

NORTHWEST AIDS EDUCATION AND TRAINING CENTER

2013 HIV Occupational PEP Update

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Updated US Public Health Service Guidelines for the Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendations for Postexposure Prophylaxis

2013

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This report updates US Public Health Service recommendations for the management of healthcare personnel (HCP) who experience occupational exposure to blood and/or other body fluids that might contain human immunodeficiency virus (HIV). Although the principles of exposure management remain unchanged, recommended HIV postexposure prophylaxis (PEP) regimens and the duration of HIV followup testing for exposed personnel have been updated. This report emphasizes the importance of primary prevention strategies, the prompt reporting and management of occupational exposures, adherence to recommended HIV PEP regimens when indicated for an exposure, expert consultation in management of exposures, follow-up of exposed HCP to improve adherence to PEP, and careful monitoring for adverse events related to treatment, as well as for virologic, immunologic, and serologic signs of infection. To ensure timely postexposure management and administration of HIV PEP, clinicians should consider occupational exposures as urgent medical concerns, and institutions should take steps to ensure that staff are aware of both the importance of and the institutional mechanisms available for reporting and seeking care for such exposures. The following is a summary of recommendations: (1) PEP is recommended when occupational exposures to HIV occur; (2) the HIV status of the exposure source patient should be determined, if possible, to guide need for HIV PEP; (3) PEP medication regimens should be started as soon as possible after occupational exposure to HIV, and they should be continued for a 4-week duration; (4) new recommendation—PEP medication regimens should contain 3 (or more) antiretroviral drugs (listed in Appendix A) for all occupational exposures to HIV; (5) expert consultation is recommended for any occupational exposures to HIV and at a minimum for situations described in Box 1; (6) close follow-up for exposed personnel (Box 2) should be provided that includes counseling, baseline and follow-up HIV testing, and monitoring for drug toxicity; follow-up appointments should begin within 72 hours of an HIV exposure; and (7) new recommendation—if a newer fourth-generation combination HIV p24 antigen–HIV antibody test is utilized for follow-up HIV testing of exposed HCP, HIV testing may be concluded 4 months after exposure (Box 2); if a newer testing platform is not available, follow-up HIV testing is typically concluded 6 months after an HIV exposure.

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testing of exposed HCP, HIV testing may be concluded 4 months after exposure (Box 2); if a newer testing platform is not available follow-up HIV testing is typically concluded 6 months after an HIV exposure.



Estimated Risk of HIV Transmission with Different Exposures

Risk of HIV Transmission in Health Care Workers		
Type of Exposure to Blood	Risk of HIV Transmission	
Percutaneous Exposure	0.3%	
Mucous Membrane Exposure	0.09%	
Nonintact Skin Exposure	< 0.09%	

Source: CDC and Prevention. MMWR Morb Mortal Weekly Rep. 2001;50(RR-11):1-42.



2013 USPHS Occupational PEP Guidelines At Risk Exposures

Infectious Fluids

- Blood
- Visibly bloody body fluids

Potentially Infectious Body Fluids

- Semen and vaginal secretions
- Cerebrospinal fluid
- Synovial fluid
- Pleural fluid
- Peritoneal fluid
- Pericardial fluid
- Amniotic fluid

Not Considered Potentially Infectious (unless visibly bloody)

- Saliva, vomitus, and feces
- Nasal secretions and sputum
- Sweat and tears
- Urine





2013 Updated Occupational HIV PEP Guidelines

- 2 versus 3 drugs
- Preferred regimen
- Rationale for 28 days of antiretroviral therapy
- Situations that warrant expert consultation
- Recommended lab follow-up



2013 USPHS Occupational PEP Guidelines At Risk Exposures

- Contact of blood, tissue, or other potentially infectious body fluids via:
 - Percutaneous injury
 - Mucous membrane exposure
 - Contact with nonintact skin

Case History HIV Exposure in a Health Care Worker

 A 41-year-old nurse has a needlestick injury on his left thumb. The site bled for about 2 minutes after the injury. The source patient has documented HIV infection, has never taken antiretroviral medications, and most lab studies showed HIV RNA level of 2,350 copies/ml and CD4 count of 658 cells/mm³.

• Based on USPHS 2013 Guidelines, what is recommended?

- A. Zidovudine-lamivudine (*Combivir*)
- B. Tenofovir-emtricitabine (Truvada)
- C. Tenofovir-emtricitabine (*Truvada*) + Raltegravir (*Isentress*)
- D. Tenofovir-emtricitabine (*Truvada*) + Darunavir (*Prezista*) + ritonavir (*Norvir*)



2013 USPHS Occupational PEP Guidelines Number of Antiretroviral Medications to Use

"As less toxic and better-tolerated medications for the treatment of HIV infection are now available, minimizing the risk of PEP noncompletion, and the optimal number of medications needed for HIV PEP remains unknown, the PHS working group recommends prescribing 3 (or more) tolerable drugs as PEP for all occupational exposures to HIV."



2013 USPHS Occupational PEP Guidelines Recommendations for Antiretroviral Regimens

Recommended Antiretroviral Regimens for Occupational PEP (28-Day Duration)			
Preferred Regimen			
INSTI	NNRTI	Pill Burden	
Raltegravir (<i>Isentress</i>) 400 mg twice daily	Tenofovir-Emtricitabine (<i>Truvada</i>) 1 pill daily		

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2013 USPHS Occupational PEP Guidelines Recommendations for Antiretroviral Regimens

Alternative Antiretroviral Regimens for Occupational PEP (28-Day Duration)		
INSTI, PI, or NNRTI	NNRTI	
Alternative Regimens: Combine from both columns (listed in order of preference)		
Raltegravir (Isentress)	Tenofovir-Emtricitabine (Truvada)	
Darunavir (<i>Prezista</i>) + Ritonavir (<i>Norvir</i>)	Tenofovir (<i>Viread</i>) + Emtricitabine (<i>Emtriva</i>)	
Etravirine (Intelence)	Tenofovir (<i>Viread</i>) + Lamivudine (<i>Epivir</i>)	
Rilpivirine (<i>Edurant</i>)	Zidovudine-Lamivudine (Combivir)	
Atazanavir (<i>Reyataz</i>) + Ritonavir (<i>Norvir</i>)	Zidovudine (<i>Retrovir</i>) + Lamivudine (<i>Epivir</i>)	
Lopinavir-Ritonavir (Kaletra)	Zidovudine (<i>Retrovir</i>) + Emtricitabine (<i>Emtriva</i>)	
Alternative Regimen: Fixed-Drug Combination		

Elvitegravir-Cobicistat-Tenofovir-Emtricitabine (*Stribild*)





Effectiveness of Tenofovoir (TDF) PEP in Macaques

SIV Inoculation	Start PEP
Study Hour	0 24 48 72
	\downarrow \downarrow \downarrow
Study Features	24h Placebo x 28d
N = 24 macaques Randomized to 6 treatment arms	24h TDF x 3d
SIV inoculated intravenously	24h TDF x 10d
SIV dose 10x 50% infective dose PEP started at 24, 48, or 72 hours	24h TDF x 28d
PEP duration: 3, 10, or 28 days PEP regimen: tenofovir (TDF) SQ	48h TDF x 28d
Analyzed for antibody and viremia	72h TDF x 28d



Source: Tsai CC, et al. J Virol. 1998;72:4265-73.

Effectiveness of Tenofovir PEP in Macaques





Source: Tsai CC, et al. J Virol. 1998;72:4265-73.

2013 USPHS Occupational PEP Guidelines Situations for Which Expert Consultation Advised

- Delayed exposure report (eg. longer than 72 hours)
- Unknown source (eg. needle in sharps disposal)
- Known or suspected pregnancy in exposed person
- Exposed person breast-feeding
- Known or suspected ARV drug resistance in source patient
- Serious medical illness in exposed persons
- Toxicity occurring in exposed person taking PEP regimen



PEPline

The National Clinicians' Post-Exposure Prophylaxis Hotline

PEPline

The National Clinician's Post-Exposure Prophylaxis Hotline

Exposure to blood-borne pathogens can present serious risks to health care providers. Prompt post-exposure treatment for HIV and hepatitis B virus can be effective, but because each exposure case is unique, determining who should receive prophylaxis and which drugs are most appropriate is not always easy.

The National Clinicians' Post-Exposure Prophylaxis Hotline (PEPline) offers treating clinicians up-to-the-minute advice on managing occupational exposures (i. e., needlesticks, splashes, etc.) to HIV, hepatitis and other blood-borne pathogens.

PEPline clinicians will respond to your call 24 hours a day, 7 days a week.

Emergency calls made during evening, weekend, and holiday hours are forwarded to on-call clinicians. Nonemergency calls will be returned during business hours.

Clinicians will help assess the risk of the exposure, discuss the most recent post-exposure prophylaxis protocols, and review specific treatment and follow-up options. Written materials supporting the telephone discussion are sent by mail or fax whenever needed.



PEP Guidelines >

Post-Exposure Prophylaxis Line (PEPline) 888-448-4911



2013 USPHS Occupational PEP Guidelines Baseline and Follow-Up for Occupational PEP

- Early Reevaluation after Exposure (within 72 hours)
- Baseline and Follow-up HIV Testing
 - Baseline HIV testing
 - Follow-up HIV testing 6, 12, and 24 weeks after exposure
 - Follow-up HIV testing at 6 and 16 weeks if 4th generation assay* used
- Baseline and Follow-up Laboratory Testing
 - Baseline renal and hepatic function tests
 - Follow-up renal and hepatic function tests at 2 weeks

*4th generation combination assay = HIV p24 antigen-HIV antibody test



Case History HIV Exposure in a Health Care Worker

- A 32-year-old physician has a needlestick injury on her hand that involves an HIV-infected patient. The source patient is taking tenofovir-emtricitabine-efavirenz (*Atripla*) and had an undetectable HIV RNA level 3 months prior.
- Based on USPHS 2013 Guidelines, would you recommend antiretroviral PEP for this physician?



2013 USPHS Occupational PEP Guidelines PEP when Source Patient has Undetectable HIV RNA Level

"Exposure to a source patient with an undetectable serum viral load does not eliminate the possibility of HIV transmission or the need for PEP and follow-up testing. While the risk of transmission from an occupational exposure to a source patient with an undetectable serum viral load is thought to be very low, PEP should still be offered."



2013 USPHS Occupational PEP Guidelines Summary of Major Changes

- 1. Eliminates evaluation of level of risk to stratify PEP regimen
- 2. All PEP regimens should contain 3 or more medications
- 3. New recommended and alternative PEP regimens
- 4. Follow up may conclude at 4 months if 4th generation HIV testing used

