Government of **Western Australia**
Department of **Health**
Public and Aboriginal Health Division

Communicable Disease Control Directorate
Guidelines

Guideline for Non-Occupational Post-Exposure Prophylaxis (NPEP) to Prevent HIV in Western Australia

Guideline 0013/ October 2022

These guidelines have been released by the Communicable Disease Control Directorate, Public and Aboriginal Health Division, Western Australian Department of Health, to provide consistent and evidence informed advice to agencies involved in the prevention of infections and management of communicable diseases in Western Australia.

ACKNOWLEDGEMENT OF COUNTRY AND PEOPLE

The Communicable Disease Control Directorate at the Department of Health acknowledge the Aboriginal people of the many traditional lands and language groups of Western Australia. We acknowledge the wisdom of Aboriginal Elders both past and present and pay respect to Aboriginal communities of today.

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1. Definitions

Term	Definition
Non-Occupational Post-Exposure Prophylaxis (NPEP)	The prompt administration of antiretroviral therapy after exposure to the HIV virus NOT in a workplace setting, in an attempt to interrupt the HIV virus's normal replication and thus prevent the establishment of infection.
Pre-Exposure Prophylaxis (PrEP)	A tablet of tenofovir disoproxil fumarate/emtricitabine, or generic bioequivalents, available to individuals to reduce their risk of acquiring HIV during an exposure event. It is usually taken once a day to prevent HIV acquisition.

2. Purpose

The purpose of this Guideline is to clarify the appropriate use and methods of access to Non-occupational Post-exposure Prophylaxis (NPEP) for WA Health. It should be read in conjunction with the Guideline for the Management of Occupational Exposure to Blood and Body Fluids in the Health Care Setting.

This Guideline supersedes Operational Directive 0077/07: Protocol for Non-Occupational Post-Exposure Prophylaxis (NPEP) to Prevent HIV in Western Australia. It supports the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM)'s Post-Exposure Prophylaxis after Non-Occupational and Occupational Exposure to HIV: Australian National Guidelines.[1] The Department of Health strongly recommends sites and services create a site or service specific NPEP protocol.

3. Introduction / Background

Post-exposure Prophylaxis

Post-exposure prophylaxis (PEP) is defined as the prompt administration of antiretroviral therapy after exposure to the HIV virus, in an attempt to interrupt its normal replication and thus prevent the establishment of infection. Studies with health care workers following occupational exposure show treatment with PEP reduces HIV transmission.

Non-Occupational Exposure

Data about the potential efficacy of non-occupational PEP have accumulated from human, animal and laboratory studies, which suggests it should be offered in appropriate at-risk settings. However, there are currently no data from randomised control trials of NPEP and many gaps exist in the scientific data. Accordingly, assumptions are made about the direction of management. Every presentation for PEP should be assessed on a case-by-case basis, balancing the potential harms and benefits of treatment.

Considerations for Using Antiretroviral Agents

Decisions to provide antiretroviral agents to individuals after possible non-occupational HIV exposure must balance the potential benefits and risks. Factors influencing the potential effectiveness of this intervention include:

- probability that the source contact is HIV-infected
- prevalence of HIV in the area the source emanates from
- likelihood of transmission by the particular exposure
- interval between exposure and initiation of therapy
- efficacy of the drug(s) used to prevent infection
- the patient's adherence to the drug(s) prescribed
- where the source is known, their clinical circumstances, level of viraemia or stage of disease.

4. Requirements (of the Guideline)

4.1 Risk Assessment

Initiation of NPEP depends on a thorough risk assessment of both the method of exposure and if the HIV status of source is unknown (Table 1) or known (Table 2). If the HIV status of the source is unknown, the source's risk of HIV infection should be assessed, based on the epidemiology of the HIV infection (See section 4.2: Determining the HIV Status of the Source).

Cofactors associated with the source and exposed individuals should also be considered in the overall risk assessment because they may increase the risk of HIV transmission. These include:

- higher plasma viral load of the source (if known)
- a sexually transmissible infection in either the source or exposed person (especially genital ulcer disease and symptomatic gonococcal infection)
- a breach in genital mucosa integrity (e.g. trauma, genital piercing or genital tract infection)
- a breach in oral mucosal integrity when performing oral sex, particularly for the receptive partner
- penetrating, percutaneous injuries with a hollow-bore needle, or direct intravenous or intra-arterial injection with a needle or syringe containing HIV-infected blood
- the uncircumcised status of the insertive HIV-negative partner practising insertive anal intercourse or insertive vaginal intercourse without the use of a condom.

Table 1. Risk of HIV Transmission Following Non-Occupational Exposure to a Source with UNKNOWN HIV status

Type of exposure with UNKNOWN HIV-positive source	**Estimated risk of HIV transmission/exposure***
Condomless receptive anal intercourse	Ejaculation: 1/700* Withdrawal: 1/1550*
Shared needles and other injecting equipment	1/12,500† (1/1250 – 1/415‡ if source is a man who has sex with men)
Condomless insertive anal intercourse	Uncircumcised: 1/1600* Circumcised: 1/9000*
Condomless vaginal intercourse	Receptive: 1/1 250 000^ Insertive: 1/1 250 000^
Oral sex	Unable to estimate risk – extremely low
Needlestick injury or other sharps exposure from a discarded needle in community	Unable to estimate risk – extremely low
Mucous membrane and non-intact skin exposure	< 1/10 000 (men who have sex with men exposure)

* Based on estimated seroprevalence 10% (9.6%) in men who have sex with men.
† Based on estimated seroprevalence 1.0%.
‡ Based on estimated seroprevalence of 29%.
^ Based on estimated seroprevalence 0.1%

This table is from *Post-Exposure Prophylaxis after Non-Occupational and Occupational exposure to HIV: Australian National Guidelines (Second edition), (2016), The Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM).*[1]

Notes (Table 1):

- Condomless receptive oral intercourse with ejaculation MAY BE CONSIDERED as a high-risk exposure ONLY IF the source is known to be HIV-positive with a detectable HIV viral load and there is oral mucosal disease or an open lesion in the mouth or throat.
- Significant exposure of non-intact skin with blood, sperm or vaginal fluids MAY ALSO BE CONSIDERED as a high-risk exposure ONLY IF the source is known to be HIV positive with a detectable HIV viral load.
- The above table references condomless intercourse.

Table 2. Risk of HIV Transmission Following Non-Occupational Exposure to a Source with KNOWN HIV positive status who is NOT on antiretrovrial treatment

Type of exposure with KNOWN HIV-positive source	**Estimated risk of HIV transmission/ exposure***
Condomless receptive anal intercourse	Ejaculation: 1/70 Withdrawal: 1/155
Shared needles and other injecting equipment	1/125
Condomless insertive anal intercourse	Uncircumcised: 1/160 Circumcised: 1/900
Condomless vaginal intercourse	Receptive: 1/1 250 Insertive: 1/2550
Oral sex	Unable to estimate risk – extremely low
Needlestick injury or other sharps exposure from a discarded needle in community	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.

† Human bites are extremely low risk.

This table is from *Post-Exposure Prophylaxis after Non-Occupational and Occupational exposure to HIV: Australian National Guidelines (Second edition), (2016), The Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM)*.[1]

4.2 Determining the HIV Status of the Source

Provision of NPEP should not be delayed while establishing the source's HIV status:

- Active attempts should be made to contact the source by the exposed individual (i.e. the patient) or, with the patient's consent, by the treating doctor or contact tracing staff.
- If the source discloses they are living with HIV, consent should be gained to seek treatment details from their doctor.
- If the source discloses they are not living with HIV, they are asked to urgently undertake an HIV test (with pre-test discussion provided).
- If the source is known to be taking PrEP (Pre-Exposure Prophylaxis), NPEP is generally not required. Decisions to prescribe NPEP should still be considered on a case-by case basis due to potential for non-adherence of the source.
- In cases where the source refuses to disclose their HIV status or to have a test for HIV, it should be assumed for the purposes of NPEP prescription that they are HIV-positive.

- If the source cannot be contacted, the seroprevalence data in Table 3 will assist in determining the need for NPEP.

Table 3. HIV Seroprevalence In Australian Populations

Community group	HIV seroprevalence (%)
Men who have sex with men (MSM) • ACT • Adelaide • Queensland • Melbourne • Perth • Sydney Actual seroprevalence may be higher than reported seroprevalence.	 8.3 7.4 11.2 9.5 4.2 8.5
People who inject drugs in Australia • MSM • All others	 30.0 0.5
Heterosexuals in Australia • New blood donors (% donations) • Sexual health clinic attendees	 <0.003 <0.5
Female commercial sex workers (Australia)	<0.1
Overall Australian seroprevalence	0.14

This table is from *Post-Exposure Prophylaxis after Non-Occupational and Occupational exposure to HIV: Australian National Guidelines (Second edition), (2016), The Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM)*.[1]

4.3 Risk Calculation and Indications for NPEP

There are a variety of scenarios when NPEP may be indicated. Ultimately, the clinician will be evaluating factors that cannot be addressed in this guideline and will make a clinical judgement considering all these variables. Therefore, this guideline is not prescriptive, but puts forward cases (see Table 4 and Table 5) where:

- NPEP is recommended.
- NPEP should be considered, where the risks of treatment may assume a greater weight and the evidence of benefit is less.
- NPEP is not recommended, where the treatment risks outweigh the risk of exposure.
- The assessment of risk exposure is based on the limited prospective data, where available. Adverse effects caused by antiretrovirals, used for both NPEP and treatment of HIV, and their impact on adherence are frequent and well recognised. Anticipated ability to complete the full 28-day course is a very important factor to consider before recommending NPEP.
- Situations where there is greater uncertainty or complexity, such as known or suspected antiretroviral resistance in the source; pregnancy; breastfeeding; or chronic hepatitis B or C, should be discussed with a physician experienced in this area – see Appendix 2.

Table 4. NPEP Recommendations After Non-Occupational Exposure To A Source With UNKNOWN HIV Status

Type of exposure with UNKNOWN HIV-positive source	Estimated risk of HIV transmission/exposure*	NPEP Recommendation
Condomless receptive anal intercourse	Ejaculation: 1/700* Withdrawal:1/1550*	2 drugs if source man who has sex with men (MSM) or from a high prevalence country (HPC - see Appendix 3)
Shared needles and other injecting equipment	1/12,500† (1/1250 – 1/415‡ if source is MSM)	2 drugs if source MSM or from HPC
Condomless insertive anal intercourse	Uncircumcised: 1/1600* Circumcised: 1/9000*	Uncircumcised:2 drugs if source MSM or from HPC Circumcised: 2 drugs if source MSM or from HPC particularly if concurrent STI, trauma or blood
Condomless vaginal intercourse	Receptive: 1/1 250 000^ Insertive: 1/1 250 000^	Receptive: Not recommended. Consider 2 drugs if source MSM or from HPC Insertive: Not recommended. Consider 2 drugs if source from HPC
Oral sex	Unable to estimate risk – extremely low	Not recommended
Needlestick injury or other sharps exposure from a discarded needle in community	Unable to estimate risk – extremely low	Not recommended
Mucous membrane and non-intact skin exposure	< 1/10 000 (MSM exposure)	Not recommended

* Based on estimated seroprevalence 10% (9.6%) in men who have sex with men.
† Based on estimated seroprevalence 1.0%.
‡ Based on estimated seroprevalence of 29%.
^ Based on estimated seroprevalence 0.1%

This table is from *Post-Exposure Prophylaxis after Non-Occupational and Occupational exposure to HIV: Australian National Guidelines (Second edition), (2016), The Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM)*.[1]

Notes (Table 4):

- Condomless receptive oral intercourse with ejaculation MAY BE CONSIDERED as a high-risk exposure ONLY IF the source is known to be HIV-positive with a detectable HIV viral load and there is oral mucosal disease or an open lesion in the mouth or throat.
- Significant exposure of non-intact skin with blood, sperm or vaginal fluids MAY ALSO BE CONSIDERED as a high-risk exposure ONLY IF the source is known to be HIV positive with a detectable HIV viral load.
- The above table references condomless intercourse.

Non-occupational exposure to a known HIV status source

If the source viral load is known to be undetectable, NPEP is not recommended, provided the source history is reliable, they are compliant with medication, attend regular follow-up and have no intercurrent STIs.

If the source is not on HIV treatment or on treatment with detectable or unknown viral load, a 3 drug PEP regimen is recommended.

Table 5. NPEP Recommendations After Non-Occupational Exposure To A KNOWN HIV Positive Source

		NPEP Recommendation	
Type of exposure with KNOWN HIV-positive source	**Estimated risk of HIV transmission/exposure***	**Source not on treatment or on treatment with detectable or UNKNOWN viral load**	**Source viral load KNOWN to be undetectable**
Condomless receptive anal intercourse	Ejaculation:1/70 Withdrawal: 1/155	3 drugs	Not recommended*
Shared needles and other injecting equipment	1/125	3 drugs	Not recommended*
Condomless insertive anal intercourse	Uncircumcised:1/160 Circumcised: 1/900	3 drugs	Not recommended*
Condomless vaginal intercourse	Receptive: 1/1 250 Insertive: 1/2550	3 drugs	Not recommended*
Oral sex	Unable to estimate risk – extremely low	Not recommended†	Not recommended*
Needlestick injury or other sharps exposure from a discarded needle in community	Not applicable	Not applicable	Not applicable
Mucous membrane and non-intact skin exposure	< 1/1000	3 drugs	Not recommended

* Provided the source history is reliable, they are compliant with medication, attend regular follow-up and have no intercurrent STI.

† PEP may be recommended for receptive oral intercourse with ejaculation if the exposed person has a breach in their oral mucous membrane.

This table is from *Post-Exposure Prophylaxis after Non-Occupational and Occupational exposure to HIV: Australian National Guidelines (Second edition), (2016), The Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM)*.[1]

4.4 Number of drugs recommended for treatment

There is no direct evidence to support the greater or lesser efficacy of three over two-drug preventative regimens. It is an extrapolation of any possible benefit conferred by increased numbers/classes of drugs for HIV treatment while also taking into account potential side effects, toxicity, adherence and cost-effectiveness of adding a third drug.

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

These calculations determine if NPEP should be recommended and how many drugs should be used. Generally, 3 drugs are **recommended** if the transmission risk is 1/1,000 or greater; 2 drugs if it is between 1/1,000 and 1/10,000; 2 drugs should be **considered** if the risk ranges from less than or equal to 1/10,000 and greater than or equal to 1/15,000, and NPEP is **not recommended** for lower- risk exposures.

See the National NPEP Guidelines[1] for more information.

4.5 Management and Advice for the Exposed Person

4.5.1 Immediate Management of an Individual with Known or Suspected Exposure to HIV

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

However, in the case of an alleged sexual assault, discuss management with the Sexual Assault Resource Centre (SARC) duty doctor first, in order to prevent destruction of any forensic evidence. [24 hour emergency line for recent sexual assault – phone (08) 6458 1828 or 1800 199 888 (free from land line only)]

4.5.2 Clinical Assessment

The following details should be documented in the patient's history:

- The time of the assessment and first dose of NPEP, if prescribed.
- Of the exposure:
  - time of exposure
  - place of exposure
  - exact mode and details of exposure, including contributory factors
  - amount of blood or body fluid involved, including trauma and
  - first aid measures applied.
- Of the exposed person:
  - most recent HIV test and result
  - potential exposures within the last three months, and earlier as indicated
  - previous post-exposure prophylaxis and history of this treatment
  - previous PrEP and history of this treatment
  - evaluation of current sexually transmissible infections (STIs), hepatitis B virus (HBV) and hepatitis C virus (HCV) infection: if a patient is known to be HBV or HCV positive, specialist advice should be sought before NPEP is commenced
  - pregnancy risk, contraception and lactation (consider emergency contraception)
  - medical history, including:
    - illnesses, medications and drug allergies
    - psychiatric history

        - drug and alcohol history
    - their knowledge of the source, if unavailable for interview.
- Of the source (provision of NPEP should not be delayed while obtaining this information):
    - HIV status and other relevant demographic features
    - if HIV-positive:
        - plasma viral load and CD4 count, date of last test, medication adherence
        - antiretroviral treatment history. For instance, has resistance been an issue, and if so, with what drugs?
        - recent HIV resistance testing
    - current or past STI, HBV and HCV status
    - whether they are known to be taking PrEP.

Pre-test and pre-NPEP discussion

- An explanation of NPEP and its indications and effectiveness, risks and benefits are provided to all potential candidates (see section 4.5.3). Thorough pre-test discussion for HIV, including risk assessment is a fundamental part of the clinical assessment. See ASHM'S National HIV Testing Policy.

4.5.3 Counselling on NPEP and its Appropriate Use

Please see the following Supporting Documents for more information:

- HIV Post-Exposure Prophylaxis Information for Consumers- Accessing NPEP In Metropolitan Areas
- HIV Post-Exposure Prophylaxis Information for Consumers-Accessing NPEP In Metropolitan Areas: Plain Language
- HIV Post-Exposure Prophylaxis Information for Consumers-Accessing NPEP In Non-Metropolitan Areas
- HIV Post-Exposure Prophylaxis Information for Consumers-Accessing NPEP In Non-Metropolitan Areas: Plain Language.

Counselling of the person who is considering NPEP MUST include information on:

- The risk of HIV infection following the exposure.
    - The occurrence of HIV infection is dependent upon the nature of the exposure and background prevalence and epidemiology of HIV in the "source" person or event.
- The side effects and adverse reactions associated with HIV prophylaxis.
    - Side effects of antiretroviral medication such as nausea, headaches, fatigue and gastro-intestinal upset occur in many individuals.
    - It is very rare for these medicines to have any long-term side effects when they are used for a short time.
- The current status of knowledge regarding the efficacy of chemoprophylaxis following exposure to HIV.
    - Data about the potential efficacy of NPEP have accumulated from human, animal and laboratory studies, which suggests it should be offered in

appropriate at-risk settings. However, there are currently no data from randomised control trials of NPEP and many gaps exist in the scientific data.
    - NPEP provides high levels of protection but does not prevent 100% of infections.
- The symptoms of seroconversion should be explained to all patients, with advice to present if these or any other symptoms occur.
    - Soon after HIV infection, some people feel as if they have the flu, with symptoms such as fever, headache, tiredness and rash.[2]
    - As the virus continues to attack the immune system, a person may start to develop symptoms.[2] These can include:[2]
        - constant tiredness
        - swollen glands
        - rapid weight loss
        - night sweats
        - diarrhoea.
- The ongoing need for safe sexual and/or injecting practices to avoid the risk of infecting others.
    - It is important to use safe sex practices and safe injecting practices until confirmation or exclusion of acquisition of HIV following the high-risk exposure.
    - Discuss PrEP for patient consideration and further discussion with their/a GP.
- Strict compliance with the treatment regimen is necessary and this must be stressed to the patient.
- The use of HIV prophylaxis in pregnancy/breastfeeding (if appropriate).
    - Some antiretroviral drugs can be used in pregnancy. Their use would be dependent on the risk assessment demonstrating a very high-risk exposure and must be done in consultation with a specialist in HIV medicine.
- Information on other agencies available for support during the period of treatment.
    - http://getpep.info/
    - the PEP Line: 1300 767 161 - this is open 24 hours a day for PEP information and advice
    - WAAC: https://waaids.com/ or 08 9482 0000.
- Follow up tests: see Table 6 in this document.

After the provision of relevant information to enable an informed choice, a decision on the use of antiretroviral therapy must be made by the exposed person (obtain patient consent).

An information sheet and consent form (see Supporting Documents) should be issued so patients can consider the information. However, it should be emphasised that NPEP is more effective when administered as soon as possible and definitely within 72 hours.

The exposed person should be informed of the potential risk of HIV transmission to their sexual or injecting partners, especially during the first six to 12 weeks following the exposure to HIV. It should be noted that antiretroviral therapy may delay seroconversion to HIV and that they should be monitored for up to three months after

exposure. Baseline HIV, hepatitis B, hepatitis C, and syphilis serology should be undertaken with appropriate pre-test and post-test discussion, and consent.

During this period, the exposed person should be advised:

- not to donate plasma, blood, body tissue, breast milk or sperm
- to protect sexual partners from contact with blood, semen or vaginal fluid by adopting safe sexual practices, e.g. use of condoms
- not to share any injecting equipment
- to avoid pregnancy until their HIV status is known
- if they are pregnant, then the full risks of treatment must be discussed with a consultant.

4.5.4 Baseline Testing and Follow-Up

The exposed person should have baseline testing for HIV antigen/antibody (routine laboratory method). Where possible, the results should be followed up within 24 hours of the specimen being collected. Urgent testing should be available to individuals who are identified as at high risk of HIV.

Follow-up testing should be carried out at four weeks and three months after exposure (see Table 6). The exposed person should also be tested for other blood-borne viruses and STIs, depending on the mode of exposure. Follow-up HIV testing is no longer recommended at six months.[1]

Individuals found to be HIV-positive on baseline testing or during follow-up require information, support, counselling, clinical assessment and immediate referral to a HIV medicine specialist **(please phone specialist in the first instance – see Appendix 2).** A consultation with a HIV medicine specialist should not be delayed as a decision on whether NPEP should be ceased in these cases must be made. There is a theoretical risk of resistance to antiretroviral therapy developing if NPEP is continued, potentially limiting therapeutic options.

Ongoing management must also be provided for those at risk of other infections or pregnancy resulting from the exposure.

Table 6. Laboratory evaluation of individuals who are prescribed NPEP

Test	Baseline (Week 0)	Week 2	Week 4–6	Month 3
HIV serology (HIV Ab and HIV Ag wherever possible)	X		X	X
Hepatitis B serology (HBsAg, Anti-HBs and Anti-HBc)*	X			X
Hepatitis C serology (HepCAb positive check HCV PCR)†	X			X
STI screen†	X	X		X
Syphilis serology†	X		X	X
LFT, EUC	X		X^	
Pregnancy test†	X		X	

* Individuals with evidence of previous immunity to hepatitis B (HBsAb positive) will require no further follow-up. Non-immune individuals require immunisation and follow-up (to 6 months). . See section 4.6.1 'Management of Possible Exposure to Other Conditions' for more information.

† Depends upon mode of exposure and mode of follow up. See section 4.6.1 'Management of Possible Exposure to Other Conditions' for more information.^ If clinically indicated.

This table is from *Post-Exposure Prophylaxis after Non-Occupational and Occupational exposure to HIV: Australian National Guidelines (Second edition), (2016), The Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM)*.

4.6 Additional Clinical Management Issues

Recommendations about how to address the following clinical management issues are provided in Appendix 1:

1. Preventive behaviours whilst being managed for HIV exposure.
2. Individuals at risk of HIV transmission who decline NPEP.
3. Individuals at negligible risk of HIV transmission who request NPEP.
4. Individuals who re-present for NPEP.
5. Individuals who are on PrEP
6. Switching from PrEP to PEP
7. Transitioning from PEP to PrEP
8. Renal disease
9. Gender identity and history
10. Individuals who have been sexually assaulted
11. Children

12. Prisoners and detainees
13. Individuals who commenced PEP overseas
14. Risk communication: understanding the risk of exposure

This information has been taken directly from *Post-Exposure Prophylaxis after Non-Occupational and Occupational exposure to HIV: Australian National Guidelines (Second edition), (2016), The Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM)*

4.6.1 Management of Possible Exposure to Other Conditions[1]

Hepatitis B

All individuals presenting for NPEP are assessed for the possibility of hepatitis B exposure. Individuals with evidence of previous immunity to hepatitis B (HBsAb positive) will require no further follow-up. Non-immune individuals require immunisation and follow-up (to 6 months). If the individual is non-immune and the source is known to have chronic hepatitis B (HBsAg positive) then a single dose of Hepatitis B Immune Globulin (HBIG) should be administered within 72 hours of the exposure and hepatitis B immunisation commenced. For further advice go to the Silver Book: https://ww2.health.wa.gov.au/Silver-book/Notifiable-infections/Hepatitis-B.

Sexually transmissible infections

Individuals presenting for NPEP should be screened for chlamydia, gonorrhoea and syphilis as indicated by the exposure, local epidemiology and guidelines. If symptoms are present, further appropriate tests and follow-up should be performed. For further advice go to the Silver Book: https://ww2.health.wa.gov.au/Silver-book.

Hepatitis C

Individuals who are potentially at risk of hepatitis C infection (e.g. people who have shared needles and other injecting equipment, or who have had a needlestick injury, or men who have sex with men that have engaged in mucosally traumatic condomless anal sex) require baseline and follow-up testing for hepatitis C. Referral may be required if hepatitis C seroconversion is detected. Patients should be informed about the symptoms of acute hepatitis, with advice to present if these occur. Highly effective antiviral treatments are available. For further advice go to the Silver Book: https://ww2.health.wa.gov.au/Silver-book/Notifiable-infections/Hepatitis-C.

Pregnancy and breastfeeding

Pregnancy tests should be provided to all sexually active women presenting for NPEP. Emergency contraception should be offered to women presenting for NPEP who are at risk of pregnancy. Follow-up pregnancy tests should be offered at 3 to 4 weeks post-exposure where indicated. Specialist advice should be sought urgently for women who require NPEP and are pregnant or breastfeeding.

Tetanus

Individuals who sustain wounds or abrasions should have their tetanus status assessed and be offered immunisation as indicated.

4.7 Recommended Treatment

4.7.1 Time of initiation

Prophylaxis should be commenced as soon as possible following exposure and certainly within 72 hours of exposure. Commencement of treatment after 72 hours following exposure may still be considered in documented very high-risk circumstances. Seek consultation from a specialist.

4.7.2 Duration of treatment

A 28-day course of NPEP is recommended practice. A proactive approach to managing side effects will assist patients to adhere to the treatment.

Metropolitan patients: *Antiretroviral drug starter packs* Drug starter packs are recommended in metropolitan hospitals to encourage follow-up, support adherence and minimise drug wastage if the course is not finished. Use only when ordered by a nominated specialist in HIV medicine. Treatment should be started as soon as possible but no later than 72 hours. Starter packs should contain sufficient drugs to treat for 7 days and further supplies should be accessed at a day 7 visit.

Regional or non-metropolitan patients: Twenty-eight days of therapy should be given at initial presentation. The patient should be contacted at 7 days to ensure tolerability and to reinforce the importance of safer sex, if the 2-week STI screen will not be performed.

For indications for treatment and the number of drugs recommended, see Table 4 and Table 5.

Advice regarding individual cases should be sought as soon as possible from a clinician experienced in the administration of drugs for the treatment of HIV (see Appendix 2).

4.7.3 Recommended drug regimen (see also Appendix 4)

The Department of Health recommends **Tenofovir disoproxil 300mg + Emtricitabine 200mg** (as a combination tablet) as **the preferred two-drug combination**.

Precautions when considering Tenofovir disoproxil 300mg + Emtricitabine 200mg include if a patient:

- has renal impairment
- is elderly
- is less than 18 years of age or
- is pregnant or breastfeeding (Category B3 drug).

The Department of Health recommends **dolutegravir 50mg** (Tivicay®) **as the preferred third drug** when a three-drug NPEP regimen is recommended.

Drug options need to be discussed with a specialist in HIV medicine (see Appendix 2).

Assessment of the exposed person and the decision to offer treatment is the responsibility of the medical practitioner. The decision to accept or decline offered treatment is that of the exposed person and should be documented.

4.7.4 Access to NPEP

Health Services should implement mechanisms to educate all health care workers on the ways to access HIV treatment drugs, following a high-risk exposure or a patient presentation with a high-risk exposure.

The drugs should be available from larger metropolitan hospitals and from the nearest regional hospital in rural areas (see Appendix 5 for more information).

Each regional hospital should have available a 28-day supply of tenofovir disoproxil 300mg/ emtricitabine 200mg, and dolutegravir 50mg to enable administration of the drugs within 72 hours of an exposure if indicated.

Each regional hospital should identify, and disseminate to all hospitals within its area, the processes to access HIV treatment drugs on a 24 hour a day basis as part of their occupational health and safety plan.

5. Relevant Legislation

- Public Health Act 2016

6. Additional Resources/ Supporting Documents

- ASHM Post-Exposure Prophylaxis after Non-Occupational and Occupational Exposure to HIV Australian National Guidelines.
- ASHM. Police and Blood-Borne Viruses. Available from: https://ashm.org.au/resources/sexual-health-resources-list/police-and-blood-borne-viruses/
- HIV Post-Exposure Prophylaxis Information for Consumers- Accessing NPEP In Metropolitan Areas
- HIV Post-Exposure Prophylaxis Information for Consumers- Accessing NPEP In Metropolitan Areas: Plain Language
- HIV Post-Exposure Prophylaxis Information for Consumers- Accessing NPEP In Non-Metropolitan Areas
- HIV Post-Exposure Prophylaxis Information for Consumers- Accessing NPEP In Non-Metropolitan Areas: Plain Language
- Management of Non-Occupational Exposure to HIV In Metropolitan Emergency Departments Flowchart
- Management of Non-Occupational Exposure to HIV In Non-Metropolitan Emergency Departments Flowchart
- Visit Schedule For Taking NPEP- Metropolitan 7 Day Supply- Print Friendly
- Visit Schedule For Taking NPEP- Metropolitan 28 Day Supply- Print Friendly
- Visit Schedule For Taking NPEP- Non-Metropolitan 28 Day Supply- Print Friendly
- Guideline: Management of Occupational Exposure to Blood and Body Fluids in the Health Care Setting
- The Australasian Society for HIV Medicine (ASHM) testing portal
- The Sexual Assault Resource Centre (SARC)

7. Guideline Contact

Enquiries relating to this Guideline may be directed to:

Sexual Health and Blood-borne Virus Program

Directorate: Communicable Disease Control Directorate

Email: shbbvp@health.wa.gov.au

8. Document Control

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0013	V.1.	03/10/2022	03/10/2023	Original version

9. Approval

Approved by	Dr Jelena Maticevic, A/Director, Communicable Disease Control Directorate, Department of Health
Approval date	

10.References

1. Australasian Society for HIV Medicine. Post-Exposure Prophylaxis after Non-Occupational and Occupational Exposure to HIV: Australian National Guidelines. Second Edition. [Internet] Australasian Society for HIV Medicine, August 2016. [cited 2021 Feb 25]; Available from: https://www.ashm.org.au/products/product/978-1-920773-47-2

2. HIV and AIDS [Internet] Perth (Australia): Government of Western Australia Department of Health. 5 November 2020; cited 13 December 2021. Available from: https://www.healthywa.wa.gov.au/Articles/F_I/HIV-and-AIDS

11.Appendices

Appendix 1: Additional Clinical Management Issues

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Appendix 1: Additional Clinical Management Issues

1. Preventive behaviours whilst being managed for HIV exposure

Patients should adopt risk-reduction practices until their seronegative status is confirmed at follow-up. This includes safer sexual and injecting behaviour as well as preventing exposing others to their body fluids through other means such as accidents or body tissue donation. Women should be counselled about pregnancy, the risk of mother-to-child transmission, contraception, and offered emergency contraception if indicated.

2. Individuals at risk of HIV acquisition who decline PEP

Education about risk reduction (including PrEP) and HIV seroconversion should be provided. It is important that the patient remain engaged with a health service to ensure follow-up testing over the following three months.

3. Individuals at negligible risk of HIV transmission who request PEP

This response may relate to anxiety and fear about an apparently negligible exposure or to undisclosed more serious risk behaviours. It is important that the clinician takes a supportive approach and documents all advice given, including if PEP was not recommended and whether it was still prescribed at the patient's request. Early follow-up and a low threshold for psychological and HIV specialist referral is recommended.

4. Individuals who re-present for NPEP

People who present for repeat NPEP should be supported, with each presentation assessed on its merits in a non-judgemental manner. It may be necessary to consider extension to an existing PEP course and this should be by a full 28 days from the last HIV exposure risk. Repeat presentation(s) and extension of PEP courses warrant careful assessment of the context of risk behaviour and should prompt consideration for PrEP, referral to mental health, risk-reduction counselling and/or AOD services (see the National HIV Testing Policy at http://testingportal.ashm.org.au/hiv). Safer sex information should be an integral part of the consultation.

5. Individuals who are on PrEP

Switching from PrEP to NPEP is only recommended if:

- the exposure risk warrants 3-drug PEP, AND
- adherence to PrEP has been < 4 doses in the week of the exposure(s), AND
- the last exposure event occurred within the 72-hour PEP window.

See Table 1A for guidance.
If switching from PrEP to NPEP occurs in an emergency department, expert advice should be sought, and the individual referred back to their PrEP prescriber as a matter of urgency. If the individual is presenting for PrEP and they have had a possible exposure within the last 72 hours, they should be offered NPEP and can then be transitioned to PrEP once confirmed to be HIV-negative.

Table 1A. Switching from PrEP to NPEP

This table is from *Post-Exposure Prophylaxis after Non-Occupational and Occupational exposure to HIV: Australian National Guidelines (Second edition)*, (2016), *The Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM)*.

Risk event	Adherence to PrEP	Recommendations
Requires 3-drug NPEP	At least 4 doses in the week of the risk event(s)	• Continue PrEP. • Consider risk-reduction counselling.
Requires 3-drug NPEP	Less than 4 doses in the week of the risk event(s)	• Transition to 3-drug NPEP if last risk event is within the 72-hour NPEP window. • Thoroughly assess context of adherence difficulty and intervene. • Test for HIV at NPEP initiation and completion. • Re-commence PrEP on completion of 28 days of NPEP. • Reassess adherence and consider increasing frequency of monitoring.
Requires 2-drug NPEP	Less than 4 doses in the week of the risk event(s)	• Continue PrEP. • Thoroughly assess context of adherence difficulty, intervene and increase monitoring. • Test for HIV.

6. Transitioning from PEP to PrEP

Ideally, HIV status should be confirmed as negative at 12 weeks post-NPEP if transitioning from NPEP to PrEP. However, individuals at-risk may never be out of the serological testing window and PrEP initiation may be a matter of urgency. Individuals should be tested for HIV at the end of their NPEP course, and transitioned immediately onto PrEP.

7. Renal disease

All patients having PEP should be assessed for renal impairment. Tenofovir should not be used if creatinine clearance is less than 60mL/min. Zidovudine with lamivudine with both doses adjusted to degree of renal function is recommended as a 2-drug regimen with a third agent as indicated.

8. Gender identity and history

Disclosure of gender identity and history is not necessary for the provision of NPEP and should always be optional. This is particularly important for people with transgender experience, or who have non-binary or fluid gender identities. It is important to not make assumptions about an individual's gender identity, the type of sex they may have (e.g. anal, vaginal/front hole) or the level of risk associated with that sex (e.g. a trans man having condomless receptive sex with a cisgender man could be at high risk regardless of whether that sex is anal or front hole). The need for NPEP should be assessed based on the type of exposure determined during the clinical assessment. It may be beneficial to use open-ended questions to allow people to choose what information they disclose about the types of sexual interaction in which they engage.

9. Individuals who have been sexually assaulted

Those who present due to sexual assault should be assessed for their need for NPEP as early as possible after the event. This is usually best done in a specialist sexual assault centre (where specialist counselling and forensic testing can also occur, such as the Sexual Assault Resource Centre: Telephone (08) 6458 1828 or 1800 199 888, available 24 hours a day). However, NPEP, if indicated, should not be delayed pending referral. Male-to-male sexual assault clients should always be offered NPEP. There are no data on HIV prevalence for convicted sexual assailants in Australia; however, from studies on HIV point prevalence in Australian correctional services it ranges between 0 to 0.6%, with most jurisdictions reporting below 0.1%.

Given that the risk of exposure is low, NPEP is generally not recommended following heterosexual sexual assault; however, the decision to prescribe NPEP should be made on a case-by-case basis. Factors such as multiple assailants, trauma or an assailant who is from a high prevalence country may increase the exposure risk. Emergency contraception should always be offered for women or trans men in this situation.

10. Prisoners and detainees

People living in correctional or detention facilities who are potentially exposed to HIV sexually, through injecting drug use or other means require assessment for PEP as soon as possible after exposure. HIV point prevalence in Australian correctional facilities is estimated at below 0.1%, although this data is drawn from small and biased samples and should be used carefully. Timely disclosure of exposure is obviously a limiting factor in

these circumstances. The provision of assessment and treatment in correctional facilities should be available across all jurisdictions.

11. Individuals who commenced NPEP overseas

Those who started PEP while overseas may have been prescribed antiretroviral drugs which are not recommended in Australia. Frequently, they may not have had all of the recommended baseline tests and STI/BBV evaluations recommended in Table 6 of the Guideline. These should be completed as soon as possible and the individual should complete the NPEP course using an Australian recommended NPEP regimen. This can cause some anxiety to the patient and should be carefully explained and the individual reassured.

12. Risk communication: understanding the risk of exposure

Communicating the risk of an action or consequence can be very difficult. Table 2A presents an approach to this that may be useful with patients.

Table 2A. Estimates To Quantify Risk

Risk	Risk description
1/1 > risk > 1/10	Very high
1/10 > risk > 1/100	High
1/100 > risk > 1/1000	Moderate
1/1000 > risk > 1/10,000	Low
1/10,000 > risk > 1/100,000	Very low
1/100,000 > risk > 1/1,000,000	Minimal
1/1,000,000 > risk > 1 in 1 billion-trillion	Negligible

Appendix 2: Healthcare Facilities with Clinicians Experienced in Prescribing Drugs For Treatment Of HIV In Western Australia

Contacts for Advice on Using Antiretrovirals

Facility	Telephone Number	Who to Contact
Royal Perth Hospital, Clinical Immunology	(08) 9224 2899 (Monday-Friday)	Clinical Immunology Registrar (Monday-Friday)
	(08) 9224 2244 (Weekends, low activity days, public holidays and after hours)	Page Immunology Registrar on call (Weekends, low activity days, public holidays and after hours)
Fiona Stanley Hospital, Infectious Diseases Department	(08) 9431 2149 (Monday-Friday)	Sexual Health Physician, South Terrace Clinic
	(08) 6152 2222 (Weekends, low activity days, public holidays and after hours)	Page Infectious Diseases Registrar on call (Weekends, low activity days, public holidays and after hours)

Contacts for Advice on Management of Sexual Exposure to Viral or Bacterial Infections

Facility	Telephone Number	Who to Contact
Royal Perth Hospital, Sexual Health Clinic	(08) 9224 2178 (Monday-Friday)	Sexual Health Physician
	(08) 9224 2244 (Weekends, low activity days, public holidays and after hours)	Page Infectious Diseases Registrar on call (Weekends, low activity days, public holidays and after hours)
Fremantle Hospital, Infectious Diseases Department	(08) 9431 2149 (Monday-Friday)	Sexual Health Physician,South Terrace Clinic,
	(08) 6152 2222 (Weekends, low activity days, public holidays and after hours)	Page Infectious Diseases Registrar at Fiona Stanley Hospital on call (Weekends, low activity days, public holidays and after hours)

Appendix 3: High Prevalence Countries (HIV prevalence > 1.0

Sub-Saharan and North Africa

Angola	Benin	Botswana	Burkina Faso
Burundi	Cameroon	Central Africa Republic	Chad
Republic of the Congo	Djibouti	Ethiopia	Equatorial Guinea
Gabon	Gambia	Ghana	Guinea
Guinea-Bissau	Kenya	Lesotho	Liberia
Malawi	Mali	Mozambique	Namibia
Nigeria	Rwanda	Sierra Leone	South Africa
South Sudan	Swaziland	Tanzania	Togo
Uganda	Zambia	Zimbabwe	

Americas

Bahamas	Barbados	Dominican Republic	Guyana
Haiti	Jamaica	Panama	Suriname
Trinidad Tobago			

Eastern Europe

Russian Federation

Ukraine

Southeast Asia

Thailand

The most up to date information is available from http://aidsinfo.unaids.org/. This information was obtained and accurate on 1st June 2022 from http://aidsinfo.unaids.org/.

Appendix 4: Recommended NPEP Drug Regimen

WA Health recommends:

Two-drug regimen:

Tenofovir disoproxil fumarate 300mg /emtricitabine 200mg

ONE (1) TABLET DAILY

Three-drug regimen:

Tenofovir disoproxil fumarate 300mg /emtricitabine 200mg

ONE (1) TABLET DAILY

AND

Dolutegravir 50mg

ONE (1) TABLET DAILY

Appendix 5: Where to Access Non-Occupational PEP

For accurate and up to date information on where **Non-Occupational Post-exposure Prophylaxis (NPEP)** stock is kept on hand, access Formulary One to see the imprest lists for wards in public hospitals in WA. Using the imprest function, search for:

- Emtricitabine 200mg Tenofovir Disoproxil Fumarate 300mg Tablet
- Emtricitabine 200mg Tenofovir Disoproxil Maleate 300mg Tablet
- Emtricitabine 200mg Tenofovir Alafenamide 25mg Tablet
- Dolutegravir 50 mg tablet.

Metropolitan NPEP Starter Packs Access

In metropolitan areas, patients will be given a 7-day starter pack of NPEP. Every metropolitan public Emergency Department (ED) should have NPEP available.

The Sexual Health Clinic at Royal Perth Hospital and the South Terrace Clinic at Fremantle Hospital have NPEP available, during business hours only.

Non-Metropolitan NPEP Access

In non-metropolitan areas, patients will be given 28 days of NPEP. The patient should be contacted at seven days to ensure tolerability and to reinforce the importance of safer sex.

The following non-metropolitan sites stock NPEP. This information was current at the time of publication of this guideline, but may become out of date and should not replace consultation with Formulary One.

Region	Site	Stock location
Kimberley	Broome	ED
	Derby	ED
	Kununurra	ED
Great Southern	Albany	Pharmacy
	Katanning	ED
Goldfields	Kalgoorlie	Pharmacy
	Esperance	ED
Midwest	Geraldton	ED
	Carnarvon	ED
	Exmouth	ED
	Murchison- Meekatharra	ED
	Burringurrah	Pharmacy
	Coral Bay Nursing Post	Coral Bay Nursing Post
	Kalbarri	ED

Region	Site	Stock location
	North Midlands (Three Springs)	ED
	Northampton	ED
	Cue	ED
	Yalgoo	ED
Pilbara	Port Hedland	ED
	Karratha	ED
	Newman	Pharmacy
	Onslow	Pharmacy
	Tom Price	Pharmacy
South West	Busselton	ED
	Bunbury	ED
	Collie	ED
	Manjimup (Warren)	ED
Wheatbelt	Northam	ED
	Narrogin	ED
	Merredin	ED

Accessing remainder of NPEP regimen for metropolitan patients

The remainder of a patient's NPEP regimen will be dispensed at a follow up appointment within seven days of the patient receiving a start pack.

In metropolitan areas, these appointments will generally take place at Royal Perth Hospital Sexual Health Clinic or Fremantle Hospital South Terrace Clinic. The hospital pharmacy will dispense the remainder of the NPEP treatment.

This document can be made available in alternative formats on request for a person with disability.

Guideline for Non-Occupational Post-Exposure Prophylaxis (NPEP) to Prevent HIV in Western Australia