

HIV POST-EXPOSURE PROPHYLAXIS (PEP) IN THE UNITED NATIONS

GUIDANCE FOR USE OF PEP KITS

MARCH 2014

FOR USE BY:

HIV PEP KIT CUSTODIANS (PAGE 1)

PATIENTS REQUIRING THE USE OF HIV PEP (PAGE 4)

HEALTH CARE PROVIDERS ADMINISTERING HIV PEP (PAGE 13)



HIV POST-EXPOSURE PROPHYLAXIS (PEP) KITS: INFORMATION FOR CUSTODIANS¹

1 WHAT IS PEP?

PEP stands for “Post Exposure Prophylaxis”. In the context of HIV, it refers to a set of services that are provided to manage the specific aspects of exposure to HIV and to help prevent HIV infection in an exposed person. These services might comprise first aid, counselling, including the assessment of risk of exposure to HIV, HIV testing, and depending on the outcome of the exposure assessment, a course of anti-HIV medication, with appropriate support and follow-up. **PEP should be initiated as soon as possible after exposure, ideally within 2 hours or less, and no later than 72 hours post-exposure. Adherence to a full 28 day course of anti-retroviral (ARV) medicines is critical** and the administration of PEP should be provided with comprehensive services in a confidential and trusting environment. Providing assurance and maintaining confidentiality of exposed individuals in all dealings and communications is vital.

While PEP is not 100% effective in preventing HIV infection following exposure, the UN Medical Services recommendations for PEP are based on careful review of available studies and constitute the considered opinion of international HIV experts. To access the reference for this leaflet, please see <http://www.who.int/hiv/pub/guidelines/PEP/en/index.html> and <http://www.who.int/hiv/pub/guidelines/arv2013/en/>.

2 PEP KITS

UN PEP Kits are provided to all duty stations in the field to facilitate prompt access to medication in case of potential exposure to HIV, allowing the time to organize referral to a trained service provider who will ensure treatment care and support throughout the full 28-day course of PEP medicines and when deemed appropriate, a medical evacuation to more adequate facilities (following UN Country HIV PEP Protocol).

The PEP Kits contain sufficient anti-HIV medications to cover **twenty-eight days’ of a three-drug anti-retroviral treatment, supplied as a combination tablet:** Tenofovir (TDF) 300 mg po qd+ emtricitabine (FTC) 200 mg po qd + Efavirenz (EFV) 600 mg po qd as a once a day single pill fixed dose combination (FDC). The full course of PEP is for 28 days and it is critical to ensure the treatment’s continuity.

Other contents of kits include:

- **Pregnancy test kit:** to identify if an exposed women was already pregnant before potential exposure to the virus. Pregnant women can take PEP and the risk benefit needs to be discussed with the clinician.
- **Emergency oral contraception** ("morning-after" pill); 2 tablets of Levonorgestrel to prevent unwanted pregnancy after sexual assault: first tablet to take as soon as possible and no later than 5 days after exposure, and second tablet 12 hours later.
- **Patient Registry Form:** to be filled and signed by the treating physician who will monitor the care.

¹ This document should be used in conjunction with the UN Country HIV PEP Protocol.

3 ELIGIBILITY

UN PEP Kits are available to all individuals with a United Nations agency contract and their spouses and dependent children who may have been accidentally exposed to HIV, regardless of means of exposure.

4 DUTIES OF THE CUSTODIAN²

- A. **Ensure safe and proper storage.** The kits should be kept in a secure space that is locked. They should be stored according to manufacturer's instructions, stored in closed containers, at temperatures below 30°C (no refrigeration required) and kept dry and protected from light, humidity and excessive heat.
- B. **Maintain adequate supplies to ensure uninterrupted availability.** Custodians should maintain proper inventory records of the kits, including recording of expiry dates. Custodians should determine when to reorder supplies, place orders to replenish supplies³, and promptly record new stock when received.
- C. **Release kits according to the UN Country HIV PEP Protocol.** Custodians should be familiar with the protocol and ensure that his or her actions to release the kits when individuals are reporting exposure follow the protocol strictly.
- D. **Ensure confidentiality of all related information and documentation.** Custodians must, at all times, maintain the strictest confidentiality in all dealings and communications surrounding the case.
- E. **Ensure 24-h accessibility to the kits.** Custodians should be contactable at all times and ensure 24-hour availability of the PEP kits to staff. If the custodian is a health care provider, he or she may be authorized to initiate treatment with the PEP kit. Non-medically qualified custodians will have to contact the physician/s indicated in the UN Country HIV PEP Protocol to conduct a risk assessment and administer the kit, if warranted.
- F. **Provide advice to staff in isolated locations who cannot see a health care provider within 72 hours.** In such cases, the custodian should advise exposed persons to call a centre of excellence on HIV, as listed in the UN Country HIV PEP Protocol that each country should establish, circulate and keep with the kits. A medical provider at the centre of excellence can perform a risk assessment over the telephone.

More information can be found in the Health Care Provider and Patient Information Sheets.

² Custodians should always be a UN system staff member. The only authorized exception relates to UN Examining Physicians (UNEPs) who may be designated as custodians – if they agree to do so, and only if all of the contents of the kit (including emergency contraception) are legal in the country in question.

³ The custodian should request replenishments of kits from UN Cares Global Coordinator – newell@unfpa.org, with a copy to pep@uncares.org.

PATIENT INFORMATION SHEET 1:

HIV AND OCCUPATIONAL EXPOSURE TO BLOOD OR BODY FLUIDS: WHAT YOU NEED TO KNOW

Several infectious diseases are spread by contact with an infected person's blood or their body fluids or tissues. Hepatitis B, hepatitis C and HIV infection are examples of diseases that are spread in this way. Someone may be infected with one of these viruses without even knowing it – and you may not realize that their body fluids or tissues are infectious.

If you have been exposed to someone's body fluids or tissues – through an accidental needlestick injury, by performing first aid, as a result of an accident or violence in the workplace or by some other means – it is important that you know what to do to minimize your risk of becoming infected with HIV or any other bloodborne virus.

First aid

Immediately after the exposure, you should take the following steps to clean the site of the exposure to help reduce the risk of infection.

If the skin is broken following an injury with a used needle or sharp instrument:

- Wash the site immediately using water and soap or a mild disinfectant solution.
- If running water is not available, clean the site with a gel or hand-rub solution.
- Do not use any strong solutions, such as alcohol, bleach or iodine, as these may irritate the wound and make the injury worse.

After a splash of blood or body fluids:

- To unbroken skin:
 - Wash the area immediately.
 - If running water is not available, clean the area with a gel or hand-rub solution.
- To the eye:
 - Wash the exposed eye immediately with water.
 - If you are wearing contact lenses, leave them in place while washing the eye, as they form a barrier over the eye and will help protect it. Once the eye has been cleaned, remove the contact lenses and clean them in the usual way. This will make them safe to wear again.
 - Do not use soap or disinfectant on the eye.
- To the mouth:
 - Spit the fluid out immediately.
 - Rinse the mouth thoroughly and spit out again. Repeat this process several times.
 - Do not use soap or disinfectant in the mouth.

Risk assessment

After first aid, immediately report the exposure to your supervisor or manager. You should then be released from your duties so that risk can be assessed.

The purpose of the risk assessment is to determine whether you are at risk of getting infected with a virus as a result of your exposure. Most workplace exposure actually carries very little risk. However, if you are assessed to have had significant exposure, you may be able to take postexposure prophylaxis.

“Prophylaxis” is something that you can do or a medicine that you can take that may prevent you from getting an infection or disease. Some types of medicine may help to prevent HIV infection after exposure to HIV. To maximize the effect, however, this medicine should be taken as soon as possible after exposure.

The things you might be asked about during risk assessment include:

- the type and size of the needle or sharp instrument;
- for what purpose the needle or sharp instrument had been used;
- the amount of blood or body fluids or tissues to which you were exposed;
- whether you were injured with a sharp object and whether the wound bled;
- whether the injury was through gloves or clothing;
- when the exposure occurred; and
- your personal risk for acquiring HIV infection.

The possibility of post-exposure prophylaxis may be discussed with you if:

- the exposure was to blood, visibly blood-stained fluid, concentrated virus, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid or amniotic fluid; and
- the exposure was from a recently used hollow bore needle or other sharp instrument visibly contaminated with blood; and
- the exposure occurred less than 72 hours previously; and
- the exposure consisted of:
 - skin penetration with spontaneous bleeding or deep puncture; or
 - a significant amount of splash of fluid to mucous membrane; or
 - prolonged contact of fluid with broken skin.

Post-exposure prophylaxis

If the exposure is assessed to carry sufficient risk, you will be offered post-exposure prophylaxis. It is your choice whether or not you take the medicine. If you decide to take post-exposure prophylaxis, you should start it as soon as possible and continue medication for the full 28 days. The medicine you will be given is intended to stop the virus from multiplying in the body, so the earlier it is taken, the more chance it has to be effective. You will need to take PEP for four weeks however, you can stop taking it at any time, but if you do, you will not get the full benefit of the medicine.

Before deciding whether or not you want to use post-exposure prophylaxis, you should be given the opportunity to discuss its advantages and disadvantages with a designated health care provider. Several things need to be discussed with you at that time.

- How and when to take the medicine: This may involve asking questions about your living and working conditions. You will be given a PEP kit containing enough medicine for twenty-eight days. During this period, a medical evaluation is recommended, particularly in the presence of side effects. A follow up HIV test is recommended at 3 and 6 months.

- **Whether you may be pregnant:** You can take post-exposure prophylaxis if you are pregnant. In fact, if you are pregnant, it is even more important that you take the medicine, as the chance of the HIV infection being passed to your unborn baby if you become infected with HIV as a result of the exposure is quite high. The risks and benefits of taking PEP in early pregnancy should be discussed with your health care provider.
- **Side effects:** Side effects are unwanted symptoms you may experience while taking the medicine. Some people, for example, feel sick or tired when taking PEP medicine.
- **No guarantee:** You should be made aware of the fact that, although strong evidence indicates that post-exposure prophylaxis may prevent infection with HIV, it is still not guaranteed.

HIV testing and pre-test counselling

A blood test may not reveal the presence of HIV and other bloodborne viruses until several months after exposure. However, it is recommended that you have a test for HIV infection within a few days of exposure. The reason for testing for HIV soon after occupational exposure is to establish a baseline against which to compare future test results. If you are HIV-negative at the baseline test but later test positive, it may be possible to show that the occupational exposure caused the infection depending on the time of the infection and on the presence of other risks or exposure incidents.

If you are HIV-positive at the baseline test, post-exposure prophylaxis is not appropriate and, if started, should be discontinued. This is to prevent you from developing resistance to medicine that may be needed later to treat HIV infection.

Before being tested, you will be given information about the HIV test to help you decide for yourself whether or not to take the test. You should receive counselling and give verbal consent before blood is taken for testing, during which your risks for HIV infection, personal as well as occupational, need to be assessed. Due to the sensitive nature of the information discussed, you may wish to have the counselling and blood testing done outside the workplace.

You should also be told how to get the results of the test. The results of HIV blood tests, whether negative or positive, should be given in person – never over the phone, in the mail or to another person. Where facilities for rapid testing are available, the result of an HIV test can be obtained within one hour. If rapid HIV testing is not available, it usually takes 2–3 days to get the result.

Follow-up blood tests for HIV need to be done to show whether you have become infected as a result of exposure. They need to be done three months after exposure and, if PEP was taken, again six months after exposure.

Prevention of transmission

If your exposure was assessed as being significant, you will be given advice about how to avoid transmitting the virus to anyone else until you know for sure that you are HIV-negative. You will be advised on how to practice safer sex – and given information on what this means – so you can protect your sexual partners. You will also be told not to share injecting equipment, not to donate blood or tissues and not to breastfeed if there are safe alternatives to exclusive breastfeeding.

Occupational health and safety

Any exposure that occurs in the workplace should be reported and a written record submitted to your supervisor. There are two reasons for this. One is to make sure that you can prove how the exposure occurred if you need to make a claim for compensation, and second, so that steps can be taken to prevent this type of exposure from happening again to another worker.

After any workplace incident, a health and safety review should be conducted to determine whether any unsafe practices or equipment in the workplace need to be changed or improved.

Summary

The risk of acquiring infection following occupational exposure is small. Nevertheless, bloodborne viruses can cause serious health problems. For this reason, should an accident occur, it is important that you know exactly what to do:

- make sure you know how to perform the appropriate first aid;
- always report exposure incidents no matter how trivial you think they are; and
- never perform your own risk assessment; a properly trained person must do this for you.

If you have any questions

To schedule or reschedule an appointment or for any problems related to your exposure or medication please ensure that you have the relevant contact names and phone numbers.

PATIENT INFORMATION SHEET 2:

PREVENTING HIV INFECTION AFTER SEXUAL ASSAULT: WHAT YOU NEED TO KNOW

What is PEP?

Post-exposure prophylaxis is a course of medicine taken to try to prevent HIV infection among people who may have been exposed to HIV, including as a result of sexual assault. PEP is only effective if taken within 72 hours of the assault. In addition to a 28-day course of medicine to prevent HIV infection, people are given first aid care, counseling and follow-up visits.

What is the risk involved with my exposure?

Determining the exact chance of becoming infected with HIV from a single exposure incident is difficult. Although the average risk of infection from one exposure incident is very small, the actual risk of a given individual from a single specific exposure incident cannot be calculated. Unfortunately, HIV infection can be acquired from a single episode of unprotected sexual intercourse.

The average risk for a single unprotected sexual exposure from a source person known to be HIV-positive is as follows. For receptive anal intercourse, the risk is between 1% and 5% (1–5 in 100) and, for receptive vaginal intercourse, between 0.1% and 1% (between 1 in 1000 and 1 in 100). The risk from receptive oral sex with ejaculation is even lower, although transmission can happen this way.

To put these figures in perspective, health care workers who experience a needle-stick injury have a risk of getting infected of about 0.3% (3 in 1000). Post-exposure prophylaxis is generally recommended in such cases. The infection risk associated with blood splashes to the eye or mouth is lower, about 0.03% (3 in 10 000). Although PEP may be offered for exposure of this type, it is not generally recommended because the risk is so small.

What do we know about the effectiveness of post-exposure prophylaxis?

We do not know for sure whether post-exposure prophylaxis will prevent HIV infection following sexual exposure, as people who have taken PEP after sexual exposure to HIV have not, for ethical reasons, been studied using randomized clinical trials. However, it has been shown to be effective in some related situations. For example, one study showed that using zidovudine among health care workers with needle-stick injury after the incident reduced the risk of getting HIV infection by about 80%. Zidovudine has also been given to pregnant women living with HIV to prevent their unborn babies from getting HIV infection. Several studies have found that babies whose mothers take zidovudine are about two thirds less likely to get HIV than those whose mothers do not. Babies who are given zidovudine (or other similar medicines) directly at birth are also much less likely to become HIV infected. Results of tests in animals also suggest that post-exposure prophylaxis medicine can help to prevent HIV infection but that the medicine works best if started as soon as possible after exposure. There is probably no benefit to using PEP medicine if the exposure happened more than 72 hours before⁴.

⁴ For more information on PEP effectiveness, please refer to: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5402a1.htm> and <http://pediatrics.aappublications.org/content/111/6/1475.full.html>.

How can I stay HIV negative?

Although the chance of getting HIV from a single sexual act is relatively low, the most helpful thing you can do is to avoid becoming infected with HIV is to not have unsafe sex. Safe sex (also called safer sex or protected sex) is a set of practices that are designed to reduce the risk of infection during sexual activities to avoid developing sexually transmitted infections, including HIV. Conversely, unsafe sex refers to engaging in sexual activities without the use of any barrier contraception or other measures to prevent the transmission of sexually transmitted infections.

You should also avoid sharing needles to inject drugs.

How does the post-exposure prophylaxis programme work?

The first time we see you, we will ask you questions about the circumstances of the sexual assault to ensure that you would benefit from post-exposure prophylaxis. We will then talk to you about taking an HIV test. A health care worker will take your health history, examine you and evaluate whether you have been exposed to the risk of HIV infection.

If you are considered to be at risk of getting HIV infection as a result of the exposure, you will be given a PEP kit containing enough medicine for 28 days. During this period, a medical evaluation is recommended, particularly if you are experiencing side effects. A follow up HIV test is recommended at 3 and 6 months.

We will also help you to make arrangements to see an HIV counselor and to get your HIV test results. At this time, your counselor or health care provider will give information about the steps you can take to help you avoid transmitting HIV in the unlikely event you do become infected as a result of your recent exposure and how you can avoid HIV infection in the future. The counselor or health care provider will want to ensure that you are taking your medicine correctly and tolerating it well.

At your appointment with the specialist doctor, you will review the medications you are taking and discuss any side effects you are experiencing and the follow-up required. The results of other tests you may have had will also be reviewed. You may be referred for more counseling or to other services that might help you. If you need or want to, you can see the HIV counsellor or health care provider again.

You will be asked to return for another HIV test in three months and again in six months, if you have taken PEP treatment. This is to ensure that you have stayed HIV negative. If, however, you should become HIV-positive, we will offer you both health care and further support.

What other resources are available?

We can refer you to a variety of counselling services and mental health programmes, legal services and other resources. We can assist you in accessing these services. Please let us know whether there is any other way we can help you.

If you have any further questions

For questions or problems related to this programme or your medication please ensure that you have the necessary contact phone numbers.

PATIENT INFORMATION SHEET 3:

PEP REGIMEN

What is post-exposure prophylaxis or PEP?

Post-exposure prophylaxis is a course of medicine that can be taken after possible exposure to HIV to help prevent infection. Prophylaxis, in this case, means medicine that you can take to protect you from getting the HIV infection.

Does post-exposure prophylaxis prevent people from getting HIV after being exposed to HIV?

Post-exposure prophylaxis may be helpful in preventing people from getting HIV infection after an exposure, but it is not guaranteed to work for everyone. It is effective only if you take the medicine soon after exposure and regularly for 28 days.

Which post-exposure prophylaxis medicine will I be taking?

The post-exposure prophylaxis medicine you will be taking is a combination pill containing three medicines, Tenofovir (TDF) 300 mg + Emtricitabine (FTC) 200 mg + Efavirenz (EFV) 600 mg as a once a day single pill fixed dose combination (FDC).

How should I take my medicine?

The combination pill may be taken with or without food but will probably be less likely to cause an upset stomach if it is taken with food. Take one pill once a day at around the same time every day. Many people prefer taking this at night time, but it can be taken at any time of the day and with or without food. Your clinician will discuss the best timing for you prior to starting.

Why is it important to take my medicine correctly?

Anti-HIV medicine works best if it is kept at a constant level in the bloodstream. Post-exposure prophylaxis medicine will not work as effectively if it is used at lower than the recommended doses, if doses are skipped or if it is not taken at regular intervals. This is why taking this medicine as instructed above is especially important.

Do these medicines interact with other medicines?

Tenofovir+Emtricitabine+Efavirenz combination pill should not be taken at the same time as the following medications. If PEP is required, then these medications may need to be stopped with advice of a medical professional: bepridil, cisapride, midazolam, pimozone, triazolam, and Ergot containing medications.

What are the possible side effects of these medicines?

Tenofovir + Emtricitabine + Efavirenz combination pill is usually well tolerated, but unwanted side effects such as rash, mild gastrointestinal symptoms (nausea, vomiting and diarrhoea), dizziness, drowsiness, dream abnormalities and impaired concentration can occur. People who take this medicine might have one or more of these symptoms for a few days, but they usually go away by themselves. More rare side effects include kidney dysfunction, severe psychiatric symptoms (depression, hallucinations, strange thoughts) and changes in the liver. All of these are very rare among people only taking 28 days of medicine, and if they occur, they will improve once the medicine is stopped.

Please ensure that you have all the necessary contact numbers with you.

PATIENT INFORMATION SHEET 5:

WHEN YOU CANNOT ACCESS A HEALTH CARE PROVIDER WITHIN 72 HOURS

If you are in an isolated location where you have no access to a health care provider within 72 hours of exposure, you should contact your organization's PEP Kit custodian immediately to access the UN PEP Kit.

Using the "Information for Health Care Provider" sheet included in the Kit, you should assess yourself for the need for PEP. To assist you in performing the risk assessment for need for PEP, you should seek guidance by calling a centre of excellence on HIV, as listed in the UN Country HIV PEP Protocol, which the United Nations in every country should establish, circulate and keep in each kit. A medical provider at the centre of excellence can perform a risk assessment over the telephone.

If, with the approval of the medical provider, you are eligible to receive the anti-retroviral medication, you can then start the first tablet of PEP medicines.

If you are female of child bearing age and you think you may be pregnant, perform the pregnancy test supplied in the kit following the instructions. PEP medicines can still be taken even if you are pregnant.

If you are female and you have been sexually assaulted, you may need to take two tablets of Levonorgestrel ("Morning After" pill) to avoid pregnancy.

DO NOT PANIC. As soon as feasible, seek medical care for appropriate follow-up.

POST-EXPOSURE PROPHYLAXIS (PEP) KITS FOR HIV: INFORMATION FOR HEALTH CARE PROVIDERS

1 WHAT IS PEP?

PEP stands for “Post-Exposure Prophylaxis”. In the context of HIV, it refers to a set of services that are provided to manage the specific aspects of exposure to HIV and to help prevent HIV infection in an exposed person. These services might comprise first aid, counselling including the assessment of risk of exposure to HIV, HIV testing, and depending on the outcome of the exposure assessment, a course of anti-HIV medication, with appropriate support and follow-up. **PEP should be initiated as soon as possible after exposure, ideally within 2 hours and no later than 72 hours after exposure. Adherence to a full 28 days course of anti-retroviral (ARV) medicines is critical** and the administration of PEP should be provided with comprehensive services in a confidential and trusting environment. Providing assurance and maintaining confidentiality of exposed individuals in all dealings and communications is vital.

While PEP is not 100% effective in preventing HIV infection following exposure, the UN Medical Services recommendations for PEP are based on careful review of available studies and constitute the considered opinion of international HIV experts. To access the reference for this leaflet, please see <http://www.who.int/hiv/pub/guidelines/PEP/en/index.html> and <http://www.who.int/hiv/pub/guidelines/arv2013/en/>.

2 PEP KITS

UN PEP Kits are provided to all duty stations in the field to facilitate prompt access to medication in case of potential exposure to HIV, allowing the time to organize referral to a trained service provider who will ensure treatment, care and support throughout the full 28-day course of PEP medicines or when deemed appropriate, a medical evacuation to more adequate facilities (following UN Country HIV PEP Protocol).

The PEP Kits contain sufficient anti-HIV medications to cover **28 days’ of a three-drug anti-retroviral treatment**, Tenofovir (TDF) 300 mg + Emtricitabine (FTC) 200 mg + Efavirenz (EFV) 600 mg **supplied as a once a day single pill fixed dose combination (FDC)** The full course of PEP is for 28 days and it is critical to ensure the treatment’s continuity.

Other contents of kits include:

- **Pregnancy test kit:** to identify if the exposed woman of childbearing age is already pregnant before the possible exposure to HIV. Pregnant women should be encouraged to take PEP as this can reduce the risk of the HIV infection being passed onto the unborn baby.

Notes on PEP and Pregnancy

- **NB.** A pregnancy test will only give a reliable result 2 weeks after fecundation. The pregnancy test is included in the kit in order to verify if the survivor was pregnant prior to the sexual assault and not as a result of the sexual assault. If the first pregnancy test was negative, it should then be repeated after two weeks to ensure that pregnancy did not occur as a result of the sexual assault.
 - **If the person is pregnant and** happened to be infected through professional exposure or after rape, the initial phase of HIV infection is linked with a very high viral load and an increased risk of transmission to the foetus. Pregnancy is an argument to provide PEP.
 - **If the person is not pregnant,** an initial negative test will only show that the person was possibly not pregnant (or that it is too early to detect the pregnancy) before exposure. In this instance the emergency contraception should be offered to the person. If the person is not correctly protected by the emergency contraception and she becomes pregnant due to the exposure, the initial test gives a chance to appropriately manage the case. It is therefore important, if there is a risk of pregnancy, to repeat the pregnancy test 15 days after exposure.
 - **In case of rape,** the pregnancy test may have a legal value. It is also important not to limit the management of the rape survivor case to the prevention of pregnancy, but also to include the prevention and treatment of STIs.
- **Emergency oral contraception** ("morning-after" pill); 2 tablets of Levonorgestrel to prevent unwanted pregnancy after sexual assault: first tablet to take as soon as possible and no later than 5 days after exposure, and second tablet 12 hours later.
 - **Patient Registry Form:** to be filled and signed by the treating physician who will monitor the care (Annex 2).
 - **Information Leaflets:** This guidance for the health care provider and the patient is included in each kit.

3 ELIGIBILITY

UN PEP Kits are available to all individuals with a United Nations agency contract and their spouses and dependent children who may have been accidentally exposed to HIV, regardless of means of exposure.

PEP should be administered to an individual only in the following circumstances:

- Exposure occurred within the past 72 hours; AND
- The potentially exposed individual is not known to be infected with HIV; AND
- There was significant exposure⁵ of mucous membrane or non-intact skin to a potentially infectious body fluid⁶; AND

⁵ In the case of **occupational exposure**, "significant exposure" refers to skin penetration with spontaneous bleeding or deep puncture, or splash of significant amount of fluid to mucous membrane, or prolonged contact of an at-risk substance with non-intact skin. In the case of **sexual assault**, it refers to receptive vaginal or anal intercourse without a condom or with a condom that broke or slipped; OR contact of perpetrator's blood or ejaculate with mucous membrane or non-intact skin during the assault; OR receptive oral sex with ejaculation; OR the survivor was drugged or otherwise unconscious at the time of the alleged assault and is uncertain about the nature of the potential exposure.

⁶ **Potentially infectious body fluid** refers to: Blood, semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, amniotic fluid. **Body fluids that do NOT pose a risk of bloodborne pathogen transmission** UNLESS visibly contaminated with blood include: Urine, saliva, non-purulent sputum, stool, emesis, nasal discharge, tears, sweat.

- The source of exposure is known and HIV infected or his/her HIV status is unknown; or the source person is unknown.

Please note that PEP is **not indicated** in the following circumstances:

- If the exposed person is HIV-positive from a previous exposure;
- In chronic exposure;⁷
- If the exposure does not pose a risk of transmission, that is, after:
 - Exposure of intact skin to potentially infectious body fluids
 - Sexual intercourse using a condom that remains intact
 - Any exposure to non-infectious body fluids (such as faeces, saliva, urine and sweat)
 - Exposure to body fluids from a person known to be HIV-negative, unless this person is identified as being at high risk for recent infection and thus likely to be within the window period⁸; and
- If the exposure occurred more than 72 hours previously.

4. PROCEDURE FOR OCCUPATIONAL EXPOSURE^{9,10}

- Treat exposure site.** Clean exposure site with soap and water, flush exposed mucous membranes with water. Do NOT apply or inject caustic agents, antiseptics or disinfectants into the wound.
- Conduct risk assessment.** Evaluate the exposure for potential to transmit HIV, HBV and HCV, based on the route and severity of exposure¹¹, and the type of body fluids involved¹².
- Assess eligibility of individual** to receive PEP according to the following eligibility criteria:
 - Less than 72 hours has elapsed since exposure, AND
 - Individual is not known to be HIV-infected, AND
 - Source person is HIV-infected or of unknown HIV status, or the source person is unknown, AND
 - Exposure was to blood, body tissues, visibly blood-stained fluid, concentrated virus, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid or amniotic fluid; AND

⁷ **Chronic exposure refers to:** Multiple exposures occurring over an extended period of time, such as regular and ongoing unprotected sex with an HIV-positive intimate partner. In cases of chronic exposure, pre-exposure prophylaxis (PrEP) should be sought.

⁸ The HIV test detects the antibodies produced by a person who has been infected with HIV. However, the test will not give a positive result until sufficient levels of antibodies are present in the blood of an infected individual. The period between the time of infection and the point at which there are sufficient antibodies is known as the **window period**. Almost everyone living with HIV (99%) will have detectable levels of antibodies three months following transmission.

⁹ For the purposes of these guidelines, individuals sustain potential **occupational exposure** to HIV in the course of their work. However, the term occupational exposure should not be assumed to be solely related to health care. Other workers, such as emergency rescue staff, waste-disposal workers, first aid providers, law enforcement personnel and fire-fighters, may be exposed to blood and other potentially infectious body fluids while performing their work duties.

¹⁰ The **probability of acquiring HIV infection following percutaneous** (through the skin) exposure to blood known to be infected with HIV is generally accepted to be about 0.3%. This figure is derived from studies carried out in well-resourced countries with a low background prevalence of HIV and may not necessarily apply to countries with higher prevalence or in more resource-constrained settings where the reuse of medical supplies and equipment is higher and the overall safety standards are lower.

¹¹ In the case of **occupational exposure**, “significant exposure” refers to skin penetration with spontaneous bleeding or deep puncture, or splash of significant amount of fluid to mucous membrane, or prolonged contact of an at-risk substance with non-intact skin.

¹² **Potentially infectious body fluid** refers to: Blood, semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, amniotic fluid. **Body fluids that do NOT pose a risk of bloodborne pathogen transmission** UNLESS visibly contaminated with blood include: Urine, saliva, nonpurulent sputum, stool, emesis, nasal discharge, tears, sweat.

- Exposure penetrated the skin with spontaneous bleeding or deep puncture or splash of significant amount of fluid to mucous membrane, or prolonged contact of an at-risk substance with non-intact skin; AND
- If the skin was penetrated, exposure was from a recently used hollow bore needle or other sharp object visibly contaminated with blood.

D. Evaluate exposure source

If source person is known:

- Do not delay initiation of PEP to determine HIV status of the source.
- Seek voluntary HIV testing of source as soon as possible after exposure.
- Evaluate for evidence of other bloodborne disease (HBV, HCV).
- Discontinue therapy if the source is found with certainty not to be infected with HIV.

If source person is unknown:

- Base treatment on assessment of bloodborne disease risk and type of exposure, but consider the source person as potentially infectious.

E. Provide individual with the “HIV PEP - Patient Information” sheets, and use the scripts in Annex 1 to discuss these issues before administration of PEP:

- ☐ The risk of HIV transmission with and without PEP.
- ☐ The benefits and risks of taking PEP.
- ☐ The importance of PEP during pregnancy.
- ☐ The risks of taking PEP if the patient already has HIV (before this exposure).
- ☐ The importance of taking continuously for 4 weeks the correct dose of the medication.
- ☐ That PEP is not fully guaranteed to prevent HIV transmission.
- ☐ The possible side-effects of the PEP medications (mainly nausea and fatigue) and how they can be reduced by taking medication with food and with anti-emetics.
- ☐ The benefits of HIV testing (now for baseline, and again at 3 and 6 months).
- ☐ Other recommended blood tests.
- ☐ The usual course of PEP is 4 weeks: If circumstances justify, I can stop the prophylaxis but this will reduce/cancel the effectiveness.
- ☐ The importance of taking precautions to prevent HIV transmission (e.g. avoiding sex or using condoms during sex, not sharing needles and not breastfeeding, if acceptable, feasible, affordable and safe alternatives exist) for the next 6 months or until testing excludes HIV infection.
- ☐ Not to donate blood, semen or body tissues for the next 6 months.
- ☐ [*For Health Care Workers*] Any safe work practices necessary for the next 6 months.

F. If the decision is made to administer PEP, initiate PEP treatment and obtain blood for baseline HIV serologic testing -based on informed consent. Do not wait for HIV test results to administer HIV PEP. Refusal to undergo baseline testing should not preclude initiation of therapy.

G. Report occupational exposure to the UN Medical Director of the agency, using the “declaration of accident” form. Details such as the date and time of exposure, details of incident and procedure leading to exposure, type, severity and amount of fluid to which individual was exposed; exposure source details (i.e. any bloodborne diseases, history of ARV therapy or resistance); post-exposure

management, including health care worker's PEP treatment decision, should be documented in the form.

H. Follow Up

- **Recommend medical evacuation** to Regional Center (Annex 3) for continuation of care if the local medical infrastructure does not provide quality services for HIV and AIDS, STI and other infectious diseases, laboratory testing, counselling, ARV, obstetrical services and legal and psycho-social support.
- **Arrange follow-up consultations** during the treatment in order to evaluate side-effects, adherence to regimen, psychosocial/emotional needs and referral needs, and at 3 and 6 months post-exposure to evaluate symptoms of HIV sero-conversion and to repeat HIV testing.
- **Prevention of other bloodborne diseases:** There is potentially a higher risk of transmission of Hepatitis B than HIV. In the absence of proven previous immunization against Hepatitis B (by vaccination or acquired) and no possibility of immediate testing, an accelerated vaccination scheme against Hepatitis B is recommended.¹³
- **Educate individual to immediately report symptoms** (lymphadenopathy, rash, sore throat, flu-like symptoms) suggestive of acute HIV sero-conversion.

¹³ CDC: Updated US Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV, and Recommendations for Postexposure Prophylaxis. MMWR Morb Mortal Wkly Rep 2001;50(RR-11):1-42. Available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm>

5 PROCEDURE FOR SEXUAL ASSAULT OR OTHER NON-OCCUPATIONAL EXPOSURE^{14,15}

- A. Initial post-assault visit**¹⁶. Provide initial crisis intervention (e.g. emotional support) and first aid. Where possible, PEP should be offered as part of an integrated package of post-rape or HIV prevention services. Explain to the survivor that you will be conducting a general medical examination and forensic examination, with the potential need to take samples for investigation. Provide routine clinical management and/or collection of forensic evidence as soon as possible. Before collection of forensic evidence, it should first be confirmed whether oral sex was performed, and if so, an oral swab should be obtained prior to taking any medication.
- B. Conduct risk assessment and assess the eligibility of the individual** according to the following eligibility criteria:
- Less than 72 hours has elapsed since exposure, AND
 - Exposed individual is not known to be HIV-infected, AND
 - Source person is HIV-infected or of unknown HIV status, AND
 - A defined risk of exposure such as:
 - a. receptive vaginal or anal intercourse without a condom or with a condom that broke or slipped; OR
 - b. contact of perpetrator blood or ejaculate with mucous membrane or non-intact skin during the assault; OR
 - c. receptive oral sex with ejaculation; OR
 - d. the survivor was drugged or otherwise unconscious at the time of the alleged assault and is uncertain about the nature of the potential exposure;
 - e. the survivor was gang raped.
- C. Evaluate exposure source**
- If source person is known:**
- Do not delay initiation of PEP to determine HIV status of the source.
 - Seek voluntary HIV testing of source as soon as possible after exposure.
 - Evaluate for evidence of other bloodborne disease (HBV, HCV).
 - Discontinue therapy if the source is found with certainty not to be infected with HIV.

¹⁴ In these guidelines, this term "**non-occupational exposure**" predominantly refers to potential exposure through sexual assault. Other forms of potential non-occupational exposure include those arising from needle-sharing among people who inject drugs and potential exposure through consensual sex.

¹⁵ The risk of acquiring HIV infection from a single episode of consensual receptive vaginal intercourse is between 0.1% (1 in 1000) and less than 1% (1 in 100), and from receptive anal sex, the risk is between 1% and 5% (1 to 5 in 100). **Risks may be higher in the context of trauma, and multiple rape.** Transmission risks are also elevated by the presence of sexually transmitted infections (STI) in either the source or exposed individual and if the exposed person is an adolescent girl.

¹⁶ If the survivor is too distraught to engage in a discussion about PEP, offer a first dose of medication and re-open the discussion about treatment initiation at a follow-up visit within the next 24 hours.

If source person is unknown:

- Base treatment on assessment of bloodborne disease risk and type of exposure, but consider the source person as potentially infectious.

D. Provide individual with the “HIV PEP - Patient Information” sheets, and using the scripts in Annex 1, discuss these issues before administration of PEP:

- ☐ The risk of HIV transmission with and without PEP.
- ☐ The benefits and risks of taking PEP.
- ☐ The use of PEP during pregnancy.
- ☐ The risks of taking PEP if the patient already has HIV (before this exposure).
- ☐ The importance of taking continuously for 4 weeks the correct dose of the medication.
- ☐ That PEP is not fully guaranteed to prevent HIV transmission.
- ☐ The possible side-effects of the PEP medications, which are mainly nausea and fatigue, that can be reduced by taking medication with food and with anti-emetics.
- ☐ The benefits of HIV testing (now for baseline, and again at 3 and 6 months).
- ☐ Other recommended blood tests.
- ☐ The usual course of PEP is 4 weeks: If circumstances justify you can stop the prophylaxis but this will reduce/cancel the effectiveness.
- ☐ The importance of taking precautions to prevent HIV transmission (e.g. avoiding sex or using condoms during sex, not sharing needles and not breastfeeding) for the next 6 months or until testing excludes HIV infection.
- ☐ Not to donate blood, semen or body tissues for the next 6 months.
- ☐ [For Health Care Workers] Any safe work practices necessary for the next 6 months.

E. If the decision is made to administer PEP, initiate PEP treatment and obtain blood for baseline HIV serologic testing - based on informed consent. Do not wait for HIV test results to administer HIV PEP. Refusal to undergo baseline testing should not preclude initiation of therapy. Any patient who refuses testing or requests that HIV testing be delayed should be given a PEP Kit and asked to return the next day for follow up.**F. Follow Up**

- **Recommend medical evacuation** to Regional Center (Annex 3) for continuation of care if the local medical infrastructure does not provide quality services for HIV and AIDS, STI and other infectious diseases, laboratory testing, counseling, ARV, obstetrical services and legal and psycho-social support.
- **Arrange follow-up consultations** at 3 and 6 months post-exposure to repeat HIV testing, evaluate side-effects, adherence to regimen, symptoms of HIV sero-conversion, psychosocial/emotional needs and referral needs.
- **Screen and treat for other bloodborne diseases and other sexually transmitted diseases:** there is potentially a higher risk of transmission of Hepatitis B than HIV. In the absence of proven previous immunization against Hepatitis B (by vaccination or acquired) and no possibility of immediate testing, an accelerated vaccination scheme against Hepatitis B is recommended.
- **Pregnancy testing and emergency contraception.** All female rape survivors should be offered a pregnancy test and if negative, should be offered emergency contraception. Emergency contraceptives can be given up to 120 hours (five days) after a sexual assault. In addition, women who are pregnant at the time of presentation can still be offered PEP.
- **Educate individual to immediately report symptoms** (lymphadenopathy, rash, sore throat, flu-like symptoms) suggestive of acute HIV sero-conversion.

6 PRESCRIBING & DISPENSING: MEDICATION IN THE KIT

The UN PEP Kit is based on a combination pill containing three medicines: Tenofovir (TDF) 300 mg + Emtricitabine (FTC) 200 mg + Efavirenz (EFV) 600 mg, as a once a day single pill fixed dose combination (FDC). The combination tablet should be taken **orally, once daily (PO qd), at about the same time**. The full 28-day regime of treatment is provided in the kit and it is critical that patients adhere to the full 28-day treatment.

7 PRESCRIBING & DISPENSING ANTIRETROVIRALS FOR PEP

Table 1 lists the recommended three-drug combination of two nucleoside-analogue reverse-transcriptase inhibitor (NRTI) drugs and one non-nucleoside-analogue reverse-transcriptase inhibitor (NNRTI) for PEP. Generally speaking, countries are advised to use the same medicines as those that form the currently recommended WHO-approved first-line antiretroviral therapy (and as specified in their national ART guidelines) for PEP.

Table 1. Recommended three-drug combination therapies for HIV PEP

Preferred regimen	Alternative regimen
Tenofovir (TDF) + emtricitabine (FTC) + efavirenz (EFV)	Zidovudine (AZT or ZDV) + lamivudine (3TC) plus efavirenz (EFV)

NOTES:

1. WHO is undergoing a guideline review process in 2014. The preferred regimen for PEP may change.
2. In most countries, tenofovir is now considered one of the preferred NRTIs and zidovudine (AZT, ZDV) is the most common alternative NRTI to pair with lamivudine (3TC) or emtricitabine (FTC). Emtricitabine is now considered equivalent to lamivudine where it is available. Stavudine (D4T), Abacavir (ABC) and didanosine (ddI) are discouraged due to their relatively higher risk of potentially serious side effects. Nevirapine (NVP) is not recommended for PEP due to risk of serious liver side effects at higher CD4 counts and saquinavir (SQV) is not recommended due to high pill burden and lack of availability in low and middle income countries.

If drug resistance to an NNRTI (EFV) is suspected then a protease inhibitor (PI) as the third drug may be necessary. In addition, nevirapine is not recommended for PEP due to the risk of toxicity. If the resistance profile of the source person is known, the selection of PEP medicines should take account of that profile. Table 2 lists the alternative triple combination therapies for PEP.

Table 2. Recommended three-drug combination therapies including a boosted protease inhibitor for HIV PEP

Preferred regimens	Alternative regimens ^a
Tenofovir + lamivudine or emtricitabine plus lopinavir with a ritonavir boost	Tenofovir + lamivudine or emtricitabine plus atazanavir with a ritonavir boost or fos-amprenavir with a ritonavir boost Zidovudine + lamivudine plus atazanavir with a ritonavir boost or fos-amprenavir with a ritonavir boost

NOTE: Emtricitabine is an acceptable alternative to lamivudine where it is available. Stavudine (D4T), Abacavir and didanosine are discouraged due to their relatively higher risk of potentially serious side effects.

Table 3: Protocols for children:

PEP treatment for children is not provided in the PEP Kits. Below is the dosage information needed to procure or prepare treatment locally.

Drug	Strength of tablets (mg) or oral liquid (mg/ml)	Number of tablets by weight-band morning and evening										Strength of tab (mg)	Number of tablets by weight-band	
		3–5.9 kg		6–9.9 kg		10–13.9 kg		14–19.9 kg		20–24.9 kg			25–34.9 kg	
		am	pm	am	pm	am	pm	am	pm	am	p m		am	pm
Solid formulations														
3TC	Tablet (Dispersible) 30mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	150	1	1
AZT	Tablet (Dispersible) 60 mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	300	1	1
Liquid formulations														
AZT	10 mg/ml	6 ml	6 ml	9 ml	9 ml	12 ml	12 ml	-	-	-	-	-	-	-
3TC	10 mg/ml	3 ml	3 ml	4 ml	4 ml	6 ml	6 ml	-	-	-	-	-	-	-

ANNEX 1. SAMPLE SCRIPTS FOR HEALTH CARE PROVIDERS

Communicating some of the concepts of these guidelines to individuals who have been potentially exposed to human immunodeficiency virus (HIV) and thus may be eligible for post-exposure prophylaxis can be difficult. The sample “scripts” given below are intended to assist health care providers in this task. Users of these guidelines are reminded that these sample scripts are designed to be adapted to suit individual and local circumstances, such as literacy and language facility, cultural factors and service availability. Users should stress the fact the information gathered in interviews and in the patient information sheets will be treated with utmost confidentiality.

SCRIPT 1: EXPLAINING HIV EXPOSURE AND TRANSMISSION RISK, AND HOW POST-EXPOSURE PROPHYLAXIS MAY HELP PREVENT INFECTION FOLLOWING OCCUPATIONAL EXPOSURE

I would like to talk with you for a few minutes about HIV and the medicine that may help to prevent HIV infection we call “post-exposure prophylaxis”.

Risk of infection

Can you tell me what you know about getting HIV infection? *(Interviewer can then correct any misconceptions the person may have.)*

Most people who are exposed to HIV just once don’t get the infection. It’s like when a child is sick and you hold him or her. You are exposed to the virus that is making the child sick, but your body fights it and you don’t get sick. Or when you walk into a room full of people who may have all sorts of infections, you are exposed but don’t necessarily get ill.

Although you have been exposed to the virus, you are not always infected with it. However the HIV virus, after you have had a needle-stick or a splash to the eye or mouth, may enter your body, and invade the immune system and you will have an HIV infection. It’s only then that the HIV test would turn positive. After getting exposed to HIV, it could take up to 3 months before the HIV test would turn positive.

Even if the person with whom you have had contact was definitely infected with HIV, the chance – or risk – of you getting the HIV infection after a needle-stick or a splash to the eye or mouth is very small. The risk of getting HIV infection from a person known to be HIV positive has been estimated to be about 3 in 1000 (0.3%) for injury with a sharp object and even less, 1 in 1000 (0.1%), for a mucous membrane splash. This means that for every 1000 people who come into contact with the blood of a person who has the HIV infection, only two or three will become infected themselves.

The risk is slightly greater for certain types of exposure, such as a needle-stick from a hollow bore needle that has visible blood on it or from needles that have been in an artery or a vein and if the source person has a high viral load (that is to say, the person is very sick).

The good news is that in all these cases your risk of getting HIV is relatively low. Hopefully post-exposure prophylaxis, if you decide you want to take it, can lower your chance of getting HIV infection even further.

Post-exposure prophylaxis medicine

Have you ever heard of a type of treatment called post-exposure prophylaxis, which is used to prevent HIV infection after a needle-stick or splash to the eye or mouth? If so, please tell me what you know about it. *(The interviewer can then correct any misconceptions the person may have.)*

This prophylactic treatment has been used in many situations where a person has been exposed to HIV. For example, it has been given to health workers who have had a needle-stick injury while working with a person who has HIV infection. Similar medicines are used to help prevent pregnant women from passing on HIV to their babies. The medicine works by helping the body to fight the virus, which stops it from getting into a person's blood system so they don't get infected. This is why we are offering you this treatment if you would like to take it. Not everyone who has taken this treatment has been protected, but research has shown that taking it does reduce the chance of getting HIV infection after exposure.

I would like to tell you a few things about post-exposure prophylaxis to help you decide if you might want to take the prophylactic treatment. The treatment is a pill that you take once a day every day for 28 days. For the medicine to work, it is important that you take a pill once a day at about the same time each day. *[Adapt to specific dosing instructions.]*

About ten percent of the people who take this medicine experience some side effects. Side effects are unwanted symptoms that you might get from taking a medicine that is meant to help you; for example, a tablet you use to take away a headache might give you heartburn. For post-exposure prophylaxis, the side effects can include rash, mild gastrointestinal symptoms (nausea, vomiting and diarrhoea), dizziness, drowsiness, dream abnormalities and impaired concentration can occur. People who take this medicine might have one or more of these symptoms for a few days, but they usually go away by themselves. More rare side effects include kidney dysfunction, severe psychiatric symptoms (depression, hallucinations, strange thoughts) and changes in the liver. All of these are very rare among people only taking 28 days of medicine, and if they occur, they will improve once the medicine is stopped. We will help you if you have severe side effects from this medicine. You need to weigh up the possible benefits – that is, that the medicine might help your body fight HIV and prevent you from getting the infection – against the possible risks – that is, that you might have side effects. We don't know for sure that taking PEP means that you won't get HIV infection, but we think it will help.

Tenofovir+Emtricitabine+Efavirenz combination pill should not be taken at the same time as the following medications. If PEP is required than these medications may need to be stopped with advice of a medical professional: bepridil, cisapride, midazolam, pimozide, triazolam, and Ergot containing medications.

To get the full benefit from post-exposure prophylaxis, you must take the pills, at the right times, for the full 28 days. If you change your mind, or if you get side effects that are too unpleasant, you can stop taking them at any time. However, it is best if you contact me, or *[name an appropriate person]*, before you stop taking them, in case there are ways in which we can help you or things that I have not explained clearly that have made you uncertain about whether you want to finish the medicine. If you do decide to take the medicine, you should start straight away.

(If the person is pregnant or there is a possibility of pregnancy) Some types of post-exposure prophylaxis medicine can be used safely in pregnancy. You would not want to expose your baby to unnecessary medicine, but if you get HIV infection during pregnancy, your baby would have some risk of becoming infected with HIV.

Can you tell me how you feel about all of this? Or perhaps you would like to ask some questions about post-exposure prophylaxis?

SCRIPT 2. EXPLAINING ABOUT HIV EXPOSURE AND THE RISK OF TRANSMISSION AND HOW POST-EXPOSURE PROPHYLAXIS MAY HELP PREVENT HIV INFECTION FOLLOWING SEXUAL ASSAULT

I would like to talk with you for a few minutes about HIV and the treatment that may help to prevent HIV infection we call “post-exposure prophylaxis”.

Risk of infection

Can you tell me what you know about getting HIV infection? *(Interviewer can then correct any misconceptions the person may have.)*

Most people who are exposed to HIV just once don’t get the infection. It’s like when a child is sick and you hold him or her. You are exposed to the virus that is making the child sick, but your body fights it and you don’t get sick. Or when you walk into a room full of people who may have all sorts of infections, you are exposed but don’t necessarily get ill.

Although you have been exposed to the virus, you are not always infected with it. However the human immunodeficiency virus (HIV), after you have had unprotected sex with someone who is infected with HIV, may enter your body, and invade the immune system, then you will have an HIV infection. It’s only then that the HIV test would turn positive. After getting exposed to HIV, it could take up to 3 months before the HIV test would turn positive.

Very few people actually get HIV infection after being raped. Many people are exposed to HIV by having unprotected sex or by being raped, but even if the sexual partner or rapist was definitely HIV positive, the chance – or risk –of getting the HIV infection is very small. In your case, the risk of getting HIV infection is:

- between 1 in 1000 (0.1%) and 1 in 100 (1%) or even less for receptive vaginal intercourse; and
- 1 and 3 in 100 (1–3%) for receptive anal intercourse.

For receptive oral intercourse with ejaculation, transmission is very rare, but it can happen.

The risk is increased with visible trauma, if either yourself or the perpetrator has any sexually transmitted infection or if there were multiple perpetrators.

[Adapt to specific circumstances – the above data refer to unprotected intercourse with a person known to be HIV-positive.]

The good news is that your risk is relatively low. Hopefully post-exposure prophylaxis, if you decide you want to take it, can lower your chance of getting HIV infection even further.

Post-exposure prophylaxis medicine

Have you ever heard of a treatment called post-exposure prophylaxis, which is used to prevent HIV infection after rape or other sexual exposure? If so, please tell me what you know about it. *(The interviewer can then correct any misconceptions the person may have.)*

This treatment has been used in many situations where a person has been exposed to HIV. It has been given to health workers who have had a needle-stick injury while working with a person who has HIV infection. Similar treatment is used to help prevent pregnant women from passing on HIV to their babies. The medicine works by helping the body to fight the virus, which stops it from getting into a person's blood system so they don't get infected. We don't know for sure whether it works in the same way after sexual exposure but we hope that it does. This is why we are offering you this treatment if you would like to take it. Not everyone who has taken this treatment has been protected, but research has shown that taking this treatment does reduce the chance of getting HIV infection after exposure.

I would like to tell you a few things about post-exposure prophylaxis to help you decide if you might want to take the medicine.

The treatment is a pill that you take once a day every day for 28 days. For the medicine to work, it is important that you take a pill once a day at about the same time each day. *[Adapt to specific dosing instructions.]*

About 10 percent of the people who take this medicine experience some side effects. Side effects are unwanted symptoms that you might get from taking a medicine that is meant to help you; for example, a tablet you use to take away a headache might give you heartburn. For post-exposure prophylaxis, the side effects can include: rash, mild gastrointestinal symptoms (nausea, vomiting and diarrhoea), dizziness, drowsiness, dream abnormalities and impaired concentration can occur. People who take this medicine might have one or more of these symptoms for a few days, but they usually go away by themselves. More rare side effects include kidney dysfunction, severe psychiatric symptoms (depression, hallucinations, strange thoughts) and changes in the liver. All of these are very rare among people only taking 28 days of medicine, and if they occur, they will improve once the medicine is stopped. We will help you if you have severe side effects from this medicine. You need to weigh up the possible benefits – that is, that the medicine might help your body fight the HIV and prevent you from getting the infection – against the possible risks – that is, that you might have side effects. We don't know for sure that taking post-exposure prophylaxis means that you won't get HIV infection, but we think it will help.

To get the full benefit from post-exposure prophylaxis, you must take the pills, at the right times, for the full 28 days. If you change your mind, or if you get side effects that are too unpleasant, you can stop taking them at any time. However, it is best if you contact me, or *[name an appropriate person]*, before you stop taking them, in case there are ways in which we can help you or things that I have not explained clearly that have made you uncertain about whether you want to finish the medicine. If you do decide to take the medicine, you should start straight away.

(If the person is pregnant or there is a possibility of pregnancy) Some types of post-exposure prophylaxis medicine can be used safely in pregnancy. You would not want to expose your baby to unnecessary medicine, but if you get HIV infection during pregnancy, your baby would have some risk of becoming infected with HIV.

Can you tell me how you feel about all of this? Or perhaps you would like to ask some questions about post-exposure prophylaxis?

SCRIPT 3: ADHERENCE COUNSELING

I want to explain to you how to take the medicine you have been prescribed.

Post-exposure prophylaxis medicine works best when the level in your blood stays roughly the same throughout the day. To make this happen, it is important that you take your medicine at regular intervals. In other words, you need to take the dose that you have been prescribed at certain times. For instance, if the medicine needs to be taken once a day, you should take it in the morning, at regular times when you have breakfast or get up, or in the evening, for example, when you eat dinner or go to bed. For some medicine, there are other instructions: for example, they must be taken with or without food.

These instructions must also be followed.

It is also important that you remember to take each dose. We should think about what you do every day to see if there is anything that might make you miss taking the medicine or if there is anything that might remind you to take it at set times. The full course of medicine is four weeks, so we need to think about what you might be doing over the next four weeks.

I have some tips that might help you take your medicine correctly.

- Use daily life events as cues to take your medicine, such as brushing your teeth or eating meals.
- Establish a set place to take your medicine.
- Try taking medicine with food as this can help to reduce nausea, a common side effect of this medicine. Is food available when you need to take your medicine?
- Consider your work or school patterns and whether taking medicine will mean telling colleagues or family members about post-exposure prophylaxis.
- Think about the days when your routine is different. For example, on weekends, a change in your routine could make you more likely to forget a dose. If you are planning to be out in the evening, it's okay to take a dose a bit early or to take a dose with you.
- Some people find that, when they lie down, although they do not intend to fall asleep, occasionally they do. If you think there is a chance that you might fall asleep if you lie down, you should consider taking the medicine before lying down, even if you do not expect to sleep.
- Set a mobile phone, or some other form of alarm, as a reminder for taking your pills.
- If you feel you can, you could ask family or friends to help you remember to take your medicine.

If you do forget to take your medicine at the right time, you should still take it if it is less than halfway to the time for your next dose. For example, if you usually take your medicine at around 10 in the morning, but forget that dose, you can still take it if you remember to do so before, say 10 in the evening. However, if you don't remember until after 11 in the evening, then don't take it, but take the next dose at 10 in the morning as usual. Never take a double dose of your medicine.

Speak to your health care worker or doctor if you have any problems or questions.

Script 4: Side-Effect Counselling

[Adapt according to the specific medicine prescribed and to the availability of clinical follow-up services.]

I want to talk about the post-exposure prophylaxis medicine you will be taking. As for any medicine, you may experience some side effects (unwanted symptoms) caused by the medicine. Not everybody experiences side effects, but about ten percent of the people taking PEP do, and these can be worse for some people than for others. Most of these symptoms are mild and will disappear in few days, but you need to know what you should do if you get any of these.

It is important for you to let us, or *[referral centre]*, know if you get any symptoms, because we can usually help you to find a way to reduce these symptoms or we may possibly change your medicine.

The medicine you are taking (Tenofovir + Emtricitabine + Efavirenz combination pill) is usually well tolerated, but unwanted side effects such as rash, mild gastrointestinal symptoms (nausea, vomiting and diarrhoea), dizziness, drowsiness, dream abnormalities and impaired concentration can occur. People who take this medicine might have one or more of these symptoms for a few days, but they usually go away by themselves. More rare side effects include kidney dysfunction, severe psychiatric symptoms (depression, hallucinations, strange thoughts) and changes in the liver. All of these are very rare among people only taking 28 days of medicine, and if they occur, they will improve once the medicine is stopped.

Tenofovir+Emtricitabine+Efavirenz combination pill should not be taken at the same time as the following medications. If PEP is required than these medications may need to be stopped with advice of a medical professional: bepridil, cisapride, midazolam, pimozide, triazolam and ergot containing medications

SCRIPT 5: EXPLAINING HIV TESTING IN THE CONTEXT OF POST-EXPOSURE PROPHYLAXIS

[This information is supplementary to that given to the person as part of standard counseling before HIV testing.]

I would like to explain to you why we would like you to have an HIV test.

Post-exposure prophylaxis will not help a person who already has HIV infection. Although the medicines you would take for it are similar to those used to treat HIV infection, you would be taking less antiretroviral medicine than someone who has HIV infection would need. If a person who has HIV infection takes post-exposure prophylaxis, the virus might develop resistance to the HIV medicines, which means that if a person is given medicine to treat the HIV infection later, the medicine will not work as well. It is important therefore to know whether you are already HIV positive, ideally as soon as possible after you start PEP.

We will give you an HIV test at the same time as we give you your post-exposure prophylaxis medicine or, if you only receive a kit, at your first follow-up visit. This first HIV test will not tell us anything about the effect of the exposure you just had. What it will tell us is whether or not you already have HIV infection from previous exposure. If you are already HIV positive, you need to stop taking PEP medicine.

The results of your first HIV test will be available within *[insert time taken for results to become available according to local arrangements for HIV testing]*. We will provide you with your HIV test result as well as counseling and information about the meaning of your results.

[In the case of a rapid HIV test:]

The rapid test is very accurate, but an initial positive test needs to be confirmed with a second rapid test or a standard test. It will take *[insert time taken for results to become available according to local arrangements for HIV testing]* for the result of the second test to come back. You may choose to take PEP while you wait for the confirmatory test result.

If your HIV test is positive, we will be able to refer you to HIV care and support services. If you need medicine to treat HIV infection, it will be available through *[insert relevant details according to local arrangements for HIV treatment and care]*.

It is recommended to take a second HIV test even if you decided not to use PEP or if you stopped taking medicine before you complete a full 28-day course. This follow-up HIV test will tell you whether you got HIV infection from either this exposure or from another exposure incident in the previous few months. If you do take the PEP medicines, we strongly recommend that you take a follow-up HIV test in 3 months' time and another 6 months after the exposure.

[The interviewer should then complete, or refer the person for, pretest counselling according to the national and/or local standard protocols for HIV testing and counselling.]

ANNEX 2. PATIENT REGISTRY FORM

Patient details ID/patient card no.: □□ □□□□ Date of first visit: □□/□□/□□□□ Date of exposure: □□/□□/□□□□ Time of exposure (range): □□:□□ – □□:□□ Hours between exposure and post-exposure prophylaxis: ----- Exposure type: ☐ Occupational ☐ Non-occupational ☐ Receptive vaginal ☐ Receptive anal ☐ Receptive oral with ejaculation ☐ Sharps injury (instrument): ----- ☐ Other (such as mucous membrane splash) ----- HIV status of source person: ☐ Known positive ☐ Unknown Anti-retroviral therapy history of source person: ☐ None or unknown ☐ Yes (describe) ----- Date of last HIV test: □□/□□/□□□□ Result of last HIV test: ☐ Positive* ☐ Negative Other exposure incidents in past six months (number and type): -----	Age (years): _____ Sex: ☐ F ☐ M Symptoms (if status unknown)* Signs of possible acute HIV infection (include duration): ----- Evaluated or referred for evaluation: ☐ Yes ☐ No Clinical assessment* Thrush: ☐ Yes ☐ No Lymphadenopathy: ☐ Yes ☐ No Kaposi sarcoma: ☐ Yes ☐ No Other: _____
Health history Pertinent past health history: ----- Alcohol use: _____ Drug allergies: ☐ None known ☐ Yes If yes, specify: _____ Current medicine taken: _____ ----- * Please note that, if the test is positive or if there are any clinical symptoms of HIV infection at the preliminary visit, post-exposure prophylaxis should not be proposed and the patient should be referred to a treatment centre.	Risk assessment and care plan HIV exposure confirmed and seeking post-exposure prophylaxis Post-exposure prophylaxis medicine: ☐ Tenofovir + emtricitabine + efavirenz one oral tablet once daily or ☐ Other _____ ☐ Reviewed with patient: drug information, adverse events, emergency phone numbers, medicine adherence and use of alcohol ☐ Follow-up appointment made ☐ Sexually transmitted infection treatment ☐ Emergency contraception Laboratory tests ordered: ☐ HIV test ☐ HIV positive (refer for counselling and evaluation) ☐ HIV negative Pregnancy test result: ☐ Positive ☐ Negative ☐ Not available ☐ Other (specify): _____ ☐ Referrals: _____ Notes: _____ Signature: _____ Date: _____

ANNEX 3: RECOGNIZED REGIONAL MEDICAL EVACUATION CENTERS

“Eligible staff members and eligible dependants may be evacuated in case of an acute illness or injury from the duty station or mission area at United Nations expense for the purpose of securing essential medical care or treatment which cannot be secured locally because of inadequate medical facilities...Medical evacuation shall normally be authorized to the nearest recognized regional medical center¹⁷”, as shown in the table below.

Countries	Recognized regional medical centres
1. Africa	
Benin Burkina Faso Cape Verde Central African Republic Chad Congo Democratic Republic of the Congo Equatorial Guinea Gambia Ghana Guinea Guinea-Bissau Liberia Mali Mauritania Nigeria Niger Sao Tome and Principe Sierra Leone Togo	Cameroon Gabon Morocco Senegal South Africa Tunisia
Burundi Djibouti Eritrea Ethiopia Rwanda Somalia Sudan Uganda United Republic of Tanzania	United Arab Emirates Kenya Egypt South Africa

¹⁷ ST/AI/2000/10, Para 2.1 and 5.1

Angola		South Africa
Botswana		
Lesotho		
Malawi		
Mozambique		
Swaziland		
Zambia		
Zimbabwe		
Comoros		Ile de la Réunion, Mauritius, South Africa
Madagascar		

<i>Countries</i>	<i>Recognized regional medical centres</i>
2. Americas	
(a) <i>Caribbean</i>	
Haiti	Dominican Republic
(b) <i>Central America</i>	
Belize, El Salvador, Honduras, Nicaragua	Mexico
(c) <i>South America</i>	
Bolivia	Chile
Guyana	Trinidad and Tobago, Venezuela
Paraguay	Argentina
3. Arab States	
Iraq	Jordan, Lebanon
Libyan Arab Jamahiriya	Egypt, Tunisia
Yemen	Egypt, Saudi Arabia, United Arab Emirates, Lebanon, Jordan

4. Asia

Afghanistan		United Arab Emirates, India
-------------	--	-----------------------------

Bangladesh		India, Thailand
Bhutan		
Pakistan		

Democratic People's Republic of Korea	China, Thailand
Maldives	India, Sri Lanka
Mongolia	China, Thailand
Nepal	India, Thailand

Cambodia		Singapore, Thailand
Lao People's Democratic Republic		
Myanmar		
Viet Nam		

5. Europe

Albania	Italy, Turkey
Republic of Moldova	Austria
Ukraine	Austria, Turkey

6. Commonwealth of Independent States

Armenia		Turkey
Azerbaijan		
Georgia		
Kyrgyzstan		

Kazakhstan		India, Turkey
Tajikistan		
Turkmenistan		
Uzbekistan		

7. Micronesia and Melanesia

All countries	Australia, New Zealand
---------------	------------------------
