

PURPOSE:

To provide guidelines for prophylactic treatment and follow-up of hospital personnel who meet the criteria for significant exposure to blood or blood products.

SVE: POLICY 201

DATE EFFECTIVE: 12/05

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DATES REVISED:

12/06, 1/09

KEY WORDS:

CROSS REFERENCED POLICIES:

ISSUING DEPARTMENT: Infection Control

POLICY:

Personnel who have had an exposure to blood or body fluids that might place the healthcare worker (HCW) at risk for HBV, HCV or HIV infection will receive post-exposure evaluation and treatment and be identified for possible prophylaxis. An exposure that might place the HCW at risk is defined as:

1. A percutaneous injury (e.g., a needlestick or cut with a sharp object that is contaminated with blood, tissue or other body fluids that are potentially infectious). A contaminated needle is defined as one which has been in contact with blood, body fluid or tissue. A needle that has not been in contact with the IV site or with bloody fluid would not be considered.
2. Contact of mucous membrane (eyes, nose or mouth) with blood, tissue or other body fluids that are potentially infectious.
3. Contact of nonintact skin (exposed skin that is chapped, abraded, afflicted with dermatitis or has any other type of open wound) with blood, tissue or other body fluids that are potentially infectious.

PROCEDURE:

• **Treatment of an Exposure Site**

1. Wounds and skin sites that have been in contact with blood or body fluids should be washed with soap and water. **DO NOT** wash exposed site with abrasive chemicals such as bleach. Such chemicals will further damage skin.
2. Mucous membranes should be flushed with water.
3. No evidence exists that using antiseptics for wound care or expressing fluid by squeezing the wound further reduces the risk of bloodborne pathogen transmission; however, the use of antiseptics is not contradicted.

- **Exposure Report/Employee Testing**
 1. Exposed personnel will fill out an Employee Incident Report.
 2. Employees will report to the Employee Health Monday – Friday from 8:00 am-4:00 pm and the Emergency Department after hours, holidays and weekends. Take the source patient chart, if known, to ED.
 3. Baseline blood testing of the HCW for HBsAB, HCVAB antibody and HIV will be accomplished.
 4. If patient source of the exposure is known; the patient’s name and room number must be included on the Incident Report.
 5. If the patient is a known HIV, Hepatitis B or Hepatitis C virus carrier or has positive lab results for either on chart, this also should be noted on the Incident Report.
- **Evaluation of the Exposure**
 1. The exposure will be evaluated for the potential to transmit HBV, HCV and HIV bases on the type of body substance involved and the route and severity of exposure (see attached worksheet).
 2. For HCV and HIV, exposure to a blood-filled hollow needle or visibly blood device suggests a higher risk exposure than exposure to a needle that was most likely used for giving an injection.
 3. For skin exposure, follow-up is indicated only if it involves exposure when there is evidence of compromised skin integrity.
 4. In clinical evaluation for human bites, possible exposure of both the person bitten and the person who inflicted the bite must be considered. If a bite results in blood exposure to either person involved, post-exposure follow-up should be provided.
- **Evaluation of the Exposure Site**
 1. The source patient should be evaluated for HBV, HCV and HIV infection. Information may be obtained from the medical record and/or the source patient.
 2. The source patient should be tested for Hepatitis B antigen (HBsAG), Hepatitis C antibody and HIV.
 3. Testing to determine the HBV, HCV and HIV status of an exposure source should be performed as soon as possible.
 4. Confidentiality of testing for the patient will be maintained.
- **Management of Exposures to HBV**
 1. The Hepatitis B vaccination status and the vaccination-response status (if known) of the exposed person should be reviewed. A summary of prophylaxis recommendations for percutaneous or mucosal exposure to blood according to the HBsAG status of the exposure source and the vaccination and vaccine-response status of the exposed person is included below:

Recommended post-exposure prophylaxis for exposure to Hepatitis B virus

	Treatment	Treatment	Treatment
Vaccination and antibody response status of exposed workers*	Source HBsAG[§] positive	Source HBsAG negative	Source Unknown or not available for testing
Unvaccinated	HBIG[¶] X 1 and initiate HB vaccine series	Initiate HB vaccine series	Initiate HB vaccine series
Previously Vaccinated			
Known Responder	No Treatment	No Treatment	No Treatment
Known non-responder	HBIG X 1 and initiate revaccination or HBIG X 2	No Treatment	In known high risk source, treat as if source were HBsAG positive
Antibody response unknown	Test exposed person for anti-HBs: <ol style="list-style-type: none"> 1. If adequate**, no treatment is necessary 2. If inadequate*, administer HBIG X 1 and vaccine booster 	No Treatment	Test exposed person for anti-HBs: <ol style="list-style-type: none"> 1. If adequate**, no treatment is necessary 2. If inadequate*, administer vaccine booster and recheck titer in 1-2 months

§ Hepatitis B surface antigen

¶ Hepatitis B immune globulin; dose is .06 mL/kg intramuscularly

**** A responder is a person with adequate levels of serum antibody to HBsAG (i.e., anti-HBs ≥ 10 mIU/mL)**

*** A non-responder is a person with inadequate response to vaccination (i.e., serum anti-HBs < 10 mIU/mL)**

- **Management of Exposure to HCV**

There is currently no recommended post-exposure prophylaxis for exposure to the Hepatitis C virus. Post-exposure management is focused on early detection and treatment of the development of Hepatitis C virus in the exposed HCW.

For the HCW exposed to an HCV-positive source:

1. Perform baseline testing for anti-HCV and ALT activity, and
2. Perform HCV RNA testing at 4 to 6 weeks
3. Perform follow-up testing (e.g., at 4-6months) for anti-HCV and ALT activity
4. If HCV infection is identified early, the HCW should be referred for medical management to a specialist knowledgeable in this area.

- **Management of Exposures to HIV:**

1. HCW exposed to HIV should be evaluated within hours (rather than days) after exposure and should be tested for HIV at baseline (i.e., to establish infection status at the time of the exposure).
2. If the source person is seronegative for HIV, baseline testing or further follow-up of the exposed person normally is not necessary.
3. PEP should be initiated as soon as possible. PEP is substantially less effective when started more than 24-36 hours post-exposure.
4. PEP should probably be administered for 4 weeks, if tolerated.
5. If the HCW is pregnant, the decision to use any antiretroviral drug during pregnancy should involve discussion between the woman and her healthcare provider(s) regarding the potential benefits and risks to her and her fetus.
6. The following recommendations apply to situations when a person has been exposed to a source person with HIV infection or when information suggests the likelihood that the source person is HIV-infected. These recommendations are based on the risk for HIV infection after different types of exposure and on limited data regarding efficacy and toxicity of PEP (post-exposure prophylaxis).

Recommended HIV post-exposure prophylaxis

	Infection Status of Source	Infection Status of Source	Infection Status of Source	Infection Status of Source	Infection Status of Source
Exposure Type	HIV + Class 1 (asymptomatic HIV infection or known low viral load(e.g.,<1,500 RNA copies/ml).	HIV + Class 2 (symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load).	Source of unknown HIV status	Unknown source	HIV-Negative
Less severe percutaneous (solid needle and superficial injury)	Recommend basic 2-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however consider basis 2-drug PEP** for source with HIV risk factors«	Generally, no PEP warranted; However consider basic 2-drug PEP** in settings where exposure to HIV-infected persons is likely	No PEP warranted
Small volume(i.e. few drops), mucous membranes or nonintact skin(i.e., dermatitis, abrasion, or open wounds)	Consider basic 2-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however consider basis 2-drug PEP** for source with HIV risk factors«	Generally, no PEP** warranted; however, consider basic 2-drug PEP** in settings where exposure to HIV-infected persons is likely	No PEP warranted
More sever percutaneous (i.e., large-bore hollow needle, deep puncture, visible blood on device, or	Recommend expanded 3-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however consider basis 2-drug PEP** for source with	Generally, no PEP** warranted; however, consider basic 2-drug PEP** in settings where exposure to	No PEP warranted

needle used in patient's artery or vein.)			HIV risk factors«	HIV-infected persons is likely	
Large volume(i.e., major blood splash), mucous membrane or nonintact skin(i.e., dermatitis, abrasion, or open wound)	Recommend expanded 3-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however consider basis 2-drug PEP** for source with HIV risk factors«	Generally, no PEP** warranted; however, consider basic 2-drug PEP** in settings where exposure to HIV-infected persons is likely	No PEP warranted

** The designation, "consider PEP", indicates that PEP is optional and should be based on an individual decision between the exposed person and the treating clinician

«If PEP is offered and taken and the source is later determined to be HIV-negative, PEP should be discontinued.

7. Recommendations for the Selection of Drugs for HIV PEP

The risk for infection must be balanced against the potential toxicity of the agent(s) used when selecting a drug regimen for HIV PEP. Because PEP is potentially toxic, its use is not justified for exposures that pose a negligible risk for transmission.

- a. Two-drug regimens should be appropriate for most HIV exposures. Two drug therapy generally utilizes two nucleoside analogues now included in Combivir.
- b. Expanded, three-drug regimens should be used for exposures that pose an increased risk for transmission. Regimens should be implemented in consultation with persons who have expertise in anti-retroviral treatment and HIV transmission.
- c. Selection of PEP regimen should consider the comparative risk represented by the exposure and information about the exposure source, including history of and response to anti-retroviral therapy based on clinical response, CD4+T cell counts, viral load measurements and current disease stage. When the source person's virus is known or suspected to be resistant to one or more of the drugs considered for the PEP regimen, the selection of drugs to which the source person's virus is unlikely to be resistant to recommended; expert consultation is advised. If this information is not immediately available, initiation of PEP, if indicated, should not be delayed; changes in the PEP regimen can be made after PEP has been started, as appropriate.

Post Exposure Prophylaxis Drugs

Basic Regimen

Drug	Dosage	Duration
Combivir	1 twice a day	4 weeks

Expanded Regimen

Drug	Dosage	Duration
Combivir	1 twice a day	4 weeks
and	and	and
Lopinavir	400 mg twice daily	4 weeks

Table 3: Primary side effects and toxicities associated with antiretroviral agents used for HIV post exposure prophylaxis, by class and agent

Class and Agent	Side Effect and Toxicity
Nucleoside reverse transcriptase inhibitors Combivir	Headache, nausea, diarrhea, fever, neuropathy, skin rashes, muscle pain
Protease Inhibitor Lopinavir	Diarrhea, fatigue, headache, nausea, and increased cholesterol and triglycerides

- **Use of PEP When HIV Infection Status of Source Patient is Unknown**

If the source person's HIV infection status is unknown at the time of exposure, use of PEP should be decided on a case-by-case basis, after considering the type of exposure and the clinical and /or epidemiologic likelihood of HIV infection in the source.

1. If indicated, start PEP as soon as possible after an exposure.
2. Reevaluation of the exposed person should be considered within 72 hours post-exposure, especially as additional information about the exposure or source person becomes available.
3. Administer PEP for 4 weeks, if tolerated.
4. If a source person is determined to be HIV-negative, PEP should be discontinued.

- **Follow-up of HCP Exposed to BBP**

1. HCW with occupational exposure to HIV should receive follow-up counseling, post-exposure testing and medical evaluation, regardless of whether they receive PEP.

2. If the HIV status of the source cannot be determined, if the source is unknown, or if the source patient is HIV positive, HIV-antibody testing should be performed on the HCW for at least 6 months past-exposure (e.g., for 12 months) is recommended for HCW who become infected with HCV following exposure to a source co-infected with HIV and HCV.
 3. HIV testing should be performed on any exposed person who has an illness that is compatible with an acute retroviral syndrome, regardless of the interval since exposure.
 4. When HIV infection is identified, the person should be referred to a specialist knowledgeable in the area of HIV treatment and counseling for medical management.
- **Monitoring and Management of PEP Toxicity**
 1. If PEP is used, HCW should be monitored for drug toxicity by testing at baseline and again 2 weeks after starting PEP.\
 2. The scope of testing should be based on medical condition in the exposed person and the toxicity of drugs included in the PEP regimen. Minimally, lab monitoring for toxicity should include a complete blood count and renal and hepatic function tests. Monitoring for evidence of hyperglycemia should be included for HCW whose regimes include any PI; if the exposed person is receiving IDV, monitoring for crystalluria, hematuria, hemolytic anemia and hepatitis should be included.
 3. If toxicity is noted, modification of the regimen should be considered after expert consultation; further diagnostic studies may be indicated.
 4. Exposed HCW who choose to take PEP should be advised of the importance of completing the prescribed regimen. Information should be provided to HCP about potential drug interactions and the drugs that should not be taken with PEP, the side effects and the methods of clinical monitoring for toxicity during the follow-up period.
 5. HCW should be advised that the evaluation of certain symptoms should not be delayed (e.g., rash, fever, back or abdominal pain, pain with urination or blood in the urine or symptoms of hyperglycemia [increased thirst and/or frequent urination]).
 6. Side effect symptoms from PEP can often be managed with antimotility and antiemetic agents or other medications that target the specific symptoms without changing the regimen.
 7. Serious adverse events should be reported to the Pharmacy for reporting to the FDA's MedWatch program.
 - **Counseling and Education**
 1. BBP-exposed HCW should be advised to use the following measures to prevent secondary transmission during the follow-up period, especially the first 6-12 weeks after the exposure when most HIV-infected persons are expected to seroconvert:
 - a. exercise sexual abstinence or use condoms to prevent sexual transmission and to avoid pregnancy
 - b. refrain from donating blood, plasma, organs, tissue or semen
 - c. if an exposed woman is breastfeeding, she should be counseled about the risk of HIV transmission through breast milk and discontinuation of breast feeding should be considered especially for high-risk exposures. Additionally, PEP medications, NRTIs and NVP are known to pass into breast milk.

- d. Exposed HCW should be advised to seek medical evaluation for any acute illness that occurs during the follow-up period. Such illness, particularly if characterized by fever, rash, myalgia, fatigue, malaise or lymphadenopathy might be indicative of acute HIV infection but also might be indicative of a drug reaction or another medical condition.
 2. The patient care responsibilities of an exposed person do not need to be modified based solely on an HIV exposure, to prevent transmission to patients. IF HIV seroconversion is detected, the person should be evaluated according to published recommendations for infected HCW.
 3. For exposures for which PEP is considered appropriated, HCW should be informed that:
 - a. knowledge about the efficiency drugs used for PEP is limited
 - b. experts recommend combination drug regimens because of increase potency and concerns about drug-resistant virus
 - c. data regarding toxicity of antiretroviral drugs in persons without HIV infection or in pregnant women are limited
 - d. although the short-term toxicity of antiretroviral drugs is usually limited, serious adverse events have occurred in persons taking PEP
 - e. any or all drugs fro PEP may be declined or stopped by the exposed person
 4. HCW who experience HIV occupational exposures for which PEP is not recommended should be informed that the potential side effects and toxicity of taking PEP outweigh the negligible risk of transmission posed by the type of exposure.
- **Employee Health Department Responsibilities**
 1. Follow-up of all results on source patient and/or employee
 2. Maintaining documentation of lab results and written consent(s)
 3. Determination of the need to administer HBIG is done through the Employee Health and Infectious Disease
 4. Counseling, initiation and follow-up of Hepatitis B vaccine to employees, and/or HIV and Hepatitis C antibody testing of employees
 5. Documenting rendered treatment on the Employee Incident Report
 6. Referral of HCW to appropriate expert medical care as needed

BOX 4. Situations for which expert* consultation for HIV postexposure prophylaxis is advised

- Delayed (i.e., later than 24–36 hours) exposure report
 - the interval after which there is no benefit from postexposure prophylaxis (PEP) is undefined
- Unknown source (e.g., needle in sharps disposal container or laundry)
 - decide use of PEP on a case-by-case basis
 - consider the severity of the exposure and the epidemiologic likelihood of HIV exposure
 - do not test needles or other sharp instruments for HIV
- Known or suspected pregnancy in the exposed person
 - does not preclude the use of optimal PEP regimens
 - do not deny PEP solely on the basis of pregnancy
- Resistance of the source virus to antiretroviral agents
 - influence of drug resistance on transmission risk is unknown
 - selection of drugs to which the source person's virus is unlikely to be resistant is recommended, if the source person's virus is known or suspected to be resistant to ≥ 1 of the drugs considered for the PEP regimen
 - resistance testing of the source person's virus at the time of the exposure is not recommended
- Toxicity of the initial PEP regimen
 - adverse symptoms, such as nausea and diarrhea are common with PEP
 - symptoms often can be managed without changing the PEP regimen by prescribing antimotility and/or antiemetic agents
 - modification of dose intervals (i.e., administering a lower dose of drug more frequently throughout the day, as recommended by the manufacturer), in other situations, might help alleviate symptoms

*Local experts and/or the National Clinicians' Post-Exposure Prophylaxis Hotline (PEPline [1-888-448-4911]).

INTERPRETATION AND ADMINISTRATION:

Infection Control Practitioner and Employee Health

SCOPE OF DISTRIBUTION:

House wide

ATTACHMENTS: N/A