DEPARTMENT: Meritus School of Osteopathic Medicine

NAME: Medical Management of Exposure to Blood or Other Potentially

Infectious Material (OPIM)

POLICY NUMBER: \*

ORIGINATOR: MSOM EFFECTIVE DATE: 7/25

### **SCOPE**

A. Meritus School of Osteopathic Medicine Students

B. Meritus School of Osteopathic Medicine Faculty and Staff

#### **PURPOSE**

To establish a uniform system for the reporting and medical management of persons sustaining exposure to blood or other potentially infectious material (OPIM) via occupational exposure such as needle stick, other percutaneous injury, mucous membrane exposure (e.g., splash to eye or mouth), or contact with non-intact skin.

#### **DEFINITIONS**

## **Bloodborne Pathogens (BBP)**

Microorganisms present in human blood and OPIM that can cause disease in humans who are exposed to blood and other OPIM containing these pathogens. These pathogens include but are not limited to such as HIV, hepatitis B and C viruses.

### Other Potentially Infectious Material (OPIM)

Certain body fluids, other than blood, that could contain enough of a bloodborne pathogen to cause infection if transmitted through non-intact skin, mucous membranes, or punctures. These body fluids include semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, ANY body fluids that are visibly contaminated with blood, ALL body fluids in situations where it is difficult or impossible to differentiate between body fluids, and any unfixed human tissue or organ from a human.

### **Occupational Exposure**

Reasonably anticipated skin, eye, mucus membrane, non-intact skin, or parenteral contact with blood and other OPIM that may occur in during performance of an employee's duties.

### **POLICY**

A. All exposures to blood and body fluids must be reported IMMEDIATELY to the attending preceptor and to the Office of Student Affairs. The exposed person must receive medical

- evaluation. The individual involved in an exposure may consent to have his/her blood tested for the presence of HIV antibodies prior to requesting HIV testing of source individual.
- B. Pre-test counseling should be provided prior to obtaining written consent for HIV testing.
- C. If exposed individual is unsure whether they wishe to be tested for HIV, a blood sample may be drawn to store for 90 days to allow the individual time to decide.
- D. If the student or faculty declines HIV testing they will acknowledge that testing was offered and elect not to be tested by signing refusal form without penalty and jeopardizing their medical care.
- E. Exposures involving an unknown source or known HIV positive source may be referred to the Emergency Department or other clinical entity as per the protocol of that health care facility.

### **PROCEDURE**

- A. Persons sustaining exposures will:
  - 1. Immediately wash the exposed area with soap and water.
  - 2. Follow all clinical site protocols for such exposure.
  - 3. Immediately report exposure to supervisor or preceptor as well as the Office of Student Affairs.

### **APPENDIX A**

# **Providing Pre-Test/Post-Test Counseling for Exposure to Blood or OPIM Exposure**

- A. Inform the employee that he/she will be tested for human immunodeficiency virus (HIV) infection.
- B. Provide information about HIV/ AIDS including but not limited to a description of how HIV is transmitted by:
  - 1. Unprotected sexual contact with an infected partner, if body fluids are exchanged.
  - 2. Blood-to-blood contact with infected blood (i.e. sharing needles or other injection drug equipment, transplant recipients, blood transfusions, etc.).
  - 3. From an infected mother to her baby during pregnancy, delivery, or breastfeeding.
- C. Provide the following recommendations for preventing infection, re-infection or transmission to others until follow-up testing by the health care provider has excluded seroconversion:
  - 1. Abstinence or safer sex techniques and the use of condoms for all sexual encounters.
  - 2. Never share needles or other injection equipment.
  - 3. Never donate blood, plasma, tissue, organs or sperm.
  - 4. Do not share items that could become contaminated with blood.
  - 5. Pregnancy planning and prenatal care to reduce mother-to-child HIV transmission if the individual is of childbearing age.
- D. Reinforce the necessity of reporting and seeking medical evaluation of any acute febrile illness occurring within twelve weeks post-exposure.
- E. Assert that while every attempt will be made to maintain confidentiality, confidentiality cannot be guaranteed.
- F. Inform the exposed individual of the following recommendations for follow-up post-exposure testing:
  - 1. If source patient is negative no follow-up testing is indicated.
  - 2. If source patient is unknown or source patient is positive, follow-up testing schedule is baseline testing, at six weeks, and then concluded at four months after the date of exposure.
- G. One-time testing should be performed for all persons with behaviors, exposures, and conditions associated with an increased risk of HCV infection. Test the source for HCV RNA. If the source is HCV RNA positive or if HCV infection statuses unknown follow the algorithm in Appendix E.

### **APPENDIX B**

# **Guidelines to Follow if Exposed Individual Refuses/Declines HIV Testing**

- A. Do not request HIV testing of source patient.
- B. Request exposed individual read and sign refusal form.
- C. Signature of refusal shall not mean that an employee gives up their right to have the HIV testing at a later date. An employee shall retain the right to change their election and may request testing at a later time by making their request to the Employee Health Service. However, they will be advised that delaying the testing is not recommended. At the time of request, their signature and date of said request will be affixed to the HIV Exposure Testing Form with the same provisions as indicated above for consent.

### **APPENDIX C**

## **Guidelines to Follow if Source Patient Refuses/Declines HIV testing**

Complete the declination section of yellow "For Source Patient Testing Only" form.

An HIV test may be ordered without consent of the source patient only when ALL of the following criteria apply:

- A. Informed consent was sought and unable to be obtained because the patient or person who has the authority to consent for the patient is unavailable or unable; OR informed consent was sought and the patient or person with authority to consent for the patient has refused and a blood sample is already obtained (source patient must be informed of this policy);
- B. There has been an exposure between the patient and a first responder or public safety worker;
- C. The public safety worker has given prompt notice of exposure and given a blood sample to be tested for HIV;
- D. The treating practitioner has decided in accordance with Centers for Disease Control and Prevention recommendations that testing the source patient would be helpful in managing the risk of disease and health outcomes of the exposed individual.

When blood is resulted from a source patient meeting the above criteria and where consent was unable to be obtained, the hospital must notify the patient of the results and, if positive, arrange for counseling and treatment recommendations for the source patient and exposed person.

The hospital may not document the test results in the source patient's medical record or in the medical record of the exposed person.

The hospital must pay for the cost of HIV testing.

### **APPENDIX D**

TABLE 2. Postexposure management of health-care personnel after occupational percutaneous and mucosal exposure to blood and body fluids, by health-care personnel HepB vaccination and response status

Health-care personnel status	Postexposure testing		Postexposure prophylaxis		Postvaccination
	Source patient (HBsAg)	HCP testing (anti-HBs)	HBIG*	Vaccination	serologic testing <sup>†</sup>
Documented responder <sup>§</sup> after complete series (≥3 doses)	No action needed				
Documented nonresponder <sup>¶</sup> after 6 doses	Positive/unknown	_**	HBIG x2 separated by 1 month	-,	No
	Negative	No action needed		78	
Response unknown after 3 doses	Positive/unknown	<10mIU/mL**	HBIG x1	Initiate revaccination	Yes
	Negative	<10mIU/mL	None		
	Any result	≥10mIU/mL	No action needed		
Unvaccinated/incompletely vaccinated or vaccine refusers	Positive/unknown	_**	HBIG x1	Complete vaccination	Yes
	Negative		None	Complete vaccination	Yes

**Abbreviations:** HCP = health-care personnel; HBsAg = hepatitis B surface antigen; anti-HBs = antibody to hepatitis B surface antigen; HBIG = hepatitis B immune globulin.

<u>CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for</u> Administering Post exposure Management

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

<sup>&</sup>lt;sup>†</sup> Should be performed 1–2 months after the last dose of the HepB vaccine series (and 4–6 months after administration of HBIG to avoid detection of passively administered anti-HBs) using a quantitative method that allows detection of the protective concentration of anti-HBs (≥10 mIU/mL).

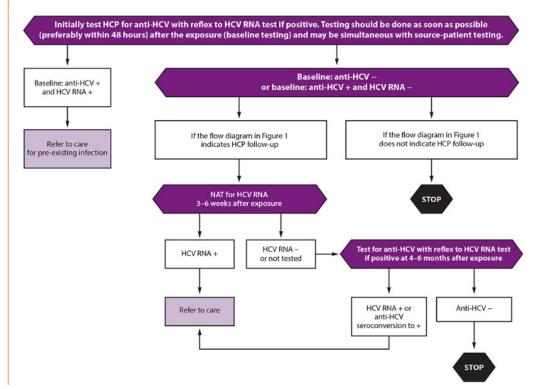
<sup>§</sup> A responder is defined as a person with anti-HBs ≥10 mIU/mL after ≥3 doses of HepB vaccine.

 $<sup>\</sup>P$  A nonresponder is defined as a person with anti-HBs <10 mIU/mL after  $\geq$ 6 doses of HepB vaccine.

<sup>\*\*</sup> HCP who have anti-HBs <10mIU/mL, or who are unvaccinated or incompletely vaccinated, and sustain an exposure to a source patient who is HBsAg-positive or has unknown HBsAg status, should undergo baseline testing for HBV infection as soon as possible after exposure, and follow-up testing approximately 6 months later. Initial baseline tests consist of total anti-HBc; testing at approximately 6 months consists of HBsAg and total anti-HBc.

### **APPENDIX E**

FIGURE 2. Testing of health care personnel after potential exposure to hepatitis C virus - CDC guidance, United States, 2020\*



**Abbreviations:** AASLD-IDSA = American Association for the Study of Liver Diseases and the Infectious Diseases Society of America; HCP = health care personnel; HCV = hepatitis C virus; NAT = nucleic acid test.

\*Baseline testing of HCP for anti-HCV with reflex to a NAT for HCV RNA if positive should be done as soon as possible (preferably within 48 hours) after the exposure and may be simultaneous with source-patient testing. If follow-up testing is recommended based on the source-patient's status, test for HCV RNA at 3-6 weeks postexposure. Testing for HCV RNA performed at 6 weeks postexposure has the advantage of coinciding with human immunodeficiency virus (HIV) postexposure testing schedules if HIV surveillance is recommended. If HCV RNA is negative at 3-6 weeks postexposure, a final test for anti-HCV at 4-6 months postexposure is recommended due to the possibility of intermittent periods of aviremia in acute HCV infection. If the HCP was anti-HCV positive and HCV RNA negative at baseline, testing at this time should be conducted for HCV RNA detection, as persons successfully treated for HCV infection will remain antiHCV positive and HCV RNA negative unless reinfected. Testing performed at 6 months postexposure has the advantage of coinciding with hepatitis B virus (HBV) postexposure testing schedules if HBV testing is recommended. HCP with anti-HCV seroconversion and negative HCV RNA should be referred for further evaluation. False-positive anti-HCV results are known to occur among low-risk populations. Anti-HCV seroconversion occurs on average 8-11 weeks after exposure, although cases of delayed seroconversion have been documented among persons with immunosuppression such as in HIV infection.

For persons who had a negative anti-HCV result and are immunocompromised, testing for HCV RNA can be considered. Also, for persons with a positive anti-HCV and negative HCV RNA result, HCV RNA testing should be repeated if an additional potential HCV exposure occurred within the past 6 months, clinical evidence of HCV infection is present, or concerns exist about specimen integrity, including handling and storage conditions that might have compromised test results. Exposed persons who develop viral syndromes suggestive of acute HCV infection at any point should be retested for HCV RNA. Persons with detectable HCV RNA at any point should be referred to care consistent with current AASLD-IDSA guidelines for evaluation and treatment of all persons with acute or chronic HCV infection. Those persons with acute infection should be treated on initial diagnosis without awaiting spontaneous resolution. Guidance for hepatitis C treatment (https://www.hcvguidelines.orgexternal icon) is evolving with emerging data on treatment with direct-acting antivirals.

<u>Testing and Clinical Management of Health Care Personnel Potentially Exposed to Hepatitis C</u> VMMWR

### **APPENDIX F**

U.S. Public Health Service (PHS) no longer recommends that the severity of exposure be used to determine the number of drugs to be offered in an HIV PEP regomen, and a regomen containing three (or more) antiretroviral drugs is now recommended routinely for all occupational exposures to HIV.

PREFERRED HIV PEP REGIMEN
Raltegravir (Isentress®; RAL) 400mg PO Twice Daily
Plus
Truvada™,1 PO Once Daily
[Tenofovir DF (Viread®; TDF) 300mg + emtricitabine (Emtriva™; FTC) 200mg]

(May combine one drug or drug p nucleoside/nucleotide reverse transcriptas unfamiliar with these agents/regimens sho	TIVE REGIMENS  pair from the left column with 1 pair of  se inhibitors from the right column. Prescribers  puld consult physicians familiar with the agents  r toxicities.)*^	
Raltegravir (Isentress®; RAL)	Tenofovir DF (Viread <sup>®</sup> ; TDF) + emtricitabi (Emtriva <sup>™</sup> ; FTC); available as Truvada <sup>™</sup>	
Darunavir (Prezista®; DRV) + ritonavir (Norvir®; RTV)	Tenofovir DF (Viread®; TDF) + lamivudine (Epivir®; 3TC)	
Etravirine (Intelence®; ETR)	Zidovudine (Retrovir <sup>18</sup> , ZDV; AZT) + lamivudine (Epivir <sup>®</sup> , 3TC); available as Combivir <sup>®</sup>	
Rilpivirine (Edurant RPV)	Zidovudine (Retrovir®; ZDV; AZT) + emtricitabine (Emtriva ™; FTC)	
Atazanavir (Reyataz®; ATV) + ritonavir (Norvir®; RTV)		
Lopinavir/ritonavir (Kaletra®; LPV/RTV)		
The following alternative is a complete fix antiretrovirals are needed: Stribild (elvit	ted-dose combination regimen and no additional regravir, cobicistat, tenofovir DF, emtricitabine)	

TERNATIVE ANTIRETROVIRAL AGENTS FOR USE AS PEP ONLY WITH
EXPERT CONSULTATION <sup>A</sup>
Abacavir (Ziagen®, ABC)
Efavirenz (Sustiva®; EFV)
Enfuvirtide (Fuzeon T ; T20)
Fosamprenavir (Lexiva®; FOSAPV)
Maraviroc (Selzentry®; MVC)
Saquinavir (Invirase®; SQV)
Stavudine (Zerit®; d4T)

ITIRETROVIRAL AGENTS GENERALLY NOT RECOMMENDED FOR USE AS
PEP
Didanosine (Videx EC®; ddI)
Nelfinavir (Viracept®; NFV)
Tipranavir (Aptivus®, TPV)

ANTIRETROVIRAL AGENTS CONTRAINDICATED AS PEP	
Nevirapine (Viramune®; NVP)	

For consultation or assistance with HIV PEP, contact PEPline at telephone 888-448-4911 or visit their website <a href="PEPline Crowdfunding Update">PEPline Crowdfunding Update</a> | National Clinician Consultation Center (ucsf.edu). For dosing information, refer to the drug package insert and/or Appendix B in the link below. <a href="Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures">Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis (cdc.gov)

## **APPENDEX G**

# **Exposure Packet Guidelines**

# **SUPERVISOR/ANS CHECKLIST**

☐ Complete the 2 registration stickers. One on the outside of the packet and one on the Registration Checklist. Circle F for female or M for male and add the last 4 of the employee's social security number.
☐ Complete Employee Incident and Accident Report for appropriate employer Meritus or Trivergent (i.e. phlebotomy/pharmacy)
☐ Employee signs Authorization for the Release of Medical Information
$\square$ Employee signs Exposed individual Consent form. If the exposed declines HIV testing, see Appendix B
$\square$ Obtain Source consent for HIV testing if exposed person has consented. If the source declines HIV testing, see Appendix C.
☐ Complete Source Testing Form
☐ Call Lead Phlebotomist at x9095 prior to tubing Source Testing form. (Forms are to be sent even if source refused HIV testing)
$\square$ Send a $\underline{\operatorname{copy}}$ of the completed Source Testing form to STAT Lab via tube system #110
$\square$ Fax the entire completed packet to Employee Health at 301-790-9319. (ANS may scan and email to the Employee Health Group.)
☐ Place originals back into Exposure Packet
□ Direct exposed person to appropriate place for treatment, having them take the Red Blood borne  Pathogen Exposure Packet with them  -Monday-Friday 0730-1600 direct them to Health @ Work after first calling the Employee Health Office.  -After hours, weekends and holidays walk them to the Emergency Department registration desk and state "This is an employee exposure Priority 1."
$\square$ Call the Employee Health Office (301-790-8319) with notification of exposure.
Supervisor/ANS Printed Name
Date <u>Time:</u>
Signature

### **REFERENCES**

- A. Centers for Disease Control and Prevention (CDC), MMWR (2001). Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Post exposure Prophylaxis. June 29, 2001. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis (cdc.gov) Accessed 4/9/21.
- B. Center for Disease Control and Prevention. MMWR (2020). Testing and Clinical Management of Health Care Personnel Potentially Exposed to Hepatitis C Virus CDC Guidance, United States, 2020. <u>Testing and Clinical Management of Health Care Personnel Potentially Exposed to Hepatitis C Virus CDC Guidance, United States, 2020 I MMWR</u>. Accessed 4/9/21.
- C. Center for Disease Control and Prevention. MMWR (2013). CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administrating Postexposure Prophylaxis. CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management Accessed 4/9/21.
- D. Centers for Disease Control and Prevention, MMWR (2013). Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Post exposure Prophylaxis. September 25, 2013. <a href="Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV">Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis. (cdc.gov) Accessed 4/9/21.
- E. Centers for Disease Control and Prevention. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis. 2015. <a href="https://npin.cdc.gov/publication/updated-us-public-health-service-guidelinesmanagement-occupational-exposures-human">https://npin.cdc.gov/publication/updated-us-public-health-service-guidelinesmanagement-occupational-exposures-human</a> Accessed 4/9/21.
- F. COMAR 10.06.06.02 Title 10. Maryland Department of Health. Diseases. Communicable Disease Prevention. Definitions. Department of Labor, Occupational Safety and Health Administration. 29 CFR Part 1910.1030. <u>Bloodborne pathogens. 1910.1030 | Occupational Safety and Health Administration (osha.gov)</u> Accessed 4/9/21.
- G. Department of Labor, Occupational Safety and Health Administration. Revision to OSHA's Bloodborne Pathogens Standard. Technical Background and Summary. Revision to OSHA's Bloodborne Pathogens Standard Accessed 4/9/21.
- H. Infectious Diseases Society of America (IDSA). HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. Recommendations for Testing, Managing, and Treating Hepatitis C | HCV Guidance (hcvguidelines.org) Accessed 4/9/21.
- I. Maryland General Article 18-338.1 Health Care Providers (2003). http://law.justia.com/codes/maryland/2005/ghg/18-338.3.html
- J. www.dsd.state.md.us/comar/comarhtml/10/10.06.06.02.htm Accessed 4/9/21.
- K. PEPline. PEPline Crowdfunding Update | National Clinician Consultation Center (ucsf.edu) 888-448-4911.