

IMMUNITY STATUS AND INITIAL LABORATORY EVALUATION & MANAGEMENT FOR BLOODBORNE PATHOGEN EXPOSURE

1. Purposes of this protocol
 - a. This protocol is to provide guidance in evaluating and managing exposures to blood or OPIM. It is designed to be started at the first contact, which is frequently a telephone call, but can be when an individual presents in person.
 - b. Use this protocol to complete the individualized evaluation, and Victim Follow-Up Surveillance Schedule.
 - c. Give copy of surveillance schedule to the exposed individual for their reference.
 - d. This is not a comprehensive document that covers every exigency that can arise from an exposure. This covers the basic and most common circumstances. When issues arise that are not covered by this protocol, and the health care provider does not know the appropriate actions to follow, consultation should be obtained immediately.

2. Perform Risk assessment for infection as low risk or high risk if source is unknown
 - a. Individual risk factors
 - i. Was the potential source a prisoner, on dialysis, or a drug abuser, etc.
 - b. Type of exposure
 - i. Percutaneous vs. mucus membrane
 - ii. Hollow bore needle vs. solid sharp
 - iii. Actual injection of blood or fluid
 - c. Based on these, and all other known considerations, perform a risk assessment for infection
 - i. HIV
 - (1) If the exposure is considered low risk, perform all follow up testing as if source is positive
 - (2) If the exposure is considered high risk, recommend PEP as if source is positive
 - (3) Perform lab surveillance for HIV seroconversion for 4 months unless victim has HCV infection (either pre-existing or by seroconversion during the surveillance period), in which case follow for one year.
 - ii. HCV - Perform surveillance testing and refer for treatment if HCV become positive.

3. Initial Labs
(HIV 1&2 Screen comprises a 4th generation combination test for HIV P-24 Ag and HIV Ab)
 - a. Source
 - i. HBs Ag; HCV; Rapid HIV; HIV 1&2 screen (confirmatory test); ALT.
 - ii. Specimen: 4 gold-top and 1 lavender-top tube
 - b. Victim
 - i. HBs Ab Quant (Immune status); HCV; HIV 1&2; ALT.
 - ii. Specimen: 4 gold-top and 1 lavender-top tube

4. Complete the Blood and OPIM Exposure Surveillance and Treatment Worksheet to establish an individualized treatment and surveillance plan.
 - a. Perform the infection risk assessment (low or high risk)
 - b. Select all of the risk factors that apply
 - c. Circle all the tests indicated based on the risk factor profile
 - d. Enter the Suggested Date for each lab visit needed and make at least the next appointment. Consider making more than one appointment in advance.
 - e. Start a Exposure Surveillance Lab Flow Sheet. One copy of this schedule should be maintained in the patient record, and one copy given to the victim.
 - f. Add the individual to the Blood and OPIM Exposure Log, including the surveillance plan. A sample page is included in this packet.

5. **If the source has a positive Rapid HIV test or if the exposure is deemed to be high risk, the exposed individual needs to start on PEP medications on the day of the exposure, ideally within two hours of the exposure.**
 - a. Self Regional Hospital will fill prescriptions for a four day supply of PEP at no cost to the individual. This allows the individual to start the medication immediately, and four days during which a payment and supply source for the remainder of the one month supply can be arranged.
 - b. Healthcare provider should obtain a pregnancy test on all females unless they are post-menopausal or have had a hysterectomy. Write prescriptions for a four day supply of each medication to be filled immediately at SRH Outpatient Pharmacy, and prescriptions for a 26 day supply. If this is a Workers' Compensation case, the individual should contact his employer immediately to make arrangements for obtaining the 26 day supply.

- c. Prescriptions
 - i. Combivir 150/300 mg one tablet twice a day
 - ii. Kaletra (Withheld if patient is pregnant. Refer patient for consultation.) 200/50 mg two tablets twice a day
6. Follow-up HIV and PEP Labs For Victims if Source HIV positive or deemed high risk for HIV infection
- a. Additional initial labs: CBC, CMET, hCG (if female capable of conception)
 - b. If HIV PEP is given:
 - i. Week 0 (Initial): CBC, CMET, HIV 1&2 screen, HBs Ab, HCV
 - ii. Week 1: CBC
 - iii. Week 2: CBC, CMET
 - iv. Week 3: CBC
 - v. Week 4: CBC, CMET
 - vi. Week 5: CBC
 - vii. Week 6: CBC, HIV 1&2 Screen
 - viii. Week 7: CBC
 - ix. Week 8: CBC, CMET
 - x. Week 12: CBC
 - xi. Week 16: CBC, HIV 1&2 Screen
7. **If source is HBs Ag positive, then for the victim:**
- a. Source HBsAg pos / HBeAg pos - Risk of clinical hepatitis 22-31%; Risk of seroconversion 37-62%.²
 - b. Source HBsAg pos / HbeAg neg - Risk of clinical hepatitis 1-6%; Risk of seroconversion 23-37%.²
 - c. Post-Exposure Prophylaxis as below

**Recommended post-exposure prophylaxis for percutaneous or permucosal exposure to hepatitis B virus –
Advisory Committee on Immunization Practices, United States²**

Vaccination and antibody response status of exposed person	Treatment		
	Source HBsAg Positive	Source HBsAg Negative	Source not tested or status unknown
Unvaccinated	HBIG x 1; Initiate HB vaccine series	Initiate HB vaccine series	Initiate HB vaccine series
Previously vaccinated:			
- Known responder	No treatment	No treatment	No treatment
- Known non-responder			
- After 3 doses	HBIG x 1 and initiate revaccination	No treatment	If known high-risk source, treat as if source were HBsAg positive
- After 6 doses	HBIG x 2 (separated by 1 month)	No treatment	If known high-risk source, treat as if source were HbsAb positive
- Antibody response unknown	Test exposed person for Anti-HBs - If adequate, no treatment - If inadequate, HBIG x 1 and vaccine booster	No treatment	Test exposed person for Anti-HGs - If adequate, no treatment - If inadequate, HBIG x 1 and vaccine booster

See:

1. US PHS Guidelines for Occupational Exposure to HIV, Sep 2013. Box 2, Page 883.
2. US PHS Guidelines for Management of Occupational Exposures to HBV, HCV, and HIV, Jun 29, 2001.

SHARPS INJURY - POST EXPOSURE CHECK LIST

Name (Victim): _____ DOB: _____ DOI: _____

- Insure immediate care was given to the employee's exposure site.**
Wounds and skin washed with soap and water, mucous membranes flushed with water, etc. If performed inadequately, perform immediately.
- Evaluate the exposure for the potential to transmit HBV, HCV and HIV.**
Exposure through a needlestick or other sharps injury or through contact with mucous membrane required further evaluation. Exposure to a blood-filled hollow needle suggests a high risk. For skin exposure, follow-up is indicated if evidence exists of compromised skin integrity.
- Test the source patient immediately if known.**
Inform the source patient immediately and obtain consent, if possible. Test for HBV, HCV, and HIV if the infection status is unknown. Test as soon as possible for HBsAg, anti-HBs, anti-HCV, Rapid HIV test, and confirmatory 4th generation combination HIV P24 antigen and HIV antibody. (In South Carolina, the source patient, if identified, does not have the right to refuse this testing. If the source individual does not consent to testing, notify a physician immediately so that the process of obtaining a court order to draw the blood can be secured.)
- Provide post-exposure treatment and counseling to the exposed employee.**
Obtain consent or declination from the exposed individual for blood tests, and treatment if indicated. If the exposed individual declines management here, offer the option to draw and hold blood for 90 days. Offer to make arrange for their evaluation and follow-up by the healthcare professional they request.
- The healthcare professional should assess the HBV immune status of the exposed person.**
If necessary, begin the hepatitis B vaccine series within 24 hours. *See: Recommended Post-Exposure Management of HBV Table.*
- The healthcare professional should assess the need for HIV PEP for the exposed person.**
When called for, PEP should be initiated within hours of exposure. The employee with occupational exposure to HIV should receive follow-up counseling, post-exposure testing and medical evaluation, regardless of whether they receive PEP. *See Recommended Post-Exposure Management of HIV Table.*
- Document the incident.**
Complete the forms included in this packet.
- Provide the exposed employee a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.**
- Provide the employer of the exposed individual a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.**
- Continue to follow-up on required and recommended tests and document them for the medical records of the exposed employee.**

I have had an opportunity to discuss these issues with a physician, and have had my questions answered to my satisfaction.

Physician Signature

Signature of Exposed Individual

Date

EMPLOYEE BLOOD OR OPIM EXPOSURE INCIDENT DESCRIPTION FORM

Employee Name: _____ **DOB:** _____ **Phone:** _____
Employer: _____ **Contact:** _____ **Phone:** _____
HB vaccination Completed Yes No Previous anti-HBs titer: Pos Neg Date _____

EXPOSURE HISTORY:

Date & Time of Exposure: _____
Location where exposure occurred: _____
Wound Care / First Aid Administered (describe) _____
Was applicable personal protective equipment (PPE: i.e. - gloves, mask, safety needles) used? Yes No

TYPE OF EXPOSURE:

A. SHARP: Needle Lancet Broken glass Other (describe): _____
Brand & Model of device (OSHA required): _____
 Clean (sterile) Contaminated with blood or OPIM Gauge of needle: _____
Visible blood on Sharp? Yes No Used for vascular access? Yes No
Deep injury? Yes No Injection into exposed individual? Yes No

B. MUCOUS MEMBRANE OR DIRECT TISSUE EXPOSURE:
 Eye Nose Mouth (Gingivitis or other evidence of non-intact mucosa? Yes No)
 Open wound or non-intact skin (describe): _____
Body Fluid: Blood Saliva Vaginal secretions Sputum Vomitus Urine Wound drainage
 CSF Joint fluid Blood visible in body fluid? Yes No

C. Human bite (describe): _____
Evidence of bleeding visible in mouth? Yes No

D. OTHER (describe): _____

SOURCE PATIENT HISTORY:

Name: _____ Phone: _____ DOB: _____ SSN: _____
Clinical diagnosis and bloodborne pathogen risk factors: _____
Is patient known to have? HIV AIDS Hepatitis B Hepatitis C
Date of previous source patient testing: _____ HIV Pos Neg Titer: _____ CD4: _____
HBsAg Pos Neg anti-HBs Pos Neg anti-HCV Pos Neg
HB vaccination Completed Yes No Previous anti-HBs titer: Pos Neg Date _____

EMPLOYEE / EXPOSED INDIVIDUAL COUNSELING:

Risk of acquiring bloodborne pathogen from occupational exposure
 Report and seek medical evaluation for any acute flu-like illness within 12 months of exposure
 Information and assistance Re: HIV Post-exposure Prophylaxis (PEP) Protocol
 Potential for baseline and follow-up serologic testing
 Observe "safer sex" practices for six months following exposure from high-risk source
 Identify and correct work practices, engineering/equipment controls, or PPE problems to avoid recurrence
 Employee starting HIV PEP medications? Yes No
Employee Signature: _____ Date: _____
Evaluating physician Signature: _____ Date: _____

Blood and OPIM Exposure Surveillance and Treatment Worksheet

Name (Victim): _____ DOB: _____ DOI: _____

Name (Source): _____ DOB: _____ Unknown

Exposure: Puncture low risk Puncture high risk Other Unknown Source: Low Risk High Risk

The following tests are done on all involved:

Source: Rapid HIV, HIV 1&2 Screen, HCV, HBs Ag, ALT

Victim: HIV 1&2 Screen, HCV, HBsAb, ALT

Risk Factors for Victim: Select all that apply (S = Source V = Victim)

- 1 S HBsAg Pos 2 S HCV Pos 3 S HIV Pos 4 S HCV & HIV Pos 5 S Unk High Risk 6 S Unk Low Risk
 7 V HBV Non-immunized 8 V HBV Non-responder 9 V HBV Response Unk 10 HIV PEP
 11 S 4 & V becomes HCV Pos during the surveillance period

Needs	Week	Suggested Date	Appt.	Procedure
<input type="checkbox"/>	0			CBC 3 CMET 3 hCG 3 HBIG 7&1, 7&5, 8&1, 8&5, 9&1, 9&5 HB Vac 1 ² 7, 8, 9 HIV PEP 3, 5
<input type="checkbox"/>	1			CBC 10
<input type="checkbox"/>	2			CBC 3, 10 CMET 3, 10
<input type="checkbox"/>	3			CBC 10
<input type="checkbox"/>	4			CBC 10 CMET 10 HB Vac 2 7, 8, ±9
<input type="checkbox"/>	5			CBC 10
<input type="checkbox"/>	6			CBC 10 HBsAb ? HIV 3, 5, 6 +/-HCV PCR 2, 5, 6 HBsAb ⁴ 9
<input type="checkbox"/>	7			CBC 10
<input type="checkbox"/>	8			CBC 10 CMET 10
<input type="checkbox"/>	12			CBC 10
<input type="checkbox"/>	16			CBC 10 HIV 3, 4, 5, 6, 10 HB Vac 3 7, 8, ±9
<input type="checkbox"/>	26			HBsAb 1, 5, 6, 7, 8, 9 HCV 2, 5, 6 HIV ^{1, 3} 4, 5, 6, 11 ALT 2
<input type="checkbox"/>	52			HIV ³ 11

- If not done at 16 weeks
- Two doses of HBIG is preferred over HBIGx1 plus revaccination, if victim is known to be a non-responder after completing two 3 dose vaccination series.
- HIV testing should be extended to 6 and 12 months if source is positive for HCV and HIV, and the victim develops Hep C infection during the surveillance period.
- HB Vac with unknown response gets booster at baseline. If titer Pos at 4 weeks, no further treatment. If Neg at 4 weeks, complete the series.



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Self Medical Group

Blood or OPIM Exposure Lab Flowsheet - Medical Record Copy

Name (Victim): _____ DOB: _____ DOI: _____

Name (Source): _____ DOB: _____ Unknown

Exposure: Puncture low risk Puncture high risk Other Unknown Source: Low Risk High Risk

Comments: _____

Keep this copy of this form in the medical record. Do not disclose the identity of the source individual.

SOURCE						
Date	HBsAg	HBsAb	HCV	Rapid HIV	HIV 1&2	ALT

VICTIM									
Week	Planned	Done	HBs Ag	HBs Ab	HCV Ab	HCV PCR	HIV	ALT	HBV Vac
0			<input type="checkbox"/>						
1			<input type="checkbox"/>						
2			<input type="checkbox"/>						
3			<input type="checkbox"/>						
4			<input type="checkbox"/>						
5			<input type="checkbox"/>						
6			<input type="checkbox"/>						
7			<input type="checkbox"/>						
8			<input type="checkbox"/>						
9			<input type="checkbox"/>						
10			<input type="checkbox"/>						
11			<input type="checkbox"/>						
12			<input type="checkbox"/>						
16			<input type="checkbox"/>						
26			<input type="checkbox"/>						
52			<input type="checkbox"/>						

¹ If HBsAb titer negative after initial vaccination.

Physician Name _____

Physician Signature _____

Date _____



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Self Medical Group

Blood or OPIM Exposure Lab Flowsheet - Exposed Individual Copy

Name (Victim): _____ DOB: _____ DOI: _____

Exposure: Puncture low risk Puncture high risk Other Unknown Source: Low Risk High Risk

Comments: _____

Give this copy to the exposed individual.

SOURCE						
Date	HBsAg	HBsAb	HCV	Rapid HIV	HIV 1&2	ALT

VICTIM									
Week	Planned	Done	HBs Ag	HBs Ab	HCV Ab	HCV PCR	HIV	ALT	HBV Vac
0			<input type="checkbox"/>						
1			<input type="checkbox"/>						
2			<input type="checkbox"/>						
3			<input type="checkbox"/>						
4			<input type="checkbox"/>						
5			<input type="checkbox"/>						
6			<input type="checkbox"/>						
7			<input type="checkbox"/>						
8			<input type="checkbox"/>						
9			<input type="checkbox"/>						
10			<input type="checkbox"/>						
11			<input type="checkbox"/>						
12			<input type="checkbox"/>						
16			<input type="checkbox"/>						
26			<input type="checkbox"/>						
52			<input type="checkbox"/>						

¹ If HBsAb titer negative after initial vaccination.

Physician Name _____

Physician Signature _____

Date _____



OCCUPATIONAL HEALTH SERVICES

Self Medical Group

Blood or OPIM Exposure Lab Flowsheet for HIV PEP

Name (Victim): _____

DOB: _____

DOI: _____

Name (Source): _____

DOB: _____

Unknown

If source is unknown:

Exposure: Puncture low risk Puncture high risk Other

Unknown Source: Low Risk High Risk

Comments: _____

Keep one copy of this form in the office and give one copy to the exposed individual.

Do not disclose the identity of the source individual on the exposed individual's copy.

SOURCE					
Date	HBsAg	HBsAb	HCV	Rapid HIV	ALT

Schedule CBC, CMET, and HIV tests as indicated below.

Schedule HBV and HCV tests as indicated on the BBP Management Worksheet.

VICTIM															
Week	Planned	Done	WBC	Hgb	Hct	AST	ALT	ALP	T Bili	Ca	Alb	HBs Ag	HBs Ab	HCV	HIV
0			✓	✓	✓	✓	✓	✓	✓	✓	✓	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	✓
1			✓	✓	✓							<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2			✓	✓	✓	✓	✓	✓	✓	✓	✓	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3			✓	✓	✓							<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4			✓	✓	✓	✓	✓	✓	✓	✓	✓	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5			✓	✓	✓							<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6			✓	✓	✓							<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	✓
7			✓	✓	✓							<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8			✓	✓	✓	✓	✓	✓	✓	✓	✓	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
9												<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10												<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
11												<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
12			✓	✓	✓							<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
16			✓	✓	✓							<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	✓
26												<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
52												<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Hep B Vaccine Dates: #1 _____ #2 _____ #3 _____ Titer _____

Physician Name _____

Physician Signature _____

Date _____



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Exposed Individual Consent for HIV Testing

I understand that the HIV test detects the Human-Immunodeficiency Virus in my blood and that it is NOT a diagnostic test for AIDS.

I understand that should the results of the HIV test show that I have antibodies in my blood, South Carolina law requires that this information be reported to DHEC. If this is a Workers' Compensation case, the Workers' Compensation insurance carrier will be notified if this result; your employer will not be notified.

I understand that the test for HIV and the results will be handled with strict confidentiality.

I understand that at any time, should my HIV test results become positive for HIV antibodies, or should the source patient test positive for HIV antibodies, I will be informed. At that time I will be offered further counseling and treatment as deemed appropriate by a physician.

I consent to HIV testing.

Exposed Individual's Signature: _____ DOB: _____ Date: _____

Health Care Professional's Signature: _____ Date: _____

I decline HIV testing.

Exposed Individual's Signature: _____ DOB: _____ Date: _____

Health Care Professional's Signature: _____ Date: _____

_____ I request that a blood sample be obtained at this time and held for 90 days. I understand that I may consent to HIV testing on this baseline specimen at any time during this 90 day period.



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HEALTH CARE PROFESSIONAL'S OPINION FOR EXPOSED INDIVIDUAL FOR POST-EXPOSURE EVALUATION AND FOLLOW-UP

Name (Victim): _____ DOB: _____ DOI: _____

SOURCE					
Date	HBsAg	HBsAb	HCV	HIV	ALT

- Employee has been informed of the results of the post-exposure evaluation.
- Employee has been informed about any medical conditions resulting from exposure to blood or other potentially infectious materials, which require further evaluation or treatment.

I have been advised of the source individual's HIV, HBV, and HCV status. I understand that the information regarding the source individual's history that has been provided to me as a result of an exposure is CONFIDENTIAL and should not be discussed with anyone other than the health care professional. I understand that disclosure of the source individual's status could expose me to severe civil and criminal penalties.

Exposed Individual's Signature: _____ DOB: _____ Date: _____

Health Care Professional's Signature: _____ Date: _____



OCCUPATIONAL HEALTH SERVICES

Self Medical Group

EMPLOYER NOTIFICATION LETTER - BLOODBORNE PATHOGEN EXPOSURE

Employer: _____ Contact: _____ Phone: _____

Employee Name: _____ DOB: _____ Phone: _____

The above named employee was evaluated for possible exposure to blood or other potentially infectious material (OPIM) on ___/___/_____. Based on evaluation of the incident:

___ Hepatitis B vaccination was NOT recommended.

___ Hepatitis B vaccination was recommended.

___ Hepatitis B vaccination was given today.

___ Dates for future Hepatitis B vaccination: ___/___/_____, ___/___/_____, ___/___/_____

___ Draw titer to confirm immunity on: ___/___/_____

___ Dates for additional labs: _____

___ Employee has additional appointments for lab testing or follow-up and has a copy of those dates.

___ The exposed individual has been informed of any medical conditions which require further evaluation or treatment as a result of the exposure.

___ The exposed individual was referred to _____ for follow-up treatment.
Consultant Physician

___ The exposed individual had an opportunity to ask a doctor questions about the risk of future complications that could arise as a result of this exposure.

All other findings or diagnoses shall remain confidential and shall not be included in this written report or communicated to the employer.

The employer should provide the employee a copy of this letter within 15 days of completion of evaluation.

Physician Signature

Date

US Dept of Labor - Occupational Safety and Health Administration
Healthcare Professional's Written Opinion (Report to Employer)

(https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10051)

1. 1910.1030(f)(5)

Healthcare Professional's Written Opinion. The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.

1910.1030(f)(5)(i)

The healthcare professional's written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination.

1910.1030(f)(5)(ii)

The healthcare professional's written opinion for post-exposure evaluation and follow-up shall be limited to the following information:

1910.1030(f)(5)(ii)(A)

That the employee has been informed of the results of the evaluation; and

1910.1030(f)(5)(ii)(B)

That the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment.

1910.1030(f)(5)(iii)

All other findings or diagnoses shall remain confidential and shall not be included in the written report.