

CORRECTIONAL MANAGED HEALTH CARE INFECTION CONTROL MANUAL	Effective Date:02/19	NUMBER: B-14.06
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MANAGEMENT OF OFFENDER BLOODBORNE EXPOSURES		

POLICY: Offenders exposed to blood and body fluids in a manner known to transmit Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) or Hepatitis C Virus (HCV) shall receive confidential counseling and testing. When indicated, post exposure prophylactic treatment will be provided.

DEFINITIONS:

The criteria for an exposure will be as defined by the Centers for Disease Control and Prevention (CDC) and the Texas Department of State Health Services. Exposures are defined as:

- Percutaneous injury (e.g., needle stick, puncture wound, laceration with a sharp object or a human bite);
- Contact of mucous membranes;
- Contact of non-intact skin (e.g., skin that is chapped, abraded or compromised by dermatitis or open wounds);
- Contact of several minutes duration of intact skin;
with
- Blood, semen or vaginal secretions, and all body fluids visibly contaminated with blood;
- Cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, or amniotic fluid.

The sexual assault also constitutes an exposure; for such exposures additional testing may be indicated for other diseases such as syphilis.

PROCEDURES:

- I. Adhering to low-risk behavior is the most appropriate way for offenders to avoid bloodborne exposures. The guidelines in this policy are not intended to provide post-exposure risk reduction in lieu of practicing risk reducing behavior. The guidelines in Procedure III should be followed when the exposure:
 - A. Is to a known source who can be tested (however, if the source refuses testing, the offender victim may still be considered for post-exposure testing and treatment for a high-risk exposure) or is known to be positive for one or more bloodborne pathogens, and
 - B. Is a result of assault, non-consensual sex or accidental injury.
 - C. Be sure to consider both the attacker and victim as potentially exposed persons.

- II. Management of a Possible Exposure
 - A. The circumstances and mechanism of the exposure will be assessed by a qualified health professional using Attachment A (note: Attachment A was written for evaluating exposures to health care workers (HCW) but the same concepts may be applied to

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offender exposures).

- B. If the exposure does not meet the CDC criteria outlined under DEFINITIONS:
1. Counsel the offender about routes of transmission and why the exposure does not present a risk of transmission of a bloodborne infection.
 2. Offer to initiate hepatitis B vaccination if the offender is unvaccinated and is otherwise eligible for vaccine.
 3. No further follow-up is needed in relation to bloodborne pathogens.
 4. The offender is not entitled to know the results of any laboratory tests on the exposure source.
- C. If the exposure does meet the CDC criteria:
1. The **unit physician and/or midlevel practitioner** with the assistance of the **Coordinator of Infectious Diseases (CID) nurse (or designee)** shall evaluate, document and provide first-aid, appropriate prophylactic or emergency treatment for the exposure and/or related injuries (including, but not limited to tetanus booster and initiation of the HBV vaccine, HBIG and/or antiretroviral treatment as indicated).
 - a. **Post-exposure counseling** will be provided to the offender by a licensed health care provider. The counselor will document counseling and the circumstances relating to the exposure.
 - b. **Baseline lab testing** should be drawn from the offender as soon as possible and include HIV-antibody, HBsAg, Anti-HBs, and Anti-HCV. There will be additional lab required for HIV chemoprophylaxis. A CBC, Renal Panel, Liver Panel and serum pregnancy test (for females) should be drawn within 48 hours of the initiation of chemoprophylaxis for HIV.
 - c. **Post-exposure prophylaxis** for hepatitis B should be offered if indicated. HBIG is not indicated unless the source is documented to be HBsAg positive by testing. HBIG **should** be given as soon as possible after exposure, if indicated, but may still be given up to 7 days after a needlestick exposure and up to 14 days after a sexual assault. Neither HBIG nor hepatitis B vaccine is indicated if the victim has a current or previously documented positive lab result for any serological marker of hepatitis B. See Attachment B for further guidance about when to offer HBIG and/or hepatitis B vaccine. See III.C.3, below regarding prophylaxis for HIV infection.
 - d. **Follow-up testing** for HIV-antibody, HBsAg, Anti-HBs and Anti-HCV should be offered to the offender at baseline, six weeks, 12 weeks, and six months. HIV-antibody testing will be done one year post-exposure. (Exception: If the offender is already positive on a baseline test then a follow-up test is unnecessary and it will not be ordered.)
 - e. **Source lab and consent.** If the source of the exposure can be identified (by name, TDCJ number, etc.) the CID nurse should determine if the offender has a positive HIV, hepatitis B and/or hepatitis C test in the medical record. If not, the offender should be counseled and offered

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testing, including post-test counseling, when appropriate.

3. **Post-Exposure Prophylaxis (PEP)** If the source of the exposure is known to be HIV-positive, **and the exposure is a percutaneous exposure to blood and/or body fluids visibly contaminated with blood or from non-consensual sexual contact**, chemoprophylaxis should be considered. See Attachment A for guidance in evaluating exposures. Generally, a percutaneous exposure to a solid sharp (razor blade, tattoo needle, etc.) does not require chemoprophylaxis unless visible blood is present or the source is known to be HIV positive; however, the decision about prophylaxis should be individualized for each exposure.
 - a. Prior to beginning the HBV immunization program or the HIV chemoprophylaxis, each eligible offender should be counseled and fully understand the benefits and risks of the medications and sign a consent (Attachment C).
 - b. Appropriate drug therapy for a regimen of chemoprophylaxis is: zidovudine 300 mg 1 tablet BID + lamivudine 150 mg 1 tablet BID and Kaletra (lopinavir 200mg + ritonavir 50 mg) 2 tablets BID. See Policy B-14.5 for information about monitoring for toxicity.
 - c. When the results of the offender's baseline tests, and source's test (if done) are received, the unit physician shall determine whether chemoprophylaxis should continue for the full 30 days.
 - d. DO NOT use drug packages prepared for employee exposures to treat an offender exposure.
 - e. Chemoprophylaxis should be started as soon as possible, preferably within two hours. It is acceptable to start two drugs and add the third as soon as it is available. Because of unproven effectiveness of HIV chemoprophylaxis started more than 72 hours after exposure, it usually is not indicated if it cannot be started within 72 hours. Even though chemoprophylaxis may be started up to 72 hours after exposure, every effort should be made to start treatment ASAP after exposure if it is indicated, including starting the drugs after hours or on weekends. Units that do not have the medications available as floor stock should obtain it from the closest facility with floor stock (i.e., a unit with inpatient beds or that houses transients).
4. **Refusal** of either testing or post-exposure prophylaxis should be documented.

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- References:
- Vernon's Civil Statute, *Health and Safety Code*, §85.116(c)
 - Centers for Disease Control (Guidelines for Health Care Workers) July 12, 1991
 - Communicable Disease Prevention and Control Act, Texas Health and Safety Code, §81.001
 - Department of Labor, Occupational Safety and Health Administration, 29, CFR Part 1910.1030
 - Occupational Exposure to Bloodborne Pathogens, Final Rule
 - TDCJ Health Services Policy B-14.4, "Prevention of Hepatitis B Virus (HBV) in TDCJ Facilities"
 - TDCJ Health Services Infection Control Policy B-14.11, "Human Immunodeficiency Virus (HIV) Infection"
 - TDCJ Administrative Directive 6.60, "Management of Inmate and Employee Bloodborne Pathogen Issues (with Special Reference to Human Immunodeficiency [HIV] and Hepatitis B Virus [HBV])"

CMHC Infection Control Manual Policy B-14.06, Attachment A

Recommended HIV post exposure prophylaxis (PEP) for percutaneous injuries

Exposure type	Infection Status of Source				
	HIV- Positive Class 1*	HIV- Positive Class 2*	Source of unknown HIV status†	Unknown source§	HIV-Negative
Less severe¶	Recommend PEP	Recommend PEP	Generally, no PEP warranted; however, consider PEP** for source with HIV risk factors††	Generally, no PEP warranted; however, consider PEP** in settings where exposure to HIV-infected persons is likely	No PEP warranted
More severe§§	Recommend PEP	Recommend PEP	Generally, no PEP warranted; however, consider PEP** for source with HIV risk factors††	Generally, no PEP warranted; however, consider PEP** in settings where exposure to HIV-infected persons is likely	No PEP warranted

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

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

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

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

** The designation “consider PEP” indicates that PEP is optional and should be based on an individualized decision between the exposed person and the treating clinician.

†† If PEP is offered and taken and the source is later determined to be HIV- negative, PEP should be discontinued.

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

Source: MMWR 50(RR-11), 6/29/01, page 24. This Table differs from the MMWR source because a two-drug PEP regimen is not recommended in TDCJ.

CMHC Infection Control Manual Policy B-14.06, Attachment A

Recommended HIV post exposure prophylaxis (PEP) for mucous membrane and nonintact skin* exposures

Exposure type	Infection Status of Source				
	HIV- Positive Class 1 [†]	HIV- Positive Class 2 [†]	Source of unknown HIV status [§]	Unknown source [¶]	HIV-Negative
Small volume ^{**}	Consider PEP ^{††}	Recommend PEP	Generally, no PEP warranted; however, consider PEP ^{††} for source with HIV risk factors ^{§§}	Generally, no PEP warranted; however, consider PEP ^{††} in settings where exposure to HIV-infected persons is likely	No PEP warranted
Large volume ^{¶¶}	Recommend PEP	Recommend PEP	Generally, no PEP warranted; however, consider PEP ^{††} for source with HIV risk factors ^{§§}	Generally, no PEP warranted; however, consider PEP ^{††} in settings where exposure to HIV-infected persons is likely	No PEP warranted

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

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

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

[¶] Unknown source (e. g., splash from inappropriately disposed blood).

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

^{††} The designation, “consider PEP,” indicates that PEP is optional and should be based on an individualized decision between the exposed person and the treating clinician.

^{§§} If PEP is offered and taken and the source is later determined to be HIV- negative, PEP should be discontinued.

^{¶¶} Large volume (i. e., major blood splash).

Source: MMWR 50(RR-11), 6/29/01, page 24. This Table differs from the MMWR source because a two-drug PEP regimen is not recommended in TDCJ.

CMHC Infection Control Manual Policy B-14.06, Attachment B

Recommended post exposure prophylaxis for percutaneous or permucosal exposure to hepatitis B virus, United States[#]

Vaccination and antibody response of exposed person	Treatment when source is		
	HBsAg* Positive	HBsAg Negative	Source not tested or status unknown
Unvaccinated	HBIG [‡] x 1; initiate HB vaccine series [§]	Initiate HB vaccine series	Initiate HB vaccine series
Previously vaccinated: Known responder [¶]	No treatment	No treatment	No treatment
Known non-responder	HBIG x 2 <i>or</i> HBIG x 1 and initiate revaccination	No treatment	If known high-risk source, treat as if source were HBsAg positive
Antibody response unknown	Test exposed person for anti-HBs** 1. If adequate [¶] , no treatment 2. If inadequate [¶] , HBIG x 1 and vaccine booster	No treatment	Test exposed person for anti-HBs 1. If adequate [¶] , no treatment 2. If inadequate [¶] , initiate revaccination

* Hepatitis B surface antigen

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

§ Hepatitis B vaccine.

¶ Responder is defined as a person with adequate levels of serum antibody to hepatitis B surface antigen (i.e., anti-HBs ≥ 10 mIU/mL); inadequate response to vaccination defined as serum anti-HBs < 10 mIU/mL.

** Antibody to hepatitis B surface antigen.

Source: MMWR, Vol. 46; No.RR-18

CMHC Infection Control Manual Policy B-14.06, Attachment C

Consent or Refusal of Post-Exposure Testing and Treatment Testing and Treatment for Exposure to Bloodborne Pathogens

Risk of HIV Infection

The risk for HIV transmission per episode of intravenous needle or syringe exposure is estimated at 0.67% (1 out of 150). The risk per episode of needle stick exposure (for example, an unsterilized tattoo needle) to HIV-infected blood is estimated at 0.4% (1 out of 250). The risk for HIV transmission per episode of receptive penile-anal sexual exposure is estimated at 0.1%–3% (1 out of 1000 to 1 out of 33); the risk per episode of receptive vaginal exposure is estimated at 0.1%–0.2% (1 out of 1000 to 1 out of 500). No published estimates of the risk for transmission from receptive oral exposure exist, but instances of transmission have been reported.

Risk of Hepatitis B or Hepatitis C Infection

The average risk of Hepatitis B infection (HBV) without having been vaccinated against hepatitis B is between six and 30 percent for a needle exposure to HBV-infected blood. The risk of hepatitis C infection (HCV) after needle exposure to HCV-infected blood is between three and 10 percent.

Testing

After a significant exposure to bloodborne pathogens certain blood tests are highly recommended, to determine whether transmission of infection occurred. It may take up to six months after exposure for a blood to turn positive, although if an infection was transmitted as a result of an exposure, the test usually turns positive in 6-12 weeks. Testing for hepatitis B, hepatitis C and HIV infection should be done within 10 days of the exposure, 6 weeks after exposure, 12 weeks after exposure and 6 months after exposure. If an offender already had a positive test for one of these infections prior to the exposure, no testing will be done for that particular disease. Pre- and post- test counseling will be done for the HIV test.

Treatment with zidovudine, lamivudine and lopinavir/ritonavir

Zidovudine, lamivudine and lopinavir/ritonavir (Kaletra) are offered to employees who have an exposure that might result in transmission of HIV infection within the scope and performance of their duties. Treatment in these circumstances is voluntary. While these drugs are approved for the treatment of HIV infection, the FDA has not approved them specifically for post exposure use, but such use has become common practice and is recommended by the Centers for Disease Control and Prevention (CDC). It is used for certain exposures because there is evidence that the drugs can prevent HIV infection from occurring if they are started within a few hours after an exposure. The CDC goes on to say, "because most occupational exposures to HIV do not result in infection transmission, potential toxicity must be carefully considered when prescribing post exposure prophylaxis (PEP)."

Each of these drugs may be associated with toxic side effects. Common side effects include upset stomach, nausea, vomiting, headache, or diarrhea. Zidovudine can cause nausea or upset stomach, headache or insomnia. This drug can also cause anemia or low white blood cell count. Both lamivudine and zidovudine may rarely cause conditions called lactic acidosis and fatty liver.

Symptoms of these conditions include extreme tiredness, unusual muscle pains, difficulty breathing, dizziness or lightheadedness, or rapid heart beat. Lopinavir/ritonavir may cause an increase in blood sugar or cholesterol and triglyceride levels. These side effects are expected to stop when the drugs are discontinued. These drugs may have interactions with other medications, so be sure the prescribing doctor knows about any medical problems you have and any other medication you are on before taking these drugs.

Blood tests will be done before or within a day or two after starting the drugs, and repeated after two weeks of treatment, to help monitor for side effects.

These drugs are not known to cause birth defects if taken while pregnant, but if you might be pregnant you should discuss the risks and benefits with your doctor as soon as possible. It is recommended that breast feeding NOT be done while on these drugs.

Treatment should normally continue for 4 weeks, unless you are advised to stop earlier. If you are thinking about stopping the drugs early because of side effects, discuss the risks and benefits with the doctor before stopping.

Be sure to report any skin rash, numbness, tingling, stomach or back pain, sore muscles, or severe nausea or diarrhea, or increased thirst or urination.

CONSENT FOR TESTING AND TREATMENT

I understand these risks and the possible benefit of testing for bloodborne pathogens and request such testing.

I understand these risks and the possible benefit of treatment for prevention of HIV infection and request such treatment.

Offender Signature

Offender Name

TDCJ #

Date

Witness Signature

Witness Name

Date

REFUSAL OF TESTING AND TREATMENT

I have been given information about the risk of transmission of bloodborne pathogens and post-exposure testing and preventive treatment, and have had an opportunity for my questions to be answered.

I do not wish to be tested for bloodborne pathogens at this time.

I understand these risks and the possible benefit of treatment and **DO NOT** request such treatment. I understand that treatment will not be started more than 72 hours after the exposure if I change my mind.

Offender Signature

Offender Name

TDCJ #

Date

Witness Signature

Witness Name

Date