

EXHIBIT I

Inyo County Health & Human Services Post Exposure Prophylaxis

Post exposure prophylaxis (PEP) for Exposed Employee to Hepatitis C, Hepatitis B, and HIV

Transmission rates in occupational exposures (positive source) for
HIV: needlesticks 0.3%, mucous membranes 0.09%, nonintact skin- unknown but estimated to be less than mucous membrane exposure.
HBV: needlesticks 6-30%
HCV: needlesticks 1.8%

Hepatitis C

In the absence of PEP for Hepatitis C exposure, recommendations are intended to achieve early identification of chronic Hepatitis C disease after exposure and refer for early treatment options.

1. For individuals exposed to Hepatitis C positive sources:
 - a. Perform baseline testing for anti-HCV and ALT activity.
 - b. Perform follow-up testing for anti-HCV and ALT activity in 4-6 months.
 - c. If earlier diagnosis of Hepatitis C infection is desired, test for HCV RNA at 4-6 weeks.
 - d. Confirm all anti-HCV results reported positive by enzyme immunoassay using supplemental anti-HCV testing.
 - e. When Hepatitis C infection is identified, the person should be referred to a specialist for follow-up care.
 - f. Immunoglobulin and antiretrovirals are not recommended for exposures to Hepatitis C positive blood.

Hepatitis B

For detailed PEP information see Table 3 *Recommended Post exposure Prophylaxis for Exposure to Hepatitis B Virus*

1. If the exposed person is known to have had adequate response to the Hepatitis B vaccine in the past (anti-HBs \geq 10mIU/ml), the anti-HBs level does not need to be tested and no PEP is needed.
2. If the anti-HBs was never tested after receiving the Hepatitis B vaccine series and there is reason to believe the exposure presents a risk for Hepatitis B transmission, the anti-HBs level of the exposed can be tested.
3. Start the Hepatitis B vaccine series immediately if exposed individual has not been previously vaccinated.
4. Hepatitis B vaccine and Hepatitis B Immune Globulin (HBIG) are not contraindicated

in pregnant or lactating women.

5. When HBIG is indicated it should be given ASAP after exposure, although it can be given up to 7 days after exposure.

6. For exposed individuals in the process of receiving the Hepatitis B vaccine series, HBIG should be given ASAP and the Hepatitis B vaccine series schedule should continue.

7. A second dose of HBIG a month later is only needed if the exposed person is a known non-responder to the Hepatitis B vaccine and the source patient is HBsAg positive.

8. If the exposed person has had prior HBV infection, he/she is considered immune and requires no PEP.

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

Vaccination and antibody response status of exposed workers*	Treatment		
	Source HBsAg [†] positive	Source HBsAg [†] negative	Source unknown or not available for testing
Unvaccinated	HBIG [‡] x 1 and initiate HB vaccine series [§]	Initiate HB vaccine series	Initiate HB vaccine series
Previously vaccinated			
Known responder**	No treatment	No treatment	No treatment
Known nonresponder [¶]	HBIG x 1 and initiate revaccination or HBIG x 2 [§]	No treatment	If known high risk source, treat as if source were HBsAg positive
Antibody response unknown	Test exposed person for anti-HBs [†] 1. If adequate,** no treatment is necessary 2. If inadequate, [¶] administer HBIG x 1 and vaccine booster	No treatment	Test exposed person for anti-HBs 1. If adequate, [†] no treatment is necessary 2. If inadequate, [¶] administer vaccine booster and recheck titer in 1–2 months

* Persons who have previously been infected with HBV are immune to reinfection and do not require postexposure prophylaxis.

[†] Hepatitis B surface antigen.

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

[§] Hepatitis B vaccine.

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

[¶] A nonresponder is a person with inadequate response to vaccination (i.e., serum anti-HBs < 10 mIU/mL).

[§] The option of giving one dose of HBIG and reinitiating the vaccine series is preferred for nonresponders who have not completed a second 3-dose vaccine series. For persons who previously completed a second vaccine series but failed to respond, two doses of HBIG are preferred.

[†] Antibody to HBsAg.

HIV

For detailed PEP see Table 4 *Recommended HIV Postexposure Prophylaxis for Percutaneous Injuries*, Table 5 *Recommended HIV Postexposure Prophylaxis for Mucous Membrane Exposures and Nonintact Skin Exposures*, and Appendix C *Basic and*

Expanded HIV Postexposure Prophylaxis Regimens.

1. Exposed EMPLOYEES should be informed that:
 - a. Most occupational exposures to HIV do not result in HIV transmission. Medication toxicity should be carefully considered when deciding to start PEP.
 - b. Prophylaxis is not indicated or justified for exposures with negligible risk.
 - c. Limited knowledge is available regarding toxicity of prophylaxis in pregnancy.
 - d. An individual can decline all prophylactic medications.
2. Considerations for prescribing PEP
 - a. Toxic medications have caused serious liver toxicity. Consider transmission risk vs. toxicity risk. Also consider individual risks: pregnancy, current breast feeding, renal disease, liver disease etc.
 - b. HIV transmission rates in occupational exposures
 - c. PEP should be started ASAP. The basic regimen, Combivir, is available in the hospital pharmacy. It is possible to start PEP and then discontinue or change the medications prescribed once the source patient's HIV status is determined.
 - d. Regardless of the PEP regimen selected, medications are to be taken for 4 weeks; if tolerated.
 - e. If unsure of which PEP regimen to begin with, start with the basic. A change can always be made later when more information regarding the source is available.
 - f. Don't stagger PEP medications- give the full regimen as ordered. Staggering medications can lead to resistance.

3. PEP Medications

The **National Clinicians Post-Exposure Prophylaxis Hotline** (PEP line) offers treating clinicians up-to-the-minute advice on managing occupational exposures to HIV, Hepatitis, and other blood-borne pathogens. It is available 24 hours per day, seven days per week. *See attached handout.*

The phone number is 888-HIV-4911 (888-448-4911)

- a. The basic regimen, Zidovudine 600mg QD and Lamivudine 150mg BID will be available in the Mammoth Hospital Pharmacy as a single tablet (Combivir). The basic regimen, Combivir is to be taken twice daily for one month. This is the most common regimen for PEP.
- b. For additional PEP regimens, please see policy *Basic and Expanded HIV Postexposure Prophylaxis Regimens* on the intranet > Employee Health Manual > Body Fluid Exposure.
- c. If another regimen besides Combivir is prescribed, call Vons or Rite-Aid for medication availability.
- d. When Vons or Rite-Aid are closed or don't have needed medications available, Dwayne's pharmacy or Northern Inyo Hospital Pharmacy can be contacted for medication availability.

- e. No pharmacy can guarantee immediate availability of PEP medications but the basic regimen can be started immediately and then when other medications become available, the prescription can be changed.

4. Follow-up care of individuals receiving HIV PEP

- a. Possible drug toxicity should be monitored by testing at baseline and again at 2 weeks after starting PEP. Tests should include at minimum: CBC, renal and hepatic function tests. In addition, any individual on a protease inhibitor should be evaluated for hyperglycemia and those on IDV should be monitored for crystalluria, hematuria, hemolytic anemia, and hepatitis.
- b. Reevaluation of the exposed person should be considered within 72 hours post exposure, especially as additional information about the exposure or source person becomes available.
- c. Inform patient that they need to report any side effects from PEP medications immediately as a dose adjustment or discontinuation of the drug may be required.
- d. If any toxicity is noted, modification of the regimen should be considered after expert consultation; further diagnostic studies may be indicated.

5. Testing of exposed EMPLOYEES

- a. EMPLOYEES exposed to HIV should be evaluated within hours (rather than days) after their exposure and should be tested for HIV at baseline (i.e., to establish infection status at the time of exposure).
- b. If the source person is seronegative for HIV, baseline testing or further follow-up of the exposed person normally is not necessary. Follow-up serologic testing (see 5c below) will be made available to all EMPLOYEES who are concerned that they might have been occupationally infected with HIV.
- c. EMPLOYEES exposed to HIV should be tested for HIV at baseline, 6 weeks, 12 weeks, and 6 months. The provider may also recommend another test at 1 year.
- d. If the exposed individual does not want test results at the time of the exposure, the blood sample may be preserved for 90 days. The employee may also elect to take the HIV antibody test at another test center (ex. Health Department).
- e. Advise exposed employee to seek medical evaluation for any illness compatible with an acute retroviral syndrome.
- f. Inform the exposed individual that the Health Officer or other designated licensed healthcare provider will receive all test results and provide follow-up counseling to the exposed individual.
- g. California HIV Confidentiality Laws will be discussed with the exposed individuals, and all staff involved with testing and counseling will adhere to confidentiality laws.

TABLE 4. Recommended HIV postexposure prophylaxis for percutaneous injuries

Exposure type	Infection status of source				
	HIV-Positive Class 1*	HIV-Positive Class 2*	Source of unknown HIV status [†]	Unknown source [‡]	HIV-Negative
Less severe [§]	Recommend basic 2-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP** for source with HIV risk factors [¶]	Generally, no PEP warranted; however, consider basic 2-drug PEP** in settings where exposure to HIV-infected persons is likely	No PEP warranted
More severe	Recommend expanded 3-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP** for source with HIV risk factors [¶]	Generally, no PEP warranted; however, consider basic 2-drug PEP** in settings where exposure to HIV-infected persons is likely	No PEP warranted

* HIV-Positive, Class 1 — asymptomatic HIV infection or known low viral load (e.g., <1,500 RNA copies/mL). HIV-Positive, Class 2 — symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of postexposure 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).

TABLE 5. Recommended HIV postexposure prophylaxis for mucous membrane exposures 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 basic 2-drug PEP [¶]	Recommend basic 2-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP [¶] for source with HIV risk factors	Generally, no PEP warranted; however, consider basic 2-drug PEP [¶] in settings where exposure to HIV-infected persons is likely	No PEP warranted
Large volume ^{¶¶}	Recommend basic 2-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP [¶] for source with HIV risk factors	Generally, no PEP warranted; however, consider basic 2-drug PEP [¶] in settings where exposure to HIV-infected persons is likely	No PEP warranted

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

[†] HIV-Positive, Class 1 — asymptomatic HIV infection or known low viral load (e.g., <1,500 RNA copies/mL). HIV-Positive, Class 2 — symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of postexposure 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).

Reference: 2001 CDC Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Post exposure Prophylaxis <http://www.cdc.gov/mmwr/PDF/rr/rr5011.pdf>

And

2005 CDC Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Post exposure Prophylaxis; and Notice to Readers: Updated Information Regarding Antiretroviral Agents Used as HIV Post exposure Prophylaxis for Occupational HIV Exposures