PROTOCOL FOR

HIV POST-EXPOSURE PROPHYLAXIS

National STD/AIDS Control Programme
Ministry of Health
Sri Lanka

2022 EDITION

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Coordinated by
Dr. W. C. J. K. Jayakody (Consultant Venereologist)

Contributors
Dr. R. Hettiarachchi – Director, NSACP
Dr. Lilani Rajapakse – Deputy Director, NSACP
Dr. K.A.M.Ariyaratne – Coordinator, SIM Unit
Dr. Himali Perera – Coordinator, HIV care
Dr. Chandrika Jayakody – Coordinator, STI care
Dr. Jayadarie Ranatunga - Consultant Venereologist
Dr. Darshani Wijewikrama - Consultant Venereologist
Dr. Thilani Rathnayaka - Consultant Venereologist
Dr. Darshani Mallikarachchi - Consultant Venereologist
Dr. Priyantha Weerasinghe - Consultant Venereologist
Dr. Chithran Hathurusinghe - Consultant Venereologist
Dr. Lasanthi Siriwardena - Consultant Venereologist
Dr. Shanika Jayasena - Consultant Venereologist
Dr. Niroshan Jayasekara - Consultant Venereologist
Dr. Nimali Widanage - Consultant Venereologist
Dr. Buddhika Perera - Consultant Venereologist
Dr. Iruka Rajapakse - Consultant Venereologist
Dr. Anuruddha Karunarathne – Acting Consultant Venereologist
Dr. Vindya Perera – Acting Consultant Venereologist
Dr. Nadeera Kumarasinghe – Senior registrar - Venereology
Dr. Duleepa Weerasiri - Registrar - Venereology
Dr. Nalaka Kulathunge - Registrar – Venereology

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Protocol for HIV post-exposure prophylaxis

1. Background

This protocol provides evidence-based recommendations for the most appropriate use of HIV post-exposure prophylaxis (PEP) following sexual, occupational and other non-occupational exposures in the community to prevent HIV transmission.

The risk of HIV transmission, the timing of PEP, preferred regimen, drug-drug interactions, follow-up, risk reduction and special scenarios are included in this protocol.

Pathogenesis studies have shown that there may be a window of opportunity to avert HIV infection by inhibiting viral replication if antiretroviral drugs were administered within a short time following an exposure. Once HIV crosses a mucosal barrier, it may take up to 48–72 h before HIV can be detected within regional lymph nodes and up to five days before HIV can be detected in the blood. Initiation of ART within this critical period has been shown to reduce the dissemination and replication of virus.

PEP should, therefore, be offered and initiated as early as possible in all individuals with an exposure that has the potential for HIV transmission, ideally within 24- 72 hours.

1.1. Seroconversion following PEP

When initiated promptly, taken appropriately and repeated exposures are avoided, PEP is proven to be highly effective. But there can be failures leading to seroconversion in spite of PEP.

Possible reasons for seroconversion following PEP include:

- Delayed initiation of PEP
- Poor/non- adherence to PEP
- Further high-risk sexual exposures after cessation of PEP
- Use of ineffective ARV regimen
- Early primary HIV infection established at the time of PEP initiation.

1.2. Safety of PEP:

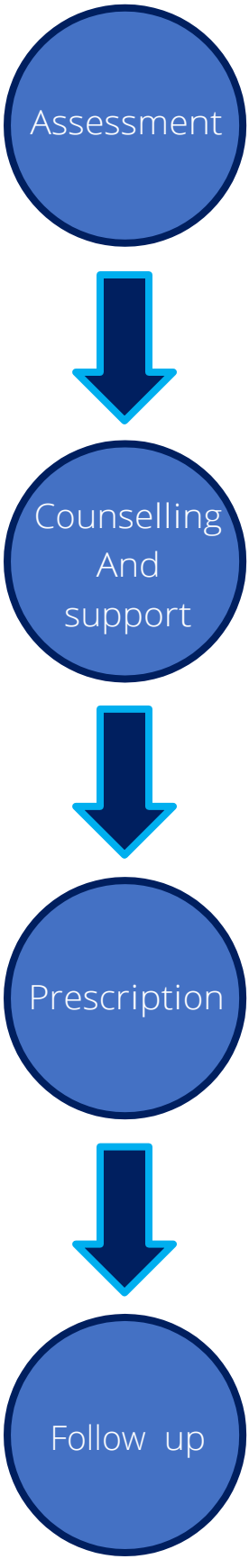
Current recommended PEP regimens are very safe and well-tolerated. However, the potential benefit of PEP must be balanced with the possibility of side effects or toxicity, considering any comorbidities the person may have.

1.3. Risk of HIV transmission

Type of Exposure	Estimated risk of HIV transmission per exposure*
Receptive anal intercourse	1 in 90
Receptive anal intercourse with ejaculation	1 in 65
Receptive anal intercourse without ejaculation	1 in 170
Insertive anal intercourse	1 in 666
Insertive anal intercourse not circumcised	1 in 161
Insertive anal intercourse and circumcised	1 in 909
Receptive vaginal intercourse	1 in 1000
Insertive vaginal intercourse	1 in 1219
Semen splash to eye	<1 in 10,000
Receptive oral sex (giving fellatio)	<1 in 10,000
Insertive oral sex (receiving fellatio)	<1 in 10,000
Mucocutaneous	1 in 1000
Blood transfusion (one unit)	1 in 1
Needlestick injury	1 in 333
Sharing injecting equipment (includes chemsex)	1 in 149
Human bite	< 1 in 10,000

* Estimated risk of HIV transmission per exposure from an HIV-positive individual who is not on suppressive ART

1.4. Care pathway for people exposed to HIV



2. HIV Post- Exposure Prophylaxis – Occupational Exposures [oPEP]

2.1. Risk of HIV transmission following occupational exposures

Preventing exposure to blood and other body fluids that might contain HIV is the primary mean of preventing occupational acquisition of HIV infection, appropriate post-exposure management is an important element of workplace safety.

Department of Health has issued a circular (Reference number -36/2001 dated 12th March 2001) which recommends all health care workers following an occupational exposure to attend STD clinic with the source blood sample as early as possible for management and follow up.

It is the responsibility of the head of the institution to make sure that

1. There is a functional system of management of healthcare workers following occupational exposure to blood and other body fluids.
2. Antiretroviral drugs (ART) are available for PEP.

In an occupational setting 'exposure' means contact with potentially infectious bodily fluids or tissues that poses a risk of transmission of HIV through either:

A. A percutaneous injury (e.g., a needlestick or cut with a sharp instrument contaminated with the index case's blood or other bodily fluids).

B. A mucous membrane (e.g., splash injury to the eye) or non-intact skin (e.g., exposed skin that is abraded, or afflicted with dermatitis) exposure.

C. A bite if the skin is broken as a result of trauma.

Definition of a Health Care Worker (HCW):

The term HCW refers to a person working in a health care setting who has the potential for exposures to infectious materials, including body substances (e.g., blood, tissue and specific body fluids), contaminated medical supplies and equipment, and contaminated environmental surfaces.

Definition of Exposure:

An "exposure" that may place a health care worker at risk for HIV infection

2.2. Consideration of PEP

Consideration of PEP is defined as follows

1. Type of Exposure

   I. Percutaneous injury – Needlestick or cut with a sharp object

   II. Contact of mucous membranes

   III. Non-intact skin- chapped, abraded or afflicted with a dermatitis

2. Type of body fluid

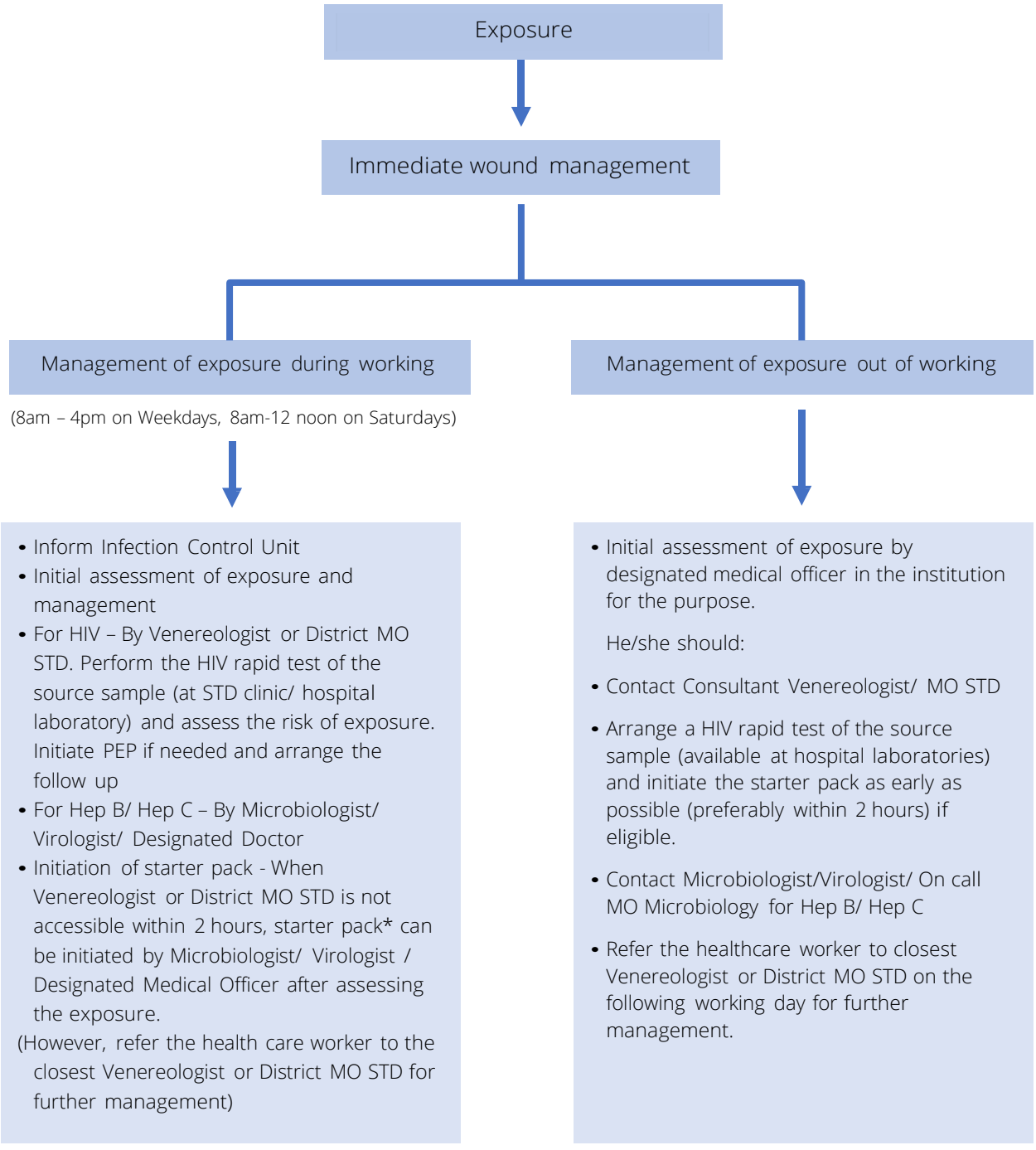
- Exposure to blood, tissue or other body fluids that are potentially infected.

  Semen, Vaginal secretions, breast milk, cerebrospinal fluid (CSF), synovial fluid, peritoneal fluid, pericardial fluid and amniotic fluid are considered potentially infectious.

- Saliva, urine, nasal secretions, vomitus and faeces bear no risk of HIV in the absence of visible blood. Exposure to tears and sweat does not require post-exposure prophylaxis.

Risk of Occupational Transmission of HIV to HCWs from HIV infected blood	
Percutaneous injury (HIV positive source index case NOT on suppressive ART)	0.30 %
Mucous membrane (HIV positive source index case NOT on suppressive ART)	0.01%

2.3. Management of occupational exposures



*Starter Pack – Antiretroviral medication for the post exposure prophylaxis for 3 - 5 days. We recommend keeping this starter pack in a readily accessible place/ places such as OPD/ ETU / ICU / PCU / Pharmacy. Please make sure the availability of starter packs at your local hospitals.

2.4. Immediate actions to be taken following an occupational exposure to reduce transmission risk

Following an exposure to blood or other body fluids, the exposed site should be immediately cleansed as follows:

1. For skin exposures, the site should be washed with soap and water.
2. Small wounds and punctures may also be cleansed with an antiseptic, for example, an alcohol-based hand hygiene solution.

   Alcohol is viricidal to HIV, hepatitis B virus (HBV), and hepatitis C virus (HCV). Other antiseptics, such as iodophors, chloroxylenol, and chlorhexidine also inactivate HIV.
3. In cases of mucosal exposure, the exposed mucous membranes should be flushed with a copious amount of water. Eyes should be irrigated with saline or water.
   Squeezing the wound to express blood is not recommended.

2.5. Types of Injuries

Needlestick and sharps injuries

The risk of HIV transmission from a percutaneous exposure ('sharps injury') from an HIV-positive index case NOT on suppressive ART is estimated to be 0.3%

Factors associated with increased risk

1. Deep injury
2. A device visibly contaminated with the patient's blood
3. Needle placement in a vein or artery
4. Terminal clinical AIDS in the index case – this is likely to indicate a high viral load in the index case

Mucocutaneous exposures or splash injuries

The risk of HIV acquisition from a mucocutaneous 'splash' injury (e.g., eye) is estimated to being around 0.01% (1 in 1000 exposures) if the HIV-positive index case is not on ART, considerably lower than a percutaneous 'sharps' injury.

HIV cannot be transmitted through intact skin.

Biting and spitting

No cases of HIV transmission relating to spitting were identified, supporting the conclusion that there is no risk of HIV transmission from spitting. Healthcare workers, emergency workers or members of the public can be fully reassured that there is no indication for PEP following spitting incidents.

Though the risk is negligible, it is increased by the presence of blood in the saliva and a high viral load in the perpetrator (>3.0 log copies/ml) plus deep wounds being inflicted. In such an incidence the Consultant Venereologist will decide the necessity of post exposure prophylaxis after performing a complete risk assessment.

2.6. When to prescribe PEP following occupational exposures (Sharps and mucosal splash injuries)

HIV-positive index case:

- PEP is recommended following a high-risk injury (sharps or mucosal splash) if the index case is known to be HIV-positive and is not on ART for >6 months.
- PEP is recommended following a high-risk injury (sharps or mucosal splash) if the index case is known to be HIV-positive and not having an undetectable viral load within the last 6 months.
- PEP is generally not indicated following a sharps injury if the index case has been on ART for last 6 months with an undetectable HIV viral load maintained for last 6 months (at the time of incident and within the previous 6 months) and reported good adherence. However due to lack of direct evidence, a case-by-case decision can be made depending on the nature of the injury.
- PEP is not recommended where there is no or negligible risk of HIV transmission e.g., through intact skin that comes into contact with HIV infected blood or other bodily fluids.
- PEP is not recommended following any splash injury where the index case has been on ART for at least 6 months with an undetectable plasma HIV viral load (at the time of the incident and within the previous 6 months) with reported good adherence.
- Where there are concerns about the viral load of the index case being detectable or concerns around ART adherence or if the injury is particularly high risk (e.g., deep wound with hollow bore needle) then PEP could be considered.
- Initiation or continuation of ART will be decided by the consultant venereologist according to the viral load of the index case in the preceding 6 months and adherence.

- If there's no reported undetectable viral load or if a viral load report is not available within preceding 6 months, the HCW should continue ART for 28 days.
- (However, continuation of ART can be decided by the relevant consultant venereologist depending on the adherence of the patient, ART history and the previous viral load reports.)
- If a report is not available last 6 months, can repeat a viral load test at the time of injury.

Index case of unknown HIV status:

- PEP is not recommended following a sharps or mucosal splash injury if the index case is untested but from a low-risk group.
- PEP is generally not recommended following a sharp or mucosal splash injury if the index case is untested and from a high-risk group (e.g., MSM or PWID), unless there were other factors that increased likelihood of transmission (e.g., a deep injury or blood bolus injected or a sharps injury from a PWID in the context of a local outbreak)
- All efforts should be made to seek prompt voluntary HIV testing of the source person
- HIV testing of the source person should not delay PEP initiation when indicated
- If the source person is unable to give informed consent for HIV testing (e.g., unconscious, altered mental status), then HIV testing can be performed if it is in the best medical interest of the source person.
- Needle prick from a dead body; PEP is generally, not recommended. Can be decided by the relevant Consultant Venereologist according to the situation.

When the source patient is not available (e.g., needles in sharp bins and laundry)

PEP is generally not recommended following these needlestick exposures. However, considering the severity of exposure and epidemiological likelihood of HIV exposure, a starter pack can be initiated. The decision regarding continuation of PEP where source person is not available should be made on case-by-case basis by consultant Venereologist /MO-STD.

PEP is not recommended following a community needlestick exposure as the risk is extremely low risk and usually, it is not possible to determine:

I. Whether the needle has been used and for what purpose.

II. HIV status of the index case

III. The interval between the needle use and the exposure.

Timing of the initiation of PEP

I. When a potential occupational exposure to HIV occurs, every effort should be made to initiate PEP as soon as possible, ideally within 2 hours. A first dose of PEP should be offered to exposed worker while the evaluation is underway.

II. Decisions regarding initiation of PEP beyond 72 hours post exposure should be made on a case-by- case basis with the understanding of diminished efficacy when timing of initiation is prolonged.

3. HIV Post- Exposure Prophylaxis – following a sexual exposure [PEPSE]:

3.1. nPEP: non-occupational PEP

There is no evidence to inform the exact risk threshold at which PEP is indicated from an individual, population-level and cost-effectiveness perspective.

Four categories are identified in making decisions on a case-by-case basis:

Recommended	The benefits of PEP are likely to outweigh the risks; PEP should be given unless there is a clear reason not to.
Consider	The risk of HIV transmission is low, the risk / benefit balance of PEP is less clear. The risk should be assessed on a case-by-case basis taking into consideration the following factors: 1. Breaches in the mucosal barrier such as genital ulcer disease and anal or vaginal trauma following sexual assault or first intercourse 2. Multiple episodes of exposure within a short period of time e.g., group sex 3. Sexually transmitted infection in either partner 4. Individuals at higher risk of acquiring HIV e.g., transgender
Generally, Not recommended	The risk of HIV transmission is very low, the potential toxicity and inconvenience of PEP is likely to outweigh the benefit unless there is a clear specific extenuating factor which increases the risk. We anticipate PEP should very rarely be given when the risk has been assessed and discussed. The risk here is generally <1/10,000 but specific factors may increase the risk to >1/10,000.
Not recommended	The risk of HIV transmission is negligible, and PEP should not be given.

3.2. When to prescribe PEP following sexual exposure

A risk assessment and risk-benefit analysis should be undertaken for every individual presenting following an exposure and the decision to initiate PEP is made on a case-by-case basis.

This should consider both the risk of:

- The index case being HIV-positive with a detectable viral load
- The risk of transmission according to exposure
- The ART status and viral load in the index case, if known

Where the index case is known to be HIV-positive but not virologically suppressed, it is important to ascertain if they have experienced prior virological failure and/or have known drug resistant mutations.

Formula used to determine the risk of HIV transmission
Risk of HIV transmission = Risk that source is HIV positive x Risk per exposure

For children and adolescents

The risk calculation/assessments for an adolescent following sexual or occupational exposure should be the same as those for an adult.

A decision on whether to offer PEP should be made in the same way. The decision about whether to complete the decision-making process and/or provide PEP with or without involvement of the parent or guardian should be made in the best interest of the child. Decisions on best interest should be assessed by the consultant/medical officer on a case-by-case basis and balanced against protecting young people from harm.

Index partner is of unknown HIV status

Proactive attempts should be made to establish the HIV status of the index partner; this should not however, delay initiation of PEP.

If the index partner is from a risk-group or country of high HIV prevalence (prevalence >1%) and is not known to be on suppressive ART, then PEP is routinely recommended following receptive anal sex.

Index partner known to be HIV-positive

Attempts should be made at the earliest opportunity to determine the plasma HIV viral load, resistance profile and treatment history of the index partner.

- PEP is not recommended if the index partner has been on ART for at least 6 months with an undetectable plasma HIV viral load (at the time of the incident and within previous 6 months) and with good, reported adherence. Observational studies have confirmed that individuals on suppressive ART cannot transmit HIV sexually regardless of sexual orientation
- Individuals should be encouraged to undergo a formal PEP assessment and verification of index partner's HIV details even when they believe the partner has an undetectable HIV viral load.
- If there are any doubts about the ART history, the index partner's adherence to ART or the viral load, then PEP should be given following condom less receptive anal intercourse

PEP is 'not-recommended' following fellatio with ejaculation as the risk is estimated to be very low at <1/10,000.

In extreme circumstances:

Acute HIV infection and oropharyngeal trauma / ulceration, PEP can be considered but in general, PEP is not recommended. PEP is also not recommended following semen splash in the eye as the risk is negligible with no documented HIV transmissions via this route.

Following insertive vaginal intercourse with an HIV-positive partner not on ART, PEP should be 'considered' rather than routinely 'recommended' as the risk is <1/1219. Again, the presence of additional factors should be reviewed, and clinician discretion applied.

Sexual assault

There is a concern that transmission of HIV is likely to be increased as a result of any trauma following aggravated sexual intercourse (anal or vaginal). Clinicians may therefore consider recommending PEP more readily in such situations, particularly if the assailant is from a high prevalence group.

If the assailant is from a low prevalence group, after discussing the risks and benefits of the patient, it is likely PEP will generally not be indicated.

Commercial sex workers

HIV prevalence among female sex workers remained low <1% in Sri Lanka.

The following formula can be used to determine the risk of HIV transmission.

Risk of HIV transmission = Risk that source is HIV positive x risk per exposure

3.3. Summary table of PEPSE prescribing recommendations

	HIV status of the source			
	Known		Unknown	
Exposure	VL unknown /detectable >200 copies/ml	VL undetectable <200 copies/ml for >6months	High prevalence country/risk group	Low prevalence country/risk group
Receptive anal sex	Recommend	Not recommended	Recommend	Not recommended
Insertive anal sex	Recommend	Not recommended	Consider	Not recommended
Receptive vaginal	Recommend	Not recommended	Generally, not recommended	Not recommended
Insertive vaginal sex	Consider	Not recommended	Generally, not recommended	Not recommended
Fellatio with ejaculation	Not recommended	Not recommended	Not recommended	Not recommended
Fellatio without ejaculation	Not recommended	Not recommended	Not recommended	Not recommended
Cunnilingus	Not recommended	Not recommended	Not recommended	Not recommended
Semen splash to eye	Not recommended	Not recommended	Not recommended	Not recommended

4. Management: HIV post exposure prophylaxis: oPEP & nPEP

4.1. Recommended PEP regimen and follow up management

Recommended 1st line PEP regimen (Three drug regimen)				
TDF 300 mg daily	+	FTC 200mg daily	+	DTG 50mg daily Or RAL 400mg bd Alternative third drug options ATV/r, LPV/r, DRV/r and EFV

- Pregnancy should be excluded in women of childbearing age, before starting DTG
- Starter packs will include Efavirenz as the third drug as all three drugs will be available in a single pill and a reasonable cost when compared to the other regimes.
- If continuation is necessary, regimen will be decided by the Consultant Venereologist out of the recommended regimens
- PEP regimen should be modified according to ART history of the source and ART resistance results.
- Simplification to two drug regimens could be considered by the Consultant Venereologist in selected rare situations if continuing a third agent is not possible.

Children

- AZT + 3TC is recommended for children 10 years and younger.
- ABC + 3TC or TDF + 3TC (or FTC) can be considered as alternative regimens.
- DTG is recommended as the preferred third drug for HIV PEP with approved DTG dosing for the weight of the child
- When available, ATV/r and LPV/r may be considered as alternative third drug options for PEP

Duration of PEP regimen

- PEP need to be continued for 28 days
- If the source patient's HIV ELISA becomes negative, PEP can be discontinued

4.2. Counselling points when commencing PEP

1. The rationale for PEP
2. The data for the efficacy of PEP
3. Start PEP as soon as possible and importance of adherence to optimize efficacy
4. The potential side-effects of PEP
5. Drug interactions including over the counter drugs such as multivitamins/antacids/iron
6. Emergency contraception (if appropriate)
7. Seek medical attention if they develop symptoms of possible seroconversion and side effects
8. The arrangement for early follow-up with District STD/HIV clinics
9. The need to continue PEP for 28 days if the baseline result is negative
10. The need to use condoms until the follow-up HIV testing is negative
11. Coping strategies, assessment of vulnerabilities and social support

4.3. Baseline testing for the exposed health care worker and follow-up

1. Confidential baseline HIV testing for the exposed worker should be obtained at the time the occupational exposure is reported or within 3 days of exposure
2. The exposed worker should be evaluated in two weeks to assess treatment adherence, side effects of treatment, interval physical complaints and emotional status.
3. Risk reduction counselling needs to be provided to HIV exposed workers to prevent secondary transmission during the 12 – week follow up period.

Investigations recommended following oPEP and nPEP

	Baseline	Week 2	Week 4	Week 6	Week 12
Clinic Visits	√	√	√	√	√
Pregnancy test	√				
FBC*/LFT/RFT**	√	√	√		
HIV rapid test + ELISA* **	√			√	√

*Follow up FBC is indicated only for those receiving a Zidovudine – containing regimen

** LFT is indicated at 2 weeks if the HCW is continued on EFV or if the baseline LFT was abnormal. Follow up LFT is not indicated for those receiving Dolutegravir as the third drug

***Week 12 HIV testing should be done by using 4th generation ELISA

DTG should not be co-administered with cation Magnesium/Aluminium containing antacids, laxatives and multivitamin or calcium/ iron supplements because of the risk of chelation. If combined, DTG should be administered two hours before or six hours after taking medications containing polyvalent cations.

Raltegravir binds to divalent cations such as iron, aluminium, magnesium, calcium and forms a complex at the level of the gastrointestinal tract which results in less Raltegravir being absorbed. concomitant use of metal cation containing antacids, iron supplements and multivitamins should ideally be avoided or should be separated by at least 4 hours from twice daily Raltegravir 400mg.

Serum Creatinine kinase has to be done if the patient develops myalgia while on Integrase inhibitors.

4.4. When to discontinue PEP due to missed doses

- If patient forgot to take a dose, it should be taken as soon possible
- However, if it is time for the next dose, need to skip that missed dose and go back to the regular schedule.
- The patient should not take a double dose to make up for a forgotten dose.

If more than 48 hours has elapsed since the last dose, then PEP should be discontinued. For dolutegravir-based PEP, if >72 hours have elapsed since the last dose then PEP should be discontinued.

If interruption of PEP (for less than 48 hours since the last missed dose) is related to intolerance to one or more ART agents, continue PEP with an alternative agent(s).

4.5. Special Circumstances

Exposed workers who are pregnant and breast feeding

1. Pregnancy is not a contraindication for PEP and recommended regimens can be used.
2. Before administering PEP to a pregnant woman, clinician should discuss the potential benefits and risks to her and the foetus.
3. Women who may have been exposed to HIV through occupational exposures need to be counselled on avoiding breastfeeding for 3 months after the exposure. If HIV infection is definitely excluded in the source patient at any time prior to 3 months post- exposure, the woman may resume breast feeding.

Drug-drug interactions

Potential drug-drug interactions are checked using the Liverpool University drug interaction website

Seroconversion during PEP

- Individuals experiencing a skin rash or flu-like illness while or after taking PEP should be advised to attend for urgent review to exclude an HIV seroconversion.
- If the HIV test is positive after PEP has already been initiated, PEP should be continued pending review by an HIV specialist.

Further high-risk exposures while on PEP

In the event of a further high-risk sexual exposure during the last two days of the PEP course, PEP should be continued until 48 hours after the last high-risk exposure for anal sex or until 7 days after the last high-risk exposure for vaginal sex.

Sexual Health considerations

- Perform chlamydia, gonorrhoea and syphilis testing (based on the clinical situation) at baseline and repeat testing following the respective incubation periods.
- Emergency contraception should be offered if indicated.
- Individuals who are at higher risk of future acquisition of HIV and repeat attendees for PEPSE should be encouraged to attend for regular sexual health check-ups and should make aware about the available risk-reduction services including HIV Pre-Exposure Prophylaxis.
- Provision of PEPSE should be fully integrated into counselling around safer sex strategies including opportunity to meet with an appropriate health care professional competent in sexual health advising.

5. Auditable Outcomes

1. Proportion of PEP attendees having a baseline HIV test performed: aim 100% within 1 working day of presenting for PEP
2. Proportion of PEP attendees having a HIV test result available within 5 days: aim 97%
3. Proportion of PEP prescriptions that fit within recommended indications (consider or recommended): aim 90%
4. Proportion of PEP prescriptions administered within 24 hours of risk exposure: aim 70%
5. Proportion of individuals completing 4-week course of PEP: aim 75%
6. Proportion of individuals prescribed PEPSE undergoing testing for STIs: aim 90%
7. Proportion of individuals for whom completion of 4-week course of PEP is indicated who undergo HIV antibody/antigen test at least 12 weeks after the completion of PEP: aim 75%
8. Proportion of patients presenting for non-occupational PEP who have a documented discussion about PrEP if eligible: aim 90%.

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