



OPERATIONAL DIRECTIVE

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Subject: **Protocol for Non-Occupational Post-Exposure Prophylaxis (NPEP) to Prevent HIV in Western Australia**

PURPOSE: The purpose of this Operational Directive is to clarify the appropriate use and methods of access to Non-occupational Post-exposure Prophylaxis (NPEP) in the Department of Health WA sites and institutions. It should be read in conjunction with *Standard and Additional Infection Control Precautions* (Operational Circular OP 2039/06) and *Management of Occupational Exposure to Blood and Body Fluids in the Health Care Setting* (Operational Circular OP 1803/04). It supersedes Operational Circular OP 1946/05. It supports the Australian Government Department of Health and Ageing's *National Guidelines for Post-Exposure Prophylaxis after Non-occupational Exposure to HIV*.

1. INTRODUCTION

1.1 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. Similarly, data from randomised controlled trials show that vertical transmission of HIV is reduced, by up to 69 per cent, as a result of antiretroviral therapy for both mother and child.

Non-occupational exposure

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.

1.2 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.

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 ¹
Receptive anal intercourse	1/120
Use of contaminated injecting equipment	1/150
Occupational needle-stick injury	1/333
Receptive vaginal intercourse	1/1000 ²
Insertive anal or vaginal intercourse	1/1000 ²
Receptive fellatio with or without ejaculation	Not measurable ³
Insertive fellatio	Not measurable
Cunnilingus	Not measurable
Bites etc	Not measurable
Other trauma	Not measurable
Non-occupational exposure of intact mucous membrane ⁴ 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.

2.1 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 HIV-positive, consent should be gained to seek treatment details from their doctor.
- If the source discloses they are not infected with HIV, they are asked to urgently undertake an HIV test (with pre-test discussion provided).
- 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 2 will assist in determining the need for NPEP.

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	14.2
• Melbourne	9.1
• Brisbane	6.0
• Perth* (2006 Gay Community Periodic Survey)	4.9
Injecting Drug Users (in Australia)	
• Homosexual Men	17.0 ⁵
• All others	1.0
Heterosexuals (in Australia)	
• Blood Donors	0.0005
• STI Clinic attendees	<0.2
Commercial sex workers (in Australia) – Australian born	0.1
HIV seroprevalence in selected regions⁶	
• Oceania, Western & Central Europe, North Africa & Middle East, East Asia, New Zealand	≤ 0.5
• Latin America, North America, S & SE Asia, Eastern Europe & Central Asia	0.6-1.0
• Caribbean	1.6
• Sub-Saharan Africa	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 www.who.int/globalatlas/.

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 directive and will make a clinical judgement considering all these variables. Therefore, the directive is not prescriptive, but puts forward cases (see Table 3) 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; and
- 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.

Risk of HIV transmission = Risk per single exposure x Risk of source being HIV-positive

The National NPEP Guidelines include two tables where the risk of HIV transmission has been calculated, based upon the risk of a single exposure and the risk of the source being HIV-positive (see Appendix 1). 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.

Recommend 3 drugs	Transmission risk \geq 1/1,000
Recommend 2 drugs	1/1,000 > transmission risk > 1/10,000
Consider 2 drugs	1/10,000 \geq transmission risk \geq 1/15,000
Does not recommend NPEP	Transmission risk < 1/15,000

TABLE 3: Indications for NPEP

<p>NPEP IS RECOMMENDED AND <u>3 DRUGS</u> ARE PRESCRIBED when:</p> <p>The source is known to be HIV-positive, and where the exposure is:</p> <ul style="list-style-type: none"> • receptive anal intercourse; • shared injecting equipment, e.g. needle and/or syringe; • receptive vaginal intercourse; • insertive anal intercourse; or • insertive vaginal intercourse. <p>The source HIV status is unknown, in some areas of high prevalence where the exposure is:</p> <ul style="list-style-type: none"> • sharing injecting equipment between men who have sex with men (MSM) (see Table 2); or • receptive anal intercourse between MSM (see Table 2).
<p>NPEP IS RECOMMENDED AND <u>2 DRUGS</u> ARE PRESCRIBED when:</p> <p>The source HIV status is unknown, and where the exposure is:</p> <ul style="list-style-type: none"> • sharing injecting equipment between MSM or a person from a high prevalence country (see Table 2); • receptive anal intercourse between MSM (see Table 2); or • receptive anal intercourse with a partner (heterosexual or MSM) from a high prevalence country.

TABLE 3: Indications for NPEP (Cont'd)

<p>NPEP (2 DRUGS) IS CONSIDERED when:</p> <p>The source is known to be HIV-positive and the exposure is:</p> <ul style="list-style-type: none">• receptive oral intercourse with ejaculation AND the oral mucosa is NOT INTACT. <p>The source HIV status is unknown and the exposure is:</p> <ul style="list-style-type: none">• insertive anal intercourse between MSM;• receptive anal intercourse and the source is a heterosexual injecting drug user (IDU);• sharing injecting equipment between heterosexuals; or• receptive vaginal or insertive vaginal or anal intercourse with a partner from a high prevalence country.
<p>NPEP IS NOT RECOMMENDED when:</p> <p>The source is known to be HIV-positive and the exposure is:</p> <ul style="list-style-type: none">• receptive oral intercourse with ejaculation WITH INTACT oral mucosa; or• non-occupational contamination of INTACT mucosa and skin with body fluids. <p>The source HIV status is unknown and the exposure is:</p> <ul style="list-style-type: none">• heterosexual anal, vaginal or oral intercourse (NOT from a high prevalence country); or• a community-acquired needle-stick injury.

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

4. MANAGEMENT AND ADVICE FOR THE EXPOSED PERSON

4.1 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.

4.2 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:
 - (i) plasma viral load and CD4 count
 - (ii) antiretroviral treatment history. For instance, has resistance been an issue. If so, with what drugs?
 - (iii) recent HIV resistance genotyping
 - current or past STI, HBV and HCV status.

- **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 4.3). Thorough pre-test discussion for HIV, including risk assessment is a fundamental part of the clinical assessment. See *National HIV Testing Policy 2006*.

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4.3 Counselling on NPEP and its Appropriate Use

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. There is no evidence of long-term toxicity from short courses of antiretroviral drugs in humans, but this cannot be discounted.
- **The current status of knowledge regarding the efficacy of chemoprophylaxis following exposure to HIV.** See section 1.1.
- **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.
- **Compliance.** 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.**

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.

An information sheet and consent form (see Appendix 5) 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 six 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; and
- if they are pregnant, then the full risks of treatment must be discussed with a consultant.

4.4. 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, three months and finally six months after exposure (see Table 4). The exposed person should also be tested for other blood-borne viruses and STIs, depending on the mode of exposure. While most people will seroconvert to HIV in the first 6 to 12 weeks, delayed seroconversion out to 6 months has occurred.

Individuals found to be HIV-positive on baseline testing or during follow-up require information, support, counselling, clinical assessment and referral. NPEP should be ceased in these cases. 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 4: Laboratory assessment of individuals who present for NPEP and their sources

Test	Baseline (Week 0)	Week 2	Weeks 4-6	Month 3	Month 6
HIV antibody	E, S		E	E	E
Hepatitis B serology (a)	E, S				E (post-immunisation)
Hepatitis C serology (b)	E, S			E	E
STI screen (b)	E, S	E (e)	E (d)	E (d)	
FBE, LFT, electrolytes	E				
Pregnancy test (b)	E	E			
HIV viral load (f)	S				
HIV resistance testing (g)	S				

Source: Department of Health and Ageing (2006) *National Guidelines for Post-exposure Prophylaxis after Non-occupational Exposure to HIV*.
E = exposed individual; S = source individual

(a) individuals screened for hepatitis B will be immune and require no further follow up; non-immune and require immunisation and follow up; or carriers and require appropriate management; (b) depending upon mode of exposure; (c) baseline and where clinically indicated; (d) repeat syphilis serology if negative at baseline after sexual exposure; (e) repeat testing for chlamydia and gonorrhoea; (f) where confirmed HIV-positive; (g) specimen to be stored and tested in the event of NPEP failure.

4.5 Additional Clinical Management Issues

Recommendations about how to address the following clinical management issues are provided in Appendix 2:

- Preventive behaviours whilst being managed for HIV exposure.
- Individuals at risk of HIV transmission who decline NPEP.
- Individuals at negligible risk of HIV transmission who request NPEP.
- Individuals who re-present for NPEP.
- Individuals who have been sexually assaulted.
- Prisoners and detainees.
- Risk communication: understanding the risk of exposure.

4.6 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.

For indications for treatment and the number of drugs recommended, see Table 3 and Appendix 1. 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. 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.

Which drug?

The Department of Health (DOH) recommends Truvada® (300mg Tenofovir + 200mg Emtricitabine) as the preferred two-drug combination.

Precautions when considering Truvada® include:

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

Other drug options are available. For further information on these options and on drugs which are not recommended for NPEP, see Appendix 4. Drug options need to be discussed with a specialist in HIV medicine (see Appendix 3).

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.

6. ACCESS TO HIV TREATMENT

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 6 for more information). Each regional hospital should have available the recommended Truvada® starter packs 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.

7. MONITORING OF NPEP - SURVEILLANCE

The DOH collects information about persons who seek medical care after possible sexual, injecting drug use, or other non-occupational HIV exposures. No names or other personal identifiers of patients are collected. More information is provided about the surveillance in Appendices 5 and 7. Healthcare providers in Western Australia are required to report all persons who receive NPEP to the Manager of the Sexual Health and Blood-borne Virus Program, DOH. The system assesses utilisation, effectiveness, and effects of medication on those who receive treatment through collection of the following information:

- characteristics of the reported exposure;
- use of antiretroviral medications, including dosage and duration;
- side effects of and adherence to therapy; and
- HIV seroconversion in patients who do or do not receive antiretroviral therapy after exposure to a known HIV-infected source.

Attending doctors are required to collect data concerning the circumstances surrounding the patient's possible exposure to HIV, their acceptance of treatment, and response to treatment at presentation, four weeks, three months and six months post-presentation.

- The initial monitoring form for this surveillance is attached (see Appendix 7). All patients offered NPEP should have this form completed and returned to the DOH.
- Four week, three month and six month follow-up forms are also available from the Sexual Health and Blood-borne Virus Program, DOH on telephone (08) 9388 4841.

Dr Neale Fong
DIRECTOR GENERAL

No Longer Applicable - Rescinded 30 June 2021

REFERENCES

1. Department of Health and Ageing. *National Guidelines for Post-exposure Prophylaxis after Non-occupational Exposure to HIV*. Commonwealth of Australia 2006.
 2. National Health and Medical Research Council. *Infection Control in the Health Care Setting* 1996.
 3. Cardo D M, Culver D H, Cielieki C A, et al. *A case-control study of HIV seroconversion in health care workers after percutaneous exposure*. CDC and Prevention Needlestick Surveillance Group. *NEJM* 1997; 337(21):1485-1490.
 4. Centers for Disease Control. *Recommendations for the use of zidovudine to reduce perinatal transmission of human immunodeficiency virus*. *MMWR* 1994; 43(rr-11):1-20.
 5. Department of Health and Ageing. *National HIV Testing Policy 2006*. Commonwealth of Australia 2006.
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APPENDICES

Appendix 1: Indications for NPEP.

Appendix 2: Additional Clinical Management Issues.

Appendix 3: Healthcare Facilities with Clinicians Experienced in Prescribing Drugs for Treatment of HIV in Western Australia.

Appendix 4: Possible NPEP Drug Regimens.

Appendix 5: HIV Post-Exposure Prophylaxis: Information and consent form for patients.

Appendix 6: Access to NPEP for HIV.

Appendix 7: HIV NPEP: Initial visit data collection form.

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INDICATIONS FOR NPEP

Risk of HIV transmission = Risk per single exposure x Risk of source being HIV-positive

Table: Risk Calculation — Contact with an MSM source

Population Group and Exposure	KNOWN HIV-Positive Source Status	UNKNOWN HIV-Positive Status ⁷
Receptive anal intercourse	1/120 X 1 = 1/120 (recommend 3 drugs)	1/120 X local seroprevalence ⁸ (recommend 2 or 3 drugs)
Contaminated injecting equipment	1/150 X 1 = 1/150 (recommend 3 drugs)	1/150 X 17% ~ 1/900 ⁹ (recommend 3 drugs at this level – may vary locally)
Insertive anal intercourse	1/1,000 X 1 = 1/1,000 (recommend 3 drugs)	1/1,000 X local seroprevalence (consider or recommend 2 drugs or recommend no NPEP)
Receptive oral intercourse with ejaculation	Not measurable (not recommended*)	Not measurable (not recommended)
Insertive oral intercourse	Not measurable (not recommended)	Not measurable (not recommended)

Source: Department of Health and Ageing (2006) *National Guidelines for Post-exposure Prophylaxis after Non-occupational Exposure to HIV*; *consider 2 drugs if the oral mucosa is not intact.

Table: Risk Calculation — Contact with a heterosexual source

Population Group and Exposure	KNOWN HIV-Positive Source Status	UNKNOWN HIV-Positive Status Seroprevalence assumed as: <ul style="list-style-type: none"> • 0.1% for a heterosexual source, • 1% for injecting drug users (IDU) and • 10% for heterosexual contact from high prevalence country (HPC)¹⁰
Receptive anal intercourse	1/120 X 1 = 1/120 (recommend 3 drugs)	1/120 X 1/1,000 = 1/120,000 (not recommended)
		1/120 X 1/100 = 1/12,000 (with IDU) (consider 2 drugs)
		1/120 X 1/10 = 1/1,200 (with person from HPC) (recommend 2 drugs)
Contaminated injecting equipment	1/150 X 1 = 1/150 (recommend 3 drugs)	(assume IDU) 1/150 X 1/100 = 1/15,000 (consider 2 drugs)
		1/150 X 1/10 = 1/1,500 (with person from HPC) (recommend 2 drugs)

⁷ Calculations are based on local data. Note transmission risk may change if sex partner also is an IDU or from a HPC.

⁸ See Table 2, page 3 - this will include individuals from HPC.

⁹ Local seroprevalence may be at a lower level so that 2 drugs may be recommended or considered, or NPEP may not be recommended.

¹⁰ Country specific information for the general population and sub groups is available through the UNAIDS/WHO online database at www.who.int/globalatlas/.

Table: Risk Calculation — Contact with a heterosexual source (Cont'd)

Population Group and Exposure	KNOWN HIV-Positive Source Status	UNKNOWN HIV-Positive Status Seroprevalence assumed as: <ul style="list-style-type: none"> • 0.1% for a heterosexual source, • 1% for injecting drug users (IDU) and • 10% for heterosexual contact from high prevalence country (HPC)¹¹
Receptive vaginal, insertive anal or insertive vaginal intercourse	1/1,000 X 1 = 1/1,000 (recommend 3 drugs)	1/1,000 X 1/1,000 = 1/1,000,000 (not recommended)
		1/1,000 X 1/100 = 1/100,000 (with IDU) (not recommended)
		1/1,000 X 1/10 = 1/10,000 (with person from HPC) (consider 2 drugs)
Receptive oral intercourse with ejaculation	Not measurable (not recommended*)	Not measurable (not recommended)
Insertive oral intercourse	Not measurable (not recommended)	Not measurable (not recommended)

Source: Department of Health and Ageing (2006) *National Guidelines for Post-exposure Prophylaxis after Non-occupational Exposure to HIV*; *consider 2 drugs if the oral mucosa is not intact.

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; two 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.

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¹¹ Country specific information for the general population and sub groups is available through the UNAIDS/WHO online database at www.who.int/globalatlas/.

ADDITIONAL CLINICAL MANAGEMENT ISSUES¹²**1. Preventive behaviours whilst being managed for HIV exposure**

Patients should adopt preventive practices until their seronegative status is confirmed at follow-up. This applies to safe sexual and injecting behaviour, as well as preventing others from exposure to their body fluids through means such as accidents or body donation. Women should be counselled about pregnancy, the risk of mother-to-child transmission and contraception.

2. Individuals at risk of HIV transmission who decline NPEP

Education about preventive behaviours and HIV seroconversion is provided to these individuals. It is important that they can maintain a positive relationship with their health service so that they are monitored clinically and tested over the following three months.

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

This response may relate to anxiety and fear about an apparently negligible exposure or undisclosed more serious risks of infection.

It is important that the clinician takes a supportive approach and documents all advice given, including that NPEP was not recommended and if it was prescribed. Early follow-up and a low threshold for psychological and HIV specialist referral is recommended.

4. Individuals who re-present for NPEP

Those who present for repeat NPEP should be supported, with each potential exposure assessed on its merits. Such presentations are an opportunity for ongoing education and counselling and assessment of predisposing medical, psychological and social factors (see *National HIV Testing Policy 2006*).

5. Individuals who have been sexually assaulted

Survivors of sexual assault should be assessed for their need for NPEP as early as possible. There is no data on HIV prevalence for convicted sexual assailants in Australia; however, studies on HIV point prevalence in Australian jails range between 0 and 0.6%, with most jurisdictions reporting below 0.1%. Sexual assaults may involve multiple assailants, unprotected vaginal, anal and oral penetration, and result in genital and other physical trauma. While these factors may increase the risk of HIV exposure, it generally remains low.

An individualised assessment of survivors is necessary to address these issues, including informed consent, in a context of psychological stress.

¹² Department of Health and Ageing. *National Guidelines for Post-exposure Prophylaxis after Non-occupational Exposure to HIV*. Commonwealth of Australia 2006.

6. Prisoners and detainees

Inmates who are potentially exposed to HIV sexually, through injecting drug use or other means, require assessment for NPEP as soon as possible after exposure. HIV point prevalence in Australian jails is estimated at less than 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. Responses should be tailored to the circumstances of jurisdictional correctional health services.

7. Risk communication: Understanding the risk of exposure

Communicating the risk of an action or consequence can be very difficult. This is compounded by the diversity of interpretations of personal risk.

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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

POSSIBLE NPEP DRUG REGIMENS¹³**Two-drug regimens:**

- 2 nucleoside reverse transcriptase inhibitors (NRTIs) (may include a nucleotide reverse transcriptase inhibitor, tenofovir).

Three-drug regimens:

- 2 NRTIs (may include a nucleotide reverse transcriptase inhibitor) + protease inhibitor (PI) or non-nucleoside reverse transcriptase inhibitor (NNRTI)
- 2 nucleoside RTIs + a nucleotide RTI.

Drugs NOT to use for NPEP:

- Nevirapine (NNRTI) is contraindicated for NPEP;
- combination d4T (stavudine) and ddl (didanosine) is not recommended and contraindicated in pregnancy;
- Abacavir (NRTI) is associated with hypersensitivity reactions that may make it unsuitable to use as NPEP; and
- Efavirenz (NNRTI) is contraindicated in pregnancy.

If in any doubt, seek expert advice from a specialist in HIV medicine about suitable treatment regimens.

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¹³ Commonly prescribed NRTIs are AZT and lamivudine (3TC) or 3TC and tenofovir or emtricitabine and tenofovir; lopinavir/ritonavir is an enhanced PI; efavirenz is a NNRTI.

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. Write down what to do, and don't be afraid to ask questions or phone the doctor later if you are unsure of something.
- 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.

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:

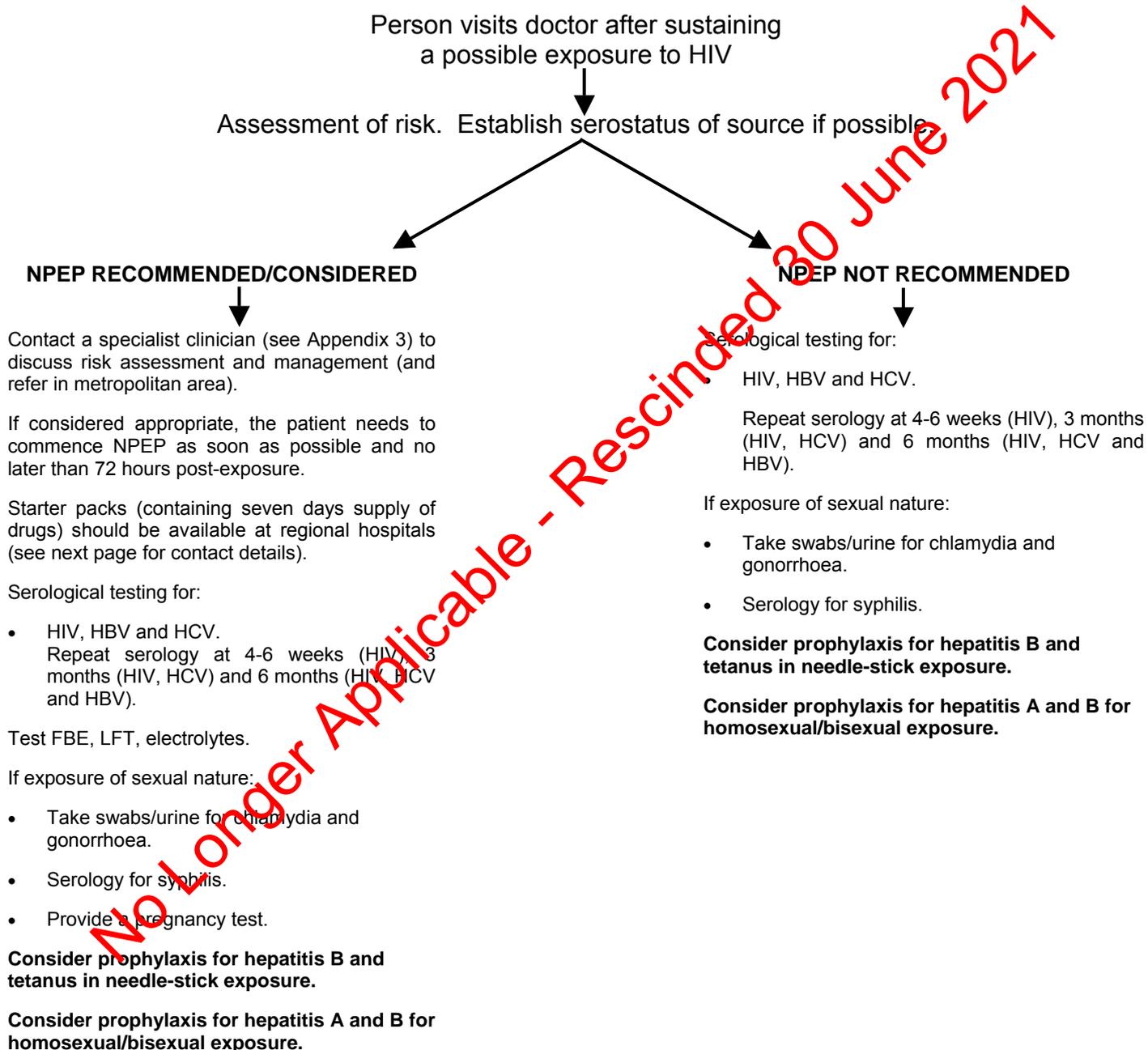
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ACCESS TO NPEP FOR HIV

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 (see Table 3), 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.



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.

**METROPOLITAN HOSPITALS WHERE ANTIRETROVIRAL STARTER KITS
SHOULD BE AVAILABLE**

HOSPITAL	CONTACT NUMBER*
Royal Perth Hospital	(08) 9224 2244
Sir Charles Gairdner Hospital	(08) 9346 3333
Fremantle Hospital	(08) 9431 3333
King Edward Memorial Hospital	(08) 9340 2222
Joondalup Health Campus	(08) 9400 9400
Rockingham/Kwinana District Hospital	(08) 9592 0600
St John of God Health Care, Subiaco	(08) 9382 6111
St John of God Health Care, Murdoch	(08) 9366 1111

* This is the main Hospital number. Please ask to be put through to the Hospital Pharmacy.

**REGIONAL HOSPITALS WHERE ANTIRETROVIRAL STARTER KITS
SHOULD BE AVAILABLE**

HOSPITAL	CONTACT NUMBER*
Albany Regional Hospital (distributes supplies to Katanning)	(08) 9892 2222
Broome District Hospital	(08) 9194 2222+
Bunbury Regional Hospital (distributes supplies to all Government hospitals in the South West Region)	(08) 9722 1000
Carnarvon Regional Hospital	(08) 9941 0555
Derby Regional Hospital (distributes supplies to Halls Creek and Fitzroy Crossing)	(08) 9193 3333
Geraldton Regional Hospital (distributes supplies to Meekatharra Hospital and other hospitals in the Mid-West Region)	(08) 9956 2222
Kalgoorlie Regional Hospital (distributes supplies to Esperance and to other hospitals, nursing posts in the region)	(08) 9080 5888
Kununurra District Hospital (distributes supplies to Wyndham)	(08) 9166 4222+
Narrogin Regional Hospital (distributes supplies to Kondinin District Health Service and Wheatbelt area)	(08) 9881 0333
Northam Regional Hospital	(08) 9690 1300
Port Hedland Regional Hospital (distributes supplies to Newman and Karratha)	(08) 9158 1666
Warburton Clinic	(08) 8956 7041#

* This is the main Hospital number. Please ask to be put through to the Hospital Pharmacy.

+ This is the main Hospital number. Please ask to be put through to the Nurse Manager.

This is the direct number for the clinic pharmacist.

IMPORTANT NOTE FOR HOSPITAL PHARMACIES

Please note that procurement of Truvada® will no longer be coordinated by the Royal Perth Hospital Pharmacy. It is now the responsibility of public and private hospital pharmacies to obtain their own supplies of Truvada® and if desired, repack into smaller starter packs. For further information about Truvada® supply, please contact the drug manufacturer.

It will be the responsibility of hospital pharmacies to ensure that they have a process in place to ensure that in-date stock is available and accessible, according to the needs of their service and in compliance with the Operational Directive.

**HIV Non-Occupational Post-Exposure
Prophylaxis
Initial Visit Data Collection Form**

Patient referred for follow-up to:
RPH Sexual Health Fremantle Sexual Health Other _____
Please send follow-up forms to the appropriate clinic
(WA NPEP Code _____ Office Use Only)

CONFIDENTIAL

Doctor's name _____

Clinic address or stamp
.....
.....
.....

Date of **initial** consultation ___/___/___

Time of **initial** consultation ____:____ am/pm

Patient's medical practice record number/code _____

**1. CHARACTERISTICS OF PATIENT
PRESENTING FOR POST-EXPOSURE
PROPHYLAXIS**

Date of birth ___/___/___

Sex: Male

Female

Transgender

Postcode of residence

Has the person been tested for HIV antibody prior to the reported exposure?

Yes No Unknown

If 'Yes', date of last test: ___/___/___

Result:

HIV antibody negative

HIV indeterminate

HIV-positive

Not reported

Was blood taken for HIV antibody at the initial visit?

Yes No

If "Yes" what was the HIV status at the initial visit?

HIV negative

HIV positive

Awaiting result

Has the person ever received NPEP before?

Yes No

If yes, how many times: _____

2. CHARACTERISTICS OF EXPOSURE

Date of exposure ___/___/___

Time of exposure ____:____ am/pm

Type of exposure (*tick all boxes below that apply to THIS exposure*).

2.1. Sexual exposure

Receptive anal sex

Insertive anal sex

Receptive vaginal sex

Insertive vaginal sex

Receptive oral sex

Other sexual exposure

Please specify _____

Were condoms used at the time of the reported exposure?

Yes No

If 'Yes', were any difficulties experienced with condom use at the time of the reported exposure:

Yes No

If 'Yes':

Condom slipped

Condom broke

Other difficulty

Please specify _____

Did ejaculation occur?

Yes No

Was the sexual partner:

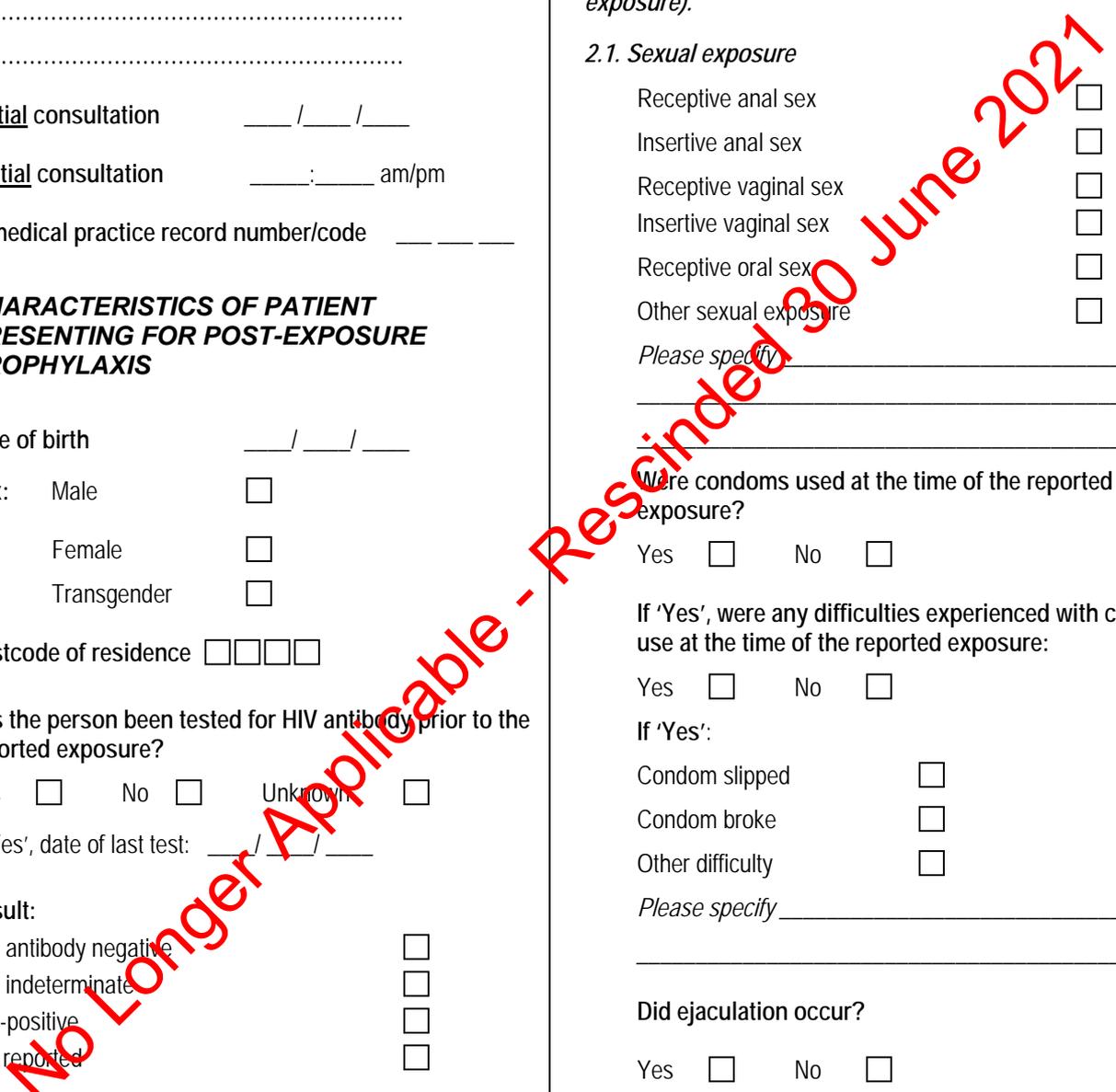
Regular

Casual

Anonymous

Other

Please specify _____



2.2 **Needlestick exposure**

- 2.2.1 **Re-use of injecting equipment**
- Re-use of needle
- Re-use of syringe
- Re-use of other
- Please specify _____
-

- 2.2.2 **Accidental needlestick**
- (a) **Depth of injury**
- Superficial scratch
- Moderate, penetrated skin
- Deep puncture or intravenous injection
- (b) **Type of needle**
- Hollow bore
- Other,
- Please specify _____

2.3 **Other exposure**

Please describe _____

3. **CHARACTERISTICS OF SOURCE PERSON**

- Sex Male
- Female
- Transgender

3.1 **Patient report of HIV status of the source person**

- Known to be HIV-positive
- Suspected to be HIV-positive
- Of unknown HIV status

3.2 **Patient report of HIV-risk behaviour of source person**

- Male homosexual contact
- Injecting drug use
- Other,

Please specify details, e.g. If source from or lived in country with high HIV prevalence, had sex with sex workers overseas, had history of sexual assault etc.

3.3 **If source person known to be HIV-positive:**

How long has the source person had HIV?

Years _____ Unknown

Has the source been diagnosed with AIDS?

Yes

No

Unknown

What is the most recent viral load of source?

Value _____ Date ____ / ____ (month/year)

Unknown

What is the most recent CD4 count of source?

Value _____ Date ____ / ____ (month/year)

Unknown

Is the source currently taking anti-retroviral drugs?

Yes

No

Unknown

If 'Yes', which ones? _____

4. **ACTION TAKEN**

Did the patient elect to receive NPEP?

Yes No

If 'Yes', which anti-retroviral drugs and at what dosage did you prescribe?

Drug	Dose	Frequency	Length of treatment
_____	_____	_____	_____ days
_____	_____	_____	_____ days
_____	_____	_____	_____ days

Do you think the patient was at high risk of HIV?

Yes No

Please provide any additional information that raised your concerns about HIV risk, e.g. vaginal bleeding occurred

5. **ADDITIONAL SCREENING**

Was blood taken for Hepatitis B screening at the initial visit?

Yes No

If "Yes" what was the HBV status?

HBV negative

HBV positive

Awaiting result

If "HBV negative", was the patient vaccinated against HBV?

Yes No

If "HBV negative", was the patient given Hepatitis B IgG?

Yes No

Was the patient screened for STIs?

Yes No

Thank you for your cooperation. Please return this form to:

Manager
Sexual Health & Blood-borne Virus Program
PO Box 8172
PERTH BUSINESS CENTRE PERTH WA 6849.

Telephone (08) 9388 4841 with any queries.

In order to assess the patient's progress four-week, three month and six month follow-up forms are also available from the Sexual Health and Blood-borne Virus Program.

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