HIV Post-Exposure Prophylaxis (PEP) in the United Nations

Guidance for Use of PEP Kits
April 2019

For use by:

HIV POST-EXPOSURE PROPHYLAXIS (PEP) KITS: INFORMATION FOR CUSTODIANS[1]

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.

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 guidance document, please see http://apps.who.int/iris/bitstream/10665/145719/1/9789241508193_eng.pdf.

2 PEP KITS

UN PEP Kits are provided to 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.

The PEP Kits contain sufficient anti-HIV medications to cover **twenty-eight days' of a three-drug anti-retroviral treatment, supplied as two separate combination tablets: Tenofovir Disoproxil Fumarate 300mg + Lamivudine 300mg (1 fixed-dose combination tablet, taken once daily) and Lopinavir (LPV) 200mg + Ritonavir (r), 50 mg (two fixed-dose combination tablets, taken twice daily).** 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); 1 tablet of Levonorgestrel to prevent unwanted pregnancy after sexual exposure to take as soon as possible and no later than 5 days after exposure.
- **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 Appendix 2, UNSMS Security Management Operations Manual "Guidelines on the Management of HIV Post-Exposure Prophylaxis (PEP) Kits."*

3 ELIGIBILITY

UN PEP Kits **are available to all UN Security Management System Personnel and their eligible dependents[2] who may have been accidentally exposed to HIV, regardless of means of exposure.**

4 DUTIES OF THE CUSTODIAN[3]

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 between 15 °C and 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 supplies[4], and promptly record new stock when received.

C. **Manage PEP kit requests, by doing the following.**

1. Ensure person requesting PEP is administratively eligible, as someone covered by the United Nations Security Management System[5].

2. Accompany person requesting kit to a physician (if custodian is not a physician) for risk assessment.

3. Release kit to physician who is attending to the person in need.

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 access 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 HIV PEP Annex to the Country Security Plan, who will 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 Appendix 2 of the UNSMS Security Management Operations Manual "Guidelines on the Management of HIV Post-Exposure Prophylaxis (PEP) Kits," which each country should establish, circulate and keep with the kits. A medical provider at the centre of excellence can perform a risk

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[2] *This refers to a broad range of UN system personnel, and those from affiliated organizations, who fall under the United Nations Security Management System, as defined in Chapter III of the United Nations Security Policy Manual on the Applicability of the United Nations Security Management System. The full text of that document can be found in Annex 4.*

[3] *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.*

[4] *The custodian should request replenishments of kits msdpublichealth@un.org.*

[5] *See footnote 2, above.*

assessment over the telephone. If not available, the requestor should contact their organization's headquarters Medical Service emergency line to receive advice.

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

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 should take post-exposure 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.

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. In the event you do not take PEP an additional follow-up test should be taken one month after exposure.

- 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, preferably in person (ie avoid giving results 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. In the event PEP is not taken, a follow-up blood test should also be done one month after the 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 or focal point for occupational safety and health where available. 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 EXPOSURE: 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 exposure. PEP is only effective if taken within 72 hours of the exposure. In addition to a 28-day course of medicine to prevent HIV infection, people are given any needed 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 0.6% (6 in 1000)[6]. 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, a large systematic review of PEP use found very few seroconversions associated with PEP failure.[7] 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%. Antiretroviral medications are also given to pregnant women living with HIV to prevent their unborn babies from getting HIV infection. Also, WHO strongly recommends the use of the antiretroviral drugs Tenofovir Disoproxil Fumarate with Lamivudine as pre-exposure prophylaxis. Results of tests in animals also suggest that post-exposure prophylaxis medicine can help to prevent HIV infection but that the medicine works

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6 Patel P, Borkowf CB, Brooks JT, Lasry A, Lansky A, Mermin J (2014) Estimating per-act HIV transmission risk: a systematic review. *AIDS* 8(10):1509-19. (http://www.ncbi.nlm.nih.gov/pubmed/24809629)

7 Ford N, Irvine C, Shubber Z, Baggaley R, Beanland R, Vitoria M, Doherty M, Mills EJ, Calmy A. (2014) Adherence to HIV postexposure prophylaxis: a systematic review and meta-analysis. AIDS. 28(18):2721-7 (http://www.ncbi.nlm.nih.gov/pubmed/25493598)

best if started as soon as possible after exposure, and ideally within 72 hours.[8] Finally, in 2013, the United States Public Health Service updated its guidelines on occupational exposure to HIV, recommending the use of PEP[9].

[8] Irvine C, Egan KJ, Shubber Z, Van Rompay KK, Beanland RL, Ford N (2015) Efficacy of HIV Postexposure Prophylaxis: Systematic Review and Meta-analysis of Nonhuman Primate Studies. Clinical Infectious Diseases. 60 Suppl 3:S165-9 (http://www.ncbi.nlm.nih.gov/pubmed/25972498)

[9] David T. Kuhar, MD; David K. Henderson, MD; Kimberly A. Struble, Pharm D; Walid Heneine, PhD; Vasavi Thomas, RPh, MPH; Laura W. Cheever, MD, ScM; Ahmed Gomaa, MD, ScD, MSPH; Adelisa L. Panlilio, MD; for the US Public Health Service Working Group, (2014) Updated US Public Health Service Guidelines for the Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendations for Postexposure Prophylaxis. *Infection Control and Hospital Epidemiology. 34* (9) 881-892.

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 exposure 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. 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 **supplied as two separate combination tablets: Tenofovir Disoproxil Fumarate 300mg + Lamivudine 300mg (1 fixed-dose combination tablet, taken once daily) and Lopinavir (LPV) 200mg + Ritonavir (r), 50 mg (two fixed-dose combination tablets, taken twice daily).**

How should I take my medicine?

PEP 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 each pill at around the same time/s 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 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 + lamivudine + lopinavir/ritonavir 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: adefovir, rifampicin, simeprevir, halofantrine, astemizole, terfenadine, midazolam, triazolam, cisapride, amiodarone, bepridil, flecainide, propafenone, dabigatrain, rivaroxaban, simvastatin, lovastatin, lercanidipine, fluphenazine, pimozide, ergotamine, dihydroergotamine, voriconazole, alfusozin, St. John's Wort, wildenafil, piroxicam and quinidine.

What are the possible side effects of these medicines?

Tenofovir + lamivudine + lopinavir/ritonavir combination pill is usually well tolerated, but gastrointestinal side-effects can occur, but will improve once the medicine is substituted. Other, more severe side effects can occur, but are very rare.

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

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PATIENT INFORMATION SHEET 4:

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 Appendix 2 of the UNSMS Security Operations Manual "Guidelines on the Management of HIV Post-Exposure Prophylaxis (PEP) Kits," 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 or otherwise exposed, you may need to take Levonorgestrel ("Morning After" pill) to avoid pregnancy, also provided in the PEP kit.

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.

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 guidance for use, please see http://www.who.int/hiv/pub/guidelines/arv2013/arvs2013upplement_dec2014/en/ and http://www.who.int/hiv/pub/arv/arv-2016/en/

2 PEP KITS

UN PEP Kits are provided to 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.

The PEP Kits contain sufficient anti-HIV medications to cover **twenty-eight days' of a three-drug anti-retroviral treatment, supplied as two separate combination tablets: Tenofovir Disoproxil Fumarate 300mg + Lamivudine 300mg (1 fixed-dose combination tablet, taken once daily) and Lopinavir (LPV) 200mg + Ritonavir (r), 50 mg (two fixed-dose combination tablets, taken twice daily).** 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 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); 1 tablet of Levonorgestrel to prevent unwanted pregnancy after sexual assault or other exposure, taken as soon as possible, and no later than 5 days after exposure.
- **Reporting Form:** hard copy to completed and returned to msdpublichealth@un.org within 24 hours of use of kit.
- **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 United Nations Security System Personnel and their eligible dependents 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 exposure[10] of mucous membrane or non-intact skin to a potentially infectious body fluid[11]; AND

[10] *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 exposure**, 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 exposure; 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.*

[11] ***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 <u>not indicated</u> in the following circumstances:

- If the exposed person is HIV-positive from a previous exposure;
- In chronic exposure;[12]
- 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 period[13]; and
- If the exposure occurred more than 72 hours previously[14].

4. PROCEDURE FOR OCCUPATIONAL EXPOSURE[15,16]

A. **<u>Treat exposure site.</u>** 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.

B. **<u>Conduct risk assessment</u>.** Evaluate the exposure for potential to transmit HIV, HBV and HCV, based on the route and severity of exposure[17], and the type of body fluids involved[18].

C. **<u>Assess eligibility of individual</u>** 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

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[12] ***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.*

[13] *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.*

[14] *Although post-exposure prophylaxis is ideally provided within 72 hours of exposure, people may not be able to access services within this time. Providers should consider the range of other essential interventions and referrals that should be offered to clients presenting after the 72 hours.*

[15] *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.*

[16] *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 0.6%. 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.*

[17] *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.*

[18] ***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*** *<u>UNLESS visibly contaminated with blood</u> include: Urine, saliva, nonpurulent sputum, stool, emesis, nasal discharge, tears, sweat.*

- 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
- 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. <u>Evaluate exposure source</u>

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. <u>Provide individual with the "HIV PEP - Patient Information" sheets, and use the scripts in Annex 1 to discuss these issues before administration of PEP</u>:

- ☐ 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 gastrointestinal side-effects).
- ☐ 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.
- ☐ 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. <u>If the decision is made to administer PEP, initiate PEP treatment and obtain blood for baseline HIV serologic testing-based on informed consent</u>. Do not wait for HIV test results to administer HIV PEP. Refusal to undergo baseline testing should not preclude initiation of therapy.

G. **<u>Report occupational exposure</u>** to the UN Medical Director of the agency, using the "declaration of accident" form relevant to your organization. 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.[19]
- **Educate individual to immediately report symptoms** (lymphadenopathy, rash, sore throat, flu-like symptoms) suggestive of acute HIV sero-conversion. In this case, another HIV test will be carried out and, in the event the person has acquired HIV, then anti-retroviral treatment should be initiated.

[19] *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/niosh/topics/bbp/guidelines.html*

5 PROCEDURE FOR SEXUAL ASSAULT OR OTHER NON-OCCUPATIONAL EXPOSURE[20,21]

A. **Initial post-assault visit[22].** 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.

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.

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*[20] 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.*

*[21] 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.*

[22] 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.

D. <u>Provide individual with the "HIV PEP - Patient Information" sheets, and using the scripts in Annex 1, discuss these issues before administration of PEP</u>:

- ☐ 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 (mainly gastrointestinal side effects)
- ☐ 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.
- ☐ 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. <u>If the decision is made to administer PEP, initiate PEP treatment and obtain blood for baseline HIV serologic testing - based on informed consent</u>. Do not wait for HIV test results to administer HIV PEP. Refusal to undergo baseline testing should not preclude initiation of PEP. 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. <u>Follow Up</u>

- **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 : **twenty-eight days' of a three-drug anti-retroviral treatment, supplied as two separate combination tablets: Tenofovir Disoproxil Fumarate 300mg + Lamivudine 300mg (1 fixed-dose combination tablet, taken once daily) and Lopinavir (LPV) 200mg + Ritonavir (r), 50 mg (two fixed-dose combination tablets, taken twice daily).** Each type of tablet should be taken **orally, at about the same time/s.** 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 boosted protease inhibitor 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. Here, the preferred regime listed is the one provided in the United Nations HIV PEP kits designated for use by personnel and eligible dependents.

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

Preferred regimen	**Alternative regimen**
Lamivudine (3TC or FTC) + Tenofovir (TDF) plus Lopinivir/ritonavir (LPV/r)	Lamivudine (3TC or FTC) + Tenofovir (TDF) plus Atazanavir/ritonavir (ATZ/r).

NOTES:
[1]For complete information about all possible drug combinations recommended by WHO for use as PEP, please refer to the "WHO Guidelines on Post-Exposure Prophylaxis for HIV…. Recommendations for a Public Health Approach," December 2014: *http://apps.who.int/iris/bitstream/10665/145719/1/9789241508193_eng.pdf?ua=1&ua=1* .

Table 2: 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.

Simplified dosing of child-friendly solid and oral liquid formulations of recommended preferred ARV drugs for post-exposure prophylaxis of HIV for twice-daily dosing among children.

Drug	**Strength of tablets (mg) or oral liquid (mg/ml)**	**Number of tablets by weight band, morning (AM) and evening (PM)**										**Strength of adult tablet (mg)**	**Number of tablets by weight band**	
		3.0 – 5.9 kg		6.0 – 9.9 kg		10.0 – 13.9 kg		14.0 – 19.9 kg		20.0 – 24.9 kg			25.0 – 34.9 kg	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM		AM	PM
Solid Formulations														
3TC	Tablet (dispersible) 30 mg	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
LPV/r	Tablet (heat stable) 100 mg/25 mg	-	-	-	-	2	1	2	2	2	2	100/25	3	3
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	-	-	-	-	-	-	-
LPV/r*	80/20 mg/ml	1 ml	1 ml	1.5 ml	1.5 ml	2 ml	2 ml	2.5 ml	2.5 ml	3 ml	3 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 human immunodeficiency virus (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 two pills, one taken once daily and the other taken twice daily every day for 28 days. For the medicine to work, it is important that you take each pill at about the same time each day. *[Adapt to specific dosing instructions.]*

A minority of 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 most common side effect is gastrointestinal upset. 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 it will help.

Lamivudine + Tenofovir and Lopinavir/Ritonavir combination pills 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: adefovir, rifampicin, simeprevir, halofantrine, astemizole, terfenadine, midazolam, triazolam, cisapride, amiodarone, bepridil, flecainide, propafenone, dabigatrain, rivaroxaban, simvastatin, lovastatin, lercanidipine, fluphenazine, pimozide, ergotamine, dihydroergotamine, voriconazole, alfusozin, St. John's Wort, sildenafil, piroxicam and quinidine.

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, it is advised that 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) Post-exposure prophylaxis 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 EXPOSURE

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 2 in 100 (1–2%) 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 two pills, one that you take once a day and one that you take twice a day every day for 28 days. For the medicine to work, it is important that your PEP medications at about the same time each day. *[Adapt to specific dosing instructions.]*

A minority of 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 most common side effect is gastrointestinal upset. 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 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, it is advised that 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) Post-exposure prophylaxis 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.
- 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 a minority 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.

A minority of 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 most common side effect is gastrointestinal upset. 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 it will help.

Lamivudine + Tenofovir and Lopinavir/Ritonavir combination pills 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: adefovir, rifampicin, simeprevir, halofantrine, astemizole, terfenadine, midazolam, triazolam, cisapride, amiodarone, bepridil, flecainide, propafenone, dabigatrain, rivaroxaban,

simvastatin, lovastatin, lercanidipine, fluphenazine, pimozide, ergotamine, dihydroergotamine, voriconazole, alfusozin, St. John's Wort, sildenafil, piroxicam and quinidine.

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 a shorter course of 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. In the event PEP is not taken, another HIV test should be carried out one month after the potential 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:

Name_____

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: _____

Risk assessment and care plan

HIV exposure confirmed and seeking post-exposure prophylaxis

Post-exposure prophylaxis medicine:

 Tenofovir + Lamivudine oral tablets once daily and Lopinavir/ritonavir tablets twice a day

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

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.

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[23]

"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 center[24]", as shown in the table below.

Countries	Recognized regional medical centres
1. Africa	
Benin	Morocco
Burkina Faso	Senegal
Cape Verde	South Africa
Central African Republic	Tunisia
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	
Burundi	United Arab Emirates
Djibouti	Kenya
Eritrea	Egypt
Ethiopia	South Africa
Rwanda	
Somalia	
Sudan	
Uganda	
United Republic of Tanzania	

23 A new version of this ST/AI is expected in 2019. The internet should be checked, as needed, for a revised version.

[24] ST/AI/2000/10, Para 2.1 and 5.1. List of regional evacuation centres amended July 2012

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

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

4. Asia

Afghanistan	United Arab Emirates, India
Bangladesh Bhutan Pakistan	India, Thailand
Democratic People's Republic of Korea	China, Thailand
Maldives	India, Sri Lanka
Mongolia	China, Republic of Korea
Nepal	India, Thailand
Cambodia Lao People's Democratic Republic Myanmar Viet Nam	Singapore, Thailand

5. Europe

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

6. Commonwealth of Independent States

Armenia Azerbaijan Georgia Kyrgyzstan	Turkey
Kazakhstan Tajikistan Turkmenistan Uzbekistan	India, Turkey

7. Micronesia and Melanesia

All countries	Australia, New Zealand

Annex 4 – Applicability of United Nations Security Management System

A. Introduction:

1) Policies, procedures, standards and other arrangements of the United Nations Security Management System are applicable to the following categories of individuals:

a) United Nations personnel:

(i) All United Nations system staff members, including temporary staff, in posts subject to international or local recruitment (except those who are both locally-recruited and paid by the hour);

(ii) United Nations Volunteers (UNVs);

(iii) Individually deployed military and police personnel in DPKO- or DPA-led missions[25], including, but not limited to:

(a) United Nations police officers, military observers, military liaison officers, military advisors and staff officers; and
(b) Military members of national contingents or members of formed police units when not deployed with their contingent or unit.

(iv) Consultants, individual contractors and experts on mission when actually employed by an organization of the United Nations system; and

(v) Officials other than United Nations Secretariat staff members and similar non-staff officials of other organizations of the United Nations system with a direct contractual agreement with a United Nations System organization;

b) Other Individuals Covered:

(i) Eligible family members (as determined by the staff rules and regulations of the organizations comprising the United Nations System);

(ii) Eligible family members (who are authorized to be at the duty station) of United Nations Volunteers;

(iii) United Nations fellows, either non-resident fellows studying in the country, or nationals who are on leave from the country of study.

(iv) Personnel and their eligible family members of Intergovernmental Organizations that have signed a Memorandum of Understanding (MOU) with an organization of the United Nations system to cooperate on security matters.

[25]It does not cover military members of national contingents or members of formed police units when deployed with their contingent or unit nor does it cover any spouses or other family members of the military and police personnel listed in sub-paragraphs (a) and (b).