Guidelines for Prevention of HIV Infection Following an Occupational Exposure to Health care Worker

Ministry of Health and Family
Republic of Maldives

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Foreword

Acronyms

3TC – Lamivudine

ABC - Abacavir

AEB- Accidental Exposure to blood

AIDS – Acquired Immuno Deficiency Syndrome

ARV – Anti Retro Viral

AZT – Zidovudine

CBC – Complete Blood Count

CCHDC – Centre for Community Health and Disease Control

CDC – Centre for Disease Control

CMV – Cyto Megalo Virus

CNS – Central Nervous System

d4T – Stavudine

FTC – Emtricitabine

HBV – Hepatitis B Virus

HCP – Health Care Personnel

HCV – Hepatitis C Virus

HIV – Human Immuno deficiency Virus

IGMH- Indra Gandhi Memorial Hospital

ILO – International Labour Organisation

IV line – Intra Venous line

LFT – Liver Function Tests

NAP – National AIDS Programme

NRTI – Nucleoside Reverse Transcriptase Inhibitors

PEP – Post Exposure Prophylaxis

PIs – Protease Inhibitors

RNA – Ribo Nucleic Acid

TB – Tuberculosis

URTI – Upper Respiratory Tract Infection

WHO- World Health Organisation

Section 1: Introduction

In health care settings, the avoidance of occupational blood exposures is the primary way to prevent transmission of HIV, hepatitis B, and hepatitis C. However, hepatitis B immunization and appropriate post exposure management form integral components of a complete program to prevent infection following blood-borne exposure. Therefore, post exposure management guidelines form an important element of work place safety. Post-exposure prophylaxis has been shown to be effective in occupational settings, not only in saving lives but also in avoiding life-long, costly treatment. The present guidelines are focused towards the post exposure prophylaxis of HIV following an occupational exposure. They provide systematic protocol for the risks of infection, the preventive measures and the procedures to follow after occupational exposure and therefore, attempts to address important concerns like:

- Who is at risk?
- What / How much is the risk?
- What practices may influence this risk and how to minimize the risk?
- What is the role of antiretroviral agents in reducing this risk?
- Issues about safety of PEP drugs and their use in pregnancy
- Operational recommendations to develop a comprehensive programme for PEP implementation with 24 hour access to needed drugs

This guideline has been prepared while referring to the WHO/ILO recommendations 2007, as well as the guidelines formulated by the US Public Health Services, 2005 and modifying the existing National guidelines for Maldives.

1.1 - Principles of providing PEP

As recommended by WHO, the provision for providing PEP for HIV shall consider the basic principle:

1. Non discrimination: The eligibility for PEP shall be based on principle of equity- and offered based purely on clinical considerations of risk. Providers should give information, services and education without discrimination
2. Confidentiality: Personal information relating to PEP, such as the reasons for seeking it, having it provided and for HIV testing, needs to be confidential. Privacy and confidentiality considerations are the same as those for HIV testing
3. Informed consent. Informed consent for HIV PEP needs to be obtained in the same way as for any other health care procedure. Consent to any HIV testing in the context of PEP must also be obtained, in accordance with standard guidelines for HIV testing and counseling. Hence, the exposed person should be counseled on the risk of HIV transmission with exposure, need for PEP and a written consent should be obtained thereafter for HIV testing.

1.2 - Important definitions in context to Post Exposure Prophylaxis of HIV

In order to have a proper understanding of the scope of PEP , occupational exposures, extent of exposure etc, it is important to understand some of the details related to the terminologies that are being used.

Health care Personnel : The term **"Health Care Personnel (HCP)"** is defined as any persons, paid or unpaid; working in healthcare settings who are potentially exposed to infectious materials (e.g. blood, tissue, and specific body fluids and medical supplies, equipment, or environmental surfaces contaminated with these substances). HCP include: emergency care providers, laboratory personnel, autopsy personnel, hospital employees, medical and nursing students and health care professionals of all levels. If required, PEP can also be given to public safety workers, including law enforcement personnel, prison staff, fire-fighters, workers in needle exchange programs, health facility cleaning staff and clinical waste handlers and workers in international HIV programs.

An exposure that might place HCP at risk for HIV infection is defined as a percutaneous injury (e.g., a needle stick or cut with a sharp object) or contact of mucous membrane or non intact skin (e.g., exposed skin that is chapped, abraded, or afflicted with dermatitis) with blood, tissue, or other body fluids that are potentially infectious. In addition to blood and visibly bloody body fluids, semen and vaginal secretions also are considered potentially infectious. Although semen and vaginal secretions have been implicated in the sexual transmission of HIV, they have not been implicated in occupational transmission from patients to HCP. Hence, it is important to note that the guidelines address the occupational exposure to HIV at present.

Occupational Exposure: It refers to exposure to potential blood-borne infections (HIV, HBV and HCV) that occurs during performance of job duties.

Non Occupational Exposure: It refers to exposure to potential blood-borne infections (HIV, HBV, HCV) outside of the work setting.

1.3 - Who is at Risk of occupational exposure in health care settings?

Those health care providers who are frequently involved with blood and blood products are under higher risks. These may involve:

- Interns and medical students
- Nursing staff and students
- Physicians
- Surgeons
- Emergency care providers

- Dentists
- Labour and delivery room personnel
- Laboratory technicians
- Health facility cleaning staff and clinical waste handlers

1.4 - What is Risk of occupational exposure in health care settings?

The risks for occupational transmission of HIV have been described; risks vary with the type and severity of exposure. In prospective studies of HCP, the average risk for HIV transmission after a percutaneous exposure to HIV-infected blood has been estimated to be approximately 0.3% and after a mucous membrane exposure, approximately 0.09%. Although episodes of HIV transmission after non intact skin exposure have been documented, the average risk for transmission by this route has not been precisely quantified but is estimated to be less than the risk for mucous membrane exposures. The risk for transmission after exposure to fluids or tissues other than HIV-infected blood also has not been quantified but is probably considerably lower than for blood exposures.

1.5 - Factors that can effect the transmission of HIV

Several studies have been undertaken epidemiologically and in laboratories to understand the factors that could have an impact on the occupational transmission of HIV. These are broadly categorized as the factors associated with exposure, and those associated with the source of exposure.

The percutaneous exposure to HIV, increased risk for HIV infection was associated with exposure to a larger quantity of blood from the source person as indicated by

1. A device (e.g., a needle) visibly contaminated with the patient's blood,
2. A procedure that involved a needle being placed directly in a vein or artery, or
3. A deep injury.

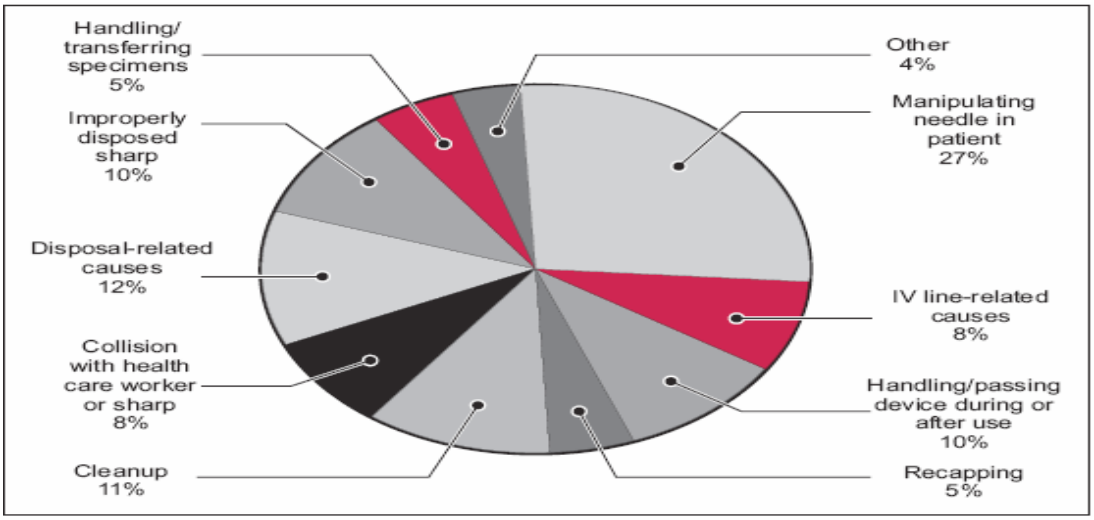
The risk also was increased for exposure to blood from source persons with terminal illness, possibly reflecting either the higher titer of HIV in blood late in the course of acquired immunodeficiency syndrome (AIDS) or other factors (e.g., the presence of syncytia-inducing strains of HIV). A laboratory study that demonstrated that more blood is transferred by deeper injuries and hollow-bore needles lends further support for the observed variation in risk related to blood quantity.

The use of source-person viral load as a surrogate measure of viral titer for assessing transmission risk has not yet been established. Plasma viral load (e.g., HIV RNA) reflects only the level of cell-free virus in the peripheral blood; latently infected cells might transmit infection in the absence of viremia. Although a lower viral load (e.g., <1,500 RNA copies/ mL) or one that is below the limits of detection probably indicates a lower titer exposure, it does not rule out the possibility of transmission.

Certain work practices increase the risk of needle stick injury such as:

- Recapping needles
- Transferring a body fluid between containers

- Failing to dispose of used needles properly in puncture – resistant sharps containers
- Poor health care waste management practices



Causes of percutaneous injuries with hollow-bore needles (CDC 1999)

Hence, the HCP should follow the following to minimize the risk of transmission of HIV following an occupational exposure:

Do's	Do not do
Plan for safe handling and disposal of needles before using them	the use of needles where safe and effective alternatives are available
Promptly dispose of used needles in appropriate sharps disposal containers	Recapping needles
Report all needle stick and sharps-related injuries promptly to ensure that you receive appropriate follow-up care	Ignore Universal Precaution
Participate in training related to infection prevention.	
Record and monitor injuries with an injury register in each location of healthcare setting.	
Follow infection control guidelines and protocols	

Section 2 - Managing an Occupational Exposure

Although strictly applying standard (universal) precautions remains the primary intervention to prevent the transmission of HIV, providing post-exposure prophylaxis offers the possibility of preventing the development of HIV in workers who may have been exposed to sources of infection in the workplace. Following potential exposure to HIV, workers should have immediate access to post exposure prophylaxis 24 hours a day, 7 days a week, regardless of the location or type of work undertaken. The minimum is risk assessment and the first dose of PEP medicine.

The step wise management of an occupational exposure to HIV can be simplified as:

1. Immediate actions after exposure- Manage exposure site
2. Establishing eligibility for PEP;
3. Counselling and obtaining informed consent;
4. Prescribing and dispensing PEP medication;
5. Conducting laboratory evaluation;
6. Ensuring record-keeping; and
7. Providing follow-up and support.

The main steps can be summarized as follows:

Step No	Main objective	Things to Do	Time line, if any
I	Manage exposure site	Depending on the site of exposure: − Wash skin / wound with soap and water − Irrigate eye with water or normal saline − Rinse mouth with water or saline and spit again	Immediately. Then refer to focal person for PEP
II	Establishing eligibility for PEP	Confirm that exposure is within 72 hours and assess: − Exposed Individual − Exposure source − Type of exposure − Risk of transmission Establish if PEP needed	At the earliest
III	Counseling for PEP	Provide information on HIV and PEP - Obtain an informed consent for HIV testing and PEP	Immediately after step II
IV	Prescribe drugs for PEP	Important to consider − Source patient's ARV status	Preferably within 2 hours of

		– If the HCP is female, pregnancy – Explain possible side effects of ARV	exposure, but certainly within 72 hours
V	Conducting laboratory evaluation	– Baseline HIV testing with pre test counseling and consent – Pregnancy test in females – CBC, LFT for monitoring ARV – Post test HIV counseling. – Hepatitis B and C screening, if available.	Baselines, and at 3 and 6 months. CBC and LFT not needed after 1 month, if not indicated.
VI	Record-keeping	– Should be simple – Starts at recording types of exposure and evaluation- patient level – Regional or national PEP Registry.	
VII	Follow up and support	– Follow up visit at 2 weeks and then at 3 and 6 months. May come in between , if needed – Assess if immunized for Hepatitis B.	HIV testing at 3 and 6 months

2.1 – Seven steps in management of occupational exposure

STEP I: Immediate actions after exposure- Manage exposure site

After a suspected occupational exposure, the exposed person may undergo various psychological stresses. However, it is important that they do not panic, and take immediate first aid measures.

If the site of exposure is skin, it should be thoroughly washed with soap and water. Do not use antiseptics, alcohol, betadine, chlorine etc. If there has been a splash on the eyes, the exposed eye should be irrigated with normal saline or water.

Dos	Do Not
If the needle prick is through gloves, remove gloves	Panic
Wash exposed site with running water and soap, on skin	Do not put finger in mouth
If eye, irrigate thoroughly	D not squeeze the injury site
	Do not use antiseptics, bleach, alcohol

STEP II: Establishing eligibility for PEP

The risk of transmission of HIV is estimated to be 0.09% after mucous membrane exposure and 0.3% after percutaneous exposure.

While establishing the eligibility of a person for PEP, the following should be considered

a. Time since exposure:
b. HIV status of the person exposed:
c. Severity of exposure and risk of transmission;
d. Assessment of source of exposure

a. ***Time since exposure***: The post exposure prophylaxis should be initiated as soon as possible preferably within 2 hours of the exposure. However, it should not be delayed beyond 72 hours. PEP has not been recommended beyond 72 hours of exposure. In animal studies, PEP has been found to be more effective when given at 12, 24 or 36 hours than at 48 or 72 hours. It has not been found to be effective after 72 hours in animal studies.

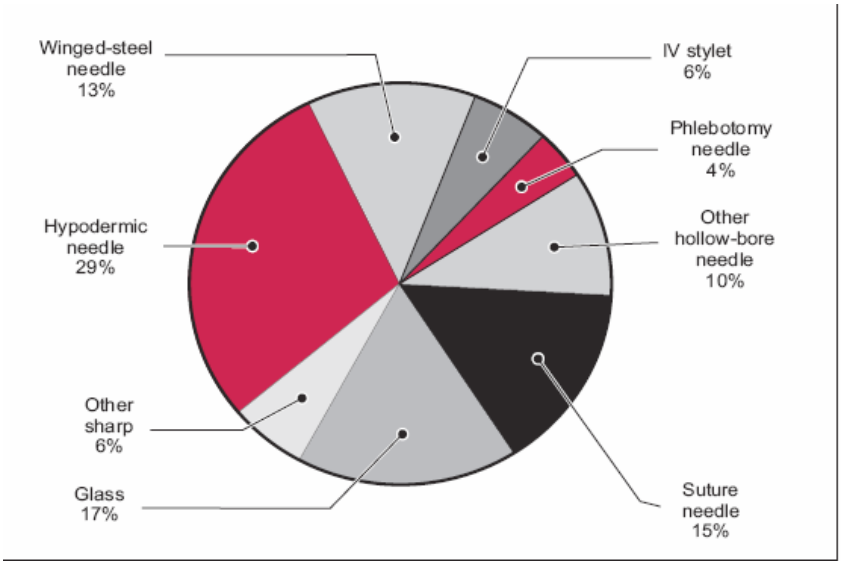
b. ***HIV status of the person exposed***: PEP is indicated only for those HCP who are HIV sero negative, In case of an exposure to a HCP already HIV positive, PEP is not to be offered. They should in fact be counseled on and referred for appropriate clinical and laboratory evaluation and linked to treatment services, if not already done so. Hence, a baseline HIV testing is always recommended before starting PEP. However, PEP, when indicated should not be delayed in want of test results (at least a blood sample to be drawn and first dose may be given, if immediate testing is not available).

c. ***Severity of exposure and risk of transmission***: 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). Depending on the amount of blood or infectious fluid involved and the port of entry, the exposures have been classified as mild, moderate and severe.

Types of exposure	Description with examples
Mild	Through mucous membrane and non intact skin, small volume of blood or potentially infectious body fluid. E.g. erosion of epidermis
Moderate	It occurs through mucous membrane and non intact skin with large volume of blood or potentially infectious body fluid. It can also occur when there is percutaneous exposure using solid needles like suture needle. E.g. : a cut or needle stick injury penetrating gloves
Severe	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.

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.



Hollow-bore needles and other devices associated with percutaneous injuries (CDC 1999)

d. Assessment of source of exposure: The knowledge of the HIV status of the source can be extremely helpful in assessing the need for PEP. It is important to remember that while a HIV positive source helps in initiating PEP, a negative test result for the source does not rule out HIV infection, as the antibody tests do not detect the HIV infection during the window period. Hence, the evaluation of the source should include a thorough physical examination, past history of any infections suggesting immune-compromised state, history of risk behaviour, blood transfusions, injection drug use etc. However, in some cases, the source status may be unknown, like occupational exposure while waste management. In such situation when the HIV status of source is unknown, it has been recommended to use the epidemiological data of the community and the geography. Hence, Maldives being a low prevalent country for HIV, such unknown source are to be considered HIV negative.

However, it is also important that the decision of the risks with the source and its evaluation is a subjective clinical judgment that is to be respected, and there cannot be a scoring grade for the same.

Status of source	Assessment indicators / Description
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 – annex 3.5)
Unknown	The risk assessment will be based only upon the exposure (HIV prevalence in the locality can be considered). Maldives is low prevalent, and hence, majority of source may be HIV negative.

STEP III: Counselling and obtaining informed consent

The counseling should include information about the importance of adherence and the possibility of side effects as well as advice about the risk of transmission as part of their counseling and thereafter to obtain the informed consent.

Counselling women of childbearing age about getting pregnant during post-exposure prophylaxis is critical. Although most drugs prescribed for PEP are regarded as safe during pregnancy, women should be told of the possible risk of transmitting HIV during pregnancy, especially at the initial stage of infection.

People who have been exposed to HIV may need emotional support in the period following the exposure. Appropriate mental health counselling is advisable for occupationally exposed people. Once people have received the appropriate information about PEP – what it entails and the risks and benefits – they will be able to provide informed consent.

Some of the important areas that need to be counseled upon during the counseling for PEP and informed consent are:

- Defining exposure and risks associated with transmission: Talk about the risk of getting HIV with sharps is 0.3%, mucous membranes is 0.1% and it can be influenced by types of exposures. Evaluate for pre existing behavioural risk factors in the HCP.
- Explaining about prophylaxis and how it prevents infection – talk about duration of 28 days, regimens that may be used, tell PEP may be discontinued if HIV test result at baseline is positive including the reason and rationale behind that decision, talk about efficacy of PEP, that it is not 100% effective and should be taken immediately, and not after 72 hours

- Pregnancy and contraception during PEP: talk about the safety of PEP in pregnant HCP, and the higher risk of transmission to infant if there is sero conversion during pregnancy, talk of breast feeding, if relevant. Reinforce contraception and condom use.
- Adherence counseling: tell that duration of PEP is 28 days. Explain how the medicines need to be taken.
- Side effect counseling: There are some side effects associated with ARV. Tell about them. Guide on what to do, and whom to contact if side effects occur.
- HIV testing in context to PEP: Explain the need for baseline as well as HIV testing after 3 and 6 months. Tell about common signs and symptoms of sero conversion.

While operationalising the availability of PEP for HIV, it is important to obtain an informed consent for the willingness as well as for the refusal done by the health care provider. Hence, every case of occupational exposure should have a document consent / refusal as per the format attached as Annex 2.

STEP IV: Prescribing and dispensing PEP medication

WHO recommends that the standard PEP regimen should comprise two nucleoside-analogue reverse-transcriptase inhibitors. Three-drug regimens, comprising two nucleoside-analogue reverse-transcriptase inhibitors plus a boosted protease inhibitor, can be considered in situations where antiretroviral therapy resistance is known or suspected. However, Maldives being a very low prevalent country with limited use of the anti retro viral therapy, it is recommended to use the two drug regime for all the cases when PEP is indicated except those with sever exposure. The recommendations can be summarized as:

Type of Exposure	**Status of Source**		
	Asymptomatic HIV positive (low risk)	**Symptomatic HIV positive (High risk)**	**Unknown HIV status**
Mild	Consider 2 drug PEP	Start 2 drug PEP	No PEP or Start 2 drug PEP
Moderate	Start 2 drug PEP	Start 3 drug PEP	No PEP or Start 2 drug PEP
Severe	Start 3 drug PEP	Start 3 drug PEP	No PEP or Start 2 drug PEP

In case the exposure is from a source exposed to ARV, a three drug regimen may be advocated**,** keeping the possibility of the resistance in mind.
Studies have also shown that delaying initiation, shortening the duration or decreasing the antiretroviral dose of PEP, individually or in combination, decreased its prophylactic efficacy. In a retrospective case control study of HCP, it was demonstrated that use of Zidovudine as PEP was associated with a reduction in the risk of HIV infection by approximately 81%. Hence, the regimens that have been recommended are:

1. Two drug regimen: Consisting of Zidovudine 300mg bid plus Lamivudine 150 mg bid. For 28 days

2. Three drug regimen: In addition to the above two drugs, a Protease Inhibitor (PI) to be added. It can be boosted Lopinavir or Nelfinavir or Indinavir, for 28 days.

It should be noted that Nevirapine is not recommended for the post exposure prophylaxis. However, it is suggested that looking into the relative toxicity with the PIs, the need for storage, multiple daily administration and procurement, as well as the fact that Maldives being a very low prevalent country for HIV, the PEP with two drug regime should be available at all the health institution, while the three drug regimes made available at the Regional Hospital / IGMH. When needed, the 2 drug regimes should be started immediately, followed by referral of the HCP immediately to referral center if 3 drug need is felt.

Dispensing the drugs: The drugs for PEP are not used frequently, and hence, bulk supply of these drugs and storage can potentially lead to expiry of unused drugs and wastage of resources. Hence, it is recommended that all the health posts and atoll hospitals should have the availability of 3 days stock of the two drug regime. As soon as the first dose is administered, the request for complete course should be made to Regional hospitals which should have stock for 3 full courses of PEP at any time in point. In case, the regional hospitals deplete their stock, it can be obtained from NAP/CCHDC who maintain and manage the national stock. This will ensure, universal availability of the PEP in health services at all level, while preventing any expiry. However, the availability of the PEP should be complimented by adequate training of the health care providers (doctors) on how to use PEP, and each health delivery point should identify a nodal person for evaluating risk of occupational exposure and administering PEP.

2.1.1 PEP in Special Circumstances

1. Pregnancy

Some antiretroviral therapy drugs are contraindicated in pregnancy. However, the regimens that have been recommended in the guidelines can be safely given except efavirenz during first trimester in pregnancy and stavudine, (if combined with didanosine)

2. Breast Feeding

PEP can be safely administered during breast feeding. However, it must be explained to the women that although if women get infected by HIV while breastfeeding, the risk of transmitting HIV through breastfeeding is higher at the early stage of infection; appropriate counselling should discuss safe alternatives to breastfeeding if they are acceptable, feasible, affordable and sustainable; However, exclusive breastfeeding is strongly recommended whenever alternatives are not possible.

Step V: Conducting laboratory evaluation

The laboratory evaluation of the HCP is an important activity during the process of giving PEP for HIV. It is not only important to establish a sero negative status of the HCP at the time of initiating PEP, but also to determine any sero conversion that might occur after 3 to 6 months of exposure, as well as to monitor any ART related side effects that may be encountered.

Even if a health care worker declines PEP or is not recommended PEP after an exposure, some baseline investigations are warranted and include HIV, HBV and HCV testing so as to follow them up and establish / rule out any sero conversion in 3-6 months.
The investigations can be summarized as:

Time	Investigations recommended based on Status of PEP administration	
	Taking PEP	**Not taking PEP**
Baseline	HIV, HBV, HCV, complete blood count*, transaminase, desirable-pregnancy test	HIV, HBV, HCV
End of 2nd and 4th week	Complete blood count, transaminase**	Clinical monitoring for hepatitis
After 3 months	HIV, HBV, HCV testing	HIV, HBV, HCV testing
After 6 months	HIV, HBV, HCV testing	HIV, HBV, HCV testing
* Important when the regimen includes zidovudine ** Useful to assess development of hepatitis due to HBV, after exposure, and developing after 2 or 4 weeks.		

STEP VI: Ensuring Record Keeping

Post-exposure prophylaxis services need to be documented at several levels. It is important to have accurate and confidential documentation of the exposures and the PEP provided. Therefore, data needs to be collected at the local level i.e. where the exposure takes place; it has to be reported to regional and National level where a PEP registry may be maintained. These will not only help to identify causes of how the exposures occur and identify safety concerns if any, but also used to evaluate the PEP services and to compare them over time and in different geographic locations. The record keeping should be simple so as to minimize the errors, as well as to respect the time constraints, if any.

Hence, documentation of the exposure and PEP is to be done at various levels as follows:

At local level:

1. Occupational Exposure to HCP- PEP Registration form - Annex 1
2. Informed Consent / Refusal Form – Annex 2
3. Quarterly Report to NAP.- Annex 3

At Central Level, a PEP registry may be developed over time.

STEP VII: Follow up and support

The exposed HCW should be followed up clinically as well as by laboratory parameters. The laboratory work up has been discussed above.

The clinical follow up should include an active search / identification of any signs or symptoms that are suggestive of acute sero conversion. These include acute fever, generalised 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 for expert opinion should be arranged rapidly. The clinical follow up should also ensure early identification of drug toxicity and side effects and adherence to the complete course of 28 days.

Any specific counseling that may be required should be available to the HCP during this period.

2.2 - A check list for the services rendered for an occupational exposure to HIV

Services	Day 0[a]	Day 3[b]	Week 4	Month 3	Month 6
1. Immediate management steps					
• First aid	X				
• Reporting and relief from duty	X				
• Exposure risk assessment	X				
If the exposure is assessed as being significant, proceed with services 2–7. If the exposure is assessed as low risk or if PEP is declined, offer services 5 and 7 only.					
2. Post-exposure prophylaxis discussion and counselling					
• Discuss post-exposure prophylaxis	X				
• Obtain informed consent	X				
• Give first dose of PEP medicine	X				
3. Source testing and risk assessment					
• Obtain consent for HIV testing or information on HIV treatment history	X				
• Conduct rapid HIV testing (if available)	X				
• Conduct risk assessment (consider window period, population prevalence and high-risk behaviour)	X				
If the source person is subsequently revealed to be HIV negative, discontinue PEP.					

Services	Day 0[a]	Day 3[b]	Week 4	Month 3	Month 6
4. Post-exposure prophylaxis prescription					
• Confirm eligibility for PEP	X				
• Assess prior HIV risk	X				
• Dispense PEP medicine	X	X (if a starter pack is given)			
• Conduct adherence counselling	X	X	X		
• Conduct side-effect counselling	X	X			
• Consider likelihood of pregnancy	X				
5. HIV testing and counselling					
• Conduct HIV counselling and testing with informed consent (arrange a further visit to obtain results when they are available)d	X	X (if not done at day 0)		X	X (if PEP medicine is taken)
• Consider counselling and support for significant others	X	X		X	
• Give advice on how to prevent transmission	X	X			
Anyone found to be HIV positive should be referred for treatment and support, and PEP, if commenced, should be discontinued. PEP medicine should not be prescribed to HIV-positive individuals.					

Services	Day 0[a]	Day 3[b]	Week 4	Month 3	Month 6
6. Other laboratory testing					
Conduct other testing (as appropriate) for:					
• pregnancy	X		X		
• hepatitis B and/or C antibodies	X			X	X
• haemoglobin			X		
7. Follow-up					
• Provide ongoing support		X	X	X	X
• Provide referrals, as appropriate	X	X	X	X	X
• Review symptoms		X	X	X	
• Conduct occupational health and safety review		X			

a : Immediately on presentation
b: It is assumed that initial 3 day doses are dispensed as per protocol.

At baseline, end of 2 and 4 weeks, serum transaminases may be done for assessing hepatitis due to HBV transmission

(Adapted from WHO/ILO guidelines 2007)

Section 3 – Annexure

3.1 - Annex 1

Occupational Exposure to HCP- PEP Registration form

PEP Registration No: _____/_ _ (number/last 2 digits of year)

Name of HCP:

Age: Gender:

Reported at: ……(hrs)/……(min) (Exact time in 24 hr format) on _ _ / _ _ /_ _ _ _

Details of Exposure

Place of exposure:

Time of exposure: ……(hrs)/……(min) (Exact in 24 hr format) on _ _ / _ _ /_ _ _ _

Time since exposure in hours;
* < 2 hrs *2-6 hrs *6-24 hrs *24-72 hrs *>72 hrs

Type of exposure:
- Intact skin - Mucosal - mucocutaneous - needle stick

Exposure with: - Blood - Other potentially infections fluid (specify)

If exposure was through needle:

Was the needle: - hollow bore - Solid

What was the size of needle?
_____
_____
_____

Describe the circumstances, in brief (like under what condition and procedure dir exposure occur)

Describe the wound / exposure in brief (like depth of percutaneous prick, splash on eyes etc)

Evaluation of the Source:

HIV Status of Source: Positive Negative Not known

If source is positive, is he Symptomatic Asymptomatic

Give more details, if any

……
……
……..

After Exposure:

Were any immediate measures / first aid taken: Yes No

If yes, please specify

……
……

Regarding PEP

Is the HCP eligible	(based on evaluation)	Yes	No
Is PEP advised		Yes	No
Did HCP agree for PEP		Yes	No
Is PEP prescribed		Yes	No

Which regimen: 2 drug (specify) ……..
3 drug (specify) ……..

Baseline Investigations done? Yes No (specify reasons, if not done)

During the course and after PEP;
Any side effects of ART observed? Yes No.
If yes, please mention

……

……
……

Did the HCP complete the 28 day course Yes No

Was HIV testing done?

a. After 3 months Yes No
b. After 6 months Yes No

The outcome of the PEP: The HCP is

1. HIV positive / negative after 3 months
2. HIV positive / negative after 6 months

Any Remarks:
……
……
……
……

Signature of nodal person for PEP

Place Date and Time.

3.2 - Annex 2

Informed Consent / Refusal Form for Post Exposure prophylaxis
(To be filled by the exposed person as well as the person for administering PEP in the institute)

Name: .....

Date of birth: ..... Sex: .....

Date of the accidental exposure: .....

I, the undersigned, ..., hereby declare:

- That I have been informed of the recommendations with regard to prophylactic treatment after accidental exposure to HIV.
- That I understand the risk of transmission after accidental exposure to blood.
- That I have been informed of the effectiveness and the possible side- effects of this treatment.

I have been offered prophylactic treatment, and:

❒ I have decided not to take it.

❒ I agree to follow this prophylactic treatment for a period of 28 days and I agree to accept medical supervision for this.

Date:.....

Signature of the exposed person: .....

Signature of the designated officer: .....

3.3 - Annex 3

Quarterly report of Occupational Exposures from health facility to National AIDS Program

Name of the institution:

Reporting Quarter Year

Date of sending the report

Month and year	Number of HCP reporting occupational Exposure to HIV	No of HCP assessed for PEP	No of HCP prescribed PEP	Regimen prescribed	Was there any break in supply of course of PEP drugs

The copy PEP registration form that was filled for each of the HCP assessed should be enclosed along with this report.

3.4- Annex 4:

Contact Details of Person for expert opinion on PEP

Dr. Ali Nazeem
Consultant in Medicine
Male' Health Service cooperation
Contact No: 7777680
dralinazeem@hotmail.com

3.5- *Annex 5:*

WHO Clinical Staging for HIV

Clinical Stage 1:

- Asymptomatic
- Persistent generalized lymphadenopathy

Clinical Stage 2:

- Unexplained moderate weight loss *(< 10% of presumed or measured body weight)*
- Recurrent URTI
  - *Sinusitis*
  - *Tonsillitis*
  - *Pharyngitis*
  - *Otitis Media*
- Oral lesions
  - *Recurrent oral ulcers*
  - *Angular chelitis*
- Cutaneous lesions
  - *Papular pruritic eruptions*
  - *Herpes zoster*
  - *Seborrhoea*
  - *Fungal nail infections*

Clinical Stage 3:

- Unexplained severe weight loss *(> 10% of presumed or measured body weight)*
- Unexplained persistent diarrhoea (> 1 month)
- Unexplained persistent fever *(above 37.5^{0}C intermittent or constant for longer than one month)*
- Oral lesions
  - *Persistent oral candidiasis*
  - *Oral hairy leukoplakia*
  - *Acute necrotising ulcerative gingivitis, stomatitis, or periodontitis*
- Severe bacterial infections
  - *Pneumonia*
  - *Empyema*
  - *Pyomyositis*
  - *Bone & joint infections*
  - *Meningitis*
  - *Bacteremia*
- Pulmonary TB
- Haematological (unexplained)

- *Anaemia (Hb < 8 gm/dl)*
- *Neutropenia (< 0.5 x 10^9 /litre)*
- *Thrombocytopenia (< 50 x10^9* /litre)

Clinical Stage 4:

- HIV wasting syndrome
- Infections
  - *Pneumocystis pneumonia (PCP)*
  - *Recurrent severe bacterial pneumonia*
  - *Recurrent septicemia (including non-typhoidal salmonella)*
  - *Extrapulmonary TB (including TB lymphnode)*
  - *Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs)*
  - *Chronic herpes simplex ulceration (orolabial, genital or anorectal > 1 month duration or visceral at a*ny sight)
- Infections needing special diagnosis
  - *CMV infections (retinitis or other organ infection)*
  - *Disseminated mycoses (extrapulmonary cryptococcosis—including meningitis, Extrapulmonary Histoplasmosis, coccidiomycosis)*
  - *Chronic cryptosporidiosis*
  - *Chronic isosporiasis*
  - *Disseminated non-TB mycobacterial infection*
  - *Atypical disseminated leishmaniasis*
- Neurological
  - *CNS toxoplasmosis*
  - *HIV encephalopathy*
  - *Progressive multifocal leukoencephalopathy (PML)*
- Malignancy
  - *Lymphoma (cerebral or B cell non-hodgkin)*
  - *Invasive cervical carcinoma*
  - *Kaposi's sarcoma*
- Symptomatic HIV cardiomyopathy
- Symptomatic HIV nephropathy

Reference: Antiretroviral therapy for HIV infection in adults and adolescents: Recommendations for a public health approach (2010 revision)

3.6 - *Annex 6:*

Common Side effects of the ARV used in PEP regimes

S No	*Possible / Suspected Adverse Effect*	*Possible ARV*	*Remarks, if any*
1	GI intolerance, with taste changes, nausea, vomiting, abdominal pain and diarrhoea.	All ARVs (less frequent with d4T, 3TC, FTC and ABC)	Usually self limiting. Give symptomatic treatment
2	Haematological toxicities (particularly anaemia and leukopenia)	AZT	
3	Dyslipidaemia, insulin resistance and hyperglycaemia	All PIs	Usually after prolonged use, Less likely for duration of PEP
4	Hepatitis	All ARVs (particularly with NVP and ritonavir boosted PIs)	
5	Lactic acidosis	All NRTIs	
6	Lipoatrophy and Lipodystrophy	All NRTI	Usually long term. Not expected in 4 weeks duration for PEP.
7	Renal toxicity (nephrolithiasis)	Indinavir	Advise plenty of fluids when indinavir prescribed