Medical Management of Exposures: HIV, HBV, HCV, Human Bites and Sexual Assaults

Federal Bureau of Prisons
Clinical Practice Guideline

June 2009

What's New in This Document?

This June 2009 version of "Medical Management of Exposures" is a targeted revision. The recommendations for management of exposures to hepatitis C are revised to match the recently updated "Guidelines for the Prevention and Treatment of Hepatitis C and Cirrhosis".

Recommendations for post-exposure management of hepatitis C include:

Baseline (at time of exposure):
Obtain anti-HCV & ALT

4 months post-exposure:
Obtain anti-HCV & ALT. If anti-HCV (+), then obtain HCV RNA. If HCV RNA (+), then evaluate for treatment.

6 months post-exposure: If 4-month anti-HCV is negative, then obtain anti-HCV & ALT.
If anti-HCV negative, then STOP follow-up.
If anti-HCV (+), then obtain HCV RNA.
If HCV RNA (+), then evaluate for treatment.

Note: RIBA testing is no longer recommended to confirm HCV-infection. Utilize an HCV RNA assay.

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Table of Contents

Appendices

1. Purpose and Overview

This BOP Clinical Practice Guideline provides specific recommendations for medically managing exposures to human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), human bites, and sexual assaults. The *Post-Exposure Worksheet (Appendix 1)* provides health care providers with a practical tool that outlines a step-wise approach for managing these exposures.

Each institution's bloodborne pathogen exposure control plan should address specific administrative, personnel, and medical procedures for implementing the guideline. Policies should include HIV testing recommendations to determine the HIV status of the source case and immediate availability of antiretroviral medications to treat individuals with HIV exposures. The institution's routine orientation and training for staff (including inmate workers) should include local procedures for providing HIV and HBV post-exposure prophylaxis.

This guideline for managing exposures is based on the recommendations of the Centers for Disease Control and Prevention (CDC) and requirements of the Occupational Safety and Health Administration (OSHA). The CDC has published two different guidelines for the management of HIV exposures, providing separate and distinct guidance for managing occupational and non-occupational exposures. CDC recommendations for post-exposure prophylaxis involve use of different regimens and different acronyms to identify the type of prophylaxis: *PEP*, referring to drug regimens for "occupational" exposures, and *nPEP*, for regimens directed at "non-occupational" exposures. In the correctional setting, occupational distinctions can become blurred. For example, while human bites in the correctional setting can be either occupational or non-occupational depending on who is bitten, common sense dictates that clinical management be the same, regardless. Therefore, this BOP guideline for post-exposure management adapts the CDC guidelines to the correctional setting, outlining HIV post-exposure management recommendations for the different types of exposure—regardless of the exposed person's occupational status.

No document on post-exposure management is complete without emphasizing that the prevention of exposures is critically important. Regular hand washing, appropriate use of gloves, adherence to recommendations for safe handling of sharps, and the strategic use of needle-less devices will prevent many exposure incidents. Risk management also entails systematic reviews of all exposure incidents—identifying contributing factors and then improving infection control policies, procedures, and training methods.

It is recommended that each facility develop a PEP packet or notebook that is readily available for emergency use. *Appendix 6A* outlines the recommended contents of the packet, including the Post-Exposure Management Worksheets, consent forms, and patient educational materials. Facility-specific instructions for post-exposure management should also be included.

2. Transmission Risk

HIV

The risk of viral transmission following an exposure incident depends on the type and extent of the exposure. The per-incident transmission risk for HIV infection depends upon the type of exposure, as shown in Table 1 below.

Table 1. Estimated Per-Incident Risk for Acquisition of HIV, by Exposure Route

Needle-sharing (injection drug use)	0.67%	Insertive anal intercourse	0.065%
Receptive anal intercourse	0.5%	Insertive penile-vaginal intercourse	0.05%
Percutaneous needle stick	0.3%	Receptive oral intercourse	0.01%
Receptive penile-vaginal intercourse	0.1%	Insertive oral intercourse	0.005%

The risk of HIV infection appears higher with:

- exposure to a larger quantity of blood or other infectious fluid;
- exposure to the blood of a patient with advanced HIV disease;
- a deep percutaneous injury;
- injury with a hollow-bore, blood-filled needle;
- exposure to source with concomitant hepatitis C viral infection;
- sexual assault (due to mucosal trauma, multiple assailants, or traumatic intercourse); and
- the presence of a sexually transmitted infection in either the source or the exposed individual.

HBV and HCV

The risk of viral transmission after a percutaneous exposure incident is highest for HBV (especially when the source is both HBsAg-positive and HBeAg-positive), followed by HCV and HIV (see Table 2 below).

Table 2. Average Transmission Risk After Percutaneous Injury

Hepatitis B:	
HBsAg-positive/HBeAg-positive	37–62%
HBsAg-positive/HBeAg-negative	23–37%
Hepatitis C	1.8% (range 0–7%)
HIV	0.3%

HBsAg = hepatitis B surface antigen; HBeAg = hepatitis B e antigen

Human Bites

Human bites have rarely resulted in transmission of HIV or HBV infection. There have been no reports of transmission of HIV or HBV following a human bite that occurred as part of an occupational exposure. Human bites, however, are associated with a significant risk for serious bacterial infection, including *Eikenella corrodens*, a gram-negative organism which is resistant to cephalosporins. Common organisms associated with human bites are *Streptococcus anginosus* and *Staphylococcus aureus,* among many others.

3. Steps in Post-Exposure Management

Consultation on post-exposure management is strongly recommended. Call the 24-hour National Clinicians' Post-Exposure Prophylaxis Hotline at 1-888-448-4911 or go to their website: http://www.ucsf.edu/hivcntr/Hotlines/PEPline.html

Frequently, evaluation of a reported "exposure" reveals that no exposure occurred (e.g., contact of intact skin with blood). These individuals should be counseled that the occurrence is *not* considered an "exposure" and that no further follow-up is needed.

Individuals who *are* exposed to bloodborne pathogens should be provided with emergent care, evaluation, and, if indicated, treatment with post-exposure medications. A follow-up evaluation by a qualified health care professional should also be obtained. If HIV post-exposure prophylaxis (PEP) is indicated, it is ideal to administer it within two hours of the exposure incident. ***Prompt evaluations of both the exposed person and the source case are essential.***

Use the following instructions for post-exposure management in conjunction with *Appendix 1, Post-Exposure Worksheet: Management of Exposed Person.* The text in **bold type** generally corresponds to text as it actually appears on the worksheet. This is an optional form, that if utilized, should be filed in the Infection Control Office to document the process of working up the exposure. A separate note in the medical record should summarize actions taken. ***Never record the identity of the source case in the exposed person's medical record.***

1. Evaluate the Exposure

The evaluating health care professional should interview the injured person to obtain details about the exposure incident and to assess risk of exposure to HIV, HBV, and HCV. Review the exposure in terms of the data on risk of transmission, as outlined in Tables 1 and 2 above.

a. Describe the exposure site and initial care provided.

The following are general instructions for treating the exposure site:

- The injured skin or wound should be emergently cleaned with soap and running water for two minutes.
- Mild bleeding should be allowed to continue. Aspiration, forced bleeding, and wound incision are not recommended.
- Antiseptics, bleach, or other cleansing agents should *not* be used.
- Mucous membranes should be rinsed with water for two minutes.
- Exposed eyes should be flushed with water or saline for two minutes.

b. Describe the incident (location, circumstances). Include detail on where the incident occurred, who was present in the room, and factors that may have contributed to the occurrence of the exposure incident.

c. Exposure occurred while exposed person was: working (including inmate workers) *or* **not working.** Check (√) the appropriate box.

d. Type of Body Fluid. Check (√) the specific types of body fluid involved.

- **Potentially infectious** body fluids are those that can spread bloodborne pathogens. Such body fluids include **blood; fluids containing visible blood; semen;** as well as **vaginal secretions;** and **cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids.** Exposure to any of these fluids—whether through a percutaneous injury (i.e., needle stick or other penetration from a sharp), contact with a mucous membrane, contact with non-intact skin, sexual exposure, or sharing injection drug use equipment—poses a risk for bloodborne virus transmission and requires further evaluation.

- **Non-infectious** body fluids are those that have not been demonstrated to spread blood-borne pathogens. These include **feces, nasal secretions, saliva, sputum, sweat, tears, urine,** and **vomitus.** Exposure to these body fluids is not considered an exposure—unless they contain visible blood. Unless the fluid is visibly bloody, no further evaluation is required.

e. Exposure Type. Check (√) the type of exposure(s) that occurred.

- **Percutaneous** (injuries that occur when the skin is penetrated by a contaminated sharp object). Document the specific type of sharp, including the brand and gauge (for needles). A tattoo applied with non-sterile needles (previously used on others) constitutes a percutaneous exposure. Indicate whether the injury is:
  - **less severe** (e.g., superficial injury; penetration with a solid needle such as a suture needle); *or*
  - **more severe** (e.g., deep puncture; penetration with a large bore, hollow needle; blood visible on the device; needle was used in an artery or vein).

- **Mucous membrane** exposure (inside the eyes, nose, or mouth) or exposure to **non-intact skin** (e.g., dermatitis, abrasion, or open wound). Indicate volume of exposure:
  - **small-volume exposure** (a few drops); *or*
  - **large-volume exposure** (larger splash).

- **Human bite.**
  - Clinical evaluation must include the possibility that the person bitten *and* the person who inflicted the bite both may have been exposed to a bloodborne pathogen.
  - Identify whether **blood exposure** is **suspected.** This includes examining:
    (1) the mouth of the biter, to assess the likelihood that the bitten person was exposed to the biter's blood, and
    (2) the wound of the person bitten, to determine if blood exposure to the mouth of the biter occurred.
  - Indicate whether the **person was bitten** (potential percutaneous exposure) or the **person was the biter** (potential mucous membrane exposure).
  - All individuals who sustain a human bite should be assessed for tetanus prophylaxis (see section 7 below, "Determine Need for Tetanus Vaccine").
  - The risk for infection with other types of organisms significantly exceeds the risk of exposure to bloodborne pathogens, and prophylactic antibiotics may be indicated (see section 8 below, "(Human bites only) Determine Need for Antibiotic Prophylaxis").

- **Sexual.** For PEP evaluation, indicate the type of sexual exposure: **receptive anal** intercourse, **receptive vaginal** intercourse, or **other** sexual exposure. For the purposes of this BOP guideline, only receptive anal or vaginal intercourse are generally considered exposures that should be considered for nPEP (except in cases that involve trauma or assault). If the behavior is recurrent or occurred more than 72 hours ago, PEP is not indicated. Any allegation made by an offender of recent sexual assault should receive prompt forensic evaluation by a health care professional trained in collecting sexual assault forensic evidence. For more information on sexual exposures see Section 9 (page 11) and CDC guidelines on sexually transmitted disease evaluation for sexual assault (*Appendix 4*).

- **Shared injection drug use equipment.** Assess the nature of the exposure and whether or not the behavior is likely to recur. If the behavior is recurrent or occurred more than 72 hours ago, PEP is not indicated.

- **Intact skin**. Exposure of intact skin (without signs of abrasion) to blood or other infectious body fluid does *not* constitute an exposure and does *not* require follow-up.

2. Evaluate the Source Case

The Post-Exposure Worksheet for the exposed person refers the practitioner to a separate form to be used in evaluating the source case (see *Appendix 2*, *Post-Exposure Worksheet: Assessment of Source Case*).

To obtain information about the source case, utilize all available information: chart review, interviewing the source, and interviewing the source person's clinician. Record previous and current laboratory results (HIV EIA, HBsAg, and anti-HCV). ***Do not record the source case's identity on the exposed person's record or worksheet.*** File this record of the source case assessment in the Infection Control Office.

- **If HIV infected:** Obtain results of the most recent HIV viral load and CD4+ T-cell count, history of antiretroviral therapy, results of resistance testing, and clinical status. Resistance testing of the source case at the time of exposure is *not* useful because the results will not be available in time to select the PEP regimen.

- **If HIV status is unknown:** Obtain history of HIV risk factors; obtain HIV test in accordance with BOP policy. (Consider rapid HIV testing per local policies and procedures, as well as guidance from the BOP Medical Director.)

- **If HBsAg positive:** Obtain HBeAg.

3. Evaluate the Health Status of the Exposed Person

Obtain the following **baseline labs** on the exposed person (preferably within 72 hours):

- **HIV EIA**
- **Anti-HBs** (test only if previous test results unavailable or vaccination status uncertain)
- **Anti-HCV**

According to OSHA regulations, if an employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.

Assess vaccination status for tetanus and HBV. If available, record dates of HBV vaccination and results of vaccine response testing. (Persons with anti-HBs ≥10m IU/ml are considered responders and immune; those with anti-HBs < 10m IU/ml are non-responders and potentially susceptible.) Persons with unknown HBV vaccine response status should be tested for anti-HBs. A pregnancy test should ordinarily be obtained for females prior to prescribing HIV PEP unless they are currently menstruating, have a history of hysterectomy, or are post-menopausal. Record other medical conditions, current medications, and drug allergies.

4. Determine Need for HIV PEP

Outlined below is the assessment process for determining need for HIV post-exposure prophylaxis. Prompt assessment and follow-up is essential. Ideally, HIV PEP is initiated within two hours of the exposure. If PEP is delayed more than 36 hours, seek expert consultation.

Consultation on post-exposure management is strongly recommended. Call the 24-hour National Clinicians' Post-Exposure Prophylaxis Hotline at 1-888-448-4911.

Determining the need for HIV PEP and the recommended PEP regimen: Recommendations for PEP are based upon the HIV status of the source case, and the type and conditions of the exposure. The chart that follows is from page 2 of the *Post-Exposure Worksheet*. Adapted from CDC recommendations, the chart can be used as a clinical tool to assist in determining the need for PEP. Use the chart to identify the **Exposure Type** and the **Condition** of the exposure; then, determine the PEP **Recommendations** based on the HIV status of the source.

The CDC recommends distinct regimens for occupational exposures (PEP) and non-occupational exposures (nPEP). BOP-preferred PEP and nPEP regimens (which include use of appropriate combination drugs) are listed in *Appendix 3*.

HIV Exposures: PEP and nPEP Recommendations				
1. Exposure Type	2. Condition	3. Recommendations Based on HIV Status of the Source		
		HIV+, Class 1 [1]	HIV+, Class 2 [2]	HIV status unknown
Percutaneous (includes illicit tattoo)	Less severe	2-drug PEP	≥3-drug PEP	Consider 2 drugs
	More severe	3-drug PEP	≥3 -drug PEP	Consider 2 drugs
Mucous membrane	Small volume	Consider 2 drugs	2-drug PEP	Generally no PEP
	Large volume	2-drug PEP	≥3-drug PEP	Consider 2 drugs
Non-intact skin	Small volume	Consider 2 drugs	2-drug PEP	Generally no PEP
	Large volume	2-drug PEP	≥3-drug PEP	Consider 2 drugs
Sexual (<72 hrs/not recurrent)	Receptive anal or vag sex	Recommend nPEP [3]		Consider nPEP [3]
	Other sexual exposure	nPEP not recommended		none
Sharing IDU equip	<72 hrs/not recurrent	Recommend nPEP [3]		Consider nPEP [3]

[1] Class 1 = asymptomatic and/or HIV viral load < 1,500 c/ml

[2] Class 2 = symptomatic HIV, AIDS, acute seroconversion, or high viral load

[3] nPEP = antiretroviral regimens for sexual and injection drug use exposures (see *Appendix 3*)
nPEP is not indicated ≥ 72 hours after exposure or if behavior is either frequent or recurrent.
For the purposes of this BOP guideline, receptive anal and vaginal intercourse are the only types of sexual exposures that should be considered for nPEP (except if trauma or assault).

Adapted from: CDC. MMWR 2005;54(No. RR-9) at http://www.cdc.gov/MMWR/preview/mmwrhtml/rr5409a1.htm and CDC. MMWR 2005;54(No. RR-2) at www.cdc.gov/mmwr/PDF/rr/rr5402.pdf

Individuals exposed to a known or suspected HIV-infected source case should be counseled about the need for the PEP regimen to be initiated promptly and carried out for 28 days. The selection of a drug regimen for HIV PEP must balance the risk of infection against the potential toxicities of the agents used. Providing appropriate symptomatic management can improve adherence. If, after evaluating the incident, there are questions about the extent of risk, starting the basic two-drug PEP is better than delaying administration.

Antiretroviral agents that are not recommended: The following drugs are generally not recommended for use as PEP or nPEP:

- delavirdine (Rescriptor®; DLV)
- abacavir (Ziagen®; ABC)
- zalcitabine (Hivid®; ddC)
- didanosine (Videx®; ddI) plus stavudine (Zerit®; d4T)

Enfurvitide (Fuzeon®;T20) is recommended for use as PEP only with expert consultation. Because of serious reported side effects, Nevirapine (Viramune®, NVP) should not be included in PEP regimens, except with expert consultation.

Monitoring and management of PEP toxicity: Exposed individuals who are prescribed PEP should be monitored for drug toxicity by testing at baseline and testing again two weeks after starting PEP. Monitoring should include at least a complete blood count and renal and hepatic function tests. If a protease inhibitor (PI) is utilized, monitor for hyperglycemia. If indinavir is utilized, also monitor for crystalluria, hematuria, and hemolytic anemia.

Post-exposure testing: Individuals with exposure to HIV should receive follow-up counseling, post-exposure testing, and medical evaluation—regardless of whether they receive PEP. Follow-up HIV-antibody testing should be performed at the following intervals after the exposure date: 6 weeks, 12 weeks, and 6 months. If the exposed person becomes HCV-infected after exposure to an HIV/HCV co-infected source, an HIV-antibody test should also be obtained at 12 months.

Special considerations for HIV PEP: While expert consultation regarding provision of HIV PEP is generally advised, it is considered essential in the following special situations:

- **Delayed initiation of HIV PEP.** PEP for occupational exposures should generally not be delayed beyond 24-36 hours post-exposure; nPEP for sexual and injection drug use related exposures should not be provided after 72 hours. The maximum time interval after which PEP provides no benefit is unknown.
- **Unknown source** (e.g., needle in a sharps container)**.** Decide about using PEP on a case-by-case basis. Consider both the epidemiological likelihood of HIV exposure and the severity of the exposure. Do not test needles or other sharp instruments for HIV.
- **Known or suspected pregnancy in the exposed person.** Pregnancy does not preclude the use of optimal PEP regimens, and PEP should not be withheld on the basis of pregnancy. The following medications are contraindicated for use in pregnant women: efavirenz, as well as the combination of didanosine and stavudine.
- **Source case has evidence of antiretroviral resistance.** Known or suspected resistance of the source virus to antiretroviral agents, particularly those that might be included in a PEP regimen, is a concern for persons making decisions about PEP. It is unknown if drug resistance has an influence on transmission risk. If the source patient's virus is known or suspected to be resistant to one or more of the drugs in a preferred PEP regimen, alternate drugs should be used.

  Resistance should be suspected in a source patient who, despite antiretroviral therapy, has had clinical progression of disease, a persistently increasing viral load, or a decline in CD4+ T-cell count. ***Resistance testing of the source case at the time of an exposure is not recommended because the results will not be available in time to influence the choice of the initial PEP regimen.*** 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, these drugs should be avoided. Always obtain expert consultation if drug resistance is known or suspected.

  The CDC guidelines provide lists of alternative regimens for PEP and nPEP:

  - CDC. MMWR 2005;54(No. RR-9) at http://www.cdc.gov/MMWR/preview/mmwrhtml/rr5409a1.htm
  - CDC. MMWR 2005;54(No. RR-2) at www.cdc.gov/mmwr/PDF/rr/rr5402.pdf.

- **PEP side effects:** Adverse reactions common to PEP include nausea, diarrhea, fatigue, and headaches. Side effects frequently can be managed, without changing the PEP regimen, by taking the PEP regimen with meals or by taking antiemetic, antimotility, and/or analgesic agents. Seek consultation when side effects are difficult to manage.

- **Expanded regimens:** The use of nevirapine in PEP regimens has been associated with severe toxicity and thus should generally not be used. Nevirapine should only be considered if no other options exist for an expanded regimen, and only after seeking expert opinion. Also seek expert consultation when considering use of dual protease inhibitors, efavirenz, and enfurvitide.

5. Determine Need for Hepatitis B PEP

Prompt assessment and follow-up is essential in the evaluation and decision-making regarding HBV post-exposure prophylaxis. Ideally, HBV PEP is initiated *within 24 hours* of the exposure. The HBV vaccination and vaccine response status (if known) should be reviewed. (Do not re-check anti-HBs for individuals for whom prior anti-HBs results are available.)

The chart below appears on page 3 of *Appendix 1, Post-Exposure Worksheet.* It is designed to assist in assessing the need for Hepatitis B post-exposure prophylaxis. Identify: (1) **Vaccination Status of Exposed Person** and then (2) **HBsAg Status of the Source**. Based on this information, determine the recommended PEP regimen.

Hepatitis B Exposures: PEP Recommendations			
1. Vaccination Status of Exposed Person	**2. HBsAg Status of the Source**		
	HBsAg Positive	**HBsAg Negative**	**HBsAg Status Unknown**
Unvaccinated	HBIG x1 ***and*** Start HBV vaccine series	Start HBV vac series	Start HBV vac series
Vaccinated: responder [1]	No treatment	No treatment	No treatment
Vaccinated: non-responder [1]	HBIG & start HBV vac series [2] ***or*** HBIG x 2 [3]	No treatment	If known high risk for HBV, treat as if source is HBsAg positive
Vaccinated: response status unknown	Test for anti-HBs If responder: no treatment If non-responder: HBIG x 1 ***and*** vaccine booster[3]	No treatment	Test for anti-HBs If responder: no treatment If non-responder: vaccine booster ***and*** re-check anti-HBs in 1-2 mos

[1] Responder = anti-HBs ≥ 10m IU/ml; *non-responder* = anti-HBs < 10m IU/ml. Do not repeat anti-HBs if previous results are available.

[2] HBIG can be administered simultaneously with HBV vaccine at different sites. HBIG dose = 0.06 mg mL/kg IM.

[3] If non-responder has received 2 full series of HBV vaccine, then administer a second dose of HBIG one month after initial dose.

Post-Exposure Prophylaxis:

- When HBIG is indicated, it should be administered as soon as possible after exposure (preferably within 24 hours). The effectiveness of administering HBIG beyond 7 days after occupational exposure is unknown. For sexual exposure, HBIG should be administered up to 14 days after exposure.

- When HBV vaccine is indicated, it should also be administered as soon as possible (preferably within 24 hours) and can be administered at the same time as HBIG, but at a separate site on the body. Vaccine should always be administered in the deltoid muscle. For exposed persons who are in the process of being vaccinated, but have not completed the vaccination series, vaccination should be completed as scheduled.

Post-exposure testing: Test for anti-HBs 1–2 months after the last dose of vaccine. *Anti-HBs cannot be ascertained if HBIG has been administered within the previous 6 weeks.*

6. Determine Need for Hepatitis C Post-Exposure Follow-Up

There is no known effective prophylaxis for persons exposed to an HCV-positive source.

- ***Baseline (at time of exposure):*** obtain anti-HCV & ALT.
- ***4 months post-exposure:*** Obtain anti-HCV & ALT. If anti-HCV is positive, then obtain HCV RNA. If HCV RNA is positive, then evaluate for treatment.
- ***6 months post-exposure:*** If 4-month anti-HCV is negative, then obtain an anti-HCV & ALT. If anti-HCV is negative, then STOP follow-up. If anti-HCV is positive, then obtain HCV RNA. If HCV RNA is positive, then evaluate for treatment.

7. Determine Need for Tetanus Vaccine

For "clean" wounds, a tetanus booster is not indicated. An example of a clean wound is when a health care worker sustains a needle stick injury from a needle that was used on a patient, but was known to be sterile prior to use. If the wound is potentially contaminated with dirt or saliva, evaluation for a tetanus booster should occur.

- For those with an **unknown history of tetanus vaccine or less than 3 doses**, administration of tetanus immune globulin and the 3-dose vaccine series* is indicated.
- For those with a **history of a complete tetanus series, who had a booster more than 5 years ago**, administration of Td or Tdap** is indicated. Tdap is preferred because it also will provide adult coverage for pertussis.
- For those with a **history of 3 or more doses of Td vaccine and whose last booster was less than 5 years ago**, no tetanus booster is required.

* *The tetanus vaccine series consists of 3 doses of Td (preferably with one of the 3 doses being Tdap) administered at 0 and 4 weeks, and again at 6–12 months.*

** *Td = Tetanus and diphtheria vaccine*
Tdap = Tetanus, diphtheria, and pertussis vaccine

8. (Human bites only) Determine Need for Antibiotic Prophylaxis

Individuals with human bite wounds have a high risk of serious bacterial infections; therefore, close monitoring of the wound is necessary. Those with the following types of human bite wounds should be considered for prophylactic antibiotic treatment: bites to the hands, feet, face, or skin overlying cartilaginous structures; or bites that penetrated deeper than the epidermal layer. *As soon as possible* (prior to signs of infection), these persons should be treated with amoxicillin-clavulanate 875/125 mg by mouth, twice daily for 5 days. For persons allergic to penicillin, treat with clindamycin together with either ciprofloxacin or trimethoprim-sulfamethoxazole (TMP-SMX). Employees should be referred to their physician for antibiotic prophylaxis. Individuals who develop cellulitis or other serious skin or soft tissue infection following a human bite should be referred urgently for IV antibiotics.

9. (Sexual exposures only) Conduct Screening for STDs

Any allegation made by an offender of recent sexual assault should receive prompt forensic evaluation by a health care professional trained in collecting sexual assault forensic evidence. Evaluation for sexually transmitted diseases should be based on the CDC 2006 STD Treatment Guidelines. The portion of the CDC guidelines on sexual assault (including specimen collection and prophylactic treatment) is reprinted in *Appendix 4*. The most common STDs among sexually assaulted women are trichomoniasis, bacterial vaginosis, gonorrhea, and chlamydial infections. Empiric antimicrobial treatment for potential STDs in sexually assaulted inmates should be considered on a case-by-case basis, considering the known medical history of the assailant, the type of exposure, and likelihood of followup (e.g., potential for release during the incubation period.) Follow BOP policy and reporting requirements, as appropriate.

10. Provide Counseling, Education, and Referral

Counseling and Education: Individuals with exposures to bloodborne pathogens should be counseled to avoid behaviors by which they could transmit the organism to another person. The table below outlines risk behaviors that should be avoided, depending on the source case status.

Educational Messages to Prevent Transmission			
Behaviors/Conditions	**HIV Exposure**	**HBV Exposure**	**HCV Exposure**
Unprotected sex	Avoid		
Pregnancy	Avoid		
Breast feeding	Avoid		
Donating blood, organs, tissue, or semen	Avoid	Avoid	Avoid

Referrals: A plan should be made for appropriate follow-up care, preferably with an experienced clinician. When indicated, also make referrals for counseling to help the exposed person cope with the stress associated with a significant exposure.

- **Employee referrals:** After initial post-exposure management, exposed employees should be referred to a physician for medical follow-up. Obtain medical release of records. Provide the health care professional evaluating the employee with the following information (required by OSHA):

  - date and time of the exposure, and a description of the employee's job duties relevant to the exposure incident;
  - details of the procedure being performed, use of protective equipment at the time of the exposure, route of the exposure, and circumstances surrounding the exposure;
  - the type, severity, and amount of fluid to which the person was exposed;
  - details about the exposure source;
  - medical documentation that provides details about post-exposure management, and review of relevant employee medical records, including vaccination status; and
  - copy of OSHA regulation 1910.1030(f)(4)(ii)(A) and "Health Care Professionals Written Opinion For Post-Exposure Evaluation" (*Appendix 5*).

  Request that the provider return the "Health Care Professionals Written Opinion For Post-Exposure Evaluation" within 15 days of the completed evaluation.

11. Complete Reporting and Documentation

General: Reporting and documentation of exposure incidents should include the following:

- Report the exposure incident to the appropriate supervisor.
- Send an incident report to the Safety Office and the Infection Control Office.
- Maintain a copy of the completed *Post-Exposure Worksheets (Appendix 1* and *Appendix 2)* or similar documentation in the Infection Control Office.
- Document exposure follow-up in the individual's medical record. ***Do not record the identity of the source case in the exposed person's medical record.***

- Utilize appropriate forms in conjunction with HIV testing, administering vaccines, etc. See *Appendix 6A* for list of available forms.

Documenting employee exposures: OSHA requires that when an occupational exposure occurs, the information listed under employee referrals (above) be documented and maintained securely for 30 years.

Analyzing the exposure incident: After providing initial post-exposure management, analyze the incident to determine how similar incidents could be prevented in the future. Consider interviewing the exposed person, or others present when the incident occurred, to identify contributing factors and insights as to how the incident could have been prevented.

An action plan and interventions to reduce blood exposure and sharp injuries should include investigating incidents, monitoring progress of actions taken, and measuring performance improvements to reduce specific types of injuries. Institutions should establish quality indicators for evaluating sharps safety and injury prevention programs; progress should be reported to the local Improving Operational Performance Committee.

References

Bloodborne Pathogens

CDC. Antiretroviral postexposure prophylaxis after sexual, injection-drug use, or other nonoccupational exposure to HIV in the United States: recommendations from the U.S. Department of Health and Human Services. *MMWR* 2005;54(No. RR-2). Available from: www.cdc.gov/mmwr/PDF/rr/rr5402.pdf

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). Available from: http://www.cdc.gov/MMWR/preview/mmwrhtml/rr5409a1.htm

CDC. Updated U.S. Public Health Service guidelines for the management of occupational exposures to HBV, HCV, and HIV and recommendations for postexposure prophylaxis. *MMWR* 2001;50(No. RR-11). Available from: http://www.cdc.gov/MMWR/preview/MMWRhtml/rr5011a1.htm

Tetanus

CDC. Diphtheria, tetanus, and pertussis: Recommendations for vaccine use and other preventive measures: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 1991;40(No. RR-10):1-28. Available from: http://www.cdc.gov/MMWR/preview/MMWRhtml/00041645.htm

CDC. Preventing tetanus, diphtheria, and pertussis among adults: use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP) and recommendation of ACIP, supported by the Healthcare Infection Control Practices Advisory Committee (HICPAC), for use of Tdap among health-care personnel. *MMWR* 2006; 55 (No. RR-17): 1-37. Available from: http://www.cdc.gov/mmwr/pdf/rr/rr5517.pdf

Human Bites

Gilbert DN, Moellering RC, Eliopoulos GM, Sande MA (editors). *The Sanford guide to antimicrobial therapy 2006*. Sperryville, VA: Antimicrobial Therapy, Inc., 2006.

Rittner AV, Fitzpatick K, Corfield A. Best evidence topic report. Are antibiotics indicated following human bites? *Emerg Med J* 2005;22:654.

Talan DA, Abrhamian FM, Moran GJ, et al. Clinical presentation and bacteriologic analysis of infected human bites in patients presenting to emergency departments. *Clin Infect Dis* 2003;37:1481-9.

Sexually Transmitted Diseases

CDC. Sexually transmitted disease treatment guidelines - 2006. *MMWR* 2006;55(No. RR-11). Available from: http://www.cdc.gov/STD/treatment/

Post-Exposure Worksheet: Management of Exposed Person (Page 1 of 4)

Incident #: __ __ __ - ___/___/___ __ (Incident # = 3-letter facility code + date (mm/dd/yy) + exposure # for that day, e.g.,1,2,3)

Last Name: | **First:** | **Initial:**

ID#: | **Date of Birth:** _____/____ /_____ | **Sex:** ☐ Male ☐ Female

Exposure: date ____/____/____ time __:___ ☐ am ☐ pm | **Evaluation:** date ____/____/____ time __:___ ☐ am ☐ pm

1. Evaluate the Exposure

a. Describe the exposure site and initial care provided: _____

b. Describe the incident (location, circumstances): _____

c. Exposure occurred while person was: ☐ working (including inmate workers) ☐ not working

d. Type of Body Fluid (check all that apply)

☐ **Potentially Infectious**
- ☐ blood
- ☐ blood-contaminated fluid: _____
- ☐ semen ☐ peritoneal fluid
- ☐ rectal secretions ☐ cerebrospinal fluid
- ☐ vaginal secretions ☐ synovial fluid
- ☐ breast milk ☐ pleural fluid
- ☐ amniotic fluid ☐ pericardial fluid

☐ **Not Infectious*** (unless visibly bloody)
- ☐ feces ☐ nasal secretions
- ☐ saliva ☐ sputum
- ☐ sweat ☐ tears
- ☐ urine ☐ vomitus

*** Post-exposure management is not required for exposures to fluids that are *not* infectious. STOP.**

e. Exposure Type (check all that apply)

☐ **Percutaneous** (by a sharp, including illicit tattoo)
- Type /brand of sharp: _____
- ☐ less severe: superficial, solid (e.g., suture) needle
- ☐ more severe: deep puncture, bore needle, blood visible on device, needle used in artery/vein

Exposure Type (continued)

☐ **Mucous membrane or ☐ Non-intact skin** (mouth/nose/eyes)
- ☐ small-volume exposure (a few drops)
- ☐ large-volume exposure (larger splash)

☐ **Human bite:**
Exposed person was: ☐biter ☐bitten
Blood exposure suspected? ☐yes ☐no
If *no*, skip to #7 on page 3.
If *yes*, check **exposure type** above:
If person was bitten: *percutaneous*
If person was biter: *mucous membrane*

☐ **Sexual**
☐ receptive anal ☐ receptive vaginal ☐other
Is behavior recurrent? ☐ yes ☐ no
Time elapsed since exposure: ___ hours

☐ **Shared injection drug use equipment**
Is behavior recurrent? ☐ yes ☐ no
Time elapsed since exposure: ___ hours

☐ **Intact skin?** This is *not* an exposure. **STOP**.

2. Evaluate the Source Case

Use *Appendix 2, Post-Exposure Worksheet: Assessment of Source Case,* to gather data regarding the source case.

3. Evaluate the Health Status of the Exposed Person

Baseline Labs:

HIV EIA ____/____/____ _____

Anti-HBs ____/____/____ _____
(NOTE: Do not repeat anti-HBs if previously tested)

Anti-HCV ____/____/____ _____
Date *Result*

Females: STAT pregnancy test if HIV PEP indicated (unless currently menstruating, s/p hysterectomy, or post-menopausal)

Last tetanus booster ☐Td ☐Tdap ____/____/____

History of Hep B vaccine: ☐ yes ☐ no

(1) ___/___/___ (2) ___/___/___ (3) ___/___/___
Date *Date* *Date*

Hepatitis B Vaccine Response Status:
- ☐ Responder (anti-HBs ≥10m IU/ml)
- ☐ Non-Responder (anti-HBs < 10m IU/ml)
- ☐ Unknown response status

Other medical conditions: _____

Current medications: _____

Drug allergies:

Last Name _____ **First** _____ **Initial** ___ **Incident #:** __ __ __ - __/__/__ __

4. Determine Need for HIV PEP ☐ N/A

Assess need for HIV PEP by consulting the chart below. If source is HIV EIA negative, PEP is *not* indicated.

1. Identify the **"Exposure Type."**
2. Identify the **"Condition"** of the exposure.
3. Determine recommended PEP (if any) based on **"HIV Status of the Source"** case.

HIV PEP should be started as soon as possible. For information about specific drug regimens, consult *Appendix 3*.

Expert consultation is recommended whenever managing exposures. National Clinician's Post-Exposure Prophylaxis Hotline (888-448-4911) is available 24 hours a day. Definitely seek consultation if delay is more than 36 hours for occupational exposures or if the source case is drug resistant. For exposures related to sex or injection drug use, nPEP should not be started after 72 hours.

HIV Exposures: PEP and nPEP Recommendations

1. ExposureType	2. Condition	3. Recommendations Based on HIV Status of the Source		
		HIV+, Class 1[1]	HIV+, Class 2[2]	HIV status unknown
Percutaneous (includes illicit tattoo)	Less severe	2 drug PEP	≥3 drug PEP	Consider 2 drugs
	More severe	3 drug PEP	≥3 drug PEP	Consider 2 drugs
Mucous membrane	Small volume	Consider 2 drugs	2 drug PEP	Generally no PEP
	Large volume	2 drug PEP	≥3 drug PEP	Consider 2 drugs
Non-intact skin	Small volume	Consider 2 drugs	2 drug PEP	Generally no PEP
	Large volume	2 drug PEP	≥3 drug PEP	Consider 2 drugs
Sexual exposure (<72 hrs/not recurrent)	receptive anal or vag sex	Recommend nPEP[3]		Consider nPEP[3]
	other sexual exposure	nPEP generally not recommended		none
Sharing IDU equip	<72 hrs/not recurrent	Recommend nPEP[3]		Consider nPEP[3]

[1] Class 1 = asymptomatic and/or HIV viral load < 1,500 c/ml
[2] Class 2 = symptomatic HIV, AIDS, acute seroconversion, or high viral load
[3] nPEP = antiretroviral regimens for sexual and injection drug use exposures (see *Appendix 3*)
nPEP is not indicated ≥ 72 hours after exposure or if behavior is either frequent or recurrent

Adapted from: CDC. MMWR 2005;54(No. RR-9) at http://www.cdc.gov/MMWR/preview/mmwrhtml/rr5409a1.htm and
CDC. MMWR 2005;54(No. RR-2) at www.cdc.gov/mmwr/PDF/rr/rr5402.pdf

Summarize actions taken, based upon evaluation of the exposed person:

Summary of HIV PEP Recommendations

☐ **HIV PEP *not* recommended**

☐ **HIV PEP recommended and exposed person refused it:** ☐ Declination form signed?

☐ **HIV PEP recommended and was accepted:** ☐ Consent signed?

☐ Prescription given ____ hours after exposure

☐ Regimen prescribed: _____ _____mg q _____ _____ _____mg q _____

_____ _____mg q _____ _____ _____mg q _____

☐ Medication provided ____ hours after exposure

☐ Patient informed of importance of immediate start of medication and duration of 28 days

☐ Baseline labs obtained: ☐ CBC ☐ AlkPhos ☐ Amylase ☐ AST ☐ Bili ☐ CK ☐ BUN

☐ Follow-up instructions: ☐ Report S/S of acute retroviral syndrome (flu-like symptoms)

☐ Return in 72 hours (as additional information about source is obtained)

☐ Referral for follow-up care to: _____

Last Name _____ **First** _____ **Initial** ___ **Incident #:** __ __ __ - __/__/__ __

5. Determine Need for Hepatitis B PEP ☐ N/A

Assess need for Hepatitis B PEP by consulting the chart below.

(1) Identify **"Vaccination Status of Exposed Person."**

(2) Determine appropriate Hepatitis B PEP (if any), based on **"HBsAg Status of the Source."**

Hepatitis B Exposures: PEP Recommendations

1. Vaccination Status of Exposed Person	2. HBsAg Status of the Source		
	HBsAg Positive	**HBsAg Negative**	**HBsAg Status Unknown**
Unvaccinated	HBIG x1 ***and*** Start HBV vaccine series	Start HBV vac series	Start HBV vac series
Vaccinated: responder [1]	No treatment	No treatment	No treatment
Vaccinated: non-responder [1]	HBIG & start HBV vac series [2] ***or*** HBIG x 2 [3]	No treatment	If known high risk for HBV, treat as if source is HBsAg positive
Vaccinated: response status unknown	Test for anti-HBs If responder: no treatment If non-responder: HBIG x 1 ***and*** vaccine booster [3]	No treatment	Test for anti-HBs If responder: no treatment If non-responder: vaccine booster ***and*** re-check anti-HBs in 1-2 mos

[1] Responder = anti-HBs ≥ 10m IU/ml; non-responder = anti-HBs < 10m IU/ml. Do not repeat anti-HBs if previous results are available.

[2] HBIG can be administered simultaneously with HBV vaccine at different sites.

[3] If non-responder has received 2 full series of HBV vaccine, then administer a second dose of HBIG one month after initial dose.

Summary of Hepatitis B PEP Recommendations

HBIG given: ____/____/____ (0.06 mL/kg IM ASAP, within 7 days for occupational, 14 days for sexual) ☐ need 2nd dose HIBIG

Hep B vaccine series initiated: ____/____/____

6. Determine Need for Hepatitis C Post-Exposure Follow-Up ☐ N/A

There is no post-exposure prophylaxis recommended for hepatitis C exposures. If the source is anti-HCV negative no follow-up is required. If source is anti-HCV positive or unknown, the following is the recommended follow-up schedule:

- Baseline (at time of exposure): Date: ___/___/___ Anti-HCV _____ ALT:_____
- 4-month post-exposure: Date: ___/___/___ Anti-HCV _____ ALT:_____. If anti-HCV (+), obtain HCV RNA.
- 6-month post-exposure: Date: ___/___/___ Anti-HCV _____ ALT:_____. If anti-HCV (+), obtain HCV RNA.

If HCV RNA is positive, then evaluate for treatment for hepatitis C.

7. Determine Need for Tetanus Vaccine ☐ N/A

If wound is clean (includes needle stick wounds from needle known to be previously sterile) –> no booster is required.

If wound is potentially contaminated with dirt or saliva –> evaluate for tetanus booster:

If unknown vaccine history or < 3 dose series –> give tetanus immune globulin (TIG) and vaccine series.*

If history of 3 or more doses and last booster > 5 years ago –> give Td or Tdap (preferred).

If history of 3 or more doses and last booster < 5 years ago –> no tetanus booster required.

** Tetanus vaccine series: 3 doses of Td (Tdap substituted for one dose). Administer at 0, 4 weeks, and 6-12 months.*

Note: *Exposed employees should be referred for tetanus vaccine.*

Administered: TIG ___/___/___ Td ___/___/___ Tdap___/___/___ Td = tetanus/diphtheria Tdap = tetanus/diphtheria/pertussis

8. (Human bites only) Determine Need for Antibiotic Prophylaxis ☐ N/A

Human bite wounds are at risk for bacterial infection. Observe closely. Consider antibiotic prophylactic treatment for the following types of human bite wounds: bites to the hands, feet, face, skin overlying cartilaginous structures or bite that penetrated deeper than the epidermal layer. *(**Note:** Exposed employees should be referred for antibiotic prophylaxis.)*

Recommended prophylaxis: (prior to S/S of infection): Amoxicillin/clavulanate 875/125 mg po 2x daily x 5 days

(If penicillen allergy: clindamycin *plus* either ciprofloxacin or TMP-SMX. Consult pharmacist.)

If signs and symptoms of cellulitis or soft tissue infection develop, refer urgently for IV antibiotic treatment.

9. (Sexual exposures only) Conduct STD Screening ☐ N/A

Any allegation of a recent sexual assault should result in a prompt forensic evaluation by a health care professional trained in collecting sexual assault forensic evidence. See CDC guidelines--Appendix 4. Follow BOP sexual assault policy.

Post-Exposure Worksheet: Management of Exposed Person (page 4 of 4)

Last Name _____ **First** _____ **Initial** ___ **Incident #:** __ __ __ - __/__/__ __

10. Provide Counseling, Education, and Referral

Check any of the following actions that have been taken.

- ☐ Provided education to the exposed person on these topics:
  - ☐ Avoiding unprotected sex/pregnancy (HIV)
  - ☐ Not to breast feed (HIV)
  - ☐ Not to donate blood/tissue/semen (HIV/HBV/HCV)
  - ☐ Wound management (signs and symptoms of infection to report)
- ☐ Employees only
  - ☐ Obtain signed medical release
  - ☐ Referred for medical follow-up to: _____
  - ☐ Provide health care professional evaluating the exposed employee with:
    - ☐ copy of OSHA regulation 1910.1030(f)(4)(ii)(A) and Health Care Professional Written Opinion for Post-Exposure Evaluation (see *Appendix 5*). Request that form be returned within 15 days of evaluation.
    - ☐ copy of this Post-Exposure Worksheet
    - ☐ documentation of the source case lab results (without revealing identity of the source case)
- ☐ Referred for counseling to: _____
- ☐ Determine recommended medical/laboratory follow-up (see table below)

Recommended Post-Exposure Laboratory Follow-Up

Time from Exposure	HIV Exposure	HBV Exposure	HCV
Baseline	HIV EIA	Anti-HBs	Anti-HCV & ALT
2 weeks (if on PEP)	CBC, AlkPhos, AST, Bili, CK, Amylase, BUN	—	—
6 weeks	HIV EIA	—	
3 months	HIV EIA	—	—
4 months			Anti-HCV* & ALT
6 months	HIV EIA	—	Anti-HCV* & ALT
1–2 months after last HBV vaccine dose**	—	Anti-HBs	—
1 year (if exposed person newly HCV-infected)	HIV EIA	—	—

** confirm positive with HCV RNA* *** cannot be ascertained if HBIG given in last 6- 8 weeks*

11. Complete Reporting and Documentation

Check off the following actions when you complete them:

- ☐ Report incident to supervisor as soon as possible.
- ☐ Give incident report to Safety Office.
- ☐ Report incident to Infection Control Office.
- ☐ Provide employee with Health Care Professional Written Opinion for Post-Exposure Evaluation (within 15 days of completion of exposure evaluation).
- ☐ Analyze exposure incident.

Health Care Provider Signature: _____ **Date:**___/___/___

Post-Exposure Worksheet: Assessment of Source Case

Incident #: __ __ __ - ___/___/___ __ **Exposure:** date ___/___/___ time __:___ ☐ am ☐ pm

Exposure type: ☐ Percutaneous ☐ Mucous Membrane ☐ Non-Intact Skin ☐ Sexual ☐ Injection Drug Use

Last Name:	**First Name:**	**Initial:**
Registration #:	**DOB:** __/__/__	**Sex:** ☐ **Male** ☐ **Female**
Location:		

Laboratory Results

For the source case, obtain previous and current test results. Consider using a rapid HIV test to facilitate prompt determination of the need for PEP. Confirm positives with standard HIV serologic tests. Sources of information:

☐ Chart review __/__/__ (*Date*) ☐ Patient/proxy interview __/__/__ (*Date*) ☐ Clinician interview: __/__/__ (*Date*) Clinician: _____

Significant medical problems/risk factors: _____

Source Case Laboratory Results

Test	Prior Tests		Current Tests	
	Date	**Result**	**Date**	**Result**
HIV EIA				
HBsAg				
HBeAg				
Anti-HCV				

HIV Infected Source Case

Clinical Status:

- ☐ AIDS
- ☐ Symptomatic HIV infection
- ☐ Asymptomatic HIV infection, not AIDS
- ☐ Unknown

History of anti-retroviral therapy?

- ☐ yes
- ☐ no
- ☐ unknown

Current anti-retroviral drugs: _____

Previous anti-retroviral drugs :_____

Most recent CD4: ___/___/___ (*Date*) ____ cells/mm^3 Most recent viral load: ___/___/___ (*Date*) ____ cps/ml

Prior CD4: ___/___/___ (*Date*) ____ cells/mm^3 Prior viral load: ___/___/___ (*Date*) ____ cps/ml

Source Case HIV Status is Unknown

HIV Risk Factors:

- ☐ has injected illegal drugs and shared equipment
- ☐ male who has had sex with another man
- ☐ has had unprotected intercourse with a person with known or suspected HIV infection
- ☐ has history of gonorrhea or syphilis
- ☐ has had unprotected sex with more than one sex partner
- ☐ is from a high risk country (in Sub-Saharan or West Africa)
- ☐ is hemophiliac or has received blood products from 1977 to 1985
- ☐ risk factors unknown because:_____

Health Care Provider Signature: _____ Date:___/___/___

Optional Form. File in Infection Control Office. Do not file in exposed person's medical record

Preferred Regimens for HIV Post-Exposure Prophylaxis

Preferred PEP regimens and dosing are listed below. The BOP recommends utilizing combination medications for PEP, so only options utilizing combination drugs are listed below. Utilize a preferred regimen unless there is a reason not to, e.g., drug resistant source case. **Generally, PEP is administered for 28 days.** For alternative regimens and information about side effects of the regimens, consult CDC guidelines referenced at bottom of the page.

Preferred PEP (for percutaneous, non-intact skin, mucous membrane and human bite exposures)

Basic (2-drug)	Combivir® ***or*** Truvada®
Expanded (3+ drugs)	Kaletra® plus Combivir® ***or*** Kaletra® plus Truvada®

Preferred nPEP (for sexual exposures, sharing IDU needles)

NNRTI-based [1]	Efavirenz [3] plus Combivir® ***or*** Efavirenz [3] plus Truvada®
PI-based [2]	Kaletra® plus Combivir®

Agents Generally *Not* Recommended for PEP

abacavir (ABC)	delavirdine (DLV)
nevirapine (NVP)	enfurvitide (T20) [4]
zalcitabine (ddC)	didanosine (ddI) combined with stavudine (d4T)

Drug Dosing

Trade Name	*Generic Name(s)/Dosage Form*	*Frequency*
Combivir®	zidovudine (ZDV) 300 mg ***and*** lamivudine (3TC) 150 mg	one tablet twice daily
Truvada®	emtricitabine (FTC) 200 mg ***and*** tenofovir DF (TDF) 300 mg	one tablet once daily
Kaletra®	lopinavir 133 mg ***and*** ritonavir 33 mg	three capsules twice daily, with food
Sustiva®	efavirenz (EFV) 600 mg	one tablet daily, at bedtime

Notes

[1] NNRTI = non-nucleoside reverse transcriptase inhibitor

[2] PI = protease inhibitor

[3] Efavirenz should not be administered to pregnant women (Pregnancy Category D).

[4] Enfurvitide should only be administered with expert consultation.

Patient Information Sheets on HIV PEP Drugs

DHHS. AIDSinfo Drug Database

Available from: http://aidsinfo.nih.gov/DrugsNew/Default.aspx?MenuItem=Drugs

CDC References (for more detailed information on PEP, side effects, alternative regimens)

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). Available from: http://www.cdc.gov/MMWR/preview/mmwrhtml/rr5409a1.htm

CDC. Antiretroviral postexposure prophylaxis after sexual, injection-drug use, or other nonoccupational exposure to HIV in the United States: recommendations from the U.S. Department of Health and Human Services. MMWR 2005;54(No. RR-2). Available from: www.cdc.gov/mmwr/PDF/rr/rr5402.pdf

Centers for Disease Control and Prevention
Sexually Transmitted Disease Treatment Guidelines 2006

Sexual Assault and STDs

Abstracted from: Centers for Disease Control and Prevention. Sexually Transmitted Disease Treatment Guidelines - 2006. MMWR 2006;55(No. RR-11):80-83.

Adults and Adolescents

The recommendations in this report are limited to the identification, prophylaxis, and treatment of sexually transmitted infections and conditions commonly identified in the management of such infections. The documentation of findings, collection of nonmicrobiologic specimens for forensic purposes, and the management of potential pregnancy or physical and psychological trauma are beyond the scope of this report. Examinations of survivors of sexual assault should be conducted by an experienced clinician in a way that minimizes further trauma to the survivor. The decision to obtain genital or other specimens for STD diagnosis should be made on an individual basis. Care systems for survivors should be designed to ensure continuity (including timely review of test results), support adherence, and monitor for adverse reactions to any therapeutic or prophylactic regimens prescribed at initial examination. Laws in all 50 states strictly limit the evidentiary use of a survivor's previous sexual history, including evidence of previously acquired STDs, as part of an effort to undermine the credibility of the survivor's testimony. Evidentiary privilege against revealing any aspect of the examination or treatment is enforced in the majority of states. In unanticipated, exceptional situations, STD diagnoses may later be accessed, and the survivor and clinician may opt to defer testing for this reason. However, collection of specimens at initial examination for laboratory STD diagnosis gives the survivor and clinician the option to defer empiric prophylactic antimicrobial treatment. Among sexually active adults, the identification of sexually transmitted infection after an assault might be more important for the psychological and medical management of the patient than for legal purposes because the infection could have been acquired before the assault.

Trichomoniasis, bacterial vaginosis (BV), gonorrhea, and chlamydial infection are the most frequently diagnosed infections among women who have been sexually assaulted. Because the prevalence of these infections is high among sexually active women, their presence after an assault does not necessarily signify acquisition during the assault. A postassault examination is, however, an opportunity to identify or prevent sexually transmitted infections, regardless of whether they were acquired during an assault. Chlamydial and gonococcal infections in women are of particular concern because of the possibility of ascending infection. In addition, HBV infection might be prevented by postexposure administration of hepatitis B vaccine. Reproductive-aged female survivors should be evaluated for pregnancy, if appropriate.

Evaluation for Sexually Transmitted Infections

Initial Examination

An initial examination should include the following procedures:

- Testing for *N. gonorrhoeae* and *C. trachomatis* from specimens collected from any sites of penetration or attempted penetration.
- Culture or FDA-cleared nucleic acid amplification tests for either *N. gonorrhoeae* or *C. trachomatis*. NAAT offer the advantage of increased sensitivity in detection of *C. trachomatis*.
- Wet mount and culture of a vaginal swab specimen for *T. vaginalis* infection. If vaginal discharge, malodor, or itching is evident, the wet mount also should be examined for evidence of BV and candidiasis.
- Collection of a serum sample for immediate evaluation for HIV, hepatitis B, and syphilis.

Follow-Up Examinations

After the initial post-assault examination, follow-up examinations provide an opportunity to 1) detect new infections acquired during or after the assault; 2) complete hepatitis B immunization, if indicated; 3) complete counseling and treatment for other STDs; and 4) monitor side effects and adherence to postexposure prophylactic medication, if prescribed.

Examination for STDs should be repeated within 1–2 weeks of the assault. Because infectious agents acquired through assault might not have produced sufficient concentrations of organisms to result in positive test results at the initial examination, testing should be repeated during the follow-up visit, unless prophylactic treatment was provided. If treatment was provided, testing should be conducted only if the survivor reports having symptoms. If treatment was not provided, follow-up examination should be conducted within 1 week to ensure that results of positive tests can be discussed promptly with the survivor and that treatment is provided. Serologic tests for syphilis and HIV infection should be repeated 6 weeks, 3 months, and 6 months after the assault if initial test results were negative and infection in the assailant could not be ruled out (see Sexual Assaults, Risk for Acquiring HIV Infection).

Prophylaxis

Many specialists recommend routine preventive therapy after a sexual assault because follow-up of survivors of sexual assault can be difficult. The following prophylactic regimen is suggested as preventive therapy:

- **Postexposure hepatitis B vaccination**, without HBIG, should adequately protect against HBV infection. Hepatitis B vaccination should be administered to sexual assault victims at the time of the initial examination if they have not been previously vaccinated. Follow-up doses of vaccine should be administered 1–2 and 4–6 months after the first dose.
- **An empiric antimicrobial regimen for chlamydia, gonorrhea, trichomonas, and BV.**
- Emergency contraception (EC) should be offered if the postassault could result in pregnancy in the survivor.

Recommended Regimens

Ceftriaxone 125 mg IM in a single dose
PLUS
Metronidazole 2 g orally in a single dose
PLUS
Azithromycin 1 g orally in a single dose OR Doxycycline 100 mg orally twice a day for 7 days

For patients requiring alternative treatments, refer to the sections in this report relevant to the specific agent. The efficacy of these regimens in preventing infections after sexual assault has not been evaluated. Clinicians should counsel patients regarding the possible benefits and toxicities associated with these treatment regimens; gastrointestinal side effects can occur with this combination. Providers might also consider anti-emetic medications, particularly if EC also is provided.

Other Management Considerations

At the initial examination and, if indicated, at follow-up examinations, patients should be counseled regarding 1) symptoms of STDs and the need for immediate examination if symptoms occur and 2) abstinence from sexual intercourse until STD prophylactic treatment is completed.

Occupational Safety and Health Administration (OSHA)

Standard CFR29 Bloodborne Pathogens – Post-Exposure Evaluation and Follow-Up (1910.1030(f))

The section of the OSHA bloodborne pathogen standard which covers post-exposure management is printed below. It should be provided to all health care professionals evaluating employees who sustain potential exposures to bloodborne pathogens. The text for the entire standard is available at: ***http://www.osha.gov/SLTC/bloodbornepathogens/index.html***

1910.1030(f) **Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up --**

1910.1030(f)(1) **General.**

1910.1030(f)(1)(I) **The employer shall make available the hepatitis B vaccine and vaccination series** to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident.

1910.1030(f)(1)(ii) **The employer shall ensure that all medical evaluations and procedures including the hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis, are:**

1910.1030(f)(1)(ii)(A) **Made available at no cost to the employee;**

1910.1030(f)(1)(ii)(B) **Made available to the employee at a reasonable time and place;**

1910.1030(f)(1)(ii)© **Performed by or under the supervision of a licensed physician** or by or under the supervision of another licensed healthcare professional; and

1910.1030(f)(1)(ii)(D) **Provided according to recommendations of the U.S. Public Health Service** current at the time these evaluations and procedures take place, except as specified by this paragraph (f).

1910.1030(f)(1)(iii) The employer shall ensure that all laboratory tests are conducted by an accredited laboratory at no cost to the employee.

1910.1030(f)(2) **Hepatitis B Vaccination.**

1910.1030(f)(2)(I) Hepatitis B vaccination shall be made available after the employee has received the training required in paragraph (g)(2)(vii)(I) and within 10 working days of initial assignment to all employees who have occupational exposure unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons.

1910.1030(f)(2)(ii) **The employer shall not make participation in a prescreening program a prerequisite for receiving hepatitis B vaccination.**

1910.1030(f)(2)(iii) If the employee initially declines hepatitis B vaccination but at a later date while still covered under the standard decides to accept the vaccination, the employer shall make available hepatitis B vaccination at that time.

1910.1030(f)(2)(iv) The employer shall assure that employees who decline to accept hepatitis B vaccination offered by the employer sign the statement in Appendix A.

1910.1030(f)(2)(v) If a routine booster dose(s) of hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available in accordance with section (f)(1)(ii).

1910.1030(f)(3) **Post-exposure Evaluation and Follow-up.** Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up, including at least the following elements:

1910.1030(f)(3)(I) **Documentation of the route(s) of exposure**, and the circumstances under which the exposure incident occurred;

1910.1030(f)(3)(ii) **Identification and documentation of the source individual**, unless the employer can establish that identification is infeasible or prohibited by state or local law;

1910.1030(f)(3)(ii)(A) The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.

1910.1030(f)(3)(ii)(B) When the source individual is already known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated.

1910.1030(f)(3)(ii)© Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

1910.1030(f)(3)(iii) **Collection and testing of blood for HBV and HIV serological status;**

1910.1030(f)(3)(iii)(A) The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.

1910.1030(f)(3)(iii)(B) If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.

1910.1030(f)(3)(iv) **Post-exposure prophylaxis**, when medically indicated, as recommended by the U.S. Public Health Service;

1910.1030(f)(3)(v) **Counseling**; and

1910.1030(f)(3)(vi) **Evaluation of reported illnesses.**

1910.1030(f)(4) **Information Provided to the Healthcare Professional.**

1910.1030(f)(4)(I) The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

1910.1030(f)(4)(ii) **The employer shall ensure that the healthcare professional evaluating an employee after an exposure incident is provided the following information:**

1910.1030(f)(4)(ii)(A) **A copy of this regulation;**

1910.1030(f)(4)(ii)(B) **A description of the exposed employee's duties as they relate to the exposure incident;**

1910.1030(f)(4)(ii)© **Documentation of the route(s) of exposure and circumstances under which exposure occurred;**

1910.1030(f)(4)(ii)(D) **Results of the source individual's blood testing,** if available; and

1910.1030(f)(4)(ii)(E) **All medical records relevant to the appropriate treatment** of the employee including vaccination status which are the employer's responsibility to maintain.

1910.1030(f)(5) **Healthcare Professional's Written Opinion.** The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.

1910.1030(f)(5)(I) The healthcare professional's written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination.

1910.1030(f)(5)(ii) The healthcare professional's written opinion for post-exposure evaluation and follow-up shall be limited to the following information:

1910.1030(f)(5)(ii)(A) That the employee has been informed of the results of the evaluation; and

1910.1030(f)(5)(ii)(B) That the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment.

1910.1030(f)(5)(iii) All other findings or diagnoses shall remain confidential and shall not be included in the written report.

1910.1030(f)(6) **Medical Recordkeeping.** Medical records required by this standard shall be maintained in accordance with paragraph (h)(1) of this section.

Health Care Professionals
Written Opinion For Post-Exposure Evaluation*

1. Employee Name:_____
2. Date of Incident:_____
3. Date of Office Visit:_____
4. Facility Address:_____
5. Facility Telephone:_____

Report as required under the OSHA Bloodborne Pathogen Standard:

□ The employee named above has been informed of the results of the post-exposure health evaluation.

□ The employee named above has been told about any health conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment.

□ Hepatitis B vaccination
- □ was recommended and
  - □ administered
  - □ refused
- □ is not indicated.

Signature of health care provider:_____ Date: _____

Printed/typed name of health care provider:_____

Within 15 days return this form to the employer in an envelope marked "Confidential" and provide a copy to the employee.

Employer Name:_____

Title:_____

Address:_____

This sample form is consistent with the OSHA required "Healthcare Professional's Written Opinion" 1910.1030(f)(5). The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completed evaluation.

Contents of Emergency PEP Packet

It is recommended that each facility prepare a packet or notebook of PEP materials to be made readily available to health care personnel who are responsible for initial post-exposure management. The purpose of the packet is to provide necessary information and forms required to efficiently respond to an exposure situation. Listed below are recommended contents of an emergency PEP packet.

□ **BOP Clinical Practice Guideline:** *Medical Management of Exposures.* (Extra copies of Appendices 1,2,5)	
□ **Local Facility PEP Procedures**	
□ **Inmate Forms**	
BP-A362	Inmate Injury Assessment and Follow-Up (Medical)
BP-S140	Injury Report - Inmate - Part 1 (use for work-related incidents)
BP-A489	HIV Counseling Documentation
BP-A490	HIV Pre-Testing Counseling
BP-A491	HIV Post-Test Counseling (Negative)
BP-A492	HIV Post-Test Counseling (Positive)
BP-A552	Information on Vaccine (Consent/Declination) for Hepatitis B Vaccine
BP-A621	Authorization For Release of Medical Information
Employee Forms	
BP-A758	Employee Injury Report
BP-A639	Employee Consent/Declination for HIV Post-Exposure Prophylaxis
BP-A849	Information on Vaccination (Consent/Declination) For Hepatitis B Vaccine
OF 522	Request For_____Other Procedures (generic consent form)
GSA 3590	Authorization For Release of Information (Privacy Act Statement)
General Forms	
BP-S809	Information on Vaccination (Consult/Declination) For Tetanus Vaccine
CDC	Tetanus, Diphtheria, Pertussis (Tdap) Vaccine: What you need to know Available from: http://www.cdc.gov/nip/publications/VIS/vis-tdap.pdf
Lab Slips / Blood Tubes (See schedule of tests *Appendix 6B*)	
□HIV EIA □HBsAg □HBeAg □Anti-HCV □complete blood count □liver enzymes □chemistry (BUN, alkaline phosphatase, bilirubin, creatinine kinase, amylase)	
Patient Education Materials	
CDC (pamphlet). *Exposure to blood - What health-care workers need to know, 2003.* Available from: www.cdc.gov/ncidod/dhqp/wrkrProtect_bp.html	
UCSF. *What is post-exposure prevention (HIV)?* Available from: www.caps.ucsf.edu/pubs/FS/PEP.php	
CDC. *Hepatitis B fact sheet.* Available from: http://www.cdc.gov/ncidod/diseases/Hepatitis/b/bfact.pdf	
CDC. *Hepatitis C fact sheet.* Available from: http://www.cdc.gov/ncidod/diseases/Hepatitis/c/cfact.pdf	
DHHS. *AIDSinfo Drug Database* (patient information sheets for HIV PEP drugs). Available from: http://aidsinfo.nih.gov/DrugsNew/Default.aspx?MenuItem=Drugs	
NLM/NIH. *Hepatitis B Immune Globulin*. Available from: http://www.nlm.nih.gov/medlineplus/druginformation.html.Scroll to Hepatitis B Immune Globulin	
NLM/NIH. *Tetanus Immune Globulin*. Available from: http://www.nlm.nih.gov/medlineplus/druginformation.html. Scroll to Tetanus Immune Globulin.	

Potential Bloodborne Pathogen Exposure
Summary of Recommended Follow-up of Exposed Person

Baseline

☐ **Medical and vaccine history**
☐ **HIV EIA**
☐ **Anti-HBs** (only if previous result is unavailable)
☐ **Anti-HCV**
☐ **(Females) STAT pregnancy test** if HIV PEP indicated
(unless currently menstruating, s/p hysterectomy, or post-menopausal)

Follow-Up [1]

Time from Exposure	HIV Exposure	HBV Exposure	HCV exposure
At time of exposure	**Prior to starting PEP:** CBC, AlkPhos, AST, Bili, CK, Amylase, BUN	Anti-HBs	Anti-HCV & ALT
2 weeks (if on PEP)	CBC, AlkPhos, AST, Bili, CK, Amylase, BUN	—	—
Within 15 days of medical evaluation	Health Care Professionals Written Opinion For Post-Exposure Evaluation (*Appendix 5*)		
6 weeks	HIV EIA	—	—
3 months	HIV EIA	—	—
4 months	—	—	Anti-HCV [2] & ALT
6 months	HIV EIA	—	Anti-HCV [2] & ALT
1–2 months after last HBV vaccine dose [3]	—	Anti-HBs	—
1 year (if exposed person newly infected with HCV)	HIV EIA	—	—

[1] Employees should be referred out for follow-up after urgent care provided.

[2] Confirm positive with anti-HCV with HCV RNA assay.

[3] Cannot be ascertained if HBIG given in last 6 - 8 weeks