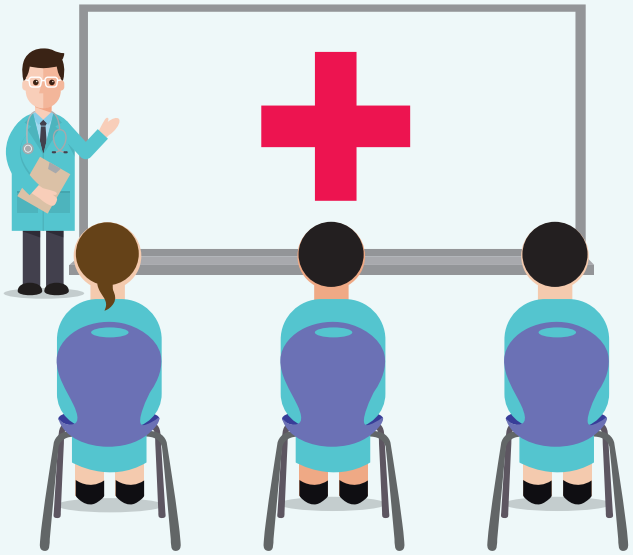
KINGDOM OF CAMBODIA

— NATION RELIGION KING —

ក្រសួងសុខាភិបាល

National Guidelines For



Post-Exposure Prophylaxis after Non-occupational and Occupational Exposure to HIV

National Center For HIV/AIDS, Dermatology and STD

February 2019

Contents

Acknowledgment

The National Center for HIV/AIDS, Dermatology and STD (NCHADS) would like to express its appreciation and thank all relevant NCHADS Units including AIDS Care, and Technical Bureau; and development partners including LINKAGES project of FHI 360, US-CDC, WHO, UNAIDS, CRS, KHANA, GIZ and others who actively contributed to the successful development of the Guidelines for Post Exposure Prophylaxis of HIV infection for health occupational and non-occupational.

Our special thanks to Dr. Samreth Sovannarith, Dr. Ngauv Bora, Dr. Touch Sarun, Dr. Ngeth Bottra, Dr. Chel Sarim, Mr. Im Chanry, Dr. Chan Sodara, Mr. Ung Polin, and Dr. Steve Wignall for taking their efforts in coordinating and developing this important guideline.

Phnom Penh, 14 / June / 2019

Director of NCHADS

Dr. Ly Penh Sun

Abbreviations

3TC	Lamivudine
ABC	Abacavir
AEM	Asian Epidemic Model
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
ATV/r	Ritonavir boosted Atazanavir
AZT	Zidovudine
cART	combination Antiretroviral Therapy
CNS	Central Nervous System
CRS	Catholic Relief Services
DTG	Dolutegravir
EFV	Efavirenz
EW	Entertainment Worker
GBV	Gender Based Violence
GIZ	Deutsche Gesellschaft Fuer International Zusammenarbeit
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
IBBS	Integrated Biological and Behavioral Assessment
IDU	Injection Drug Use
KP	Key Population
KHANA	Khmer HIV/AIDS NGO (Non-Governmental Organization) Alliance
LPV/r	Ritonavir boosted Lopinavir
MSM	Men Who have Sex with Men
NCHADS	National Center for HIV/AIDS, Dermatology and STI
NSHN	National Healthcare Safety Network
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitor
NRTI	Nucleoside Reverse Transcriptase Inhibitor
PEP	Post-Exposure Prophylaxis
PrEP	Pre-Exposure Prophylaxis
RTI	Reproductive Tract Infections
STI	Sexually Transmitted Infection
TDF	Tenofovir Disoproxil Fumarate
TG	Transgender SOP: Standard Operating Procedure
PI	Protease Inhibitor
PLHIV	People Living with HIV
PWUD	People Who Use Drugs
PWID	People Who Inject Drugs
VL	Viral Load
UD	Undetermined
UK	Unknown

I. Background and Rationale

This PEP guideline is substantially changed from the 2006 PEP guideline and the PEP section of National HIV clinical management guidelines for Adults and Adolescents, 4th Revision in 2015.

The PEP guideline in 2006 was focusing on occupational only but this PEP guideline is extended to |non-occupational exposures.

The risk of HIV transmission exists if an HIV-negative person comes into contact with the blood, semen or vaginal fluids of an HIV-positive person. HIV transmission is possible if HIV-containing material enters the body by:

- Needle stick injury or incision by surgical instruments,
- Exposure of damaged skin or mucosal membranes,
- Unprotected sexual intercourse with infected person (including sexual accidents, i.e., broken condom, etc.),
- needle or injecting equipment sharing,
- Transmission of HIV-contaminated blood or blood products.

HIV is not a very contagious pathogen. The transmission rates via one of the methods mentioned above ranges between 1:100 and 1:1000. Several factors influence the probability of transmission and include the amount of source-incorporated virus transmitted and the length of exposure time. Contact with body fluids of a patient with a high viral load theoretically holds a greater risk of contagion than a similar contact with body fluids of a patient on ART with a suppressed viral load. Also, rapid removal of infectious materials, e.g., from damaged skin or mucosal membrane by washing or disinfection, presumable decreases the risk of transmission.

Table 1: Estimated HIV transmission risk per exposure for specific activities and events

Activity	Risk-per-exposure
Vaginal sex, female-to-male, studies in high-income countries	0.04% (1:2,380)
Vaginal sex, male-to-female, studies in high-income countries	0.08% (1:1,234)
Vaginal sex, female-to-male, studies in low-income countries	0.38% (1:263)
Vaginal sex, male-to-female, studies in low-income countries	0.30% (1:333)
Vaginal sex, source partner is asymptomatic	0.07% (1:1,428)
Vaginal sex, source partner has late-stage disease	0.55% (1:180)
Receptive anal sex amongst gay men, partner unknown status	0.27% (1:370)

Activity	Risk-per-exposure
Receptive anal sex amongst gay men, partner HIV positive	0.82% (1:123)
Receptive anal sex with condom, gay men, partner unknown status	0.18% (1:555)
Insertive anal sex, gay men, partner unknown status	0.06% (1:1,666)
Insertive anal sex with condom, gay men, partner unknown status	0.04% (1:2,500)
Receptive fellatio	0.00% to 0.04% (1:2,500)
Mother-to-child, mother takes at least two weeks antiretroviral therapy	0.8% (1:125)
Mother-to-child, mother takes combination therapy, viral load below 50	0.1% (1:1,000)
Injecting drug use	0.63% (1:158) to 2.4% (1:41)
Needle stick injury, no other risk factors	0.13% (1:769)
Blood transfusion with contaminated blood	92.5% (9:10)

Sources: http://www.aidsmap.com/Estimated-risk-per-exposure/page/1324038/

Post-exposure prophylaxis refers to taking ARV by an HIV negative individual after being potentially exposed to HIV to prevent becoming infected. The first dose of PEP should be administered ideally within 2 hours (but certainly within the first 72 hours) of exposure and the risk evaluated as soon as possible.

II. Objectives

Post Exposure Prophylaxis (PEP) is short-term use of antiretroviral therapy (ART) to reduce the likelihood of HIV infection after potential exposure, occupationally (health care providers) and non-occupationally. PEP should be provided as part of a comprehensive universal precautions package that reduces HIV transmission risk in such situations.

2.1 Overall objective: Reduce the risk of HIV infection after occupational or non-occupational exposures (Sexual assault and the partner of HIV infected person (sero-discordance couple) enrolled in ART clinic but not yet started antiretroviral drugs or started antiretroviral drugs less than 3 months or the last VL test result > 1,000 copies/ml had unprotect sexual intercourse or broken condom).

2. 2 Specific objectives of the guideline are to:

- Increase knowledge about the use of PEP to health care providers in all services in health facilities.
- Provide clear guidance to implement PEP at the ART clinic and emergency department in the hospitals.

III. Who is PEP eligible for this guideline?

3.1 Occupational:

- Nursing staff
- Emergency care providers
- Labour and delivery room personnel
- Surgeons and operation theatre staff
- Laboratory technicians
- Physicians
- Interns and medical students
- Dentists
- Health facility cleaning staff, mortuary staff and clinical waste handlers in the health care setting

3.2 Non-occupational

- Sexual assault victim (Virginal, anus and oral)
- Key population (EW, MSM, TG, PWID) reported no condom used or condom broken
- Partner of HIV infected person (sero-discordance couple) enrolled in ART clinic but not yet started antiretroviral drugs or started antiretroviral drugs less than 3 months or the last VL test result more than 1,000 copies/ml had unprotected sexual intercourse or broken condom less than 72 hours.

IV. Assessment of the risk of HIV transmission

4.1 What is the HIV transmission risk/exposure?

a. All sexual risk estimations are for condomless sexual contact. It is assumed that a similar risk is incurred when a condom fails.

Table 2: Exposure and transmission risk/exposure with known HIV-positive source who is not on antiretroviral treatment

Type of exposure with known HIV-positive source who is NOT on antiretroviral treatment	Estimated risk of HIV transmission/exposure*
Receptive anal intercourse	
- Ejaculation	1/70
- Withdrawal	1/155
Shared needles and other injecting equipment	1/125
Insertive anal intercourse uncircumcised	1/160
Insertive anal intercourse circumcised	1/900
Receptive vaginal intercourse	1/1250
Insertive vaginal intercourse	1/2500
Receptive or insertive oral intercourse	Unable to estimate risk, Extremely low
Needle-stick injury or another sharps exposure	1/440
Mucous membrane and non-intact skin exposure	<1/1000

* These estimates are based on prospective studies, not cross-sectional data or figures derived from modelling. These estimates do not take into account source viral load, which if undetectable markedly reduces risk estimates. For individuals with high viral load, obviously transmission risk would increase. Source: ASHM August 2016

Many factors modify the risk of HIV transmission and should be considered in the risk assessment.

Factors that increase the risk of HIV transmission:

- Higher plasma VL is associated with increased risk of HIV transmission
- A sexually transmissible infection (STI) in the source or exposed individual, especially genital ulcer disease and symptomatic gonococcal infections
- Source ejaculation during receptive anal or vaginal intercourse,

- A breach in genital mucosal integrity when performing oral sex,
- A breach in oral mucosal integrity when performing oral sex,
- Penetrating, percutaneous injuries with a hollow bore needle, direct intravenous or intra-arterial injection with a needle or syringe containing HIV-infected blood,
- The uncircumcised status of the insertive HIV-negative partner practicing insertive anal intercourse (IAI) or insertive vaginal intercourse (IVI).
- Exposure to a larger quantity of blood or other infectious fluid.
- Prolonged or extensive exposure of non-intact skin or mucous membrane to blood or other infectious fluid or concentrated virus in a laboratory setting.
- Exposure to the blood of a patient in an advanced disease stage or with a higher HIV viral load.
- A deep percutaneous injury.
- A procedure wherein the sharp was in the vein or artery of an infected source patient.
- An injury with a hollow-bore, blood-filled needle.
- Limited or delayed access to post-exposure prophylaxis.

b. Body fluids that pose a risk of HIV infection:

- Blood,
- blood-stained saliva,
- breast-milk,
- genital secretions and cerebrospinal fluid
- amniotic, rectal, peritoneal, synovial, pericardial or pleural fluids

c. Body fluids that do not pose a significant risk of HIV infection, and therefore do not require PEP

- Tears,
- Non-blood-stained saliva,
- Urine and sweat.

4.2 What is the HIV status of the source individual?

Once HIV positive status of the source is confirmed provision of PEP should not be delayed.

Ideally, active attempts should be made to contact the source and ask them to have an urgent HIV test; however, the often-anonymous nature of exposures makes this impractical for non-occupational exposure.

Therefore:

- If the source cannot be contacted, the seroprevalence data (see Table 3) will assist in determining the need for PEP.
- If the source is contactable and:
    - Discloses they are HIV positive; consent should be gained to seek treatment details from their doctor. It is useful to know if they are on treatment or not, and if their viral load is undetectable.

- Is known to be taking PrEP (Pre-Exposure Prophylaxis), PEP is generally not required if it can be determined that the individual was reasonably adherent. Decisions to prescribe PEP should still be considered on a case-by-case basis due to potential for non-adherence of the source.
- Chooses not to disclose their HIV status or have an HIV test, it should be assumed (for the purposes of PEP prescription) that they are HIV positive.

Table 3: Estimated Cambodian HIV prevalence by demographic characteristic

Population / subpopulation	Prevalence	Source
General adult population	0.6%	AEM 2016
People who inject drugs (PWID)	15.2%	IBBS 2017
People who use drugs (PWUD)	5.7%	IBBS 2017
Entertainment worker (Freelance)	11.8%	IBBS 2016
Entertainment worker	3.2%	IBBS 2016
Transgender women	5.9 %	IBBS 2016
MSM	2.3%	IBBS 2014

To estimate the risk from an exposure from an unknown source:

Risk of transmission = risk per exposure x risk of source being HIV positive (prevalence)

Examples of calculations of estimates of risk of a particular event in Cambodia

- The risk to a HCW who has a needle stick injury from a known PLHIV = 1/440 or 0.23%
- The risk to a HCW who has a needle stick injury from a person from the general adult population, HIV status unknown = 1/440 (0.23%) x 0.6% = 0.0014%

Multiple exposures, and from multiple sources should be added to estimate risk:

- The risk to a woman who is vaginally and anally raped by a PWUD (1/1250 x 5.7%)+ (1/70 x 5.7%) = 0.0046% + 0.081% = 0.086%
- The risk to a woman who is vaginally raped by 5 PWUD = 5 x 1/1250 x 5.7% = 0.023%

However, note that:

1) The real risk may increase due to biological factors and factors outlined above
2) In the case of rape, the demographic of the source(s) may be unknown.

4.3 What is the HIV status the exposed individual?

All candidates for PEP are required baseline HIV testing. Where possible, the results of the test should be ready within 24 hours after the specimen being collected but PEP should be prescribed immediately without waiting the test result. If HIV rapid test reactive stop PEP regimen.

V. Clinical assessment and follow-up

The following information should be obtained and documented in the patient's file:

5.1 Information about the exposure

a. Date and time of exposure

b. Type of exposure, including blood or body fluids involved, trauma, first aid measures applied and any contributory factors.

5.2 Information about the exposed person

a. Most recent HIV test and result

b. Potential exposures within the last three months (or earlier if last HIV test longer than three months ago)

c. Previous use of PEP or PrEP

d. Evaluation of current STIs

e. Hepatitis B (HBV) and C (HCV) infection

f. Pregnancy risk, contraception and lactation (consider emergency contraception)

5.3 Information about the source person

Provision of PEP should not be delayed while obtaining this information.

a. HIV status if known

b. Demographics factors, e.g. gender,

c. If HIV positive: Plasma viral load, date of last test, medication adherence

d. Current STIs; hepatitis B and C status

e. Whether the source is known to be taking PrEP

5.4 Follow-up

The recommended timing of follow-up HIV and other testing is outlined in Table 4 – Individuals found to be HIV positive or indeterminate on baseline testing, or during follow-up, require immediate referral to an HIV national mentor.

VI. Laboratory assessment and follow-up

After potential exposure to HIV, individuals should have baseline and follow-up testing Table 4 for HIV and other infections (depending on mode of exposure).

Table 4 sets out the recommended schedule of testing for individuals who are prescribed PEP. Follow-up HIV testing is no longer recommended at six months. The management of an exposed patient who seroconverts is not included. The symptoms of seroconversion should be explained to all patients, with advice to present if these or any other symptoms occur.

Individual need to be referred to family health clinic (STI clinic) for appropriate care and treatment of STI in case sexual exposure and if a victim is a woman in a reproductive age should be referred to family planning service for emergency contraceptive ((Refer to national guideline for management violence against women and children in health system in 2014: 2.4.6.3.3 prevent STI on page 20 and 2.4.6.3.2 guideline for pregnancy prevention on page 20-21).

Table 4: Timing of Laboratory Tests Pre and Post PEP

Test	Baseline	Week 6	Month 3
HIV serology	x	x	x
Syphilis serology	x	x	x
Hepatitis B serology	x		x
Hepatitis C serology	x		x
Pregnancy test	x	x	

VII. Prescribing PEP

PEP services are available at the ART clinic where PEP regimen is prescribed by ART clinician on working days and at working hours. Out of working days or public holidays, PEP drug is available in Emergency department in the hospitals where ART clinics located within. The clinician at Emergency prescribes PEP drug for maximum 4 days and make appointment with clients to visit ART clinician at ART clinics on working days.

7.1 When to prescribe PEP

The decision to prescribe PEP needs to be made on a case-by-case basis. Prescribing PEP in this guideline is mainly focused on occupational and non-occupational exposure to HIV as described in chapter II (Who is PEP eligible for this guideline?).

7.2 Occupational exposure to HIV

Health care workers who are at risk of occupational exposure to HIV, including but not limited to:

- Nursing staff
- Emergency care providers
- Labour and delivery room personnel
- Surgeons and operation theatre staff
- Laboratory technicians
- Physicians
- Interns and medical students
- Dentists
- Health facility cleaning staff, mortuary staff and clinical waste handlers in the health care setting

If the source is unable to be tested immediately, the exposed healthcare worker should be commenced on PEP without waiting for the results if the source is at high risk of being HIV positive (Within 4-6 hours).

If the source is unable to be identified or tested, then the risk of the source being HIV positive must be assessed from any epidemiological or other information available. The use of PEP should be decided on a case-by-case basis, and it is recommended that an experienced clinician on HIV area is always consulted in this situation.

The risk carried by exposures that occur in the healthcare setting include but not limited to the following:

- Deep puncture wound with a hollow bore needle
- Needle-stick injury after it was used for IM/IV/subcutaneous injection,
- Injury from a sharp instrument visibly contaminated with blood.

- Exposure for more than 1 minute or extensive exposure of non-intact skin or mucous membrane to blood or other infectious fluid or concentrated virus in a laboratory setting.
- Exposure to the blood of a patient in an advanced disease stage of AIDS or with a higher HIV viral load.

It is reasonable to always offer PEP to a healthcare worker who has had a significant exposure to a source who is HIV positive, even if the source has an undetectable HIV viral load.

7.3 Exposure reporting

When an occupational exposure occurs, the circumstances and post exposure management procedure applied should be recorded in the exposed person's confidential form for easy follow up and care. Information to be recorded in the health worker's confidential medical report should include:

- Date and time of exposure.
- Details of the procedure being performed and the use of protective equipment at the time of exposure.
- Type, severity and amount of fluid that the healthcare worker was exposed to.
- Details of the exposure source person.
- Medical documentation that provides details about post-exposure management.

7.4 Management of Non-Occupational exposure to HIV

PEP must be initiated within 72 hours post assault but preferably as soon as possible after the event (within 4-6 hours) with any victim who has been sexually assaulted when vaginal, anal or oral penetration with a penis has occurred, regardless of condom use or ejaculation, or with any victim who does not remember the sexual assault. In case of physical injury with life threatening, ART clinician needs to refer victim to emergency service immediately and PEP will be prescribed later, but must be within 72 hours. If the victim required for forensic examination certificate by authority, police, lawyer, then need to refer victim to the forensic clinical committee of the hospital. After PEP prescribed victim should be provided and/or referred to appropriated services, family planning services for assessing and providing emergency contraception (women in a reproductive age) and family clinic for STI treatment and psychosocial service for specific psychosocial support.

There are two factors that contribute to the risk of HIV transmission following sexual assault:

a. The risk that the assailant is HIV positive,

b. The risk of the exposure.

Table 5: PEP is strongly recommended with situation below

High-Risk Exposure	Yes
Anal penetration	X
Vaginal penetration	X
Oral penetration	X
High-Risk Assailant	
Known HIV positive assailant	X
Known high-risk assailant:	
- people who inject drugs	X
- men with sexual contact with men	X
- from endemic area	X
Unknown-Risk Assailant: Unknown or Known with unknown HIV status	**X**

On the other hand, PEP is not offered or recommended when no risk of exposure with any type of assailant:

- No vaginal penetration.
- No anal penetration.
- No oral penetration.

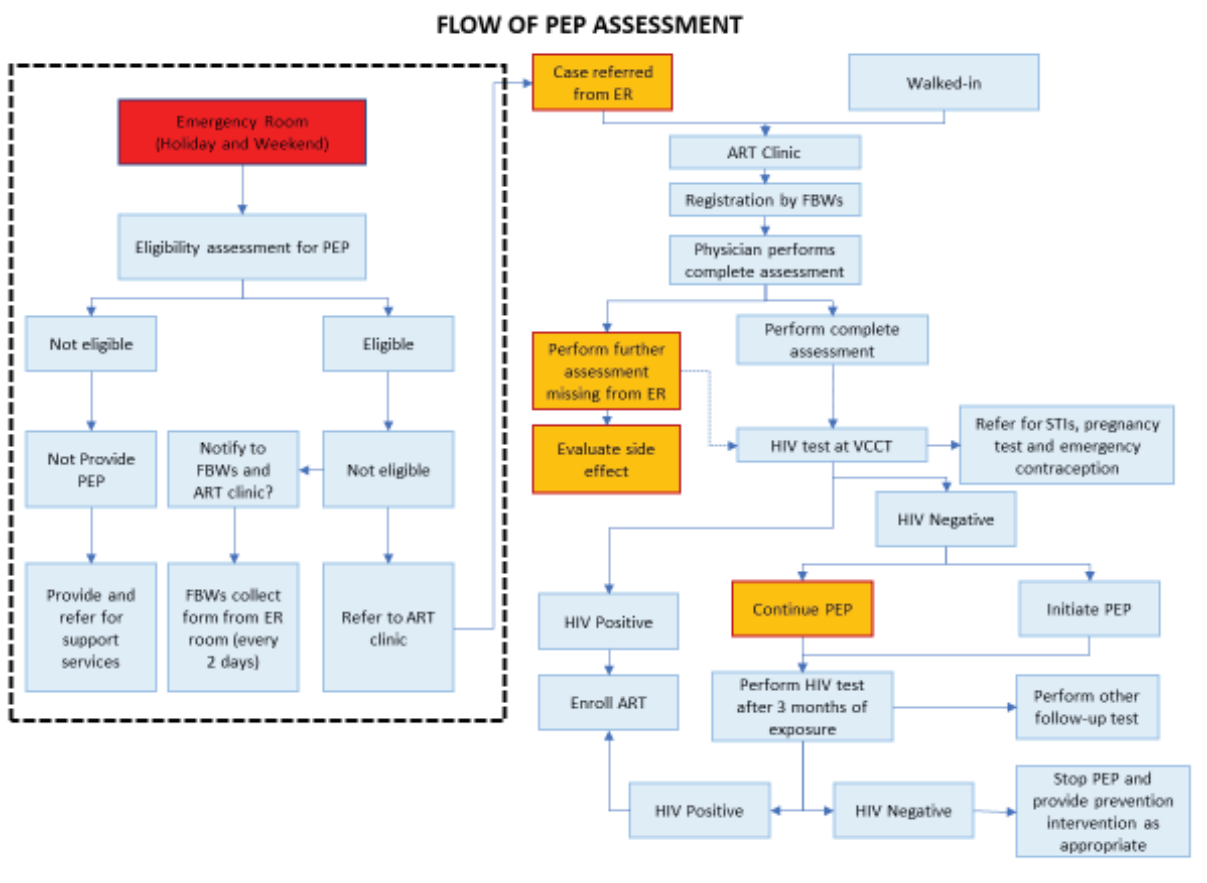
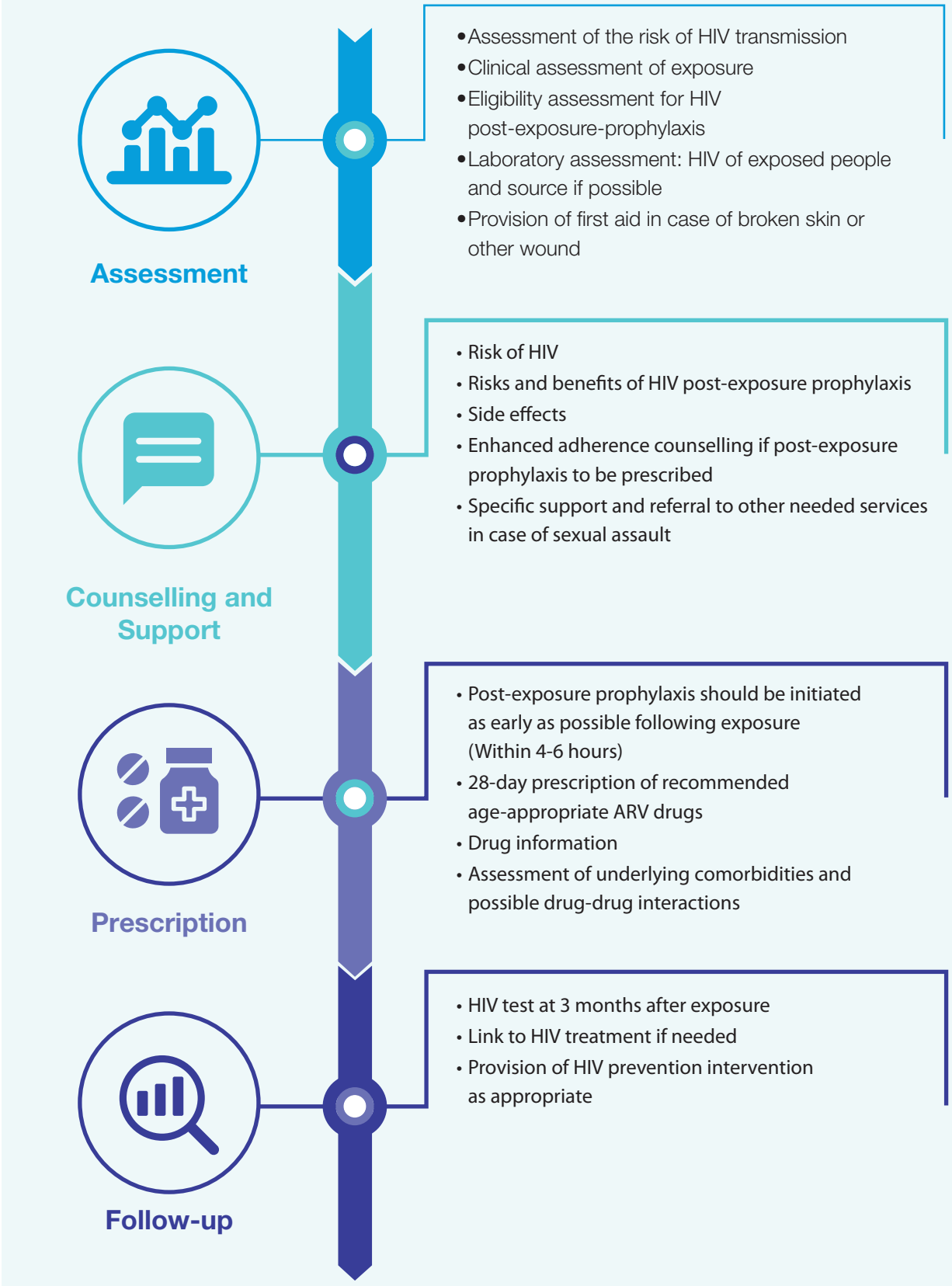


Figure 1: Summary Flow of Care for people exposed to HIV



7.5 ARV regimen for PEP

Adverse effects caused by antiretrovirals and their impact on adherence are well recognized. Drug choice is determined by: safety, tolerability, ease of dosing, HIV resistance patterns in the local infected population, the medical history of the exposed person. When known, source information concerning antiretroviral treatment history and the results of past HIV resistance testing may also determine the choice of drugs for PEP. We now have PEP regimens that are well tolerated, with minimal side effects, drug–drug interactions, dosing requirements and pill burden. Clinicians must inform patients who are prescribed PEP about the following:

- PEP provides high levels of protection but does not prevent 100% of infections
- the importance of adherence
- the potential adverse effects of treatment and possible drug interactions
- measures for preventing re-exposure to HIV
- follow-up HIV testing
- HIV seroconversion signs and symptoms.

PEP should generally not be prescribed after 72 hours but may be considered on a case-by-case basis in consultation with a specialist. Earliest possible initiation of PEP has the greater likelihood of success.

PEP consists of a regimen of 3 ARV agents: 2 NRTI + Integrase Inhibitor drug regimens are preferred, at standard treatment doses. In case of Integrase Inhibitor (Dolutegravir) is not available, the second choice is 2NRTI + PI drugs. PEP must be started as soon as possible after exposure (Within 4-6 hours) and continued daily for 28 days post exposure.

7.5.1 PEP regimen for adolescents and adults

Preferred standard PEP regimen:

TDF (300 mg) + 3TC (150 mg) + DTG (50 mg) Once daily for 28 days

Alternative PEP regimen:

TDF (300 mg) + 3TC (150 mg) + ATV/r (300 mg/100 mg) Once daily for 28 days

7.5.2 PEP regimen for children and adolescents

Age	Preferred Treatment Regimen	Duration
Children <10 years OR <35 Kg	ABC or AZT + 3TC + LPV/r*	28 days
Adolescents ≥10 years AND ≥35 kg	TDF + 3TC + DTG or ABC or AZT + 3TC + ATV/r or LPV/r*	28 Days

*EFV may be used as an alternative to the protease inhibitors should there be a reason why these cannot be prescribed.

Notice:

- If a third drug is not available or contraindicated, a two NRTI ARV regimen is acceptable provided the exposure is not from a source with known or suspected cART failure.
- Efavirenz is a possible 3rd PEP agent, however it may not be effective in the setting of transmitted NNRTI resistance, and the early CNS side effects may be difficult in someone who has anxiety related to the recent exposure.

7.6 There is a theoretical risk of hepatic flare among people infected with HBV

Once TDF + 3TC -based PEP is stopped, as has been seen for people receiving ART. Assessment of HBV infection status should not be a precondition for offering TDF+ 3TC -based PEP, but people known HBV infection should be clinically monitored for hepatic flare after discontinuation of TDF+3TC -based PEP.

7.7 Immediate management of an individual exposed to known or suspected HIV+ patient

- Do not douche the vagina or rectum after sexual exposure.
- After oral exposure, spit out blood/body fluids and rinse mouth with water.
- Wash wounds and skin sites that have been in contact with blood or body fluids with soap and water.
- Irrigate mucous membranes and eyes (remove contact lenses) with water or saline.
- Do not inject antiseptics or disinfectants into wounds.

7.8 ARV Side effects

In practice and from HCP studies, it has been observed that many HCP do not complete the full course of PEP because of side-effects. Side-effects can be reduced by prescribing regimens that do not include a protease inhibitor (PI), by giving medications to reduce nausea and gastritis and by educating clients about how to reduce side effects e.g. taking PEP medications with food. It is important that side effects should be explained before initiating PEP so that the symptoms are not confused with symptoms of seroconversion to HIV. Table 6 below gives guidance on management of common side effects of PEP drugs.

Table 6: Management of minor ARV drug side effects

Sign or Symptom	Management at health facility
Nausea	Take with food; reassure that this is usually self -limited. Treat symptomatically
Headache	Give paracetamol. If on EFV, reassure that this is common and usually self-limited. If persists more than 2 weeks, call for advice or refer.
Diarrhoea	Hydrate. Follow diarrhoea guidelines. Reassure patient that if it is due to ARV, it will improve in a few weeks. Follow up in 2 weeks. If it does not improve, call for advice or refer.
Fatigue	This commonly lasts 4 to 6 weeks. Take 'sick leave' from work. If severe or longer than this, call for advice or refer.
CNS side effects: Anxiety, nightmares, psychosis, depression	This may be due to EFV. Take EFV at night before sleeping; Counsel and support (usually lasts < 3 weeks). The initial difficult time can be managed with amitriptyline at bedtime. Call for advice or refer if severe depression or suicidal tendencies or psychosis (stop EFV)
Rash	If on EFV, assess carefully. Is it a dry or wet lesion? Call for advice.
Fever	Assess clinically for Hepatitis, see if this could be primary (acute) HIV infection or other non-HIV related infections e.g. concurrent common cold. Call for advice or refer
Jaundice or abdominal or flank pain	Stop drugs; Call for advice or refer If jaundice or liver tenderness is present, send for ALT test and stop ARVs. Call for advice or refer.

See detail of monitoring and substitutions for ART toxicity of national HIV clinical management guidelines for Adults and Adolescents (4th Revision in 2015), Chapter 10, page 57-62.

VIII. Reporting

Provision of PEP and follow-up must be reported and documented. There are separate forms for occupational exposure and non-occupational exposure.

- Occupational and Non-occupational exposure data collection form – annex 2.
- PEP reporting template – annex 3

8.1 The indicator of PEP

1. Number (%) of clients have PEP prescribed.	
Definition	Number clients who visited ART clinic for PEP purpose who meets the criteria for PEP and have PEP prescribed, divided by the total number of clients visited ART clinic for PEP purpose, multiplied by 100.
Purpose	To measure the magnitude of potential HIV infection exposure among occupational and non-occupational clients.
Method of Measurement	Count the number of clients seeking PEP at the ART clinic, then compute for percentage using numerator and denominator below.
Frequency	Monthly
Numerator	Number clients having PEP prescribed during the reported month.
Denominator	Total number of clients seeking for PEP and meet PEP criteria during the reported month.
Disaggregation(s):	By occupational and non-occupational
Source of data	PEP reporting Forms at ART clinic.
Interpretation	High percent of non-occupational PEP may reflect high risk behavior to contract HIV infection is going on among publics. High percent of occupational PEP may reflect the need to strengthen the infection control measures among health professional staff.

2. Number (%) of clients who have been prescribed PEP returned for follow-up visit at day fifth	
Definition	Number clients who have been prescribed PEP, and returned for the follow-up visit on day fifth divided by the total number of clients prescribed PEP at the ART clinic, multiplied by 100.
Purpose	To measure the follow-up rate and adherence to PEP of the clients for the short period. Appropriate interventions need deciding during the follow-up visit.
Method of Measurement	Count the number of clients prescribed PEP at the ART clinic, then compute for percentage using numerator and denominator below.
Frequency	Monthly
Numerator	Number clients who have been prescribed PEP returned for the follow-up visit on day fifth (or as appointment date) during the reported month.
Denominator	Total number of clients who have been prescribed PEP during the reported month.
Disaggregation(s):	By occupational and non-occupational
Source of data	PEP reporting Forms at ART clinic.
Interpretation	Appropriate decision need taking in accordance with the results at the follow-up visit.

3. Number (%) of clients who have been prescribed PEP returned for follow-up visit 3 months after the first visit data.	
Definition	Number clients who have been prescribed PEP, and returned for the follow-up visit 3 months after the first visit date divided by the total number of clients who have been prescribed PEP during the last three months, multiplied by 100.
Purpose	To measure the follow-up rate and outcome of PEP of the clients. Appropriate interventions need taking during the follow-up visit.
Method of Measurement	Count the number of clients prescribed PEP at the ART clinic, then compute for percentage using numerator and denominator below.
Frequency	Monthly
Numerator	Number clients who have been prescribed PEP returned for the follow-up visit 3 months after the first visit date (or as appointment date) during the reported month.
Denominator	Total number of clients who have been prescribed PEP in the last three months
Disaggregation(s):	By occupational and non-occupational
Source of data	PEP reporting Forms at ART clinic.
Interpretation	Appropriate decision need taking in accordance with the results at the follow-up visit.

4. Number (%) of clients have HIV test positive at follow-up visit 3 months after the first visit date.	
Definition	Number clients who have been prescribed PEP returned for the follow-up visit 3 months after the first visit date, and have HIV test positive divided by the total number of clients who have been prescribed PEP and returned for the follow-up visit 3 months after the first visit date, multiplied by 100.
Purpose	To measure the HIV infectivity rate after completed PEP. Appropriate interventions need taking during the follow-up visit.
Method of Measurement	Count the number of clients prescribed PEP at the ART clinic, then compute for percentage using numerator and denominator below.
Frequency	Monthly
Numerator	Number clients who have been prescribed PEP returned for the follow-up visit 3 months after the first visit date, and have HIV test positive during the reported month.
Denominator	Total number of clients prescribed PEP and returned for the follow-up visit 3 months after the first visit date during the reported month.
Disaggregation(s):	By occupational and non-occupational
Source of data	PEP reporting Forms at ART clinic.
Interpretation	Appropriate decision need taking in accordance with the results at the follow-up visit 3 months after the first visit date.

IX. Annexes

Annex 1: Detailed Care Pathway for People Exposed to HIV

1. Assessment and immediate management

- First aid
  - Oral exposure: spit out blood/body fluids and rinse with water.
  - Wounds: wash wounds /skin sites that had contact with blood / body fluids.
  - Mucous membranes and eyes: irrigate with water /saline (remove contact lenses).
  - Do not inject antiseptics or disinfectants into wounds.
  - Do not douche the vagina or rectum after sexual exposure
- HIV testing of the exposed and the source (if possible)
  - Do not delay initiation of PEP around testing, it can be started and ceased if source is found to be HIV negative, or exposed is found to be HIV positive
- Assess risk and eligibility for PEP based on the nature of the exposure and source HIV status

2. Counselling re risks and options re PEP

- Explain the estimated risk of transmission (see above)
- Explain the risks and benefits of PEP:
  - PEP significantly reduces but does not eliminate the risk of transmission
  - PEP has to be taken continuously for 28 days
  - PEP ARV side effects
- Obtain verbal informed consent to initiate PEP

3.Initiate PEP as soon as possible following exposure, TAKE THE FIRST DOSE NOW!

- Check for drug interactions with any concurrent medications
- Provide adherence counseling and drug information
- Do not delay PEP whilst gathering information or filling in paperwork
- Women counseled that PEP will not harm fetus if they are possibly pregnant?
  - Standard PEP ARV regimen: Refer to regimen for children, adolescent and adult differently
  - Take the first dose straight away.
  - Give initial prescription / supply for 4 days and return for refill drug for another 24 days of the total 28 days

4. Assess and provide emergency contraception and STI treatment in the context of sexual exposure (Refer to National Guidelines on Sexually Transmitted Infections and Reproductive Tract Infections Case Management, 2019, Module 6: Prevention and care STI/RTI for vulnerable peoples in chapter 7: Sexual Violence and STIs/RTIs, page 182).

- Presumptive treatment of STI with Azithromycin 1g and Cefixime 400mg stat.
- Emergency contraception, and baseline + follow up pregnancy testing.

5. Assess for exposure to other infections

- HBV: high risk through parenteral and sexual exposure. Test source for HBsAg and eAg if sAg +.
- HCV: high risk through parenteral, and if traumatic sexual exposure, anal and vaginal. Test source
- Tetanus: Individuals who sustain wounds (bites, abrasions or cuts) should have their tetanus status assessed and be offered immunization if indicated.
- Syphilis: Source checked if possible

6. Explain need for secondary prevention:

- Measures must be taken to avoid secondary transmission of possible HIV infection until HIV Ab check in 3 months.
- If signs of primary HIV infection come immediately
- Use condoms, safe-injecting practices, and avoid blood donation. Risks and benefits of continuing to breast-feed should be discussed.

7. For sexual assault provide/refer for specific psychosocial support:

- See also national guideline on STI, 2019 which detail management of sexual assault

8. Complete documentation:

- Annex 2: Data collection form and Annex 3: Reporting form

9. Follow up on PEP

- Return to the clinic in 4 days for assessment of adherence and tolerability, and check that all results are available and that PEP is still indicated.
- If the source is established to be HIV negative, post-exposure prophylaxis should be discontinued.
- Prescribe further 24 days

10. Follow up testing

- HIV test 3 months after exposure or earlier if signs of primary infection
- Syphilis test at 3 months after sexual assault. Assumes source and patient tested at evaluation
- HBV, HCV testing at 6 months after exposure.

Annex 2: Data collection form

Facility Details

Hospital Name _____☐ ER ☐ ART clinic, ART site code ☐☐☐☐
☐ Referred from ER ☐Walked-in
Date of Visit (DD-MM-YYYY): _____/_____ / _____

Demographic details of Exposed Individual

Surname: _____ Name: _____ ○ Male ○ Female ○ Transgender women
Date of birth (DD/MM/YYYY) _____ /_____ / _____ UUIC: _____
Phone number: _____
Is he/she a member of Key Population? ☐ No ☐ Yes, specify (EW, MSM, TG, PWID)……

Categories of Exposures

☐ Occupational, specify_____
☐ Non-Occupational
- ○ Victim of sexual assault
- ○ Condom broken
- ○ No condom used with partner known HIV positive and VL detected
- ○ No condom used with unknown HIV status partners

Timing of Exposure

Date of exposure _____(dd/mm/yy) Time of Exposure _____ Hours from exposure to PEP:_____

Source person HIV status

At time of presentation ☐Positive ☐Negative ☐Unknown
If PLHIV, are they on ART? ☐Yes ☐No ☐Unknown
Date commenced ART ____/___/_____ ☐Unknown
Most recent VL result _____ Date___/___/_____(dd/mm/yy) ☐Unknown

Is source person available for HIV test? ☐Yes ☐No
Is the source person high risk assailant? ☐Yes ☐No ☐Unknown
Source HIV status follow up result ☐UD ☐Positive ☐Negative Date___/___/____

Exposed person's HIV status (If HIV positive, do not start/nor continue PEP when known)

At time of presentation: ☐Positive ☐Negative ☐Unknown
Ever had HIV test? ☐No ☐Yes Date ___/___/_____
HIV test at baseline: ☐Positive ☐Negative ☐UD Date ___/___/_____

Nature of Exposure

Occupational		
Deep puncture wound with a hollow bore needle	☐Yes	☐No
Needle-stick injury after it was used for IM/IV/subcutaneous injection	☐Yes	☐No
Injury from a sharp instrument visibly contaminated with blood	☐Yes	☐No
Exposure for > 1min or extensive exposure of non-intact skin or mucous membrane to blood or other infectious fluid or concentrated virus in a laboratory setting	☐Yes	☐No
Exposure to the blood of a patient in an advanced disease stage or with a higher HIV viral load	☐Yes	☐No

Non-occupational (if all "No", PEP is not indicated)			
Vaginal penetration Anal penetration Oral penetration Number of assailant _____	☐ Yes ☐Yes ☐Yes	☐No ☐No ☐No	

PEP	
Patient counselled: ☐Yes ☐No Verbally consented to PEP? ☐Yes ☐No	
Is PEP indicated? ☐Yes ☐No	
Regimen prescribed _____ days	
Adolescents and adults ☐TDF + 3TC + DTG ☐TDF + 3TC + ATV/r	
Children and adolescents ☐ABV + 3TC + LPV/r	☐AZT + 3TC + ATV/r
☐ABV + 3TC + ATV/r	☐TDF + 3TC + LPV/r
☐AZT +3TC +LPV/r	☐TDF + 3TC + ATV/r
Other/describe (EC, STI treatment) _____	
Time and date of 1st dose taken? (give as soon as possible, whilst in the consultation) Date ___/___/_____ Time: _____	
Other Care and Support referral	
Emergency contraception: ☐No (☐Referred ☐Not referred) ☐Yes, specify_____ STI presumptive treatment ☐No (☐Referred ☐Not referred) ☐Yes, specify_____ Psychosocial support ☐No (☐Referred ☐Not referred) ☐Yes, specify_____	
Status of other infections	
HBV ☐Yes ☐No ☐Unkwon	Chlamydia ☐Yes ☐No ☐Unkwon
HCV ☐Yes ☐No ☐Unkwon	Gonorrhea ☐Yes ☐No ☐Unkwon
Syphilis ☐Yes ☐No ☐Unkwon	
Follow up appointment (stress the importance of this): Date ___/___/_____	
Doctor to sign	

(to be filled out by ART clinic in case exposure individual first presented at ER) **Follow up consultation (4 days)** **Date ___/___/_____**
Attend: ☐Yes ☐No, then notify for Active Case Management
If Yes, complete info below Side effects? ☐No ☐Yes Describe:_____ Adherent? ☐Yes ☐No Describe:_____ Blood test from source checked? ☐No ☐Yes, result_____(if HIV negative, discontinue PEP) Blood test from exposed checked? ☐No ☐Yes, result_____(if HIV positive, discontinue PEP) Continue PEP? ☐Yes ☐No, explain:_____ Same regimen? ☐Yes ☐No, explain:_____
Follow up appointment: (stress the importance of this): Date ___/___/_____

Follow up (3 months)	**Date ___/___/_____**
Attend: ☐Yes ☐No If No ® Notify for Active Case Management	
Adherent? ☐Yes ☐No	If No, describe:
Symptoms or signs of possible acute HIV infection? ☐Yes ☐No	If Yes, describe:
HIV test performed?	☐No ☐Yes ☐Positive ☐Negative Date ____/_____/_____
☐ STI screened ☐HBV Ab ☐HCV Ab ☐Pregnancy test	
Follow up required? Yes☐ No☐	If No, describe: _____
Doctor to sign:	

Annex 3: Reporting form

មជ្ឈមណ្ឌលជាតិប្រយុទ្ធនឹងជំងឺអេដស៍ សើស្បែក និងកាមរោគ

National Centre for HIV/AIDS Dermatology and STD

*****

របាយការណ៍ប្រចាំត្រីមាសស្តីពីការលេបថ្នាំបង្ការក្រោយពេលមានប្រឈម

Post-Exposure Prophylaxis Quarterly Report

គ្រឹះស្ថានសុខាភិបាល (Facility)	**លេខកូដគ្រឹះស្ថានសុខាភិបាល (Facility Code)**
ស្រុកប្រតិបត្តិ (Operational District)	**ខេត្ត-ក្រុង (Province)**
ឆ្នាំ (Year)	**ត្រីមាសទី (Quarter)**

ល.រ (No.)	**សូចនាករ (Indicator)**	**អាយុ (Age)**	**អ្នកមានអាជីពការងារ Occupational**		**អ្នកមិនមែនអាជីពការងារ Non-occupational**		**សរុបរួម Total**
			ប្រុស (M)	**សុី (F)**	**ប្រុស (M)**	**ស្រី (F)**	
	ចំនួនអតិថិជនដែលបានស្វែងរកសេវា PEP ក្នុងត្រីមាសនេះ Total number of clients seeking for PEP during this quarter	0 - 14					
		>14					
		Total					
	ចំនួនអតិថិជនដែលបានទទួលការព្យាបាលបង្ការ PEP ក្នុងត្រីមាសនេះ Number patients having PEP prescribed during this quarter	0-14					
		>14					
		Total					
	ចំនួនអតិថិជនដែលបានទទួលការព្យាបាលបង្ការ PEPបានត្រឡប់មកតាមដានបន្តនៅថ្ងៃទី៥(ឬតាមថ្ងៃណាត់ជួប) ក្នុងត្រីមាសនេះ Number clients prescribed PEP returned for the follow-up visit on day fifth (or as appointment date) during this quarter	0-14					
		>14					
		Total					
	ចំនួនអតិថិជនដែលបានទទួលការព្យាបាលបង្ការ PEP បានត្រឡប់មកតាមដានបន្ត៣ខែបន្ទាប់ពីការពិនិត្យលើកទី១ (ឬតាមថ្ងៃណាត់ជួប) ក្នុងត្រីមាសនេះ Number clients prescribed PEP returned for the follow-up visit 3 months after the first visit date (or as appointment date) during this quarter	0 - 14					
		>14					
		Total					

គ្រឹះស្ថានសុខាភិបាល (Facility)	លេខកូដគ្រឹះស្ថានសុខាភិបាល (Facility Code)
ស្រុកប្រតិបត្តិ (Operational District)	ខេត្ត-ក្រុង (Province)
ឆ្នាំ (Year)	ត្រីមាសទី (Quarter)

លរ (No.)	សូចនាករ (Indicator)	អាយុ (Age)	អ្នកមានអាជីពការងារ Occupational		អ្នកមិនមែនអាជីពការងារ Non-occupational		សរុបរួម Total
			ប្រុស (M)	សុី (F)	ប្រុស (M)	ស្រី (F)	
ចំនួនអតិថិជនដែលបានទទួលការព្យាបាលបង្ការ PEP បានត្រឡប់មកតាមដានបន្ត ៣ខែ បន្ទាប់ពីការពិនិត្យលើកទី១ (ឬតាមថ្ងៃណាត់ជួប) និងមានវិជ្ជមានមេរោគអេដស៍ ក្នុងត្រីមាសនេះ Number patients prescribed PEP returned for the follow-up visit 3 months after the first visit date, and have HIV test positive during this quarter	0 - 14						
	>14						
	Total						
ថ្ងៃ ខែ ឆ្នាំធ្វើរបាយការណ៍ (Date Reported):							
ឈ្មោះ និងហត្ថលេខាអ្នកធ្វើរបាយការណ៍ (Report completed by):							
ឈ្មោះ និងហត្ថលេខាអ្នកអនុម័តឱ្យធ្វើរបាយការណ៍ (Report Approved by):							

X. References

Australian Sexual Health Medicine: National guidelines for post-exposure prophylaxis after non-occupational and occupational exposure to HIV. Second edition, 2016.

Australian Sexual Health Medicine: National guidelines for post-exposure prophylaxis after non-occupational and occupational exposure to HIV. 2013.

Nam aidsmap: Estimated risk per exposure, April 2009. http://www.aidsmap.com/Estimated-risk-per-exposure/page/1324038/, retrieved July 09, 2018.

Christian Hoffmann and Jürgen K. Rockstroh: HIV 2010; p. 629-635

NCHADS: National HIV clinical management guidelines for Adults and Adolescents. 4th Revision 2015; p. 164-168

Baggaley R, White R and Boilly M. HIV transmission risk through anal intercourse: systematic review, meta-analysis and implications for HIV prevention. International Journal of Epi 2010;39:1064-5.

Grulich AE et al. HIV transmission in male serodiscordant couples in Australia, Thailand and Brazil. 2015 Conference on Retroviruses and Opportunistic Infections (CROI 2015), February 23-26 2015, Seattle. Late breaker poster 1019 LB. http://www.croiconference.org/sessions/hiv-transmission-male-serodiscordant-couples-australia-thailand-and-brazil.

Safran SA, Mayer KH, Ou SS, et al. Adherence to early antiretroviral therapy: Results from HPTN 052, a phase III, multinational randomized trial of ART to prevent HIV-1 sexual transmission in serodiscordant couples. J Acquir Immune Defic Syndr. 2015 Jun 1;69(2):234-40.

Rodger AJ, Cambiano V, Bruun T, et al. Sexual Activity Without Condoms and Risk of HIV Transmission in Serodifferent Couples When the HIV-Positive Partner Is Using Suppressive Antiretroviral Therapy.JAMA. 2016;316(2):171-181.

https://www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/post-exposure-prophylaxis.

National Guidelines on Diagnosis and Antiretroviral Treatment of HIV Infection in Infants, Children and Adolescents in Cambodia, 4th Edition August 2016.

National technical guidelines on antiretroviral treatment of National AIDS Control Programme Care Support and Treatment Services (Ministry of Health, government of INDIA), October 2018.

Supported by