POLICY ON POST EXPOSURE PROPHYLAXIS

1. POLICY:

It shall be the policy to offer counselling and follow-up services to employees who sustain significant exposure to blood or body fluids from patients with AIDS, HIV infection, or risk factors for HIV infection. Post exposure prophylaxis should be initiated promptly, preferably within 1-to-2 hours post exposure according to CDC guidelines

2. PURPOSE:

The purpose of this document is to establish a 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 Sero-conversion) to prevent chronic infection. This policy has been developed from the most current medical literature.

This prophylaxis protocol and regimen will be continuously updated with the most recent medical information

3. DEFINITIONS:

Occupational exposures requiring the initiation of prophylaxis are defined as:
Percutaneous injury (e.g. needle stick, laceration with a sharp object)

3.1. Percutaneous injury (e.g. needle stick, laceration with a sharp object)
3.2. Contact of mucous membranes or ocular membranes
3.3. 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).
3.4. 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).

4. BACKGROUND:

The management of personnel who clearly have a significant percutaneous, mucous membrane, or non-intact skin exposure to blood or body substances depends on:

a. The type of body substance exposure.
b. Whether the source of the exposure is known or unknown.
c. Whether the HIV status of the source is obtainable or unobtainable.
d. The source's degree of risk for infection with HIV.

5. TYPE OF EXPOSURE:

The following body substances are identified by the Centre for Disease Control as capable of transmitting HIV:

a. Blood or blood products
b. Anybody substance containing visible blood
c. Semen
d. Vaginal secretions
e. Tissue
f. The following fluids: synovial, pleural, peritoneal, pericardial, amniotic, cerebrospinal fluid

Source Risk Factors for Transmission of HIV:

a. Social history of intravenous drug use.
b. Social history of homosexual or bisexual behaviour.
c. Social history of multiple sexual partners.
d. Medical history of transfusions of blood or blood products, especially between the years of 1978-1985.
e. Known medical history of AIDS, HIV disease, or positive HIV antigen or antibody.
f. Unknown patient source

6. **PROCEDURE:**

6.1. Employee:

The employees who are exposed to blood or body fluids reports the exposure to his/her supervisor immediately and fills out an Incident form. The form should include the name of the source patient, if known, the circumstances of the incident, and the route of exposure (splash, needle stick, bite, etc.). The employee reports to the Emergency Room.

6.2. Duties of the Supervisor:

a. Assist the employee with filling out Incident form as necessary
b. Obtain risk information on patient source, if known. Nursing Supervisor of the respective area of source patient may be contacted for assistance
c. Send exposed person to Emergency Room as soon as possible.
d. If the exposed person is evaluated in the Emergency Department, the ER/Attending Physician writes the order to HIV testing for source patient whenever possible unless the HIV carrier status of the source is known. Consideration should be given to repeating the HIV antibody of a source that tested negative more than one month previously if the source is in a high-risk category. The area nursing supervisor obtains the consent.
e. Document employee's refusal of care

6.3. Duties of the CMO- Emergency Department:

a. Initiate HBV screening of the employee and source patient according to policy and protocol
b. Initiate HBV vaccine or prophylaxis as well as tetanus prophylaxis, if indicated
c. Request HIV testing for the source patient whenever possible unless the HIV carrier status of the source is known. Consideration should be given to repeating the HIV antibody of a source that tested negative more than one month previously if the source is in a high-risk category. This will require contacting the attending physician to write the order and obtain the consent

d. Inform the employee, student or volunteer that all follow-up treatment and testing shall be accomplished through the supervision of the Occupational Health Department
e. Administer PEP under the guidance of the PEP designated officer
f. Store required quantity of PEP drugs and replenish as and when necessary from the pharmacy stores as part of imprest stock maintenance

7. **TREATMENT:**

a. Wound Care First Aid:

i. Irrigate wound with normal saline or sterile water.
ii. Flush mucous membranes with water or saline.
iii. Injuries requiring suturing or other intervention should be treated as usual.
iv. Evaluate the exposed person clinically and serologically for evidence of HIV infection as soon as possible after the exposure, as follows:
1. Take a medical history of any current symptoms, especially regarding fever of unknown cause, lymphadenopathy, persistent diarrhoea, or cough
2. Perform baseline physical examination
3. Order HIV antibody (informed consent required). If sero-negative, retest at six (6) weeks, three (3) and six (6) months
4. Advise the exposed person to report any of the above significant persistent symptoms to PEP – Designated officer should they occur during the follow-up period
5. Advise the exposed person of the current information regarding the probability of HIV sero-conversion by means of the reported exposure.
6. Counsel the exposed person about the risk of infecting others and for preventing transmission of HIV during this follow-up period, especially the first three (3) months when most infected persons are expected to seroconvert.

b. Tetanus Prophylaxis:

i. Tetanus and diphtheria toxoids (Td): 0.5 mg IM if ≥10 years since last Immunization.
ii. Tetanus immune globulin: not required.

c. Laboratory Evaluation:

i. Source patient (if known)
1. HBsAG
2. Anti HIV: The source's physician or qualified individual should be the one who requests and explains the reason for the HIV test and obtains consent.

ii. Exposed person
1. Anti-HBs
2. Anti-HIV (with exposed person's consent)

d. Hepatitis B Prophylaxis:

Source HBsAG positive, high risk, or unknown (dialysis patient, IV drug user, etc.)

1. Exposed unvaccinated and not known anti-HBs positive:

a. Hepatitis B vaccine: 1.0 ml IM. Second and third immunizations in one (1) and six (6) months at Occupational Health as function of serologic results on exposed.

b. HBIG: 0.06 ml/kg IM.

2. Source HBsAG negative:

a. Exposed unvaccinated and not known anti-HBs positive:

Hepatitis B vaccine: 1.0 ml IM. Second and third immunizations in one (1) and six (6) months at Occupational Health as function of serologic results on exposed person.

ii. HBIG: Not indicated. Treatment advised as per serological test results on source and exposed person.

b. Exposed vaccinated: no hepatitis B vaccine or HBIG in ED. Treatment advised as per serological test results on source and exposed person

Prophylaxis Management:

a. Exposure Risk Classification:

i. Highest Risk:

1. Large volume of blood (deep injury with large diameter hollow needle previously in source patient's vein or artery, especially involving and injecting of source patient's blood).

2. Blood containing a high titre of HIV (source with acute retroviral illness and end-stage AIDS).
3. Parenteral exposure to laboratory materials containing high titres of HIV.

ii. Increased Risk:

1. Exposure to large volume of blood.
2. Blood with a high titre of HIV.
3. Skin exposed to high titre of HIV, prolonged contact, an extensive area, or an area in which skin integrity is visibly compromised.
4. Percutaneous exposure to tissue or semen, vaginal secretions, synovial, pleural, peritoneal, pericardial, and amniotic fluids containing visible blood.

iii. No Increased Risk:

1. No exposure to a large volume of blood.
2. No exposure to blood with a high titre of HIV (example, solid suture needle injury from source patient with asymptomatic HIV infection which pierces the skin but does not cause bleeding).

MANAGEMENT AND POLICY FOR NEEDLE STICK INJURY OR ACCIDENTAL INOCULATION AND PERCUTANEOUS MUCUS MEMBRANE EXPOSURE TO BLOOD AND BODY FLUID SUBSTANCES

(BASED ON CDC GUIDELINES AND RECOMMENDATIONS FOR PEP, 2001 AND NACO GUIDELINES, GOVT. OF INDIA)

OBJECTIVE

To standardize medical care following a Blood or Bodily Fluid Exposure (BBFE)

SCOPE

All exposed Individuals (as defined below) who present for post-exposure management of BBFE's.

DEFINITIONS

Exposed Individual – for the purpose of this policy, an exposed individual shall refer to any individual occupationally exposed to blood or bodily fluid of another individual.

BBFE (Blood or Bodily Fluid Exposure) - Any percutaneous (puncture or cut through skin), mucosal (e.g., eyes or mouth) or non-intact dermal (e.g. abraded skin, chapped skin or dermatitis) exposure to blood or a potentially infectious bodily fluid of another individual ("source").

HBC – Hepatitis B Virus

HCV – Hepatitis C Virus

HIV – Human Immunodeficiency Virus

Potentially Infectious Material - Blood, tissue, visibly bloody fluids, semen, vaginal, secretions, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, amniotic fluid and inflammatory exudates are considered potentially infectious materials for HIV, HBV and HCV. Materials which are not considered potentially infectious materials for HIV, HBV and HCV

include feces, urine, nasal secretions, saliva, sputum, sweat, tears and vomitus, unless these materials are visibly bloody.

POLICY

1. Upon presentation for post-exposure management of a BBFE, the risk of exposure will be assessed considering the nature and severity of the exposure and the risk level of the source of the blood or bodily fluid. The exposed individual will be appropriately counseled, with care provided according to CDC guidelines and current medical practices, and shall be offered post-exposure prophylaxis if clinically indicated.
2. Attempts will be made to rapidly identify and test the source patient for HIV, HBV and HCV. If HIV positive, attempts will be made to determine the history of antiretroviral drug treatment and /or prior genotypic antiretroviral resistance testing (GART).
3. Baseline testing of the exposed individual will be performed for HIV, HVB and HCV. Those found to be infected on baseline will be referred to their personal physician for management.
4. Informed consent will be obtained prior to testing or treatment. For HIV testing, this will include a specific HIV test consent form.
5. Physician or Gastroenterologist consultation

PROVISIONS

1. All Inodaya employees with BBFEs must complete an incident report and Consult a Medical Gasteroenterologist / Physician with in 72 hour

There is no alternative to Standard Precautions.

Action to be taken in case of staff member facing needle stick injury or accidental inoculation accident: Circumstances.

A needle stick injury or an inoculation accident includes a skin prick, contamination of an abrasion, spillage into the eye or onto mucus membrane (eg. mouth, nose etc) heavy soiling of intact skin or mucus membrane with blood or body fluids.

Action – 1

Skin sites and wounds that have been in contact with blood / body fluids or wounds sustained at the time of needle stick injury shall be immediately washed with soap and water (pending non availability of soap, with plenty of water) mucus membrane shall be flushed with plenty of water

Action – 2

Report to the Concerned Departmental Incharge, Same shall be informed to ICN and primary treatment to be taken in Emergency department

Action – 3

10ml of sample from the source patient and 10ml of blood sample from the exposed staff member shall be immediately collected and sent to Microbiology Laboratory, in a plain red capped vacutainer tube.

HBsAg, anti HCV and anti HBS titers if vaccinated shall be carried out on both the samples in Microbiology Laboratory.

The sample shall be accompanied by appropriate accidental exposure form. No billing is required for the staff as well as the source, if known.

POST EXPOSURE PROPHYLAXIS (PEP) AND MANAGEMENT

HBV

HBsAg

If the staff member is already HBsAg positive: NO FURTHER ACTION IS NEEDED.

If staff member is HBsAg negative and patient is HBsAg negative.

- Immunize the staff member with one of the vaccine available.
- If the staff member has been vaccinated with one/two dosage, the vaccine schedule of the course shall be followed.
- If protected antibodies (anti HBs) titers were demonstrated once, it is protective for life.
- If partial responder (less than 10IU/L but reactive) – Administer a booster dose of vaccine.

Recommendations for Hepatitis B Prophylaxis Following Percutaneous or Permucosal Exposure (Post Exposure Prophylaxis or PEP)

(Based on CDC guidelines and Recommendations for PEP, 2001)

Treatment depending on status of source person and exposed staff.

Treatment when:

Status of source person

Exposed Staff Status	HBs Ag Positive	HBs Ag Negative	Source not tested or Unknown
Exposed Person Unvaccinated	Test Exposed person for Anti HBs 1. If Adequate **:No treatment		If known High risk source shall treat, as if source were HBs Ag Positive
Previously Vaccinated Known Seroconversion (RESPONDER)	Test Exposed person for Anti HBs 1. If Adequate **:No treatment 2.If Inadequate : HB vaccine Booster dose	No Treatment	No Treatment
Known Non-Seroconversion (NON-RESPONDER)	HBIG X 2 or HBIG x1 +1 Dose HB Vaccine	No Treatment	If known High risk source shall treat, as if source were HBs Ag Positive
UNKNOWN SEROCONVERSION (Anti-HBs unknown)	Test exposed person for Anti HBs titres	No Treatment	Test exposed person for Anti HBs
	Anti HBs 1.If inadequate:HBIG X 1+ HB vaccine Booster dose 2.If Adequate : No		Anti HBs 1.If inadequate:HBIG X 1+ HB vaccine Booster dose recheck titres after 1-2 months 2.If

	treatment		Adequate : No treatment

***** Hepatitis B Immunoglobulin (HBIG) : Recommended Adult dose 400 units (0.06ml/kg IM).

(But please follow manufacturer's instructions strictly.

****** An adequate antibody level, is-greater than 10 milli. International Units per ml, (10 IU/L) approximately equivalent to 10 sample ratio units (SRU), by radio immuno-assay, (RIA) or positive by enzyme-immuno-assay (EIA).

- "Persons who have previously been infected with HBV are immune to re-infection and do not require PEP (Post Exposure Prophylaxis)".
- HBsAg – Hepatitis B Virus Surface Antigen.
- "Seroconversion (Responder) – A responder is a person with adequate antibody levels (>10 IU/L):.
- "Non sero conversion (Non Responder) – A Non Responder is a person with inadequate response to Vaccination (i.e., Sera anti HBs < 10 IU/L).
- Anti HBs – Antibody to HBsAg.
- The option of giving one dose of HBIG and Reinitiating the vaccine series is preferred for non-responders who have not completed a second 3 – dose Vaccines series.

- For persons who have previously completed a second Vaccine series but have failed to respond two doses of HBIG are preferred, one month apart.
- When HBIG is indicated, it shall be administered as soon as possible, preferably within 24 hours but not later than 7 days.
- When HB Vaccine is indicated, it shall be administered as soon as possible, preferably within 24 hours.
- HB Vaccine can be administered simultaneously with HBIG at a separate site.
- Vaccine shall always be administered in the deltoid muscle. However Manufacturer's instructions shall be followed).
- If the source patient refuses to get an HBsAg done, proceed as if he/she was positive.

POST EXPOSURE PROPHYLAXIS FOR HCV (PEP)

If source patient is HCV antibody positive (anti HCV), the following shall be done in the exposed person:

- Base line anti HCV & ALT activity to be done.
- Follow up retest after 3 months with anti HCV / ALT (At 4-6 weeks – HCV RNA can be looked for) then after 6 months and at one year.
- All anti HCV reported positive shall be confirmed by RIBA/HCV – RNA) / HCV Antigen.
- No immunization or Antiviral agents are currently recommended as PEP for HCV.

- If HCV infection is identified early, the exposed person shall be managed by a physician specialist in that area (preferably a Senior Consultant in Gastroenterology).

Post-Exposure Management for HIV:

Risk Assessment: Risk for transmission of HIV shall be assessed based upon the exposure material (type of potentially infectious material), the type and severity of sharp or splash exposure, and the source status. The following provide general guidelines for categorizing risk, recognizing that some situations may fall between categories and will require clinical judgment. Consultation with an infectious disease expert shall be sought whenever the clinician is in doubt.

Sharp (e.g. needle stick or other sharp object) percutaneous exposures are considered less severe when the puncture is superficial or results from a solid needle. Exposures are considered more severe when the exposure involves a large bore needle, a deep puncture wound, the needle has been in an artery or vein of the source patient, or there is visible blood on the device.

Source Testing – Following a BBFE, source patient testing shall include a rapid HIV test in order to facilitate decision – making regarding ART.

What is infectious and what is not?

Exposure to blood, semen, vaginal secretions, cerebrospinal fluid, synovial, pleural, peritoneal, pericardial fluid, amniotic fluid and other body fluids contaminated with visible blood can lead to infection. Exposure to tears, sweat, saliva, urine and faeces is non-infectious unless these secretions contain visible blood.

Step 1: First and in management of exposure

For skin – if the skin is broken after a needle – stick or sharp instrument:

- Immediately wash the wound and surrounding skin with water and soap, and rinse. Do not scrub.
- Do not use antiseptics or skin washes (bleach, chlorine, alcohol, betadine).

After a splash of blood or body fluids on unbroken skin:

- Wash the area immediately.
- Do not use antiseptics.

For the eye:

- Irrigate exposed eye immediately with water or normal saline. Sit in a chair, tilt head back and ask a colleague to gently pour water or normal saline over the eye.
- If wearing contact lens, leave them in place while irrigating, as they form a barrier over the eye and will help protect it. Once the eye is cleaned, remove the contact lens and clean them in the normal manner. This will make them safe to wear again.
- Do not use soap or disinfectant on the eye.

For mouth:

- Spit fluid out immediately.
- Rinse the mouth thoroughly, using water or saline and spit again. Repeat this process several times.
- Do not use soap or disinfectant in the mouth.

- Consult the designated physician of the institution for management for the exposure immediately.

Don'ts
Do not panic.
Do not put pricked finger in mouth.
Do not squeeze wound to bleed it.
Do not use bleach, chlorine, alcohol, betadine, iodine or any antiseptic or detergent.

Step 2: Establish eligibility for PEP

The HIV sero-conversion rate of 0.3% after an AEB (for percutaneous exposure) is an average rate. The risk of infection transmission is proportional to the amount of HIV transmitted, which depends on the nature of exposure and the status of the source patient. A baseline rapid HIV testing of exposed and source person must be done for PEP. However, initiation of PEP should not be delayed while waiting for the results of HIV testing of the source of exposure. Informed consent should be obtained before testing of the source as per national HIV testing guidelines.

First PEP dose within 72 hours

A designated person / trained doctor must assess the risk of HIV and HBV transmission following an AEB. This evaluation must be quick so as to start treatment without any delay,

ideally within two hours but certainly within 72 hours; PEP is not effective when given more than 72 hours after exposure. If the risk is insignificant, PEP could be discontinued, it already commenced.

Assessing risk of transmission

Exposure is defined under three categories based on the amount of blood / fluid involved and the entry port. These categories are intended to help in assessing the severity of the exposure but may not cover all possibilities.

Categories of exposure	
Category	**Definition and example**
Mild Exposure	Mucous membrane/non-intact skin with small volumes Eg: a superficial wound (erosion of the epidermis) with a plain or low calibre needle, or contact with the eyes or mucous membranes, subcutaneous injections following small-bore needles.
Moderate Exposure	Mucous membrane/non-intact skin with small volumes OR Percutaneous superficial exposure with solid needle Eg: a cut or needle stick injury penetrating gloves
Severe Exposure	Percutaneous with large Volume eg: an accident with a high calibre needle(>18 G) 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 been previously used intravenously or intra-arterially.

The wearing of gloves during any of these accidents constitutes a protective factor.
Note: In case of an AEB with material such as discarded sharps/needles, contaminated for over 48 hours, the risk of infection is negligible for HIV, but still remains significant for HBV. HBV survives longer than HIV outside the body

Assess exposed individual.

The exposed individual should have confidential counseling and assessment by an experienced physician. Exposed individuals 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 clinical and laboratory assessment to determine eligibility for antiretroviral therapy (ART). Besides the medical assessment, counseling exposed HCP is essential to allay fear and start PEP.

Step 3 : Counseling for PEP.

Exposed persons (clients) should receive appropriate information about what PEP is about and the risk and benefits of PEP in order to provide informed consent for taking PEP. It should be clear that PEP is not mandatory.

Counseling of the individual potentially exposed to HIV shall include :

Risk of occupational exposure based on up to date epidemiologic information from the CDC. Currently, the risk of HIV transmission following a typical percutaneous needle stick exposure is believed to be approximately 0.3% (3 per 1,000). The risk for a typical mucosal exposure is believed to be approximately 0.09% (9 per 10,000) and the risk for a typical exposure to non-intact skin is believed to be less.

Prevention of secondary transmission to others shall be discussed, including safer sex practices and the need to avoid blood donation, pregnancy and breast feeding, especially during the first 6 to 12 weeks following exposure. No modifications to an exposed individual's patient – care responsibilities are necessary solely based upon the exposure incident.

Safe work practices and prevention of future exposure.

The benefits and side effects or risks of antiretroviral therapy (ART) for the prevention of HIV transmission based upon up to date information from the CDC. The counseling should include the following:

Current studies suggest that ART may reduce risk of HIV transmission by as much as 80%. As of the publication of the September 20,2005 MMWR, while many persons have taken ART following BBFE, there have only been 6 cases worldwide of individuals who developed HIV infection despite taking ART.

Individuals taking Lopinavir/ Ritonavir who rely upon oral contraceptives must be abscised to use supplemental contraceptions, as Lopinavir/ Ritonavir may impair the effectiveness of oral contraceptives.

There may be yet unknown side effects of these medications. Data regarding the long-term effects in otherwise healthy persons, including mutagenesis, carcinogenesis, teratogenesis, and fertility are lacking or inadequate.

Psychological support

Many people feel anxious after exposure. Every exposed person needs to be informed about the risks, and the measures that can be taken. This will help to relieve part of the anxiety. Some clients may require further specialized psychological support.

Document exposure

Documentation of exposure is essential. Special leave from work should be considered initially for a period of two weeks. Subsequently, it can be extended based on the assessment of the exposed person's mental state, side effects and requirements.

Practical application in the clinical settings

- For prophylaxis treatment the exposed person must sign consent form.
- Informed consent also means that if the exposed person has been advised PEP, but refuse to start it, this needs to be recorded. This document should be kept by the designated officer for PEP.
- An information sheet covering the PEP and the biological follow-up after any AEB must be given to the person under treatment. However, this sheet cannot replace verbal explanations.

Consultation with and / or counseling by an Infectious Disease Expert shall be arranged when : Individual is pregnant or breast feeding.

Source is known positive and is or has been on ART, or has had genotypic antiretroviral resistance testing (GART) performed.

Individual has a pre-existing medical condition which may increase the risks associated with ART (e.g. renal or hepatic disease, bone marrow suppression or disorder).

Individual is taking a drug or herbal remedy that may interact with ART.

Individual has previously been treated with ART.

HIV seroconversion is suspected in the source.

Initial presentation is delayed (Over 24-36 hours from time of BBFE).

Side effects of ART might require altering the ART regimen.

Either the treatment clinician or the patient has questions which would be best answered by such a consultation.

Step 4 : Prescribe PEP

Deciding on PEP regimen.

There are two types of regimens :

- Basic regimen : 2 – drug combination.
- Expanded regimen : 3 – drug combination.
  The decision to initiate the type of regimen depends on the type of exposure and HIV sero status of the source person.

HIV PEP Evaluation			
Exposure	**Status of source**		
	HIV+ and Asymptomatic	**HIV+ and clinically symptomatic**	**HIV Status Unknown**
Mild	Consider 2-drug PEP	Start 2-drug PEP	Usually No PEP or consider 2-drug PEP

Moderate	Start 2-drug PEP	Start 3-drug PEP	Usually No PEP or consider 2-drug PEP
Severe	Start 3-drug PEP	Start 3-drug PEP	Usually No PEP or consider 2-drug PEP

In the case of a high risk exposure from a source patient who has been exposed to or is taking antiretroviral medications, consult an expert to choose the PEP regimen, as the risk of drug resistance is high. Refer / consult expert physician. Start 2-drug regimen first.

- 2 Drug regime is made available in Emergency Department

Seek expert opinion in case of

- Delay in reporting exposure (>72 hours).
- Unknown source
- Known or suspected pregnancy, but initiate PEP.
- Breast feeding mothers, but initiate PEP.
- Source patient is on ART.
- Major toxicity of PEP regimen.

Step 5: HIV chemoprophylaxis

Because post-exposure prophylaxis (PEP) has its greatest effect if begun within two hours of exposure, it is essential to act immediately. The prophylaxis needs to be continued for four weeks. Exposure must be immediately reported to designated authority and therapy administered.

	Dosage of Drugs for PEP	
Medication	**2-drug Regimen**	**3-drug Regimen**

Zidovudine(AZT)	300 mg twice a day	300 mg twice a day
Stavudine(d4T)	30 mg twice a day	30 mg twice a day
Lamivudine(3TC)	150 mg twice a day	150 mg twice a day
Protease Inhibitors		**1st choice**
		Lopinavir/ritonavir (LPV/r) 400/100mg twice a day or 800/200 mg once a day with meals
		2nd choice
		Nelfinavir (NLF)1250 mg twice a day or 750 mg three times a day with empty stomach
		3rd choice
		Indinavir(IND) 800 mg every 8 hours and drink 8-10 glass of water daily(1.5 litres).
Note: If Protease Inhibitor is not available and 3rd drug is indicated, one can consider using Efavirenz (EFV 600 mg once daily)		
Monitoring should be instituted for side effects of this drug eg CNS toxicity such as nightmares,Insomnia etc.		
*Fixed dose Combination(FDC) are preferred, if available. Ritonavir requires refrigeration.		

PEP regimens to be prescribed by health centres		
	Preferred	**Alternative**
2-drug regimen(basic PEP regimen)	Zidovudine (AZT) +Lamivudine (3TC)	Stavudine(d4T)+Lamivudine(3TC)
3-drug Regimen(consult expert opinion for starting 3 drugs eg LPV/r, NLF or IND regimen)		
Not recommended	ddl+d4T combination NNRTI such as Nevirapine should not be used in PEP	
More information on alternative schedules is available in the latest update USPHS guidelines issued 30 September 2005		

No ART will be provided without counseling and informed consent. The individual must agree to compliance with treatment monitoring and the HIV testing protocol.

All females of reproductive capacity will undergo a rapid pregnancy test, and it pregnant, the case will be discussed with an infectious disease expert prior to beginning ART. Breast feeding women will be counselled to discontinue breastfeeding for at least 6 weeks.

If the individual is either known to be positive for HIV or tests positive for HIV on baseline testing, then he or she will be referred to his or her personal physician, and will not be treated with ART.

Drugs taken by the exposed individual, including over the counter and herbal remedies, and drug allergies will be documented, and consideration be given to known drug interactions prior to beginning ART.

When there are clinical indications for using another regimen, an infectious disease expert shall be consulted.

Selection of PEP regimen when the source patient is on ART

The physician should consider the comparative risk represented by the exposure taking in view exposure source's history of and response to antiretroviral therapy based on clinical view exposure source's history of and response to antiretroviral therapy based on clinical response, CD4 cell counts, viral load measurements (if available), and current disease stage (WHO clinical staging and history). If the source person's virus is known or suspected to be resistant to one or more drugs considered for the PEP regimen, exposed person needs to be given alternate PEP drug regimen and referred for expert opinion.

Changes in the PEP regimen can be made after PEP has been started. Re-evaluation of the exposed person should be considered within 72 hours post-exposure, especially as additional information about the exposure or source person becomes available.

Monitoring ART toxicity – upon beginning ART, baseline tests shall include a CBC, a blood chemistry panel which includes hepatic and renal function tests, a urinalysis, and blood

glucose. Testing shall be repeated and reviewed by the physician every two weeks until two weeks following the completion of ART. Symptoms will be reported to the physician, who will provide treatment as clinically indicated. Blood glucose will be monitored weekly for women who are pregnant and receiving ART.

Medication intolerance – if the exposed individual is experiencing medication intolerance to the extent that compliance may be compromised, as infectious disease expert shall be consulted to consider modifications to the ART regimen.

Follow-up HIV testing – In addition to the baseline HIV test, the exposed individual will be tested for HIV at 6 weeks, 12 weeks and 6 months. If the source was positive for both HCV and HIV, and the exposed individual becomes HCV positive but not HIV positive, then HIV testing will also be performed at 12 months. If the exposed individual should developed an illness compatible with acute retroviral syndrome, then HIV testing will be repeated regardless of the interval since exposure.

Any exposed individual who is confirmed positive for HIV infection on baseline testing will be referred to his or her personal physician. Any individual who is confirmed positive for HIV infection on follow up testing will be referred to a specialist knowledgeable in the management of HIV infection.

Testing of the source patient : OHS / ED will alert Administrative Manager / Supervisor of unit to contact attending physician to initiate testing (order as HCW exposure). Attending

physician is responsible for counseling the patient. Assistance to Epidemiology with post test counseling may be requested.

Antiretroviral drugs during pregnancy: If the exposed person is pregnant, the evaluation of risk of infection and need for PEP should be approached as with any other person who has had an HIV exposure. however, the decision to use any antiretroviral drug during during pregnancy should involve discussion between the woman and her health-care provider's regarding the potential benefits and risks to her and her fetus. Data regarding the potential effects of antiretroviral drugs on the developing fetus or neonates are limited. There is a clear contraindications for Efavirenz (first 3 months of pregnancy) and indinavir (prenatal). In conclusion for a female HCP considering PEP, a pregnancy test is recommended if there is any chance that she may be pregnant, Pregnant HCp are recommended to begin the basic 2 drug regimen,and if a third drug is needed. Nelfinavir is the drug of choice.

Amount of medication to dispense for PEP:

- All clints starting on PEP must take 4 weeks (28 days) of medication
- In all cases, the first dose PEP should be offered as soon as possible, once the decision to give PEP is made.
- HIV testing or results of the source HIV test can come later.
- As usage of PEP drugs is not frequent and the shelf life is 1 to 15 Years. It is proposed that starter packs for 7 days can be put in the emergency department with instructions

to go to a designated Clinic / Officer with 1-3 days for a complete risk assessment, HIV counseling and testing and dispensing of the rest of the medications and management.

Laboratory Follow – up

Follow up of HIV testing of exposure is done at 3 months & 6 Months.

b. Post Exposure Prophylaxis should be initiated promptly, preferably within 1-to-2 hours post- exposure
c. Chemoprophylaxis should be recommended to exposed workers after occupational exposures associated with the highest risk for HIV transmission and for exposure with a lower, but non-negligible risk. A three-drug combination regimen with Zidovudine (ZDV) plus Lamivudine (3 TC) and Indinavir (IDV) following high-risk percutaneous exposure to HIV contaminated blood is recommended. Prophylactic treatment with two drugs Zidovudine (ZDV) and lamivudine (3TC) are recommended for lower risk exposures including contact with mucous membranes, skin and exposure to HIV contaminated body fluids other than blood.

POST EXPOSURE PROPHYLAXIS (PEP) – NACO GUIDELINES

"Post exposure prophylaxis" (PEP) refers to the comprehensive management given to minimize the risk of infection following potential exposure to blood-borne pathogens (HIV, HBV, HCY).

This includes:

1. First aid
2. Counseling
3. Risk assessment
4. Relevant laboratory investigations based on informed consent of the source and exposed person
5. Depending on the risk assessment, the provision of short term (4 weeks) of antiretroviral drugs
6. Follow up and support

"Exposure" which may place an HCPat risk of blood-borne infection is defined as:

- Per cutaneous injury (e.g. needle-stick or cut with a sharp instrument),
- Contact with the mucous membranes of the eye or mouth,
- Contact with non-intact skin (particularly when the exposed skin is chapped, abraded, or afflicted with dermatitis), or
- Contact with intact skin when the duration of contact is prolonged (e.g. several minutes or more) with blood or other potentially infectious body fluids

Table 46: Potentially infectious body fluids

Exposure to body fluids considered *'at risk'*	Exposure to body fluids considered *'not at risk'*	
Blood Semen Vaginal secretions Cerebrospinal fluid Synovial, pleural, peritoneal, pericardial fluid Amniotic fluid Other body fluids contaminated with visible blood	Tears sweat Urine and faeces saliva	*unless these secretions contain visible blood*

Table 47: HIV transmission risk of different routes

Exposure route	HIV
Blood transfusion	90–95%
Perinatal	20–40%
Sexual intercourse	0.1 to 10%
Vaginal	0.05–0.1%
Anal	0.065–0.5%
Oral	0.005–0.01%
Injecting drugs use	0.67%
Needle stick exposure	0.3%
Mucous membrane splash to eye, oro-nasal	0.09%

Note: Needle-stick exposure for HBV is 9–30% and for HCV is 1–10%

STEP 1: MANAGEMENT OF EXPOSURE SITE – FIRST AID

For skin-If the skin is broken after a needle-stick or sharp instrument:
Immediately wash the wound and surrounding skin with water and soap, and rinse. Do not scrub. Do not use antiseptics or skin washes (bleach, chlorine, alcohol, betadine).

After a splash of blood or body fluids:

To *unbroken skin:*

- Wash the area immediately
- Do not use antiseptics

***For the** eye:*

- Irrigate exposed eye immediately with water or normal saline.
- Sit in a chair, tilt head back and ask a colleague to gently pour water or normal saline over the eye.
- If wearing contact lens, leave them in place while irrigating, as they form a barrier over the eye and will help protect it.
- Once the eye is cleaned, remove the contact lens and clean them in the normal manner. This will make them safe to wear again.
- Do not use soap or disinfectant on the eye.

For mouth:

- Spit fluid out immediately.
- Rinse the mouth thoroughly, using water or saline and spit again. Repeat this process several times.
- Do not use soap or disinfectant in the mouth.
- Consult the designated physician of the institution for management of the exposure immediately.

Table 49: Summary of do's and don't	
Do	Do Not
Remove gloves, if appropriate	**Do not** panic
Wash the exposed site thoroughly with running water	**Do not** put the pricked finger in mouth
Irrigate with water or saline if eyes or mouth have been exposed	**Do not** squeeze the wound to bleed it
Wash the skin with soap and water	**Do not** use bleach, chlorine, alcohol, betadine, iodine or other antiseptics/detergents on the wound
** Do - Consult the designated physician immediately as per institutional guidelines for management of the occupational exposure **	

Step 2: Establish Eligibility for PEP

The HIV sero-conversion rate of 0.3% after an AEB (for percutaneous exposure) is an average rate. The real risk of transmission depends on the amount of HIV transmitted (= amount of contaminated fluid and the viral load).

A designated person/trained doctor must assess the risk of HIV and HBV transmission following an AEB. This evaluation must **be made rapidly,** so as to start any treatment as soon as possible after the accident (Ideally within 2 hours but certainly within 72 hours). This assessment must be made thoroughly (because not every AEB requires prophylactic treatment).

The first dose of PEP should be administered within the first 72 hours of exposure and the risk evaluated as soon as possible. If the risk is insignificant, PEP could be discontinued, if already commenced. Two main factors determine the risk of infection:

- The nature of exposure and
- The status of the source patient.

2.1 Assessing the Nature of Exposure and risk of transmission:

Three categories of exposure can be described based on the amount of blood/fluid involved and the entry port. These categories are intended to help in assessing the severity of the exposure but may not cover all possibilities.

Table 50: Categories of exposure

Category	Definition and example
Mild exposure :	mucous membrane/non-intact skin with small volumes E.g.: a superficial wound (erosion of the epidermis) with a plain or low calibre needle, or contact with the eyes or mucous membranes, subcutaneous injections following small-bore needles
Moderate exposure:	mucous membrane/non intact skin with large volumes **OR** percutaneous superficial exposure with solid needle E.g.: a cut or needle stick injury penetrating gloves
Severe exposure :	percutaneous with large volume e.g.: • an accident with a high calibre needle (≥18 G) 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.

The wearing of gloves during any of these accidents constitutes a protective factor.

Note: In case of an AEB 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. HBV survives longer than HIV outside the body.

2.2 Assessing the HIV Status of the exposure:

- PEP needs to be started as soon as possible after the exposure and within 72 hours. In animal studies, initiating PEP within 12, 24 or 36 hours of exposure was more effective than initiating PEP 48 hours or 72hours following exposure.
- PEP is not effective when given more than 72 hours after exposure. A baseline rapid HIV testing should be done before starting PEP.
- Initiation of PEP where indicated should not be delayed while waiting for the results of HIV testing of the source of exposure.
- Informed consent should be obtained before testing of the source as per national HIV testing guidelines.

Table 51: Categories of situations depending on results of the source

Source HIV Status	Definition of risk in source
HIV negative	Source is not HIV infected but consider HBV and HCV
Low risk	HIV positive and clinically asymptomatic
High risk	HIV positive and clinically symptomatic (see WHO clinical staging)
Unknown	Status of the patient is unknown, and neither the patient nor his/her blood is available for testing (e.g. injury during medical waste management the source patient might be unknown). The risk assessment will be based only upon the exposure (**HIV prevalence in the locality can be considered**)

2.3. Assessment of the exposed individuals:

- The exposed individual should have confidential counseling and assessment by an experience physician.

- The exposed individual should be assessed for pre-existing HIV infection intended for people who are HIVnegative at the time of their potential exposure to HIV.
- Exposed individuals 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 clinical and laboratory assessment to determine eligibility for antiretroviral therapy (ART).
- Besides the medical assessment, counseling exposed HCP is essential to allay fear and start PEP (if required) at the earliest.

STEP 3: COUNSELING FOR PEP

- Exposed persons (clients) should receive appropriate information about what PEP is about and the risk and benefits of PEP in order to provide informed consent.
- It should be clear that PEP is not mandatory.
- Informed Consent.
- Psychological support: Many people will feel anxious after exposure. Every exposed person needs to be informed about the risks and the measures that can be taken. This will help to relieve part of the anxiety, but some may require further specialized psychological support.
- Documentation on record is essential. Special leave from work should be considered for a period of time ego2 weeks (initially) then, as required based on assessment of the exposed person's mental state, side effects and requirements.

STEP 4: PRESCRIBE PEP

4.1. Deciding on PEP regimen.

There are two types of regimens:

Basic regimen: 2-drug combination

Expanded regimen: 3-drug combination

The decision to initiate the type of regimen depends on the type of exposure and HIV sera status of the source person.

Table 53: HIV Post-exposure Prophylaxis evaluation

Exposure	Status of source		
	HIV+ and asymptomatic	HIV+ and Clinically symptomatic	HIV status unknown
mild	Consider 2-drug PEP	Start 2- drug PEP	Usually no PEP or consider 2-drug PEP
moderate	Start 2-drug PEP	Start 3-drug PEP	Usually no PEP or consider 2-drug PEP
severe	Start 3-drug PEP	Start 3-drug PEP	Usually no PEP or consider 2-drug PEP

- HIVtesting of the source patient should not delay the decision about whether or not to start PEP.
- Start 2-drugs first if required, then send for consultation or refer.
- In the case of a high risk exposure fram a source patient who has been exposed to or is taking antiretroviral medications, consult an expert to choose the PEP regimen, as the risk of drug resistance is high.
- Refer/consult expert physician. Start 2 drug regimens first.

PEP must be initiated as soon as possible, preferably within 2 hours

4.3. INITIATE HIV CHEMOPROPHYLAXIS

- Because post-exposure prophylaxis (PEP) has its greatest effect if begun within 2 hours of exposure, it is essential to act immediately. There is little benefit if >72 hours later. The prophylaxis needs to be continued for 4 weeks.
- Report exposure immediately to appropriate authority.
- Never delay start of therapy due to debate over regimen. Begin with basic 2-drug regimen, and once expert advice is obtained, change as required.
- The 3rd drug can be added after consultation with an expert.

Table 54: Dosages of the drugs for PEP

Medication	2-drug regimen	3-drug regimen
Zidovudine (AZT)	300 mg twice a day	300 mg twice a day
Stavudine (d4T)	30 mg twice a day	30 mg twice a day
Lamivudine (3TC)	150 mg twice a day	150 mg twice a day
Protease Inhibitors		1st choice : Lopinavir/ritonavir (LPV/r) 400/100 mg twice a day or 800/200 mg once daily with meals 2nd choice : Nelfinavir (NLF) 1250 mg twice a day or 750 mg three times a day with empty stomach 3rd choice : Indinavir (IND) 800 mg every 8 hours and drink 8–10 glasses (≥ 1.5 litres) of water daily

Table 55: PEP regimens to be prescribed by health centers

	Preferred	Alternative
2-drug regimen (basic PEP regimen)	**1st choice:** Zidovudine (AZT) + Lamivudine (3TC)	**2nd choice:** Stavudine (d4T) + Lamivudine (3TC)
3-drug regimen (expanded PEP regimen) - consult expert opinion for starting 3rd drug eg LPV/r, NLF or IND		
Not recommended	ddI + d4T combination NNRTI such as Nevirapine should not be used in PEP	

4.4 Selection of the PEP regimen when the source patient is known to be on ART: The physician should consider the comparative risk represented by the exposure and information about the exposure source, including history of and response to antiretroviral therapy based on clinical response, CD4cell counts, viral load measurements (if available), and current disease stage (WHO clinical staging and history). When the source person's virus is known or suspected to be resistant to one or more of the drugs considered for the PEP regimen, the selection of drugs to which the source person's virus is unlikely to be resistant is recommended. Refer for expert opinion.

4.5 If this information is not immediately available, initiation of PEP, if indicated, should not be delayed. Give the 2 drug (basic) regimen. Changes in the PEP regimen can be made after PEP has been started, as appropriate. Re-evaluation of the exposed person should be considered within 72 hours post-exposure, especially as additional information about the exposure or source person becomes available.

4.6 Antiretroviral during pregnancy

If the exposed person is pregnant, the evaluation of risk of infection and need for PEP should be approached as with any other person who has had an HIV exposure. However, the decision to use any antiretroviral drug during pregnancy should involve discussion between the woman and her health-care provider (s) regarding the potential benefits and risks to her and her fetus. Data regarding the potential effects of antiretroviral drugs on the developing fetus or neonate are limited. There is a clear contraindication for Efavirenz (first 3 months of pregnancy) and Indinavir (pre natal). In conclusion, for a female HCP considering PEP, a **pregnancy test** is recommended if there is any chance that she may be pregnant. Pregnant HC Pare recommended to begin the basic 2-drug regimen, and if a third drug is needed, Nelfinavir is the drug of choice.

4.7 Side effects and adhere to PEP

Studies of HCP taking PEP have reported more side effects than PLHAs taking ART, most commonly nausea and fatigue. Possible side-effects occur mainly at the beginning of the treatment and include nausea, diarrhea, muscular pain and headache. The person taking the treatment should be informed that these may occur and **should be dissuaded from stopping the treatment** as most side-effects are mild and transient, though possibly uncomfortable. Anemia and/or leucopenia and/or thrombocytopenia may occur during the month of treatment. A complete blood count and liver function tests (transaminases) may be performed at the beginning of treatment (as baseline) and after 4 weeks. In practice and from HCP studies, many HCP did not complete the full course of PEP because of side effects. Side effects can be reduced by prescribing regimens that do not include a protease inhibitor (PI), by giving medications to reduce nausea and gastritis and by educating clients about how to reduce side effects ego taking PEP medications with food. It is important that side effects should be explained before initiating PEP so that the symptoms are not confused with

symptoms of sero conversion to HIV. Adherence information is essential with psychological support. More than 95% adherence is important in order to maximize the efficacy of the medication in PEP.

4.8. Amount of medication to dispense for PEP:

- All clients starting on PEP must take 4 weeks (28 days) of medication.
- In all cases, the **first dose of PEP** should be offered as soon as possible, once the decision to give PEP is made.
- HIV testing or results of the source HIV test can come later.
- As usage of PEP drugs is not frequent and the shelf life is 1 to 1.5 years, it is proposed that **starter packs for 7 days** can be put in the emergency department with instructions to go to a designated clinic/officer within 1-3 days for a complete risk assessment, HIV counseling and testing and dispensing of the rest of the medications and management.
- At least 3 such kits are provided in the casualty department.

STEP 5: LABORATORY EVALUATION

The reason for HIV testing soon after an occupational exposure is to establish a "baseline" against which to compare future test results.
If the HCP is HIV-negative at the baseline test, it is in principle possible to prove that subsequent infection identified by follow-up testing is related to the occupational exposure (Depending on the timing of infection and consideration of other risks or exposures).

• When offered HIV testing, the exposed person should receive standard pre-test counseling according to the national HIV testing and counseling guidelines, and should give informed consent for testing.

• Confidentiality of the test result must be ensured. There are different reasons for possibly delaying HIV testing: the HCP may be unable to give informed consent immediately after the

exposure due to anxiety, the exposure occurs outside working hours or in settings where HIV testing is not readily available.

• The HIV test may be done up to several days after the exposure, based on informed consent and with pre- and post-test counseling and ensuring confidentiality.

Do not delay PEP if "HIV testing is not available.

STEP 6: FOLLOW - UP OF AN EXPOSED PERSON

Whether or not PEP prophylaxis has been started, follow up is indicated to monitor for possible infections and provide psychological support.

6.1 Clinical follow-up

In addition, in the weeks following an AEB, the exposed person must be monitored for the eventual appearance of signs indicating an HIV sero conversion: acute fever, generalized lymphadenopathy, cutaneous eruption, pharyngitis, non-specific flu symptoms and ulcers of the mouth or genital area.

- These symptoms appear in 50%-70% of individuals with an HIV primary (acute) infection and almost always within 3 to 6 weeks after exposure. When a primary (acute) infection is suspected, referral to an ART centre or for expert opinion should be arranged rapidly.
- An exposed person should be advised to use precautions (e.g., avoid blood or tissue donations, breastfeeding, unprotected sexual relations or pregnancy) to prevent secondary transmission, especially during the first 6-12 weeks following exposure. Condom use is essential.
- Adherence and side effect counseling should be provided and reinforced at every follow up visit. Psychological support and mental health counseling is often required.

6.2 Laboratory follow ups:

- **Follow up HIV testing:** Exposed persons should have post – PEP HIV tests. Testing at the completion of PEP may give an initial indication of sero - conversion outcome if the availability antibody test is very sensitive.
- However, testing at 4-6 weeks may not be enough as *use of PEP may prolong the time to sero conversion;* and there is not enough time to diagnose all persons who sera convert.
- Therefore, testing at 3 months and again at 6 months is recommended.
- Very few cases of sera conversion after 6 months have been reported. Hence, no further testing is recommended if the HIV test at 6 months is negative.

Table 59: Recommended follow-up laboratory tests

Timing	In persons taking PEP (standard regimen)	In persons not taking PEP
Weeks 2 and 4	Transaminases* Complete blood count §	Clinical monitoring for hepatitis
Week 6	HIV-Ab	HIV-Ab
Month 3	HIV-Ab, anti-HCV, HBsAg Transaminases*	HIV-Ab, anti-HCV, HBsAg
Month 6	HIV-Ab, anti-HCV, HBsAg Transaminases*	HIV-Ab, anti-HCV, HBsAg

Table 59: Drug stock at the healthcare facility

Level of health care facility	Designated person/team in charge of PEP	Minimum drug stock of PEP exposure-response kits*
Tertiary hospitals and medical colleges	**Team:** Infection control officer, Physician, Casualty officer Where ART centers are within the same institution, the ART nodal officer should be the reference person for PEP	3 kits of 7 days supply ie. FDC (AZT/3TC) 2 tabs/day x 7 days x 3 kits = 42 tabs If ART centre available, to link for supply and referrals
Secondary – district, taluk	**Team:** infection control officer, casualty officer The district/taluk physician (internal medicine) should be the reference person for PEP	3 kits of 5 days supply Ie. FDC (AZT/3TC) 2 tabs/day x 5 days x 3 kits = 30 tabs If ART centre available, to link for supply and referrals
Primary – CHC	The medical officer of the CHC is the reference person for PEP	2 kits of 3 days supply. Ie FDC (AZT/3TC) 2 tabs/day x 3 days x 2 kits = 12 tabs
Primary Health centers (PHC)	The PHC medical officer is in-charge of referring for PEP to CHC or district level	Link to CHC or district level for PEP

Exclusion criteria:

1. Prior diagnosis of HIV infection in exposed
2. Underlying renal sufficiency (Sr. Creatinine> 3.0)
3. Underlying hepatic insufficiency (SGOT, SGPT, or total bilirubin > 5 times normal)
4. Bone marrow dysfunction (Hb: < 9 g/dl): granulocytes < 1.000/mm3)

IMMUNIZATION FOR HEALTH CARE WORKERS

Hepatitis B immunization

- The infection control dept provides Hepatitis B vaccination & Typhoid Vaccination. All health care workers are advised to receive Hepatitis B immunization. This is told during the induction program. Typhoid vaccination will be given to all Food Handlers, Tetanus for all Housekeeping and Maintenance staff.
- The dose and schedule is 1 ml (20mg) IM deltoid at 0, 1 and 6 months. The time of the next vaccination is told to the health care worker during administration of the doses. It is the HCW's responsibility to report to the infection control dept on the scheduled date for the subsequent doses.