STANDARD OPERATING PROCEDURE For NEEDLE STICK INJURY

1. PURPOSE

The purpose of this SOP is to institutionalize an effective system to ensure that all Health Care workers of BMHRC who experience a needle stick injury, or have a mucocutaneous exposure to blood or body fluids, are aware of the correct action to take to deal with the situation rapidly and appropriately.

2. SCOPE

The SOP will provide practical guidelines for all health care workers of BMHRC who sustains an exposure injury.

3. RESPONSIBILITY

It is the duty of Hospital Infection Control Team (HICT) to train and guide Doctors, Residents, Nursing staff and Hospital employees, time to time and instruct to follow this SOP, for getting immunized against Hepatitis B, so as to prevent oneself from needle stick and sharp injuries and also preventing from skin and mucous membrane exposure, preventing the transmission of infection of HIV, HBV& HCV from patients to health workers.

4. INFECTIOUS AND NON-INFECTIOUS MATERIAL

Potentially Infectious	Non-Infectious (Unless Contaminated with Visible Blood)	
Blood/Serum/Plasma	Tears	
Semen	Saliva	
Vaginal Secretions	Urine	
Body fluids—Cerebrospinal, Synovial, Pleural,	Stool Sputum	
Peritoneal, Pericardial, Amniotic fluids.		
Any other fluids / Secretions contaminated with visible blood	Nasal secretions	
	Sweat	
Tissues	Vomitus	
Laboratory specimens that contain concentrated		
virus		

POST-EXPOSURE MANAGEMENT

Steps to be followed after accidental exposure to blood/other potentially infectious materials:

- 1. First aid.
- 2. Report to Emergency Medicine.
- 3. Identify the source status.
- 4. Risk assessment by Casualty Medical Officer (based on type of injury and source status).
- 5. Report to Deputy Nursing Superintendent.
- 6. Testing for HIV, HBV and HCV for source and Health Care Worker (HCW).
- 7. Take first dose of PEP for HIV (based on source status).
- 8. Decision on prophylactic treatment for HIV and HBV.
- 9. Monitoring and follow up of HIV, HBV and HCV status.
- 10. Documentation and recording of exposure.

5.1 (a) Dos and Don'ts for the Exposed Individual

	Don'ts		Do's
1.	Do not panic	1.	Stay calm
2.	2. Do not place the pricked finger into 2. Remove gloves, if appropriate		Remove gloves, if appropriate
3.	the mouth reflexly Do not squeeze blood from wound	3. Wash exposed site thoroughly vound running water and soap. Irrig	
4.	Do not use bleach , Alcohol , Iodine , Antiseptic, Detergent, etc.		thoroughly with water, if splashes have gone into the eyes or mouth
		4.	Consult the designated Physician / Personnel immediately as per Institutional guidelines, for management of the Occupational exposure.

5.1 (b) First Aid: Management of Exposed Site

FOR SKIN	FOR THE EYE	FOR MOUTH	
Immediately wash the wound and surrounding skin	Immediately irrigate the exposed eye thoroughly with running tap water or normal saline at least for	1. Spit fluid out immediately.	
with water and soap, and rinse with flowing water or normal saline.	5 min for blood splash (15 min for chemical splash).2. If wearing contact lenses, leave them in place while irrigating as	2. Rinse the mouth thoroughly using water or saline and spit again. Repeat the process	
2. In case of skin and mucus membrane exposure immediately wash	they form a barrier over the eye and will help protect it.	several times. 3. Do not use soap or	

	the area and do not use antibiotics.	3.	Once the eye is cleaned, remove the contact lens and clean them	ie
3	Do not scrub.		in a normal manner. This will make them safe to wear again.	
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4.	Do not use antiseptics or skin washes	4.	Do not use soap or disinfectant on the eye.	

5.2 Identify the Source

If source is found to be **negative**, first dose of Post Exposure Prophylaxis (**PEP**) for exposed person is **not required** but the exposure should be reported to the HICT in writing for documenting the Needle Stick Injury (NSI).

If the source status is unavailable or found as **positive** for HIV or source is unknown, then first dose of **PEP** is **essentially required**.

5.3 Reporting to the Infection Control Team

Immediately report to Emergency Medicine (Casualty) and Consult Casualty Medical Officer / designated Infection Control Nurse (who so ever is available earliest) for the management of exposure immediately. (The helpline numbers (0755-2742212 Ext – 9007, 1040) are displayed in charts provided at every hospital area). The helpline support is available for 24 hours.

5.4 Risk Assessment

The evaluation to be done by Casualty Medical Officer preferably within 2 hours and certainly initiate PEP within 72 hours if required. Categories of exposure based on amount of blood/fluid involved and the entry port. These include.

5.5.1 Mild Exposure

Mucous membrane / non-intact skin with small volumes.

Example: A superficial wound (erosion of the epidermis) with a plain or low calibre needle, contact with the eyes or mucous membranes, or subcutaneous injections following small bore needles.

5.5.2 Moderate Exposure

Mucous membrane / non-intact skin with large volumes or percutaneous superficial exposure with solid needle.

Example: A cut or needle stick injury penetrating gloves.

5.5.3 Severe Exposure

Percutaneous with Large Volume

Example: An accident with a high calibre needle (2:18G) visibly contaminated with blood; A deep wound (Haemorrhagic wound and/or very painful); Transmission of a significant volume of blood; an accident with material that has previously been used intravenously or intra-arterially.

In case of an exposure with material such as discarded sharps /needles, contaminated for over 48 hours, the risk of infection becomes negligible for HIV, but still remains significant for HBV. Hepatitis-B virus survives longer than HIV outside the body.

5.6 Take First Dose of PEP

The first dose of PEP should be administered preferably within the first 2 hours of exposure but certainly within 72 hours.

If the risk is insignificant, PEP could be discontinued, if already commenced.

*Consult at Integrated Counseling and Treatment Centre (ICTC), BMHRC ORHC – 5

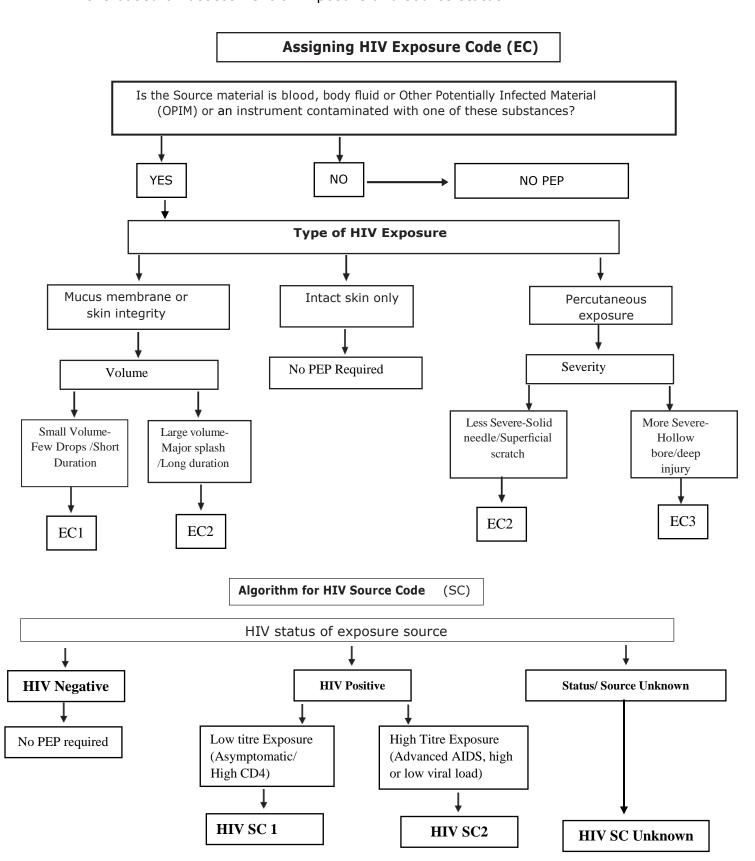
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5.7 Testing for HIV, HBV and HCV for Source and HCW

- Once the HCW reports to the Infection Control Team, both the source (in case the status of the source is unknown and source is available for) and the HCW are tested for their baseline status for HIV (Antibody), HCV (Antibody), and HBV (HBsAg) by rapid methods.
- If the HCW is Prior Vaccinated for Hepatitis-B, then Check for HBsAb (Anti HBsAg) Titre.
- (HCW's baseline status is determined. Otherwise, it may be difficult to attribute the infection acquired due to exposure in the occupational setting.
- A baseline HIV testing should be done after proper Counseling; Informed consent should be obtained before testing of the source as well as person exposed. Initiation of PEP, where indicated, should not be delayed while waiting for the results of HIV testing of the source of exposure.
- Exposed individual who are known or discovered to be HIV positive should not receive PEP. They should be offered Counseling and information on prevention of transmission and referred to Anti-retroviral-Therapy (ART)
 Centre after their complete laboratory work up which also includes testing

5.8 Decision on Prophylactic Treatment for HIV and HBV

This is based on assessment of Exposure and source status



	DETERMINE PEP RECOMMENDATION					
EC	EC HIV SC PEP recommendation					
1	1	P.E.P. may not be warranted . Exposure type does not pose a known risk for HIV transmission				
1	2	Consider basic regimen. Exposure type poses a negligible risk for HIV transmission. A high HIV titer in the source may justify consideration of PEP				
2	1	Recommend basic regimen Most HIV exposures are in this category; no increased risk for HIV transmission has been observed but use of PEP is appropriate.				
2	2	Recommend expanded regimen. Exposure type represents an increased HIV transmission risk.				
3	1 or 2	Recommend expanded regimen Exposure type represents an increased HIV transmission risk.				
UNKNOWN		If the source or, in the case of an unknown source the setting where the exposure occurred, suggests a possible risk for HIV exposure and the E.C. is 2 or 3, consider P.E.P. basic regimen.				

Exposure Codes	HIV Source Codes	PEP Recommendations	Duration
EC1	SC1	Not Recommended	28 Days
EC1	SC2	Recommended	
EC2	SC1		
EC2	SC2		
EC3	SC1 or 2		
EC2/3	SC Unknown	Consider PEP, if HIV prevalence is high in the given population and risk categorization	

5.8.1 PEP Regimen for HIV Refer to HIV Centre

 Wherever PEP is indicated and source is ART naive or unknown: recommended regimen is Tenofovir 300mg + Lamivudine 300mg + Efavirenz 600mg once daily for 28 days. Wherever available, single pill containing these formulations should be used. Dual drug regimen should not be used any longer in any situation for PEP.

- The first dose of PEP regular should be administered as soon as possible, preferably within 2 hours of exposure and the subsequent dose should be given at bed time with clear instruction to take it 2-3hours after dinner and to avoid fatty food in dinner
- In case of intolerance to Efavirenz, regimen containing Tenofovir + Lamivudine
 + PI (ATV/rorLPV/r) can be used after expert consultation by an experienced physician.
- In case of exposure where source is on ART, Tenofovir300mg + Lamivudine 300mg + Efavirenz 600 mg should be started immediately, and an expert opinion should be sought urgently by phone.
- Appropriate and adequate counseling must be provided regarding possible side effects, adherence and follow-up protocol.
- PEP is continued for 28 days in all sources positive and source unidentified cases, regardless of the risk of exposure and CD4 count of the source.

5.8.2 Follow up

HIV antibody testing should be done for at least 6 months post-exposure (e.g. at baseline, 6 weeks, 3 months, and 6 months) to ensure no transmission has occurred.

5.8.2 PEP for Hepatitis B

Hepatitis B measures are as follows:

- For vaccinated HCW with subsequent documented Anti-HBs > 10mIU/ml No need to assess the source status. No post-exposure management is necessary.
- For vaccinated HCW with Anti HBs < 10mIU/ml after two complete vaccination series (i.e. non-responders)
- Assess the source status as soon as possible. If the source status is positive or unknown give 2 doses of HBIq, one month apart.

For vaccinated HCW whose antibody titres are unknown: Check the titres and assess this risk as early as possible.

- If the titres are > 10mIU/ml, no action needed irrespective of the source status.
- If the titres are < 10mIU / ml and if the source is negative, give revaccination series of hepatitis B (0-1-6).
- If the titres are < 10mIU/ml and if the source is positive or unknown give one dose of HBIg and start revaccination series of hepatitis-B.
- If the HCW is unvaccinated or incompletely vaccinated or vaccine refusers and if the source is positive or unknown, Do HBsAg and AntiHBc for the HCWs and give HBIg one dose and complete the vaccination series. If the source is negative complete the vaccinations schedule.

When to check HBsAb titre?

Done after 1–2 months of the last dose of Hepatitis B vaccine.
 When immunoglobulin is received along with vaccination, post-vaccination serology is done after 4 – 6 months to avoid detection of passively administered Anti-HBs.

<u>Post-Exposure Prophylaxis for Percutaneous Or Per Mucosal Exposure To Hepatitis B Virus</u>

Vaccination/Serostatus	<u>Source</u>			
	HBsAg- Positive	HBsAg- negative	Unknown	
Unvaccinated	Hepatitis B immunoglobulin (HBIG) single dose and initiate vaccination	Initiate vaccination	Initiate vaccination	
Responder to vaccine (protected)	No treatment	No treatment	No treatment	
Non-responder				
After one series (3-dose) of vaccination	HBIG single dose and initiate revaccination	No treatment	If source known to be high risk: treat as if source were HBsAg- positive (HBIG single dose and initiate revaccination)	

After 2 series (6 doses) of vaccination	HBIG two doses (separated by 1 month)	No treatment	If source known to be high risk: (treat as if source were HBsAg- positive) HBIG single dose and initiate revaccination
Antibody response unknown	Test exposed person for Anti-HBs: If t 10 mIU /ml: no treatment If t < 10 mIU/ml: HBIG single dose and vaccine booster	No treatment	Test exposed person for anti-HBs If t 10 mIU/mI: no treatment If t < 10 mIU/mI: initiate revaccination

Source: Adapted from Immunization of Health-Care Personnel: Recommendations of the Advisory Committee on Immunization Practices (ACIP) MMWR 2011 /60(RR07)

<u>Post-exposure management of healthcare personnel after occupational percutaneous and mucosal exposure to blood and body fluids, by hepatitis B vaccination and response status of the individual</u>

HCW Status	Post Exposure Testing		Post Exposure Prophylaxis		Post Vaccination
	Source patient (HbsAg)	HCW testing (Anti-HBs)	HBIG	Vaccination	Serological
Documented responder (after 3 doses)			No action	needed	
Documented non- responder (after 6 doses)	Positive/ Unknown		HBIG x 2 1 month apar	t	No
(arter o acces)	Negative	Negative No action needed			
Response unknown (after 3 doses)	Positive/ Unknown	<10 mIU/ml	HBIG x 1	Initiate	
	Negative	<10 mIU/ml	None	revaccination	Yes
	Any result	10 mIU/mI	mIU/ml No action needed		ed
Unvaccinated/ incompletely	Positive/ Unknown		HBIG x 1	Complete vaccination	Yes
vaccinated or vaccine refusers	Negative		None	Complete vaccination	Yes

5.8.2 PEP for HCV

There is no known effective post-exposure prophylaxis for Hepatitis C. The risk of HCV infection after exposure is approximately 1.8%. Testing should occur within 48 hours of exposure, and the typical guidelines for management and treatment of Hepatitis C should be followed.

6 Monitoring and follow up of HIV, HBV, and HCV status

- Whether or not PEP prophylaxis has been started, follow up is indicated to monitor for possible infections and provide psychological support.
- HIV testing (HIV Ab) follow-up is done: at 6weeks, 3 months and 6 months after

- exposure.
- HBV (HbsAg) and HCV (Anti HCVAb) testing follow- up is done: at 3 months and at 6 months after exposure.

Precautions during the follow up period: During the follow up period, especially the first 6-12 weeks, the following measures are to be adopted by the HCW.

- Refraining from Blood, Semen, Organ donation
- Abstinence from sexual inter course or use of latex condom
- Women should not breast-feed their infants.
- The exposed person is advised to seek medical evaluation for any febrile illness that occurs within 12 weeks of exposure.

6.1 Documentation and Recording of Exposure

- A structured Performa (annexure 1) should be used to collect the information related to exposure: Date, time, and place of exposure, type of procedure done, type of exposure: percutaneous, mucus membrane, etc., duration of exposure and exposure source and volume; type of specimen involved.
- Consent form: For prophylactic treatment the exposed person must sign a consent form. If the individual refuse to initiate PEP, it should be documented. The designated officer for PEP should keep this document.

REFERENCES

- [1] NACOPEP Guidelines
- [2] CDC Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Post Exposure Prophylaxis.

https://www.aiimsraipur.edu.in/pdf/Hospital-Infection-Control-Manual-AIIMS-Raipur2019.pdf https://www.ncbi.nlm.nih.gov/books/NBK562734/#nycgpep.s11.5

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