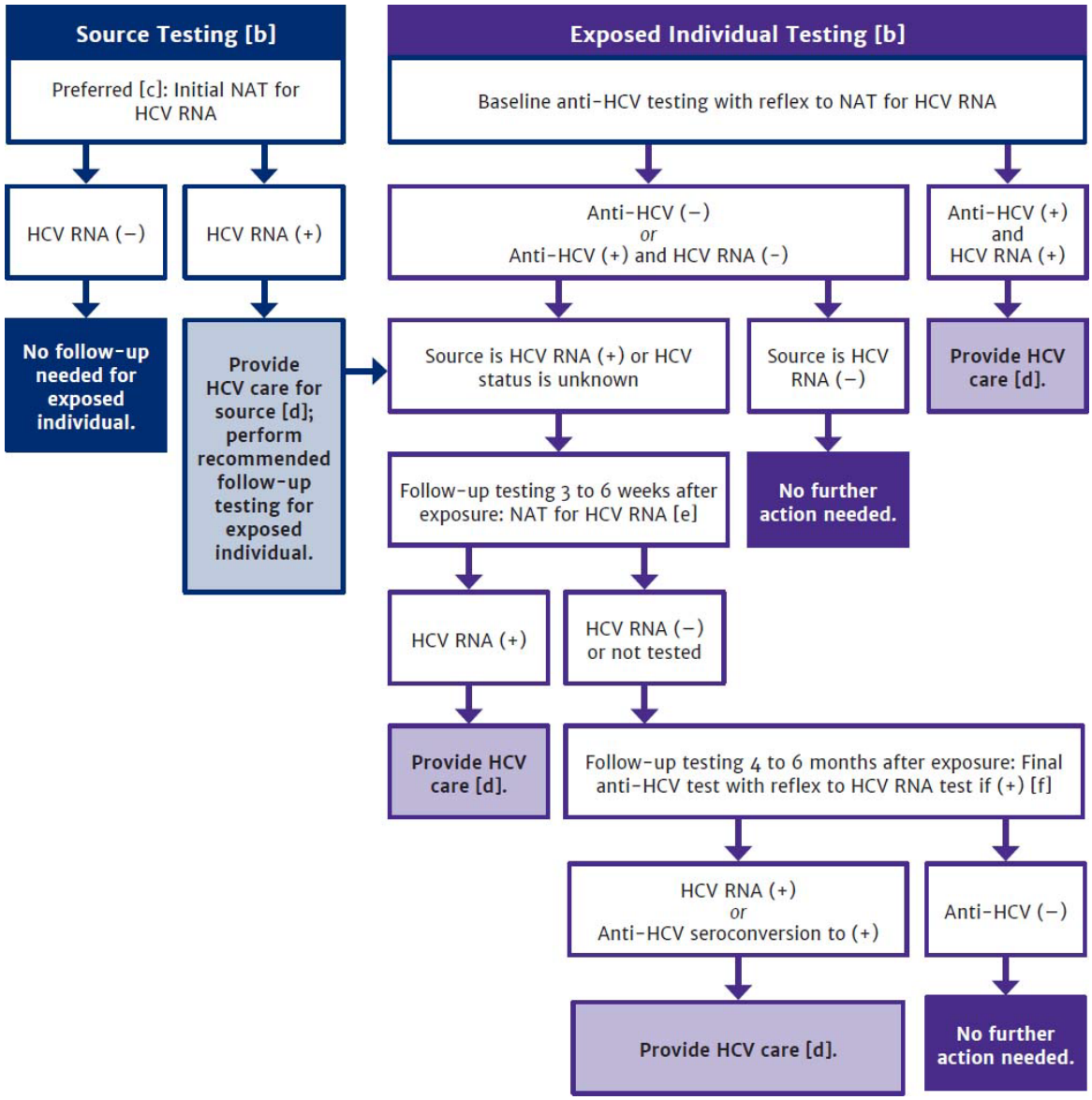
Follow-up: For individuals who are exposed to a source with HCV, regular follow-up with HCV RNA testing is recommended in addition to HCV antibody testing. HCV RNA testing can identify acute infection within 2 weeks of exposure, whereas the antibody test may not provide an accurate result for up to several months after acute infection (during the "window period"). HCV antibodies can be detected by enzyme-linked immunosorbent assay (ELISA) in 90% of patients within 5 weeks of exposure, 80% of patients within 15 weeks of exposure, and at least 97% of patients within 6 months of exposure[CDC(a) 2001]. The ELISA test is highly sensitive but relatively nonspecific, resulting in a low positive predictive value in low-prevalence populations. Positive ELISA test results require confirmation by a quantitative viral load assay, such as an HCV polymerase chain reaction assay. This committee recommends linking newly diagnosed patients to HCV care for monitoring and assessment for treatment.

→ 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.

Figure 5, below, shows recommended testing of the source and exposed individual after a potential exposure to HCV.

Figure 5: Recommended Testing After Potential Exposure to Hepatitis C Virus [a]



Abbreviations: anti-HCV, HCV antibody; CDC, Centers for Disease Control and Prevention; HBV, hepatitis B virus; HCV, hepatitis C virus; NAT, nucleic acid test.

Notes:

a. Adapted from Figures 1 and 2 of CDC Testing and Clinical Management of Health Care Personnel Potentially Exposed to Hepatitis C Virus — CDC Guidance, United States, 2020.
b. Testing should be performed as soon as possible (preferably within 48 hours) after exposure; exposed individual and source patient testing may be performed simultaneously.
c. For alternative testing option, see CDC Figure 1.
d. Individuals with detectable HCV RNA at any point should be provided the recommended evaluation and treatment for acute or chronic HCV infection.
e. Follow-up testing of the exposed individual is recommended if the source patient is HCV RNA positive, anti-HCV positive with unknown HCV RNA status, or cannot be tested. HCV RNA testing performed 6 weeks after exposure has the advantage of coinciding with HIV post-exposure testing schedules if HIV surveillance is recommended.
f. If the HCV RNA test result is negative 3 to 6 weeks after exposure, a final test for anti-HCV at 4 to 6 months after exposure is recommended because of the possibility of intermittent periods of aviremia in acute HCV infection. If the exposed individual was anti-HCV positive and HCV RNA negative at baseline, testing at this time should be conducted for HCV RNA detection, as individuals successfully treated for HCV infection will remain anti-HCV positive and HCV RNA negative unless reinfected. Testing performed 6 months after exposure has the advantage of coinciding with HBV post-exposure testing schedules if HBV testing is recommended. For immunocompromised individuals with negative anti-HCV result, testing for HCV RNA can be considered. Exposed individuals who develop viral syndromes suggestive of acute HCV infection at any point should be retested for HCV RNA.

Appendix: Dosing of nPEP Medications for Pediatric Patients Who Weigh <40 kg and/or Cannot Swallow Tablets

Table A1: Dosing of nPEP Medications for Pediatric Patients Who Weigh <40 kg and/or Cannot Swallow Tablets [a,b]

Medication	Strength, Formulation	Age, Weight, Dosing	Maximum Dose
Tenofovir disoproxil fumarate (TDF; Viread)	40 mg/g oral powder [c]	**Children aged ≥2 years who weigh ≥10 kg and adolescents:** • 8 mg/kg/dose once daily • 10 to <12 kg: 80 mg (2 scoops) • 12 to <14 kg: 100 mg (2.5 scoops) • 14 to <17 kg: 120 mg (3 scoops) • 17 to <19 kg: 140 mg (3.5 scoops) • 19 to <22 kg: 160 mg (4 scoops) • 22 to <24 kg: 180 mg (4.5 scoops) • 24 to <27 kg: 200 mg (5 scoops) • 27 to <29 kg: 220 mg (5.5 scoops) • 29 to <32 kg: 240 mg (6 scoops) • 32 to <34 kg: 260 mg (6.5 scoops) • 34 to <35 kg: 280 mg (7 scoops) • ≥35 kg: 300 mg (7.5 scoops)	300 mg/**dose**
	150 mg, 200 mg, 250 mg, and 300 mg oral tablets [d]	**Children aged >2 years who weigh ≥17 kg and adolescents:** • 17 to <22 kg: 150 mg once daily • 22 to <28 kg: 200 mg once daily • 28 to <35 kg: 250 mg once daily • ≥35 kg: 300 mg once daily	
Emtricitabine (FTC; Emtriva)	10 mg/mL oral solution	**Neonates and infants aged <3 months:** 3 mg/kg/dose once daily **Infants and children aged ≥3 months to 17 years:** 6 mg/kg/dose once daily	240 mg/**day**
	200 mg capsules [e]	**Children who weigh ≥33 kg:** 200 mg once daily **Adolescents:** Combination product TDF/FTC (Truvada) recommended	240 mg/**day**
Raltegravir (RAL; Isentress)	10 mg/mL oral suspension [f,h]	**Infants and children aged <2 years:** 6 mg/kg/dose twice daily	100 mg/**dose**
	25 mg and 100 mg chewable tablets [g,h]	**Children aged ≥2 years:** • 11 to <14 kg: 75 mg twice daily • 14 to <20 kg: 100 mg twice daily • 20 to <28 kg: 150 mg twice daily • 28 to <40 kg: 200 mg twice daily • ≥40 kg: 300 mg twice daily	300 mg/**dose**
	400 mg film-coated tablet	**Preferred in children aged 6 to 12 years who weigh ≥25 kg and are able to swallow a tablet whole:** 400 mg twice daily	400 mg/**dose**

Table A1: Dosing of nPEP Medications for Pediatric Patients Who Weigh <40 kg and/or Cannot Swallow Tablets [a,b]			
Medication	**Strength, Formulation**	**Age, Weight, Dosing**	**Maximum Dose**
Zidovudine (ZDV; Retrovir)	10 mg/mL IV infusion [i]	Infuse over 30 minutes; dosed every 12 hours: • **Full term (≥35 weeks GA):** 3 mg/kg/dose • **Premature (≥30 to <35 weeks GA):** – PNA ≤14 days: 1.5 mg/kg/dose – PNA ≥15 days: 3 mg/kg/dose • **Premature (<30 weeks GA):** – PNA ≤28 days: 1.5 mg/kg/dose – PNA ≥29 days: 3 mg/kg/dose	300 mg/**dose**
	10 mg/mL oral syrup [j]	All dosed every 12 hours: • **Full term (≥35 weeks GA) infants, children:** – PNA <4 weeks: 4 mg/kg/dose – PNA ≥4 weeks, 4 to <9 kg: 12 mg/kg/dose – PNA ≥4 weeks, 9 to <30 kg: 9 mg/kg/dose – ≥30 kg: 300 mg/dose • **Premature (≥30 to <35 weeks GA) infants:** – PNA ≤14 days: 2 mg/kg/dose – PNA ≥15 days: 4 mg/kg/dose • **Premature (<30 weeks GA) infants:** – PNA ≤28 days: 2 mg/kg/dose – PNA ≥29 days: 4 mg/kg/dose	
	100 mg capsules, 300 mg tablets	**Children who weigh ≥30 kg and adolescents:** 300 mg twice daily	
Lamivudine (3TC; Epivir) [k]	10 mg/mL oral solution	**Neonates, infants aged ≤27 days:** 2 mg/kg/dose twice daily **Infants aged ≥28 days, children, adolescents:** 4 mg/kg/dose twice daily	150 mg/**dose**
	150 mg scored tablet	**Children and adolescents aged <16 years who weigh ≥14 kg and are able to swallow tablets:** • 14 to <20 kg: 75 mg (1/2 tablet) twice daily • 20 to <25 kg: 75 mg (1/2 tablet) in the morning and 150 mg (1 tablet) in the evening • ≥25 kg: 150 mg (1 tablet) twice daily	
	100 and 300 mg tablets	**Adolescents aged ≥16 years who weigh <50 kg:** 4 mg/kg/dose twice daily	
Lopinavir/ritonavir (LPV/RTV; Kaletra)	80/20 mg/mL oral suspension	**Children aged ≥14 days to 12 months:** 16/4 LPV/RTV mg/kg/dose or 300/75 mg/m^2/dose twice daily **Children and adolescents aged >12 months to 18 years:** • <15 kg: 12/3 mg/kg/dose twice daily • 15 to 40 kg: 10/2.5 mg/kg/dose twice daily	400/100 mg/**dose**
	100/25 mg tablets 200/50 mg tablets	**Children aged>12 months to 18 years who weigh ≥15 kg and are able to swallow tablets:** • ≥15 to 25 kg: Two 100/25 mg tablets daily (200/50 mg total) • >25 to 35 kg: Three 100/25 mg tablets daily (300/75 mg total) • >35 kg: Four 100/25 or two 200/50 mg tablets daily (400/100 mg total)	

Table A1: Dosing of nPEP Medications for Pediatric Patients Who Weigh <40 kg and/or Cannot Swallow Tablets [a,b]

Medication	Strength, Formulation	Age, Weight, Dosing	Maximum Dose
Darunavir (DRV; Prezista) *plus* Ritonavir (RTV; Norvir) [l]	DRV: 100 mg/mL oral suspension RTV: 80 mg/mL oral solution	**Children aged ≥3 to <18 years who weigh ≥10 kg, administered twice daily with food:** • 10 to 15 kg: dose is 20 mg/kg DRV and 3 mg/kg RTV per kg • 10 to <11 kg: DRV 200 mg (2 mL) *plus* RTV 32 mg (0.4 mL) • 11 to <12 kg: DRV 220 mg (2.2 mL) *plus* RTV 32 mg (0.4 mL) • 12 to <13 kg: DRV 240 mg (2.4 mL) *plus* RTV 40 mg (0.5 mL) • 13 to <14 kg: DRV 260 mg (2.6 mL) *plus* RTV 40 mg (0.5 mL) • 14 to <15 kg: DRV 280 mg (2.8 mL) *plus* RTV 48 mg (0.6 mL) • 15 to <30 kg: DRV 375 mg (3.8 mL) *plus* RTV 48 mg (0.6 mL) • 30 to <40 kg: DRV 450 mg (4.6 mL) *plus* RTV 100 mg (1.25 mL)	RTV: 600 mg/**dose**
	DRV: 75 mg, 150 mg, 600 mg, and 800 mg tablets RTV: 100 mg tablets, 100 mg soft gelatin capsules	**Children who weigh >15 kg and can swallow tablets whole, twice daily with food:** • 15 to <30 kg: DRV 375 mg *plus* RTV 48 mg • 30 to <40 kg: DRV 450 mg *plus* RTV 100 mg	

Abbreviations: GA, gestational age; IV, intravenous; nPEP, non-occupational post-exposure prophylaxis; PNA, postnatal age.

Notes:

a. Adapted from Lexidrug.
b. See also DHHS: Recommendations for the Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States > Table 14 or CDC: Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV — CDC Recommendations, United States, 2025.
c. TDF oral powder: Must administer with food. Measure dose only using the supplied dosing scoop. One level scoop equals 40 mg TDF; can be mixed with 2 to 4 oz of soft food that does not require chewing (applesauce, baby food, yogurt) and swallowed immediately to avoid bitter taste. Do *not* mix in liquid (powder may float on top of liquid even after stirring).
d. TDF oral tablets: May be administered without regard to meals and can be dissolved in water.
e. FTC oral capsules: Can be opened and dissolved in water.
f. RAL oral suspension: Add entire contents of 1 packet (100 mg) and 10 mL of water to the provided mixing cup, close lid, and swirl in a circular motion for 45 seconds (do not shake or turn the mixing cup upside down); resultant concentration is 10 mg/mL. Once mixed, immediately measure recommended suspension dose using the provided oral syringe. Must be administered within 30 minutes of reconstitution. Discard any remaining suspension in the trash.
g. RAL chewable tablets: The 25 mg chewable tablet can be chewed, crushed, or swallowed whole. For patients unable to chew the chewable 25 mg tablet, it may be crushed by placing tablet and ~5 mL of liquid (e.g., water, juice, breast milk) in a small cup; the tablet should break apart within 2 minutes; crush any remaining pieces of undispersed tablet with a spoon and administer the entire mixture immediately. If any dose remains in cup, add ~5 mL of liquid, swirl, and administer immediately. The 100 mg chewable scored tablet can be split in half.
h. Coadministration of RAL with antacids, laxatives, or other products containing polyvalent cations (Mg, Al, Fe, Ca, Zn), including iron, calcium, or magnesium supplements; sucralfate; buffered medications; and certain oral multivitamins can reduce absorption of RAL. Administer RAL at least 2 hours before or at least 6 hours after cation-containing medications or products; however, RAL can be coadministered with calcium carbonate-containing antacids.
i. ZDV IV infusion: Administer over 1 hour; in neonates, dose may be infused over 30 minutes. Do not administer intramuscularly; do not administer IV push or by rapid infusion.
j. ZDV oral suspension: May be administered without regard to meals; use calibrated measuring device to accurately measure oral liquid dose; for neonatal patients, graduations of 0.1 mL are necessary due to small dose volumes.
k. 3TC oral solution: May be administered without regard to meals.
l. DRV/RTV: Administer with food (bioavailability is increased). In patients taking DRV twice daily, if a dose of DRV or RTV is missed by >6 hours, the next dose is taken at the regularly scheduled time. If a dose of DRV or RTV is missed by <6 hours, the dose is taken immediately and then the next dose is taken at the regularly scheduled time. RTV tablets should be swallowed whole, not chewed, broken, or crushed. Because of its bad taste, consider reserving liquid formulation for use in patients receiving tube feeding. Liquid formulation may be mixed with milk, pudding, ice cream, or a liquid nutritional supplement. Other techniques to increase tolerance include first dulling the taste buds with ice, popsicles, or spoonfuls of partially frozen juice; coating the mouth with peanut butter before administration; and offering foods such as maple syrup, cheese, or chewing gum immediately after a dose. Oral solution is highly concentrated; shake well and use a calibrated oral dosing syringe to measure and administer.

Supplementary Materials

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

NYSDOH AIDS Institute, November 2025

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 Occupational Safety and Health Administration [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, as per OSHA guidance, has immediate access* to post-exposure services after a reported event. Services must be available 24 hours per day, 7 days per week. Organizations that do not have on-site occupational health services are encouraged to form agreements or contracts with another facility, emergency department, or private practitioner for such services.

*See Occupational Safety and Health Standards 1910.1030 Bloodborne Pathogens.

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 for People With Developmental Disabilities, Office of Children and Family Services, Office of Addiction Services and Supports, or the Department of Corrections and Community Supervision
- Emergency response (paid or volunteer, including emergency medical technicians, firefighters, law enforcement or local correctional officers, and 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.

Exposed workers who sustain an occupational exposure should be ensured access to post-exposure services immediately after* a reported event. This may require 24-hour and weekend coverage. Procedures should identify how workers access services during regular work hours and during evening, night, or weekend shifts. Organizations that do not have on-site 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 HIV test using an antigen/antibody combination immunoassay. This can be on site or a send-out test, but post-exposure prophylaxis (PEP) initiation should not be delayed awaiting HIV testing results.
- Supportive counseling

*See Occupational Safety and Health Standards 1910.1030 Bloodborne Pathogens.

Federal law requires covered employers to ensure that all medical evaluations and procedures, vaccines, and post-exposure prophylaxis are made available within a reasonable timeframe, at a reasonable location, and 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 states that the following should be included 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.

*See Occupational Safety and Health Standards 1910.1030 Bloodborne Pathogens.

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 individuals with a workplace exposure of significant risk.

When the source is already known to be infected with HBV, HCV, or HIV, testing for the source'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 source's HIV regimens, and, if available, HIV drug resistance 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 and New York State recommend testing with an HIV-1/2 antibody/antigen combination immunoassay. This can be on site or sent to a lab, but PEP initiation should not be delayed awaiting HIV testing results.
- The source should be tested as soon as possible to determine HIV, HBV, and HCV infectivity.
- Results of the source'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: The source should be made aware of the exposure and that HIV testing will be done and given the option to decline. If the source declines, HIV testing cannot be done. The employer should document that the HIV test was declined. Testing for HBV and HCV should also be obtained and may be performed with a general consent to provide the patient with routine medical care; a signed, written consent is not necessary to perform these specific tests.

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 Family Health Care Decisions Act (FHCDA) 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 their 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 and 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.

New York State Workers' 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
  Email: 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:

- Eliminating unnecessary use of needles or other sharps
- Using devices with safety features
- Verifying training and compliance with safety features
- Avoiding needle recapping
- Planning, before beginning any procedure using needles or other sharps, for safe handling and prompt disposal in sharps disposal containers
- Promoting 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 exposed individual declines PEP

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, November 2025

New York State 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 Unit. 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. Engaging 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.

New York State 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 (New York State Public Health Law 2805-I). In New York State, 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 PEP. SAFEs help 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
- New York State Rape Crisis and Sexual Violence Prevention Unit
- New York State Sexual Assault Victim Bill of Rights

Reimbursement for SAFE services: Provider reimbursement under the Office of Victim Services (OVS) Forensic Rape Exam 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. 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.

All Recommendations

☑ ALL RECOMMENDATIONS: PEP TO PREVENT HIV INFECTION

First Dose of PEP and Management of the Exposure Site

First Dose of PEP: Exposure to HIV is an emergency

- Clinicians should administer the first dose of PEP immediately—ideally within 2 hours of and no later than 72 hours after exposure—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 unknown. (A2)
- Clinicians should administer a preferred or alternative PEP regimen (the following recommended regimens also have activity in the rare possibility of an exposure to known HIV-2 or a source patient at risk of HIV-2 infection): (A2)
  - Preferred single-tablet regimen: BIC/TAF/FTC by mouth once daily (preferred because of the lower discontinuation rates and minimal adverse effects)
  - Preferred multi-tablet regimen [a,b]: TDF/FTC plus either DTG or RAL; 3TC may be substituted for FTC in either regimen
  - See Table 2: Preferred PEP Regimens for Patients Who Weigh ≥40 kg.
  - For alternative regimens, see Table 3: Alternative PEP Regimens for Patients Who Weigh ≥40 kg.
- **First dose of PEP for an individual who weighs <40 kg (88 lb):** Clinicians should administer a preferred or alternative PEP regimen; see Table 4: PEP Regimens for Pediatric Patients Who Weigh <40 kg. (A2)
- **If the patient is pregnant or trying to conceive [a,b]:** Clinicians should recommend TDF/FTC plus either DTG or RAL (A2); or BIC/TAF/FTC (A3).
- **Patients with impaired renal function:** Clinicians should not initiate TDF/FTC as PEP for any individual with a confirmed CrCl <60 mL/min and should discontinue it in patients with a confirmed CrCl <50 mL/min; in such cases, initiate or switch to a TAF-containing regimen. (A1)
- 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, clinicians should recommend initiation of ART and refer the patient to an experienced HIV care provider. (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 after exposure, clinicians should perform baseline HIV testing and recommend serial HIV testing at 4 and 12 weeks after exposure. (A2)
- When an individual who has been taking PrEP with **daily adherence** requests PEP following a sexual exposure, clinicians should advise that additional ARVs for PEP are not warranted in most situations (see guideline text 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)

Evaluating Exposure Risk

All Exposures

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

Sexual Assault Exposures

- 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.

☑ ALL RECOMMENDATIONS: PEP TO PREVENT HIV INFECTION

- Clinicians should administer the first dose of the 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 gonorrhea, chlamydia, and trichomoniasis. (A3)

Exposures in Children

- Clinicians should recommend PEP—ideally within 2 hours of and no later than 72 hours after an exposure—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 are known or suspected to 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 gonorrhea, chlamydia, and trichomoniasis. (A3)
- Clinicians should administer the first dose of the HPV vaccine for children aged 9 to 17 years who have not yet been vaccinated. (A3)
- Clinicians should provide prophylaxis for HBV exposure in a child if indicated (see guideline section Management of Potential Exposure to Hepatitis B Virus). (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 PEP if not already 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)
- 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 Ab differentiation immunoassay or plasma HIV RNA test results are positive, 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 an undetectable viral load (HIV RNA <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 ART or if the source's viral load is unknown, 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 their medical record is available, clinicians should obtain the source's viral load, ART history, and ARV drug resistance profile to inform decisions regarding formulation or completion of the 28-day PEP regimen. (A3)

☑ ALL RECOMMENDATIONS: PEP TO PREVENT HIV INFECTION

  - 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. PEP initiation 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 (HIV RNA <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)

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 HIV RNA test result is positive, clinicians should recommend that the exposed individual compete the 28-day PEP regimen. (A2)
  - Clinicians should discontinue PEP if the source has an undetectable viral load (HIV RNA <200 copies/mL) 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 an FDA-approved HIV-1/2 Ag/Ab combination immunoassay, preferably at the time of PEP initiation, but no later than 72 hours after exposure. (A1)
  - Rapid oral HIV tests are not recommended because of the 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 HIV exposure, clinicians should document the refusal in the patient's medical record. (A3)
- If the result of a baseline HIV-1/2 Ag/Ab combination immunoassay is reactive, clinicians should recommend the continuation of PEP until the positive result is confirmed with an HIV-1/HIV-2 Ab differentiation immunoassay or HIV-1 RNA test. (A3)
- Clinicians should continue PEP in any individual 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 ART and continue the 3-drug PEP regimen as ART. (A1)
- Clinicians should perform additional baseline laboratory testing specified in Table 1: Baseline Testing of Exposed Individuals. (A2)
- If the exposed individual declines to complete the 28-day PEP regimen, the clinician should recommend HIV testing at weeks 4 and 12 after 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 gonorrhea, chlamydia, and trichomoniasis. (A3)

Selecting and Initiating a 28-Day Course of PEP

Preferred Regimens

- Clinicians should administer a preferred or alternative PEP regimen (the following recommended regimens also have activity in the rare possibility of an exposure to known HIV-2 or a source patient at risk of HIV-2 infection): (A2)

☑ ALL RECOMMENDATIONS: PEP TO PREVENT HIV INFECTION

- Preferred single-tablet regimen: BIC/TAF/FTC by mouth once daily (preferred because of the lower discontinuation rates and minimal adverse effects).
- Preferred multi-tablet regimen [a,b]: TDF/FTC plus either RAL *or* DTG; 3TC may be substituted for FTC in either regimen.
- For alternative regimens, see Table 3: Alternative PEP Regimens for Patients Who Weigh ≥40 kg.

ARV Medications to Avoid for PEP

- Clinicians should not initiate TDF/FTC as PEP for any individual with a confirmed CrCl <60 mL/min and should discontinue it in patients with a confirmed CrCl <50 mL/min; in such cases, initiate or switch to a TAF-containing regimen. (A1)
- Clinicians should not prescribe the following medications for PEP: ABC, EFV, IDV, MVC, NFV, NVP, and ZDV. (A2)
  - ZDV remains a recommended medication for the prevention of perinatal transmission of HIV and for pediatric PEP.

PEP During Pregnancy or Breast/Chestfeeding

- When a significant exposure to HIV occurs at any time during an exposed individual's pregnancy or while that individual is breast/chestfeeding a baby, clinicians should initiate PEP with a preferred or alternative regimen (see Tables 2 and 3 for preferred and alternative PEP regimens). (A2)
- Clinicians should advise individuals who may have been exposed to HIV to avoid breast/chestfeeding for 3 months after the exposure. (A2)
  - Individuals confirmed to be HIV negative may breast/chestfeed. (A1)

Providing PEP Medications and Other Services

- **All exposures:** If possible, clinicians should provide patients with a 28-day supply of post-exposure prophylaxis (PEP) medications. (A3) If a 28-day supply cannot be provided and if the patient does not have immediate access to a 28-day supply, then clinicians should provide a starter pack as indicated below.
- **Occupational exposure:** Clinicians should provide at least a 7-day starter pack of PEP medications to a worker assessed as having a high-risk exposure to HIV. (A3)
- **Non-occupational exposure:** Clinicians should provide a 7-day starter pack of PEP medications to an individual assessed as having a high-risk exposure to HIV. (A3)
- **Sexual assault exposure:** Hospital clinicians are required by New York State law to provide a full 28-day PEP regimen to sexual assault patients, regardless of age (effective February 3, 2026).
- **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 PrEP:** Clinicians should recommend or refer for PrEP any individual reporting a non-occupational exposure who: (A1)
  - Reports an exposure for which PEP is not indicated following assessment of risk
  - Engages in risk behaviors such as condomless sex or intravenous drug use
  - Continues to engage in risk behaviors after completing the 28-day PEP regimen

Sequential HIV Testing and Laboratory Monitoring

All Exposures

HIV Testing at 4 and 12 Weeks After Exposure

- Clinicians should follow up with an in-person visit (preferred) at 4 weeks after exposure to perform HIV testing and other laboratory testing specified in Table 6: Recommended Laboratory Monitoring After PEP Initiation. (A3)

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- 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 after exposure, using an FDA-approved laboratory-based HIV-1/2 Ag/Ab combination immunoassay. (A2)
  - 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 after 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 Laboratory Monitoring After PEP Initiation. (A2)

Serial HIV Testing in Children

- If an exposed child older than 2 years 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.

Management of Potential Exposure to Hepatis B Virus

Initial Testing After Potential HBV Exposure

- When an individual reports a potential exposure to HIV or other STIs, clinicians should assess for concurrent exposure to HBV. (A2)
- 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 HBV or whose HBV status is unknown, the clinician should obtain HBV vaccination history and the following baseline tests, preferably within 48 hours (A1):
  - **Exposed individual:** Triple panel testing for HBsAg, anti-HBc, and anti-HBs (if the exposed individual has known anti-HBs ≥10 mIU/mL or chronic HBV infection, no further intervention is needed)
  - **Source:** Triple panel testing for HBsAg, anti-HBc, and anti-HBs when possible

HBV Vaccination as PEP

- Clinicians should recommend HBV vaccination for all individuals who may have been exposed to HBV except those with known anti-HBs ≥10 mIU/mL, chronic HBV infection, or HBV vaccine nonresponse [c]. (A1)
- Clinicians should administer the first dose of the HBV vaccine series during the initial evaluation, ideally within 24 hours of exposure [d]; vaccination should not be delayed for triple panel testing results. (A1)
- Clinicians should complete the HBV vaccine series for exposed individuals with anti-HBs <10 mIU/mL on triple panel testing or who did not previously receive the full vaccine series. (A1)
- Clinicians should obtain anti-HBs testing within 1 to 2 months after the exposed individual's completion of the last dose of the HBV vaccine if there is ongoing risk for HBV exposure (test at 6 months if given HBIG). (A3)

Hepatitis B Immune Globulin as PEP

- If the exposed individual is unvaccinated, did not complete the HBV vaccine series, or is known to be nonimmune to HBV, and if the source has known acute or chronic HBV (HBsAg positive), the clinician should administer prophylactic HBIG; for occupational exposures, HBIG can also be administered if the source's HBV status is unknown. (A1)
- Clinicians should administer HBIG as soon as possible after HBV exposure, ideally within 7 days and no later than 14 days, and should be administered at a different site from the HBV vaccine in the exposed individual. (A2)

☑ ALL RECOMMENDATIONS: PEP TO PREVENT HIV INFECTION

Management of Potential Exposure to Hepatitis C Virus

Initial Testing After Potential HCV Exposure

- When an individual reports a potential exposure to HIV or other STIs, clinicians should assess for concurrent exposure to HCV. (A2)
- 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 HCV or whose HCV status is unknown, the clinician should obtain the following baseline tests, preferably within 48 hours (A2):
  - **Exposed individual:** HCV antibody test, with reflex to NAT for HCV RNA if positive; liver function tests, including liver enzyme test
  - **Source:** HCV RNA test (an HCV antibody test, with reflex to NAT for HCV RNA if positive, is an alternative if no concern for acute HCV)

No PEP for Potential HCV Exposure

- Clinicians should not administer immunoglobulin or antiviral agents for HCV PEP. (A2)

Follow-Up Testing After Potential HCV Exposure

- If the source is unavailable for testing or tested positive for HCV antibody or RNA, clinicians should follow up with the exposed individual as follows (A2):
  - 3 to 6 weeks later [e]: HCV RNA test
  - 4 to 6 months later [e]: HCV antibody test, with reflex HCV RNA test if positive (if the exposed individual is immunocompromised, an HCV RNA test is recommended)
- If HCV infection is identified, the clinician should offer or refer for HCV treatment. (A2)
  - See the NYSDOH AI guideline Treatment of Chronic Hepatitis C Infection in Adults.

Abbreviations: 3TC, lamivudine (brand name Epivir); Ab, antibody; ABC, abacavir (brand name Ziagen); Ag, antigen; ALT, alanine aminotransferase; anti-HBs, hepatitis B surface antibody; ART, antiretroviral therapy; ARV, antiretroviral medication; BIC/TAF/FTC, bictegravir/tenofovir alafenamide/emtricitabine (brand name Biktarvy); CrCl, creatinine clearance; DTG, dolutegravir (brand name Tivicay); EFV, efavirenz (brand name Sustiva); FDA, U.S. Food and Drug Administration; HBIG, hepatitis B immune globulin; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; HCV, hepatitis C virus; HPV, human papillomavirus; IDV, indinavir (brand name Crixivan); INSTI, integrase strand transfer inhibitor; MVC, maraviroc (brand name Selzentry); NAT, nucleic acid test; NFV, nelfinavir (brand name Viracept); NVP, nevirapine (brand name Viramune); PEP, post-exposure prophylaxis; PI, protease inhibitor; POC, point-of-care; PrEP, pre-exposure prophylaxis; RAL, raltegravir (brand name Isentress); STI, sexually transmitted infection; TDF/3TC, tenofovir disoproxil fumarate/lamivudine (brand name Cimduo); TDF/FTC, tenofovir disoproxil fumarate/emtricitabine (brand name Truvada); ZDV, zidovudine (brand name Retrovir).

Notes:

a. The high-dose formulation of RAL (RAL HD) should not be given to pregnant patients.
b. 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[Zash, et al. 2022].
c. Nonresponse defined as documented inadequate response (serum anti-HBs <10 mIU/mL) to 2 vaccine series. Adults with nonresponse who received only a nonadjuvanted HBV vaccine series should initiate a recombinant adjuvanted HBV vaccine series (approved by the U.S. Food and Drug Administration in 2017).
d. 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 adjuvanted vaccine (see guideline text for more information).
e. Weeks 6 and 24 coincide with HIV PEP testing.

All Selected Good Practice Reminders

→ ALL SELECTED GOOD PRACTICE REMINDERS: PEP TO PREVENT HIV INFECTION

First Dose of PEP and Management of the Exposure Site

- **All exposures:** 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.

Evaluating Exposure Risk

- **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 (ARS):** 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 PEP is declined:** 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 ARS.
  - 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:** Identify and assess all specific behaviors that may have resulted in exposure to HIV.
- **PrEP:** 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:** The Centers for Disease Control and Prevention recommends 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 the source's confirmatory testing is positive (HIV-1/HIV-2 Ab differentiation immunoassay or HIV-1 RNA test), link 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.
- **Counseling:** Provide counseling and education to the exposed individual.
- **Follow-up:** 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.
- **If the source's viral load at the time of a sexual exposure is available:** Offer information about U=U to reassure the exposed individual. 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 exposure will not transmit the virus through

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sex[Rodger, et al. 2019; Cohen, et al. 2016; Rodger, et al. 2016]. U=U does not apply to exposure through needle sharing, breast/chestfeeding, or needlestick injury.

Baseline Testing of the Exposed Individual

- **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 ART initiation and provide a referral for HIV care.
- **ART initiation:** Rapid ART initiation is recommended for all patients diagnosed with HIV.
- **Arrange for HIV care:** If HIV infection is confirmed, seroconversion is suspected, or HIV infection cannot be ruled out, refer the exposed individual for HIV care and rapid ART initiation.
- **Pregnancy testing:** Perform pregnancy testing in all individuals of childbearing capacity.
- **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.

Selecting and Initiating a 28-Day Course of PEP

- **Avoid drug-drug interactions and medication-related adverse effects:** 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 effects.
- **Impaired renal function:** Do not initiate TDF/FTC as PEP for any individual with a confirmed CrCl <60 mL/min, and discontinue it in patients with a confirmed CrCl <50 mL/min; in such cases, initiate or switch to a TAF-containing regimen and continue monitoring while completing a 28-day course of PEP.
- **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 a 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, 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)**:** Hospital clinicians are required by New York State law to provide a full 28-day PEP regimen to sexual assault patients, regardless of age (effective February 3, 2026).
- **Medication access:** Ensure the patient can 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 adverse 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

- **If HIV infection is confirmed in the exposed individual:** Explain the benefits of rapid ART initiation 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 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.
- **Risk reduction:** Individuals who report ongoing high-risk sexual exposure are candidates for PrEP.

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  - 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, initiate 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:** 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

- **Discuss signs and symptoms of ARS:** 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:**
  - 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.
- **Refer for follow-up care:** Refer or arrange for follow-up care as needed, including referral to an experienced HIV care provider if needed.

Follow-Up for 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, the patient should be given a referral for PrEP care.
- **Plan for follow-up care:** Review the plan for follow-up care with the patient and 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 trichomoniasis was given at the initial presentation.

Follow-Up for Sexual Assault Exposures

- **Plan for follow-up care:** Review the plan for follow-up care with the patient and 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 trichomoniasis was given at the initial presentation.
- **STI testing:** Baseline testing for STIs may be offered, along with syphilis testing at week 2.

Abbreviations: Ab, antibody; Ag, antigen; ARS, acute retroviral syndrome; ART, antiretroviral therapy; CrCl, creatinine clearance; FDA, U.S. Food and Drug Administration; PEP, post-exposure prophylaxis; POC, point-of-care; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection; TAF, tenofovir alafenamide; TDF/FTC, tenofovir disoproxil fumarate/emtricitabine (brand name Truvada); U=U, undetectable equals untransmittable.

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Supplement: Guideline Development and Recommendation Ratings

Table S1: Guideline Development: New York State Department of Health AIDS Institute Clinical Guidelines Program	
Developer	New York State Department of Health AIDS Institute (NYSDOH AI) Clinical Guidelines Program
Funding source	NYSDOH AI
Program manager	Clinical Guidelines Program, Johns Hopkins University School of Medicine, Division of Infectious Diseases. See Program Leadership and Staff.
Mission	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.
Expert committees	The NYSDOH AI Medical Director invites and appoints committees of clinical and public health experts from throughout New York State to ensure that the guidelines are practical, immediately applicable, and meet the needs of care providers and stakeholders in all major regions of New York State, all relevant clinical practice settings, key New York State agencies, and community service organizations.
Committee structure	• 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 • Contributing members • Guideline writing groups: Lead author, coauthors if applicable, and all committee leaders
Disclosure and management of conflicts of interest	• 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. • 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. Disclosures are listed for each committee member.
Evidence collection and review	• Literature search and review strategy is defined by the guideline lead author based on the defined scope of a new guideline or update. • 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. • A targeted search and review to identify recently published evidence is conducted for guidelines published within the previous 3 years. • 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.
Recommendation development	• The lead author drafts recommendations to address the defined scope of the guideline based on available published data. • Writing group members review the draft recommendations and evidence and deliberate to revise, refine, and reach consensus on all recommendations. • When published data are not available, support for a recommendation may be based on the committee's expert opinion. • 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.

Table S1: Guideline Development: New York State Department of Health AIDS Institute Clinical Guidelines Program	
Review and approval process	• Following writing group approval, draft guidelines are reviewed by all contributors, program liaisons, and a volunteer reviewer from the AI Community Advisory Committee. • 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. • Final approval by the committee chair and the NYSDOH AI Medical Director is required for publication.
External reviews	• External review of each guideline is invited at the developer's discretion. • External reviewers recognized for their experience and expertise review guidelines for accuracy, balance, clarity, and practicality and provide feedback.
Update process	• 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. • 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 and will invite full committee review as indicated.

Table S2: Recommendation Ratings and Definitions		
Strength	**Quality of Evidence**	
A: Strong B: Moderate C: Optional	1	Based on published results of at least 1 randomized clinical trial with clinical outcomes or validated laboratory endpoints.
	*	Based on either a self-evident conclusion; conclusive, published, in vitro data; or well-established practice that cannot be tested because ethics would preclude a clinical trial.
	2	Based on published results of at least 1 well-designed, nonrandomized clinical trial or observational cohort study with long-term clinical outcomes.
	2†	Extrapolated from published results of well-designed studies (including nonrandomized clinical trials) conducted in populations other than those specifically addressed by a recommendation. The source(s) of the extrapolated evidence and the rationale for the extrapolation are provided in the guideline text. One example would be results of studies conducted predominantly in a subpopulation (e.g., one gender) that the committee determines to be generalizable to the population under consideration in the guideline.
	3	Based on committee expert opinion, with rationale provided in the guideline text.