

Blood Borne Pathogen Exposure

This protocol is for use after potential exposure (non-recreational) to a possible blood borne pathogen source, in particular HIV, Hepatitis B, or Hepatitis C. This protocol is based on U.S. Public Health Service recommendations for the management of health-care personnel (HCP) who have occupational exposure to blood and other body fluids that might contain hepatitis B virus (HBV), hepatitis C virus (HCV), or human immunodeficiency virus (HIV).

In brief:

- HIV exposure – percutaneous or compromised skin exposure to infected body fluids (including semen; vaginal secretions; and cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids), Visibly Bloody Fluid, or Blood itself from a source with HIV virus is potentially infectious. Emergent initiation of Anti-HIV medications may reduce the risk of development of disease. Recommendations for HIV PEP include a regimen of two drugs, or three drugs for HIV exposures that pose an increased risk for transmission. When the source person's virus is resistant to one or more of the drugs considered for the PEP regimen, consultation with a specialist is recommended.
- Hepatitis B - Recommendations include initiation of the hepatitis B vaccine series to any susceptible, unvaccinated person. Post-exposure prophylaxis (PEP) with hepatitis B immune globulin (HBIG) and/or hepatitis B vaccine series may be considered, depending on source status, and vaccination status.
- Hepatitis C - Immune globulin and antiviral agents are not recommended for PEP of hepatitis C. The HCV status of the source and the exposed person should be determined, and for exposure to an HCV positive source, follow-up HCV testing should be performed to determine if infection develops.

Significant exposures should be considered urgent medical concerns to ensure timely post-exposure management and administration of HBIG, hepatitis B vaccine, and/or HIV PEP.

Skill Level: RN or LPN with MD consultation if medications are started.

Procedure:

1. **First Aid: Irrigate** wound with water or saline, **Flush** mucous membranes with water or saline.
Clean exposure site with soap and water.
Serious injuries and other wound care dictated by injury or accident.
2. **Initial Exposure information:**
 - a. Exposure substance: Non-infectious Body Fluid, Infectious body fluids (including semen; vaginal secretions; and cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids), Visibly Bloody Fluid, or Blood
 - b. Method of injury/exposure: Skin, compromised skin, mucous membrane, percutaneous with solid sharp or hollow needle.
 - c. Exposure amount: Microscopic, a few drops, or a major splash.

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For HCV and HIV, exposure to a blood-filled hollow needle or visibly bloody device suggests a higher risk exposure than exposure to a needle that was most likely used for giving an injection.

For skin exposure, follow-up is indicated only if it involves exposure to a body fluid previously listed and evidence exists of compromised skin integrity (e.g., dermatitis, abrasion, or open wound). In the 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.

Initial Source person information: the source should be evaluated for HIV, HBV, and HCV infection.

If the source is known, but the HBV, HCV, and/or HIV infection status of the source is unknown, testing may be requested following standard procedures, including obtaining informed consent. Testing to determine the HIV status of source should be performed as soon as possible with an FDA-approved rapid HIV-antibody test. Testing of needles or other sharp instruments is not recommended.

If the source person is known to have HIV infection, available information about this person's stage of infection (i.e., asymptomatic, symptomatic, or AIDS), CD4+ T-cell count, results of viral load testing, current and previous antiretroviral therapy, and results of any genotypic or phenotypic viral resistance testing should be gathered for consideration in choosing an appropriate PEP regimen. 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.

If the source person is HIV seronegative and has no clinical evidence of AIDS or symptoms of HIV infection, no further testing of the person for HIV infection is indicated. The likelihood of the source person being in the "window period" of HIV infection in the absence of symptoms of acute retroviral syndrome is extremely small.

3. Risk assessment and Decision to treat HIV: See chart

Sharp – Table 1

Skin – Table 2

If unclear, consider consultation with on-call provider, or with specialist.

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4. Management of Exposures to Hepatitis C

Individual institutions should establish policies and procedures for testing HCP for HCV after percutaneous or mucosal exposures to blood and ensure that all personnel are familiar with these policies and procedures. The following are recommendations for follow-up of occupational HCV exposures:

- For the source, perform testing for anti-HCV.
- For the person exposed to an HCV-positive source:
 - perform baseline testing for anti-HCV and ALT activity; and
 - perform follow-up testing (e.g., at 4--6 months) for anti-HCV and ALT activity (if earlier diagnosis of HCV infection is desired, testing for HCV RNA may be performed at 4--6 weeks).

APPROVED:

Medical Services Manager

Date

Chief Medical Officer

Date

Steve Sherman MD

Medical Director

10/6/09

Date

Effective Date: 10/09
Revised: August 2009

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TABLE 1. Recommended HIV post-exposure prophylaxis for percutaneous injuries

Exposure type	Infection status of source				
	HIV-Positive Class 1*	HIV-Positive Class 2*	Source of unknown HIV status†	Unknown source‡	HIV-Negative
Less severe†	Recommend basic 2-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 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 severe‡	Recommend expanded 3-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 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

* HIV-Positive, Class 1 – asymptomatic HIV infection or known low viral load (e.g., <1,500 RNA copies/mL). HIV-Positive, Class 2- symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of post-exposure prophylaxis (PEP) should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.

† Source of unknown HIV status (e.g., deceased source person with no samples available for HIV testing).

‡ Unknown source (e.g., a needle from a sharps disposal container).

† Less severe (e.g., solid needle and superficial injury).

**The designation “consider PEP” indicates that PEP is optional and should be based on an individualized 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

‡ More severe (e.g., large-bore hollow needle, deep puncture, visible blood on device, or needle used in patient’s artery or vein).

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TABLE 2. Recommended HIV post-exposure prophylaxis for mucous membrane exposures and non-intact skin* exposures

Exposure type	Infection status of source				
	HIV-Positive Class 1†	HIV-Positive Class 2‡	Source of unknown HIV status†	Unknown source‡	HIV-Negative
Small volume**	Consider basic 2- drug PEP!!	Recommend basic 2-drug PEP	Generally, no PEP warranted; however, consider basic 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
Large volume†	Recommend basic 2-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 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

* For skin exposures, follow-up is indicated only if there is evidence of compromised skin integrity (e.g., dermatitis, abrasion, or open wound).

† HIV-Positive, *Class 1* – asymptomatic HIV infection or known low viral load (e.g., <1,500 RNA copies/mL). HIV-Positive, *Class 2*- symptomatic HIV infection, AIDS, acute sero-conversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of post exposure prophylaxis (PEP) should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.

‡ Source of unknown HIV status (e.g., deceased source person with no samples available for HIV testing).

‡ Unknown source (e.g., splash from inappropriately disposed blood).

** Small volume (i.e., a few drops).

!! The designation “consider PEP” indicates that PEP is optional and should be based on an individualized 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

† Large volume (i.e., major blood splash).

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RECOMMENDED BASIC REGIMENS FOR HIV PEP:

- AZT 300mg bid and lamivudine (Epivir[®]; 3TC) 150mg bid
(Readily available in institutions as stock supply.)
- Tenofovir DF (Viread[®]; TDF) + emtricitabine (Emtriva[™]; FTC); available as Truvada[™]
 - TDF: 300 mg once daily
 - FTC: 200 mg once daily
 - As Truvada[™]: one tablet daily

PREFERRED EXPANDED REGIMEN

- Basic regimen + Lopinavir/ritonavir (Kaletra[®]; LPV/RTV) (2 tabs twice daily)
(Readily available in institutions as stock supply.)
- If the source of transmission has used antiretroviral therapy, genotypic drug resistance testing is recommended if that person's viral load is above 1000 copies/mL.

More options can be found at references listed below.

References

1. [CDC. Update: provisional Public Health Service recommendations for chemoprophylaxis after occupational exposure to HIV. MMWR 1996; 45:468--72.](#)
2. [CDC. Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis. MMWR 2005;54\(No. RR-9\):1--17.](#)
3. US Department of Health and Human Services, Panel on Clinical Practices for Treatment of HIV Infection. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents---December 1, 2007. Available at <http://aidsinfo.nih.gov/contentfiles/adultandadolescentgl.pdf>.
4. http://www.nccc.ucsf.edu/Clinical_Resources/FAQ.html
5. http://www.nccc.ucsf.edu/Clinical_Resources/PEPGuidelines.html
6. <http://hivinsite.ucsf.edu/>

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Management of Exposures to Hepatitis B antigen

TABLE 3. Recommended postexposure prophylaxis for exposure to hepatitis B virus

Vaccination and Antibody response status of exposed workers*	Treatment		
	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	If known high risk source, treat as if source were HBsAg positive
Antibody response unknown	Test exposed person for anti-HBs ‡ 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 1. If adequate,** no treatment is necessary 2. If inadequate, administer vaccine booster and recheck titer in 1-2 months

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

† Hepatitis B surface antigen.

§ Hepatitis B immune globulin; dose is 0.06 mL/kg intramuscularly.

‡ Hepatitis B vaccine.

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

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

The option of giving one dose of HBIG and reinitiating the vaccine series is preferred for non-responders 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.

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SOURCE TESTING/INFORMATION RELEASE

I have been advised that there is significant reason to believe that another individual has been exposed to my blood or other potentially infectious body fluid in a manner that puts that individual at risk for serious infection. I understand that knowledge that I do or donot have particular blood borne infectious diseases will affect treatment decisions for this exposed individual.

I have been asked to:

_____ Consent to release of current information

_____ Consent to blood test and release of these results.

I am willing to:

_____ Consent to testing for:

HIV _____ YES _____ NO

HBV _____ YES _____ NO

HCV _____ YES _____ NO

_____ Consent to release results to the physician caring for the individual exposed to my blood or body fluid concerning:

HIV _____ YES _____ NO

HBV _____ YES _____ NO

HCV _____ YES _____ NO

Printed Name

Witness Printed Name

Signature

Witness Signature

Date

Date

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LAB ORDERS

For an exposure where treatment is offered, recommended, or strongly recommended, even if the patient does not elect to take medications.

Schedule the following labs:

- HIV antibody test: Baseline, 6 weeks, 3 months (optional)
- Baseline HIV tests drawn as part of this post exposure protocol should be sent to a testing laboratory that has a fast turn around time. The State Lab often takes 1-2 weeks; we do not advise using this resource.
- Hepatitis B surface antibody
- Hepatitis C antibody
- Schedule an appointment with Provider.

If the patient elects to take medications for post-exposure HIV prophylaxis also do:

STAT PREGNANCY TEST for females of child bearing capacity. None of these three drugs may be given to a pregnant person without further consulting and counseling.

Schedule follow up appointment with Provider, and HIV counselor.

Schedule:

- CBC, chemistry panel, Urinalysis with micro, every two (2) weeks while on treatment.
- Symptom history and focused physical exam, every two (2) weeks while on treatment.

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INITIAL SOURCE PATIENT INFORMATION - HIV

1. Do you know who the source person is?

YES _____ NO _____

2. If you do not know the source person, are there any factors about possible sources to be considered? _____

3. If the source person is known, check one:

- a. Their HIV status is not known (no testing has been done) _____
- b. They have a known NEGATIVE HIV test _____
- c. They have a known POSITIVE HIV test _____

4. If the patient has a known positive HIV test fill out all that you can:

Asymptomatic _____

Symptomatic _____

AIDS _____

CD4 count _____

Viral Load _____

Current antiviral medication(s) _____

Untested source individuals will be asked to consent to testing.

Random "blind" testing of blood drawn at Oregon Department of Corrections intake shows a prevalence of:

HIV + blood – men 0.08% (8 out of 1000), women 1.2% (12 per 1000)

HCV + blood – men 29%, women 35%

Blood Borne Pathogen Exposure PATIENT CONSENT TO TREAT

When the source of a blood exposure is known to have HIV, or is high risk for having HIV, medication can be given to theoretically try to prevent the exposed person from acquiring HIV disease. The decision whether or not to initiate a combination of medications for post exposure prophylaxis is difficult. There are no references or resources that can guarantee outcome. What has been found helpful has been a combination of the following:

1. Be candid with the exposed individual.
2. The tables in this protocol have been adapted from the National Guidelines recommendations for post exposure treatment. Tell them we are using an aggressive interpretation of the most up to date national guidelines for post exposure treatment. The decision to recommend or not recommend Post-Exposure Prophylaxis treatment is based on the type of exposure combined with an estimate of source virus amount.
3. If the patient source of the exposure is positive for HIV, or unknown, I may be offered Anti-HIV medications. I have been told that if I am going to take any of these three medications I should start immediately, as the sooner I start the greater the chance that it may help. I may need to take the medications for a total of four weeks. If I begin the medications and the patient is found to be negative for HIV, I may be able to stop taking the medications. I will need to have my blood checked now and in 2 and 4 weeks for side effects. If I am female, I will need to have a pregnancy test prior to my first dose. If I am pregnant or breast feeding, the most current recommendations for post exposure treatment will be discussed with me.
4. Because HIV is blood borne, it can be spread through sexual activity. During the six months I am considered at risk of developing HIV from this incident, I should avoid or practice safe sex.
5. Because I have been exposed to another person's blood or body fluids, I need to also be aware that I may have been exposed to a number of hepatitis viruses. I will be considered for hepatitis prevention which can include the use of globulins and/or the Hepatitis B vaccine.
6. I am always free to decline recommended treatment following an exposure. Additionally, if I begin a course of post exposure treatment and change my mind about continuing, I may stop treatment at any time without having any effect on my future treatment.

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7. I understand that I am ineligible to participate in the Post-Exposure Prophylaxis treatment protocol if any of the following criteria are present:
- Pregnant or breast-feeding.
 - Men or women declining pregnancy avoidance.
 - Active malignancy, hepatic, pancreatic, or renal disease, or other serious current medical illness.
 - Failure to give written informed consent within 48 hours.
8. I have read or have had read to me, all of the above. I understand what it says and have reported anything that contraindicates my taking the Post-Exposure medications. If I have questions I can ask the physicians or nurses to help answer them. I am aware of the risks of being involved in an exposure to another person's blood or body fluids. I am aware of the risks and the possible benefits of prophylactic treatment for HIV. A copy of this Information Sheet will be given to me.

Patient Signature

Witness Signature

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Frequently Asked Questions as answered by the
University Of California San Francisco 2008

What is the risk for getting HIV after a needlestick, an injury with a sharp instrument, or a splash?

The average infection risk from injuries involving HIV-infected needles or other sharp instruments is about 1 in 300, or 0.3%. However, some specific factors are associated with increased risk:

- an exposure to blood from a terminally-ill AIDS patient
- an exposure caused by a needle which was used in a blood vessel
- an exposure caused by a visibly-bloody device
- a deep puncture

The risk for infection from a bloody splash to mucous membranes or to open skin is very low - less than 1 in 1000.

Can drug treatment after exposure prevent HIV infection?

We now believe that treatment with antiretrovirals DOES lower the chance of getting HIV after an exposure to infected blood or other hazardous body fluid. A CDC study (MMWR, 1995;44) showed that the risk of HIV infection in health care workers who took zidovudine after needlestick exposures to HIV was 79% lower than those who were not treated. Also, giving zidovudine to pregnant HIV-infected women and their newborns lowered the risk of infection among the newborns by 67% (MMWR, 1994;43). There is also animal data to support the efficacy of PEP for HIV. The CDC issued new treatment recommendations for HIV exposures in 2001 (MMWR, June 29, 2001). These guidelines recommend preventive treatment with antiretroviral drugs after serious exposures to HIV.

Is it true that some people have taken zidovudine (AZT) after an exposure and still become infected?

In the world, there are now less than 20 published cases of health care workers who took antiretroviral drugs after exposure and still got HIV infection. We do not know how many people exposed to HIV initiated ARV therapy and did NOT get infected. Although ARV therapy does not always work, it is still likely to lower the chance of infection.

Why are BOTH zidovudine (AZT) and lamivudine (3TC) recommended after HIV exposures?

As more people with HIV use zidovudine, more HIV becomes resistant to it. Using both drugs increases the chance that at least one will be active against the HIV strains involved in the occupational exposure. When given together to HIV-infected patients, zidovudine and lamivudine work well together for several months, even when the virus at first was zidovudine resistant.

What about adding nevirapine (NVP) to the regimen?

In special cases of serious exposure and/or when the treating clinician suspects exposure to drug resistant HIV, other drugs may be added to the treatment plan. Because health care workers have had serious side effects when taking additional drugs (e. g., nevirapine; see "[An Important Update: Serious Adverse Events Attributed to Nevirapine Regimens for Post-exposure HIV Prophylaxis](#)" it is safest to use them only when really necessary.

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What are the side effects of treatment?

In our experience with using zidovudine alone, about a third of the health care workers had NO side effects at all. However, most (2/3) had some side effects (usually minor), including headache, sleeping trouble, and stomach upset. No serious toxicity occurred in our study of over 250 health care workers, and no one had to stop taking zidovudine because of toxicity.

The side effects of lamivudine are like those of zidovudine. The only serious additional toxicity reported has been pancreatitis in a very small number (less than 0.5%) of HIV-infected adults on long-term treatment.

The side effects of indinavir (IND), are also like those seen with zidovudine and lamivudine. Also, kidney stones and liver problems can occur.

The side effects of nelfinavir (NEL), are also like those seen with zidovudine and lamivudine. Also, diarrhea is quite common during treatment.

Serious side effects, including liver damage and severe allergy, have been seen in health care workers taking nevirapine. This drug should not be given for PEP without expert consultation.

SEE

[PEPline Guidelines for Nevirapine \(NVP, Viramune\) Administration for Post-Exposure Prophylaxis](#)

Serious side effects can occur with all these drugs and should be discussed with the treating clinician. Also, the drugs are all new and we do not fully understand their toxicity when used alone or together. To make treatment as safe as possible, close follow-up is needed. This includes checking blood counts, and liver, kidney, and pancreas functions regularly, to detect any problems at a very early stage.

When should treatment be started?

It is best to start as soon as possible after the exposure, hopefully within the first hour or two. After an exposure, most health care workers are upset and find that decisions about treatment are very hard to make. When in doubt about treatment, it is probably best to start. Treatment can be stopped later, after the exposed person has had a chance think about the risks and benefits and talk to their clinician and loved ones. Once the immediate crisis has passed, it is usually easier to make the best decision.

How long does treatment last after an exposure?

We recommend 28 days (4 weeks) of treatment. This is expected to provide protection during the "window of opportunity," before HIV infection is established. This advice is consistent with that provided by the US Public Health Service.

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CHECKLIST – BLOOD BORNE PATHOGEN EXPOSURE PROTOCOL

Treatment Checklist (Blood Borne Pathogen Exposure 0809.doc)

This will be a 2-patient scenario, keep them straight – label Patient A, Patient B. Use one Exposure Packet for each patient; use two checklists, one for the person exposed and one for the person who is the source of the exposure.

Initial contact _____ Emergency care of wound / first aid
 _____ Fill out the INITIAL SOURCE PATIENT INFORMATION (ISPI) forms, page 10

Decision on TX _____ Based on information gathered in the ISPI's notify physician and together decide on extent of treatment using the information
 _____ in Table #1, page 3, for percutaneous exposure
 _____ in Table #2, page 4, for mucous membrane and non-intact skin exposures
 _____ in Table #3, page 6, for exposure to Hepatitis B antigen;
 _____ in #4, page 7, for exposure to Hepatitis C

Review of medications you may need: Bite – Augmentin 875mg if no allergy penicillin; 2-drug or 3- drug regimen, page 5; Td and Twinrix or Hep B vaccine, HBIG (Table #3, page 6), order from pharmacy when needed. Give HBIG within one (1) week of exposure, if indicated.

If aggressive treatment is determined to be necessary do the following:

Patient A	Patient B	
_____	_____	1. <u>Inform the patients.</u>
_____	_____	2. Get consent forms signed for the following:
_____	_____	a.) Twinrix Vaccine, if used
_____	_____	b.) Tetanus/Diphtheria Vaccine if needed
_____	_____	c.) Source Testing/Information Release (page 8)
_____	_____	d.) Patient Consent to treat (page 11-12)
_____	_____	3. STAT pregnancy test on females, if indicated
_____	_____	4. Draw baseline blood (request ASAP) (page 7&9)
_____	_____	a.) HIV antibody test: Baseline, 6 weeks, 3 months (optional)
_____	_____	b.) Hepatitis B surface antibody
_____	_____	c.) Hepatitis C antibody
_____	_____	d.) If patient elects to take medications: Do CBC, Chem panel, U/A with micro every two (2) weeks while on treatment (f/u appt. q 2 wk with provider).
_____	_____	5. Schedule follow-up appt. with provider and HIV counselor, if available
_____	_____	6. If injury is from a bite, see Human/Animal bite Protocol

Include the following information in the exposure packet:

- See Blood Borne Pathogen Exposure 0809.doc protocol and forms (Nursing Protocols Word Version)
- Human Bite Protocol
- Dip/Tet informed consent and info sheet
- Twin Rix informed consent and Hep A/B info sheet
- HIV Education (BHS referral form enclosed)
- Interpath Lab Requisition