

DEPARTMENT OF HEALTH AND HOSPITALS

OFFICE OF PUBLIC HEALTH

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From: Erin Brewer, M.D., M.P.H.

Medical Director and Assistant State Health Officer

Subject: Protocol for Managing Needle Stick Injuries and Other Unintentional Exposures to Blood or Potentially Infectious Body Fluids

This policy updates and amends Policy Memorandum No. 205 (REVISED) issued December 12, 2005. This updated and amended policy updated in accordance with the Centers for Disease Control and Prevention's updated Guidelines issued September 30, 2005. Note that this revision and the updated guidelines pertain only to human immuno-deficiency virus (HIV) exposure in an occupational setting. These updates are contained in the following narrative and in Tables 1-6.

As in the previous policy, reference may also be made to Policy Memorandum No. 170 (December 1, 1990) "Hepatitis B Vaccine Recommendations for Office of Public Health Employees" and Policy Memorandum No. 128 Addendum 2 Revised (October 13, 1997) "Policy on Blood Specimen Collection and Infectious Waste Management in Office of Public Health Facilities."

Form Epi-31 is included in this policy and, if needed, should be photocopied as necessary. Other forms are available from the Regional or Central Office Safety Administrator or the forms warehouse.

This Policy Memorandum must also be included in the Employee Health and Safety Index in your facility. Questions regarding this memorandum may be addressed to the HIV/AIDS Program staff at (504) 568-7524.

Approved for Redirection or Redistribution

Regional Administrator

Date

**OFFICE OF PUBLIC HEALTH PROTOCOL FOR MANAGING NEEDLE STICK INJURIES AND
OTHER UNINTENTIONAL EXPOSURES TO BLOOD OR POTENTIALLY INFECTIOUS BODY
FLUIDS**

I. Evaluation of Exposure and Exposure Source

Health care workers (HCW) are at risk for occupational exposures to Human Immuno-deficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) through injuries involving needle sticks and other unintentional exposure to blood and body fluids. The most important response to this risk is prevention by strict adherence to guidelines, the “universal precautions,” which minimize the likelihood of such exposures. The guidelines that follow are meant to be used when an exposure of this type does occur in an Office of Public Health (OPH) facility.

Following national guidelines issued by the United States Public Health Service Centers for Disease Control and Prevention (CDC), exposure is contact with blood or body fluids, for which universal precautions apply, from a known or unknown patient source, through percutaneous inoculation (such as injury with a hypodermic needle or other “sharps”) or through contact with an open wound, non-intact skin or mucous membranes (splatter into eyes, nose or mouth). The body fluids for which universal precautions apply are: blood, amniotic fluid, pericardial fluid, peritoneal fluid, pleural fluid, synovial fluid, cerebrospinal fluid, semen, and vaginal secretions. Feces, nasal secretions, saliva, sputum, sweat, tears, urine and vomitus are not considered potentially infectious for HIV, HBV, or HCV unless they contain blood. The purpose of this protocol is to guide employees, who have had such exposure through the appropriate procedures in assessing risk, taking appropriate prophylaxis, follow-up and reporting the incident.

<p>Evaluation of Occupational Exposure Sources</p> <p>Known Sources</p> <ul style="list-style-type: none">-Test known sources for HBsAg, anti-HCV and HIV antibody-Consider using a rapid HIV antibody test-If the source person is not infected with a blood-borne pathogen, baseline testing or further of the exposed person is not necessary follow-up -For source patients whose infection status remains unknown, e.g. the source pateint refuses testing, consider medical diagnoses, clinical symptoms and history of risk behaviors - Do not test discarded needles for blood-borne pathogens <p>Unknown Sources</p> <ul style="list-style-type: none">-For unknown sources, evaluate the likelihood of exposure to a source at high risk of infection- Consider likelihood of blood-borne pathogen infection among patients in the exposure setting

II. Immediate Wound Care

Immediately following percutaneous exposure the site should be washed with soap and water, following a mucous membrane exposure flush with copious amounts of water, and following exposure to the eye irrigate with copious amounts of saline solution or other sterile irrigants. There is no data to suggest that use of other antiseptic agents is of additional benefit.

III. Risk Assessment and Prophylaxis

A. HIV

The risk of HIV infection after exposure depends on (1) the nature of the exposure, and (2) the HIV status or risk of HIV infection in the source patient. CDC has developed national guidelines for evaluating this risk. These guidelines are to be used as follows:

1. The Nature of the Exposure

- The average risk of infection from a percutaneous (e.g. needle stick) exposure to HIV is 0.3%.
- The risk of infection from a mucous membrane exposure to HIV is 0.9%.

The risk of infection from non-intact skin exposure is estimated to be less than that for mucous membrane exposure.

Employees should assess the type of exposure and amount of blood or fluid involved in the exposure.

2. Determining the HIV Status of the Source Patient

This may be done by searching medical records (e.g. STD, Prenatal or Family Planning charts or clinic records) or by requesting a blood sample for an HIV antibody test from a source patient. In most circumstances the source patient will be willing to provide consent for testing. If the source patient refuses and his or her blood has already been drawn for other purposes, under certain circumstances that blood may be used to test for HIV after it is used for the reason for which it was originally drawn. Consult with central office if this situation occurs. If it is not possible to determine the HIV status of the source patient, it is useful to remember that, in general, patients in OPH clinics are at very low risk for HIV infection, because of their being children or adults lacking the risk factors for infection.

For those rare instances in which the source patient is known to be HIV+, it is useful to check medical records to estimate his or her severity of disease (presence of AIDS [Acquired Immuno-deficiency Syndrome]) and the drugs, including the anti-retroviral drugs, being used to treat the disease.

3. Combine the information about the status of the source patient and the nature of the exposure to estimate the risk of infection. It should then be determined whether or not post-exposure prophylaxis (PEP) should be considered or is recommended by national guidelines. Most source patients in OPH clinics have an unknown HIV status. *If the OPH source patient's HIV status cannot be determined, the guidelines would not suggest nor recommend that PEP for HIV infection for an OPH employee after an occupational exposure be started.*

4. Determine whether or not prophylactic measures will be taken. These are drugs that are felt to decrease the risk of HIV infection following an actual occupational HIV exposure. *The drugs involved can cause side effects or serious toxicity; toxic effects from an attempt to prevent infection are often far more likely than the risk of HIV infection!* The decision regarding whether these medications should be taken or not should be made by the exposed person after reviewing this information and after consultation with other medical professional persons. Employees and supervisors considering the use of prophylactic drugs should consult immediately with the regional medical director, their private physician and/or the medical director of the HIV/AIDS Program in OPH. Additionally the advice of an infectious disease medical specialist should be sought. The following must be considered:

- If prophylactic drugs are used, they should be started as soon as possible after exposure, preferably within 1 to 2 hours.
- The drugs should continue to be taken for four weeks.

NOTE: PLEASE SEE ACCOMPANYING TABLES 1-6

IN THE PREVIOUS PUBLIC HEALTH SERVICE (PHS) GUIDELINES, A COMBINATION OF STAVUDINE (D4T) AND DIDANOSINE (DDI) WAS CONSIDERED ONE OF THE FIRST-CHOICE POSTEXPOSURE PROPHYLAXIS (PEP) REGIMENS; HOWEVER, THIS REGIMEN IS NO LONGER RECOMMENDED BECAUSE OF CONCERNS ABOUT TOXICITY (ESPECIALLY NEUROPATHY AND PANCREATITIS) AND THE AVAILABILITY OF MORE TOLERABLE ALTERNATIVE REGIMENS.

PREVIOUSLY, INDINAVIR (IDV), NELFINAVIR (NFV), EFAVIRENZ (EFV), OR ABACAVIR (ABC) WERE RECOMMENDED AS FIRST-CHOICE AGENTS FOR INCLUSION IN AN EXPANDED PEP REGIMEN.

PHS NOW RECOMMENDS THAT EXPANDED PEP REGIMENS BE PROTEASE-INHIBITOR (PI) BASED. THE PI PREFERRED FOR USE IN EXPANDED PEP REGIMENS IS LOPINAVIR/RITONAVIR (LPV/RTV). OTHER PI'S ACCEPTABLE FOR USE IN EXPANDED PEP REGIMENS INCLUDE ATAZANAVIR (ATV), FOSAMPRENAVIR (FOSAPV), RTV-BOOSTED IDV, RTV-BOOSTED SAQUINAVIR (SQV), OR NFV. ALTHOUGH SIDE EFFECTS ARE COMMON WITH NNRTIS, EFV MAY BE CONSIDERED FOR EXPANDED PEP REGIMENS, ESPECIALLY WHEN RESISTANCE TO PI'S IN THE SOURCE PERSON'S VIRUS IS KNOWN OR SUSPECTED. REMEMBER, CAUTION IS ADVISED WHEN EFV IS USED IN WOMEN OF CHILDBEARING AGE BECAUSE OF THE RISK OF TERATOGENICITY.

Combivir will continue to be the PEP stocked in OPH clinical facilities' emergency carts. If exposed employees choose to take these medications, they or their supervisors should contact the regional medical director and/or the HIV/AIDS Prevention Program Medical Director to help obtain the drugs. The initial five-day supply is available on the emergency cart in each OPH clinical site. The Office of Public Health pharmacy can supply the remainder of the prophylactic drug Combivir to complete the usual 28-day prophylactic regimen. This combination drug is also generally available at local pharmacies. Additional drugs, if needed, may be supplied on an individual need basis, if expanded PEP is needed, as indicated in the updated guidelines.

If the regional medical director or HIV/AIDS program medical director is not immediately available, the employee and/or supervisor should contact their own physician or a physician at the regional HIV/AIDS clinic, which is located in each regional state-run (Charity) hospital. In all instances, the employee must seek medical consultation from their own physician as soon as possible regarding continuing prophylaxis.

All OPH clinical sites must replenish their stock of Combivir on the emergency cart as soon as the initial package is used. The OPH clinical facilities must always be stocked with a five-day supply of Combivir. As mentioned above, in all instances staff using these drugs must consult with their own physician as soon as possible regarding medical follow-up and continuation of the drugs.

Pregnancy in an exposed person is not a contraindication to starting PEP for HIV. The decision to use any anti-retroviral drug during pregnancy should involve discussion between the pregnant woman and her physician regarding the potential benefits and risks to her and her fetus. Certain drugs should be avoided in pregnant women. Because teratogenic effects were observed in primate studies, as mentioned above, efavirenz is not recommended during pregnancy. Reports of fatal lactic acidosis in pregnant women treated with a combination of didanosine and stavudine have prompted warnings about these drugs during pregnancy. Because of risk of hyperbilirubinemia in newborns, indinavir should not be administered to pregnant women shortly before delivery.

5. Have a baseline HIV antibody test done. All exposed persons who have experienced an exposure serious enough to consider PEP (regardless of whether or not drugs were actually taken) should be tested for HIV antibodies at the time of exposure. The blood sample for this test should be sent to the OPH Laboratory.

Table 1

TABLE 1. Recommended HIV postexposure 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 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 in which 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 in which 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 ribonucleic acid copies/mL). HIV-positive, class 2 — symptomatic HIV infection, acquired immunodeficiency syndrome, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of 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.

† For example, deceased source person with no samples available for HIV testing.

§ For example, a needle from a sharps disposal container.

¶ For example, solid needle or superficial injury.

** The recommendation "consider PEP" indicates that PEP is optional; a decision to initiate PEP should be based on a discussion between the exposed person and the treating clinician regarding the risks versus benefits of PEP.

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

§§ For example, large-bore hollow needle, deep puncture, visible blood on device, or needle used in patient's artery or vein.

Table 2

TABLE 2. Recommended HIV postexposure prophylaxis (PEP) 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 ^{§§}	Generally, no PEP warranted	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 in which exposure to HIV-infected persons is likely	No PEP warranted

* For skin exposures, follow-up is indicated only if evidence exists 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 ribonucleic acid 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 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.

[§] For example, deceased source person with no samples available for HIV testing.

[¶] For example, splash from inappropriately disposed blood.

^{**} For example, a few drops.

^{††} The recommendation "consider PEP" indicates that PEP is optional; a decision to initiate PEP should be based on a discussion between the exposed person and the treating clinician regarding the risks versus benefits of PEP.

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

^{¶¶} For example, a major blood splash.

Table 3

TABLE 3. Primary side effects and toxicities associated with antiretroviral agents used for HIV postexposure prophylaxis, by class and agent

Class and agent	Side effect and toxicity
Nucleoside reverse transcriptase inhibitors (NRTI)	Class warning: all NRTIs have the potential to cause lactic acidosis with hepatic steatosis
Zidovudine (Retrovir®; ZDV, AZT)	Anemia, neutropenia, nausea, headache, insomnia, muscle pain, and weakness
Lamivudine (Epivir®, 3TC)	Abdominal pain, nausea, diarrhea, rash, and pancreatitis
Stavudine (Zerit™; d4T)	Peripheral neuropathy, headache, diarrhea, nausea, insomnia, anorexia, pancreatitis, elevated liver function tests (LFTs), anemia, and neutropenia
Didanosine (Videx®; ddi)	Pancreatitis, lactic acidosis, neuropathy, diarrhea, abdominal pain, and nausea
Emtricitabine (Emtriva, FTC)	Headache, nausea, vomiting, diarrhea, and rash. Skin discoloration (mild hyperpigmentation on palms and soles), primarily among nonwhites
Nucleotide analogue reverse transcriptase inhibitor (NtRTI)	Class warning: All NtRTIs have the potential to cause lactic acidosis with hepatic steatosis
Tenofovir (Viread®; TDF)	Nausea, diarrhea, vomiting, flatulence, and headache
Nonnucleoside reverse transcriptase inhibitors (NNRTIs)	
Efavirenz (Sustiva®; EFV)	Rash (including cases of Stevens-Johnson syndrome), insomnia, somnolence, dizziness, trouble concentrating, abnormal dreaming, and teratogenicity
Protease inhibitor	
Indinavir (Crivivan®; IDV)	Nausea, abdominal pain, nephrolithiasis, and indirect hyperbilirubinemia
Nelfinavir (Viracept®; NFV)	Diarrhea, nausea, abdominal pain, weakness, and rash
Ritonavir (Norvir®; RTV)	Weakness, diarrhea, nausea, circumoral paresthesia, taste alteration, and elevated cholesterol and triglycerides
Saquinavir (Invirase®; SQV)	Diarrhea, abdominal pain, nausea, hyperglycemia, and elevated LFTs
Fosamprenavir (Lexiva®, FOSAPV)	Nausea, diarrhea, rash, circumoral paresthesia, taste alteration, and depression
Atazanavir (Reyataz®; ATV)	Nausea, headache, rash, abdominal pain, diarrhea, vomiting, and indirect hyperbilirubinemia
Lopinavir/ritonavir (Kaletra®; LPV/RTV)	Diarrhea, fatigue, headache, nausea, and increased cholesterol and triglycerides
Fusion inhibitor	
Enfuvirtide (Fuzeon®; T-20)	Local injection site reactions, bacterial pneumonia, insomnia, depression, peripheral neuropathy, and cough

Sources: Package inserts; Panel on Clinical Practices for Treatment of HIV Infection. Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents—April 7, 2005. Washington, DC: National Institutes of Health; 2005. Available at http://aidsinfo.nih.gov/guidelines/default_db2.asp?id=50.

Table 4

TABLE 4. Prescription and over-the-counter drugs that should not be administered with protease inhibitors (PIs) because of drug interactions*

Drug	Comment
Antimicrobials: rifampin	Decreases plasma concentrations and area under plasma concentration curve of the majority of PIs by approximately 90%, which might result in loss of therapeutic effect and development of resistance
Benzodiazepines: midazolam, triazolam	Contraindicated because of potential for serious or life-threatening events (e.g., prolonged or increased sedation or respiratory depression)
Ergot derivatives: dihydroergotamine, ergotamine, ergonovine, methylergonovine	Contraindicated because of potential for serious or life-threatening events (e.g., acute ergot toxicity characterized by peripheral vasospasm and ischemia of the extremities and other tissues)
Gastrointestinal motility agent: cisapride	Contraindicated because of potential for serious or life-threatening events (e.g., cardiac arrhythmias)
HMG-CoA reductase inhibitors ("statins"): lovastatin, simvastatin	Potential for serious reactions (e.g., myopathy, including rhabdomyolysis); atorvastatin may be used cautiously, beginning with lowest possible starting dose, and monitoring for adverse events
Neuroleptic: pimozide	Contraindicated because of potential for serious or life-threatening events (e.g., cardiac arrhythmias)
Inhaled steroids: fluticasone	Coadministration of fluticasone and ritonavir-boosted protease inhibitors are not recommended unless the potential benefit to the patient outweighs the risk for systemic corticosteroid side effect
Herbal products:	
St. John's wort (hypericum perforatum), garlic	Coadministration might reduce plasma concentrations of protease inhibitors, which might result in loss of therapeutic effect and development of resistance Garlic might lower saquinavir level

* This table does not list all products that should not be administered with PIs (atazanavir, lopinavir/ritonavir, fosamprenavir, indinavir, nelfinavir, saquinavir). Product labels should be consulted for additional information regarding drug interactions.

Sources: US Department of Health and Human Services. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Washington, DC: US Department of Health and Human Services; 2005. Available at http://www.aidsinfo.nih.gov/guidelines/adult/AA_040705.pdf; University of California at San Francisco Center for HIV Information. Database of antiretroviral drug interactions. Available at <http://hivinsite.ucsf.edu/InSite?page=ar-00-02>.

Table 5

TABLE 5. Prescription and over-the-counter drugs that should not be administered with efavirenz because of drug interactions*

Drug	Comment
Antifungal: voriconazole	Contraindicated because efavirenz substantially decreases voriconazole plasma concentrations
Benzodiazepines: midazolam, triazolam	Contraindicated because of potential for serious or life-threatening events (e.g., prolonged or increased sedation or respiratory depression)
Ergot derivatives: dihydroergotamine, ergotamine, ergonovine, methylergonovine	Contraindicated because of potential for serious or life-threatening events (e.g., acute ergot toxicity characterized by peripheral vasospasm and ischemia of the extremities and other tissues)
Gastrointestinal motility agent: cisapride	Contraindicated because of potential for serious or life-threatening events (e.g., cardiac arrhythmias)
Herbal products:	Coadministration might reduce plasma concentrations of protease inhibitors, which might result in loss of therapeutic effect and development of resistance
St. John's wort (<i>hypericum perforatum</i>), garlic	Garlic might lower saquinavir levels

* This table does not list all products that should not be coadministered with efavirenz. Efavirenz product labeling should be consulted for additional information regarding drug interactions.

Sources: US Department of Health and Human Services. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Washington, DC: US Department of Health and Human Services; 2005. Available at http://www.aidsinfo.nih.gov/guidelines/adult/AA_040705.pdf; University of California at San Francisco Center for HIV Information. Database of antiretroviral drug interactions. Available at <http://hivinsite.ucsf.edu/InSite?page=ar-00-02>.

Table 6

TABLE 6. Reported instances of failure of combination drug postexposure prophylaxis (PEP) to prevent HIV-infection among health-care personnel exposed to HIV-infected blood through percutaneous injury

Year of incident	Device	PEP regimen*	Time to first dose (hrs)	No. of days to onset of retroviral illness	No. of days to document seroconversion†	Source-patient		
						HIV-infection status	On anti-retrovirals	Virus resistant to antiretrovirals§
1992¶	Biopsy needle	ZDV, ddl	0.5	23	23	AIDS, terminally ill	Yes	Unknown
1996**	Hollow-bore needle	ZDV, ddl††	1.5	45	97	Asymptomatic HIV infection	No	Not tested
1997**	Large or hollow-bore needle	ZDV, 3TC, IDV§§	1.5	40	55	AIDS	Yes	No
1998¶¶	Hollow-bore needle	ZDV, 3TC, ddl, IDV	0.7	70	83	AIDS	Yes	Yes
1999***	Unknown sharp	ddl, d4T, NVP†††	2.0	42	100	AIDS	Yes	Yes
2001§§§	Phlebotomy needle	ZDV, 3TC, IDV¶¶¶	1.6	24	~90	AIDS	Yes	Yes

* ZDV = zidovudine; ddl = didanosine; 3TC = lamivudine; IDV = indinavir; d4T = stavudine; and NVP = nevirapine.

† By enzyme immunoassay for HIV-1 antibody and Western blot.

§ By genotypic or phenotypic resistance testing.

¶ Source: Jochimsen EM. Failures of zidovudine postexposure prophylaxis. *Am J Med* 1997;102(Suppl 5B):52-5.

** Source: Lot F, Abiteboul D. Occupational infections with HIV in France among health-care personnel [French]. *Bull Epi Hebdom* 1999;18:69-70.

†† ZDV and ddl taken for 48 hours and then changed to ZDV alone.

§§ ZDV, 3TC, and IDV taken for 48 hours and then changed to d4T, 3TC, and IDV.

¶¶ Source: Perdue B, Wolde Rufael D, Mellors J, Quinn T, Margolick J. HIV-1 transmission by a needlestick injury despite rapid initiation of four-drug postexposure prophylaxis [Abstract no 210]. In: Program and abstracts of the 6th Conference on Retroviruses and Opportunistic Infections. Chicago, IL: Foundation for Retrovirology and Human Health; 1999.

*** Source: Beltrami EM, Luo C-C, de la Torre N, Cardo DM. Transmission of drug-resistant HIV after an occupational exposure despite postexposure prophylaxis with a combination drug regimen. *Infect Control Hosp Epidemiol* 2002;23:345-8; CDC, unpublished data, 1999.

††† ZDV and 3TC taken for 1 dose and then changed to ddl, d4T, and NVP; ddl was discontinued after 3 days as a result of severe vomiting.

§§§ Source: Hawkins DA, Asboe D, Barlow K, Evans B. Seroconversion to HIV-1 following a needlestick injury despite combination post-exposure prophylaxis. *J Infect* 2001;43:12-5.

¶¶¶ ZDV, 3TC, and IDV initially and then changed after first dose to d4T, ddl, and NVP; then ddl discontinued after 8 days; and d4T and NVP taken for 4 weeks.

B. Hepatitis B

All OPH employees with potential occupational exposure to blood or body fluid should be vaccinated against Hepatitis B. Such pre-exposure vaccination is the best protection against Hepatitis B infection in the event of an exposure occurring. Employees with potential occupational exposures who have not already been immunized should consult their supervisors to obtain the Hepatitis B immunization series.

If an exposure to blood or potentially infectious body fluid does occur, the decision regarding whether or not to provide post-exposure Hepatitis B vaccine must include consideration of the likelihood that the source patient is positive for Hepatitis B surface antigen (HBsAg) and the likelihood that the exposed person already is protected against Hepatitis B infection. Several items to consider when evaluating this situation are:

- The probability of the source being positive for HBsAg is about 1% in the Louisiana adult population and is about 5-15% in high-risk groups, e.g. men who have sex with men, intravenous drug users.
- Of persons who have not had prior Hepatitis B vaccinations or post-exposure prophylaxis, a needle stick from a needle used on an infected source patient may result in an infection rate of up to 62%, the rate in large part depending on the positivity in the source patient of both HBSAG..
- In previously unimmunized persons, Hepatitis B vaccines are 70%-75% effective when given within one week after HBV exposure. Hepatitis B vaccine and Hepatitis B Immune Globulin (HBIG) combination treatment is 85%-95% effective in preventing Hepatitis B following an exposure

The actions to be taken after an exposure are to:

1. Determine the HBsAg status of the source patient. This may be done by searching the medical records or requesting a blood specimen from the source patient and sending it to the OPH Laboratory for testing for HBsAg. In most circumstances source patients are willing to consent to have their blood tested. If the source patient refuses and his or her blood has already been drawn for other purposes, under certain circumstances the blood may be used to test for HBsAg after it is used for the reason for which it was originally drawn. Please **consult the Epidemiology section if this situation arises**.
2. Determine the Hepatitis B vaccination status and if possible the Hepatitis B antibody status of the exposed person. Vaccination records of exposed persons should be examined to verify whether or not vaccination was initiated and completed, and if post-exposure antibody testing was ever done. If this information is not available, consideration should be given to test the exposed person for Hepatitis B surface antibody (anti-HBs), depending on whether or not this information would influence the vaccination decision following the guidelines given below.
3. Decide whether or not vaccination of the exposed person is recommended. In general, *previously unvaccinated persons* should receive Hepatitis B vaccine for all exposures, because it is advisable for all HCW's to be protected against Hepatitis B. If in addition the source patient is known to HBsAg+, the exposed person should be given HBIG in combination with Hepatitis B vaccine. *Previously vaccinated persons* should be managed according to the status of the source patient and their own antibody response to the previous Hepatitis B vaccination. Details of the recommendations are presented in the following table:

Recommended Post-Exposure Prophylaxis for Exposure to Hepatitis B Virus

Treatment

Vaccination and Antibody Response Status of Exposed HCW*	Source HBSAG [†] positive	Source HBsAg [†] negative	Source Unknown or not available for testing
Unvaccinated	HBIG § x 1 and initiate Hepatitis B vaccine series¶	Initiate Hepatitis B vaccine series	Initiate Hepatitis B vaccine series
Previously vaccinated Known responder**	No treatment	No treatment	No treatment
Known non-responder††	HBIG x 1 and initiate revaccination or HBIG x 2§§	No treatment	If known high risk source patient, treat as if source patient 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 re-check titer in 1-2 months

* Persons who have previously been infected with HBV are immune to reinfection and do not require post-exposure 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 non-responder is a person with inadequate response to vaccination (i.e. serum anti-HBs less than 10 mIU/ml)

§§ The option of giving one dose of HBIG and re-initiating the vaccine series is preferred for non-responders who have not completed a second three 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

If post-exposure vaccination is considered, OPH staff should be aware of the following:

- HBIG should be administered as soon after exposure as possible and within 24 hours.
- The first dose of Hepatitis B vaccine should be administered at a separate site and can be administered simultaneously with HBIG or within 7 days of exposure.
- Testing for anti-HBs is available through the OPH Laboratory and through many hospital laboratories. However the test results are not available within 24 hours unless special arrangements are made with the laboratory. If decisions regarding Hepatitis B vaccination are to be made based on these laboratory test results, employees and their supervisors should speak directly with laboratory personnel to arrange for rapid testing.

4. Conduct baseline tests of the exposed person. All employees who are receiving HBIG or Hepatitis B vaccine as prophylaxis for an exposure should be tested before receiving the first dose of vaccine for anti-HBs and HBsAg. The results of these baseline tests can be used later with the results of follow-up testing to assess whether or not an infection occurred from the exposure.

C. Hepatitis C

The risk of transmission of Hepatitis C following a needle stick from an infected source patient is probably greater than the risk for HIV but less than the risk for Hepatitis B. In follow-up studies of HCW's who sustained percutaneous exposure to blood from anti-HCV positive patients, the incidence of anti-HCV seroconversion averaged 3.5%. Following a needle stick, it is recommended that, if possible, the source patient be tested for anti-HCV antibodies. For employees exposed to an anti-HCV positive source patient, baseline and follow-up anti-HCV testing are recommended. Anti-HCV testing is now available through the OPH Laboratory; however this test has many false positive results, so employees with positive anti-HCV tests should be referred to their physician for evaluation and supplemental Hepatitis C testing, e.g. RT-PCR.

IV. Follow-Up

A. HIV

Employees with an exposure that is high risk for HIV should be tested for HIV antibodies at baseline, six weeks, twelve weeks and six months after HIV exposure. In rare cases, seroconversion has occurred more than six months after HIV exposure; therefore for severe injuries with a high risk of infection, testing should also be conducted twelve months after exposure. Extended HIV follow-up, e.g. for twelve months, is recommended for any HCW who becomes infected with HCV following exposure to a source patient co-infected with HIV and HCV. Whether or not extended follow-up is indicated in other circumstances, e.g. exposure to a source patient co-infected with HIV and HCV in the absence of HCV seroconversion or for exposed persons with a medical history suggesting an impaired ability to develop an antibody response to acute infection, is unclear. Although rare instances of delayed HIV seroconversion have been reported in the medical literature, the infrequency of this occurrence does not warrant adding to the anxiety level of the exposed persons by routinely extending the duration of post-exposure follow-up.

Employees who take prophylactic drugs should discuss with the prescribing physician the possibility of tests for medication toxicity at baseline and at the time of the two week follow-up. These tests would be complete blood count, renal and hepatic function tests.

HIV testing should be performed on any exposed person who has an illness that is compatible with an acute retroviral syndrome, regardless of the interval since exposure. When HIV infection is identified, the person should be referred to a specialist, knowledgeable in the area of HIV treatment and counseling, for medical management.

B. Hepatitis B

Employees of unknown anti-HBs status who begin Hepatitis B vaccination, pending the results of testing and who later are found to have anti-HBs in the baseline blood sample, do not need to complete the Hepatitis B vaccination series, and do not need additional Hepatitis B testing.

Employees who begin Hepatitis B vaccination and do not have measurable anti-HBs in the baseline blood sample should finish off the three dose Hepatitis B vaccine series with the standard one month and six month doses. One to two months after the Hepatitis B series is complete, these employees should be tested for HBsAg and Anti-HBs to assess whether or not an infection occurred and whether or not the employee responded to the vaccination.

C. Hepatitis C

Employees who have had a needle stick injury from anti-HCV positive source patient and who are tested at baseline, should have follow-up testing for anti-HCV antibodies and liver enzymes (Alanine aminotransferase [ALT]) six months later. This testing can be done by the OPH Laboratory. The purpose of this testing is to document whether or not Hepatitis C infection occurred, and to initiate treatment, if infection did, indeed, occur.

V. Reporting and Documentation

A. Forms Needed

- Incident Reporting Form (DA 200 Rev 08-12-99), from the Office of Risk Management
- Employer's Report of Occupational Injury or Diseases (DA 1973 Rev 09-99), from Human Resources office, if Workmen's Compensation claim is considered
- Epi-31 (Employee's Report of Exposure to Known or Possible Contaminated Blood or Body Fluids), attached
- HIV Counseling and Testing Form (Lab 100), if HIV antibody testing is done
- Hepatitis Laboratory Form (Lab 95) if Hepatitis B and/or Hepatitis C testing is done

B. Procedure

- Report the incident of injury or exposure to the supervisor using the incident reporting form.
- Offer the exposed employee confidential pre and post-test counseling regarding their antibody screenings.
- Complete the first two pages of the Epi-31 (with the exception of the source patient’s test results) within 24 hours of the incident.
- Get a baseline test for HBV, HCV, and HIV antibodies on the exposed person and the source patient within 48 hours of the incident, complete appropriate laboratory forms, and enter on the Epi-31 (in Follow-Up section).
- Make sure that consent forms are signed by the source patient and the exposed individual. Also validate that the exposed individual signed the Epi-31 form.

C. Supervisor Follow-Up:

Contact the employee to assure the follow-up vaccinations and follow-up tests for HIV and Hepatitis B are conducted on schedule as described above. Enter the results on the Epi-31 form.

When the Epi-31 form is complete it should be sent to the regional nurse manager and kept on file at the regional office.

Primary Side Effects Associated with Basic 2 Drug and Expanded 3 Drug Anti-retroviral Agents

Anti-retroviral Class/Agent	Primary Side Effects and Toxicities
<p>Nucleoside Reverse Transcriptase Inhibitors (NRTI’s)</p> <p>Zidovudine (Retrovir; AZT, ZDV)</p> <p>Lamivudine (Epivir; 3TC)</p> <p>Combivir (CBV)</p>	<p>Anemia, neutropenia, nausea, headache, insomnia, muscle pain, weakness, lactic acidosis</p> <p>Abdominal pain, nausea, diarrhea, rash, pancreatitis, lactic acidosis</p> <p>As for zidovudine and lamivudine above</p>
<p>Protease Inhibitors (PI’s)</p> <p>Indinavir (Crixivan; IDV)</p> <p>Nelfinavir (Viracept; NFV)</p>	<p>Nausea, abdominal pain, nephrolithiasis, indirect hyperbilirubinemia, lipodystrophy</p> <p>Diarrhea,, nausea, abdominal pain, weakness, rash, lipodystrophy, hyperglycemia, reduced effect of oral contraceptives</p>

This information includes only those drugs recommended in the basic 2 drug and expanded 3 drug post-exposure prophylaxis. For further information on side effects of the other drugs used for anti-retroviral therapy, please consult the United States Centers for Disease Control and Prevention (CDC) publication “MMWR Recommendations and Reports, Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis,” June 29, 2001, Vol. 50/ No. RR-11. This is also available on the CDC Website, <http://www.cdc.gov>

OCCUPATIONAL EXPOSURE MANAGEMENT RESOURCES AND REFERENCES

<p>National Clinicians' Postexposure Prophylaxis Hotline (PEpline)</p> <p>Run by University of California-San Francisco/San Francisco General Hospital staff; supported by the Health resources and Services Administration Ryan White Care Act, HIV/AIDS Bureau, AIDS Education and Training Centers, and CDC</p>	<p>Phone: 1(888) HIV-4911 1(888) 448-4911 Internet: http://www.ucsf.edu/hivcntr</p>
<p>Needlestick!</p> <p>A website to help clinicians manage and document occupational blood and body fluid exposures. Developed and maintained by the University of California, Los Angeles (UCLA), Emergency Medicine Center, UCLA School of Medicine, and funded in part by CDC and the Agency for Healthcare Research and Quality.</p>	<p>Internet: http://www.needlestick.mednet.ucla.edu</p>
<p>Hepatitis Hotline</p>	<p>Phone: 1(888) 443-7232 Internet: http://www.cdc.gov/hepatitis</p>
<p>LSU-Delta Region AIDS Education and Training Center - Clinical Consultation</p> <p>Educational and medical consultative service for HIV infection, AIDS and AIDS-related disorders.</p>	<p>Phone: 1(504) 903-0788 Internet: http://www.deltaetc.org</p>
<p>HIV/AIDS Treatment Information Service</p>	<p>Internet: http://www.hivatis.org</p>

Instructions - EPI - 31 Form

Page 1

Employee Last Name: Please print name clearly.

Employee First Name: Please print name clearly.

Home Phone Number: Include Area Code and home telephone number

Work Phone Number: Include Area Code and work telephone number

Date of Incident: Write in month, day and year in the spaces provided.

Place Incident Occurred: Please be as specific as possible; e.g. Immunization Room of X Parish Health Unit

Description of Incident: Please be as specific as possible as to circumstances of incident, including time of day it occurred, and others involved in the incident, e.g. other employees by name and/or patients, by name.

Hepatitis B Vaccination Status: Please be specific as to dates and please do not check unknown unless verification of vaccination history has been impossible to obtain.

Source Person: Please complete this section as completely as possible, including laboratory data requested, in a timely manner. Antigen and antibody test results and dates, and medical history of risk should be sought in the source person's medical records as thoroughly as possible.

Baseline Counseling/Testing of Source Patient: Please complete this section as completely as possible and fill in test results as soon as they are obtained back from the testing laboratory.

Note: NA = not applicable, is to be checked only if deemed that testing is not needed at time of exposure incident.

Page 2

Recommendations Regarding Prophylaxis: This must be completed by the parish health unit nursing supervisor, the regional medical director, or a laboratory unit supervisor. The name and title of the person providing the recommendations must be included, and may be, for example, the exposed person's own physician, the regional medical director, and/or an AIDS medical consultant from a medical center or Office of Public Health central office. Include all names and titles of persons consulted regarding recommendations.

Employee Selection of Options: This is an informed consent. Employee's full name must be printed in the blank space in this section. Circle all applicable answers (yes or no) for the Baseline testing and for Prophylactic Vaccination and Medications section. Employee signature must match the employee name as printed on the form in the blank space, as noted above. The Supervisor's signature should be the person completing the form, as mentioned above, e.g. the parish health unit nursing supervisor, the regional medical director, or a laboratory unit supervisor.

Page 3

Follow Up: The supervisor completing this section should be the same person completing the previous sections, unless there has been a change in supervisors. If so, then that should be explained on the form after the name of the new supervisor has been printed in the space on this page. The appropriate drug names should be checked if applicable, the time interval between exposure and first dose should be expressed in hours, e.g. 1 ½ hours = one hour and thirty minutes, and the name of the physician prescribing the drugs should be printed in the space provided.

The serological testing information requested must be filled out completely; as is also true for the vaccine, immune globulin, and ALT (alanine aminotransferase liver function test) information requested. Dates should be specified by month, day and year in the spaces provided. The follow-up completed date should also be specified by month, day and year in the space provided and the supervisor's signature should be that of the supervisor named at the top of page 3.

EMPLOYEE REPORT OF EXPOSURE TO KNOWN OR POSSIBLE CONTAMINATED
BLOOD OR BODY FLUIDS

Exposed Employee Data:

Employee Last Name: _____ Employee First Name: _____

Home Telephone number: _____ Work Telephone Number: _____

Date of Incident: ___/___/___ Place Incident Occurred: _____

Description of Incident: _____

Hepatitis B Vaccination Status: (check one) _____ completed three dose vaccination; month/year _____

_____ incomplete HBV vaccination: # doses _____

Month/year last dose _____

_____ not vaccinated against Hepatitis B

_____ vaccination status unknown

Source person: (check one) _____ Known _____ Unknown

If known, source person's Last Name: _____ First Name: _____

Clinic Number: _____

Previous test results (if known): anti-HCV _____

HBsAg _____

HBsAg test date _____

HIV antibody _____

HIV antibody test date _____

Known Risk Status of Source (if known): (check all that are known)

_____ Intravenous drug user _____ Man who has sex with men

_____ Sex partner HIV+ _____ Chronic liver disease

Baseline Counseling/Testing of Source Patient:

Patient consented to HIV testing _____ Yes _____ No _____ NA

If yes, result of HIV test: _____ Negative _____ Positive _____ Indeterminate

Date of HIV test: _____

Patient consented to HBsAg testing _____ Yes _____ No _____ NA

If yes, result of HBsAg test: _____ Negative _____ Positive _____ Indeterminate

Date of HBsAg test: _____

Patient consented to anti-HCV testing _____ Yes _____ No _____ NA

If yes, result of anti-HCV test: _____ Negative _____ Positive _____ Indeterminate

Date of anti-HCV test: _____

Hepatitis B: Hepatitis B Vaccine recommended: _____ Yes _____ No
HBIG recommended: _____ Yes _____ No

HIV: AZT, 3TC or other antiviral drugs recommended _____ Yes _____ No

Person providing above recommendations Name _____

Title _____

Employee Selection of Options Regarding HIV and HBV testing and therapy:

I, _____, have reported an incident of exposure to blood or body fluids. I have been offered confidential testing to establish baseline HIV antibody status, with the option of counseling and testing by qualified persons outside of the program in which I work. I have been counseled regarding the post-exposure use of AZT, 3TC and other anti-virals if the source patient was HIV positive or suspected to be so and had these medications offered to me. I have also been offered the opportunity to receive Hepatitis B vaccine and Hepatitis B immune globulin.

Circle yes or no for each:

Baseline testing:

I consent to have a baseline test for anti-HBS and HBsAg _____ Yes _____ No

I consent to have a baseline test for anti-HCV _____ Yes _____ No

I consent to have a baseline test for HIV antibodies _____ Yes _____ No

Prophylactic vaccination and medications:

I agree to receive hepatitis B vaccine _____ Yes _____ No

I agree to receive hepatitis B immune globulin _____ Yes _____ No

I agree to receive AZT, 3TC and/or other antivirals to prevent
HIV infection _____ Yes _____ No

I choose to follow up with my own physician and supply him or her
with this protocol _____ Yes _____ No

I realize that if I am not tested for HIV at this time, it will be impossible to document HIV serconversion as a result of this injury.

Employee signature

Supervisor signature

Follow Up on Exposed Employee, to be Completed by Unit Supervisor

Name of Supervisor Completing Follow Up _____

Medications Taken (check all that apply): _____ AZT (ZDV, zidovudine)

Remember: AZT + 3TC = "Combivir"

_____ 3TC (lamivudine)

_____ IDV (indinavir)

_____ nelfinavir

Time interval between exposure and first dose (hours): _____

Medications prescribed by (physician): _____

HIV Serology:	Date due	Date drawn	Result
Baseline	__/__/__	__/__/__	_____
6 week follow up	__/__/__	__/__/__	_____
12 week follow up	__/__/__	__/__/__	_____
6 month follow up	__/__/__	__/__/__	_____
12 month follow up	__/__/__	__/__/__	_____

Hepatitis B Vaccine: Dose 1 Date __/__/__ administered by _____
 Dose 2 Date __/__/__ administered by _____
 Dose 3 Date __/__/__ administered by _____

HBIG given: YES [] Date __/__/__ administered by _____
 NO []

Hepatitis B serology results:	Date due	Date drawn	HbsAg	Anti-HBS
Baseline	__/__/__	__/__/__	_____	_____
Follow up*	__/__/__	__/__/__	_____	_____

*one to two months after vaccination series completed, if vaccinated post-exposure or six months after incident occurred, if employee does not have antibodies at baseline and is not vaccinated post-exposure

Hepatitis C Serology Results:	Date due	Date drawn	Anti-HCV	ALT
Baseline	__/__/__	__/__/__	_____	_____
6 month follow up	__/__/__	__/__/__	_____	_____

Comments: _____

Follow up completed Date __/__/__

Signature of supervisor _____