

UN Medical Directors Guidelines for Use of UN-Issued HIV Post-Exposure Prophylaxis (PEP) Kits for Occupational/Non-Occupational HIV Exposure Occurring in UN Personnel and Dependents

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For any questions, contact DHMOSH Public Health at dos-dhmosh-hiv@un.org



(PHOTO OF HIV PEP KIT CONTENTS)



Division of Healthcare Management and Occupational Safety and Health

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Introduction

This UN Medical Directors' document provides key information and usage instructions to stakeholders of the UN's HIV Post-Exposure Prophylaxis (PEP) kit programme, including PEP kit custodians, patients/personnel receiving the kits, and UN healthcare providers administering the kit.

This guidance document was prepared by the DHMOSH Public Health section, which coordinates and manages this inter-agency programme on behalf of the United Nations Medical Directors. Please contact <u>dos-dhmosh-hiv@un.org</u> for any questions related to the UN System's global HIV PEP Kit programme or this document.

HIV Post-Exposure Prophylaxis (PEP): Information For UN Custodians¹

1 What is HIV PEP?

HIV Post-Exposure Prophylaxis (HIV PEP) are antiretroviral (ARV) medications to help prevent HIV infection in an exposed individual.

When blood and bodily fluid exposure occurs, there are a set of actions that are required to manage the specific aspects of possible exposure to HIV and to help prevent HIV infection in an exposed person. These actions include immediate first aid, counselling, assessment of the risk of exposure to HIV, HIV testing, and depending on the outcome of the exposure assessment, a course of anti-HIV medication (antiretrovirals), also known as HIV PEP, will be administered, with appropriate support and follow-up.

PEP should be initiated as soon as possible after exposure, ideally within two hours or less, and no later than 72 hours post-exposure. Adherence to a full 28-day course of ARV medicines contained in the HIV PEP kit is critical, and the administration of HIV PEP should be provided with comprehensive services in a confidential and trusting environment. Providing assurance and maintaining the confidentiality of exposed individuals in all dealings and communications is vital.

The recommendations of the Division of Healthcare Management and Occupational Safety and Health (DHMOSH) of the United Nations and the UN Medical Directors' (UNMD) recommendations for HIV PEP are based on a careful review of available studies. HIV experts from the World Health Organization (WHO) have also reviewed this document. To access the reference for this guidance document, please see https://www.who.int/publications/i/item/WHO-CDS-HIV-18.51

2 United Nations HIV PEP Kits

The UN HIV PEP kits are provided to all UN duty stations in the field to facilitate prompt access to medication in case of potential exposure to HIV. Initiating the treatments within the HIV PEP kit allows

¹ This document should be read alongside Annex 4 of the UNSMS Security Management Operational Manual "Guidelines on the Management of HIV Post-Exposure Prophylaxis (PEP) Kits", available at

https://hr.un.org/sites/hr.un.org/files/CHAPTER%20VIII%20Guidelines%20on%20the%20Management%20of%20HIV%20Post-Exposure%20Prophylaxis%20%28PEP%29%20Kits%20%20%20%20%20%20%20_0.pdf

time post-exposure to organize a referral to a trained health service provider who will ensure treatment and support throughout the full 28-day HIV PEP administration course and, when deemed appropriate, a medical evacuation to more adequate facilities.

Each HIV PEP Kit contains the following:

- Sufficient HIV PEP medications: To cover 28 days of a three-drug antiretroviral treatment, supplied as fixed-dose combination of one pill containing: Tenofovir Disoproxil Fumarate 300mg + Lamivudine 300mg + Dolutegravir 50mg, taken once daily. It is critical to ensure that the ARV medication is taken once daily for a full 28 days.
- □ **Pregnancy test kit:** Used to identify if an exposed woman was already pregnant before potential exposure to the virus. Pregnant women can take HIV PEP, however the clinician needs to discuss the risk-benefit with the client during the assessment.
- Emergency oral contraception ("morning-after" pill); One tablet of Levonorgestrel 1.5mg to prevent an unwanted pregnancy after sexual exposure. This must be taken as soon as possible and no later than five days after exposure.
- □ Information Leaflet/Instruction on the two necessary forms (Annex 5 "Custodian Reporting Form", and Annex 2 "Physician Assessment Form") that must be printed, completed and submitted to <u>dos-</u><u>dhmosh-hiv@un.org</u> with the use of each kit.



PHOTO OF HIV PEP KIT CONTENTS

3 Eligibility

The United Nations HIV PEP Kits are available to all UN Security Management System personnel and their eligible dependents², except for IGOs/NGO staff and family members.

4 **Duties of the Custodian³**

A. Ensure safe and proper storage

The HIV PEP kits should be kept in a secure space that is locked, and according to the manufacturers' instructions. The kits should be stored according to the manufacturer's instructions, and stored in closed containers, at temperatures between 15 $^{\circ}$ C and 30 $^{\circ}$ C (no refrigeration

² This refers to a broad range of UN system personnel, and those from affiliated organizations, which 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. Note that IGOs/NGO staff and family members are not covered under this UN programme. Note that the programme also 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).

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.

required), and kept dry and protected from light, humidity, and excessive heat (See details in the leaflet inserted inside medication box).

B. <u>Maintain adequate supplies to ensure uninterrupted availability (24-hour accessibility)</u>

Custodians of HIV PEP kits should maintain proper inventory records of the kits, including the recording and monitoring of expiry dates. Custodians should determine when to re-order supplies, place orders to replenish supplies⁴, and promptly record new stock when received. Custodians should be reachable at all times and ensure 24-hour availability of the HIV PEP kits to staff. If the custodian is a healthcare provider, he or she may be authorized to initiate treatment with the HIV PEP kit. Non-medically qualified custodians will have to contact the physician(s) listed in the UN Country HIV PEP Protocol, (which the United Nations in every country should establish). The physician should conduct a risk assessment and administer HIV PEP if warranted.

C. Manage HIV PEP kit requests by doing the following:

- 1. Ensure person requesting HIV PEP is administratively eligible (someone covered by the United Nations Security Management System⁵).
- **2.** Accompany person requesting the kit to a physician (if the custodian is not a physician) for risk assessment.
- **3.** Release kit to the physician who is attending to the person in need, as required.
- **4.** Ensure that Annex 5 "Custodian Reporting Form" is fully completed and is submitted immediately via email to <u>dos-dhmosh-hiv@un.org</u>.
- **5.** Custodians who are medical professionals are required to complete fully Annex 2 "Physician Assessment Form" and submit this document also to <u>dos-dhmosh-hiv@un.org</u>.
- **6.** Non-medical custodians should ensure that the patient provides a copy of Annex 2 to their own physician, for completion and subsequent submission to <u>dos-dhmosh-hiv@un.org</u>.

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. <u>Provide advice to staff in isolated locations who cannot see a healthcare provider within 72 hours</u> 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 (which the United Nations in every country should establish). A medical provider at the centre of excellence can perform a risk assessment over the telephone. If not available, the requestor should contact their organization's headquarters Medical Service emergency line or <u>dos-dhmosh-hiv@un.org</u> to receive advice. More information can be found in the subsequent Patient Information Sheets and Healthcare Provider Guidance.

⁴ The custodian should request replenishment of kits from <u>dos-dhmosh-hiv@un.org</u>.

⁵ See footnote 2, above.

Patient Information Sheet 1: HIV and Occupational Exposure to Blood or Body Fluids: What You Need to Know

Several infectious diseases are spread by exposure to an infected person's blood or their body fluids or tissues. Hepatitis B, hepatitis C, and HIV viruses are examples of bloodborne viruses (BBVs) that spread with this type of exposure to an infected person's blood.

For those who have had occupational exposure to someone's body fluids or tissues, it is important to know what to do to minimize the risk of becoming infected with HIV or any other BBVs.

Key steps:

- 1. Perform immediate first aid (clean the affected area with soap and water) and allow to bleed freely. Do not squeeze the wound as this actually increases the risk of infection.
- 2. Report the exposure, so a risk assessment can be completed.
- 3. If appropriate, baseline HIV testing with pretest counselling will be conducted.
- 4. HIV PEP will be offered if the exposed person meets the administrative and clinical criteria.
- 5. HIV prevention and transmission will be discussed with the exposed person.
- 6. An occupational health and safety report should be submitted.

1. Perform Immediate first aid (clean the area)

After exposure, do not squeeze the area but allow it to bleed freely. Immediately clean the site 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 soap and running water are 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
 - \circ $\;$ Wash the area immediately.
 - If soap and running water are not available, clean the area with a gel or hand-rub solution.
- To the eye
 - \circ $\;$ Wash the exposed eye immediately with water.
 - Leave contact lenses 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 with water and spit out again. Repeat this process several times.
 - Do not use soap or disinfectant in the mouth.

2. Report the exposure so a risk assessment can be completed

After initial 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, and appropriate referral made when deemed necessary.

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 carries very little risk of HIV acquisition, although risk varies depending on the type of exposure. However, if you are assessed to have had significant exposure, you will be offered HIV PEP. This is the medication that can be taken to reduce the likelihood of becoming infected with HIV. To ensure maximal effect, these medications should be taken as soon as possible after exposure.

a) 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
- source HIV status.

b) HIV PEP may be offered 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:
 - o skin penetration with spontaneous bleeding or deep puncture; or
 - o a significant amount of splash of fluid to mucous membrane; or
 - o prolonged contact of fluid with broken skin.

3. If appropriate, baseline HIV testing with pretest counselling will be conducted

It is recommended that a test for HIV infection be administered within a few days following exposure to establish a baseline against which to compare future test results. An HIV-negative result at the baseline test with a later positive test, may indicate that the occupational exposure caused the infection depending on the time of the infection and on the presence of other risks or exposure incidents. Follow-up blood tests for HIV need to be done to show whether you have become infected as a result of exposure. This will be discussed with you by the attending the custodian/physician during their assessment and review of your case.

If you are HIV-positive at the baseline test, HIV PEP is not appropriate and will not be prescribed; if started, it should be discontinued immediately. This is to prevent the development of resistance to medication that may be needed later to treat HIV infection. Those with HIV-positive results should seek medical attention for treatment of HIV through normal medical channels, or follow up with their physician.

Before being tested, information about the HIV test will be provided, in order to help with the decision on whether or not to take the test. Counselling should be provided, and verbal consent given, before blood is taken for testing. Due to the sensitive nature of the information discussed, you may wish to have the counselling and blood testing done outside the workplace.

Information should also be provided on how to get the results of the test. The results of HIV blood tests, whether negative or positive, should be given preferably in person (i.e. avoid if at all possible obtaining results over the phone, in the mail or through 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.

4. HIV Post-Exposure Prophylaxis (HIV PEP) will be offered if deemed appropriate

If the exposure is assessed to carry sufficient risk, HIV PEP will be offered. It is ultimately an individual decision whether or not to take the medicine, although generally HIV PEP is provided when the risk of HIV infection is higher than risk of PEP. If a decision to take HIV PEP is taken, the course of treatment should start as soon as possible and continue for the full 28 days. The medication is intended to prevent the virus from establishing infection in the body, so the earlier it is taken the greater the chance it has to be effective.

PEP needs to be taken for four weeks (28 days). Doses should not be skipped or missed.

Before deciding whether or not to take HIV PEP, the advantages and disadvantages should be discussed with a designated healthcare provider. Several things should to be discussed:

- How and when to take the medicine: This may involve asking questions about living and working conditions. The course of HIV PEP treatment is 28 days, and during this period a medical evaluation is recommended, particularly in the presence of side effects. A follow-up HIV test is recommended at three months. If a fourth generation HIV test is not utilized, or in the case of potential co-infection with hepatitis C ,then an additional follow-up test should occur at six months. In the event HIV PEP treatment is declined, an additional follow-up test should be taken one month after exposure.
- Whether you may be pregnant: HIV PEP may be taken while pregnant. In fact, it is even more important for pregnant women to take the medicine, as the chance of the HIV infection being passed to the fetus as a result of the exposure is quite high. The risks and benefits of taking HIV PEP in early pregnancy should be discussed with the healthcare provider.
- Side effects: Side effects are unwanted symptoms which may be experienced while taking the medicine. Some side effects include insomnia, headache, agitation, nausea, diarrhea, and skin rash (patients should inform their healthcare provider immediately if they develop a rash).
- No guarantee: It will be explained that, although strong evidence indicates that HIV PEP may prevent infection with HIV, it is not guaranteed.

5. Prevention of transmission will be discussed

If the exposure was assessed as being significant, advice will be provided about how to avoid transmitting the virus to anyone else until the HIV test results are available. Advice on how to practice safe sex—and information on what this means—will be provided, so sexual partners may be protected. Warnings will be

provided against share injecting equipment, donating blood or tissues, and breastfeeding (alternatives to exclusive breastfeeding will be explained).

6. Occupational health and safety report should be completed

Any exposure that occurs in the workplace should be reported and a written record submitted to the appropriate supervisor or focal point for occupational safety and health, where available.

There are two reasons for this:

- The first is to make sure that information on how the exposure occurred is available, in the event it is needed for a claim for compensation; and
- The second is 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.

If you have any questions

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

Patient Information Sheet 2: Preventing HIV Infection After Sexual Exposure: What You Need to Know

What is HIV PEP?

HIV PEP are antiretroviral (ARV) medications given to help prevent HIV infection in an exposed individual, for occupational and non-occupational exposure, including as a result of sexual assault.

When blood and body fluid exposure occurs, there are a set of actions required to manage the specific aspects of possible exposure to HIV and to help prevent HIV infection in an exposed person. These actions include first aid, counselling, assessment of risk of exposure to HIV, HIV testing, and, depending on the outcome of the exposure assessment, a course of anti-HIV medication also known as HIV post-exposure prophylaxis (HIV PEP) may be provided, with appropriate support and follow-up.

HIV PEP should be initiated as soon as possible after exposure, ideally within two hours or less, and no later than 72 hours post-exposure. Adherence to a full 28-day course of ARV medicines is critical, and the administration of HIV 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 attending physician during their assessment will advise if there is need for HIV PEP for other infections, such as gonorrhea or chlamydia.

What is the risk involved with exposure?

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 with accuracy. 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% (between 1 in 100 and 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, healthcare 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 HIV PEP may be offered for exposure of this type, it is not generally recommended because the risk is so small.

What is known about the effectiveness of post-exposure prophylaxis?

It is not definitively known that HIV PEP 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 HIV PEP use found very few

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)

seroconversions associated with PEP failure.⁷ One study showed that among healthcare workers with needle-stick injuries, using zidovudine after the incident reduced the risk of getting HIV infection by about 80%⁸. Antiretroviral medications are also given to pregnant women living with HIV to prevent transmission of HIV to the fetuss. 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, and ideally within 72 hours.⁸

How to stay HIV negative?

Although the chance of getting HIV from a single sexual act is relatively low, the best way 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 and to avoid developing sexually transmitted infections, including HIV.
- 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.
- Sharing needles to inject drugs should also be avoided.

How does the HIV PEP programme work?

- The first time a person is seen, questions will be asked about the circumstances of the HIV exposure to ensure that HIV PEP would be appropriate.
- An HIV test will be discussed and recommended.
- A healthcare worker will take information on health history, perform an examination, and evaluate whether there is a risk of HIV infection.
- If the exposure is assessed to be an HIV risk, an HIV PEP kit will be provided, containing enough medication for 28 days. During this period, a medical evaluation is recommended, particularly if there side effects are experienced. A follow-up HIV test is recommended at three months and again in six months.
- HIV counseling services, including around HIV test results should be offered and arranged. At this time, the counselor or healthcare provider will give information about the steps to be taken to avoid transmitting HIV in the unlikely event the exposure results in an HIV-positive result, and also how to avoid HIV infection in the future. The counselor or healthcare provider will want to ensure that the HIV PEP medicine is being taken correctly and is being tolerated well.
- At the appointment with the specialist doctor, the medications will be reviewed, any side effects discussed, and instructions for required follow-up given. The results of other tests which may have been administered will also be reviewed. Referrals for more counseling or to other services may be made. Follow-up visits with the HIV counsellor, specialist doctor or healthcare provider can be arranged.
- Follow-up HIV tests are recommended at three months and again in six months in cases where HIV PEP is taken. This is to ensure that the HIV-negative test results continue. If, however, follow-up tests have HIV-positive results, healthcare and further support will be offered.

What other resources are available?

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)

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 (<u>http://www.ncbi.nlm.nih.gov/pubmed/25972498</u>)

We have resources that can help you deal with other associated challenges you may face as an exposed client on HIV PEP. We can refer you to counselling services and mental health programs, 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 there are additional questions

For questions or problems related to this programme or the medication, please ensure that the necessary contact phone numbers are provided for reference and future use.

Patient Information Sheet 3: HIV PEP Regimen and Follow Up

What is HIV post-exposure prophylaxis (PEP)?

HIV PEP are antiretroviral medications given to prevent HIV infection in an exposed individual. Prophylaxis, in this case, means medicine that you can take to protect you from getting the HIV infection.

Does HIV PEP 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 (ideally within two hours and no later than 72 hours after exposure) and comply with the 28-day course.

Which post-exposure prophylaxis medicine is in the HIV PEP kit?

The post-exposure prophylaxis included in the HIV PEP kit is combination of three medicines: Tenofovir Disoproxil Fumarate 300mg + Lamivudine 300mg + Dolutegravir 50mg (1 fixed-dose combination tablet).

How should the medicine be taken?

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. A clinician will discuss the best timing prior to starting the medication. The medication should be taken as directed by the physician on a daily basis for the next 28 days.

Why is it important to take my medicine correctly?

Antiretrovirals work best if kept at a constant level in the bloodstream. HIV PEP 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 is especially important.

Do these medicines interact with other medicines?

Tenofovir + Lamivudine + Dolutegravir should not be taken at the same time as certain medications, and a physician should always be consulted in this regard. If HIV PEP is required, then these medications may need to be stopped or dosage modification may be required with advice of a medical professional: dofetilide, carbamazepine, phenobarbital, phenytoin, rifampicin, halofantrine, simeprevir, lovastatin, simvastatin, metformin, astemizole, terfenadine, polyvalent cation products (containing Mg, Al, Fe,Ca and Zn), adefovir, midazolam, triazolam, cisapride, amiodarone, bepridil, flecainide, propafenone, dabigatrain, rivaroxaban, lercanidipine, fluphenazine, pimozide, ergotamine, dihydroergotamine, voriconazole, alfusozin, St. John's Wort, wildenafil, piroxicam and quinidine.

Who should not receive these medicines?

The HIV PEP medications should not be taken by people who have:

- previous hypersensitivity or allergic reaction to Dolutegravir;
- previous intolerance/anaphylaxis to these medications;
- uncontrolled diabetes;
- kidney/renal impairment with creatinine clearance <50 ml/min;
- liver impairment with ascites, albumin <2.8 g/dL; total bilirubin >50 mmol/L;
- encephalopathy;
- the incident/potential exposure to HIV occurred more than 72 hours ago; and/or
- the individual is HIV positive.

What are the possible side effects of these medicines?

Tenofovir + Lamivudine + Dolutegravir combination pill is usually well tolerated in many patients and with very minimal gastrointestinal side effects. Other, more severe side effects can occur, but are very rare.

What follow-up testing is required when HIV PEP is prescribed?

During the period when HIV PEP medications are being taken, a medical evaluation is recommended, particularly if side effects are experienced. A follow-up HIV test is recommended at three months and in some circumstances additional testing with blood work is required at six months. All the necessary contact information and numbers should be retained for reference.

Patient Information Sheet 4: When You Cannot Access a Healthcare Provider within 72 Hours

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

Using the "*Information for Healthcare Provider*" on page 14 onwards included in this guideline, you should assess yourself for the need for HIV PEP. To assist you in performing the risk assessment for need for HIV PEP, you should also try to 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 PEP kit). A medical provider at the centre of excellence can perform a risk assessment over the telephone.

If you are unable to contact such a medical provider, you should contact your organization's headquarters Medical Service emergency line or email <u>dos-dhmosh-hiv@un.org</u> for support.

If, with the approval of the medical provider, you are eligible to receive the antiretroviral medication, you can then start the course of anti-retroviral medication (1 pill daily for 28 days).

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

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

HIV Post-Exposure Prophylaxis (PEP): Information for UN Healthcare Providers

1 What is HIV PEP?

HIV PEP kits contain antiretroviral medications given to help prevent HIV infection in an exposed individual. When a blood and body fluid exposure occurs, there are a set of actions required to manage the specific aspects of possible exposure to HIV and to help prevent HIV infection in an exposed person. These actions include immediate 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 also known as HIV post-exposure prophylaxis (PEP), with appropriate support and follow-up.

HIV PEP should be initiated as soon as possible after exposure, ideally within two hours and no later than 72 hours after exposure. Adherence to a full 28-day course of antiretroviral medicine is critical and the administration of HIV 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 recommendations of the Division of Healthcare Management and Occupational Safety and Health (DHMOSH) of the United Nations and the UN Medical Directors' (UNMD) for HIV PEP are based on a careful review of available studies and considered opinion of international HIV experts including from the World Health Organization (WHO). To access the reference for this guidance document, please see https://www.who.int/publications/i/item/WHO-CDS-HIV-18.51.

2 HIV PEP Kits

UN HIV 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 HIV PEP Kits contains:

- Sufficient HIV PEP medications to cover 28 days of a three-drug antiretroviral treatment, supplied as fixed dose combination of three drugs taken once daily: Tenofovir Disoproxil Fumarate 300mg + Lamivudine 300mg + Dolutegravir 50mg. It is critical to ensure the medication is taken for a full 28 days.
- Pregnancy test kit to identify if an exposed woman was already pregnant before potential exposure to the virus. Pregnant women can take HIV PEP, however the risk-benefit needs to be discussed with a clinician.
- □ **Emergency oral contraception** ("morning-after" pill) to prevent unwanted pregnancy after sexual assault. This one tablet of Levonorgestrel should be taken as soon as possible and no later than five days after exposure.

** Notes on PEP and Pregnancy **

- Important: A pregnancy test will only give a reliable result two weeks after fecundation. The
 pregnancy test is included in the HIV PEP kit in order to verify if the survivor was pregnant prior to the
 sexual assault, and not to determine whether the survivor is pregnant 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 fetus. Pregnancy is an argument to provide HIV 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 ("morning after pill") should be offered to the person. If the person is not correctly protected by the emergency contraception, and she becomes pregnant due to the means of 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 other sexually transmitted infections (STIs) which may also warrant PEP, e.g. gonorrhea and chlamydia.

3 Eligibility to Access UN HIV PEP Kit in Duty Stations

UN HIV PEP kits are available to all personnel covered under the United Nations Security System⁹ in the country and their eligible dependents, who may have been accidentally exposed to HIV, regardless of means of exposure.

4. **Procedure for Occupational Exposure**^{10,11}

Key Steps:

A. Ensure the exposed individual has performed first aid on the 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.

⁹ This refers to a broad range of UN system personnel, and those from affiliated organizations, which 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. Note that IGOs/NGO staff and family members are not covered under this UN programme. Note that the programme also 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). ¹⁰ 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 healthcare. Other workers, such as emergency rescue staff, waste-disposal workers, first aid providers, law enforcement personnel and firefighters, may be exposed to blood and other potentially infectious body fluids while performing their work duties.

¹¹ 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.

- **B.** Conduct risk assessment. Evaluate the exposure for potential to transmit HIV, HBV and HCV, based on the route and severity of exposure¹², and on the type of body fluids involved¹³.
- **C.** Assess eligibility of exposed individual to receive HIV PEP according to the following eligibility criteria:
 - Less than 72 hours has elapsed since exposure; AND
 - The potentially exposed 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
 - 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.

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

- If the exposed person is HIV-positive from a previous exposure.
- In cases of chronic exposure,¹⁴ pre-exposure prophylaxis (PrEP) should be considered. PrEP is a way of preventing HIV infection from those who do not currently have it and who are at a very high risk of getting HIV due to regular or ongoing exposures.
- If the exposure does not pose a risk of transmission, including:
 - Exposure of intact skin to potentially infectious body fluids;
 - Sexual intercourse using a condom that remained intact;
 - Any exposure to non-infectious body fluids (such as feces, saliva, urine and sweat); or
 - 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 period¹⁵.
- If the exposure occurred more than 72 hours previous¹⁶.
- If the patient has any of the below contraindications:
 - o previous hypersensitivity or allergic reaction to Dolutegravir;
 - o previous intolerance/anaphylaxis to these medications;
 - uncontrolled diabetes;
 - kidney/renal impairment with creatinine clearance <50 ml/min;
 - o liver impairment with ascites, albumin <2.8 g/dL; total bilirubin >50 mmol/L; or
 - encephalopathy.

¹² 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.

¹³ **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</u> <u>blood</u> include: urine, saliva, nonpurulent sputum, stool, emesis, nasal discharge, tears, sweat.

¹⁴ 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.

¹⁵ 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.

¹⁶ 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.

If source person is known:

- Do not delay initiation of HIV PEP to determine HIV status of the source.
- Seek voluntary HIV testing of the source as soon as possible after exposure.
- Evaluate for evidence of other bloodborne disease (HBV, HCV).
- Discontinue HIV PEP if/when 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.
- D. If the decision is made to administer PEP, initiate HIV PEP 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 the initiation of therapy.
- 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 HIV PEP.
 - □ The benefits and risks of taking HIV PEP.
 - □ The importance of HIV PEP during pregnancy.
 - □ The risks of taking HIV PEP if the patient already has HIV (before this exposure).
 - □ The importance of taking continuously for 28 days 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 contraindication of HIV PEP medications.
 - □ The benefits of HIV testing (now for baseline, and again at three and six months).
 - □ Other recommended blood tests.
 - □ The usual course of HIV PEP is 28 days.
 - □ 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 to breastfeeding exist)] for the next six months or until testing excludes HIV infection.
 - □ Not to donate blood, semen or body tissues for the next six months or until testing excludes HIV infection.
 - □ [For Healthcare Workers] Any safe work practices necessary for the next six months or until testing excludes HIV infection.
- F. If the decision is made to administer PEP, initiate HIV 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 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 healthcare worker's HIV PEP treatment decision, should be documented in the form.

H. Follow up of exposed individual

- **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, STIs and other infectious diseases, laboratory testing, counselling, ARV, obstetrical services, and/or 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. At three and again at six months post-exposure, schedule follow-up consultations to evaluate symptoms of HIV sero-conversion and to repeat HIV testing.
- **Prevention of other bloodborne viruses**, such as Hepatitis B than HIV, for which there is a higher risk. 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.¹⁷
- Educate individual to immediately report and seek medical attention if they have symptoms (lymphadenopathy, rash, sore throat, flu-like symptoms) suggestive of acute HIV seroconversion. In this case, another HIV test will be carried out and, in the event the person has acquired HIV, then antiretroviral treatment should be initiated.

5 Procedure for Sexual Assault or other Non-Occupational Exposure^{18,19}

Key steps:

- A. Set up initial post-assault visit.
- B. Conduct risk assessment to assess the eligibility of the exposed individual for HIV PEP.
- C. If the decision is made to administer HIV PEP, initiate PEP treatment and obtain blood for baseline HIV serologic testing—based on informed consent.
- D. Provide individual with the "HIV PEP Patient Information" sheets. Using the scripts in Annex 1, discuss these issues before administration of PEP:
- E. Arrange medical follow up for the exposed individual.
- A. <u>Initial post-assault visit²⁰</u>: Provide initial crisis intervention (e.g. emotional support) and first aid. Where possible, HIV PEP should be offered as part of an integrated package of post-rape or HIV-prevention services. Explain to the survivor that a general medical examination and forensic examination will be conducted, 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.

 $^{^{17}}$ NIOSH: Bloodborne Infectious Diseases: HIV/AIDS, HEPATITIS B, HEPATITIS C, available at

http://www.cdc.gov/niosh/topics/bbp/guidelines.html

¹⁸ 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.

¹⁹ 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 (STIs) in either the source or exposed individual, and if the exposed person is an adolescent girl.

²⁰ 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.

B. Conduct risk assessment and assess the eligibility of the exposed individual for HIV PEP according to the following eligibility criteria:

- Less than 72 hours have 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 and during consensual sex; OR
 - c. receptive oral sex with ejaculation; OR
 - d. the survivor was drugged or otherwise unconscious at the time of the assault and is uncertain about the nature of the potential exposure, OR
 - e. the survivor was raped, or gang raped.

C. Evaluate exposure source

If source person is known:

- Do not delay initiation of HIV 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 viruses (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 virus risk and type of exposure but consider the source person as potentially infectious.
- Do not delay initiation of HIV PEP to locate the source and/or to determine HIV status of the source.
- D. If the decision is made to administer HIV 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 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.

E. 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 HIV PEP.
- □ The use of HIV PEP during pregnancy.
- □ The risks of taking HIV PEP if the patient already has HIV (before this exposure).
- □ The importance of taking the correct dose of the medication continuously for 28 days.
- □ That PEP is not fully guaranteed to prevent HIV transmission.
- □ The possible side effects of the PEP medications (mainly gastrointestinal side effects).
- □ The contraindications of HIV PEP medications.
- □ The benefits of HIV testing (now for baseline, and again at three and six months).
- Other recommended blood tests.
- □ The usual course of HIV PEP is 28 days.

- □ 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 six months or until testing excludes HIV infection.
- □ Not to donate blood, semen or body tissues for the next six months.
- □ [*For Healthcare Workers*] Any safe work practices necessary for the next six months.

F. Follow up for exposed individual

- **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, STIs and other infectious diseases, laboratory testing, counseling, ARV, obstetrical services, and/or legal and psycho-social support.
- Arrange follow-up consultations at three and six months post-exposure to repeat HIV testing, evaluate side-effects, determine adherence to regimen, monitor symptoms of HIV sero-conversion, address psychosocial/emotional needs, and assess referral needs.
- Screen and treat for other bloodborne diseases and other sexually transmitted diseases, as 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** should be offered to all female rape survivors, and, if negative, **emergency contraception** should be offered. 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 HIV PEP.
- Educate individual to immediately report and seek medical attention if symptoms arise (lymphadenopathy, rash, sore throat, flu-like symptoms) suggestive of acute HIV seroconversion.

6 Prescribing and Dispensing: Medication in the HIV PEP Kit

The UN HIV PEP kit is based on **28 days of a three-drug antiretroviral treatment, supplied as Tenofovir Disoproxil Fumarate 300mg + Lamivudine 300mg + Dolutegravir 50mg, taken once daily.** The tablet should be taken **orally, at about the same time/s each day.** 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 and Dispensing Antiretrovirals for HIV PEP

Generally speaking, countries are advised to use the same medicines as those that form the currently recommended WHO-approved first-line antiretroviral therapy for HIV 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 PEP²¹

Recommended regimen	Alternative regimen
Tenofovir (TDF) + Lamivudine (3TC) + Dolutegravir	Lamivudine (3TC or FTC) + Tenofovir (TDF) plus Lopinavir
(DTG)	/Ritonavir (LPV/r)

²¹ The December 2018 document, "Interim Guidelines: Updated recommendations on first- and second-line antiretroviral regimens and postexposure prophylaxis and recommendations on early infant diagnosis of HIV", may be found here: <u>https://apps.who.int/iris/bitstream/handle/10665/277395/WHO-CDS-HIV-18.51-eng.pdf?Ua=1</u>

Based on the latest guidance from World Health Organization, Tenofovir Disoproxil Fumarate (TDF) 300mg + Lamivudine (3TC) 300mg + Dolutegravir (DTG) 50mg is the preferred combination for HIV PEP. This regimen was recommended because the highest completion rates for HIV PEP were reported for TDF + 3TC (or FTC) in combination with DTG (90%, 95% confidence interval 84%–96%). These regimens were also associated with the lowest rates of discontinuation or substitutions because of adverse events (1%, 95% confidence interval 1%–4% for DTG). For adults, the Guideline Development Group recommends that DTG may be used as the preferred third drug for HIV post-exposure prophylaxis. This recommendation considered the high rates of post-exposure prophylaxis completion and low rates of adverse events as well as the established high tolerability of DTG when used in Antiretroviral Therapy (ART)²².

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 *fixed-dose solid formulations for twice-daily* dosing in infants and children 4 weeks of age and older^a

Drug	Strength of pediatric tablets	Number of tablets by weight band morning and evening								Strength of adult tablet	Number tablets weight	by		
		3 kg-5.9) kg	6 kg-9.9) kg	10 kg-2	13.9 kg	14 kg-	19.9 kg	20 kg-2	24.9 kg		25kg –3	4.9 kg
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM		AM	PM
AZT/3TC	Tablet (dispersible) 60 mg/30 mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	300 mg/150 mg	1	1
AZT/3TC/ NVP ^b	Tablet (dispersible) 60 mg/30 mg/50 mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	300 mg/150 mg/ 200 mg	1	1
ABC/3TC	Tablet (dispersible) 60 mg/30 mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	600 mg/300 mg	0.5	0.5
ABC/3TC	Tablet (dispersible) 120/60 mg	0.5	0.5	0.5	1	1	1	1	1.5	1.5	1.5	600 mg/300 mg	0.5	0.5

^a For infants younger than 4 weeks of age, refer to Table 4 for more accurate dosing, which is reduced due to the decreased ability to excrete and metabolize medications. For infants who are at least 4 weeks of age but less than 3 kg, immaturity of renal and hepatic pathways of elimination are less of a concern but uncertainty still exists on the appropriate dosing of ARVs in preterm and low birth-weight infants.

^bPlease note that this regimen and formulation is no longer recommended and should only be used in special circumstances where other age-appropriate formulations are not available.

Simplified dosing of child-friendly *solid formulations for once-daily dosing* in infants and children 4 weeks of age and older^a

Drug	Strength of pediatric tablet	Nu	mber of tablets	s or capsules by	Strength of adult tablet	Number of tablets or capsules by weight band once daily		
		3 kg–5.9 kg	6 kg–9.9 kg	10 kg–13.9 kg	14 kg–19.9 kg	20 kg–24.9 kg		25 kg–34.9 kg
EFV ^b	Tablet (scored) 200 mg	-	-	1	1.5	1.5	_	2
ABC/3TC	Tablet (dispersible) 60/30 mg	2	3	4	5	6	600 mg/300 mg	1
ABC/3TC	Tablet (dispersible) 120/60 mg	1	1.5	2	2.5	3	600 mg/300 mg	1
ATV ^c	Capsules 100 mg	-	-	2	2	2	300 mg	1 ^d
	Capsules 200 mg	-	-	1	1	1		
DRV ^e	Tablet 600 mg	-	-	-	1	1	600 mg	1
	Tablet 150 mg	-	-	-	4	4		

RTV ^f	Tablet 25 mg	-	-	-	4	4	100 mg	1
	Tablet 50 mg	-	-	-	2	2		
DTG ^g	Tablet 50 mg	-	-	-	-	TBC ^g	50 mg	1

^a Doses for this age group are reduced to account for the decreased ability to excrete and metabolize medications. For infants who are at least 4 weeks of age but less than 3 kg, immaturity of renal and hepatic pathways of elimination are less of a concern but uncertainty still exists on the appropriate dosing of ARVs in preterm and low birth weight infants. ^b EFV is not recommended for children younger than 3 years and weighing less than 10 kg.

^cATV is only approved for use in children 3 months and older. ATV single-strength capsules should be administered with RTV 100 mg for all weight bands. ATV powder formulation has limited availability in lower middle-income countries (LMICs) but enables administration of ATV to infants and children as young as 3 months. Infants and children 5kg-15 kg should be administered 200 mg of ATV powder (4 packets, 50 mg/ packet) with 80 mg of RTV oral solution (1 ml). <u>https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/</u>021567s042,206352s007lbl.pdf

^d A 300 mg dose for 25 kg-29.9 kg is recommended on the basis of findings from the PRINCE-2 study^{vii}.

At the time of this update, DTG film-coated tables were approved for children above 6 years by the FDA (35mg for weight 30 kg to < 40 kg, 50 mg for weight40 kg)^{III} and by the EMA (20 mg for 15 kg to < 20 kg, 25 mg for 20 kg to < 30 kg, 35 mg for 30 kg to < 40 kg, and 50 mg for weight 40 kg)^{III} based on data from the IMPAACT 1093 trial^{IV}. Simplified weight band dosing is being investigated in the Odyssey trial which supports the use of 50 mg dose for all children 25 kg, as proposed here. An anticipated dose of 50 mg in children 20 kg to 25 kg is based on predicted exposure derived from PK results on DTG 25mg (FCT) in this weight band, more data to confirm this and further inform optimal dosing in the 14 to 25 kg weight bands is expected at the beginning of 2019 and will be included in an updated version of this annex . For adolescents living with HIV weighing more than 30 kg, a fixed-dose formulation of TDF 300mg/3TC 300mg/DTG 50mg (TLD) can be used and is preferred.

Annex 1. Sample Scripts for Healthcare Providers

Communicating some of the concepts of these guidelines to individuals who have been potentially exposed to HIV, and thus may be eligible for HIV PEP, can be difficult. The sample "scripts" given below are intended to assist healthcare 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 this "HIV post-exposure prophylaxis" or "HIV PEP".

Risk of infection

Can you tell me what you know about how a person can get the 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 a 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. You will then 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 three 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 the 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, the 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.

HIV 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 one pill, taken once 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 risk 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.

Tenofovir + Lamivudine + Dolutegravir should not be taken at the same time as certain other medications. If PEP is required, then these medications may need to be stopped or dosage modification may be required with the advice of a medical professional: Dofetilide, Carbamazepine, phenobarbital, phenytoin, rifampicin, halofantrine, simeprevir, lovastatin, simvastatin, metformin, astemizole, terfenadine, polyvalent cation products (containing Mg, Al, Fe, Ca and Zn), adefovir, midazolam, triazolam, cisapride, amiodarone, bepridil, flecainide, propafenone, dabigatrain, rivaroxaban, lercanidipine, fluphenazine, pimozide, ergotamine, dihydroergotamine, voriconazole, alfusozin, St. John's Wort, wildenafil, piroxicam and quinidine.

You should not receive the HIV PEP medications if you have certain medical conditions. Please let me know if you are aware that you may have or have had any of these conditions:

- previous hypersensitivity or allergic reaction to Tenofovir, Lamivudine or Dolutegravir;
- previous intolerance/anaphylaxis to any of the three medications;
- uncontrolled diabetes;
- kidney/renal impairment with creatinine clearance <50 ml/min;
- liver impairment with ascites, albumin <2.8 g/dL, total bilirubin >50 mmol/L;
- encephalopathy;
- the incident/potential exposure to HIV occurred more than 72 hours ago; or
- you are HIV positive.

To get the full benefit from post-exposure prophylaxis, you must take the pill once a day for the full 28 days. If you do decide to take the medicine, you should start straight away.

If you change your mind about taking the HIV PEP medication, 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. There may be ways in which we can help you to manage your side effects, or things that I have not explained clearly that have made you uncertain about whether you want to finish the medicine.

(*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. You will be referred for proper HIV management and how to prevent transmission of HIV to your baby if you get HIV while you are pregnant.

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 postexposure 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, which we call "post-exposure prophylaxis".

Risk of infection

Can you tell me what you know about how people can get the 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 or have been raped by someone who is infected with HIV, the virus 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 three months before the HIV test would turn positive.

Very few people actually get HIV infection through sex. 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.

The risk of getting the HIV infection through sex is:

- between 1 in 1000 (0.1%) and 1 in 100 (1%) or even less for receptive vaginal intercourse;
 1 and 2 in 100 (1–2%) for receptive anal intercourse.; and
- For receptive oral intercourse with ejaculation, transmission is very rare, but it can happen.

Unfortunately, the risk is increased with visible trauma—such as rape—or 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.

Tenofovir + Lamivudine + Dolutegravir should not be taken at the same time as certain medications. If HIV PEP is required, then these medications may need to be stopped or dosage modification may be required with advice of a medical professional: Dofetilide, Carbamazepine, phenobarbital, phenytoin, rifampicin, halofantrine, simeprevir, lovastatin, simvastatin, metformin, astemizole, terfenadine, polyvalent cation products (containing Mg, Al, Fe,Ca and Zn), adefovir, midazolam, triazolam, cisapride, amiodarone, bepridil, flecainide, propafenone, dabigatrain, rivaroxaban, lercanidipine, fluphenazine, pimozide, ergotamine, dihydroergotamine, voriconazole, alfusozin, St. John's Wort, wildenafil, piroxicam and quinidine.

You should not receive the PEP HIV medications if you have certain medical conditions. Please let me know if you are aware that you have or have had any of these conditions:

- previous hypersensitivity or allergic reaction to Tenofovir, Lamivudine or Dolutegravir;
- previous intolerance/anaphylaxis to any of the three medications;
- uncontrolled diabetes;
- kidney/renal impairment with creatinine clearance <50 ml/min;
- liver impairment with ascites, albumin <2.8 g/dL, total bilirubin >50 mmol/L;
- encephalopathy;
- the incident/potential exposure to HIV occurred more than 72 hours ago; and/or
- you are HIV positive.

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 one pill taken once every day for 28 days. For the medicine to work, it is important that you take your HIV 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 risk that you might have side effects. We don't know for sure that taking HIV PEP means that you won't get HIV infection, but it will help. If you do decide to take the medicine, you should start straight away.

To get the full benefit from post-exposure prophylaxis, you must take the pill 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. There may be ways in which we can help you to manage your side effects, or to give you more information about things that I may have not explained clearly which have made you uncertain about whether you want to finish the medicine.

(*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. You will be referred for proper HIV management and how to prevent transmission of HIV to your baby if you get HIV while you are pregnant.

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, when you have breakfast or get up; or in the evening, when you eat dinner or go to bed.

For some medicines, 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 pill.
- 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 healthcare 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 HIV 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 experience 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 risk that you might experience side effects. We don't know for sure that taking HIV PEP means that you won't get HIV infection, but it will help.

The tablet (Tenofovir + Lamivudine + Dolutegravir) should not be taken at the same time as certain medications. If HIV PEP is required, then these medications may need to be stopped or dosage modification may be required with advice of a medical professional: Dofetilide, Carbamazepine, phenobarbital, phenytoin, rifampicin, halofantrine, simeprevir, lovastatin, simvastatin, metformin, astemizole, terfenadine, polyvalent cation products (containing Mg, Al, Fe,Ca and Zn), adefovir, midazolam, triazolam, cisapride, amiodarone, bepridil, flecainide, propafenone, dabigatrain, rivaroxaban, lercanidipine, fluphenazine, pimozide, ergotamine, dihydroergotamine, voriconazole, alfusozin, St. John's Wort, wildenafil, 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 post-exposure prophylaxis 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, it is important that they receive appropriate counselling and medical follow up, including the offer to start lifelong antiretroviral therapy. It is important therefore to know whether you are already HIV positive, ideally as soon as possible after you start HIV 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 will need to stop taking the HIV 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 (second) 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 HIV PEP or if you stopped taking the medicine before you completed 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 or further in the past. In the event HIV PEP is not taken, another HIV test should be carried out one month after the potential exposure.

If you do take the PEP medicines, we strongly recommend that you have a follow-up HIV test in three months' time, and another test six 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.]

HIV POST-EXPOSURE PROPHYLAXIS (PEP) PHYSICIAN ASSESSMENT REPORTING FORM

This form must be filled and signed by the assigned/designated physician who will monitor the care of the patient. Ideally, this form is completed before administration of HIV PEP kits to UN personnel or their eligible dependents who are exposed to HIV in mission and duty stations. **Complete this form and scan/email back to DHMOSH Public Health at** <u>dos-dhmosh-hiv@un.org.</u>

	PATIENT INFORMAT	ION
Patient Name: (First):	(Last):	Date of Birth (DD/MM/YY): / /
Sex: M 🗆 F 🗆	Country/Location/Duty Station:	
Organization/Division/Office:		
UN Staff Index No:	Staff 🗖 Dependent 🗖	Other 🗖 (Please specify):
Email Address:		Phone:

EXPOSURE DETAILS					
When did the exposure occur?	Date: Time:				
Did the exposure occur within the past 72 hours?	 Yes □ No □ Unsure NOTE: If more than 72 hours has passed since exposure, HIV antiretrovirals are not indicated. 				
What type of exposure occurred?	Occupational Exposure (i.e. exposure which occurred while at work) Needle stick injury Human bite resulting in blood Other exposure resulting in blood-to-blood, semen, or vaginal fluid contact If the exposure occurred while at work, is the patient who was exposed a healthcare provider? Yes No Unsure Please explain: Unprotected sexual intercourse (vaginal or anal) Use of shared needles or needle stick injury Human bite resulting in blood Other Please explain: Sexual Assault Potential exposure to blood or semen from the assailant through an open wound or through intercourse Please explain:				
Did the patient know the source person?	☐ Yes ☐ No ☐ Unsure If the patient knew the person they were exposed to, please explain:				
Does the patient know if the source person has HIV?	□ Yes □ No □ Unsure □ Not applicable				

	Date of source person's last HIV test (if applicable): 🗆 N/A
If the source person does have HIV, does the patient know if they are currently receiving treatment?	□ Yes □ No □ Unsure □ Not applicable Current treatment (if applicable):□ N/A
Does the source person have any of the following risk factors? [Please check all that apply]	 Man who has sex with men Current/ex intravenous drug user Born or recently arrived from area of high HIV prevalence Recipient of multiple blood transfusions or blood products pre-1985 Sexual partner of person with any of the risk factor(s) above
Please explain any additional expo	osure details or information about the source person here:

PATIENT HEALTH HISTORY						
Does the patient have a history of HIV?	□ Yes □ No □ Unsure					
	Date of last HIV test:					
	Result: Positive Negative Not completed					
	If the patient does not have a history of HIV, a baseline HIV test should be completed.					
Was a baseline HIV test completed?	□ Yes □ No □ Not applicable					
	Date of baseline HIV test:					
	Result of baseline HIV test: Positive Negative Not completed					
	If a baseline HIV test was not completed, please explain why here:					
Is the patient pregnant?	□ Yes □ No □ Unsure □ Not applicable					
	Date of pregnancy test: □ N/A					
	Result of pregnancy test: 🗆 N/A					
	PEP is not contraindicated for pregnant women. Moreover, because pregnancy has					
	been demonstrated to increase susceptibility to sexual HIV acquisition, PEP can be					
	especially important for women who are pregnant at the time of sexual HIV exposure.					
Does the patient have a history	Liver problems 🛛 Yes 🗆 No 🗖 Unsure					
of any of the following health	Kidney problems \Box Yes \Box No \Box Unsure					
conditions? (Please check all	Bleeding problems 🛛 Yes 🗆 No 🖾 Unsure					
that apply):	HIV 🛛 Yes 🗆 No 🖾 Unsure					
	Hepatitis B 🛛 Yes 🗆 No 🗖 Unsure					
	Hepatitis C 🛛 Yes 🗆 No 🗖 Unsure					
	If yes to any of the above, please explain:					

TREATMENT PROVIDED TO PATIENT

Patient took morning-after pill	□ Yes □ No □ Not applicable							
provided in kit								
Patient was instructed to take	I Yes I No							
HIV antiretrovirals								
	If yes, was the patient given the following information:							
	Education HIV antiretroviral treatment							
	Education on the importance of follow up							
	Education on the importance of finishing medication							
	If HIV antiretroviral were not provided, what was the reason?							
	If the patient was instructed to take HIV antiretrovirals, baseline liver and kidney							
	function tests should be completed.							
If the patient was instructed to	Serum liver enzyme testing (ALT/AST) 🛛 Yes 🛛 No 🛛 Result:							
take HIV antiretrovirals, were	Blood Urea Nitrogen (BUN) 🛛 Yes 🖾 No 🛛 Result:							
the following baseline labs								
drawn?	Creatinine 🗆 Yes 🔲 No Result:							
	If no to any of the above, please							
	explain:							
Was the patient screened for	□ Yes □ No □ Not applicable							
STIs?								
	If no, please explain:							
	Patients with sexual exposure should be screened for chlamydia, gonorrhea, syphilis,							
	Hepatitis B, and Hepatitis C.							
	Chlamydia 🛛 Yes 🗆 No Result:							
	Gonorrhea 🛛 Yes 🗆 No Result:							
	Syphilis 🛛 Yes 🗆 No Result:							
	Hepatitis B 🛛 Yes 🖾 No Result:							
	Hepatitis C 🛛 Yes 🗆 No Result:							
Was the patient treated for	🛛 Yes 🖾 No 🖾 Not applicable							
injuries related to the exposure?								
	If yes, please explain:							
	If yes, were these injuries a result of rape? 🛛 Yes 🖾 No 🖾 Unsure							

PATIENT EDUCATION AND FOLLOW UP						
If the patient was instructed to	□ How to take PEP					
take HIV antiretrovirals, was the	Potential side effects of medication					
following reviewed with the	□ Importance of follow-up					
patient? 🛛 Safer sex/condom use for three months						
	□ Safe injecting practice (if applicable)					
	□ Avoiding donation of plasma, blood, tissue, or semen until confirmatory negative					
	testing					
	□ Not applicable					
I have informed the patient to	□ 4-6 weeks (date)					
return for follow up HIV blood	□ 3 months (date)					
work in:	\square 6 months (if co-Infection with Hepatitis C or if HIV-2 is strongly suspected)					

(date)
□ Not applicable

Physician Name:	Signature:	Date: (DD/MM/YY):	/	/	
Physician Email:	Contact No:				
Department/Hospital Name:					

Please submit completed form to DHMOSH Public Health at <u>dos-dhmosh-hiv@un.org</u>

Annex 3: Recognized Regional Medical Evacuation Centers

"Eligible staff members and eligible dependents 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 center²², as shown in the table below.

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

²² ST/AI/2000/10 <u>https://documents-dds-ny.un.org/doc/UNDOC/GEN/N00/652/11/pdf/N0065211.pdf?OpenElement</u> List of regional evacuation centers amended July 2012.

	Angola Botswana Lesotho Malawi Mozambique Swaziland Zambia Zimbabwe	South Africa
	Comoros Madagascar	 lle de la Réunion, Mauritius, South Africa
Co	untries	Recognized regional medical centres
	Americas Caribbean Haiti	Dominican Republic
(b)	Central America Belize, El Salvador, Honduras, Nicaragua	Mexico
(c)	South America Bolivia Guyana Paraguay	Chile Trinidad and Tobago, Venezuela Argentina
3.	Arab States Iraq Libyan Arab Jamahiriya Yemen	Jordan, Lebanon Egypt, Tunisia, Morocco 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 Maldives Mongolia Nepal	China, Thailand India, Sri Lanka China, Republic of Korea India, Thailand
	Cambodia Lao People's Democratic Republic Myanmar Viet Nam	Singapore, Thailand
5.	Europe Albania Republic of Moldova Ukraine	Italy, Turkey, Austria Austria 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 System²³

A. Introduction:

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 missions²⁴, including, but not limited to:
 - United Nations police officers, military observers, military liaison officers, military advisors and staff officers; and
 - 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.
- 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.

²³ Note that IGOs/NGO staff and family members are not covered under this UN programme.

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 paragraphs (a) and (b).

UNITED NATIONS HIV POST-EXPOSURE PROPHYLAXIS (PEP) KIT PROGRAM **CUSTODIAN AND PATIENT REPORTING FORM**

Instructions: Patient should complete Part A and return to custodian before PEP kit is given to the patient. Custodian should then complete Part B and follow the instructions below.

Part A – TO BE COMPLETED BY PERSON REQUESTING PEP KIT

PATIENT INFORMATION				
Patient Name: (First) :	(Last):			Date of Birth (DD/MM/YY): / /
Sex : M 🗆 F 🗆	Country/Loca	tion/Duty	Station:	
Organization:	Staff Depe	endent 🗆	Others	5 □ (Please specify):
Email Address:		Pho	one:	
PATIENT HISTORY				
Are you HIV positive?		🗆 Yes	🗆 No	🗆 Unsure
Are you currently pregnant?		🗆 Yes	🗆 No	Unsure Not applicable
What is the reason you are requesting this P	EP Kit?	🗆 HIV a	anti-retr	ovirals medication
(Please check all that apply)		🗆 Preg	nancy te	est
		□ Mor	ning-afte	er pill
Please remember, all patient information is	s kept			
confidential.				
Are able to make a follow up appointment w	ith a treating	🗆 Yes		
physician?		🗆 No		
Note: Scheduling a follow up appointment is very		🗆 I have	e been gi	iven this kit by a UN doctor
important as additional testing may be reco	mmended			

Part B – TO BE COMPLETED BY CUSTODIAN

After completion, please scan both pages and email to dos-dhmosh-hiv@un.org

CUSTODIAN INFORMATION			
Date of submission of this form to DHMOSH at <u>dos-dhmosh-hiv@un.org</u> (DD/MM/YY)://			
Date of Issuance of HIV PEP Kit to individual requesting (DD/MM/YY):/			
Custodian's Name (First):	(Last):		
Custodian's Phone:	Custodian's Email Address:		
CONTACT DETAILS OF ATTENDING PHYSICIAN/MEDICAL STAFF (if different from Custodian)			
First Name:	Last Name:		
Phone :	Email Address:		
NOTE:			

- 1) It is mandatory to submit this form for every HIV PEP kit issued from your duty station.
- 2) All forms must be submitted WITHIN 24 HOURS OF KIT USAGE.
- 3) Replacement kits will not be issued to your duty station if reporting forms of previously used kits are not submitted to DHMOSH.
- 4) You should inform the patient that his/her treating physician should also submit a detailed Physician assessment form to dos-dhmosh-hiv@un.org
- 5) Please inform the patient that after submission of this form to DHMOSH, he/she may get a confidential follow-up contact with a DHMOSH/UN medical staff regarding the HIV PEP kit issued.
- 6) All forms and other PEP Guidance documents can be found here: <u>https://hr.un.org/page/hiv-pep-kit-management</u>

CUSTODIAN CHECKLIST			
Did the person requesting the PEP take all contents of the	Yes 🗆 No 🗆		
kit?			
	If the person requesting the PEP kit did not take all		
	contents, which contents did they take? (Please check		
	all that apply)		
	HIV antiretrovirals medication		
	Pregnancy test		
	Morning-after pill		
	No kit was given		
Have you referred the person requesting the PEP kit to	Yes 🗆 No 🗆		
make an appointment with a UN physician?	If no, please explain:		
Have you informed the person requesting the PEP kit that	Yes 🗆 No 🗆		
they may get follow up call/email from DHMOSH?	If no, please explain:		

PLEASE SUBMIT BOTH PAGES OF THIS FORM WITHIN 24 HOURS of ISSUANCE OF THE HIV PEP KIT TO DHMOSH PUBLIC HEALTH SECTION AT:

dos-dhmosh-hiv@un.org