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

Federal Bureau of Prisons

Clinical Practice Guidelines

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What's New in This Document?

Changes included in the October 2012 guidelines:

All substantive changes are highlighted in yellow. In particular:

- ***Specific guidance for management of exposures for BOP employees is no longer included in these guidelines. This guidance will be provided separately.***
- *Appendix 3, Preferred Regimens for HIV Post-Exposure Prophylaxis,* has been updated.
- Nelfinavir (Viracept®) is added to the list of medications *not* to be given to *pregnant women*.
- See *Appendix 4, "Sexual Assault and STDs," CDC 2010 Treatment Guidelines for Adults and Adolescents,* updated by the CDC in 2010 to replace the 2007 guidelines.

Changes that were made in the June 2009 version of the guidelines:

In the June 2009 version of these guidelines, the recommendations for management of exposures to hepatitis C were revised to match the 2009 update to the BOP *Clinical Practice Guidelines for the Prevention and Treatment of Hepatitis C and Cirrhosis*. Recommendations for post-exposure management of hepatitis C were revised to include:

Baseline (at time of exposure):

- Obtain anti-HCV & ALT

Four 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.

Six months post-exposure:

- If the four-month anti-HCV is negative, then obtain anti-HCV and 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.

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

Table of Contents

1. Purpose and Overview

Note: Specific guidance for management of exposures for BOP employees is no longer included in these guidelines. This guidance will be provided separately.

These BOP Clinical Practice Guidelines provide specific recommendations for medically managing potential exposures to human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), human bites, and sexual assaults. The Post-Exposure Worksheet in *Appendix 1* provides a step-wise approach to managing these exposures.

Consultation on post-exposure management is strongly recommended. Call the National Clinicians' Post-Exposure Prophylaxis Hotline (PEPline) at 1-888-448-4911 (9:00 a.m. –2:00 a.m. EST), or go their website at http://www.nccc.ucsf.edu/about_nccc/pepline/

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

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

No document on post-exposure management is complete without emphasizing that the prevention of exposures is critically important. Regular hand washing, appropriate use of protective gear such as gloves and face shields, 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 Worksheets, consent forms, and patient educational materials. Facility-specific instructions for post-exposure management should also be included.

➡ ***Any incidents involving inmate workers that are deemed to be true exposures must be reported to the Safety Office for inclusion in the OSHA 300 Log.***

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 on 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%

Source: 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):7.

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, as indicated by higher viral load.
- A deep percutaneous injury.
- Injury with a hollow-bore, blood-filled needle.
- Exposure to a source with concomitant hepatitis C viral infection.
- Sexual assault (due to mucosal trauma, multiple assailants, or traumatic intercourse).
- 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, as shown in *Table 2* below.

Table 2. Average Transmission Risk After Percutaneous Injury

Hepatitis B: HBsAg-positive/HBeAg-positive HBsAg-positive/HBeAg-negative	 37–62% 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 that 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

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

Individuals who are evaluated to have exposure 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 healthcare 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.*

Consultation on post-exposure management is strongly recommended. Call the National Clinicians' Post-Exposure Prophylaxis Hotline (PEPline) at 1-888-448-4911 (9:00 a.m. –2:00 a.m. EST), or go their website at http://www.nccc.ucsf.edu/about_nccc/pepline/

Follow Steps 1–11 below for post-exposure management, in conjunction with *Appendix 1*, *Post-Exposure Worksheet: Management of Exposed Person.* The Post-Exposure Worksheet is itself 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 exposed inmate's medical record should summarize the actions taken.

➡ ***Never record the source case's identity on the exposed person's record or worksheet.***

Step 1. *Evaluate* the Exposure

The evaluating healthcare 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 the risk of transmission, as outlined in *Table 1* and *Table 2*.

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 five minutes.
- Exposed eyes should be flushed with water or saline for five 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 *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; rectal and vaginal secretions; breast milk; 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 in the case of needles. A tattoo applied with non-sterile needles (i.e., 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 that 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 Step 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 Step 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 these BOP guidelines, 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 inmate of recent sexual assault should receive prompt forensic evaluation by a healthcare professional trained in collecting sexual assault forensic evidence. For more information on sexual exposures, see Step 9 below and the CDC guidelines on sexually transmitted disease evaluation for sexual assault in *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.

Step 2. Evaluate the Source Case

The Post-Exposure Worksheet for managing the exposed person (*Appendix 1*) refers the practitioner to a separate form for evaluating the source case (see *Appendix 2*).

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). File this record of the source case assessment in the Infection Control Office.

➡ ***Do not record the source case's identity on the exposed person's record or worksheet.***

- **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. (Ideally, perform a rapid HIV test per local policies and procedures, as well as guidance from the BOP Medical Director.)

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

Step 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**

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.

Step 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 National Clinicians' Post-Exposure Prophylaxis Hotline (PEPline) at 1-888-448-4911 (9:00 a.m. –2:00 a.m. EST), or go their website at http://www.nccc.ucsf.edu/about_nccc/pepline/

Determining the need for HIV PEP: Recommendations for PEP are based on the HIV status of the source case, and the type and conditions of the exposure. *Table 3* below is from page 2 of the Post-Exposure Worksheet for the exposed person (*Appendix 1*). The table is adapted from CDC recommendations and can be used as a clinical tool to assist in determining the need for PEP. This table should be used to identify **(1) Exposure Type** and **(2) Condition** of the exposure; then, determine the **(3) Recommendations Based on HIV status of the Source**.

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 preferred to delaying administration.

Table 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

An expanded 3-drug regimen is recommended for all nPEP when treatment is indicated (see *Appendix 3*).

nPEP is not indicated ≥ 72 hours after exposure or if behavior is either frequent or recurrent.

For the purposes of these BOP guidelines, 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/pdf/rr/rr5409.pdf and CDC. *MMWR*. 2005;54(No. RR-2) at http://www.cdc.gov/mmwr/PDF/rr/rr5402.pdf

Preferred regimens for HIV PEP: 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*.

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

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

➡ Enfurvitide (Fuzeon®; T20) and nevirapine (Viramune®; NVP) should not be included in PEP regimens, *except with expert consultation*, because of serious reported side effects.

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

Post-exposure follow-up: 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, in consultation with the PEPline. 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 and nelfinavir, 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 agents that might be included in a PEP regimen, is a concern when making decisions about PEP. It is unknown if drug resistance has an influence on transmission risk.

  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. 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, these drugs should be avoided and alternate drugs should be used. Always obtain expert consultation if drug resistance is known or suspected.
- **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.

Step 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.)

Table 4 below is from the Post-Exposure Worksheet for the exposed person (see page 3 of *Appendix 1*). 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.

Table 4. 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:[1] *If responder:* no treatment *If non-responder:* HBIG x 1 ***and*** vaccine booster[3]	No treatment	Test for anti-HBs:[1] *If responder:* no treatment *If non-responder:* vaccine booster ***and*** re-check anti-HBs in 1–2 months

[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.

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

There is no known effective prophylaxis for persons exposed to an HCV-positive source. If the source is anti-HCV positive or unknown, the following is the recommended follow-up schedule for the exposed person:

- ***Baseline (at time of exposure):*** Obtain anti-HCV and ALT.
- ***4 months post-exposure:*** Obtain anti-HCV and 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 and 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.

Step 7. Determine Need for Tetanus Vaccine

For "clean" wounds, a tetanus booster is not indicated. An example of a clean wound is when an individual 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, the exposed person should be evaluated as follows:

- **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 indicated if the person is not known to have received it previously, to 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

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

Individuals with human bite wounds have a high risk of serious bacterial infections; close monitoring of the wound is therefore 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 for five days with clindamycin (450 mg three times daily) together with *either* ciprofloxacin (500 mg twice daily) *or* sulfamethoxazole/ trimethoprim (800/160 mg twice daily).

Individuals who develop cellulitis or other serious skin or soft tissue infection following a human bite should be referred urgently for IV antibiotics.

Step 9. (Sexual exposures only) Conduct Screening for STDs

Any allegation made by an individual of recent sexual assault should receive prompt forensic evaluation by a healthcare professional trained in collecting sexual assault forensic evidence. Evaluation for sexually transmitted diseases should be based on the CDC 2010 STD Treatment Guidelines (see *References* page). 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, type of exposure, and likelihood of follow-up (e.g., potential for release during the incubation period.) Follow BOP policy and reporting requirements, as appropriate.

Step 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. *Table 5* below outlines risk behaviors that should be avoided, depending on the source case status.

Table 5. Educational Messages to Prevent Transmission

Behaviors/Conditions	HIV Exposure	HBV Exposure	HCV Exposure
Unprotected sex	Avoid	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.

Step 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. The Safety Office must include in the OSHA 300 Log any worker incidents deemed to be true exposures (including those involving inmate workers).
- 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.

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):1–19. Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5402.pdf

CDC. Updated information regarding antiretroviral agents used as HIV postexposure prophylaxis for occupational HIV exposures. *MMWR.* 2007;56(No.49):1291–1292. Available from: http://www.cdc.gov/mmwr/pdf/wk/mm5649.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):1–17. Available at: http://www.cdc.gov/mmwr/pdf/rr/rr5409.pdf

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 at: http://www.cdc.gov/MMWR/preview/MMWRhtml/rr5011a1.htm

DHHS, HRSA, HIV/AIDS Bureau. Health care maintenance and disease prevention (section 3). In: *Guide for HIV/AIDS Clinical Care*; 2011. Available at: http://hab.hrsa.gov/deliverhivaidscare/clinicalguide11/.

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 at: 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 at: http://www.cdc.gov/mmwr/pdf/rr/rr5517.pdf

Human Bites

Gilbert DN, Moellering RC, Eliopoulos GM, Sande MA, eds. 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;37:1481–1489.

Sexually Transmitted Diseases

CDC. Sexually transmitted diseases treatment guidelines, 2010. *MMWR.* 2010;59(No. RR-12):1–119. Available at http://www.cdc.gov/mmwr/pdf/rr/rr5912.pdf .

Appendix 1: Post-Exposure Worksheet – Management of Exposed Person

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

****** Optional Form. File in Infection Control Office.******

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	

Step 1. Evaluate the Exposure

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

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

_____

_____

c. Exposure occurred while individual was: ☐ working ☐ 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 of this form.

If yes, check **exposure type** above as follows:

- ▸ 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!**

Step 2. Evaluate the Source Case

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

Step 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/m l)

☐ Non-Responder (anti-HBs < 10m IU/ml)

☐ Unknown response status

Other medical conditions: _____

Current medications: _____

Drug allergies: _____

Post-Exposure Worksheet: Management of Exposed Person (Page 2 of 4)

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

Step 4. Determine Need for HIV PEP ☐ NA

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*.

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

An expanded 3-drug regimen is recommended for all nPEP when treatment is indicated (see *Appendix 3*).

nPEP is not indicated ≥ 72 hours after exposure or if behavior is either frequent or recurrent.

For the purposes of these BOP guidelines, 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/pdf/rr/rr5409.pdf and CDC. *MMWR*. 2005;54(No. RR-2) at http://www.cdc.gov/mmwr/PDF/rr/rr5402.pdf

b. Expert consultation is recommended whenever managing exposures. The National Clinician's Post-Exposure Prophylaxis Hotline (PEPline) is available at 888-448-4911, 9 a.m. to 2 a.m. EST; find helpful information online at http://www.nccc.ucsf.edu/about_nccc/pepline/. Definitely seek consultation if delay is more than 36 hrs., or if the source case is drug-resistant. For exposures related to sex or injection drug use, nPEP should not be started after 72 hrs.

PEPline Consultation: Date: __/__/__ Time: _____ Recommendations: _____

c. Summarize actions taken, based on evaluation of 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: _____

Post-Exposure Worksheet: Management of Exposed Person (Page 3 of 4)

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

Step 5. Determine Need for Hepatitis B PEP ☐ NA

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:[1] *If responder:* no treatment *If non-responder:* HBIG x 1 ***and*** vaccine booster [3]	No treatment	Test for anti-HBs:[1] *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: ____/____/____

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

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-months post-exposure:** Date: ___/___/___ Anti-HCV _____ ALT:_____. If anti-HCV (+), obtain HCV RNA.
- **6-months post-exposure:** Date: ___/___/___ Anti-HCV _____ ALT:_____. If anti-HCV (+), obtain HCV RNA.

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

Step 7. Determine Need for Tetanus Vaccine ☐ NA

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.*

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

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

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.

Recommended prophylaxis (prior to S/S of infection)**:** Amoxicillin/clavulanate 875/125 mg po 2x daily x 5 days
(If penicillin allergy, treat for 5 days with: clindamycin (450 mg 3x daily) *plus either* ciprofloxacin (500 mg 2x daily) *or* sulfamethoxazole/trimethoprim (800/160 mg 2x daily).
If signs and symptoms of cellulitis or soft tissue infection develop, refer urgently for IV antibiotic treatment.

Step 9. (Sexual exposures only) Conduct STD Screening ☐ NA

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

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

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

Step 10. Provide Counseling, Education, and Referral ☐ NA

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)

☐ **Referred for counseling to:** _____

☐ **Determined 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.*

Step 11. Complete Reporting and Documentation ☐ NA

Check off the following actions when you complete them:

- ☐ Report incident to supervisor as soon as possible.
- ☐ Give incident report to Safety Office, which must include in the OSHA 300 Log any incident deemed to be a worker exposure (including that of inmate workers).
- ☐ Report incident to Infection Control Office.
- ☐ Analyze exposure incident.

Healthcare Provider Signature: _____ **Date:**___/___/___

Appendix 2: Post-Exposure Worksheet – Assessment of Source Case

Post-Exposure Worksheet: Assessment of Source Case

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

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

Exposure type: ☐ percutaneous ☐ mucous membrane ☐ non-intact skin ☐ sexual ☐ injection drug use

Last name:	**First:**	**Initial:**
Registration #:	**Date of birth:** _____/____ /_____	**Sex:** ☐ male ☐ female
Location:		

Laboratory Results

For the source case, obtain previous and current test results. Ideally use 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: ___/___/____ ____ cells/mm^3 Most recent viral load: ___/___/____ ____ cps/ml

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

HIV Status of Source Case 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:_____

Healthcare Provider Signature: _____ **Date:**___/___/___

Appendix 3: Preferred Regimens for HIV Post-Exposure Prophylaxis

Treatment is prescribed on a case-by-case basis in consultation with the PEPline (888-448-4911, 9 a.m.–2 a.m. EST). *Preferred PEP and nPEP regimens and dosing are listed below. The BOP recommends utilizing combination medications for PEP, so the options listed below primarily involve the use of combination drugs. In general, a preferred regimen should be utilized unless there is a reason not to, such as a drug-resistant source case.* ***Generally, PEP is administered for 28 days.*** *For alternative regimens and information about side effects, consult the DHHS guidelines referenced below.*

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

Basic Regimen	***2-Drug Nucleoside Reverse Transcriptase Inhibitors (NRTIs):*** • Truvada® one tablet once daily ***or*** • Combivir® one tablet twice daily
Preferred Expanded Regimen	**Basic Regimen (above) plus:** Kaletra® two tablets twice daily
Alternative Expanded Regimens	• **Basic Regimen (above) plus:** Atazanavir***** 300 mg **and** ritonavir 100 mg once daily ***or*** • **Basic Regimen (above) plus:** Darunavir 800 mg **and** ritonavir 100 mg once daily ***or*** • **Combivir® one tablet twice daily plus:** Atazanavir***** 400 mg once daily

*******Do not use with proton pump inhibitors, e.g., omeprazole. Unboosted atazanavir (i.e., atazanavir without ritonavir) should not be used in combination with tenofovir or Truvada®.*

nPEP Regimens *(for sexual exposures, sharing IDU needles)*

Preferred nPEP Regimen	• **Basic Regimen (above) plus:** Kaletra® two tablets twice daily
Alternative nPEP Regimens	• **Basic Regimen (above) plus:** Darunavir 800mg **and** ritonavir 100mg once daily ***or*** • **Basic Regimen (above) plus:** Atazanavir***** 300 mg **and** ritonavir 100 mg once daily ***or*** • **Combivir® one tablet twice daily plus:** Atazanavir***** 400 mg once daily

*******Do not use with proton pump inhibitors, e.g., omeprazole. Unboosted atazanavir (i.e., atazanavir without ritonavir) should not be used in combination with tenofovir or Truvada®.*

Combination Drug Dosing

Trade Name	*Generic Name(s)/Dosage Form*	*Frequency*
Truvada®	emtricitabine 200 mg ***and*** tenofovir 300 mg	one tablet once daily
Combivir®	zidovudine 300 mg ***and*** lamivudine 150 mg	one tablet twice daily
Kaletra®	lopinavir 200 mg ***and*** ritonavir 50 mg	two tablets twice daily

Agents *Not* Recommended for PEP or nPEP

The following agents are not recommended for PEP or nPEP:
- abacavir
- delavirdine
- zalcitabine
- didanosine combined with stavudine

The following agents should be administered only with expert consultation, due to reports of serious side effects:
- enfurvitide
- nevirapine

The following agents should not be administered to pregnant (known or suspected) women:
- efavirenz
- nelfinavir (Viracept®)

Patient Information Sheets on HIV PEP Drugs

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

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

DHHS, HRSA, HIV/AIDS Bureau. Health care maintenance and disease prevention (section 3). In: *Guide for HIV/AIDS Clinical Care*; 2011. Available at: http://hab.hrsa.gov/deliverhivaidscare/clinicalguide11/

Appendix 4: "Sexual Assault and STDs," CDC 2010 Treatment Guidelines for Adults and Adolescents

The following is abstracted from the CDC's 2010 Sexually Transmitted Disease Treatment Guidelines.
Source: Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines, 2010. MMWR. 2010;59 (No. RR-12):90–95. Available at: http://www.cdc.gov/mmwr/pdf/rr/rr5912.pdf as a pdf file or online at http://www.cdc.gov/std/treatment/2010/sexual-assault.htm.

The recommendations in this report are limited to the identification, prophylaxis, and treatment of STDs and conditions commonly identified in the management of such infections. The documentation of findings, collection of nonmicrobiologic specimens for forensic purposes, and 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 also is enforced in most states. Although it rarely occurs, STD diagnoses might later be accessed, and the survivor and clinician might opt to defer testing for this reason. While collection of specimens at initial examination for laboratory STD diagnosis gives the survivor and clinician the option to defer empiric prophylactic antimicrobial treatment, compliance with follow up visits is traditionally poor. Among sexually active adults, the identification of an STD might represent an infection acquired prior to the assault, and therefore might be more important for the psychological and medical management of the patient than for legal purposes.

Trichomoniasis, BV, gonorrhea, and chlamydial infection are the most frequently diagnosed infections among women who have been sexually assaulted. Such conditions are relatively prevalent, and the presence after an assault does not necessarily imply acquisition during the assault. However, a postassault examination presents an important opportunity to identify or prevent STDs. Chlamydial and gonococcal infections in women are of particular concern because of the possibility of ascending infection. In addition, HBV infection can be prevented by postexposure administration of hepatitis B vaccine. Reproductive-aged female survivors should be evaluated for pregnancy, if appropriate.

Evaluating Adults and Adolescents for Sexually Transmitted Diseases

Initial Examination

An initial examination might include the following procedures:

- NAATs for *C. trachomatis* and *N. gonorrhoeae*. These tests are preferred for the diagnostic evaluation of sexual assault victims, regardless of the sites of penetration or attempted penetration.
- Wet mount and culture or point-of-care testing of a vaginal-swab specimen for *T. vaginalis* infection. The wet mount also should be examined for evidence of BV and candidiasis, especially if vaginal discharge, malodor, or itching is evident.
- A serum sample for immediate evaluation for HIV infection, hepatitis B, and syphilis. Decisions to perform these tests should be made on an individual basis.

Follow-Up Examinations

After the initial postassault examination, follow-up examinations provide an opportunity to:

- Detect new infections acquired during or after the assault.
- Complete hepatitis B vaccination, if indicated.
- Complete counseling and treatment for other STDs.
- Monitor side effects and adherence to postexposure prophylactic medication, if prescribed.

Examination for STDs can 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 can 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 can 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 *Risk for Acquiring HIV Infection below*).

Prophylaxis

Compliance with follow-up visits is poor among survivors of sexual assault. As a result, routine preventive therapy after a sexual assault should be encouraged. The following prophylactic regimen is suggested as preventive therapy:

- Postexposure hepatitis B vaccination, without HBIG. This vaccine should be administered to sexual assault survivors 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, and trichomonas.
- Emergency contraception. (This measure is necessary only when the assault could result in pregnancy in the survivor.)

Recommended Regimens

- **Ceftriaxone** 250 mg IM in a single dose ***OR*** **Cefixime** 400 mg orally 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 those requiring alternative treatments, refer to the specific 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.

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.

Risk for Acquiring HIV Infection

HIV seroconversion has occurred in persons whose only known risk factor was sexual assault or sexual abuse, but the frequency of this occurrence is probably low. In consensual sex, the risk for HIV transmission from vaginal intercourse is 0.1%–0.2% and for receptive rectal intercourse, 0.5%–3%. The risk for HIV transmission from oral sex is substantially lower. Specific circumstances of an assault (e.g., bleeding, which often accompanies trauma) might increase risk for HIV transmission in cases involving vaginal, anal, or oral penetration.

Site of exposure to ejaculate, viral load in ejaculate, and the presence of an STD or genital lesions in the assailant or survivor also might increase the risk for HIV.

Postexposure therapy with zidovudine was associated with a reduced risk for acquiring HIV in a study of health-care workers who had percutaneous exposures to HIV-infected blood. On the basis of these results and the results of animal studies, PEP has been recommended for health-care workers who have occupational exposures to HIV. These findings have been extrapolated to other types of HIV exposure, including sexual assault. If HIV exposure has occurred, initiation of PEP as soon as possible after the exposure likely increases benefit. Although a definitive statement of benefit cannot be made regarding PEP after sexual assault, the possibility of HIV exposure from the assault should be assessed at the time of the postassault examination. The possible benefit of PEP in preventing HIV infection also should be discussed with the assault survivor if the assault poses a risk for HIV exposure.

Several factors impact the medical recommendation for PEP and affect the assault survivor's acceptance of that recommendation, including 1) the likelihood of the assailant having HIV, 2) any exposure characteristics that might increase the risk for HIV transmission, 3) the time elapsed after the event, and 4) the potential benefits and risks associated with the PEP. Determination of the assailant's HIV status at the time of the assault examination usually is not possible. Therefore, the health-care provider should assess any available information concerning 1) characteristics and HIV risk behaviors of the assailant(s) (e.g., a man who has sex with other men and persons who use injection drugs or crack cocaine), 2) local epidemiology of HIV/AIDS, and 3) exposure characteristics of the assault. When an assailant's HIV status is unknown, factors that should be considered in determining whether an increased risk for HIV transmission exists include 1) whether vaginal or anal penetration occurred; 2) whether ejaculation occurred on mucous membranes; 3) whether multiple assailants were involved; 4) whether mucosal lesions are present in the assailant or survivor; and 5) any other characteristics of the assault, survivor, or assailant that might increase risk for HIV transmission.

If PEP is offered, the following information should be discussed with the patient: 1) the unproven benefit and known toxicities of antiretrovirals; 2) the importance of close follow-up; 3) the benefit of adherence to recommended dosing; and 4) the necessity of early initiation of PEP to optimize potential benefits (i.e., as soon as possible after and up to 72 hours after the assault). Providers should emphasize that PEP appears to be well-tolerated in both adults and children and that severe adverse effects are rare. Clinical management of the survivor should be implemented according to the following guidelines. Specialist consultation on PEP regimens is recommended if HIV exposure during the assault was possible and if PEP is being considered. The sooner PEP is initiated after the exposure, the higher the likelihood that it will prevent HIV transmission if HIV exposure occurred; however, distress after an assault also might prevent the survivor from accurately weighing exposure risks and benefits of PEP and from making an informed decision to start such therapy. If use of PEP is judged to be warranted, the survivor should be offered a 3–5-day supply of PEP, and a follow-up visit should be scheduled several days later to allow for additional counseling.

Recommendations for Postexposure Assessment of Adolescent and Adult Survivors Within 72 Hours of Sexual Assault

- Assess risk for HIV infection in the assailant.
- Evaluate characteristics of the assault event that might increase risk for HIV transmission.
- Consult with a specialist in HIV treatment, if PEP is being considered.
- If the survivor appears to be at risk for HIV transmission from the assault, discuss antiretroviral prophylaxis, including toxicity and lack of proven benefit.
- If the survivor chooses to start antiretroviral PEP, provide enough medication to last until the next return visit; reevaluate the survivor 3–7 days after initial assessment and assess tolerance of medications.
- If PEP is started, perform CBC and serum chemistry at baseline (initiation of PEP should not be delayed, pending results).
- Perform HIV antibody test at original assessment; repeat at 6 weeks, 3 months, and 6 months.

Appendix 5: OSHA Bloodborne Pathogens Standard

The section of the OSHA bloodborne pathogen standard that covers post-exposure management is printed below. It should be provided to all healthcare professionals evaluating workers who sustain potential exposures to bloodborne pathogens. The text for the entire standard, as well as other informational materials, are available at: http://www.osha.gov/SLTC/bloodbornepathogens/index.html.

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

Occupational Safety and Health Administration (OSHA)

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)(C) **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)(C) 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)(C) **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.

Appendix 6a: 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 healthcare 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 Guidelines:** *Medical Management of Exposures.*
(including extra copies of Appendices 1, 2, 5)

☐ **Local Facility PEP Procedures**

☐ **Inmate Forms**

BP-A0362	Inmate Injury Assessment and Follow-Up (Medical)
BP-A0140	Injury Report - Inmate - Part 1 (use for work-related incidents)
BP-A0489	HIV Counseling Documentation
BP-A0490	HIV Pre-Testing Counseling
BP-A0491	HIV Post-Test Counseling (Negative)
BP-A0492	HIV Post-Test Counseling (Positive)
BP-A0621	Authorization For Release of Medical Information

☐ **Lab Slips / Blood Tubes** (see schedule of tests in *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 Healthcare Personnel Need to Know, 2003.* Available at: http://www.cdc.gov/ncidod/dhqp/pdf/bbp/Exp_to_Blood.pdf
- UCSF. *What is post-exposure prevention (PEP)?* (and other fact sheets in English and Spanish) Available at: http://caps.ucsf.edu/resources/fact-sheets
- CDC. Hepatitis B Fact Sheets. Available at: http://www.cdc.gov/hepatitis/B/PatientEduB.htm#cdc
- CDC. Hepatitis C Fact Sheets. Available at http://www.cdc.gov/hepatitis/HCV/PatientEduHCV.htm#cdc
- DHHS. AIDSinfo Drug Database. (patient information sheets for HIV PEP drugs). Available at: http://aidsinfo.nih.gov/DrugsNew/Default.aspx?MenuItem=Drugs
- NLM/NIH. *Hepatitis B Immune Globulin*. Available at: http://www.nlm.nih.gov/medlineplus/druginformation.html.
- NLM/NIH. *Tetanus Immune Globulin*. Available at: http://www.nlm.nih.gov/medlineplus/druginformation.html.

Appendix 6b: 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

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	—	—
6 weeks	HIV EIA	—	—
3 months	HIV EIA	—	—
4 months	—	—	Anti-HCV[1] & ALT
6 months	HIV EIA	—	Anti-HCV[1] & ALT
1–2 months after last HBV vaccine dose[2]	—	Anti-HBs	—
1 year (if exposed person newly infected with HCV)	HIV EIA	—	—

[1] Confirm positive with anti-HCV with HCV RNA assay.
[2] Cannot be ascertained if HBIG given in last 6–8 weeks