MEDICAL MANAGEMENT OF EXPOSURES: HIV, HBV, HCV, HUMAN BITES, AND SEXUAL EXPOSURES

Federal Bureau of Prisons

Clinical Guidance

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WHAT'S NEW IN THIS DOCUMENT?

Changes included in the April 2017 guidelines:

- Specific guidance for management of exposures for BOP employees is provided in *PS 6130.01 Medical Management of Staff Exposures to Bloodborne Pathogens*.
- Guidance related to postexposure testing for hepatitis C has been updated to reflect the most recent CDC guidance. See *Section 3, Step 6*.
- Recommended HIV PEP regimens have been updated to reflect the most recent CDC guidance. See *Appendix 3.*
- Rapid HIV testing of source cases is *preferred* in order to facilitate timely decision-making regarding the need for HIV PEP.
- Recommended lab monitoring related to HIV PEP has changed. See *Appendix 5*.
- A table has been added on interpretation of Hepatitis B virus serologies. See *Table 4*.
- Refer to the CDC 2015 STD Treatment Guidelines for specific guidance regarding sexual assault and evaluation for sexually transmitted infections. See the *References* section.
- Consultation with the PEPline (1-888-448-4911) is *recommended* when available. PEPline hours have changed. See *Section 3*.
  - *For more information, go to their website, which also posts a PEP Quick Guide with FAQs: http://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/*

Changes included in the March 2014 guidelines:

- Revisions were made to reflect the updated 2013 guidance from the U.S. Public Health Service on managing exposures to HIV (see the *References* section). USPHS guidelines now recommend 3-drug HIV PEP for all exposures to HIV, regardless of the severity of the exposure. Emtricitabine *plus* tenofovir (may be dispensed as Truvada) *plus* raltegravir is recommended as HIV PEP for exposures to HIV unless otherwise contraindicated (e.g., known antiretroviral resistance, preexisting renal disease).
- Rapid HIV testing should be available at each institution to test source cases in exposure incidents, in order to facilitate timely decision making regarding the need for HIV PEP after exposure to sources whose HIV status is unknown.
- Revisions were made to reflect the December 2013 guidance from the CDC on managing exposures to hepatitis B virus (see *References* section). In particular, *STEP 5* of *Postexposure Management* was updated, and a new appendix was added. *Appendix 6* provides detailed guidance on HBV postexposure management, based on the hepatitis B vaccination status of the exposed person.

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1. PURPOSE AND OVERVIEW

➔ *Specific guidance for management of exposures for BOP employees is provided in PS 6130.01 Medical Management of Staff Exposures to Bloodborne Pathogens.*

This *BOP Clinical Guidance for the Medical Management of Exposures* is based on the recommendations of the U.S. Public Health Service (**USPHS**) and the Centers for Disease Control and Prevention (**CDC**), as well as the Occupational Safety and Health Administration (**OSHA**) *Bloodborne Pathogen Standard (1910.1030).* This guidance provides specific recommendations for medically managing BOP inmates who have experienced potential exposures to human immunodeficiency virus (**HIV**), hepatitis B virus (**HBV**), or hepatitis C virus (**HCV**) through various means, including human bites and sexual exposures.

➔ *The information in Section 3, **Steps in Postexposure Management**, can be used in conjunction with the **Postexposure Worksheet** in Appendix 1.*

BLOODBORNE PATHOGEN EXPOSURE CONTROL PLAN (ECP)

- **Each institution's ECP should address specific administrative, personnel, and medical procedures for implementing this guidance.** The plan should include recommendations for the following: preventing exposures to blood and body fluids; prompt reporting and management of possible exposures; expert consultation; HIV testing to determine the HIV status of the source case; and providing immediate availability of antiretroviral medications to treat individuals with HIV exposures, as well as treatment for virologic, immunologic, and serologic signs of infection.

  ➔ *Program Statement 6190.04 requires that BOP facilities annually update an ECP that meets OSHA requirements. An optional fill-in-the-blank ECP template is available on Sallyport, Bureau's internal website.*

- The institution's routine orientation and training for inmate workers should cover the local procedures for providing HIV and HBV postexposure management.

TERMINOLOGY: "PEP" VS. "OPEP" VS. "NPEP"

The CDC has published separate and distinct guidelines for managing occupational and non-occupational HIV exposures. The CDC recommendations use different acronyms to identify two types of postexposure prophylaxis (**PEP**): **OPEP** 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. The BOP guidance for HIV postexposure management, therefore, adapts the USPHS and CDC guidelines without regard to the exposed person's occupational status. For example, common sense dictates that clinical management of human bites in the correctional setting be the same, whether the circumstances are occupational or non-occupational.

➔ *All references to **postexposure prophylaxis** in this guidance, whether derived from nPEP or oPEP source guidelines, will be referred to as **PEP** for the reasons described above.*

PREVENTION AND RISK MANAGEMENT

No document on postexposure 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.

Emergency PEP packet: It is recommended that each facility develop a PEP packet or notebook that is readily available for emergency use. See *Appendix 4* for a checklist of the recommended contents of the packet, including copies of the ***Postexposure Worksheets*** (*Appendix 1* and *Appendix 2*) and consent forms. Facility-specific instructions for postexposure management should also be included in the packet.

➔ *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

The risk of viral transmission from an exposure incident depends on the type and extent of the exposure.

TRANSMISSION RISKS FOR HIV

The per-incident transmission risk for HIV infection depends on the type of exposure, as shown in ***Table 1*** below.

➔ *It is worth noting that repeated exposure to even low-risk behaviors can increase the likelihood of transmission over time.*

TABLE 1. ESTIMATED PER-INCIDENT RISK FOR ACQUISITION OF HIV, BY EXPOSURE ROUTE

Estimated Per-Incident Risk for Acquisition of HIV *(risk per 10,000 exposures)*			
Receptive anal intercourse	138	Receptive penile-vaginal intercourse	8
Needle-sharing (injection drug use)	63	Insertive penile-vaginal intercourse	4
Percutaneous needle stick	23	Receptive oral intercourse	low
Insertive anal intercourse	11	Insertive oral intercourse	low

Note: *The following types of exposure have negligible risk of transmitting HIV: biting, spitting, throwing/splashing bodily fluids, sharing sex toys.*

Source: *CDC. Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act (2016). https://www.cdc.gov/hiv/risk/estimates/riskbehaviors.html*

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 higher viral loads, which usually occurs in acute or uncontrolled late-stage HIV infection.
- 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

RISKS AFTER PERCUTANEOUS EXPOSURE: HBV, HCV AND HIV

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*	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 are very unlikely to result in transmission of HIV or HBV infection.**
- **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 POSTEXPOSURE MANAGEMENT

➔ **PEPLINE consultation on postexposure management is recommended when it is available.**

Call the PEPline: 1-888-448-4911, 9:00 a.m.–9:00 p.m., ET, 7 days/week.

The postexposure prophylaxis hotline is operated by the UCSF Clinician Consultation Center. For more information, go to their website, which also posts a ***PEP Quick Guide*** *with FAQs:*

http://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/

Evaluation of a reported "exposure" often reveals that no clinically significant exposure has actually occurred (e.g., contact of intact skin with blood). The individuals should be counseled that this type of incident has a negligible risk of transmission, and that no further follow-up is needed.

Individuals who are evaluated as having been exposed to bloodborne pathogens should be provided with emergent care, evaluation, and, if indicated, treatment with postexposure medications. A follow-up evaluation by a qualified healthcare professional should also be obtained.

➔ ***Prompt evaluation of both the exposed person and the source case is essential. If HIV PEP is indicated, it is optimal to administer it as soon as possible, preferably within hours rather than days, of the exposure incident.***

Follow STEPS 1–11 below for postexposure management, in conjunction with *Appendix 1*, *Postexposure Worksheet: Management of Exposed Person*, and other appendices noted below.

- This optional worksheet is designed to help personnel keep track of the steps involved in postexposure management. If utilized, it 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 medical records/worksheet.***

STEP 1. Evaluate the potential exposure.

All inmates who have come into direct contact with blood or potentially infectious body fluids should be evaluated for potential exposure risk. The evaluating healthcare professional should interview the potentially exposed person to obtain details about the 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*** above.

a. Describe the exposure site and the 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 freely for 30 seconds. Pressure should then be applied to stop bleeding and bandage as necessary. 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 at least two minutes.
- Exposed eyes should be flushed with water or saline for at least 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. Check (✓) whether the exposure occurred when the exposed person was working *or* not working.

d. Check (✓) the type(s) of body fluid(s) involved.

- **Potentially infectious body fluids are those that can spread bloodborne pathogens, including:** blood; tissue; 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, including:** 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. Check (✓) the type(s) of exposure 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., chapped, 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.
  - 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.
- **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 guidance, only receptive anal or vaginal intercourse are generally considered exposures that should be considered for PEP (except in cases involving 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, available at: *https://www.cdc.gov/std/tg2015/sexual-assault.htm*.

- **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 *Postexposure 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). **Obtain HIV, HbsAg, and anti-HCV of the source case if current status is unknown.** Management of HIV, HBV, and HCV infection in the source should be addressed in accordance with the respective BOP clinical guidance.

➔ *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 medical record or worksheet.***

GENERAL PRINCIPLES

- **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. Past resistance test results, if available, should be reviewed with expert consultation. 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.
  - **Whenever the source case is known, the HIV status of that person should be determined to guide appropriate use of HIV PEP.** Rapid HIV testing is preferred in order to facilitate timely decision-making regarding the need for HIV PEP after exposure to sources whose HIV status is unknown. FDA-approved rapid tests can produce reliable test results within 30 minutes.
  - **Administration of PEP, if indicated, should not be delayed while awaiting test results.** If the source patient is determined to be HIV negative, PEP should be discontinued, and no follow-up HIV testing for the exposed patient is indicated.
- **If anti-HCV is positive, then obtain quantitative HCV RNA to assess for HCV infection.**

STEP 3. Evaluate the health status of the exposed person.

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

- **HIV:** Determine HIV infection status preferably by using rapid combined Ag/Ab, or antibody blood tests.
- **HBsAg**
- **Anti-HBs:** Obtain if the individual previously completed hepatitis B (HepB) vaccination series (or vaccination status is uncertain) *and* if post vaccination anti-HBs test results are unavailable.
- **Total Anti-HBc:** Obtain if post-vaccination anti-HBs < 10 mIU/mL, or if the individual either was not vaccinated ***or*** was incompletely vaccinated.
- **Anti-HCV:** Obtain quantitative HCV RNA if anti-HCV positive.

Other medical assessments:

- **Assess vaccination status for tetanus.**
- **Vaccination status for HepB:** If available, record dates of HepB vaccination and results of vaccine response testing. Persons with anti-HBs ≥ 10 mIU/ml after ≥ 3 vaccine doses are considered responders and immune; those with anti-HBs < 10 mIU/ml after ≥ 6 vaccine doses are non-responders and potentially susceptible. Persons with unknown HepB vaccine response status should be tested for anti-HBs.
- **Pregnancy testing:** 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.
- **Other information:** Record other medical conditions, current medications, and drug allergies.

STEP 4. Determine the need for HIV PEP and follow-up.

a. Expert consultation is recommended when managing exposures to HIV, HBV, and HCV.

Call the PEPline: 1-888-448-4911, 9:00 a.m.–9:00 p.m., ET, 7 days/week.

The postexposure prophylaxis hotline is operated by the UCSF Clinician Consultation Center. For more information, go to their website, which also posts a ***PEP Quick Guide*** *with FAQs:*

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b. Assess 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 adapted from USPHS/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**.

TABLE 3. RECOMMENDATIONS FOR HIV PEP, BASED ON EXPOSURE

1. Exposure Type	2. Condition	3. Recommendations Based on HIV Status of the Source	
		HIV+	HIV Status Unknown
Percutaneous (includes illicit tattoo)	Any severity	PEP	Consider PEP**
Mucous membrane	Small volume	PEP	Generally no PEP
	Large volume	PEP	Consider PEP**
Non-intact skin	Small volume	PEP	Generally no PEP
	Large volume	PEP	Consider PEP**
Sexual* (≤72 hrs/ not recurrent)	Receptive anal or vaginal sex	PEP	Consider PEP**
	Other sexual exposure	PEP generally not recommended	PEP not recommended
Sharing IDU equip*	≤72 hrs/not recurrent	PEP	Consider PEP**

* ***PEP is generally not indicated > 72 hours after exposure or if behavior is either frequent or recurrent.*** PEP may be considered after longer intervals (e.g., one week) on a case-by-case basis for exposures that represent an extremely high risk of transmission.

** PEP determination is made on a case-by-case basis by assessing the risk of exposure (see ***Table 1***). If the risk associated with the exposure is high, it is recommended that PEP be started and then a decision be made whether to continue PEP after the source's HIV status is determined. ***Expert consultation in these situations is strongly recommended.***

Adapted from:

USPHS. Updated USPHS guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis**.** *Infect Control Hosp Epidemiol*. 2013;34(9):875–892. Available at: *http://www.jstor.org/stable/10.1086/672271*

CDC. Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016. Available via: *https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf*

c. Prescribe and manage HIV PEP regimen.

► **GENERAL PRINCIPLES:**

- See *Appendix 3* for preferred regimens for HIV PEP.
- **PEP should be initiated as soon as possible**, preferably within hours of exposure.
- **HIV PEP** should be prescribed as a 28-day course of a 3-drug antiretroviral regimen.
- **Consultation with a BOP pharmacist or physician** with expertise in HIV PEP, as well as antiretroviral medication drug interactions and adverse effects, is strongly encouraged.
- **Counseling of exposed individuals:** Individuals exposed to a known or suspected HIV-infected source case should be counseled about the need for a 28-day PEP regimen to be initiated promptly. Exposed individuals should also be counseled to avoid behaviors by which they could transmit the organism to another person (see *STEP 10* below.)
- **Caution:** Newer antiretroviral agents are better tolerated than those previously used, and have preferable toxicity profiles. However, they still can be associated with severe side effects and are not justified for exposures that pose a negligible risk for transmission.

► **MONITORING AND MANAGEMENT OF PEP TOXICITY:**

- **Monitoring for toxicities:** Monitoring exposed individuals on PEP is recommended at baseline and again at two weeks after starting PEP, including at least a serum creatinine and ALT/AST. If a protease inhibitor (PI) is utilized, monitoring for hyperglycemia should be considered for diabetic patients. If toxicities are identified, modification of the regimen should be considered after expert consultation.
- **Patient education:** Patients should be informed about measures that may assist in minimizing the side effects of PEP and about the methods of clinical monitoring for toxicity during the follow-up period. Patients should be advised that certain symptoms should be reported immediately to their health care provider—e.g., fever, rash, back or abdominal pain, pain on urination or blood in the urine, dark urine, yellowing of the skin or whites of the eyes, or symptoms of hyperglycemia.

► **POSTEXPOSURE FOLLOW-UP:**

➔ ***All individuals with exposure to HIV should receive follow-up counseling, postexposure testing, and medical evaluation—regardless of whether they receive PEP*.**

- **Signs and symptoms of HIV:** At the initial visit, patients should be instructed to be alert for signs and symptoms associated with acute (primary) HIV infection—fever, fatigue, myalgia, skin rash, headache, pharyngitis, cervical adenopathy, arthralgia, night sweats and diarrhea. Signs or symptoms that develop (especially fever and rash) during or after PEP is completed should be evaluated.
- **HIV-antibody testing:** If the baseline HIV test is negative, follow-up HIV-antibody testing should be performed at the following intervals: 6 weeks, 12 weeks, and 6 months after the exposure date. 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:**

While expert consultation via the PEPLINE regarding provision of HIV PEP is generally advised, it is considered particularly important in the following special situations:

- **Delayed initiation of HIV PEP:**

  When indicated, HIV PEP for percutaneous, mucous membrane, and non-intact skin exposures should be administered as soon as possible after exposure. If initiation of PEP is delayed, the likelihood increases that benefits might not outweigh the risks inherent in taking antiretroviral medications. The maximum time interval after which PEP provides no benefit is unknown. ***Decisions regarding initiating PEP more than 72 hours after exposure ended are made on a case-by-case basis in consultation with an expert.*** Initiating therapy after a longer interval (e.g., 1 week) might still be considered for exposures that represent an extremely high risk of transmission.

  HIV PEP for sexual and injection drug use related exposures is generally not recommended after 72 hours. PEP is not recommended for cases of ongoing sexual or injection drug use exposures.

- **Unknown source (e.g., needle in a sharps container/tattoo needles):** In such cases, 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. However, expert consultation should be sought in all cases in which antiretroviral medications are prescribed for PEP to pregnant patients.

  The following medications are contraindicated for use in pregnant women: efavirenz (during first trimester) and nelfinavir, as well as the combination of didanosine and stavudine.

- **Source case has evidence of antiretroviral resistance:** When the source patient's virus is known or suspected to be resistant to one or more of the drugs being considered for the PEP regimen, it is recommended that these drugs *not* be selected as part of the regimen for the exposed person; ***expert consultation is strongly advised in these cases.***

  If information on the source case is not immediately available, then PEP, if indicated, should be initiated *without delay*. The PEP regimen can later be modified if relevant information becomes available.

- **PEP side effects:** Health care providers who are knowledgeable about the possible drug toxicities, drug interactions, and need for adherence should discuss these issues with the patient. PEP regimens are generally well-tolerated, but if side effects do occur, they frequently can be managed without changing the PEP regimen. ***Seek expert consultation when side effects are difficult to manage.***

- **Expanded regimens:** ***Regimens other than the preferred regimen or alternative regimens (Appendix 3) normally should only be selected in consultation with an HIV PEP expert.*** Consultation should be considered when the source patient has known antiretroviral resistance or when the treated patient has preexisting renal disease.

STEP 5. Determine the need for HBV PEP and follow-up.

Management of exposures is dependent upon the source case test results and the vaccination status of the exposed person. Prompt assessment and follow-up is essential in the evaluation and decision-making regarding HBV postexposure management.

➔ ***Consultation with the PEPLINE is recommended.***

GENERAL PRINCIPLES

- **The source case** should be tested for HBsAg.
- **The exposed person** should be assessed for HepB vaccination status and vaccine response status (previous anti-HBs result). **(1)** Previously vaccinated persons who were tested post-vaccination do not need further testing to assess anti-HBs levels. **(2)** Previously vaccinated persons who were not tested for anti-HBs post-vaccination should be tested for anti-HBs, using a quantitative method that allows detection of the protective concentration of anti-HBs.
  - A **vaccine responder** is defined as a person with anti-HBs ≥10 mIU/mL after ≥3 doses of HepB vaccine.

- A **vaccine nonresponder** is defined as a person with anti-HBs <10 mIU/mL after 2 complete series (≥6 doses) of HepB vaccine.

- **Testing both the source patient and the exposed person should occur promptly.** Testing the source patient should not be delayed while waiting for the exposed person's anti-HBs test results; likewise, testing the exposed person should not be delayed while waiting for the source patient HBsAg results.

- **Exposed persons who are potentially susceptible** (i.e., do not have evidence of a post-vaccination anti-HBs ≥10 mIU/mL), should be administered hepatitis B immune globulin (HBIG) and HepB vaccine, if indicated, as soon as possible after an exposure. The effectiveness of HBIG when administered > 7 days after exposures is unknown. HBIG dosage is 0.06 mL/kg.
  - *If a person is currently in the middle of a HepB vaccine series when exposed, the vaccine should continue to be given according to the usual schedule (in addition to HBIG).*
  - *Incompletely vaccinated persons should receive additional dose(s) to complete the 3-dose vaccine series. The vaccine series does not need to be restarted; however, minimum dosing intervals should be heeded. Minimum dosing intervals are 4 weeks between the first and second dose, 8 weeks between the second and third dose, and 16 weeks between the first and third dose.*

See **Table 4** *below for interpretation of HBV testing.*

TABLE 4. HBV SEROLOGY INTERPRETATION

HBsAg*	Anti-HBc*	Anti-HBs*	IgM Anti-HBc*	Interpretation
Negative	Negative	Negative	—	Susceptible
Negative	Positive	Positive	—	Immune (natural infection)
Negative	Negative	Positive	—	Immune (prior vaccination)
Positive	Positive	Negative	Negative	Chronic hepatitis B virus infection
Positive	Positive	Negative	Positive	Acute hepatitis B virus infection
Negative	Positive	Negative	—	Unclear—might be: • Resolved infection (most common) • False-positive anti-HBc; susceptible • "Low level" chronic infection • Resolving acute infection

* **HBsAg** = hepatitis B surface antigen; **anti-HBc** = hepatitis B core antibody; **anti-HBs** = hepatitis B surface antibody; **Anti-HBc** = IgM antibody against hepatitis B core antigen

RECOMMENDATIONS FOR HBV POSTEXPOSURE MANAGEMENT

See the flow chart in *Appendix 6* for postexposure management recommendations for persons who have sustained a bloodborne exposure to an HBsAg-positive or unknown source. The recommendations are categorized by the vaccination status of the exposed person.

A more detailed description of these six CATEGORIES is provided below:

1. **THREE DOSES & RESPONDER:** Exposed persons with documentation of a complete HepB vaccine series (≥3 doses), and subsequent post-vaccination anti-HBs ≥10 mIU/mL, are considered to be **RESPONDERS** and hepatitis B immune.
   - Immunocompetent persons have long-term protection against HBV and do not need further testing to assess anti-HBs levels.
   - No HBV postexposure management is necessary, regardless of the source patient's HBsAg status.
2. **THREE DOSES & RESPONSE UNKNOWN:** Exposed persons with documentation of a complete HepB vaccine series (≥3 doses), and no documentation of post-vaccination anti-HBs results, should undergo anti-HBs testing as soon as possible after the exposure.
   - If the anti-HBs is ≥10 mIU/mL, then the person is considered a **RESPONDER**, and no HBV postexposure management is necessary.
   - If the anti-HBs is <10 mIU/mL, see instructions below for ***CATEGORY 3*** below.

For CATEGORIES 3–6 (*see below*):

Persons in **CATEGORIES 3–6**, those who have a post-vaccination anti-HBs <10mIU/mL or who are unvaccinated or incompletely vaccinated, are presumed to be susceptible and require follow-up laboratory testing for HBV infection. They should undergo baseline testing (anti-HBc) as soon as possible after exposure, and follow-up testing approximately 6 months later (anti-HBc and HBsAg).

- Anti-HBc is drawn at the time of the exposure. Vaccination and HBIG should not be delayed while awaiting test results.

  A positive anti-HBc indicates past or current HBV infection. If the anti-HBc is positive, discontinue vaccination and then test for HBsAg.★
- Anti-HBc and HBsAg is drawn 6 months after the exposure.★

★ ***If anti-HBc is positive and HBsAg is negative***, then the exposed person is considered to have natural immunity to HBV and requires no additional vaccination and no special evaluation unless they become immunosuppressed or immunocompromised.

If HBsAg is positive, then evaluate for chronic HBV infection. See the BOP Clinical Practice Guideline, *Stepwise Approach for Detecting, Evaluating, and Treating Chronic Hepatitis B Virus Infection*.

3. **THREE DOSES & ANTI-HBS < 10 MIU/ML:** Vaccinated exposed persons with anti-HBs <10 mIU/mL after one complete HepB vaccine series (3 doses) should receive 1 dose of HBIG and a HepB vaccine dose as soon as possible and be tested for anti-HBc. The exposed person should then receive 2 more HepB doses to complete a second vaccine series, according to the vaccination schedule (6 doses total when accounting for the original 3-dose series). To assess responder status, an anti-HBs is drawn 1–2 months post-vaccination, and at least 4–6 months after HBIG is administered.

4. **NOT VACCINATED:** An exposed person who has no history of HepB vaccination should receive 1 dose of HBIG and 1 dose of HepB vaccine as soon as possible, and be tested for anti-HBc. To assess responder status, an anti-HBs is drawn 1–2 months post-vaccination, and at least 4–6 months after HBIG is administered.

5. **ONE OR TWO DOSES ONLY (INCOMPLETE):** The incompletely vaccinated exposed person (history of 1 or 2 vaccine doses) should receive 1 dose of HBIG and be tested for anti-HBc. If the person is currently in the middle of a vaccine series, vaccine dosing should continue according to schedule. If vaccination occurred sometime in the past, then a vaccine dose should be given immediately. Those in need of a third dose to complete the 3-dose series should be vaccinated $\geq$ 8 weeks later. To assess responder status, an anti-HBs is drawn 1–2 months post-vaccination, and at least 4–6 months after HBIG is administered.

6. **TWO SERIES OF THREE DOSES & NON-RESPONDER:** An exposed person who has documentation of HepB vaccination, with anti-HBs <10 mIU/mL after two complete, 3-dose HepB vaccine series (6 doses), should receive 1 dose of HBIG and be tested for total anti-HBc. A second dose of HBIG should be administered 1 month later.

STEP 6. Determine the need for HCV postexposure follow-up.

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

a. Baseline (within 48 hours of exposure): Obtain anti-HCV.

- **If anti-HCV negative:** Proceed to step **b** below.
- **If anti-HCV positive:** Obtain quantitative HCV RNA test.
  - **If HCV RNA positive: STOP.** Refer for care for preexisting HCV infection.
  - **If HCV RNA negative:** Proceed to step **b** below.

b. 3–6 Weeks Post-Exposure: Obtain quantitative HCV RNA.

- **If HCV RNA negative:** Test indicates that it is extremely unlikely that the person was infected with HCV as a result of the exposure. Consider a 6-month post-exposure anti-HCV test (step **c** below).
- **If HCV RNA positive:** Result indicates that the person did become infected as a result of the exposure. There is a possibility that the infection will clear. Proceed to step **c** below.

c. $\geq$ 6 Months Post-Exposure

- **If HCV RNA negative at 3–6 weeks, consider obtaining anti-HCV.**
  - **If anti-HCV negative:** Test confirms no infection.
  - **If anti-HCV positive:** Obtain quantitative HCVRNA.
    - **If HCV RNA is positive**: Test confirms new infection. Refer for follow-up care.
    - **If HCV RNA is negative**: Test indicates prior infection that has cleared.
- **If HCV RNA positive at 3–6 weeks: Obtain follow-up quantitative HCV RNA.**
  - **If HCV RNA negative:** Test indicates infection has cleared (no infection).
  - **If HCV RNA positive:** Test indicates chronic HCV infection. Refer for follow-up care.

STEP 7. Determine the 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 neither minor nor clean (e.g., 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 Tdap 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 the need for antibiotic prophylaxis.

Individuals with human bite wounds have a high risk of serious bacterial infections, making close monitoring of the wound absolutely 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 have penetrated deeper than the epidermal layer.
- **These persons should be treated as soon as possible (prior to signs of infection):** amoxicillin-clavulanate 875/125mg by mouth, twice daily for 5 days.
- **For persons allergic to penicillin:** Treat for five days with clindamycin (450mg three times daily), together with *either* ciprofloxacin (500mg twice daily) *or* sulfamethoxazole/ trimethoprim (800/160mg 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 2015 *STD Treatment Guidelines* for sexual assault, available at: https://www.cdc.gov/std/tg2015/sexual-assault.htm.

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	—	—
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.

Reporting and documentation of exposure incidents should include the following:

- For inmate workers, report the exposure incident to the appropriate supervisor as soon as possible and send an incident report to the Safety Office. The Safety Office must include in the OSHA 300 Log any worker incidents deemed to be true exposures (including those involving inmate workers).
- Notify the Infection Control Office.
- Maintain a copy of the completed Postexposure 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 4* for a list of available forms.

After providing initial postexposure 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 Infection Prevention and Control Committee.

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APPENDIX 1: POSTEXPOSURE WORKSHEET – MANAGEMENT OF EXPOSED PERSON

Postexposure 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:**
Reg.#:	**Date of birth:** _____/____ /_____	**Sex:** ☐ male ☐ female
Exposure: date ____/____/____ time ___:____ ☐ am ☐ pm	**Evaluation:** date ____/____/____ time ___:____ ☐ am ☐ pm	

STEP 1. Evaluate the potential exposure.

a. Describe exposure site & initial care: _____

_____

b. Describe incident (location, circumstances): _____

_____

c. Exposure occurred while individual was: ☐ working ☐ not working

d. TYPE OF BODY FLUID (check all that apply)

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

➔ ***Postexposure management is NOT required for exposures to fluids that are not infectious.*** **STOP!**

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

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

e. EXPOSURE TYPE (*continued*)

☐ **Intact skin?** ***This is not a bloodborne exposure.*** **STOP!**

☐ **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 STEP 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

STEP 2. Evaluate the source case.

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

STEP 3. Evaluate the health status of the exposed person.

BASELINE LABS	***Date***	***Result***
HIV EIA	____/____/____	_____
HBsAg	____/____/____	_____
Anti-HBs	____/____/____	_____
(if previously vaccinated & no post-vaccination test result)		
Total Anti-HBc	____/____/____	_____
(if not vaccinated or incompletely vaccinated)		
Anti-HCV	____/____/____	_____
HCV RNA	____/____/____	_____
(if anti-HCV positive)		

FEMALES: STAT pregnancy test if HIV PEP indicated

History of tetanus series? ☐ yes ☐ no ☐ unknown

Last tetanus booster: ☐ **Td** ☐ **Tdap** _____/____/____

History of HepB vaccine: ☐ yes ☐ no
(1) ___/___/___ (2) ___/___/___ (3) ___/___/___

Hepatitis B Vaccine Response Status: ___/___/___
☐Responder (anti-HBs ≥10 mIU/mL)
☐Non-Responder (anti-HBs < 10 mIU/mL)
☐Unknown response status

Other medical conditions: _____

Current medications: _____

Drug allergies: _____

Postexposure Worksheet: Management of Exposed Person (Page 2 of 4)

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

STEP 4. Determine the need for HIV PEP and follow-up. ☐ NA

a. Expert consultation is recommended, if available, whenever managing exposures. The UCSF Clinician Consultation Center's Postexposure Prophylaxis Hotline (PEPline) is available at 888-448-4911, 9:00 a.m. to 9:00 p.m., ET, 7 days/week. See also their website at: *http://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/*.

Definitely seek consultation if the delay is more than 36 hours, or if the source case is drug-resistant. For exposures related to sex or injection drug use, PEP should not be started after 72 hours.

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

_____

b. Assess the need for HIV PEP.

➔ **If source is HIV EIA negative, PEP is NOT indicated.**

In the table below, determine the recommendation for HIV PEP by checking the appropriate box, based on:

1. **Exposure Type**
2. **Condition**
3. **HIV Status of the Source**

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

Recommendations for HIV PEP, Based on Exposure

1. ExposureType	2. Condition	3. HIV PEP Recommendations Based on HIV Status of the Source			
		Source HIV+		Source HIV Status Unknown	
Percutaneous (includes illicit tattoo)	Any severity		PEP		Consider PEP**
Mucous membrane	Small volume		PEP		Generally no PEP
	Large volume		PEP		Consider PEP**
Non-intact skin	Small volume		PEP		Generally no PEP
	Large volume		PEP		Consider PEP**
Sexual* (≤72 hrs/not recurrent)	Receptive anal/ vag sex		PEP		Consider PEP**
	Other sexual exposure		Generally no PEP		PEP not recommended
Sharing IDU equip*	≤72 hrs/not recurrent		PEP		Consider PEP**

PEP is generally not indicated >72 hours after exposure or if behavior is either frequent or recurrent. PEP may be considered after longer intervals (e.g., one week) on a case-by-case basis for exposures with high transmission risk.

** PEP determination is made on a case-by-case basis by assessing the risk of exposure (see ***Table 1***).

Adapted from: See ***Table 3*** in text for sources.

c. Summarize actions taken, based on evaluation of the exposed person:

Summary of HIV PEP Recommendations

☐ **HIV PEP *not* recommended**
☐ **HIV PEP recommended and exposed person refused it.** (Document refusal in medical record.)
☐ **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: ☐ AST ☐ ALT ☐ Serum creatinine ☐ Other_____
☐ Follow-up instructions: ☐ Report S/S of acute retroviral syndrome (flu-like symptoms)
☐ Return in 72 hours (as additional information about source is obtained)
☐ Return in 2 weeks (monitor for drug toxicity(e.g., CBC and renal and hepatic function tests)
☐ Referral for follow-up care to: _____

Postexposure Worksheet: Management of Exposed Person (Page 3 of 4)

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

STEP 5. Determine the need for HBV PEP and follow-up. ☐ NA

a. Assess need for HBV postexposure management by consulting *Appendix 6*.

Vaccination Status of Exposed Person at Time of Exposure	
☐ 3 Doses & Responder	☐ 1 Dose Only (incomplete)
☐ 3 Doses & Response Unknown	☐ 2 Doses Only (incomplete)
☐ 3 Doses & Anti-HBs < 10mIU/mL	☐ 2 Series of 3 Doses & Non-Responder
☐ Not Vaccinated	

Source HBsAg Results
☐ Positive ☐ Negative ☐ Unknown

b. See *Appendix 5* for specific recommendations for lab follow-up. If tests are performed, record results below to summarize:

Lab Tests Performed		
Test	***Date***	***Results***
Anti-HBs	___/___/_____	_____
Anti-HBs	___/___/_____	_____
Total anti-HBc	___/___/_____	_____
Total anti-HBc	___/___/_____	_____
HBsAg	___/___/_____	_____
HBsAg	___/___/_____	_____

c. See *Appendix 6* for specific recommendations for giving HepB vaccine and HBIG. Record below if given.

HBIG 0.06 mLkg IM Date: ___/___/_____ **HepB Vaccine** Date: ___/___/_____ Date: ___/___/_____

HBIG 0.06 mLkg IM Date: ___/___/_____ Date: ___/___/_____

STEP 6. Determine the need for HCV postexposure follow-up. ☐ NA

There is no PEP recommended for hepatitis C exposures.

➔ *See Step 6 in the text for more information about recommended follow-up, based on the test results in steps a, b, and c.*

- **If the *source* is anti-HCV negative, *OR* anti-HCV positive & HCV RNA negative, no follow-up is required for the exposed person.**
- **If the *source* is HCV RNA positive or unknown, the following is the recommended follow-up testing schedule for the exposed person:**

a. BASELINE (within 48 hrs): Obtain anti-HCV. **Date:** __/__/___ **Anti-HCV:** _____

- If anti-HCV negative ➔ step b.
- If anti-HCV positive ➔ quantitative HCV RNA. **Date:** __/__/___ **HCV RNA:** _____
  - If HCV RNA negative ➔ step b.
  - If HCV RNA positive ➔ refer for preexisting HCV.

b. 3–6 WEEKS POST-EXPOSURE: Obtain quantitative HCV RNA. **Date:** __/__/___ **HCV RNA:** _____

- If HCV RNA negative ➔ consider anti-HCV in step c (to confirm no infection).
- If HCV RNA positive ➔ obtain follow-up quantitative HCV RNA in step c (to see if cleared).

c. ≥ 6 MONTHS POST-EXPOSURE: Date: __/__/___ **Anti-HCV :** _____ **Date:** __/__/___ **HCV RNA:** _____

- If 3–6 week HCV RNA negative ➔ anti-HCV. If anti-HCV negative ➔ confirms no infection.
  If anti-HCV positive➔ quantitative HCV RNA. If HCV RNA positive ➔ refer for care for new infection.
- If 3–6 week HCV RNA positive ➔ retest HCV RNA. If HCV RNA negative ➔ infection cleared.
  If HCV RNA positive ➔ refer for care for chronic infection.

Postexposure Worksheet: Management of Exposed Person (Page 4 of 4)

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

STEP 7. Determine the need for tetanus vaccine. ☐ NA

- **If wound is clean** (e.g., needle stick wounds from needle known to be 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 (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. (Td = tetanus/diphtheria Tdap = tetanus/diphtheria/pertussis)*

ADMINISTERED: TIG ___/___/___ Tdap___/___/___ Td ___/___/___ Td ___/___/___

STEP 8. (Human bites only) Determine the 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 bites 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
- **In cases of 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 screening for STDs. ☐ 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 *2015 STD Treatment Guidelines* for sexual assault at: *https://www.cdc.gov/std/tg2015/sexual-assault.htm* . Follow BOP policy.

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 *Appendix 5*)

STEP 11. Complete Reporting and Documentation ☐ NA

Check off the following actions when you complete them:

☐ If inmate worker, report incident to supervisor as soon as possible.
- ☐ For inmate workers, give incident report to Safety Office, which must include in the OSHA 300 Log any incident deemed to be a worker exposure.

☐ Report incident to Infection Control Office.

☐ Analyze exposure incident.

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

APPENDIX 2: POSTEXPOSURE WORKSHEET – ASSESSMENT OF SOURCE CASE

Postexposure 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. Rapid HIV testing is preferred 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 Ab				
HBsAg				
HBeAg *(if available)*				
Anti-HCV				
HCV RNA *(if anti-HCV positive)*				

If HIV Infected Source Case

HIV Status:

Last CD4 counts/% and viral loads:

Date: _____ Count: _____ %: ____ VL: _____

Date: _____ Count: _____ %: ____ VL: _____

History of anti-retroviral therapy? ☐Yes ☐No ☐Unknown

If Yes, current medications: _____

History of resistance to anti-retroviral therapy? ☐Yes ☐No ☐Unknown

If Yes, resistance to which medications: _____

_____

If 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 PEP

- **Treatment is prescribed on a case-by-case basis, in consultation with the PEPline (888-448-4911, 9 a.m-9 p.m. ET, 7 days/week).**
- Preferred and alternative PEP regimens are listed in the first section below. The BOP recommends utilizing a combination of three medications for PEP, including Truvada® ***plus*** either raltegravir ***or*** dolutegravir.
  - ➔ *Truvada = emtricitabine 200mg plus tenofovir 300mg, in a fixed-dose combination tablet.*
- In general, these regimens should be utilized unless there is a reason not to, such as a drug-resistant source case or preexisting renal disease.
- PEP is administered for 28 days.
- For alternative regimens and information about side effects, consult the USPHS and/or CDC guidelines referenced below.

PEP REGIMENS*	
Preferred Regimens	• Truvada once daily ***plus*** • Raltegravir 400mg twice daily ***or*** dolutegravir 50 mg once daily
Alternative Regimen	• Truvada once daily ***plus*** • Darunavir 800mg once daily ***plus*** • Ritonavir 100mg once daily

*** Renal disease or pregnancy:** *Expert consultation should be sought in all cases in which antiretroviral medications are prescribed for PEP to pregnant patients and patients with preexisting renal disease*.

AGENTS *NOT* RECOMMENDED FOR PEP

The following agents are not recommended for PEP:

- Didanosine
- Nelfinavir
- Tipranavir
- Nevirapine (contraindicated)

SOURCES *(for more detailed information on PEP, side effects, alternative regimens)***:**

USPHS. Updated US Public Health Service guidelines for the management of occupational exposures to human immunodeficiency virus and recommendations for postexposure prophylaxis. *Infect Control Hosp Epidemiol*. 2013;34(9):875–892. Available at: http://www.jstor.org/stable/10.1086/672271

CDC. Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to hiv. *MMWR*. 2016; 65:458. Available at: https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf

APPENDIX 4: CONTENTS OF EMERGENCY PEP PACKET

It is recommended that each BOP facility prepare a packet or notebook of PEP materials to be made readily available to healthcare personnel who are responsible for initial postexposure management. The packet should provide information and forms that will enable personnel to respond efficiently and effectively to an exposure situation.

The recommended contents of an emergency PEP packet include:

☐	**A copy of this *BOP Clinical Guidance on Medical Management of Exposures*,** *including extra copies of **Appendix 1** and **Appendix 2**.*
☐	**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-A0492 HIV Post-Test Counseling (Positive)
	BP-A0621 Authorization For Release of Medical Information

APPENDIX 5: SUMMARY OF RECOMMENDED FOLLOW-UP FOR PERSONS WITH POTENTIAL EXPOSURE TO BLOODBORNE PATHOGENS

BASELINE

☐ **Medical and vaccine history**

☐ **HIV Antibody (Ab)**

☐ **Anti-HBs** *(if previously vaccinated and post-vaccination result is unavailable)*

☐ **Anti-HBc** *(if post-vaccination anti-HBs < 10 mIU/mL, or not vaccinated, or incompletely vaccinated)*

☐ **Anti-HCV**

☐ **Quantitative HCV RNA** *(if anti-HCV is positive)*

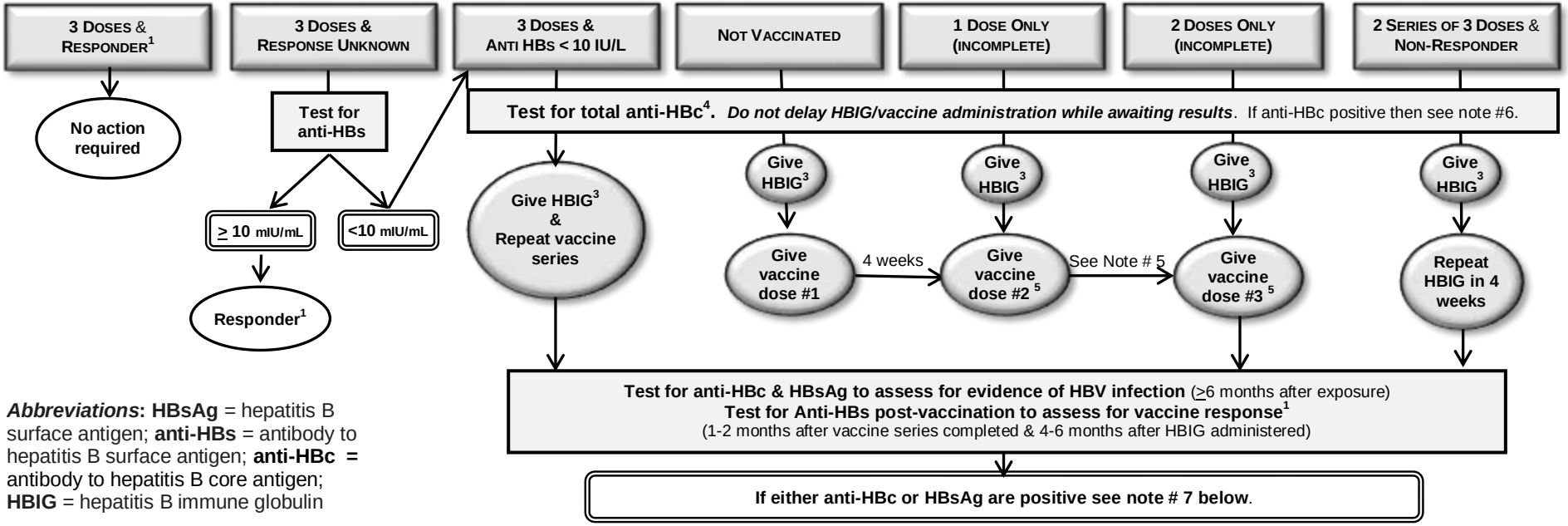
☐ **(Females) STAT pregnancy test if HIV PEP is indicated**
(unless currently menstruating, s/p hysterectomy, or post-menopausal)

FOLLOW-UP*

Time from Exposure	*HIV Exposure*	*HCV Exposure*	*HBV Exposure*
At time of exposure	**Prior to starting HIV PEP:** Serum creatinine, AST, ALT		Based on HepB vaccination status. See *Appendix 6*.
2 weeks	**If on HIV PEP, test for toxicities:** Serum creatinine, AST, ALT	—	
3-6 weeks	—	HCV RNA	
6 weeks	HIV AB**		
3 months	HIV AB**	—	
6 months	HIV AB**	• If 3–6 week HCV RNA test is negative, consider anti-HCV. If anti-HCV is positive, obtain HCV RNA. • If 3–6 week HCV RNA test is positive, repeat HCV RNA (to see if cleared).	
1 year (if exposed person becomes HCV+ after exposure to HIV/HCV-infected source)	HIV AB	—	

* Note: CDC guidance varies on the timetable and tests for toxicity monitoring for HIV PEP.
** Test for HIV at 6 weeks, 12 weeks, and 6 months, regardless of whether HIV PEP was given.

APPENDIX 6: MANAGEMENT OF EXPOSURE TO AN HBSAG+ OR UNKNOWN SOURCE, BY VACCINATION STATUS



***Abbreviations*: HBsAg** = hepatitis B surface antigen; **anti-HBs** = antibody to hepatitis B surface antigen; **anti-HBc =** antibody to hepatitis B core antigen; **HBIG** = hepatitis B immune globulin

[1] A **responder** is defined as a person with anti-HBs ≥10 mIU/mL after ≥3 doses of HepB vaccine**.** A **nonresponder** is defined as a person with HBs <10 mIU/mL after 2 complete vaccine series (usually ≥6 doses) of HepB vaccine

[2] **Test for anti-HBs** should be performed 1–2 months after the last dose of the HepB vaccine series and 4–6 months after administration of HBIG, to avoid detection of passively administered anti-HBs. Testing should use a quantitative method that allows detection of the protective concentration of anti-HBs (≥10 mIU/mL).

[3] HBIG should be administered intramuscularly as soon as possible after exposure when indicated. The effectiveness of HBIG when administered >7 days after percutaneous, mucosal, or nonintact skin exposures is unknown. HBIG dosage is 0.06 mL/kg.

[4] Persons who have anti-HBs <10mIU/mL, or who are unvaccinated or incompletely vaccinated, and sustain an exposure to a source patient who is HBsAg-positive or has unknown HBsAg status, should undergo baseline testing for HBV infection as soon as possible after exposure, and follow-up testing approximately 6 months later. Initial baseline tests = total anti-HBc; testing at approximately 6 months = HBsAg and total anti-HBc. If total anti-HBc or HBsAg are positive then see note # 7.

[5] If exposed person is currently in the middle of the HepB vaccination series, then continue vaccine series according to routine schedule. If exposed person started vaccine sometime in the past, then give immediate post-exposure vaccine dose ASAP. Dose 2 should be at least 4 weeks from dose 1; dose 3 should be at least 8 weeks from dose 2; and there should be at least 16 weeks between dose 1 and dose 3.

[6] A positive anti-HBc indicates past or current HBV infection. Stop vaccination. Test for HBsAg: If positive see Note #7.

[7] If anti-HBc positive and HBsAg is negative person is considered to have natural immunity to HBV and requires no additional vaccination and no special evaluation unless they become immunosuppressed or immunocompromised. If HBsAg positive, then evaluate for chronic HBV infection. See: BOP Clinical Practice Guideline. *Stepwise Approach for Detecting, Evaluating and Treating Chronic Hepatitis B Virus Infection.*

Adapted from: CDC guidance for evaluating health-care personnel for hepatitis B virus protection and for administering postexposure management. *MMWR.* 2013, 62(10):1–24.