UC RIVERSIDE
Occupational Health

Exposure Response Plan for Human Immunodeficiency Virus (HIV)

Background/Hazard Identification

Characteristics

Human Immunodeficiency Virus (HIV) is a member of the *Retroviridae* family, genus Lentivirus. HIV is an icosahedral, enveloped virus, of approximately 100 to 110 nm in diameter, and has a single-stranded, linear, positive-sense RNA genome. HIV has two recognized strains: HIV-1 and HIV-2. Upon entry into the host cell, retroviral RNA is converted to DNA by virally encoded reverse transcriptase enzyme, the DNA transcript is integrated into the host's chromosomal DNA.

Pathogenicity/Toxicity

Acquired Immunodeficiency Syndrome (AIDS), the disease caused by Human Immunodeficiency Virus (HIV) infection, is characterized by symptoms and infections caused by the breakdown of the immune system (by destruction or functional impairment of CD4 receptor positive T-cells). HIV can infect many cell types, mainly lymphocytes, but also macrophages, and microglia in the brain, and other neurological cells, resulting in profound asthenia, dementia, and damage to peripheral nervous system. Due to immunodeficiency, patients succumb to various fungi, parasites, bacteria, and/or viruses and are prone to certain tumors. Globally, *Mycobacterium tuberculosis* is the most common cause of death of HIV-infected individuals. The clinical features of HIV infection vary depending on the stage of the disease. Acute infection is accompanied by non-specific "flu-like" and "mononucleosis-like" symptoms such as myalgia, arthralgia, diarrhea, nausea, vomiting, headache, hepatosplenomegaly, weight loss, and neurological symptoms. Early-stage disease refers to the period of clinical latency between the time of the primary infection and the development of symptoms indicative of advanced immunodeficiency. Typically, when the patient's CD4+ T-cell count falls below 500 cells/μL, syndromes indicative of depressed cell mediated immunity can appear. Example include oropharyngeal and recurrent vulvovaginal candidiasis, bacillary angiomatosis, recurrent or multidermatomal herpes zoster, listeriosis, infections due to *Rhodococcus equi,* pelvic inflammatory disease, oral hairy leukoplakia associated with Epstein-Barr virus, cervical dysplasia, long lasting diarrhea, idiopathic thrombocytopenic purpura, and peripheral neuropathy. Late-stage disease refers to the period when the patient's CD4+ T-cell count falls below 200 cells/μL. The loss of the integrity of cell-mediated immune responses allows ubiquitous environmental organisms with limited virulence to become life threatening pathogens. Examples of conditions (as set out by the US Centers for Disease Control and Prevention) include candidiasis of bronchi, trachea, lungs or esophagus,

invasive cervical cancer, coccidioidomycosis, cryptococcosis, cryptosporidiosis, cytomegalovirus disease (other than liver, spleen, or nodes), cytomegalovirus retinitis (with loss of vision), HIV-related encephalopathy, herpes simplex, histoplasmosis, isosporiasis, Kapsoi's sarcoma, Burkitt's lymphoma, immunoblastic lymphoma, primary lymphoma of the brain, Mycobacterium avium complex, Mycobacterium tuberculosis, Pneumocystis jirovecii pneumonia, recurrent pneumonia, progressive multifocal leukoencephalopathy, recurrent salmonella septicemia, toxoplasmosis of the brain, and wasting syndrome due to HIV.

Epidemiology

Human Immunodeficiency Virus (HIV) is a major global problem with approximately 25 million HIV-related deaths, and another 40.2 (36 to 45.3) million infected individuals worldwide. Acquired Immunodeficiency Syndrome (AIDS) was first described in 1981. The new retrovirus (HIV-1) was found in tissues from AIDS patients in 1983 and the causative relationship between HIV and AIDS was established in 1984. HIV-2 was discovered in 1986 and is the least pathogenic form of HIV, displaying low rates of transmission and rarely causing AIDS. The majority of people with HIV live in the developing world (approximately 95% of the individuals infected worldwide). Sub-Saharan Africa is by far the worst-affected area in the world. This region has slightly more than 10% of the world's population but is home to more than 60% of the total population living with HIV/AIDS. Globally, infants who acquire the disease from their mothers constitute about 11% of all HIV infections. Ten percent of infections worldwide are associated with injection drug use; 5 to 10% are transmitted by sex between men; and 5 to 10% occur in health care settings. The predominant means of infection is sex between men and women, which accounts for nearly two thirds of new infections, and 85% of existing infections worldwide. About 50% of all new HIV infections worldwide occur in individuals younger than 25 years old.

Modes of Transmission/Exposure

Human Immunodeficiency Virus (HIV) is transmitted either by exposure of the virus to oral, rectal or vaginal mucosa during sexual activity; by intravascular inoculation through transfusion of contaminated blood products; by using contaminated equipment during injection drug use; or from mother to infant during pregnancy, delivery or breastfeeding. There are no obvious differences in disease manifestations in individuals infected by mucosal versus blood-borne routes. Sexual transmission accounts for more than 90% of HIV infections worldwide.

1. **Modes of Exposure in Laboratory Settings**
    a. High Risk Exposures

i. Skin puncture or injection
ii. Exposure of the virus to mucous membranes (eyes, nose, mouth)
iii. Contact with non-intact skin (abrasions, cuts, scrapes)
iv. Bite from an HIV-infected mouse – risk of transmission of HIV in this situation is unknown, so we take a precautionary approach and recommend prophylaxis.

b. Low Risk/Potential Exposure:
i. Contact with intact skin.

Immediate Response Following Exposure

1. Immediate First Aid

a. **Intact Skin Exposure**
Immediately go to a sink and wash the affected area thoroughly with soap and water for **10–15 minutes**.

b. **Non-Intact Skin Exposure (cuts, abrasions, dermatitis)**
Immediately go to a sink and wash the affected area thoroughly with soap and water for **10–15 minutes**.
Initiate the post-exposure prophylaxis (PEP) protocol described in the Treatment section below.

c. **Splash to Eyes, Nose, or Mouth**
Immediately flush the affected area with clean, running water for **at least 3 minutes**.
If available, use an **eyewash station located adjacent to the laboratory**. All personnel working with HIV must know the location of and how to use the nearest eyewash station.

d. If possible, continue flushing for 10–15 minutes.
Initiate medical evaluation and the PEP protocol **described in the Treatment section below.**
If an eyewash station is not available, proceed immediately to Treatment section 2(a) **or** 2(b)**.**

2. Medical Treatment and Post-Exposure Prophylaxis (PEP)

a. Medical Evaluation
The employee should report to the nearest **UCR** Medical Treatment Facilities if the exposure occurs during business hours, or to the **nearest Emergency Room** after hours.

b. Expert Consultation
Immediate counseling and guidance are available by contacting the **UCI Medical Center Infectious Disease Fellow on call at 714-456-6011**.UCR maintains an

agreement with the **UCI Center for Occupational and Environmental Health (COEH)**, which serves as UCR's Occupational Health provider and reviews the Animal Occupational Health Program.

Timing and Urgency of Post-Exposure Prophylaxis (PEP)

PEP effectiveness is highly time-dependent. The first dose must be administered as soon as possible after exposure. The optimal window for initiation is within hours—ideally within 2 hours—not days.

Although 72 hours post-exposure is generally considered the outer limit for initiating PEP, this timeframe is based primarily on animal studies, and no definitive clinical data establish a strict cutoff for effectiveness. Initiation of PEP beyond 72 hours requires immediate consultation with an infectious disease specialist.

This potential exposure risk has already been evaluated by the Occupational Health Physician during review of your Occupational Health Surveillance System (OHSS) medical questionnaire. *You are receiving this document to ensure that both you and the treating provider understand that this risk was anticipated in advance and that prompt medical action is required if an exposure occurs.

Note: Potential HIV exposures are considered medically urgent/emergent. PEP should be started immediately. If subsequent evaluation confirms that the source individual is not HIV-positive, PEP may be discontinued.

Important Instruction for the Exposed Individual

***Provide this information sheet to the treating physician to ensure they understand that a potential HIV exposure has occurred and that this situation constitutes a medical emergency.**

HIV Baseline Testing

For an individual who will be **working in a laboratory setting with HIV**, the **baseline HIV testing** is recommended **before occupational exposure**. A **HIV-1/2 Antigen/Antibody (Ag/Ab) Immunoassay** is the standard baseline test. It detects:

- **HIV-1 and HIV-2 antibodies** (evidence of prior infection)
- **P24 antigen** (allows earlier detection of recent infection)

The test establishes that an individual is **HIV-negative at baseline** before work starts.

Baseline testing is recommended because it provides a **reference point** in case of:

- Needlestick injuries
- Mucous membrane exposure and
- Other potential occupational exposures

This ensures that any future positive result can be accurately assessed as **work-related or non-occupational** and to support appropriate post-exposure evaluation and follow-up if needed.

HIV baseline testing is **confidential**, and a **positive baseline result does not automatically disqualify** someone from laboratory work; this is evaluated on a case-by-case basis with Occupational Health. Additional follow-up testing only occurs **if an exposure incident happens**.

Personal Protection

Risk Group Classification

Risk Group 3

Containment Requirements

Please refer to the Biosafety Directive for Human Immunodeficiency Virus (HIV) and Human T-cell Lymphotropic Virus Type 1 (HTLV-1).

Protective Clothing

Solid-front gowns with tight-fighting wrists, gloves, and respiratory protection should be worn over laboratory clothing when infectious materials are directly handled.

Other Precautions

All activities with infectious material should be conducted in a biological safety cabinet (BSC) or other appropriate primary containment device in combination with personal protective equipment. Centrifugation of infected materials must be carried out in closed containers, placed in sealed safety cups, or in rotors that are unloaded in a biological safety cabinet. The use of needles, syringes, and other sharp objects should be strictly limited. Open wounds, cuts, scratches, and grazes should be covered with waterproof dressing. Additional precautions should be considered with working involving animals or large-scale activities.

Laboratory Hazards

Laboratory-Acquired Infections

Although there have been many reported cases of Human Immunodeficiency Virus (HIV) infection through occupational transmission, the numbers of laboratory acquired infections are low. As of 2001, there were a total of 57 cases of documented occupationally acquired HIV among U.S. health care workers.

Feces, nasal secretions, sputum, sweat, vomitus, saliva, tears, and urine are not considered potentially infectious unless they are visibly bloody.

Sources/Specimens

Blood, semen, vaginal secretions, cerebrospinal fluid, synovial fluid, peritoneal fluid, pleural fluid, pericardial fluid, amniotic fluid, other specimens containing visible blood, breast milk, unscreened or inadequately treated blood products, and infected human tissues.

Primary Hazards

Needlestick, contaminated sharp objects, and/or direct contact with non-intact skin or mucous membranes with HIV-infected specimens/tissues.

Special Hazards

Extreme care must be taken to avoid spilling and/or splashing infected materials. HIV should be presumed to be in/on all equipment and devices coming in direct contact with infected materials.

Signs and Symptoms

The only way to know for sure if you have Human Immunodeficiency Virus (HIV) is to get tested. You cannot rely on symptoms to tell whether you have HIV. Knowing your HIV status gives you information so you can take steps to keep yourself healthy.

Most people have flu-like symptoms within 2 to 4 weeks after infection. Symptoms may last for a few days or several weeks. It depends on the person and what stage of the disease they are in. HIV has three stages, each with different symptoms a person may have. Not everyone will have the same symptoms.

Flu-like symptoms can include the following:

Fever, chills, rash, night sweats, muscle aches, sore throat, fatigue, swollen lymph nodes, mouth ulcers.

If you think you may have been exposed to HIV, get an HIV test, whether you have symptoms or not.

Incubation Period

Variable. Commonly the time from infection to the development of detectable antibodies is generally 1 to 3 months; however, the time from Human Immunodeficiency Virus (HIV) infection to diagnosis of Acquired Immunodeficiency Syndrome (AIDS) had an observed range of less than 1 year to 15 years or longer.

Prophylaxis

Human Immunodeficiency Virus (HIV) postexposure prophylaxis regimens are based on the nature of the exposure. The majority of HIV exposures will warrant a three drug regimen, the preferred regimen according to the US public Health Service Guidelines for the Management of Occupational Exposure to Human Immunodeficiency Virus is two NTRIs, Emtricitabine and Tenofovir (Viread, TDF) in a combination (Truvada) plus an INSTI (Raltegravir, trade name Isentress). Alternative regimens combine a pair of NTRIs with one or two other drugs. (52). View Selection of Agents for HIV PEP, and Table 1 for additional information regarding postexposure prophylaxis.

HIV Safety Protocols: Handling, Inactivation, and Disposal Requirements

Handling and Storage

Infectious material should be stored in sealed, leak-proof containers that are appropriately labelled.

Spills

Allow aerosols to settle and, while wearing protective clothing, gently cover the spill with paper towels and apply 1% sodium hypochlorite starting at the perimeter, working inwards towards the center. Allow sufficient contact time before clean-up.

Susceptibility to Disinfectants

Human Immunodeficiency Virus (HIV) is susceptible to fresh 2% glutaraldehyde, 2% Jodopax (detergent and iodine), hypochlorite, iodine, phenolics, and to less extent 70% ethanol, NaOH and isopropanol.

Physical Inactivation

Human Immunodeficiency Virus (HIV) is inactivated by ultraviolet (UV) light; however, the level of the inactivation is heavily influenced by the proximity of the UV source to the sample and concentration of protein in the sample environment. HIV is easily inactivated in a cell free medium; however, in cell associated samples and blood samples complete inactivation requires much longer exposures to the UV source. HIV is also inactivated at pH higher or lower than the optimal level of 7.1. A temperature of 60 degrees Celsius for 30

minutes will likely inactivate HIV; however, higher temperatures and incubations may be required depending on the initial titer of the virus.

Survival Outside Host

Human Immunodeficiency Virus (HIV) can remain viable in blood in syringes at room temperature for 42 days, and in blood and cerebrospinal fluid from autopsies for up to 11 days. Although drying in the environment is known to cause rapid reduction in HIV concentration, under experimental conditions, cell-free HIV dried onto a glass coverslip in 10% serum can survive for longer than 7 days, depending on the initial titer.

Disposal

Decontaminate all materials for disposal by steam sterilization, chemical disinfection, and/or incineration.

First-Aid

Surveillance

Human Immunodeficiency Virus (HIV) is diagnosed by tests that assess whether an individual's immune system has produced an HIV-specific immune response. Common tests include the indirect binding assay, antibody capture assay, the double antigen sandwich, ELISA, immunofluorescence, Western blotting, line immunoassays, and PCR, as well as viral isolation.

First AID/Treatment

Acquired Immunodeficiency Syndrome (AIDS) must be managed as a chronic disease. Antiretroviral treatment is complex, involving a combination of drugs, Nuceloside and Nucleotide Reverse Transcriptase inhibitors (NRTIs), Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs), Protease Inhibitors (PIs), Fusion inhibitors (FIs), Integrase Strand Transfer Inhibitors (INSTIs), and chemokine (C-C motif) receptor 5 (CCR5) can be combined to provide highly active antiretroviral therapy (HAART). For many (but not all) patients, HAART converts an inexorably fatal disease into a chronic disease with a fairly good prognosis (2013, Infect Control Hosp Epidemiol 34:875-892 and 2018 Update https://stacks.cdc.gov/view/cdc/20711).

Immunization

None

Reporting Exposure Incidents

Any exposure incident—such as contact with HIV with eyes, nose, mouth, skin contamination, needlestick and/or sharps exposure—must **be immediately reported** to:

- **Your PI or laboratory supervisor**
- **UCR Biosafety Officer (BSO)** and **EHSRM at (951) 827-5528.**
- **Occupational Health ehsocchealth@ucr.edu**
- **You may contact the UCI Medical Center Infectious Disease Fellow on call at 714-456-6011 for immediate counseling and guidance. UCR maintains an agreement with the UCI Center for Occupational and Environmental Health (COEH) Clinic, which serves as our Occupational Health provider and reviews UCR's Animal Occupational Health Program.**

Undergraduate Student Employees report your injury to your supervisor (or go to Employee Injuries).

For life-threatening injuries, call 911 immediately.

For all other injury types, seek Medical Treatment at UCR's Medical Treatment Facilities.

Post Exposure Testing

HIV Exposure Protocol Reference Information/Background

Background for Clinical Providers

Excerpted from: Updated U.S. Public Health Service Guidelines for Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis

Human Immunodeficiency Virus (HIV) testing should be used to monitor health care providers (HCP) for seroconversion after occupational HIV exposure. After baseline testing at the time of exposure, follow-up testing should be performed at 6 weeks, 12 weeks, and 6 months after exposure. Use of fourth generation HIV Ag/Ab combination immunoassays allow for earlier detection of HIV infection. (47, 23, 10) If a provider is certain that a fourth-generation combination HIV Ag/Ab test is used, HIV follow-up testing could be concluded earlier than 6 months after exposure. In this instance, an alternative follow-up testing schedule could be used (e.g., baseline testing, 6 weeks, and then concluded at 4 months after the exposure). Extended HIV follow-up (e.g., for 12 months) is recommended for HCP who become infected with Hepatitis C Virus (HCV) after exposure to a source who is co-infected with HIV and HCV. Whether extended follow-up is indicated in other circumstances (e.g., exposure to a source co-infected with HIV and HCV in the absence of HCV seroconversion or for exposed persons with a medical history suggesting an impaired ability to mount an antibody response to acute infection) is unknown. Although rare instances of delayed HIV seroconversion have been reported, (61, 22) adding to an

exposed persons' anxiety by routinely extending the duration of postexposure follow-up is not warranted. However, decisions to extend follow-up in a particular situation should be based on the clinical judgment of the exposed person's health-care provider and should not be precluded because of HCP anxiety. HIV tests should also be performed on any exposed person who has an illness compatible with an acute retroviral syndrome, regardless of the interval since exposure. A person in whom HIV infection is identified should be referred to a specialist who has expertise in HIV treatment and counseling for medical management. Health-care providers caring for persons who have occupationally acquired HIV infection should

Post-Exposure Medical Surveillance

HIV Exposure Protocol Reference Information/Background

Background for Clinical Providers

Excerpted from: Updated U.S. Public Health Service Guidelines for Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis

Importance of Follow-Up of Exposed HCP

Health care providers (HCP) who have experienced occupational exposure to HIV should receive follow-up counseling, postexposure testing, and medical evaluation regardless of whether they take Post Exposure Prophylaxis (PEP). Greater emphasis is placed upon the importance of follow up of HCP on HIV pep within 72 hours of exposure and improving follow-up care provided to exposed HCP (Appendix B). Careful attention to follow-up evaluation within 72 hours of exposure can 1) provide another (and perhaps less anxiety-ridden) opportunity to allow the exposed HCP to ask questions and for the counselor to make certain that the exposed HCP has a clear understanding of the risks for infection and the risks and benefits of PEP, 2) ensure that continued treatment with PEP is indicated, 3) increase adherence to HIV PEP regimens, 4) manage associated symptoms and side-effects more effectively, 5) provide an early opportunity for ancillary medications or regimen changes, 6) improve detection of serious adverse effects, and 7) improve the likelihood of follow-up serologic testing for a larger proportion of exposed personnel to detect infection. Closer follow-up should in turn reassure HCP who become anxious after these events (5, 50) The psychological impact of needlesticks or exposure to blood or body fluid should not be underestimated for HCP. Exposed personnel should be advised to use precautions (e.g., use of barrier contraception, avoid blood or tissue donations, pregnancy, and if possible, breastfeeding) to prevent secondary transmission, especially during the first 6-12 weeks postexposure. Providing HCP with psychological counseling should be an essential component of the management and care of exposed HCP.

Selection of Agents for HIV PEP

Consult **Table 1** for initial preferred and alternative PEP regimens for HCP following occupational exposure to HIV. (52).

Three-drug PEP regimens are now considered the standard approach for all exposures. There are some special circumstances in which a two-drug regimen can be considered, e.g., recommended agents are unavailable or concern for potential toxicity or adherence challenges. Consultation is recommended if a two-drug regimen is considered.

PREFERRED 3-DRUG HIV PEP REGIMENS (WITH DOSING INFORMATION) FOR MOST ADULTS AND ADOLESCENTS WITHOUT RELEVANT CONTRAINDICATIONS*:

Co-formulated bictegravir (BIC)/emtricitabine (FTC)/tenofovir alafenamide (TAF) [Biktarvy®] 50/200/25mg, 1 tablet by mouth once daily

OR

Dolutegravir (DTG) [Tivicay®] 50mg, 1 tablet by mouth once daily

PLUS

Any of the following co-formulations:

- Tenofovir disoproxil fumarate (TDF)/emtricitabine (FTC) [Truvada®] 300/200mg, 1 tablet by mouth once daily; or
- Tenofovir alafenamide (TAF)/emtricitabine (FTC) [Descovy®] 25/200mg, 1 tablet by mouth once daily; or
- Tenofovir disoproxil fumarate (TDF)/lamivudine (3TC) [Cimduo®] 300/300mg, 1 tablet by mouth once daily.

Duration: 28 days

Side effects and drug-drug interactions are described below

**For people with renal/hepatic impairment, please see other section for medication selection and dosing recommendations*.

PREFERRED AND ALTERNATIVE REGIMENS FOR PATIENTS WITH RENAL DYSFUNCTION OR HEPATIC IMPAIRMENT:

Moderate renal dysfunction (creatinine clearance (CrCl) 30-49 mL/min)*

Preferred combinations include co-formulated bictegravir (BIC)/emtricitabine (FTC)/tenofovir alafenamide (TAF) [Biktarvy®] 50/200/25mg, 1 tablet by mouth once daily

OR

Dolutegravir (DTG) [Tivicay®] 50mg, 1 tablet by mouth once daily plus co-formulated tenofovir alafenamide (TAF)/emtricitabine (FTC) [Descovy®] 25/200mg, 1 tablet by mouth once daily.

***Alternative* combinations are available** but may introduce challenges such as additional pill burden, side effects, and drug interaction concerns. Options identified by the CDC include: dolutegravir PLUS dose-reduced tenofovir disoproxil fumarate PLUS either emtricitabine or lamivudine; co-formulated darunavir/cobicistat/tenofovir alafenamide/emtricitabine; and ritonavir-boosted darunavir PLUS either tenofovir alafenamide or dose-reduced tenofovir disoproxil fumarate PLUS either emtricitabine or lamivudine. Please consult NCCC or a local expert for further information including dosing considerations.

Severe renal dysfunction (CrCl under 30 mL/min) and on hemodialysis*
On days of hemodialysis, PEP medications should be administered after completion of hemodialysis.

Preferred combinations include co-formulated bictegravir (BIC)/emtricitabine (FTC)/tenofovir alafenamide (TAF) [Biktarvy®] 50/200/25mg, 1 tablet by mouth once daily

OR

Dolutegravir (DTG) [Tivicay®] 50mg, 1 tablet by mouth once daily plus co-formulated tenofovir alafenamide (TAF)/emtricitabine (FTC) [Descovy®] 25/200mg, 1 tablet by mouth once daily.

***Alternative* combinations are available** but may introduce challenges such as additional pill burden, side effects, and drug interaction concerns. Options identified by the CDC include: dolutegravir PLUS dose-reduced tenofovir disoproxil fumarate PLUS either emtricitabine or dose-reduced lamivudine; co-formulated darunavir/cobicistat/tenofovir alafenamide/ emtricitabine; and ritonavir-boosted darunavir PLUS either tenofovir alafenamide or dose-reduced tenofovir disoproxil fumarate PLUS either emtricitabine or dose-reduced lamivudine. Please consult NCCC or a local expert for further information including dosing considerations.

Hepatic impairment (Child-Pugh class A/B)*
Preferred combinations include co-formulated bictegravir (BIC)/emtricitabine (FTC)/tenofovir alafenamide (TAF) [Biktarvy®] 50/200/25mg, 1 tablet by mouth once daily

OR

Dolutegravir (DTG) [Tivicay®] 50mg, 1 tablet by mouth once daily

PLUS

Any of the following co-formulations:

- Tenofovir disoproxil fumarate (TDF)/emtricitabine (FTC) [Truvada®] 300/200mg, 1 tablet by mouth once daily; or
- Tenofovir alafenamide (TAF)/emtricitabine (FTC) [Descovy®] 25/200mg, 1 tablet by mouth once daily; or
- Tenofovir disoproxil fumarate (TDF)/lamivudine (3TC) [Cimduo®] 300/300mg, 1 tablet by mouth once daily.

***Alternative* combinations are available** but may introduce challenges such as additional pill burden, side effects, and drug interaction concerns. Options identified by the CDC include: boosted darunavir PLUS either tenofovir alafenamide or tenofovir disoproxil fumarate PLUS either emtricitabine or lamivudine. Please consult NCCC or a local expert for further information including dosing considerations.
Expert consultation is recommended for people with severe hepatic impairment (Child-Pugh class C) or severe renal dysfunction (CrCl < 30 mL/min) and not on dialysis*.

*****Note: For additional detailed information on dosing, side effects, and drug-drug interactions, please see University of California San Francisco's (UCSF) antiretroviral drug tables on their website's Pharmacy section.

Pregnancy, Lactation, and Reproductive Health Precautions

1. Mandatory Reproductive Health Consultation

Personnel who are pregnant, planning pregnancy, undergoing IVF/fertility treatment, or breastfeeding must be offered a confidential reproductive health and exposure-risk consultation through Occupational Health *before* participating in work involving Human Immunodeficiency Virus (HIV)

How to Contact UCR Occupational Health

UCR Occupational Health
✉ *ehsocchealth@ucr.edu*
📞 *951-827-5528*

Supervisors and PIs must maintain confidentiality and coordinate with HR Disability Management as needed for formal accommodations.

2. Management of HIV Exposures During Pregnancy

Excerpted from: PEP Quick Guide for Bloodborne Pathogen Exposures: HIV

HIV exposures in pregnant individuals should be managed promptly and thoughtfully, using principles similar to those applied to non-pregnant individuals, while accounting for pregnancy-specific considerations.

Post-Exposure Prophylaxis (PEP) Initiation

- Decisions to initiate PEP should be based on the nature and risk of the exposure and should involve **shared decision-making** between the clinician and the exposed person.
- Counseling should include a discussion of the **potential benefits and risks of maternal and fetal exposure** to antiretroviral (ARV) medications.

Pregnancy-Specific Considerations

- Both the pregnant person and the fetus are at risk for HIV acquisition. **Acute HIV infection during pregnancy carries a high risk of perinatal transmission**, underscoring the importance of timely PEP when indicated.
- Available data indicate that use of ARVs during pregnancy, **including the first trimester**, does not appear to increase the risk of birth defects compared with the general population.
- Safety events associated with currently recommended PEP regimens are **not thought to be increased during pregnancy**.

Reporting and Follow-Up

- All ARV exposures during pregnancy should be reported to the Antiretroviral Pregnancy Registry, which collects outcome data on ARV-exposed pregnancies regardless of HIV status.
- Clinicians should consult the DHHS Perinatal HIV Clinical Guidelines, particularly Appendix B (Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy), for detailed, agent-specific information.

3. Antiretroviral Drugs During Pregnancy and Lactation

HIV Exposure Protocol Reference Information/Background

Background for Clinical Providers

Excerpted from: Updated U.S. Public Health Service Guidelines for Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis

The decision to offer Human Immunodeficiency Virus (HIV) Postexposure Prophylaxis (PEP) to a pregnant or breastfeeding healthcare provider should be based upon the same considerations that apply to any provider who sustains an occupational exposure to HIV. The risk of HIV transmission poses not only a threat to a mother, but also to the fetus and infant, as the risk of mother-to-child HIV transmission is markedly increased during acute HIV infection during pregnancy and breastfeeding. (44) However, unique considerations are associated with the administration of antiretroviral agents to pregnant health care providers (HCP), and the decision to use antiretroviral drugs during pregnancy should involve both counseling and discussion between the pregnant woman and her healthcare provider(s) regarding the potential risks and benefits of PEP for both the healthcare provider and for her fetus.

The potential risks associated with antiretroviral drug exposure for pregnant women, fetuses and infants depends on the duration of exposure as well as the number and type of drugs. Information about the use of newer antiretroviral agents, administered as PEP to HIV-uninfected pregnant women, is limited. For reasons including the complexities associated with appropriate counseling about the risks and benefits of PEP, as well as the selection of antiretroviral drugs in pregnant women, expert consultation should be sought in all cases in which antiretroviral medications are prescribed to pregnant HCP for PEP

In general, antiretroviral drug toxicity has not been shown to be increased in pregnancy. Conflicting data have been published concerning the risk of preterm delivery in pregnant women receiving antiretroviral drugs, particularly protease inhibitors; (45) in studies that have reported a positive association, the increase in risk was primarily observed in women who were receiving antiretroviral drug regimens at the time of conception and continued during pregnancy. Fatal (64) and nonfatal (46) lactic acidosis has been reported in pregnant women treated throughout gestation with a combination of d4T and ddl. Prescribing this drug combination for PEP is not recommended. Physiologic changes that occur during pregnancy may alter antiretroviral drug metabolism, and, therefore, optimal drug dosing. The clinical significance of these changes is not clear, particularly when used for PEP in HIV-uninfected women. For details on antiretroviral drug choice and dosing in pregnancy, see Recommendations for use of Antiretroviral drugs in Pregnant HIV-1 Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States. (52).

Excerpted from: PEP Quick Guide for Bloodborne Pathogen Exposures: HIV

The PEP regimens that are currently preferred for most adults and adolescents are also preferred for use in exposed persons who are pregnant or breastfeeding:

Co-formulated bictegravir (BIC)/emtricitabine (FTC)/tenofovir alafenamide (TAF) [Biktarvy®] 50/200/25mg, 1 tablet by mouth once daily

OR

Dolutegravir (DTG) [Tivicay®] 50mg, 1 tablet by mouth once daily

PLUS

Any of the following co-formulations:

- **Tenofovir disoproxil fumarate (TDF)/emtricitabine (FTC) [Truvada®] 300/200mg, 1 tablet by mouth once daily;** or
- **Tenofovir alafenamide (TAF)/emtricitabine (FTC) [Descovy®] 25/200mg, 1 tablet by mouth once daily;** or
- **Tenofovir disoproxil fumarate (TDF)/lamivudine (3TC) [Cimduo®] 300/300mg, 1 tablet by mouth once daily.**

Duration: 28 days

See above for common side effects and drug-drug interactions; additional considerations for use in pregnancy are described below

Other PEP options can be considered in the event of intolerance, source persons with HIV drug resistant virus, medication access/adherence challenges, or EP preference. In these instances, providers should seek expert consultation, as pharmacokinetics in pregnancy may affect drug levels of some agents in the second and third trimesters.

Advantages

- Well-tolerated
- BIC, DTG, TDF/FTC, and TAF/FTC are preferred agents for use in pregnant people with HIV per current HHS Perinatal Guidelines
- Generally few drug-drug interactions

Potential Challenges

- Nausea and other gastrointestinal side effects are somewhat common with TDF/FTC and TAF/FTC initiation
- BIC and DTG interact with polyvalent cations including iron and calcium which are included in many prenatal vitamin formulations

How should HIV exposures in lactating exposed persons be managed?

- Breastfeeding is not a contraindication for PEP: starting PEP in lactating exposed persons should be based on considerations similar to those of non-pregnant/lactating exposed persons and involve shared decision-making.
- Additionally, the treating clinician and exposed person should discuss any potential concerns regarding infant exposure to ARV medications through breast milk. The decision to take PEP and/or continue breastfeeding is complex and individualized, requiring an exploration of various options (*see below*). Expert consultation is available.

Special considerations:

- The lactating exposed person *and* breastfeeding infant are at risk for HIV acquisition.
- Acute HIV in a breastfeeding person greatly increases the risk of HIV transmission to the breastfed infant.
- There are limited data on PEP medications in breast milk (details are available in LactMed®, a database which contains information on drugs and other chemicals to which breastfeeding mothers may be exposed).
  – Bictegravir (BIC, a component of Biktarvy®) and dolutegravir (DTG, Tivicay®) – Low levels have been detected in breast milk and breastfed infants.
  – Tenofovir disoproxil fumarate (TDF, Viread®, component of Truvada® and Cimduo®) and tenofovir alafenamide (TAF, Vemlidy®, component of Descovy® and Biktarvy®) can occasionally be detected in breast milk and breastfed infants in very limited amounts.
  – Lamivudine (3TC, Epivir®, component of Cimduo®) and emtricitabine (FTC, component of Truvada® and Descovy® and Biktarvy®) can be detected in breast milk and breastfed infants at levels which are a small fraction of the therapeutic doses used to treat HIV.
- For breastfeeding people who choose to take PEP, pumping and discarding is an option that allows continuation of lactation while preventing infant ARV and (possible) HIV exposure.
- For breastfeeding people who do not take PEP, pumping and storing breast milk while waiting for the source person's HIV testing results is an option. This allows continuation of lactation while not exposing infants (and breastfeeding people) to ARVs or potentially to HIV.

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Excerpted from: 2025 U.S. Public Health Service Guidelines for Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis in Healthcare Settings (52)

Table 1 Initial Preferred and Alternative Human Immunodeficiency Virus (HIV) Post Exposure Prophylaxis (PEP) Regimens for Healthcare Personnel [§,¶,,††]**

Group	Preferred [§] / Alternative	Regimen
Healthcare personnel without conditions specified below	**Preferred**	**Integrase Strand Transfer Inhibitors PLUS Two Nucleoside Reverse Transcriptase Inhibitors** • Bictegravir/emtricitabine/tenofovir alafenamide • Dolutegravir PLUS (tenofovir alafenamide OR tenofovir disoproxii dumarate) PLUS (emtricitabine or lamivudine)
	Alternative	**Boosted Protease Inhibitor PLUS Two Nucleoside Reverse Transcriptase Inhibitors** • Darunavir and cobicistat OR darunavir and ritonavir PLUS (tenofovir alafenamide OR tenofovir disoproxil fumarate) PLUS (emtricitabine OR lamivudine)
Pregnancy; expert consultation recommended[¶]	**Preferred**	**Integrase Strand Transfer Inhibitors PLUS Two Nucleoside Reverse Transcriptase Inhibitors** • Bictegravir/emtricitabine/tenofovir alafenamide • Dolutegravir PLUS (tenofovir alafenamide OR tenofovir disoproxii dumarate) PLUS (emtricitabine or lamivudine)
	Alternative	**Boosted Protease Inhibitor PLUS Two Nucleoside Reverse Transcriptase Inhibitors** • Darunavir and ritonavir (twice daily) PLUS (tenofovir alafenamide OR tenofovir disoproxil fumarate) PLUS (emtricitabine OR lamivudine)
Moderate renal dysfunction (creatine clearance 30-49 mL/min); expert consultation recommended[¶]	**Preferred**	**Integrase Strand Transfer Inhibitors PLUS Two Nucleoside Reverse Transcriptase Inhibitors** • Bictegravir/emtricitabine/tenofovir alafenamide • Dolutegravir PLUS tenofovir alafenamide PLUS (emtricitabine OR lamivudine[§§)]
	Alternative	**Integrase Strand Transfer Inhibitors PLUS Two Nucleoside Reverse Transcriptase Inhibitors** • Dolutegravir PLUS dose-reduced tenofovir disoproxil fumarate*** PLUS (emtricitabine OR lamivudine[§§]) **Boosted Protease Inhibitor PLUS Two Nucleoside Reverse Transcriptase Inhibitors** • Darunavir/cobicistat/tenofovir alafenamide/emtricitabine

		• Darunavir and ritonavir PLUS (tenofovir alafenamide OR dose-reduced tenofovir disoproxil fumarate***) PLUS (emtricitabine OR lamivudine[§§])
Group	**Preferred [§]/ Alternative**	**Regimen**
Severe renal dysfunction (creatine clearance <30 mL/min) and on hemodialysis; expert consultation recommended[¶]	**Preferred**	**Integrase Strand Transfer Inhibitors PLUS Two Nucleoside Reverse Transcriptase Inhibitors** • Bictegravir/emtricitabine/tenofovir alafenamide • Dolutegravir PLUS tenofovir alafenamide PLUS (emtricitabine OR dose-reduced[†††] lamivudine)
	Alternative	**Integrase Strand Transfer Inhibitors PLUS Two Nucleoside Reverse Transcriptase Inhibitors** • Dolutegravir PLUS dose-reduced tenofovir disoproxil fumarate PLUS (emtricitabine OR dose-reduced[†††] lamivudine)
Severe renal dysfunction (creatine clearance <30 mL/min; not on hemodialysis); expert consultation recommended[¶]		Consult HIV specialist
Hepatic impairment (Child-Pugh A or B); expert consultation recommended[¶]	**Preferred**	**Integrase Strand Transfer Inhibitors PLUS Two Nucleoside Reverse Transcriptase Inhibitors** • Bictegravir/emtricitabine/tenofovir alafenamide • Dolutegravir PLUS (tenofovir alafenamide OR tenofovir disoproxil fumarate) PLUS (emtricitabine OR lamivudine)
	Alternative	**Boosted Protease Inhibitor PLUS Two Nucleoside Reverse Transcriptase Inhibitors** • Darunavir and cobicistat OR darunavir and ritonavir PLUS (tenofovir alafenamide OR tenofovir disoproxil fumarate) PLUS (emtricitabine OR lamivudine)
Hepatic Impairment (Child-Pugh C); expert consultation recommended[¶]		**Consult HIV specialist**

The regimens below are recommended for initial use as PEP in HCP exposed to HIV. When the recommended preferred regimens are not available, alternative regimens are suitable for use. Although a raltegravir-based regimen is not included in the table due to having a higher burden and potential for decreased adherence, it remains an efficacious options for occupational post-exposure prophylaxis if neither preferred nor alternative regimen(s) can be prescribed.

§Preferred PEP Regimens are categorized as Recommendations supported by Moderate Confidence in evidence.

¶ Alternative PEP Regimens and consultation recommendations are categorized as Good Practice Statements based on Existing Recommendations.

** The following are available as single tablet complete PEP regimens: bictegravir/tenofovir alafenamide /emtricitabine (BIC/TAF/FTC; a preferred regimen) and darunavir/cobicistat/tenofovir alafenamide /emtricitabine (DRV/c/TAF/FTC; an alternative regimen). Generic drug forms are available for darunavir (DRV), ritonavir (RTV), tenofovir disoproxil fumarate (TDF)/emtricitabine access are all considered when selecting an nPEP regimen. Some single tablet regimens may be inappropriate for people with organ dysfunction. Healthcare professionals unfamiliar with these medications should use local infectious disease or other expert consultation resources, or call the National Clinician Consultation Center PEPline [888-448-4911 or https://nccc.ucsf.edu/clinican-consultation/pep-post-exposure-prophylaxis/] or the Perinatal HIV Line [888-448-8765 or https://nccc.ucsf.edu/clinican-consultation/perinatal-hiv-aids/].

††Regimens within categories are listed in alphabetical order and not according to preference.

§§ The prescribing information for lamivudine recommends dosage adjustments from 300 mg once daily to 150 mg once daily for patients with CrCl 30-49 mL/min. However, the prescribing lamivudine when administered as a standalone tablet or part of a FDC tablet.

*** Tenofovir DF (TDF) 300 mg every 48 hours.

††† Please see manufacturer's package insert for dosing instructions for individual agents or consult the Guidelines for the Use of Antiretroviral Agents.

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Appendix A

Situations for Which Expert Consultation for Human Immunodeficiency Virus (HIV) Postexposure Prophylaxis (PEP) is Recommended.

Delayed (i.e., later than 72 hours) exposure report

- Ï Interval after which benefits from PEP are undefined

Unknown source (e.g., needle in sharps disposal container or laundry)

- Ï Use of PEP to be decided on a case-by-case basis
- Ï Consider severity of exposure and epidemiologic likelihood of HIV exposure
- Ï Do not test needles or other sharp instruments for HIV

Known or suspected pregnancy in the exposed person

- Ï Provision of PEP should not be delayed while awaiting expert consultation

Breastfeeding in the exposed person

- Ï Provision of PEP should not be delayed while awaiting expert consultation

Known or suspected resistance of the source virus to antiretroviral agents

- Ï If source person's virus is known or suspected to be resistant to one or more of the drugs considered for pep, selection of drugs to which the source person's virus is unlikely to be resistant recommended.
- Ï Do not delay initiation of PEP while awaiting any results of resistance testing of the source person's virus

Toxicity of the initial PEP regimen

- Ï Symptoms (e.g., GI symptoms and others) often manageable without changing PEP regimen by prescribing antimotility or antimetric agents.
- Ï Counseling and support for management of side effects is very important as symptoms are often exacerbated by anxiety.

Serious medical illness in the exposed person

- Ï Significant underlying illness (e.g., renal disease) or an exposed provider already taking multiple medications may increase the risk of drug toxicity and drug-drug interactions.

Expert consultation can be made with local experts or by calling the National Clinicians' Post - Exposure Prophylaxis Hotline (PEP line) at 888-448-4911.

Appendix B:

Follow-Up of Health-Care Personnel (HCP) Exposed to Known or Suspected Human Immunodeficiency Virus (HIV)-Positive Sources

Counseling (At the time of exposure, and at follow-up appointments) Exposed HCP should be advised to use precautions (e.g., use of barrier contraception, avoid blood or tissue donations, pregnancy, and if possible, breastfeeding) to prevent secondary transmission, especially during the first 6-12 weeks postexposure.

For exposures for which PEP is prescribed, HCP should be informed regarding:

- possible drug toxicities (e.g., rash and hypersensitivity reactions which could imitate acute HIV seroconversion and the need for monitoring)
- possible drug interactions, and
- the need for adherence to PEP regimens

Early Reevaluation after Exposure Regardless of whether a healthcare provider is taking PEP, reevaluation of exposed HCP within 72 hours after exposure is strongly recommended, as additional information about the exposure or source person may be available.

Follow-up Testing and Appointments Follow-up testing at a minimum should include:

- HIV testing at baseline, 6 weeks, 12 weeks, and 6 months postexposure; Alternatively, if the clinician is certain that a 4th generation combination HIV p24 antigen-HIV antibody test is being utilized, then HIV testing could be performed at baseline, 6 weeks, and concluded at 4 months postexposure
- Complete Blood counts, Renal and Hepatic Function Tests (At baseline and 2 weeks postexposure; further testing may be indicated if abnormalities were detected)

HIV testing results should preferably be given to the exposed healthcare provider at face-to-face appointments.

University of California, Riverside
INFECTIOUS AGENT CARD

My job requires me to work with the Human Immunodeficiency Virus (HIV) and animals injected with HIV.

After a high-risk occupational exposure to HIV, the following clinical management is recommended by the US Public Health Service. High-risk exposures are contact with non-intact skin, or mucus membranes (eyes, nose, mouth) to an HIV contaminated material.

First Aid: Rinse exposed area with water for 15 minutes.

Baseline Testing: A complete blood count (CBC) and comprehensive metabolic panel (CMP) should be performed to monitor for PEP toxicity. HIV testing should be offered.

Postexposure Prophylaxis (PEP): Isentress (Raltegravir) 400mg by mouth twice daily, plus Truvada (tenofovir DF 300MG + emtricitabine 200mg) by mouth once daily is the preferred regimen in HIV naïve patients, exposed to HIV without suspected drug resistance. Optimally, PEP should be taken within 2 hours of exposure. PEP should be taken for 28 days.

Follow Up: with the UCI Center for Occupational and Environmental Health (COEH) within 72 hours (949) 824-8685

For additional information regarding HIV PEP, call the PEP hotline at (888) 448-4911.

Acknowledgement of Working with *Human Immunodeficiency Virus (HIV).*

By signing below, I confirm that I have reviewed and understood the requirements for working with HIV. I agree to comply with all outlined responsibilities, including:

- Following safe laboratory practices and use of appropriate PPE
- Applying proper first aid and decontamination procedures in the event of an exposure
- Promptly reporting any exposures, incidents, or safety concerns to my supervisor, Biosafety Officer, and Occupational Health

Name (Print)	Identification*	Signature	Date	Supervisor / Principal Investigator

*Identification: Provide your UCR Student ID, Employee ID, UCR NetID, UCR Email, or Date of Birth.