01.2 Bloodborne Pathogens (BBP) - Occupational Post-Exposure Prophylaxis

Purpose

The purpose of this document is to establish UTMB policy for the initiation of prophylaxis after occupational exposure to the human immunodeficiency virus (HIV) and hepatitis B virus (HBV) and early treatment of infection with the hepatitis C virus (at time of seroconversion) to prevent chronic infection. This policy has been developed from the most current medical literature, clinical experience at UTMB and the September 30, 2005 recommendations from the Centers for Disease Control and Prevention (CDC). This prophylaxis protocol and regimen will be continuously updated with the most recent medical information.

Audience

All employees of UTMB hospitals, clinics, outpatient surgical center, contract workers, volunteers, and students.

Definitions

- An occupational exposure requiring the initiation of prophylaxis is defined as:
  - § Percutaneous injury (e.g. needlestick, laceration with a sharp object)
  - § Contact of mucous membranes or ocular membranes
  - § Contact of non-intact skin (e.g. skin that is chapped, abraded)

    with

    Blood or other potentially infectious fluid (semen; vaginal secretions; and cerebrospinal, synovial, pleural, peritoneal, pericardial and amniotic fluids; bloody body fluids and unfixed tissue).

- An occupational exposure requiring monitoring is defined as:
  - § Percutaneous injury (e.g. needlestick, laceration with a sharp object)
  - § Contact of mucous membranes or ocular membranes
  - § Contact of non-intact skin (e.g. skin that is chapped, abraded)
  - § Contact with intact skin that is prolonged or involves an extensive area

    with

    Blood or other potentially infectious fluid (semen; vaginal secretions; and cerebrospinal, synovial, pleural, peritoneal, pericardial and amniotic fluids; bloody body fluids and unfixed tissue).

Occupational Exposure Monitoring

All UTMB employees and students with a documented occupational exposure shall have the exposure evaluated and documented by a healthcare provider following the standard protocol. The healthcare provider shall:

- Recommend prophylaxis for percutaneous exposures, contact of mucous membranes or non-intact skin.

  with

- Blood or other potentially infectious fluid (semen; vaginal secretions; and cerebrospinal, synovial, pleural, peritoneal, pericardial and amniotic fluids; bloody body fluids and unfixed tissue).
- Refer other exposures to the Employee Health Center/Student Health Services at UTMB for enrollment in the occupational monitoring program.

Prophylaxis

Prophylaxis shall be recommended to all UTMB employees or students:

- HIV:
  - For percutaneous exposures, contact of mucous membranes or non-intact skin.

    with

  Blood or other potentially infectious fluid (semen; vaginal secretions; and cerebrospinal, synovial, pleural, peritoneal, pericardial and amniotic fluids; bloody body fluids and unfixed tissue).
  - Ideally within two hours after exposures, but may be initiated up to 96 hours after exposure.
  - With appropriate drug therapy.
  - Until the source-patient blood has been obtained and analyzed. If the source-patient HIV status is determined to be negative, prophylaxis will be discontinued.
  - HBV-Prophylaxis for HBV prevention will be evaluated on an individual basis.
  - HCV-Employees/students testing positive for Hepatitis C Qualitative RNA (PCR) at 6 weeks, 3 months or 6 months, will be referred immediately to a hepatologist for early treatment to prevent chronic hepatitis C infection.

EMPLOYEE/STUDENT CHECKLIST

r Wash exposed area immediately.

r Notify Supervisor immediately (supervisor to assist with obtaining source consent & lab work).

  r Have supervisor document in source's medical record "source of occupational exposure" and
  that labs were drawn for HIV, HCV, and HBS (Hepatitis B surface antigen) with source's consent.

r Seek post-exposure care:

for employees on campus report to	*for students on campus report to*
Employee Health (7:30 AM-4:30 PM) (409) 747-9172	Student Wellness (8AM-5PM) (409) 747-9320

r Report to Emergency Department, after hours, weekends, or holidays (**Follow-up in Employee Health/Student Wellness the next business day).**

Employee/student should report to Employee Health/Student Wellness or Emergency Department as soon as possible, but at least within 2 hours of exposure.

r Off-site Exposures - Follow clinic specific policy.
Obtain packet from supervisor or visit website (see below) for required forms, procedures, and information.

  r Complete "Bloodborne Pathogen (BBP) Exposure Notification Form" [In packet & available at Employee Health].

  - Off-site – Complete form and fax to Employee Health/Student Wellness.
  - On-campus – Report to Employee Health/Student Wellness (form will be completed there).
  - If seen in the Emergency Department, form should be completed there and faxed
  - to Employee Health/Student Wellness.

Employee Health	Student Wellness
Fax (409) 747-9182	Fax (409) 747-9330

*****You must report the exposure and have HIV lab testing done within ten (10) days to receive maximum benefits if a Worker's Comp claim were to be filed in the future.**

r Follow up with Employee Health/Student Wellness.

r ***For questions, visit:*** ***www.utmb.edu/policy/hcepidem/search/01-02.pdf***

SUPERVISOR/FACULTY CHECKLIST

r Refer employee/student for post exposure care immediately.

for employees on campus report to	*for students on campus report to*
Employee Health **(409) 747-9172**	**Student Wellness** **(409) 747-9320**

Employee/student should report to Emergency Department, after hours, weekends, or holidays (**Follow-up in Employee Health/Student Wellness the next business day).**

Employee/student should report to Employee Health/Student Wellness or Emergency Department as soon as possible, but at least within 2 hours of exposure.

r Assist employee/student with obtaining source consent and source lab work.

r Document in source's medical record "source of occupational exposure" and that labs were drawn for HIV, HCV, and HBS with source's consent.

r Remind employee/student to report exposure by completing "BBP Exposure Notification Form".

- Off-site – Complete form and fax to Employee Health/Student Wellness.

Employee Health	Student Wellness
Fax (409) 747-9182	Fax (409) 747-9330

- On-campus – Report to Employee Health/Student Wellness (form will be completed there).
- If seen in the Emergency Department, form should be completed there and faxed to

Employee Health/Student Wellness.

Employee Health	Student Wellness
Fax (409) 747-9182	Fax (409) 747-9330

r For questions call Employee Health Center at (409)747-9172 or Student Wellness at (409)747-9320; after hours call the Access Center at 1-800-917-8906.

For questions, visit www.utmb.edu/policy/hcepidem/search/01-02.pdf

PROVIDER CHECKLIST

r Provide necessary medical care to treat the injury/exposure.

r Refer to the BBP Flow Chart and Procedures [Enclosed] as a guide for post-exposure. care

r Use Laboratory testing forms [enclosed] as a reference.

r Use UTMB Occupational Exposure prescription to prescribe only enough medication until follow-up appointment or source results available.

r Complete the BBP Exposure Notification Form [enclosed] and fax to Employee Health/Student Wellness.

- Employee Health – FAX # (409) 747-9182
- Student Wellness – FAX # (409) 747-9330

r Provide patient education information [enclosed].

r Complete Informed Consent for Prophylaxis form [enclosed].

r Billing may be submitted to:

UTMB, Employee Health
Attn: Kathryn Jinkins
301 University Boulevard, Route 1161
Galveston, TX 77555-1161

Reimbursement will be for reasonable & customary charges for authorized or medically necessary tests as noted in enclosed information. Any additional charges will not be reimbursed.

POST-EXPOSURE PROCEDURE

I. MANAGE THE EXPOSURE

A. Wash the area immediately with soap and water.

B. For exposure to eyes, mouth, and/or nose flush area with water.

II. NOTIFY SUPERVISOR/FACULTY IMMEDIATELY

A. Supervisors will assist in obtaining source consent and lab work.

B. Supervisors & faculty shall release the employee or student from their duties immediately to seek post-exposure care.

III. PROCEDURE FOR SOURCE TESTING

A. Obtain source consent & lab specimen.

B. Use Physician Order Entry (POE) for HIV consent for alert and oriented patients.

C. General consent for comatose/general anesthesia patients will suffice but needs to be documented on Lab Requisition (form MM 68693).

D. Refusals should be documented on Lab Requisition (form MM 68693). Notify UTMB Legal 24 hours/day. The Legal Department will make the decision on how source blood will be obtained. (Contact Legal by calling the hospital operator).

E. Complete Lab Requisition (form MM 68693).

- § Employees who are off campus can contact employee health and they will fax a completed lab slip to put in the bag with the specimens.

F. Assure consent status is documented on form.

G. Obtain one (1) serum separator tube.

H. Label tube

I. Document exposure in source's medical record & that labs were drawn for "source of occupational exposure".

J. Send blood to Laboratory Medicine, Sample Management, Rm. 5.136, McCullough Building.

K. Laboratory results for personnel will be sent to Employee Health/Student Wellness for follow-up. Source laboratory results will be placed in the source's medical record when consent is granted, or when general consent is invoked. If source refuses testing, results will be sent to Employee Health/Student Wellness.

IV. EMPLOYEE/STUDENT POST EXPOSURE CARE

A. Monday through Friday 7:30 AM to 4:30 PM go immediately to the Employee Health Center. Students are seen in Student Wellness 8AM to 5PM.

B. Holidays, weekends, or after hours – Go to the Emergency Department immediately.

1. Triage to ensure initiation of prophylaxis within 2 hours of exposure (percutaneous injury or contamination of mucous membranes or nonintact skin with blood, body fluids visibly contaminated with blood, unfixed tissue, semen, vaginal secretions, and cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids).
2. Obtain consent for HIV through Physician Order Entry (POE).
3. Submit Employee/Student specimens using form MM 68693 – two serum separator tubes labeled appropriately.
   a. Order labs for exposed individual [HIV-1/HIV-2 antibody, HCV antibody and HBA]. HBS should be ordered for employees/students who have never received vaccine or who have a history of HBV immunization prior to coming to UTMB.
   b. Additional lab if Employee/Student is starting prophylaxis – CBC (use additional lavender top tube for CBC), ALT, AST, total bilirubin, GGT, Creatinine and BUN. Females must have a urine or serum pregnancy test.
   c. Assure consent for testing is documented.
   d. Send specimens to Sample Management, Room 5.136 McCullough.
4. Post-exposure Treatment
   a. Offer tetanus/diphtheria booster following percutaneous injury if none within last 10 years.
   b. Offer HBV vaccine if source is known to be positive for hepatitis B or is high risk for hepatitis B and employee/student has not been vaccinated against hepatitis B.
   c. Offer Hepatitis B Immune Globulin 0.06 ml/kg IM if source is known to be positive for hepatitis B or is high risk and employee/student has not been vaccinated against hepatitis B.
   d. Employees/students testing positive for Hepatitis C Qualitative RNA (PCR) at 6 weeks, 3 months or 6 months, will be referred immediately to a hepatologist.
   e. Recommend HIV prophylaxis following percutaneous injury or contamination of mucous membranes or nonintact skin with blood, body fluids visibly contaminated with blood, unfixed tissue, semen, vaginal secretions, and cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids (goal is to begin within 2 hours of exposure).
   f. See Appendix A for warnings on drug interactions.
   g. Prophylaxis medications – write "***UTMB Occupational Exposure***" on prescription
      1) Fos-amprenavir (Lexiva 700mg tab), 2 tablets by mouth with food every 12 hours for 4 weeks.
      2) Emtricitabine (Emtriva 200mg cap), one capsule by mouth every 24 hours for 4 weeks.
      3) Tenofovir (Viread 300 mg tab), one tablet by mouth every 24 hours for 4 weeks.
      4) Provide with 72-96 hour supply of medication.
      5) Assure Consent for Post-Exposure Prophylaxis is completed.

h. Employee/Student is Pregnant – For pregnant women, prophylaxis should be reserved for those with HIGH RISK exposures, and tenofovir (Viread) should not be used. In this case, an alternate regimen should be used:
   1) Combivir (300 mg [AZT] and 150 mg lamivudine [Epivir], in fixed dose combination cap), one capsule by mouth with food every 12 hours and for 4 weeks.
   2) Kaletra (lopinavir/ritonavir 200/50mg tabs), 2 tablets by mouth with or without food every 12 hours for 4 weeks.
   3) Provide with 72 – 96 hour supply of medication.
   4) Assure Consent for Post-Exposure Prophylaxis is completed.
   5) Pregnant employees/students will be followed up by Employee Health/Student Wellness and will be referred to the Maternal/Child Clinic (409)772-2798.

V. OFF-CAMPUS EXPOSURE OF UTMB EMPLOYEES/STUDENTS

A. Maternal-Child Health Clinics – refer to clinic specific policies for initial management.

B. Primary Care Outpatient Clinic – refer to clinic specific policies for initial management.

C. TDCJ – refer to TDCJ specific policies for initial management. Procedure Questions

Employee Health (7:30 AM-4:30 PM)	Student Wellness (8AM-5PM)
(409) 747-9172	409) 747-9320

VI. **Any employee claiming a work-related exposure to HIV infection must provide the employer with the BBP Notification Form and document that within 10 days after the date of the exposure, the employee had a test result indicating absence of HIV, HBV, or HCV infection. (Texas Vernon's Civil Statute, Health & Safety Code Section 85.116 (c) for the purpose of qualifying for workers' compensation or any other similar benefits or compensation.**

After hours, weekends, and holidays – call the Access Center (1-800-917-8906). Employees/students with off campus exposure shall notify Employee Health/Student Wellness as soon as possible even when treatment initiated elsewhere.

References

1. CDC. Updated U.S. Public Health Service guidelines for the management of occupational exposures to HBV, HCV, and HIV and recommendations for Postexposure Prophylaxis. MMWR 2001; 50 (No. RR-11):1-53.
2. CDC. Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for Postexposure Prophylaxis. MMWR 2005; 54 (No. RR-9):1-13.
3. Jaeckel E, Cornberg M, Wedemeyer H, et al. Treatment of acute hepatitis C with interferon alfa-2b. N Engl J Med 2001; 345:1452-7.
4. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. January 29, 2008; 1-128. Available at
   http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf

NOTIFICATION FORM

Person completing form_____Signature_____Date/Time_____

Name_____ r Employee r Student

Dept/School _____

Supervisor/Faculty _____

Home # _____Work # _____Pager #_____

Employee# or Student SSN _____Date of Exposure ____/_____/____Time ____am_ pm __

Location where exposure occurred *(Building, Floor, Rm)* _____

Personal Protective Equipment Used: r Gloves r Goggles/Mask/Faceshield r Gown r Other
Was a safety device being used? r Yes r No If so, did it work? r Yes r No
Type & Brand of safety device _____
Body part exposed *(circle one)* hand, eye, mouth, other *(please identify)*_____
Describe how exposure occurred. _____
_____

Type of body fluid exposed to: r blood r body fluid contaminated by blood r semen
r vaginal secretions r CSF r synovial r peritoneal
r pericardial r amniotic r unfixed human tissue

Type of exposure: r needlestick…..Depth of injury _____
(check all that apply) r cut…….Depth of injury _____
Fluid injected r Yes r No – Estimated volume: _____
r Mucous membrane
r Non-intact skin (e.g., chapped, abraded, or otherwise non-intact)

Did this exposure occur during the employee's/student's normal work activities? r Yes r No
Is patient source known? r Yes r No Was source consent obtained? r Yes r No
Source lab testing done? r Yes r No Source on antiretroviral therapy? r Yes r No
List Drugs _____
Was source blood sent to lab? r Yes r No
Source name _____ UH#_____ Location_____
Exposed employee/student lab testing done? r Yes r No
(For Females)- Pregnancy test result_____
Was prophylaxis initiated? r Yes r No Date/Time of 1st dose ____/_____/____Time ____am_ pm __
Have you had training on Universal Precautions within the last 12 months? r Yes r No

FAX THIS FORM TO:

(409) 747-9182-Employees (409) 747-9330-Students

For questions call:

Mon-Fri 7:30am-4:30 pm Mon-Fri 8:00am-5:00pm
(409) 747-9172-Employees (409) 747-9320-Students
Access Center 1-800-917-8906

BLOODBORNE PATHOGENS EXPOSURE MANAGEMENT FORM *

University of Texas Medical Branch – Employee Health/Student Wellness

Name _____
(Last) (First) (MI)

r Employee r Student Employee Dept._____ Position_____

Phone: _____ _____ _____
(Home) (Pager) (Work)

Date of Exposure _____ Time of Exposure _____ am/pm

Initial Care of Injury/Exposure

Site_____

_____

Date of Evaluation (Initial) _____ Time of Evaluation (Initial) _____ am/pm

r Completed BBP Notification Form attached.

SOURCE INFORMATION AT TIME OF INCIDENT r Known Source r Unknown Source

Name _____UH#_____

Account # _____Location _____

SOURCE LAB RESULTS

	Date Drawn	Results
HIV		
HBS (Hep B surface antigen)		
HCV		

HEPATITIS AND TETANUS

Hepatitis B Vaccine [0] [1] [2] [3]
Last Dose: _____
Antibody Response: r Positive r Negative r Unknown
Hepatitis B Vaccine Given: r Yes r No Date Given: _____
Immunoprophylaxis: HBIG r Yes r No Date Given: _____
Tetanus/Diptheria Booster (dT/Tdap): Date of Last Dose: _____
Booster Given: r Yes r No Date Given: _____

* See Appendix B for flow diagram on exposure management.

HIV EXPOSURE
INITIAL VISIT

BP_____ P_____ R_____ T_____ WT_____ HT_____
Medication(s) _____ Drug Allergy(s) _____
_____
_____

Clinical Findings:

_____

_____

_____

_____

_____

EMPLOYEE/STUDENT BASELINE LAB

Consent for HIV Testing r Yes
r No

Date _____

EMPLOYEE/STUDENT RESULTS

	Date Drawn	Results
HIV1/HIV2		
HBA* (Hep B surface antibody)		
HCV antibody		
HBS (Hep B surface antigen)		

*For employees/students who have never received vaccine or who have a history of HBV immunization prior to coming to UTMB, a HBS (Hepatitis B surface antigen) test should be done.

Prophylaxis Baseline Labs:	**RESULTS**
CBC	
Total bilirubin, ALT, AST, GGT	
Pregnancy Test (urine or serum)	
Creatinine, BUN	
Blood glucose	

Employee/Student (Circle one)
Results
Reported ___/___/___ Via _____ By_____

CHECK FOLLOW-UP NEEDED:

- r **2 Weeks** (If on prophylaxis)
- r **4 Weeks** (If on prophylaxis)
- r **6 Weeks** (HIV+source. HCV+source)
- r **3 Months** (HIV+source. HCV+source. Unknown source)
- r **6 Months** (HIV+source. HCV+source. Unknown source).
- r **12 Months** (HIV+source)

FOLLOW-UP DIRECTIONS:

HIV+source = HIV drawn
HCV+source = HCV Qual-RNA (PCR) drawn
HIV/HCV (-) = HIV drawn
Unknown source = HIV and HCV drawn

2 WEEK FOLLOW-UP ___/___/___ RESULTS

If placed on prophylaxis:

CBC	
Total bilirubin, ALT, AST, GGT	
Pregnancy Test (urine or serum)	
Creatinine, BUN	
Blood glucose	

Results Reported __/__/__ Via ____ By _____

4 WEEK FOLLOW-UP __/__/__ RESULTS

If placed on prophylaxis:

CBC	
Total bilirubin, ALT, AST, GGT	
Creatinine, BUN	
Blood glucose	

Results Reported __/__/__ Via ____ By _____

6 WEEK FOLLOW- UP ___/___/___ RESULTS

HIV, CBC	
Total bilirubin, ALT, AST, GGT Creatinine, BUN, blood glucose	
HCV Qual RNA (PCR) (only if source blood Hep C+)	

Results Reported __/__/__ Via ____ By _____

3 MONTH FOLLOW-UP __/__/__ RESULTS

HIV	
HCV Qual RNA (PCR) (only if source blood Hep C+)	

Results Reported __/__/__ Via _____ By_____

6 MONTH FOLLOW-UP __/__/__ RESULTS

HIV	
HCV Qual RNA (PCR) (only if source blood Hep C+)	

Results Reported ___/___/___ Via _____ By _____

12 MONTH FOLLOW UP __/___/___RESULTS

HIV	

Results Reported ___/___/___ Via _____ By_____

ASSESSMENT/RECOMMENDATIONS:

Warnings discussed to avoid pregnancy and/or breast feeding during treatment (females) r Yes r No

Employee Assistance Program/Counseling r Referral Made r Declined

Post-Exposure Treatment: r Recommended r Not Recommended

Informed Consent: r Obtained r Refused

Post-Exposure Prophylaxis: r Declined r Provided

Date/Time of 1st dose ____/____/____-_____AM/PM

Printed Materials Provided: r Yes r No

Comments: _____

_____

_____

Nurse _____Date _____

Healthcare Provider _____Date _____

Provider Information: Name _____

Clinic _____

Address_____

_____

Phone _____

After follow-up is completed, provider is to forward to:

for employees
Employee Health
Primary Care Pavilion
400 Harborside Drive
Route 1161
FAX (409) 747-9182

for students
Student Wellness
Rebecca Sealy Hospital
301 University Boulevard
Route 0169
FAX (409) 747-9330

For questions call: Employees (409) 747-9172 Students (409) 747-9320
Access Center (800) 917-8906

Patient Information

Risk of HIV Infection

The average risk of HIV infection due to all types of reported percutaneous exposures to HIV-infected blood is 0.3%. A percutaneous exposure is defined as a needlestick or laceration/puncture with a sharp object.

The risk appears to be greater than 0.3% for exposure to HIV (+) patients involving deep injury, visible blood on the device causing the injury, a device previously placed in the source patient's vein or artery, or the source patient dying of AIDS within 60 days post-exposure.

Risk of Hepatitis B or Hepatitis C Infection

The average risk of Hepatitis B virus (HBV) infection in susceptible persons after percutaneous exposure to HBV-infected blood is 6 – 30%. The risk of Hepatitis C virus (HCV) infection after percutaneous exposure to HCV-infected blood is 7.4% (95% CI 3.9%-12.5%).

Prophylaxis for Exposure to HIV (Revised March 2008)

Prophylaxis is being offered to employees and students who have a percutaneous injury, contamination of mucous membranes or nonintact skin, to HIV during the performance of their duties. Prophylaxis in these circumstances is voluntary. The FDA has not approved antiretroviral therapy for post-exposure use; therefore, use of these medications post-exposure for healthcare workers is considered investigational. The CDC says "Because most occupational exposures to HIV do not result in infection transmission, potential toxicity must be carefully considered when prescribing post-exposure prophylaxis (PEP)".

Medication Schedule

Regimen 1

Prophylaxis will be treatment for four weeks with:

fos-amprenavir (Lexiva 700 mg tab), two tablets by mouth with food every 12 hours
emtricitabine (Emtriva 200 mg cap), one capsule by mouth with or without food every 24 hours and
tenofovir (Viread 300 mg tab), one tablet by mouth with or without food every 24 hours.

Side effects associated with fos-amprenavir (Lexiva) that may go away with treatment include diarrhea, headache, nausea, vomiting, stomach pain, and rash. If they continue or are bothersome, check with your doctor. There may be allergic reactions in patients with sulfa hypersensitivity. There may be hyperglycemia (increased blood sugar), new onset or exacerbation of diabetes mellitus.

Side effects associated with emtricitabine (Emtriva) include nausea, diarrhea, abdominal pain, headache, rash and skin discoloration. Treatment-limiting toxicities are very uncommon with this medication.

Side effects associated with tenofovir (Viread) include nausea, vomiting, dizziness, gas, loss of appetite, joint or muscle pain, or rash. Rarely, this medication may cause jaundice with dark urine, yellowing of the skin or eyes, and in some cases abdominal or stomach pain.

Regimen 2 (see below) is to be used instead of Regimen 1 during pregnancy or if pregnancy is possible, for those with sulfa hypersensitivity, or if there is intolerance to components of Regimen 1.

Regimen 2

Treatment will also be for four weeks with:

Combivir (300 mg [AZT] and 150 mg lamivudine [Epivir] in fixed dose combination cap) one capsule by mouth with food every 12 hours for 4 weeks and
Kaletra (lopinavir/ritonavir (200/50mg tabs), 2 tablets by mouth with or without food every 12 hours for 4 weeks.

Side effects associated with AZT include headache, nausea, muscles aches and pains, fatigue, and trouble sleeping. These side effects are expected to stop when AZT is discontinued. Severe anemia (low red blood cells), neutropenia (low white blood cells), and liver cell damage are serious side effects that may develop in individuals taking AZT.

Side effects associated with lamivudine (Epivir) are uncommon and include nausea, diarrhea, abdominal pain, muscle pain, headache, dizziness, and difficulty sleeping. Any history of pre-existing renal impairment should be noted, and the dose should be reduced if renal insufficiency (creatinine clearance < 50% of normal) is present.

Side effects associated with lopinavir/ritonavir (Kaletra) include nausea, vomiting, diarrhea, weakness, hyperlipidemia, elevated serum transaminases, hyperglycemia, and fat maldistribution.

The risk of long-term toxicities, for example, birth defects, reproductive capacity, development of tumors, or other long-term effects of these medications are unknown.

Pregnancy

The risks of adverse effects to a developing fetus from antiretroviral therapy taken by a pregnant woman are unknown, but the risks are likely to be greater in the first trimester. Therefore, females taking antiretroviral therapy post-exposure should be aware that there may be risks associated with antiretroviral therapy during pregnancy, and prophylaxis should be reserved for those with HIGH RISK exposures. If a female is found to be HIV ELISA positive or to have a low value on viral load test, they should be referred to the HIV Maternal Fetal Child Health Clinic (409) 772-2798.

Routine Occupational Exposure Follow-up

Follow-up is determined by the results of the initial lab work drawn on the source of the occupational exposure. It proceeds as follows:

HIV(+) source known	Obtain HIV antibody @ exposure	
		6 weeks
		3 months
		6 months
		12 months
HCV(+) source known	Obtain HCV antibody @ exposure	
Obtain HCV Qual RNA (PCR) at		6 weeks
		3 months
		6 months
Unknown source	Obtain HIV& HCV antibody @ exposure	
		3 months
		6 months

If the source results are HIV (-) and HCV (-), you will be offered a one-time 6-month follow-up at which time only an HIV will be drawn.

Special Precautions after an HIV(+) or High Risk Exposure

- Do not share a toothbrush. Gums can bleed easily, getting blood on the toothbrush.
- Do not share razors as blood may go undetected on the blade.
- Avoid pregnancy until HIV infection is ruled out (i.e. generally 6 months following exposure, but up to one year).
- Use safe sex practices-male/female latex condoms for barrier protection or abstain from sex during the follow-up period until HIV infection has been ruled out.
- Do not donate blood, plasma, organs, tissue or semen during the follow-up period.
- Seek medical evaluation for any acute illness that occurs during the follow-up period.

INFORMED CONSENT FOR PROPHYLAXIS AFTER BLOODBORNE PATHOGENS EXPOSURE

As a patient, you have the right to be informed about your risk after a bloodborne pathogens (BBP) exposure and the recommended prophylaxis. This disclosure is not meant to alarm you; however, there are certain side effects which are associated with prophylaxis. I have read and understand the patient information entitled "Occupational Exposures to Bloodborne Pathogens-Patient Information," which explains risks of infection, prophylaxis, medication schedule, pregnancy precautions, follow-up and special precautions.

r I hereby voluntarily consent to prophylaxis for exposure to blood and body fluids infected or possibly infected with human immunodeficiency virus-1(HIV-1). The medications include:

_____

_____

_____

_____

_____

_____

_____

r I hereby decline prophylaxis following my exposure to bloodborne pathogens. The healthcare provider has informed me of the possible risks associated with refusing this medication. The nature and purpose of the proposed prophylaxis & the risks and hazards if the treatment is withheld, have been explained to me by a healthcare provider. I have had an opportunity to discuss these matters with a healthcare provider and to ask questions about my exposure, alternatives, and the proposed treatment.

EMPLOYEE	Date	Time
HEALTHCARE PROVIDER	Date	Time
WITNESS	Date	Time

***** Please forward to Employee Health/Student Wellness *****

The University of Texas Medical Branch Hospitals
301 University Boulevard • Galveston, Texas 77555-0701
(409) 772-1011

(Pt. Name)

(Address)

AGE: _____ WT: _____

DATE: ALLERGIES:

A generically equivalent drug product will be dispensed unless the practitioner hand writes the words **"Brand Necessary"** or **"Brand Medically Necessary"** on the face of the prescription.

℞

SIG:

1. *Fos-amprenavir 1400mg (700mg tabs x 2) p.o .Q 12 hours x ___ days supply*
2. *Emtricitabine 200mg p.o. Q day x ___ days supply*
3. *Tenofovir 300 mg p.o. Q day x ___ days supply*

Dispense:
6 months ☐
3 months ☐
1 month ☐

Quantity # _____

(CONTROLLED SUBSTANCES REQUIRE QUANTITY NUMBER AND WRITTEN WORD.)

DO NOT REFILL ☐

REFILL ☐1 ☐2 ☐3 ☐4 ☐5

INDICATION: _____

M.D. _____ M.D.

PRINTED NAME M.D. SIGNATURE

DEA No. AG3353973- _____ or DEA No. _____ Telephone/ Pager _____

MM68706–Rev. 5/02

Emergency Department Instructions:

Sun – Thurs … prescribe 2 days of medication

Fri – Sat … prescribe 3 days of medication

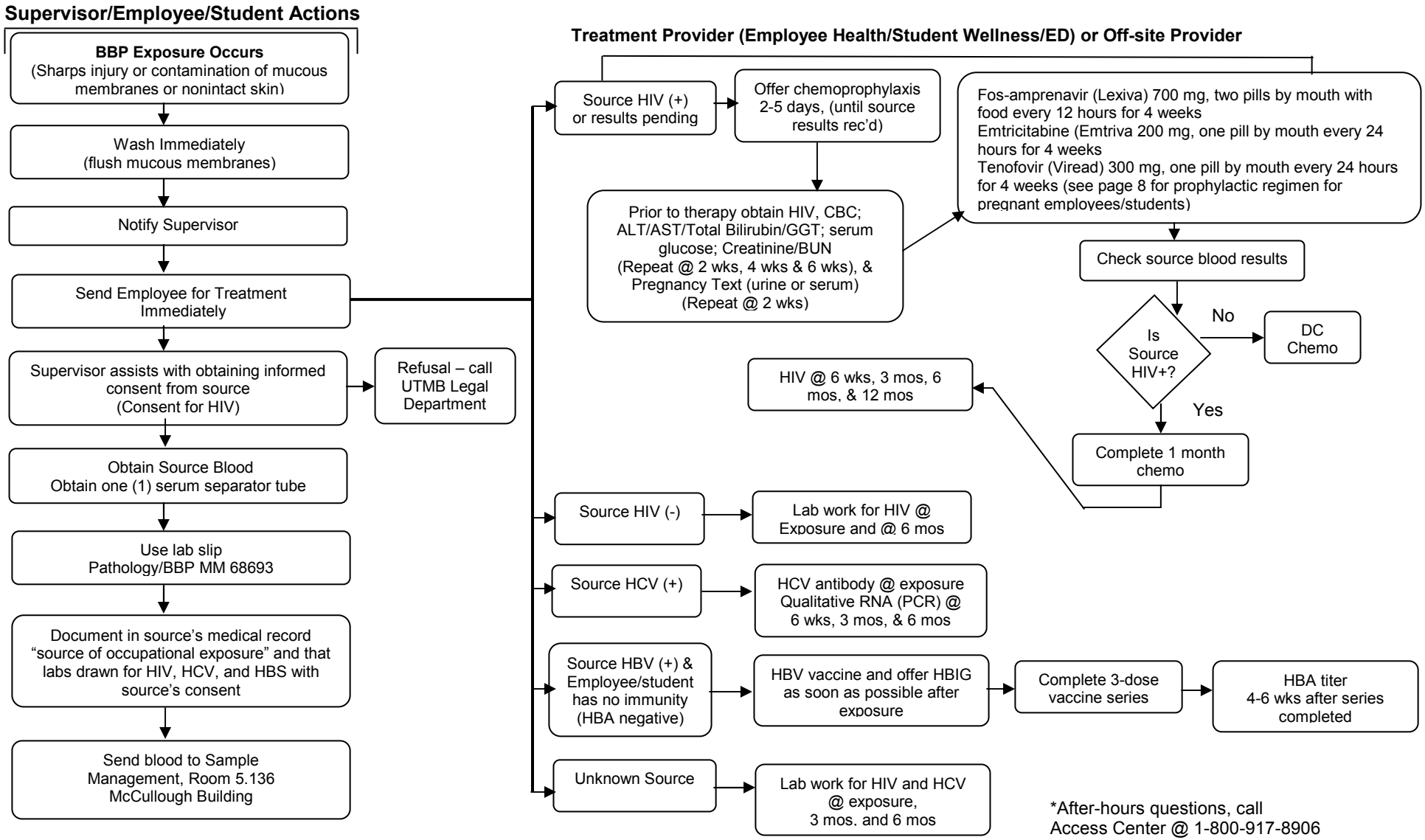
(Allow for additional days if a Holiday falls in this time period)

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

Drug	Comment
Antimycobacterials: 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, methylegonovine	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:	Coadministration might reduce plasma concentrations of protease inhibitors, which might result in loss of therapeutic effect and development of resistance
St. John's wort (hypericum perforatum),	
garlic	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.

Appendix B. OCCUPATIONAL EXPOSURES TO BLOODBORNE PATHOGENS (BBP)*



* Off-site clinics refer to your agency specific policy.