Non-Occupational Post-Exposure Prophylaxis (NPEP) To Prevent HIV in Western Australia Protocol

Preamble	The purpose of this protocol is to clarify the appropriate use and methods of access to Non-Occupational Post-Exposure Prophylaxis (NPEP) to prevent HIV in Western Australia.

1 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; and
- where the source is known, their clinical circumstances, level of viraemia or stage of disease.

2 Risk Assessment:

Initiation of NPEP depends on a thorough risk assessment of both the method of exposure (Table 1) and the source's risk of HIV infection, based on the epidemiology of the HIV infection (Table 2). 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:

- high viral plasma load (a low load does not eliminate HIV transmission);
- 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 or genital tract infection);
- a breach in oral mucosal integrity when performing oral sex, particularly for the receptive partner; and/or
- penetrating, percutaneous injuries with a hollow-bore needle, or direct intravenous or intra-arterial injection with a needle or syringe containing HIV-infected blood.

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TABLE 1: Risk of transmission following a single unprotected exposure to an HIV-infected person

Type of Exposure with Known HIV-Positive Source	Estimated Risk of HIV Transmission/ Exposure [i]
Receptive anal intercourse	1/120
Use of contaminated injecting equipment	1/150
Occupational needle-stick injury	1/333
Receptive vaginal intercourse	1/1000 [ii]
Insertive anal or vaginal intercourse	1/1000[2]
Receptive fellatio with or without ejaculation	Not measurable [iii]
Insertive fellatio	Not measurable
Cunnilingus	Not measurable
Bites etc.	Not measurable
Other trauma	Not measurable
Non-occupational exposure of intact mucous membrane [iv] and skin	Not measurable
Community needle-stick injury	Not measurable

Source: Department of Health and Ageing (2006) *National Guidelines for Post-exposure Prophylaxis after Non-occupational Exposure to HIV*

[1] These estimates are based on prospective studies, not cross-sectional data or figures derived from modelling.
[2] This estimate has been rounded down from 1/909 to 1/1000.
[3] Although there have been some case reports of transmission, the risk associated with the exposures below is so low that it is not measurable.
[4] Conjunctival, oral or nasal mucosa

3 Determining the HIV Status of the Source:

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.

TABLE 2: Risk that the source is HIV-positive in Australian and overseas populations

Community Group	Estimated HIV Seroprevalence (%)
Homosexual Men (Men who have sex with men) in Australia • Sydney • Melbourne • Brisbane • Perth* (2006 Gay Community Periodic Survey)	 14.2 9.1 6.0 4.9
Injecting Drug Users (in Australia) • Homosexual Men • All others	 17.0 [v] 1.0
Heterosexuals (in Australia) • Blood Donors • STI Clinic attendees	 0.0005 <0.2
Commercial sex workers (in Australia) – Australian born	0.1
HIV seroprevalence in selected regions [vi] • Oceania, Western & Central Europe, North Africa & Middle East, East Asia, New Zealand • Latin America, North America, S & SE Asia, Eastern Europe & Central Asia • Caribbean • Sub-Saharan Africa	 ≤ 0.5 0.6-1.0 1.6 7.2

Source: Department of Health and Ageing (2006) *National Guidelines for Post-exposure Prophylaxis after Non-occupational Exposure to HIV;* * Zablotska I, Brown G, Frankland A, Prestage G, Kippax S, & Langdon T. (2007). *Gay Community Periodic Survey: Perth 2006* (GCPS Report 3/2007). Sydney: National Centre in HIV Social Research, The University of New South Wales.

5 The rates of HIV in homosexual injecting drug users vary considerably between different studies; they are also based on small samples. Prescribers are recommended to seek out local data to assist.

[6] This varies greatly. A predictor of HIV-positivity is being born in a country with a high prevalence of HIV (>1%). Other predictive factors include injecting drug use, commercial sex work and men who have sex with men. Country specific information for the general population and subgroups is available at http://www.who.int/globalatlas/

4 Management And Advice For The Exposed Person

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.

Clinical Assessment

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

The time of the assessment and first dose, 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;
- evaluation of current sexually transmissible infections (STIs), hepatitis B virus (HBV) and hepatitis C virus (HCV) infection;
- pregnancy risk, contraception and lactation, consider emergency contraception;
- medical history, including illnesses, medications and drug allergies;
- psychiatric history;
- drug and alcohol history; and
- their knowledge of the source, if unavailable for interview.

Of the source

- HIV status and other relevant demographic features; or
- if HIV-positive:

  - o plasma viral load and CD4 count
  - o antiretroviral treatment history. For instance, has resistance been an issue, if so, with what drugs?
  - o recent HIV resistance genotyping
- current or past STI, HBV and HCV status.

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; and
- if they are pregnant, then the full risks of treatment must be discussed with a consultant.

Management of Possible Exposure to Other Conditions

Hepatitis B

All individuals presenting for NPEP are assessed for the possibility of hepatitis B exposure and are managed according to the guidelines from the Australian Immunisation Handbook http://www9.health.gov.au/immhandbook/pdf/handbook.pdf.

Sexually transmissible infections

Individuals presenting for NPEP are 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.

Hepatitis C

Individuals who are potentially at risk of hepatitis C infection after exposure, require follow-up for this and specialist referral if seroconversion is detected. They should be informed of symptoms of acute hepatitis, with advice to present if these occur.

Pregnancy

Pregnancy tests are provided to all sexually active women presenting for NPEP. Emergency contraception is offered to women presenting for NPEP who are at risk of pregnancy. Follow-up pregnancy tests should be offered at two 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 are offered immunisation as indicated.

5 Recommended Treatment

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.

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.

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 3).

Antiretroviral drug starter packs:

Drug starter packs are recommended 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. Refer to appendix 3 for contact advice. Use preferably within hours but no later than 72 hours. Starter packs contain sufficient drugs to treat for 7 days and further supplies should be accessed at the day 7 visit. Refer to appendix 3 for contact advice.

Reference

1. Needle and syringe Disposal. 2008. The University of Western Australia. Safety & Health. University Safety Committee. http://www.safety.uwa.edu.au/policies/sharps
2. Staff accidental inoculation policy. 2007. Women's & children health service. Infection Control Manual. Policy 3.2
3. Department of Health. Western Australia. Protocol for non-occupational post exposure prophylaxis (NPEP) to prevent HIV in Western Australia. Operational directive 0077/07
4. National HIV testing policy 2006. http://www.health.gov.au/internet/main/Publishing.nsf/Content/health-pubhlth-strateg-hiv_hepc-hiv-index.htm#testing

Appendix 1

HIV Post-Exposure Prophylaxis

Information and Consent Form for patients

What is the risk?

You can become infected with HIV if you have been exposed to blood and other body fluids from someone who is already infected. However, the risk is not high. Studies on health care workers, who were exposed to infected blood through injection or broken skin, show that only about 1 in 333 became infected.
The following table estimates the risk of becoming infected with HIV each time you have sex or share a needle with a HIV-positive person.

Table: Risk of transmission, following a single unprotected exposure to a HIV-infected person

Type of Exposure with Known HIV-Positive Source	Estimated Risk of HIV Infection per Exposure
Occupational exposure Needle-stick injury	 1 in 333
Unprotected sexual exposure Anal intercourse (receptive) Vaginal intercourse (receptive) Insertive anal/vaginal intercourse Oral sex (receptive)	 1 in 120 1 in 1,000 1 in 1,000 Not measurable
Use of contaminated injecting equipment	1 in 150
Community needle-stick injury	Not measurable
Non-occupational intact mucous membrane (e.g. nose or mouth)/skin exposure	Not measurable
Bites	Not measurable

Your risk of acquiring HIV infection is markedly increased if you have recently acquired a sexually transmissible infection (STI), such as genital herpes. If this is the case, please inform your doctor.

What is PEP?

Studies in health care workers and in animals show that treatment with anti-HIV drugs soon after exposure to HIV, may prevent infection, but the evidence is not clear. This treatment is called Post-exposure Prophylaxis or PEP. We know that PEP reduces the risk of HIV infection after exposure, but not in every case.
The Department of Health believes that PEP should be considered after high-risk exposure to HIV. Since you and your doctor feel that you have had a high-risk exposure to someone

infected with HIV, you are now being offered a free four-week course of PEP, referred to as NPEP, because your exposure is non-occupational.

The doctor has given you information to help you decide if you want to take NPEP treatment. The final decision is yours. However, you must start NPEP as early as possible after being exposed to HIV and definitely within 72 hours. The sooner you start the treatment, the better the chance of it working

Factors in deciding to take NPEP

In deciding what to do, you really need to think about the following:

- The real chance of becoming infected with HIV, following a definite exposure is low, especially outside a work setting (see the table above).
- We still do not really know how well NPEP works. One study showed that treatment with a drug called zidovudine (or AZT) soon after needle-stick exposure in health care workers greatly reduced the risk of HIV transmission, so it is recommended for high-risk occupational injuries. Using more than one type of anti-HIV drug is better than one drug and they must be taken for four weeks.
- The risk of getting HIV varies according to how you were exposed to the infection and how healthy you are. This includes the amount of HIV in the infected person's blood, and if you or they already have an STI.
- It is particularly important to practice safe sex with any partner for at least three months after risky exposure. If you inject drugs it is important not to share injecting equipment. Be aware that your blood or body fluids could potentially be a hazard to others.
- Many people using NPEP show some side effects such as nausea (feeling sick) and stomach upsets, headaches and tiredness.
- There is no evidence that using these drugs for a short time has any long-term effects, but because this treatment is new, we cannot be sure of this.
- If you decide to take the treatment you must tell the doctor of any drugs you are taking. This includes prescription, non-prescription and illegal drugs.
- If you are or might be pregnant, or if you are breastfeeding, you can take some antiviral drugs. However, it is important to talk to your doctor or a specialist in HIV medicine before you begin any treatment.
- It is important to stick to the treatment in the way your doctor tells you. If you have any questions to contact Sexual Health Department at Fremantle hospital (08) 9431 2149.
- You need to see your doctor again as soon as the treatment is finished, and then at about three and six months after exposure. Your doctor will take some blood to test if you have developed HIV infection.

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Monitoring of NPEP

To understand how well NPEP treatment works, the Department of Health is collecting information on people who have the treatment. Your doctor will ask you:

- how you think you were exposed to HIV;
- whether you decided to take NPEP;
- the type of treatment you receive;
- how you felt about the treatment, including any side-effects; and
- results of your blood tests over the six-month period after exposure.

The information will be completely confidential, your doctor will only give us your date of birth and your medical record number so we can link all the information we receive during the six months after your exposure.

I have read and understood the above. I have also discussed the use of NPEP with:

Dr ……..

After thinking about the information I have been given,
I have decided to take#/not to take# Post-exposure Prophylaxis.
(#Strike out whichever is not applicable)

Signed: ……

Print Full Name: ……

Witness: ……

Print Full Name: ……

Date: ……/……../……

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Appendix 2

Access To NPEP For HIV

Non Occupational Post Exposure Prophylaxis (NPEP) Should be Given as Soon as Possible Following Exposure and No Later Than 72 Hours.

Prior to administration of NPEP, the exposed person should be assessed for risk, in conjunction with a clinician experienced in prescribing antiretroviral drugs (see Appendix 3). In addition, counselling should be given and consent for treatment should be obtained.

Person visits doctor after sustaining a possible exposure to HIV

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Assessment of risk. Establish sero status of source if possible.

↙ ↘

NPEP Recommended/Considered

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Contact a specialist clinician (see Appendix 3) to discuss risk assessment and management (and refer in metropolitan area).

If considered appropriate, the patient needs to commence NPEP as soon as possible and no later than 72 hours post-exposure.

Starter packs (containing seven days supply of drugs) should be available at regional hospitals (see next page for contact details).

Serological testing for:
HIV, HBV and HCV.
Repeat serology at 4-6 weeks (HIV), 3 months (HIV, HCV) and 6 months (HIV, HCV and HBV).

Test FBE, LFT, electrolytes.

NPEP Not Recommended

↓

Serological testing for:

HIV, HBV and HCV.

Repeat serology at 4-6 weeks (HIV), 3 months (HIV, HCV) and 6 months (HIV, HCV and HBV).

If exposure of sexual nature:

Take swabs/urine for chlamydia and gonorrhoea.

Serology for syphilis.

Consider prophylaxis for hepatitis B and tetanus in needle-stick exposure.

Consider prophylaxis for hepatitis A and B for homosexual/bisexual exposure.

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If exposure of sexual nature:
Take swabs/urine for chlamydia and gonorrhoea.
Serology for syphilis.
Provide a pregnancy test.

Consider prophylaxis for hepatitis B and tetanus in needle-stick exposure.

Consider prophylaxis for hepatitis A and B for homosexual/bisexual exposure.

Antiretroviral drugs need to be given for a period of four weeks (28 days), inform the patient of the importance of completing the full treatment and how to access further medication, e.g. supply prescriptions for the further doses and the hospital will dispense.

There is no cost to the patient for these drugs, **but they may have to pay a small handling fee for the prescription. The patient needs to be counselled on the benefits and side effects of the drugs and their decision to accept or decline treatment should be documented.**

Appendix 3

Healthcare Facilities with Clinicians Experienced In Prescribing Drugs for Treatment of HIV in Western Australia

Contact Advice on Using Antiretrovirals

Facility	Telephone Number	Who to Contact
Royal Perth Hospital, Clinical Immunology	(08) 9224 2899 (Monday-Friday) (08) 9224 2244 (Weekends, low activity days, public holidays and after hours)	Clinical Immunology Registrar (Monday-Friday) Page Immunology Registrar on call (Weekends, low activity days, public holidays and after hours)
Fremantle Hospital, Infectious Diseases Department	(08) 9431 3333	Infectious Diseases Physician
Princess Margaret Hospital, Department of Immunology	(08) 9340 8222	Clinical Immunologist

General Contact for Advice on Management of Sexual Exposure to Viral or Bacterial Infectors

Facility	Telephone Number	Who to Contact
Fremantle Hospital, Sexual Health Service, Infectious Diseases Department	(08) 9431 2149	Sexual Health Physician
Royal Perth Hospital, Sexual Health Clinic	(08) 9224 1644 (08) 9224 2178	Sexual Health Physician

Delivering a Healthy WA

Rockingham Peel Group

Pre-Test Counselling for Blood Borne Viruses (BBV)

Information Sheet
(Infection Control Manual)

The purpose of pre and post test counselling is to fully inform the individual being tested of the medical, psychological and social implications of the possible outcomes of being tested for blood borne viruses.

Appendix 3 identifies additional support, contact details and advice from Healthcare Facilities with experienced Clinicians in prescribing and supporting individuals through the process BBV. These are what the affected individual should understand:

Confidentiality

- Confidentiality and privacy issues are a major concern for people undergoing blood-borne viruses testing (particularly HIV). Therefore, confidentiality and privacy issue should be explained in detail.

Informed consent obtained

- Gaining informed consent of an individual to be tested is fundamental to an effective best-practice testing process.
- Informed consent should be obtained and documented in the medical notes or consent form during pre-test discussion. This discussion should also incorporate an assessment of risk, an explanation of testing process as well as discussion of the possible outcomes of the test.
- Assess the person's preparedness to be tested and assurance that the person wishes to proceed with testing.

HIV Testing

- A positive test can occur as early as 2 weeks from initial infection. Virtually all infected individuals are positive at 6 months. Therefore, testing should be performed at 6 weeks, 3 months and 6 months post exposure.
- Following infection the individual may remain asymptomatic for many years. During this time a predictable derangement of immune function occurs.

- AIDS as defined by opportunistic infections, malignancy or neurological disorders is a late manifestation of HIV infection and reflects a progressive deterioration in immune function.

Hepatitis B and Hepatitis C Testing

- Hepatitis B and Hepatitis C can have a window period of four to six months from initial infection. Repeat testing is recommended at three and six months.

- A HCW or patient is immune to hepatitis B as indicated by a Hepatitis B surface antibody of 10 or more. In this situation, this person is unlikely to acquire or transmit hepatitis B infection.

- A positive hepatitis C serology indicates exposure to hepatitis C infection. To determine whether the HCW or patient has a current active infection, Hepatitis C PCR testing is required.

What a positive result means in regard to:

Medical Aspects

- If a high risk exposure has occurred, post-exposure prophylaxis may be commenced before results are available.

- HCWs or patients found to be positive in HIV, hepatitis B or C will be referred to a specialist physician for immediate and further management.

- Similarly, if the source if found to be positive for blood borne viruses, the HCW who was exposed will be referred to a specialist physician for immediate and further management.

Psychological Aspects

- It is important to anticipate how a HCW or patient is likely to react in the event of a positive HIV, Hepatitis B or Hepatitis C antibody test. Adequate time and the correct setting should be planned to discuss the results of HIV, Hepatitis B and Hepatitis C antibody test, whether positive or negative. This should not be undertaken over the telephone. Only in person.
- The HCW or patient should be given plenty of opportunities to ask questions at the time of interview and/or at a later time.

Notification Requirements

- It is important to inform the HCW or patient that it is mandatory for true positive results to be notified to the Health Department.

- No identifiable information about the HCW or individual will be submitted unless he/she has AIDS

- If the patient is asymptomatic, then the notification is done by code using the first two letters of the first name and surname, date of birth, occupation and includes the status of the disease and possible mode of acquisition. However, if the patient is AIDS-positive, the patient is to be notified by full name and address. This information is used for epidemiological purposes and is maintained in the strictest confidence.

Social Aspects

- There may be implications for work, family, sexual activity, blood donation, etc if testing is performed regardless or whether the result is positive or negative.
- Insurance companies may ask if HIV antibody tests have been performed and if so, may request results of those tests. Some insurance companies may take the performance of an HIV antibody test as evidence that the person has been at risk.

What a Negative Result Means

- If the source is confirmed negative for blood-borne viruses, the HCW should be offered follow up testing at 3 months for reassurance. No behavioural or work practice modifications are required.
- Further testing at 6 months may be necessary is there is a reason to suspect that the source was high risk for blood borne viral infection.