2021

MSF HIV WG

Post Exposure Prophylaxis after Accidental Exposure to Blood or Body Fluids

RECOMMENDATIONS

INTERSECTION DOCUMENT

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CONTENTS

1.	Introduction	1
2.	Risk of transmission	2
3.	Preventing Exposure to HIV and Other Viruses	2
4.	Procedures after Accidental Exposure to Blood or Body Fluids	4
5.	First Aid after Accidental Exposure to Blood or Body Fluids	5
6.	Evaluating the Risk of Transmission	5
7.	Decision to give Post-Exposure Prophylaxis against HIV	7
8.	Post exposure prophylaxis (PEP) regimens against HIV	8
9.	Post Exposure Measures against Hepatitis B and C	10
10.	Counselling	11
11.	Follow Up of an Exposed Person	12
12.	Sexual Exposure to Blood or Body Fluids and Sexual Violence	13
13.	Administrative Procedures	13
14.	Financial aspects	14
15.	Supply	14
16.	References	15
17.	Appendixes	16
A	Appendix 1. Dosage of ARVs for PEP according to weight	16
A	Appendix 2: Universal precautions to be taken during health care	19
A	Appendix 3: Administrative procedures after AEB	20
A	Appendix 4: Information sheet on PEP and follow-up after an AEB	22
A	Appendix 5: PEP treatment informed consent/refusal form	23
A	Appendix 6: AEB Notification form (confidential)	24
A	Appendix 7: Contact details	28

ABBREVIATIONS

3TC Lamivudine Ag Antigen Ab Antibody

AEB Accidental Exposure to Blood or Body Fluids

ATV/r Atazanavir/ritonavir

AZT Zidovudine

CDC Center for Disease Control
CrCl Creatinine Clearance
DAA Directly Acting Antivirals
DRV/r Darunavir/ritonavir

DTG Dolutegravir EFV Efavirenz

FDC Fixed-Dose Combination

FTC Emtricitabine

HIV Human Immunodeficiency Virus

HBV Hepatitis B Virus
HCV Hepatitis C Virus
HQ Headquarters
HR Human Resources
LPV/r Lopinavir/ritonavir
MedCo Medical Coordinator

NVP Nevirapine

OC Operational Centre (A: Amsterdam, B: Brussels, BA: Barcelona, G: Geneva, P: Paris)

PEP Post Exposure Prophylaxis
PLWH People Living with HIV

RAL Raltegravir SHU Staff Health Unit

TDF Tenofovir

TLD Tenofovir/Lamivudine/Dolutegravir fixed-dose combination

WHO World Health Organisati

1. Introduction

Occupational accidental exposure to blood or body fluids (AEB) is a work accident and need to be treated as such.

The prevalence of human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV) infection is high in many of the settings where MSF works. These viruses can be transmitted through exposure of mucosal surfaces or damaged skin to contaminated blood or body fluids, including:

- Injury with a needle or other sharp instrument;
- Contact with mucous membranes or damaged skin (e.g. cutaneous cuts, abrasions);
- Unprotected sexual contact (oral, vaginal or anal, including rape);
- Unsafe blood transfusion.

Health care workers are at risk of occupational exposure and infection during the exercise of their professional activities. In this guideline we consider personnel working with MSF or a partner organisation, including the ministry of health. We focus on occupational exposure but also cover exposure to unprotected sex.

Guidance on post-exposure prophylaxis (PEP) in other circumstances, such as sexual violence and rape, can be found in the MSF HIV/TB Clinical Guide for Primary Care 2020 and the MSF Medical protocol for sexual violence care 2020.

Accidental Exposure to Blood or Body Fluids (AEB) is defined as any contact with blood or a body fluid which might contain HIV, hepatitis or other infectious agents as a result of an injury with a needle or other sharp instrument or exposure of mucous membranes or damaged skin. HIV infection after AEB can be prevented through prompt initiation of PEP with antiretroviral treatment; hepatitis B can be prevented through vaccination and/or immunoglobulins. There is no vaccine or prophylaxis against hepatitis C, but there is effective treatment.

MSF proposes PEP to MSF personnel at risk of infection from an AEB. This guideline is based on current international recommendations and previous experience, and is adapted to the field context.

MSF personnel share an individual and collective responsibility for preventing AEB. All MSF staff must be informed about universal precautions, measures to prevent AEB, and procedures to follow after AEB, at the beginning of their employment, and be reminded of this information at least once per year.

A designated member of the medical staff, preferably a medical doctor, has to be identified and is responsible for AEB prevention and management in each location. AEB PEP guidelines, AEB posters and PEP treatment must be available in each project site.

The medical coordinator has the responsibility for AEB prevention and PEP at country level. Questions on AEB and PEP can be addressed to the Staff Health Unit and/or the HIV referral person for every section:

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2. RISK OF TRANSMISSION

Accidental Exposure to Blood (AEB) is defined as any contact of open skin or mucosae with blood or a body fluid.

Occupational exposures include needle-stick injuries, deep percutaneous sharps injuries, splashes of blood or body fluids onto mucous membranes of eye/ mouth/ nose or an existing cutaneous condition (wound, scratch, eczema etc.).

Sexual exposures include sexual assault involving vaginal or rectal penetration, consensual intercourse and/or burst condoms.

Inadvertent exposures include sharing needles during recreational intravenous drug use, accidental injuries with improperly disposed of medical waste/ needles, contact with used condoms, human bites, contact sports with blood exposure, roadside assistance at motor vehicle accidents (contact with body fluid and non-intact skin), expressed breast milk from another mother given to infant unintentionally, or breastfeeding of infant of another mother, pre-mastication of food if sores in mouth of person chewing food.

Infectious body fluids and materials include blood or any blood-stained fluids, tissue or other material; vaginal secretions or penile pre-ejaculate and semen; fluid from any body cavity such as pleural, pericardial, amniotic, peritoneal, synovial and cerebrospinal fluids; any other fluids, excretions or secretions that are visibly blood-stained; and breast milk.

Non-infectious fluids for HIV and hepatitis B/C include tears, non-blood-stained saliva, sputum or vomitus, sweat, urine, and stools.

Health care personnel are at risk of infection with hepatitis B, hepatitis C and HIV as the result of an AEB, depending on the status of the source patient. This risk does not only concern medical staff but also non-medical staff such as cleaners. The average risk for HIV transmission after a single percutaneous exposure to HIV-positive blood is low (table 1), and considerably lower than that arising from hepatitis B and C viruses (respectively 100 and 10 times less). There is also a risk of transmission of any other infectious agent present in the blood (haemorrhagic fevers, trypanosomiasis etc.).

Agent	Mode of exposure	Risk of infection
HIV	Percutaneous exposure	0,3%
HIV	Mucocutaneous contact*	0,03-0,09%
HBV	Percutaneous exposure	10-30%
HCV	Percutaneous exposure	0-10%

^{*} Exposure of mucous membranes or cutaneous cuts or abrasions

The most common procedures presenting a risk of accidental exposure to blood/body fluids include:

- Handling sharps after taking blood and samples of other body fluids visibly contaminated with blood;
- Inserting and handling drips, particularly when done in a rush;
- Surgery, particularly during major and/or long surgical interventions or where haemorrhages may occur;
- Handling of blood or infectious body fluids by laboratory staff;
- Cleaning, handling and destroying contaminated medical material and medical waste.

Performing any of these activities in a rush carries an additional risk.

HIV and other viruses are far more likely to be transmitted through **UNPROTECTED SEX** or **BLOOD TRANSFUSIONS** that have not been tested for viruses than through occupational accidental exposure to blood or body fluids.

3. Preventing Exposure to HIV and Other Viruses

Information, Education, Communication

All MSF staff should be informed about how to protect themselves against HIV and other pathogens transmitted by blood or sexual contact. Medical coordinators have the responsibility to inform all new staff about:

- Universal precautions to be followed in health services (see appendix 1);
- The use of condoms in private life;
- Other preventive measures to be taken against these viruses (including vaccination);

• The procedures to be followed in case of an AEB.

Staff must be reminded of these precautions on a regular basis, at least once per year. All MSF staff share an individual and collective responsibility in this regard. The Medical Coordinator must ensure that AEB guidelines, information material and PEP treatment are available in each project site, and that procedures are followed appropriately.

Since some of these infections can be transmitted through sexual contact, condoms should be available in every project and the use of condoms should be promoted.

PROTECTION AGAINST HEPATITIS B AND C

All MSF medical staff that might be exposed to Hepatitis B virus must be vaccinated; the standard scheme is one dose at Day 0, Month 1 and 6¹. If possible, an anti-HBs antibody test should be performed 4-8 weeks after the last dose to check whether the level of protection is sufficiently high. If the level of anti-HBs antibody is lower than 10 IU/L, an additional dose is recommended. It is important that the staff health responsible at national and project level verify and keep track of vaccination status of every staff member.

There is no danger in vaccinating someone who is already infected with HBV. However, chronic hepatitis B can lead to liver cancer and should be diagnosed and treated.

In some settings the prevalence of chronic hepatitis B is high and testing for hepatitis B surface antigen (HBsAg) prior to vaccination should be considered. MSF should provide treatment for chronic hepatitis B to staff that need it, or identify adequate referral options.

There is no vaccine or prophylaxis available against hepatitis C. However, there is an effective treatment available if seroconversion occurs and viremia persists for more than 6 months after AEB.

HIV TESTING AND COUNSELLING

For medical and insurance reasons it is **strongly recommended** (but not mandatory) that each individual working with MSF gets **tested for HIV** confidentially before starting his employment. Information on where to obtain free (or reimbursed by insurance or MSF) and confidential HIV testing services must be available in every project. Living with HIV is not a contraindication to work with MSF, and antiretroviral treatment must be accessible for all MSF staff, either provided by MSF or by an external service provider, of which the quality of care has been verified by MSF.

PEP PREPAREDNESS

In each country the following should be identified:

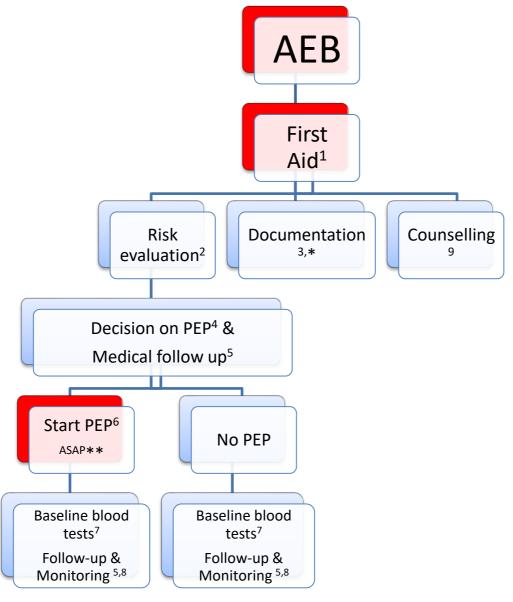
- A medical doctor who can initiate and follow up PEP
- A medical doctor who is responsible for the notification of AEB for all staff
- A person responsible for the availability of PEP in every site (ordering, stock, expiry, storage...)
- A laboratory with the capacity for testing for HIV, HBV and HCV serology, pregnancy test, creatinine, and ALT.
- Access to human immunoglobulin against hepatitis B (HIGB) in less than 24 hours, either in the MSF project or through an external service provider.
- An administrative person responsible for reimbursement of medical care and insurance matters.

In each clinic/site/project the following should be available:

- A minimum of two PEP kits, each with the full 28 days of ARV medication; rapid tests for HIV, HBV and HCV.
- This guideline for PEP after AEB + a template of the PEP consent/refusal forms and AEB notification forms (Appendix 5 &
 6)

¹ Information provided in these guidelines refers to specific vaccine formulations: Engerix-B®, Recombivax HB® and Twinrix® and cannot be extrapolated when other HBV containing vaccines are used.

4. PROCEDURES AFTER ACCIDENTAL EXPOSURE TO BLOOD OR BODY FLUIDS



AEB: Accidental exposure to blood or body fluids; PEP: Post-Exposure Prophylaxis

^{1.} Chapter 5; ^{2.} Chapter 6; ^{3.} Chapter 13; ^{4.} Chapter 7; ^{5.} Chapter 10; ^{6.} Chapter 8 & 9; ^{7 & 8.} Chapter 11

^{*} All accidental exposures to blood must be notified whether or not prophylactic treatment is started. Contact the persons responsible for staff health at field, mission and headquarters as soon as possible. See Appendix 3.

^{**} As soon as possible after the accident; and up to 72 hours later. Blood test should not delay initiation of PEP.

5. FIRST AID AFTER ACCIDENTAL EXPOSURE TO BLOOD OR BODY FLUIDS

PERCUTANEOUS EXPOSURE

- Let the wound bleed (do not squeeze or rub the lesion),
- Immediately wash wound and surrounding skin with water and soap and rinse
- Disinfect the wound and surrounding skin for 5 minutes with:
 - Polyvidone iodine 10% (Betadine) or
 - Chlorine solution of 0.05-0.1% or
 - Alcohol 70%

Chlorhexidine Cetrimide is active against HIV, but not against HBV; it is therefore not recommended for persons who are not vaccinated against HBV and thus should not be used after AEB.

EXPOSURE INVOLVING THE EYES OR MUCOUS MEMBRANES

Rinse the exposed area immediately with an isotonic saline solution for 10 minutes. If this saline solution is not available, hold the eye under a running tap. Antiseptic eye drops can also be used for eye exposure. If none of these solutions are available, use clean water. If contact lenses are worn, leave these in place while irrigating 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 normal manner. Do not use soap or disinfectant on the eye.

In the unlikely event of a splash in the mouth, spit the fluid out immediately, rinse the mouth with water, disinfect by rinsing with povidone iodine 1% solution or chlorine 0.05% solution and rinse with water again.

6. EVALUATING THE RISK OF TRANSMISSION

The likelihood of transmission depends on the type of exposure, the type of fluid, the amount of fluid transmitted and the health status and viral load of the source patient.

A medical doctor must assess the risk of HIV and hepatitis transmission following an AEB. **This evaluation must be made rapidly and thoroughly**, so as to start treatment as soon as possible after the accident². Not every AEB requires prophylactic treatment.

Type of Exposure

Percutaneous exposure occurs when the skin is broken; mucous membrane contact includes sexual exposure, splashes to eye, nose or oral cavity.

Massive exposure:

- Needle-stick injury with a hollow needle used for arterial or venous access.
- Deep wound from an item contaminated with blood.

Moderate exposure:

- Needle-stick injury with a suture needle or a needle used for intramuscular or subcutaneous injection.
- Cut from a scalpel
- Mucous membranes or damaged skin in contact with a significant amount of blood or body fluid.

Minimal exposure:

• Bite, scratch, contact with blood on undamaged skin, contact of drops of blood on mucous membranes or skin, contact with other body fluids not containing blood (e.g. saliva, urine), needle stick injury from an abandoned syringe.

These definitions are intended to help the doctor assess the gravity of the exposure. All possibilities cannot be covered and it is up to the medical doctor to classify the exposure appropriately.

² As soon as possible after the accident and not later than 72 hours. After 72 hours, the prophylaxis will have no effect.

Percutaneous accidents in the following situations have a higher risk of transmission:

- Hollow needle > plain needle (suture needle).
- Intravascular device or needle > non-intravascular.
- Deep needle stick wound (bleeding and painful) > superficial.
- Visible blood in/on the object > no visible blood.

N.B. AEBs with material contaminated for over 48 hours considerably reduce the risk of infection with HIV, but remain significant for HBV (HBV is more resistant than HIV).

Wearing gloves is protective. Double gloving is recommended in countries with a high prevalence of HBV, HCV and HIV for long surgical procedures (>30 minutes), for procedures with contact with large amounts of blood or body fluids, and for some high-risk orthopaedic procedures WHO Glove Use Information Leaflet.pdf (August 2009).

TYPE OF FLUID

The following fluids may contain HIV: blood or any blood-stained fluids, breast milk and sexual secretions.

The following may contain HIV but involve invasive procedures: amniotic, peritoneal, synovial, pericardial or pleural fluids and cerebrospinal fluid.

The following are considered to be non-infectious (if not contaminated with above fluids): sweat, tears, saliva, sputum, urine and stool.

HIV STATUS OF THE SOURCE PATIENT

It is important to evaluate if the source patient is infected with HIV, HBV or HCV and whether the person is already on antiviral treatment for such conditions. It is essential to obtain a complete treatment history (which antiretroviral drugs has the patient already received) and to review all previous genotypes if done.

HIV testing of the source patient is recommended if the following conditions are met:

- The patient provided informed consent and is given the choice of knowing results or not.
- Confidential counselling is available.
- Medical and psychosocial care for HIV is available. ARV treatment will be prescribed and follow/up will be done as far as possible by the project. Medical care will be given in accordance with national guidelines.

When the patient wants to know the result (preferable), the first screening test must be confirmed by 2 additional tests of different types as per WHO recommendations³.

Important: Rapid HIV diagnostic tests do not detect recent HIV infection. During the so called «window period», which lasts approximately 3 weeks, antibody levels are too low for detection – but infected persons can have a high viral load and be highly infectious. A **negative test result does not entirely exclude HIV infection** and it is important that the source patient is given a clinical examination concentrating on signs and symptoms of acute HIV infection.

If the source patient declines to be tested, try to determine risk of HIV through a detailed history and clinical examination, and epidemiological criteria. If this is not possible, or in case of doubt, consider the source as unknown and give PEP.

The source patient has a:

- High risk of being HIV infected if:
 - Family history, personal history and/or clinical examination suggest possible HIV infection.
 - (S)he belongs to a population at high risk of HIV (sex worker, men who have sex with men, intravenous drug user, prisoner, coming from high HIV prevalence setting)
 - (S)he has high risk behaviours (multiple sexual partners, no condom use...)
 - Comes from a region with high HIV prevalence (>1%)

³ https://www.who.int/publications/i/item/consolidated-guidelines-on-hiv-testing-services-for-a-changing-epidemic

- Low risk of being HIV infected if:

The source patient comes from a region with low HIV prevalence, the medical history does not indicate any risk factors for HIV infection and there are no signs or symptoms of acute infection, HIV-related illnesses or AIDS on clinical examination.

7. DECISION TO GIVE POST-EXPOSURE PROPHYLAXIS AGAINST HIV

The following are considered not to be at risk and are therefore not eligible for PEP:

- The exposed person is already HIV positive.
- The source patient is proven HIV-negative by a negative HIV test done after the exposure.
- The exposure is to body fluids that are not infectious.

Infective fluids	Blood or any blood-stained fluids, tissue or other material; vaginal secretions or penile
	per-ejaculate and semen; fluid from any body cavity such as pleural, pericardial, amniotic,
	peritoneal, synovial and cerebrospinal fluids; any other fluids, excretions or secretions that are visibly blood-stained; breast milk
Non infective fluids	Saliva, urine, stools, vomiting, tears, sputum, sweat (Not blood stained)

Table 1 HIV risk evaluation after AEB and indications for PEP

Type of exposure	HIV status of source								
	Positive	Unknown*	Negative High Risk**	Negative Low Risk					
Percutaneous exposure to infectious fluids	PEP	PEP	PEP	No PEP					
Mucous membrane exposure to infectious fluids	PEP	PEP	PEP	No PEP					
Mucous membrane exposure to non-infectious fluids	No PEP	No PEP	No PEP	No PEP					
Intact skin exposure to any fluids	No PEP	No PEP	No PEP	No PEP					

^{*} For example undetermined clinical examination or the source person is not present

It is essential that the exposed person is medically monitored whether or not she is taking the prophylaxis (chapters 10 and 11). If in doubt whether PEP is required, start PEP and consult a HIV specialist or staff health contacts (see Appendix 3).

^{**} Source is in a high risk group (e.g. commercial sex worker, men who have sex with men, injecting drug user, high risk sexual behaviour) or comes from a country where HIV prevalence is >1%.

8. Post exposure prophylaxis (PEP) regimens against HIV

Start PEP within 4 hours after an AEB and certainly within 72 hours. Do NOT delay initiation of PEP to take blood tests or because of unavailability of laboratory. Treatment after 72 hours may be considered in case of massive exposure – a situation that requires the opinion of an HIV specialist (chapter 13).

SOURCE PATIENT HAS NEVER BEEN ON ANTIRETROVIRAL TREATMENT (ART)

[Tenofovir 300 mg/Lamivudine 300 mg/Dolutegravir 50 mg⁴] 1 tab. once/day for 28 days

The fixed dose combination (FDC) of **tenofovir/lamivudine/dolutegravir (TDF/3TC/DTG or TLD)** has a high genetic barrier, low pill burden (1 tablet/day), and excellent tolerance and safety (much better than alternative PEP options).

Source patient already exposed to ART

If the medical history of the source patient is available, review cautiously all antiretroviral drugs received in the past and efficacy of current ART (viral load). Review any past genotypes for resistance to any antiretroviral drug. If resistance is present at any time, or if there is a history of treatment failure, the concerned ARV drug(s) should not be used.

• If there is no history of prior treatment failure on, or genotypic resistance to, tenofovir or dolutegravir, or if the source patient has a recent (<1 month) undetectable viral load on tenofovir/lamivudine/dolutegravir, prescribe TLD for 28 days:

[TDF 300 mg + 3TC 300 mg + DTG 50 mg] FDC, one tab. once/day for 28 days

• If medical history is unclear or unavailable, ARV treatment history is difficult, lengthy or impossible to obtain, adherence is uncertain or viral load unknown, PEP should contain at least one drug that the patient has never received. In this case we add Darunavir/ritonavir (DRV/r, an ARV used in 3rd line ART) to TLD:

[TDF 300 mg + 3TC 300 mg + DTG 50 mg] FDC, one tablet once/day, AND

[Darunavir 400 mg 2 tab. (or 800 mg 1 tab.) + ritonavir 100 mg 1 tab.] once/day, to be taken with food

This treatment can be simplified according to the patient's ARV treatment history and efficacy when available.

ALTERNATIVE REGIMENS

If TLD is not available or contra-indicated the following alternatives are recommended.

- If TDF is not available or there is known abnormal renal function and Hb is > 8g/dl substitute TLD with [Zidovudine (AZT) 300mg + Lamivudine (3TC) 150 mg] one tab. 2x/day + DTG 50 mg one tab. once/day.
- If DTG is not available substitute with:
 - o [Atazanavir 300mg + ritonavir 100mg (ATV/r)] 1 tab. once/day, OR
 - [Lopinavir 200mg + ritonavir 50mg (LPV/r)] 2 tab. 2x/day, OR
 - o [Darunavir 400 mg 2 tab. (or 800 mg 1 tab.) + ritonavir 100 mg 1 tab] once/day, to be taken with food

CONTRA-INDICATIONS

Zidovudine (AZT) can cause severe anaemia and should not be used if Hb < 8 g/dL. Tenofovir is contra-indicated in people with renal failure if clearance of creatinine is < 30 mL/min. There is a very small potential increased risk of neural tube defects in embryos less than 8 weeks when dolutegravir is taken around the time of conception. Check that no early pregnancy is ongoing. If this is the case, explain the risks and offer the option of another prophylaxis (e.g. [TDF/3TC + DRV/r] once/day). All women of reproductive age will be offered contraception until the final serological status is obtained.

SIDE EFFECTS AND DRUG INTERACTIONS

Possible side-effects may occur mainly at the beginning of the treatment, and can include tiredness, insomnia, nausea and diarrhoea. The person taking the treatment should be informed that these may occur and **should be informed of the**

⁴ Currently the most prescribed first line regimen.

importance of not missing any doses and dissuaded from stopping the treatment as most side effects are mild and transient, though possibly uncomfortable.

Zidovudine (AZT) can cause severe anaemia, leucopoenia and thrombocytopenia. Monitor haemoglobin and contact HIV specialist if drop in Hb. AZT can also cause nausea, vomiting, fatigue, headaches.

TLD is generally very well tolerated. Occasionally nausea, diarrhoea, tiredness or insomnia can occur.

DRV/r can cause nausea, diarrhoea, headache, rarely severe cutaneous drug eruption or hepatitis. Advise patients to contact the prescribing physician immediately if a skin rash develops. Caution is recommended for persons with known allergy to sulfamides. Monitor liver function tests, especially if patient already has liver disease.

Antiemetics (e.g. metoclopramide or dimenhydrinate) may be prescribed in case of nausea or vomiting.

Completion of 28 days of PEP without missing doses is essential for efficacy of PEP.

Advise the patient to contact the doctor immediately if side effects become severe or difficult to tolerate.

Always enquire about current medication of the exposed patient and check for drug interactions. Consult an HIV specialist if the exposed patient is on medication with significant interactions with PEP.

Rifampicin significantly reduces the levels of lopinavir/ritonavir (LPV/r), atazanavir (ATV), and dolutegravir (DTG). Darunavir is contra-indicated with rifampicin. If the exposed person is on rifampicin, increase the dose of LPV/r, double the dose of dolutegravir (DTG) to 50 mg twice daily and do not use ATV or DRV.

CONDITIONS FOR MANAGEMENT OF PEP IN THE FIELD

A PEP kit with antiretroviral treatment should be present at every clinical site where MSF works, so that PEP can be started as soon as possible after the exposure.

Treatment can be completed in the field if the conditions required for follow-up of the exposed person are available:

- There is a medical doctor on site who can supervise the treatment and follow up;
- The exposed person and the doctor agree that this is the best approach;
- Laboratory testing for HIV (incl. confirmation tests), HCV and HBV are performed within 8 days, at 6 and 12 weeks after
 exposure (Chapter 11). This requires every mission to identify whether tests are available locally or regionally. This is also
 required for insurance purposes.
- Serum creatinine and liver function tests (ALAT) should be measured at the start of treatment wherever possible. ALAT will be repeated in case of risk of hepatitis. This is not absolutely necessary if a good clinical monitoring is ensured.

It is the responsibility of the medical coordinator to assess whether necessary conditions are met before allowing continuation of PEP in the field, to ensure a buffer stock of PEP kits, and to replace expired and/or consumed kits.

PEP IN CHILDREN

Any sexual exposure in children is sexual violence. Consult the MSF Medical Protocol for Sexual Violence Care.

In the rare event of accidental exposure to blood or body fluids in children (e.g. cuts with contaminated needles or blood on open wounds) the same principles as for adults apply. However, PEP in children is complicated because paediatric formulations of ARVs are not always available. **Contact your HIV adviser to discuss best options. Dosages according to weight can be found in Appendix 1.**

AZT + 3TC + DTG is the preferred regimen for HIV PEP in children, with the addition of DRV/r for the same indications as in adults. As paediatric formulations will not always be available consider alternatives below.

ABC + 3TC or TDF + 3TC (or FTC) can be used as alternatives to AZT + 3TC.

ATV/r, DRV/r, LPV/r and RAL can be used as alternatives to DTG.

TDF and ATV/r are contra-indicated in children <30 kg.

ABC should be avoided if possible, as there is a small risk of severe hypersensitivity reactions.

9. Post Exposure Measures against Hepatitis B and C

HEPATITIS B

All MSF medical staff must be vaccinated against Hepatitis B virus (chapter 3).

Blood contains the highest HBV titres of all body fluids and is the most important vehicle of transmission in health-care settings. HBsAg is also found in several other body fluids (including breast milk, bile, cerebrospinal fluid, faeces, nasopharyngeal washings, saliva, semen, sweat, and synovial fluid) which are not efficient vehicles of transmission because they contain low quantities of infectious HBV, despite the presence of HBsAg.

HBV has been demonstrated to survive in dried blood at room temperature on environmental surfaces for at least 1 week

Although percutaneous injuries are among the most efficient modes of HBV transmission, these exposures probably account for only a minority of HBV infections among the staff. In several investigations of nosocomial hepatitis B outbreaks, most infected health staff could not recall an overt percutaneous injury⁵.

The risk of acquiring HBV through a percutaneous exposure has been reported to be approximately 30 per cent if the source has chronic HBV. The use of post-exposure prophylaxis with hepatitis B vaccine and/or immunoglobulins (HBIG) can reduce HBV transmission by 70 to 90 per cent when administered within 12 to 24 hours of an exposure.

Post-exposure hepatitis B vaccination should be initiated (1st dose) for all persons at risk of exposure regardless of hepatitis B vaccination history, and should not be delayed while waiting for hepatitis B serology results (if available).

If evidence of protective Ab titre (Anti HBs >10 UI/ml) is not available take a blood sample (from the exposed person) for hepatitis B surface antibody (anti-HBs), hepatitis B core antibody (anti-HBc), and hepatitis B surface antigen (HBsAg) as soon as possible after the exposure. If the results of the blood sample show protective Ab (Anti HBs >10 UI/ml) the management at subsequent controls can be adapted according to recommendations (see table 2).

TABLE 2 HEPATITIS B RISK EVALUATION AFTER AEB AND INDICATIONS FOR PEP

			Vacc	nation status of the ex	cposed person	
		Fully	vaccinated (with docu	Partially vaccinated (with documentation)	Not vaccinated/ vaccination status not documented	
		Anti-HBs >10 UI/mI	Anti-HBs <10 UI/ml ^a	Anti-HBs unknown		
of the	HBsAg Negative	No intervention	Full vaccination ^b	1 booster dose*	Complete vaccination ^c	Full vaccination ^b
HBsAg status source	HBsAg Positive or Unknown	No intervention	Rapid schedule vaccination* ^e Immunoglobulins ^d			

a. Non-responder to HBV vaccine; b. Provide 3-dose schedule: day 0, 1 month, 6 months; c. Resume vaccination schedule in order to complete the three doses (day 0, 1 month, 6 months). d. Give 1 dose of hepatitis B immunoglobulin (100 IU) with the first dose of vaccine and in a separate location; e. Rapid schedule vaccination: day 0, 7, 21 days and 12 months. * If the results of the blood sample when available shows protective Ab (Anti HBs >10 UI/mI) there is no need to administer additional vaccine doses at the follow up visits.

10

⁵ https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm

Note: In case the source is HBsAg positive or unknown and the exposed person has documentation of 3-dose vaccination **but anti-HBs titre unknown,** the administration of immunoglobulin can be delayed of few hours if the blood results can be available the same day.

If the exposed person is HIV positive, hepatitis B vaccine antigen should be doubled (20 to 40 mcgr per dose) to improve immunological response, especially if CD4 are low.

Staff vaccinated with rapid schedule should receive one dose at 12 months. Without this 4th dose, long-lasting immunity cannot be assured (0, 7, 21 days and 1 year).

In case vaccination or a booster dose was administered because Anti-HBs titre was unknown or <10 UI/ml, the serology test needs to be performed 4-8 weeks after the last dose of the vaccine. Follow up is not needed if the exposed person is immune (anti-HBs >10 UI/ml).

HEPATITIS C

There is no prophylactic treatment or vaccine but there is effective treatment for hepatitis C. If there is seroconversion to hepatitis C virus, perform a HCV viremia. HCV treatment will be started if viremia lasts more than 3-6 months. Direct Acting Antiviral (DAA) can be started in the field. Contact the medical department.

10. Counselling

PEP studies report low completion rates in all populations, especially in adolescents and following sexual assault. During a confidential encounter with the exposed person, the following points should be addressed:

- Management of anxiety is always to be taken seriously and may need more than one counselling session.
- Prescription of PEP depends on the exposure and the HIV status of the source patient.
- Explain that the risk, even with a significant exposure, is still very low if PEP is taken correctly and timeously. The average risk of HIV transmission after percutaneous exposure is very small (0.3%) and PEP significantly further reduces this risk of HIV transmission (estimated >80% risk reduction).
- PEP is most effective when:
 - Started less than 4 hours after AEB;
 - No doses of ARVs are missed;
 - o The full 28 day course is completed;
 - The exposed person does not engage in high risk activities (unsafe sex, IVDU etc.)
- Explain the drugs, their side effects and the timeline for the process in the future. Side effects can cause some discomfort, but are usually mild and transient and shouldn't lead to stop PEP. Serious side effects are very rare (hepatitis, severe rash) and can be detected with lab tests or clinical examination. Encourage the patient to return if side effects are unmanageable, rather than stopping the medication.
- The exposed person should use condoms during 3 months after AEB to protect partners from possible infection.
- For insurance reasons, it is strongly recommended to perform blood tests within 8 days after the exposure. This is a medico-legal requirement to confirm that an eventual seroconversion was due to the work accident, and is required for compensation. It is essential that the serology monitoring timetable is adhered to.
- Laboratory results must be kept by the exposed person and in the medical file.

An information sheet covering the PEP and follow-up after any AEB (see Appendix 6) is given to the exposed person.

Counselling and testing should also be offered to the source patient, especially if the HIV, HBV or HCV status is unknown.

11. FOLLOW UP OF AN EXPOSED PERSON

Whether PEP prophylaxis has been started or not, it is important to set up medical follow-up in order to encourage treatment compliance, monitor any side effects or any infections linked with HIV, HBV, HCV (see table 3). This includes clinical follow up and laboratory tests. It is a medico-legal requirement to perform blood tests within 8 days after the accidental exposure and again at 6 and 12 weeks, to confirm that an eventual seroconversion is due to the occupational exposure. It is essential that the serology monitoring timetable is adhered to.

LABORATORY MONITORING⁶

	PEP given	No PEP given ³
	HIV ² & HCV rapid test or serology;	
Day 1 – 7 ¹	HBV : If anti-HBs <10 UI/ml or unknown, test for anti-HBs, anti-HBc & HBsAg as soon as possible after exposure.	HIV ² & HCV rapid test or serology;
	Creatinine clairance ⁴ , pregnancy test	
	ALAT if on DRV/r or ATV/r; Hb if on AZT	
Day 14	Creatinine clearance ⁴ ; ALAT if on DRV/r	
Week 6	HIV ⁵ ; HCV RNA if source HCV RNA+ ALAT if on DRV/r or ATV/r; Hb if on AZT	HIV
Month 3	HIV ² & HCV rapid test or serology; Anti-HBs titre must be checked 4-8 weeks after the last dose of vaccine. HBsAg if non-immune at baseline.	HIV ² & HCV rapid test or serology; HBsAg if non-immune at baseline.

Anti-HBs: hepatitis B surface antibody; anti-HBc: hepatitis B core antibody; HBsAg: hepatitis B surface antigen

- 1. The tests between D0 and D7 are mandatory for the accident to be recognized as professional and for insurance purpose. **Only the tests in bold are absolutely necessary.** If the other tests are not available, it is acceptable to manage PEP without doing them.
- 2. Follow MSF/WHO guidelines⁶. Confirmation of HIV+ status requires 3 different positive HIV rapid tests.
- 3. Serological follow up for HBV is not needed if person immune to HBV (Anti HBs >10 UI/ml). Anti-HBs titre must be checked and documented 8 weeks after the last dose of vaccine.
- 4. TDF rarely causes renal failure. If creatinine is not available, clinical monitoring is acceptable.
- 5. The HIV test done at 6 weeks if negative can reassure the exposed person. However, it does not fully guarantee an absence of future seroconversion especially in persons under ARV prophylaxis where the immune response might be deferred.
- 6. Rapid tests for HIV, HBV and HCV should be present in every project. If the rapid tests cannot be performed locally (HIV, HCV, Ag HBs) coagulated blood can be sent to a referral laboratory ensuring the cold chain is maintained (4-8°C). Ensure at capital level which tests can be done and where (if in different laboratories, take several tubes).

CLINICAL FOLLOW-UP

- Clinical follow-up of tolerance to PEP: Review the patient after 8 days and 1 month.
- Clinical follow-up of signs of seroconversion:

Whether PEP is taken or not, in the weeks following an AEB, the exposed person must be monitored for signs and symptoms of acute HIV infection: acute fever, generalized lymphadenopathy, cutaneous eruption, pharyngitis, non-specific flu symptoms, and ulcers in the mouth or genital area. These symptoms appear in 50-70% of individuals with an HIV primo-infection and almost always within 3 to 6 weeks of exposure.

⁶ https://www.who.int/publications/i/item/consolidated-guidelines-on-hiv-testing-services-for-a-changing-epidemic

The exposed person must also be monitored for signs of hepatitis B (if they have not been vaccinated against HBV) or hepatitis C. Transaminase levels can be useful for this.

• Psychological care and emotional support:

An AEB and the prescription of PEP can cause great anxiety for the person concerned. The medical doctor should ensure psychological and emotional support through active listening and regular check-ins. Repatriation must be proposed to expatriate staff with a new diagnosis of HIV, HBV or HCV.

• Adherence Support

It can be difficult to complete a full course of PEP, encouragement and support of the exposed person needs to be provided in order to maximise adherence. TLD and TLD+DRV/r have been shown to have the best completion rates due to good tolerability and once a day dosing.

12. Sexual Exposure to Blood or Body Fluids and Sexual Violence

The risk of HIV transmission after a single occurrence of unprotected sex is small but real, of the same magnitude as the risk after a percutaneous exposure. PEP could be required after a risk evaluation.

Sexual violence, including rape, presents a higher risk of HIV and STDs transmission because of traumatic lesions of genital mucous membranes. Consult detailed guidance in the **MSF Medical Protocol for Sexual Violence Care 2020**.

In the case of unprotected sex or condom tear/slip, the risk of HIV transmission must be assessed according the status of the source (HIV, HBV and STIs), type of exposure, and type of fluids. The risk of transmission is highest with anal receptive intercourse, followed by vaginal receptive, then vaginal penetrative. The risk is very low with oral sex. Infectious fluids include semen, vaginal fluid, and blood. Mucosal lesions, inflammation and sexually transmitted infections increase the risk of transmission of HIV and HBV. PEP should be proposed on a case-by-case basis and must be in line with the measures and procedures for an AEB. Other prophylactic regimens can also be proposed (post-coital contraception and presumptive STI treatment). If such exposures are recurrent, discuss risks and modes of prevention.

Post exposure prophylaxis in case of sexual exposure, including sexual violence:

- a) The same measures and procedures as for the **provision of PEP** after AEB should be applied. Repatriation or referral to a specialized centre is highly recommended. Psychological support after sexual violence is of the utmost importance.
- b) Provide Emergency contraception within 120 hours after sexual exposure: Levonorgestrel 1.5 mg 1 tab.
- c) Other sexually transmitted infections (STIs) may be transmitted as a result of rape and STI treatment may also be indicated (immediately or a few days after PEP and post-coital contraception to avoid additive gastro-intestinal side-effects).

Table 3. Prophylactic treatment of STIs for adults and adolescents > 45 kg

Gonorrhoea	Ceftriaxone 250 mg IM stat OR cefixime 400 mg PO stat (2 nd choice)
Chlamydia, syphilis and chancroid	Azithromycin 2 g PO stat
Trichomoniasis	Tinidazole 2 g PO stat OR metronidazole 2 g PO stat (2 nd choice)

13. ADMINISTRATIVE PROCEDURES

CONFIDENTIALITY must be respected in the notification of an AEB, even during emergencies and stressful situations. This applies to everyone in the field, country capital and headquarters. To ensure confidentiality when forms are sent by email: Enter "Confidential" in the subject line, then in the message options mark "high importance", then "confirm delivery", "delivery priority high" and "delivery receipt".

After first aid, the AEB must be reported by the exposed person to the project's doctor responsible for PEP in order to take a medical decision as quickly as possible. The doctor should then report the accident to the country medical coordinator who will inform the responsible for PEP at headquarters.

In every case of accidental exposure to blood, whether or not PEP was prescribed, there are a number of administrative forms to be filled. AEB is an occupational injury and gives the exposed person specific benefits in most social protection systems and through MSF's own insurances. To obtain these benefits the accident must be reported officially within a very short time-span.

Refer to the appendices for detailed description of administrative procedures and forms.

14. FINANCIAL ASPECTS

As with all medical issues CONFIDENTIALITY in the administrative handling of reimbursements must be respected.

- The costs of repatriation or referral to a specialized centre are met by MSF or covered by the insurance. This includes the cost of treatment, tests, etc. The exposed person is then considered to be on sick leave.
 - For international staff, costs incurred in the field and once back home will be paid directly by the staff member and reimbursed by the social security and/or insurance (as with all other health costs). <u>OCP:</u> For reimbursement of any outstanding costs, the international staff member should contact the HRA in charge of insurance matters in Human Resources department (Elsa Fibleuil, HRA: +33 (0)1 40 21 27 87, e-mail: elsa.fibleuil@paris.msf.org).
 - For national staff, payment of costs will be organized according to the system in place in the project. However, it is recommended that any costs not covered by these policies and insurance be met by MSF.

It is particularly important to show flexibility in handling this kind of occupational accident, as they often cause considerable stress to the people concerned. In all cases, any costs not covered by the social security system or by the insurance, will be met by MSF.

15. SUPPLY

AVAILABILITY AND ORDERING OF PEP KITS

Two PEP kits each containing 28 days of ARVs available in each clinic site and project/coordination office. The coordinator at capital level must send a replacement PEP kit to the field in case another AEB occurs or the drugs in the kit get expired.

These kits (KMEDMPEP03- MODULE, PEP, post exposure prophylaxis 2021) contain the Guidelines on Post-Exposure Prophylaxis after Accidental Exposure to Blood or Body Fluids and the following antiretroviral medicines:

- DORATELD1TPEP: 30 tablets of Tenofovir 300 mg/Lamivudine 300 mg/Dolutegravir 50 mg
- DORATELA1T-: 30 tablets of Tenofovir 300 mg/Lamivudine 300 mg
- DORADARU4T-: 60 tablets of Darunavir 400 mg (or 30 tablets of 800 mg) to be boosted by
- DORARITO1T2: 30 tablets of Ritonavir 100 mg

A sufficient quantity of ARVs is to be kept in the central stock to restock the field kit after use.

Projects and missions can order the PEP KIT with code: KMEDMPEP03- MODULE, PEP, post exposure prophylaxis 2021. For further supply, it is recommended to include the ARV order in the standard international order and that the teams make sure there is a buffer stock as for any drug.

In countries where there is an HIV/AIDS project, the drug module can be taken from the project only if sources are WHO prequalified. **OCP:** In countries that cannot import ARV drugs, orders should clearly specified "to be sent through the departure box from Paris headquarters". In this case no generic drugs will be provided.

Immunoglobulins against hepatitis B must be accessible in every project, either stocked by MSF [code DVACIMHB1V--IMMUNOGLOBULIN HUMAN HEPATITIS B, 180 IU/ml, 1ml, vial] or by an external provider (e.g. private clinic). Immunoglobulins are expensive and need to be stored at 8 degrees Celsius and thus need cold chain for transport. Therefore, an external provider is preferable, if the quality of storage and cold chain can be verified.

STOCK MANAGEMENT

The drugs have a shelf-life of two years. They should be stored at room temperature (between 2° and 30°C) in a dry place away from direct light. The medical coordinators are responsible for supervising stock management and should keep a watch on expiry dates and storage conditions.

16. REFERENCES

- 1. Cardo D.M., Culver D.H., Ciesielski CA. et al. A case control study of HIV seroconversion in health-care workers after percutaneous exposure. N Engl J Med, 337: 1485-1490, 1997.
- 2. Updated US Public Health Service Guidelines for the Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendations for Post exposure Prophylaxis. 2013. https://www.jstor.org/stable/pdf/10.1086/672271.pdf?refreqid=excelsior%3A082000002f139772660aa71dcff6308e
- 3. Rapport Morlat 2019 : Prise en charge des accidents d'exposition sexuelle et au sang (AES) chez l'adulte et l'enfant (mise à jour septembre 2017) https://cns.sante.fr/wp-content/uploads/2017/10/experts-vih_aes.pdf
- 4. WHO 2018. Updated recommendations on first and second lines antiretroviral regimens and post-exposure prophylaxis and recommendations on early infant diagnosis of HIV. Supplement to the 2016 consolidated guideline. https://apps.who.int/iris/bitstream/handle/10665/277395/WHO-CDS-HIV-18.51-eng.pdf?ua=1

17. APPENDIXES

APPENDIX 1. DOSAGE OF ARVS FOR PEP ACCORDING TO WEIGHT

		HIV PEP dosage	s for adults, children and adolescents	> 30 kg ⁷				
	Preferred regimen		Alternative regimens					
Drug	Dose	Frequency	Drug	Frequency				
Tenofovir (TDF)/ 300 mg/ 300 mg 1 tablet once a Zidovu		Zidovudine (AZT) ⁹ / lamivudine (3TC)	300 mg/ 150 mg	1 tablet twice a day				
lamivudine (3TC) ⁸	AND	day		AND				
			Atazanavir (ATV)/ritonavir (r)	300 mg/ 100 mg	1 tablet once a day			
			or					
			Lopinavir (LPV)/ ritonavir(r)	200 mg/ 50 mg	2 tablets twice a day			
Dolutegravir (DTG)	50 mg	1 tablet once a	or					
Dolategravii (D10)	30 1118	day	Darunavir (DRV)/ritonavir (r)	DRV 400 mg +	(2 tablets of DRV + 1 tablet of			
			Dardilavii (Ditv)/Titoliavii (I)	RTV 100 mg	RTV) once a day			
				or				
			Raltegravir (RAL)	400 mg	1 tablet twice a day			

⁷ Children >30kg should be given **TLD**: **T**enofovir (TDF), **L**amivudine (3TC) and **D**olutegravir (DTG)

⁸ Tenofovir (TDF)/lamivudine (3TC)/dolutegravir (DTG) can be offered in a fixed dose combination or separate tablets. Fixed dose combinations are preferable for improved adherence.

⁹ AZT is contra-indicated in children with anaemia. In that case, consider individualized management of the regimen (options could include for example: DTG-3TC).

				HIV PEP do	sages for children 2	0 to 30 kg								
	Prefer	red regimen				Alterna	tive regimens							
	20-24	4.9 kg	2	5-30 kg		20-24.9	9 kg	2	5-30 kg					
Drug	Dose	Frequency	Dose	Frequency	Drug	Drug Dose Frequency		Dose	Frequency					
Zidovudine/ lamivudine	Dispersible tablet	3 tablets	300/150	1 tablet twice	Abacavir (ABC)/	Dispersible tablet 120/60 mg	1.5 tablets twice a day	600/300	0.5 tablet twice					
(AZT/3TC)	60/30 mg	twice a day	mg	a day	lamivudine (3TC) ¹⁰	Dispersible tablet 60/30 mg	3 tablets twice a day	mg	a day					
		And					And							
				1 tablet once a day	Atazanavir (ATV)/ ritonavir (r)	ATV capsules 200 mg + r tablets 100 mg	1 ATV tablet + 1 r tablet once a day	300/100 mg	1 tablet once a day					
			50 mg		Or									
						Tablet 100/25 mg	2 tablets twice a day	100/25 mg	3 tablets twice a day					
		1 tablet once a day			Lopinavir (LPV)/ ritonavir (r)	Tablet 200/50 mg	1 tablet twice a day	200/50 mg	2 tablets in the morning, 1 tablet at night					
Dolutegravir (DTG)	50 mg					Pellets or granules 40/10 mg	6 pellets or granules twice a day	-	-					
						Syrup 80/20 mg/ml	3 mL twice a day	-	-					
					Or									
										Darunavir (DRV)/ ritonavir (r)	DRV 75 mg + r 25 mg	5 DRV tablets and 2 r tablets twice a day	400 mg/ 100 mg	(1 DRV tablet + 1 r tablet) twice a day
							Or							
					Raltegravir (RAL)	Chewable tabs 25mg	6 tablets twice a day	400 mg tablets	1 tablet twice a day					

¹⁰ There is no experience on ABC use in HIV negative children and Abacavir can cause life-threatening hypersensitivity reactions in people with the HLA-B*5701 allele gene. While hypersensitivity can affect 3–4% of Caucasian and Asian children, it is very rare among African children. The potential use of ABC in the PEP regimen while contraindicated in Asian and Caucasian descent, it could be considered in children of African origin. It should be discussed with your HIV/TB advisor.

	HIV PEP dosages for children < 20 kg																					
				Alternative regimens																		
		ı	Numb	er of ta	blets an	d frequ	ency l	y weigh	t				Num	ber of ta	blets an	d freque	ncy by w	eight/				
Drug	Dose	3-5.9	kg	6-9.9	kg	10-13 kg	.9	14-19.9	9 kg	Drug	Drug Dose		Drug Dose 3		Dose 3-5.9 kg		6-9.9 kg		10-13.9 kg		14-19.9 kg	
		- <u>`</u> Ċ-	C	- <u>`</u> Ċ-	C	- <u>`</u> Ċ-	C	- <u>`</u> Ċ-	C			-;Ċ;-	C	- <u>;</u> Ċ-	C	- <u>`</u> Ċ;-	C	- <u>;</u> Ċ-	C			
Zidovudine (AZT)/ lamivudine (3TC) ¹³	Dispersible tablet 60mg/30mg	1	1	1.5	1.5	2	2	2.5	2.5	Abacavir (ABC)/ lamivudine (3TC) ¹¹ 12	Dispersible tablet 12 mg/60	0 0.5	0.5	0.5	1	1	1	1	1.5			
	AND																					
Dolutegravir scored dispersible tab. (DTG DT) ¹³	10 mg	0.5 tab.		1.5 tab.		2 tab.		2.5 tab.		Atazanavir (ATV)/ ritonavir (r) ¹⁴	(ATV)/ ritonavir ATV 15 capsules 200 mg+ r Tablet 100 mg		1 ATV	1 ATV + 1 r 1		1 ATV + 1 r						
										OR												
Lopinavir	Pellets or granules 40 mg/10 mg	2	2	3	3	4	4	5	5													
(LPV)/ ritonavir (r) ¹⁶	Tablet 100 mg/25 mg	-	-	-	-	2	1	2	2	Raltegravir	10 mg/ml (oral altegravir granules 100		2	ml		3 ml						
	200 mg/50 mg	-	-	- -	-			1	1	(RAL) mg/ sachet)		g/ sachet) 3 ml			3 1111		5 ml					

¹¹ Lamivudine (3TC) and emtricitabine (FTC) are interchangeable

¹² There is no experience on ABC use in HIV negative children and therefore not recommended in principle. In addition, Abacavir can cause life-threatening hypersensitivity reactions in people with the HLA-B*5701 allele gene. While hypersensitivity can affect 3–4% of Caucasian and Asian children, it is very rare among African children. The potential use of ABC in the PEP regimen while contraindicated in Asian and Caucasian descent, it could be considered in children of African origin. It should be discussed with your HIV/TB advisor.

 $^{^{13}}$ Generic DTG scored dispersible tablets are expected to be available in the course of 2021

¹⁴ Atazanavir (ATV) is only approved for use in children 3 months and older. Atazanavir (ATV) single strength capsules should be administered with RTV 100 mg for all weight bands. Atazanavir (ATV) powder formulation has limited availability in low- and middle-income countries but enables administration of Atazanavir (ATV) to infants and children as young as 3 months. Infants and children 5-15 kg should be administered 200 mg of Atazanavir (ATV) powder (4 packets, 50 mg/ packet) with 80 mg of ritonavir (RTV) oral solution (1 ml). (WHO, December 2018. Interim guidelines. Updated recommendations on first-line and second-line antiretroviral regimens and post-exposure prophylaxis and recommendations on early infant diagnosis of HIV)

¹⁵ Atazanavir (ATV)/ritonavir (r) can be given in multiple combinations of ATV 100 mg, ATV 200 mg, Ritonavir (RTV) 25 mg and Ritonavir (RTV) 50 mg, as long as the correct dosages are given.

¹⁶ Lopinavir (LPV)/ ritonavir (r), Atazanavir (ATV)/ritonavir (r) or Raltegravir (RAL) should be changed to Dolutegravir (DTG) as soon as DTG DT 10 mg becomes available.

APPENDIX 2: UNIVERSAL PRECAUTIONS TO BE TAKEN DURING HEALTH CARE

Standard precautions are intended to prevent exposure of medical personnel and patients to blood-borne pathogens. They must be observed for everything concerning blood and body fluids of all patients, regardless of their level of infection.

These universal precautions include:

- Proper use of protections designed to prevent direct contact with blood and body fluids (gloves, masks, apron glasses and boots);
- Safe handling and removal of sharp waste: never recap needles, use needle containers for sharp / cutting edges;
- Decontamination of instruments;
- Hand washing after any medical procedure;
- During an accidental cut or scratch, cover and protect the injury;
- Safe handling and disposal of sharp edges.

For more details, see:

- 1. Bouvet E et al. *Politique de prévention des AES*, in: *Accident d'exposition au VIH*. *Bases scientifiques et recommandations pour la prise en charge*, Bash éditions médicales, 1999.
- 2. CDC. Perspective in disease prevention and health promotion update: Universal precautions for prevention of transmission of VIH, VHB and other blood-borne pathogens in health-care settings, MMWR 37;377-88. 1988.
- 3. Actualisation des précautions standard. 2017. SF2H. Risques infectieux et soins. https://sf2h.net/wp-content/uploads/2017/06/HY XXV PS versionSF2H.pdf

APPENDIX 3: ADMINISTRATIVE PROCEDURES AFTER AEB

All OCs

For medico-legal and insurance purposes, every AEB of a national or international staff must be notified as a work accident as soon as possible after the exposure, regardless of whether PEP is given or not.

A confidential **notification form** is to be filled in by the medical doctor in charge of PEP.

- International (expatriate) staff: the <u>notification form</u> has to be sent to headquarters, and <u>a</u>
 <u>copy</u> kept by the exposed person and <u>another copy</u> by the Medco in the staff's medical file.
- National staff: the <u>notification form</u> is to be sent to the medical coordinator and kept in the staff's medical file and <u>a copy</u> kept by the exposed person.

Procedures vary by operational centres and contracting sections, but most insurance companies need to be notified on a work accident within 48-72 hours, whether PEP was started or not.

The exposed person must receive the <u>information sheet</u> on prophylaxis and medical follow-up after the AEB (Appendix 4). It is the duty of the doctor responsible for staff health to explain the content and to make sure the exposed person understands fully the importance of medical follow up, including tests to be done at baseline, 6 and 12 weeks. The <u>test results</u> will be kept confidentially in the medical file and <u>a copy</u> kept by the exposed staff.

If PEP was recommended, an <u>informed consent/refusal form</u> must be filled in and signed by the exposed person and countersigned by the doctor.

The exposed person may be unable to work for the first few days (e.g. due to anxiety or side-effects of PEP) and is entitled to sick leave if needed. The same applies for any medical event occurring during the follow up period. If so, a medical certificate has to be signed by the doctor responsible for staff health as per the usual medical and HR procedures. The HRCO should ensure that the administrative follow up (e.g. insurance, reimbursement of medical care, etc.) for national and international staff still on mission is supported.

At the end of the mission and/or employment, the staff member will receive the original forms from the Medco along with his/her complete medical file.

OCP

When the accident involves an international (expatriate) staff, <u>an identified copy (name) of the notification form</u> has to be sent as soon as possible to the HR department (Elsa Fibleuil: <u>elsa.fibleuil@paris.msf.org</u>; +33 1 40 21 27 87). The <u>original</u> is handed over to the exposed person.

When the accident involves a national staff, <u>an identified copy</u> has to be sent to the MedCo, who will liaise with the finco as soon as possible in order to start the process of notification to the local insurance. The original is handed over to the exposed person.

In both cases, <u>a copy of the notification form</u> is sent to the OCP Staff Health Unit (<u>Paris-sante-focalpoint@paris.msf.org</u>; +33 1 40 21 27 67)

For international (expatriate) staff, regardless of nationality, ALWAYS contact the person in charge of insurance matters in Human Resources department, either by e-mail or telephone (Elsa Fibleuil). If Elsa is absent, inform someone else in her team who will assess how urgently the administrative documents need to be forwarded. Give the first and last name of the person involved in the accident, as well as their date of birth, the date, time

and place of the accident and the name of the doctor signing the AEB medical certificate. No other medical information is required at this stage. This information must be received within 48 hours so that the necessary notifications can be made in due time.

For international staff, send the <u>informed consent/refusal form</u> to Elsa Fibleuil (HRA) in a sealed envelope marked "Confidential". For national staff <u>a copy</u> should be kept by the country medical coordinator in the staff's personal medical file.

All OCs

Exposed staff (national or international) should report immediately to a field doctor. The doctor should contact the Medical coordinator immediately by e-mail or phone; (s)he will help to evaluate the degree of emergency. All the administrative documents for occupational accidents should be available in the field and should be filled whether or not PEP has been initiated (surname, first name and date of birth of the exposed person, and date, time and place of the accident must be provided by the field). The name of the doctor signing the AEB medical certificate is also required. No other medical information is required at this stage.

The Insurance Company must be informed of any incident involving a salaried expatriate so that a file can be opened within 72 hours of the accident. This is why the accident should be reported by email to the Health Staff Unit as soon as possible. Ensure serological follow up of the exposed person in the field before day 8, at month 3 and month 6.

The medical responsible in the project site must immediately inform the MedCo, who then informs the Staff Health Unit (SHU) in Amsterdam, Barcelona, Brussels or Geneva. Scans of the AEB notification form (Appendix 6) and the PEP treatment refusal/ consent form (Appendix 5) must be sent to the SHU, for both international and national staff.

Refusal of PEP: If the exposed person (national or international staff) has been advised to commence PEP but refuses (s)he should sign a <u>refusal form</u> (Appendix 5).

A copy of both documents should be kept by the concerned person

In case the person returns home, the follow up will be ensured by the SHU.

Staff Health Units:

- OCA: staffhealthunit.physical@amsterdam.msf.org; +31 20 520 8700
- OCB: staffhealthunit@brussels.msf.org; +32 2 474 75 51
- o OCBA: staffhealth@barcelona.msf.org; +34 68 129 0560
- o OCG: Staff-Health.GVA@geneva.msf.org; +41 22 849 8967
- OCP: Paris-sante-focalpoint@paris.msf.org +33 1 40 21 27 67

APPENDIX 4: INFORMATION SHEET ON PEP AND FOLLOW-UP AFTER AN AEB

The doctor assessed that there is a risk of transmission of HIV and/or hepatitis B infection as a result of this accident and that you should start PEP with antiretroviral medicines and/or hepatitis B vaccination and/or immunoglobulins, if you agree.

Key information on PEP:

- PEP must be started as soon as possible, preferably within 4 hours of the AEB (maximum 72 hours).
- The risk of HIV seroconversion after AEB is small. Administration of PEP significantly reduces this risk. A study showed that administration of a single ARV drug reduced the risk of seroconversion by 79%. PEP with triple ART reduces the risk even more.
- HIV PEP may cause minor side effects, especially nausea, headache, fatigue, malaise. If these appear, discuss them with your doctor.
- HIV PEP must be taken regularly once per day for four weeks;
- HIV PEP must be backed up by regular medical check-ups (see below);

Vaccination against hepatitis B effectively protects against acquisition of hepatitis B for most people.

To ensure that you are adequately protected it is important to measure the level of antibodies against hepatitis B after you have completed vaccination.

Complete vaccination requires 3 doses, at month 0, 2 and 6.

If you are exposed to hepatitis and you are not vaccinated (or not immune) a 4-dose rapid schedule vaccination is required (at day 0, 7, 21, and at 12 months).

Risk of transmission is further reduced with the use of immunoglobulins.

- You should use condoms until the results of the 12 weeks serology are known;
- You should use of efficient contraception until the results of 12 weeks serology are known;
- Requires your consent.

There is no preventive treatment for hepatitis C. However, there is a very effective treatment.

Blood tests for HIV, hepatitis B and C, as well as liver and kidney function are indicated at week 0, 1, 2, 6 and 12, depending on the circumstances.

APPENDIX 5: PEP TREATMENT INFORMED CONSENT/REFUSAL FORM

When PEP has been advised this form should be filled in and signed by the exposed person, and signed by the medical doctor in charge of PEP in the field. It must be sent to the Staff Health Unit or person in charge in headquarters or coordination for both national and international staff. A copy should be given to the exposed person.

Surname and first name of the exposed person:
Date of birth: Sex:
Date of the accident:
I, the undersigned,, hereby declare that:
 I have been informed about and understand the risk of infection, the preventive measures and the procedures to follow after an accidental exposure to body fluids or blood (AEB), as well as the effectiveness and side-effects of prophylactic treatment.
• I was offered prophylactic treatment (PEP) for HIV and (please select accordingly):
lacksquare I agree to follow this PEP for a total period of one month
☐ I agree to accept medical supervision
☐ I have decided <u>not</u> to take it
• I was offered prophylaxis to prevent hepatitis B and (please select accordingly):
☐ I agree to follow prophylactic booster, rapid vaccination and/or immunoglobulins
☐ I accept medical supervision
☐ I have decided <u>not</u> to take it
I was offered prophylaxis for any other diseases (please precise):
☐ I agree to follow this prophylactic treatment and I accept medical supervision
☐ I have decided <u>not</u> to take it
Date:
Name and signature of the exposed person:
Name and signature of the medical doctor in charge:

APPENDIX 6: AEB NOTIFICATION FORM (CONFIDENTIAL) Date:..../..../.... Country: Project: Surname and first name of exposed person (in capital letters)..... M/F Date of birth: Age: Staff: MSF contract: National International (please specify the contracting section):.... HQ Visitor Consultant Other:.... Non MSF contract (please specify): Profile (circle the appropriate word): Doctor: GP - Surgeon - Gyneco - Anesthetist - Other: ... \Box Paramedic: Nurse - Midwife - Other: ... П Cleaner - Laundry Staff - Sterilization Agent - Watsan - Logistician Lab technician -Other (specify)..... \Box Date and time of the accident: **Exposure to:** Blood \Box Other body fluid containing blood (please precise): \Box Other body fluid not containing blood (please precise): П If unknown, please explain why..... Type of exposure: Needle stick injury Cut with soiled instrument □ Splash in the eye(s) □ Splash in the mouth □ Splash on damaged skin □ Splash on plain skin Unprotected sexual contact □ Other type of exposure Precise activity when accident occurred: IV, IM or SC injection Taking samples of blood or other body fluids contaminated with blood Handling of blood or infectious body fluids Placement of a peripheral venous catheter Suturing During surgical intervention (e.g. cut, puncture, splash...) During obstetrical intervention П Suction of upper airways (nose, mouth, throat, bronchi) Manipulation of soiled linen \Box Manipulation of soiled medical or surgical instruments Manipulation of waste Other:

П

Describe the circumstances of the accident (for example how and why does it happen?):
Description of the wound:
If the accident involved a needle, specify □ hollow needle □ plain needle Size :
Protective equipment during accident: One pair of gloves Double pair of gloves Mask Goggles /glasses Apron Closed Shoes/Boots Measures taken immediately after the accident Rinsing with water Cleaning with water and soap Disinfection with
If Yes, describe facts (circumstances + Name, first name and address of the personal describe facts)
Health status of the source patient:
The source patient is identified Yes No
Patient of a high risk group (sex worker, injecting drug user) Yes No Unknown
HIV high serological prevalence setting > 1%? Yes No Unknown
HIV status of source patient Positive Unknown
Clinical assessment of the source patient reveals suspicion or presence of HIV infection within the previous six months or more? Yes No Unknown
If known HIV positive status – current treatment regimen, viral load, etc.:
Hepatitis B serological status of source patient is Positive Negative Unknown Hepatitis C serological status of source patient is Positive Negative Unknown
Clinical assessment and/or diagnostic tests reveal other relevant transmittable diseases? Yes: No
Medical status of the exposed person prior to the exposure:
HIV test done prior to exposure Yes No Unknown Date & result latest test: Unknown Date & result latest test: Unknown Date & result latest test: Hep B test done prior to exposure Yes No Unknown Date & result latest test:

			Vacci	exposed person		
		Fully vaccinated (with documentation)			Partially vaccinated (with documentation)	Not vaccinated/ vaccination status not documented
		Anti-HBs	Anti-HBs <10	Anti-HBs		
		>10 UI/ml	UI/mI	unknown		
HBsAg status of the source	HBsAg	No	Full vaccination	1 booster dose	Complete	Full vaccination
	Negative	intervention	Tuli vacciliation		vaccination	i dii vaccination
	HBsAg Positive or Unknown	No intervention	Rapid schedule vaccination Immunoglobulins	Rapid schedule vaccination Immunoglobulins	Rapid schedule vaccination Immunoglobulins	Rapid schedule vaccination Immunoglobulins

 HB	Immunoglobulin gi	ven: Yes	- No					
Post exposure	e prophylaxis:							
HIV post expo	osure prophylaxis	(HIV PEP):	Advised		Yes	No		
		(Prescribed		Yes	No		
				exposed person	Yes		No	
Type of HIV PEP prescribed: drugdrugdrug				mğtiı	mes/day			
Time elapsed	between the accid	dent and the b	eginning of HIV	PEP				
< 4h	between 4 and 2	bet	tween 24 and 48	h longer (sp	ecify):			
Follow-Up vac	cination and/or Titr	e result neede	d (if ves. specify):					
	ther vaccination or) e.g. Tetanus:	post-exposure	prophylaxis giver	n: 🛘 yes 🗖 no				
Post Exposure	e Tests Advised (mo	ore info in the	guideline)					
	PEP given			No PEP given				
Day 1 – 7	HIV & HCV rapid test or serology; HBV: If anti-HBs <10 UI/ml or unknown, test for anti-Hanti-HBc & HBsAg as soon as possible after exposure Creatinine clearance ⁴ , pregnancy test ALAT if on DRV/r or ATV/r; Hb if on AZT			HIV & HCV rapid test or serology;				
Day 14	Creatinine clearance	; ALAT if on DRV,	/r					
Week 6	HIV; HCV RNA if source HCV RNA+;			HIV				
Week 0	ALAT if on DRV/r or ATV/r; Hb if on AZT			IIIV				
Month 3	HIV & HCV rapid test or serology;			HIV & HCV rapid test of	or serology			
	Anti-HBs titre must l	be checked 4-8 v	HBsAg if non-immune at baseline					

Only the tests in bold are absolutely necessary. If the other tests are not available, it is acceptable to manage PEP without doing them. Original results should be kept in the medical record. Give a copy of the results to the exposed person.

Whenever tests turn out to be positive for HIV, HBV or HCV:

For international staff, please contact MSFOC Staff Health Unit

dose of vaccine; HBsAg if non-immune at baseline.

For national staff, please contact the Medical Coordinator for further follow up according to national policies.

Sick leave advised?	☐ Yes	□ No	If yes, number	r of days		
Medical Evacuation or Repatri	ation advise	ed/taken::	☐ yes	□ No		
Information:						
The exposed person						
□ Received the info	Received the information sheet on prophylaxis and follow-up after an AEB (appendix 1)					
□ Signed the PEP	Signed the PEP treatment consent /refusal form (appendix 2)					
Date:		Place:				
Name of doctor in capital lette	ers:			Signature of doctor		

APPENDIX 7: CONTACT DETAILS

Report any AEB to the staff health responsible in the project as soon as possible. This person should immediately inform the country responsible for staff health, who should immediately notify the staff health responsible at headquarter level. Any AEB needs to be notified with 72 hours for insurance purposes.

OCA: Staff Health Unit

Staffhealthunit.physical@amsterdam.msf.org

+31 20 520 8700

OCG: Staff Health Unit

Staff-Health.GVA@geneva.msf.org

+41 22 849 8967

OCB: Staff Health Unit

Staffhealthunit@brussels.msf.org

+32 2 474 75 51

OCBA: Staff Health Unit

Staffhealth@barcelona.msf.org

+34 68 129 0560

OCP: Staff Health Unit

Paris-sante-focalpoint@paris.msf.org +33 1 40 21 27 67

OCP; Insurance contact: Elsa Fibleuil, field human resources coordinator elsa.fibleuil@paris.msf.org

+33 1 40 21 27 87

For medical advice on decision to start PEP, management of AEB, or management of PEP, you can contact your Staff Health Unit or for OCP: Elisabeth Szumilin: Elisabeth.Szumilin@paris.msf.org (+33 1 40 212 824), Suna Balkan: Suna.Balkan@paris.msf.org (+33 1 40 212 912), the medical department manager (+33 1 40 212 765) or Pr Olivier Bouchaud (+33 1 48 955 421; +33 662 327 796; olivier.bouchaud@avc.ap-hop-paris.fr).