

The Credit Valley Hospital – CLINICAL PRACTICE GUIDELINE

Folder Name: Clinical Practice Guideline

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Issued By: Chief of Medical Staff

Title: Blood Borne Disease Exposure CPG

PURPOSE

To provide guidelines to assist clinicians in the appropriate management of community personnel/patient and health care workers who have potential exposure to blood and other body fluids that might contain hepatitis B virus (HBV), hepatitis C virus (HCV), or human immunodeficiency virus (HIV).

SELECTION CRITERIA

Inclusion Criteria:

Exposure to blood, bloody fluid, other potential infectious material (OPIM), or an instrument contaminated with HBV, HCV or HIV.

The exposure should be evaluated for the potential to transmit HBV, HCV, and HIV based on the type of body substance involved and the route and severity of the exposure.

Factors to consider in assessing the need for follow up include:

Type of exposure

- Percutaneous injury
- Mucous membrane exposure
- Non-intact skin exposure
- Bites resulting in blood exposure to either person involved

Type and amount of fluid/tissue

- Blood
- Fluids containing blood
- Potentially infectious fluid or tissue (semen; vaginal secretions; and cerebrospinal, synovial, pleural, peritoneal, pericardial, or amniotic fluids)
- Direct contact with concentrated virus
- Breast milk

Infectious status of source

- Presence of Hepatitis B surface antigen (HBsAg)
- Presence of HCV antibody (Anti-HCV)
- Presence of HIV antibody

Susceptibility of exposed person

- Hepatitis B vaccine and vaccine response status
- HBV, HCV immune status, and HIV serostatus

Exposed Person:

Community personnel/patient includes members of the community at risk, but are not exclusive to:

- Police officers (e.g. clenched fist injuries, brawl)
- Corrections officers, prisoners
- Day care workers, or those in daycare (e.g. bites)
- Teachers
- Victims of crime, or good Samaritans

Title: Blood Borne Disease Exposure

Health care workers (HCW) are defined as persons whose activities involve contact with patients or with blood or other body fluids from patients in a health care, laboratory, or public safety setting.

Exclusion criteria: None

ASSESSMENT AND TREATMENT

1.1 Assessment and Initial Treatment:

1. **Cleanse** the wound thoroughly with soap and water and allow to bleed freely. If the eyes, nose or mouth are involved, flush them well with large amounts of water. Apply an appropriate antiseptic to the wound.
2. Assess tetanus immunization status; give Td Absorbed (tetanus and diphtheria toxoids adsorbed) if not given in the previous ten years.
3. Make a reasonable effort to test the source person/patient for HBsAg (Hepatitis B surface antigen), HCV antibody, and HIV.
4. **Informed verbal consent must be obtained for HIV testing of both the source and exposed patient.**
 - Community personnel/patient: Counsel the victim to contact the Public Health Department for source identification/testing if not readily available at time of triage in ER. If the source person is known and refuses testing where exposure occurred in the following circumstances; a victim of crime, during the provision of emergency care or first aid refer to Health Protection and Promotion Act (HPPA) section 22.1. More information may be obtained from your local medical officer of health and on the Web site: <http://www.health.gov.on.ca> (**Search Bill 105**).
 - HCW: The ER physician will contact the source patient's MRP to ensure that the source patient is tested for HBsAg (Hepatitis B surface antigen), Anti-HCV and HIV.
5. HCW CVH staff members responsibilities:
 - Notify the manager or immediate supervisor as appropriate and complete an employee incident report
 - Immediately following the incident, contact the Occupational Health and Safety Department (OHSD) or report to the Emergency Department.
 - i. OHSD Hours: 07:30 – 16:30 Monday to Friday
 - ii. Off hours: Report to the Emergency Department
 - iii. When the incident is managed through the Emergency Department the staff member is responsible for contacting the OHSD in the morning.
6. Draw exposed persons baseline labwork: Hepatitis B surface antibodies (Anti-HBs), Hepatitis B surface antigen (HBsAg), Hepatitis C antibodies (Anti-HCV) and Human Immunodeficiency Virus (HIV). Consider AST and ALT.
7. Additional labwork may be indicated. Refer to the following guidelines for post exposure testing included under the specific potential suspected blood borne disease exposure.
8. Complete post exposure assessment form to determine HIV risk associated with exposure. **Appendix A**, and preprinted orders **Blood Borne Disease Exposure (Adult) 00008 D HR**.
9. Refer to post exposure prophylaxis (PEP) guidelines to determine recommended treatment and monitoring for exposures posing risk of infection transmission.

Title: Blood Borne Disease Exposure

1.2 Post Exposure Prophylaxis Guidelines:

RECOMMENDED ACTIONS AFTER POTENTIAL EXPOSURE TO Hepatitis B Virus (HBV)

Post Exposure Testing:

Centers for Disease Control and Prevention (CDC) recommends baseline testing of the exposed patient for Hepatitis B surface antigen (HBsAg) and Hepatitis B surface antibodies (anti-HBs). If anti-HBs is negative, retesting for HBsAg after 6 months is recommended.

Hepatitis B core antigen, (Anti-HBc) should be obtained if the exposed person is susceptible, a non-responder, or has an unknown anti-HBs status at the time of injury.

Post Exposure Prophylaxis:

Recommended Post Exposure Prophylaxis (PEP) for exposure to Hepatitis B virus
(These recommendations assume the real possibility of exposure in ways in which HBV is known to be transmitted.)

HBIG and vaccine should be given within 24 hours of exposure but may be effective up to 7 days.

Vaccination and antibody response status of exposed HCW *	Treatment		
	Source HBsAg positive	Source HBsAg negative	Source unknown or not available for testing
Unvaccinated	HBIG (0.06 mL/kg IM) x 1 now and then initiate hepatitis B vaccine series	Initiate hepatitis B vaccine series	Initiate hepatitis B vaccine series
Previously vaccinated			
Known responder (Serum anti-HBs ≥ 10 mIU/mL)	No treatment	No treatment	No treatment
Known non responder (Serum anti HBs < 10 mIU/mL)	HBIG (0.06 mL/kg IM) x 1 now and then initiate revaccination or HBIG x 2 **	No treatment	If known high risk source, treat as if source were HBsAg positive
Antibody response unknown	Test exposed person for anti-HBs 1. If adequate (serum anti-HBs ≥ 10 mIU/mL) no treatment is necessary 2. If inadequate (serum anti-HBs < 10 mIU/mL), administer HBIG (0.06 mL/kg IM) x 1 and vaccine booster	No treatment	Test exposed person for anti-HBs 1. If adequate (serum anti-HBs ≥ 10 mIU/mL), no treatment is necessary 2. If inadequate (serum anti-HBs < 10 mIU/mL), administer hepatitis B vaccine booster and recheck titre in 1-2 months

* Persons who have previously been infected with HBV are immune to reinfection and do not require post exposure prophylaxis.

** The option of giving 1 dose of HBIG and reinitiating the vaccine series is preferred for nonresponders who have not completed a second 3 dose vaccine series. For persons who previously completed a second vaccine series but failed to respond, two doses of HBIG are preferred.

HBsAg – Hepatitis B surface antigen

Anti-HBs – Hepatitis B surface antibodies

RECOMMENDED ACTIONS AFTER POTENTIAL EXPOSURE TO Hepatitis C Virus (HCV)

Post Exposure Testing:

If the source person is known HCV positive or considered at high risk for HCV, or if the source person is unknown, perform baseline LFTs, Hepatitis C antibodies (Anti HCV) on the exposed person and repeat at 3 and 6 months after exposure.

If the source person is known HCV negative on a recent blood test and has no known risk factors for HCV disease, no further follow up of the exposed person for HCV is required.

Post Exposure Prophylaxis:

Currently there is **no prophylactic** treatment available for a person exposed to the blood of a patient with Hepatitis C virus infection. The use of immune globulin (IG) or antiviral agents in this situation is not advised.

RECOMMENDED ACTIONS AFTER POTENTIAL EXPOSURE TO HIV CONTACT

Post Exposure Testing:

- Personnel exposed to HIV should be evaluated **as soon as possible after their exposure and should be assigned CTAS L2 when presenting to the Emergency Department**. They should be tested for HIV at baseline (i.e., to establish infection status at the time of exposure). PEP should be initiated as soon as possible if the decision is made to offer therapy.
- If the source person is seronegative for HIV, baseline testing or further follow up of the exposed person normally is not necessary. Serologic testing should be made available to all HCW who are concerned that they might have been occupationally infected with HIV.
- Community personnel should make a reasonable effort to have serologic testing of the source person whenever possible. If the source patient is known and refuses testing and the exposure occurred in the following circumstances; a victim of crime, during the provision of emergency care or first aid refer to HPPA section 22.1. More information may be obtained from you local medical officer of health and on the Web site: <http://www.health.gov.on.ca> (**Search Bill 105**).
- Baseline labwork prior to starting PEP should include: CBC and creatinine.
- A Beta HCG is indicated if pregnancy is suspected.

Post Exposure Prophylaxis:

For purposes of considering HIV PEP, the evaluation also should include information about medications the exposed person might be taking and any current or underlying medical conditions or circumstances (i.e., pregnancy, breast feeding, or renal or hepatic disease) that might influence drug selection.

The follow recommendations in **Appendix A: Exposure to Blood Borne Diseases in the Community: Determining the need for HIV post exposure prophylaxis (PEP)**

Title: Blood Borne Disease Exposure

after an occupational exposure 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. Because most occupational HIV exposures do not result in the transmission of HIV, potential toxicity must be carefully considered when prescribing PEP. The data below may be used to guide decision making.

Risk of dying in the next 12 months, examples of risks in everyday life:

Overall risk of dying in the next 12 months (all causes)	1/3,000
Specific cause of death in the next 12 months	
In an accident in your bathtub or shower	1/1,000,000
Choking to death on food	1/160,000
Drowning	1/50,000
In a work related accident (overall)	1/11,000
From any kind of accident	1/3,000

Estimated per-act risk for acquisition of HIV by exposure route:

(Reference: MMWR January 21, 2005/54(RR02);1-20)

Exposure route	Risk per 10,000 exposures to an infected source
Blood transfusion	9,000
Needle-sharing injection-drug use	67
Receptive anal intercourse	50
Percutaneous needle stick	30
Receptive penile-vaginal intercourse	10
Insertive anal intercourse	6.5
Insertive penile-vaginal intercourse	5
Receptive oral intercourse **	1
Insertive oral intercourse **	0.5

*Estimates of risk for transmission from sexual exposure assume no condom use.
 ** Source refers to oral intercourse performed on a man.

The use of PEP when HIV infection status of source persons is unknown at the time of exposure 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. If these considerations suggest a possibility for HIV transmission and HIV testing of the source person is pending, initiating the basic regimen until laboratory results have been obtained and later modifying or discontinuing the regimen accordingly is reasonable.

HIV post exposure prophylaxis recommendations include the following:

- If indicated, start PEP **as soon as possible** after an exposure. PEP is substantially less effective after 24 -48 hours but may still be beneficial for very high risk exposures after 36 hours.
- 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. Refer ER patients to their respective OHSD, Infectious Disease Specialist, and/or Family Physician as indicated for follow up.
- Administer PEP for 4 weeks, if tolerated.
- If a source person is determined to be HIV negative, PEP should be discontinued.
- Provide the patient with PEP drug information by giving them the information sheets available in the ER and OHSD.
- Provide the patient with a 24 or 72 hour supply of medication as applicable. An Emergency Drug Kit is available in the ER department.

Title: Blood Borne Disease Exposure

- **If the exposed person is pregnant**, the evaluation of risk of infection and need for PEP should be approached as with any other person who has had an HIV exposure. The decision should involve discussion between the women and her health-care provider(s) regarding the potential benefits and risks to her and her fetus.
- **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 is recommended; expert consultation is advised. If this information is not immediately available, initiation of PEP is indicated and should not be delayed; changes can be made when reevaluated within 72 hours post exposure.

Drug Selection:

BASIC REGIMEN:

Combivir (Zidovudine 300 mg and Lamivudine 150 mg) po bid

EXPANDED REGIMEN:

Combivir (Zidovudine 300 mg and Lamivudine 150 mg) po bid

AND

Kaletra (Lopinavir 400 mg and Ritonavir 100 mg) po bid

Potential Adverse Effects with PEP treatment:

Side Effects	Side Effects Management	Dose Adjustment	Safety in Pregnancy
Combivir: Zidovudine + Lamivudine (NRTI – Nucleoside Reverse Transcriptase Inhibitor)			
Headache (35%) Nausea (33%) Diarrhea (18%) Fatigue (18%) Vomiting (17%) Anorexia (17%) Neuropathy (12%) <10%: Dizziness, malaise, insomnia Rarely: Anemia, neutropenia	Nausea: • Antiemetics Diarrhea: • Loperamide or diphenoxylate Anorexia: • Chew gum • Frequent, small meals • Lozenge	Dosage adjustment required in renal impairment. Avoid fixed dose combination in this setting.	Perinatal HIV Guidelines Working Group recommends this dual combination NRTI in pregnancy
Kaletra: Lopinavir + Ritonavir (PI - Protease inhibitor)			
Risk of: Pancreatitis, hepatotoxicity, altered glucose tolerance, multiple drug interactions ** , hypercholesterolemia (3% to 39%), increased triglycerides (4% to 36%), diarrhea (5% -28%), nausea (5%- 16%), abdominal pain (2%- 11%)	Diarrhea: • Loperamide or diphenoxylate Nausea: • Antiemetics • Take meds with food Abdominal pain: • Eat small frequent meals • Simethicone/ Domperidon	Metabolized and cleared by liver, although no specific dose adjustment, caution should be exercised in patients with hepatic impairment	Pregnancy category C. Perinatal HIV Guidelines Working Group considers this a recommended combination in pregnancy

**** Consult with a pharmacist if patient on multiple medications to assess for drug interactions as soon as possible after initial dose.**

1.3 Consultation:

Consultation with an Infectious Disease Specialist or Infection Control Officer is advised if:

- Delayed presentation of exposure (i.e., later than 24-36 hours)
- Unknown source
- Uncertain transmission risk
- Known or suspected pregnancy in the exposed person
- Resistance of the source virus to antiretroviral agents or source is known HIV positive and receiving antiretroviral therapy
- Toxicity of the initial PEP regimen

1.4 Follow Up:

1.4.1 Follow Up Post Exposure Testing:

Exposed persons with blood borne disease exposure should receive follow up counseling, postexposure testing, and medical evaluation, regardless of whether they receive PEP. HIV-antibody testing should be performed for at least 6 months postexposure (e.g., at 6 weeks, 12 weeks, and 6 months). Extended HIV follow up (e.g., for 12 months) is recommended for exposed persons who become infected with HCV following exposure to a source coinfecting with HIV and HCV. Extending the duration of post exposure follow up in individual situations should be based on the clinical judgment of the exposed person's health care provider since rare delayed HIV seroconversions have been reported. Direct virus assays for routine follow up of exposed persons are not recommended. HIV testing should be performed on any exposed person who has an illness compatible with an acute retroviral syndrome.

1.4.2 Monitoring and Management of PEP Toxicity:

- Laboratory monitoring for toxicity should include a baseline and 2 weeks after starting PEP – CBC and renal function tests. Hepatic function tests if hepatitis exposure is a concern. For patients starting on Kaletra baseline cholesterol, triglyceride and blood sugar levels should be obtained.
- Patients should receive drug information sheets to educate them on potential drug interactions and side effects management.
- Side effect management should be implemented to ensure completion of PEP.

1.4.3 Treatment Duration and Discontinuation of Therapy

Usual treatment duration is four weeks. However, negative HIV status on the source (if obtained), or reconsideration of the risk circumstances of the exposure may justify premature termination of PEP in consultation with an Infectious Diseases Specialist.

1.4.4 Counseling and Education:

Access to professionals knowledgeable about occupational HIV transmission should be provided through OHSD, Infectious Disease Specialist and/or Family Physician.

Secondary prevention and counseling should include:

- Sexual abstinence or condom use
- Avoid pregnancy
- Refrain from donating blood, plasma, organs, tissue, or semen for at least 6 months post exposure unless source found to be negative

Title: Blood Borne Disease Exposure

- Discontinuation of breast feeding should be considered
- Medical attention to evaluate for an acute illness characterized by fever, rash, myalgia, fatigue, malaise, or lymphadenopathy is required to assess for an acute HIV infection

1.5 Blood Borne Disease Exposure Resources:

HCW can be referred to several resources that provide guidance regarding the management of occupational exposures which include:

AIDS Information US Department of Health and Human Service	Internet: www.aidsinfo.nih.gov/
Canadian AID's Treatment and Education	Internet: www.catie.ca
National HIV/AIDS Clinician Consultation Center	Internet: www.ucsf.edu/hivcntr
Hepatitis Hotline	Internet: www.cdc.gov/ncidod/diseases/hepatitis/index.htm
MMWR	Internet: http://www.cdc.gov/mmwr/PDF/RR/RR5402.pdf and http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5409a1.htm
Reporting to CDC:	(800) 803-0485
HIV Antiretroviral Pregnancy Registry (US resource)	(800) 258-4263 to register pregnant patients on antiretrovirals to monitor birth defects – no medical advice. Internet: www.gilaxowellcome.com/preg_reg/antiretroviral
Health Canada	www.hc-sc.gc.ca

1.6 Documentation:

The circumstances and postexposure management should be recorded in the exposed person's health record.

Recommendations on the contents of the exposure report:

<ul style="list-style-type: none">• Date and time of the exposure;• Details of the procedure being performed, including where and how the exposure occurred; if related to a sharp device, the type and brand of device and how and when in the course of handling the device the exposure occurred;• Details of the exposure, including the type and amount of fluid or material and the severity of the exposure (e.g., for a percutaneous exposure, depth of injury and whether fluid was injected; for a skin or mucous membrane exposure, the estimated volume of material and the condition of the skin [e.g., chapped, abraded, intact]);• Details about exposure source (e.g., whether the source material contained HBV, HCV, or HIV; if the source is HIV-infected, the stage of disease, history of antiretroviral therapy, viral load, and antiretroviral resistance information, if known);• Details about the exposed person (e.g., hepatitis B vaccination and vaccine-response status); and• Details about counseling, postexposure management, and follow up
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REFERENCES

MMWR, Antiretroviral Postexposure Prophylaxis after Sexual, injected drug use or other non-occ exposure to HIV in the US. January 21, 2005

<http://www.cdc.gov/mmwr/PDF/RR/RR5402.pdf>

MMWR, Recommendations and Reports: Updated U.S. Public Health Service Guideline for the Management of Occupational Exposure to HIV and Recommendations for Post Exposure Prophylaxis. Sept 30, 2005/54(RR09);1-17. Retrieved March 13, 2008 from

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5409a1.htm>

MMWR, Recommendations and Reports: Updated US Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for

Postexposure Prophylaxis. June 29, 2001/50(RR11);1-42 and 47-52

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm>

Appendix C Basic and Expanded HIV Postexposure Prophylaxis Regimens

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a4.htm>

Lexi-Comp Online: <http://online.lexi.com>

Canadian AID's Treatment and Education: Medication fact sheets: <http://www.catie.ca>

The Toronto Hospital HIV Clinic: Medication fact sheets: <http://www.tthivclinic.com>

Vertesi, L. Risk Assessment Stratification Protocol (RASP) to help patients decide on the use of postexposure prophylaxis for HIV exposure. CJEM Jan 2003 Vol.5 No. 1

Available:

<http://www.caep.ca/template.asp?id=0867239757B441F78C265B04547245D1>

Spence, JM. Should Emergency Departments offer Postexposure Prophylaxis for non-occupational exposure to HIV? CJEM Jan 2003 Available:

<http://caep.ca/template.asp?id=15E49C1164F14E5BA6DF47501F29B1EB>

EDUCATION

The document leader will provide written correspondence to ensure staff members directed by the information updates contained in the clinical practice guideline are notified. New staff will receive education through hospital and/or department orientation.

EVALUATION

Review compliance with the use of the pre printed physicians order for Blood Borne Disease Exposure (Adult)

DEVELOPED BY

ER Program Steering CPG subcommittee
Document Leader - ER nurse educator

Title: Blood Borne Disease Exposure

APPROVED BY

2008-03 Infectious Disease Specialist
2008-03 Infection Prevention and Control Committee
2008-03 Occupational Health and Safety
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2008-06 MPC (FYI)
2008-06 PPAC (FYI)
2008-08 MAC (FYI)

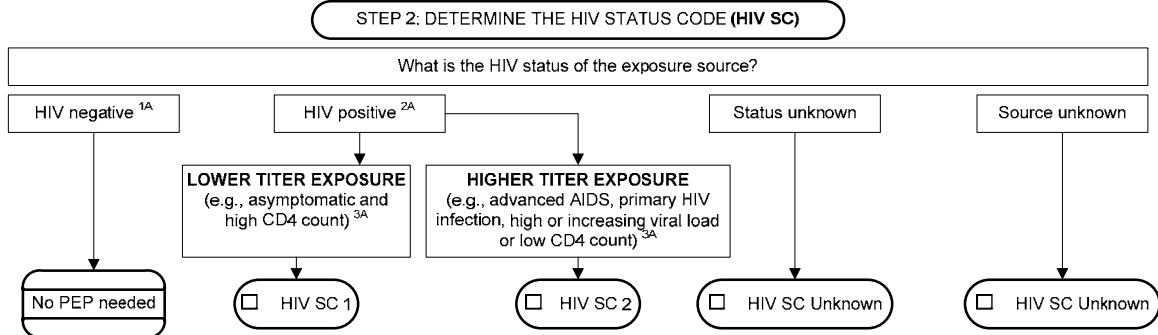
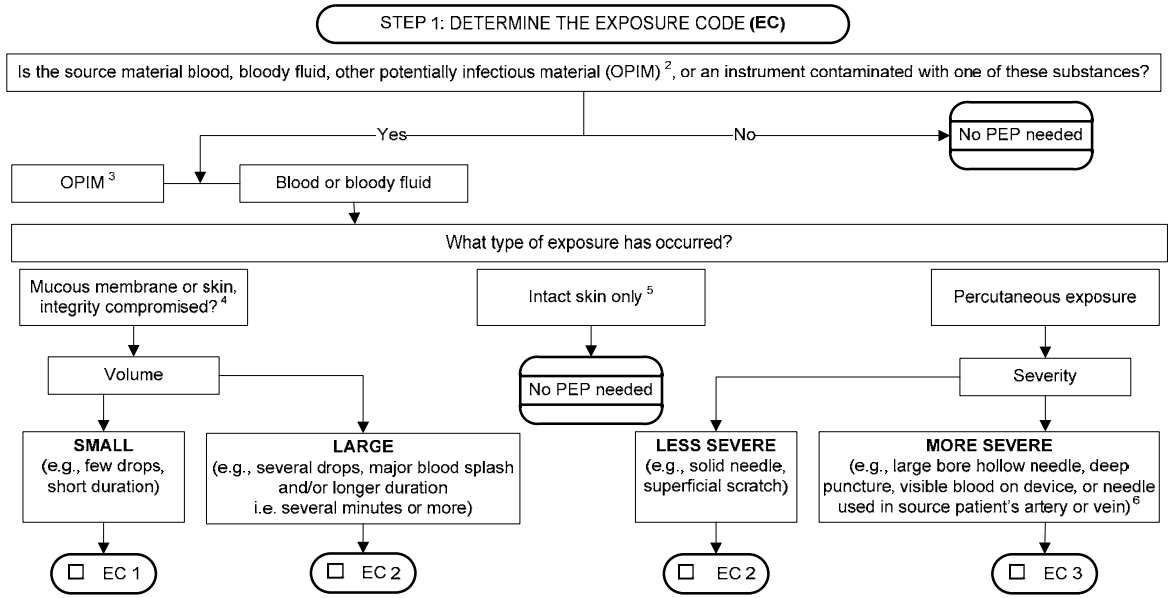
SUPERCEDES

2005-06

Title: Blood Borne Disease Exposure

Appendix A

Exposure to Blood Borne Diseases Determining the need for HIV post exposure prophylaxis (PEP) after an exposure ¹



EC	HIV SC	Recommendation
<input type="checkbox"/> 1	1	PEP may not be warranted. Exposure type does not pose a known risk for HIV transmission. Whether the risk for drug toxicity outweighs the benefit of PEP should be decided by the exposed person and treating physician.
<input type="checkbox"/> 1	2	Consider basic regimen. Exposure type poses a negligible risk for HIV transmission. A high HIV titer in the source may justify consideration of PEP. Whether the risk for drug toxicity outweighs the benefit of PEP should be decided by the exposed person and treating physician.
<input type="checkbox"/> 2	1	Recommend basic regimen. Most HIV exposures are in this category; no increased risk for HIV transmission has been observed but use of PEP is appropriate.
<input type="checkbox"/> 2	2	Recommend expanded regimen. Exposure type represents an increased HIV transmission risk.
<input type="checkbox"/> 3	1 or 2	Recommend expanded regimen. Exposure type represents an increased HIV transmission risk.
<input type="checkbox"/> 1	Unknown	PEP may not be warranted. Exposure type does not pose a known risk for HIV transmission. Whether the risk for drug toxicity outweighs the benefit of PEP should be decided by the exposed person and treating physician.
<input type="checkbox"/> 2 or 3	Unknown	Consider basic regimen if the setting where the exposure occurred suggests a possible risk for HIV exposure.

- This algorithm is intended to guide initial decisions about PEP and should be used in conjunction with other guidance provided in the CDC report: www.cdc.gov/mmwr/preview/mmwrhtml/00052722.htm
- Semen or vaginal secretions; cerebrospinal, synovial, pleural, peritoneal, pericardial or amniotic fluids; or tissue. Breast milk.
- Exposure to OPIM must be evaluated on a case-by-case basis.
- Skin integrity is considered compromised if there is evidence of chapped skin, dermatitis, abrasion, or open wound.
- Contact with intact skin is not normally considered a risk for HIV transmission. However, if the exposure was to blood, and the circumstance suggests a higher volume exposure (e.g. an extensive area of skin was exposed or there was prolonged contact with blood), the risk for HIV transmission should be considered.
- The combination of these severity factors (e.g. large-bore hollow needle and deep puncture) contribute an elevated risk for transmission if the source person is HIV positive.

1A. A source is considered negative for HIV infection if there is laboratory documentation of a negative HIV antibody, HIV polymerase chain reaction (PCR), or HIV p24 antigen test result from a specimen collected at or near the time of exposure and there is no clinical evidence of recent retroviral-like illness.

2A. A source is considered infected with HIV (HIV positive) if there has been a positive laboratory result for HIV antibody, HIV PCR or HIV p24 antigen or physician-diagnosed AIDS.

3A. Examples are used as surrogates to estimate the HIV titer in an exposure source for purposes of considering PEP regimens and do not reflect all clinical situations that may be observed. Although a high HIV titer (HIV SC 2) in an exposure source has been associated with an increased risk for transmission, the possibility of transmission from a source with a low HIV titer also must be considered.