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

National Guidelines

National guidelines for post-exposure prophylaxis after non-occupational and occupational exposure to HIV

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Contents

Introduction

National guidelines for post-exposure prophylaxis after non-occupational and occupational exposure to HIV

These guidelines outline the management of individuals who have been exposed (or suspect they have been exposed) to HIV in occupational and non-occupational settings. There are currently no data from randomised controlled trials of the use of post-exposure prophylaxis (PEP), and there are many gaps 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.

These National PEP guidelines are:

- replacing the National guidelines for Non-Occupational Post-Exposure Prophylaxis to HIV (DoHA 2006) and the HIV component of the Management of Exposure to Blood/Body Fluids in an Occupational Health Setting, ANCAHRD Bulletin No 29 September 2002
- produced by the Australasian Society for HIV Medicine (ASHM)
- located at www.ashm.org.au/pep-guidelines
- funded by the Commonwealth Department of Health and Ageing (DoHA)
- endorsed by the Australasian College for Emergency Medicine November 2013
- to be reviewed through ASHM, for advice to DoHA
- supported by a literature review[1] and other documents at www.ashm.org.au/pep-guidelines.

The advice provided is necessarily general. Any unusual or complex presentation should be discussed with an expert in HIV medicine before deciding whether or not PEP should be prescribed.

Specific implementation details in response to regional differences are available through state, territory and local agencies.

Assessment of the risk of HIV transmission

The risk of HIV transmission through a single exposure is determined by:

- The nature of the exposure with its estimated risk/exposure (Table 1)
- The risk that the source is HIV positive, if their status is unknown (Table 2)
- Factors associated with the source and exposed individuals.

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

1. What is the HIV transmission risk/exposure?

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

Table 1: Exposure and transmission risk/exposure with known HIV positive source
See Literature Review[1] section *Transmission risks associated with different exposures* for further information.

Type of exposure with known HIV positive source	Estimated risk of HIV transmission/exposure[a]
Receptive anal intercourse (RAI) – ejaculation – withdrawal	 1/70 1/155
Contaminated injecting equipment	1/125
Insertive anal intercourse (IAI) uncircumcised	1/160
Insertive anal intercourse (IAI) circumcised	1/900
Receptive vaginal intercourse (RVI)	1/1250* (See next page)
Insertive vaginal intercourse (IVI)	1/2500* (See next page)
Receptive or insertive oral intercourse	Unable to estimate risk – extremely low
Needlestick injury (NSI) or other sharps exposure	1/440
Mucous membrane and non-intact skin exposure	< 1/1000

[a] These estimates are based on prospective studies, not cross-sectional data or figures derived from modelling.

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

Factors that may **increase** the risk of HIV transmission include:

- a high plasma viral load (a high load when seroconverting or with advanced disease)
- a sexually transmissible infection in the source or exposed individual, especially genital ulcer disease and symptomatic gonococcal infections
- a breach in genital mucosal integrity (eg trauma, genital piercing or genital tract infection)
- a breach in oral mucosal integrity when performing oral sex
- penetrating, percutaneous injuries with a hollow bore needle, direct intravenous or intra-arterial injection with a needle or syringe containing HIV infected blood
- the uncircumcised status of the insertive HIV negative partner practising IAI or IVI.

*Early initiation of antiretroviral therapy, compared with delayed therapy, resulted in a relative reduction of 96% in the number of linked HIV transmissions in serodiscordant heterosexual couples. Therefore the transmission risk for vaginal intercourse with an HIV positive partner with an undetectable viral load may be estimated to be **decreased by a factor of 20.**

2. What is the HIV status of the source individual?

Provision of PEP should not be delayed while establishing the source status.

- Ideally, active attempts should be made to contact the source and ask them to have an urgent HIV test; however, the often anonymous nature of exposures makes this impractical.
- If the source discloses they are HIV positive, consent should be gained to seek treatment details from their doctor. At the very least it is useful to know if they are on treatment or not and if their viral load is undetectable.
- In cases where the source refuses to disclose their HIV status or have an HIV test, it should be assumed (for the purposes of PEP prescription) that they are HIV positive.
- If the source cannot be contacted, the seroprevalence data (see Table 2) will assist in determining the need for PEP.

Table 2: HIV seroprevalence in Australian populations

See Literature Review[1] section *HIV status of the source individual* for further information.

Community group	HIV seroprevalence (%)
Homosexual men (MSM – men who have sex with men)[2-7] • ACT • Adelaide • Brisbane • Melbourne • Perth • Sydney Actual seroprevalence may be higher than reported seroprevalence[8]	 4.2 5.4 8.8 8.1 4.5 11.8
Injecting drug users in Australia[9] • homosexual • all others	 29.2 1.0
Heterosexuals in Australia[9] • blood donors (% donations) • STI clinic attendees	 0.0004 <0.5
Commercial sex workers (Australia)[9]	<0.1
Overall Australian seroprevalence [9]	0.1

HIV seroprevalence in overseas populations

The seroprevalence overseas varies widely, with a High Prevalence Country (HPC) being defined as having a prevalence of >1% in the general population. However, variance is not only between countries but also in different risk groups. Highest seroprevalence is in Southern Africa (up to 25%) and in injecting drug users in South East Asia (up to 40% in Thailand and Indonesia). For seroprevalence for individual countries go to www.unaids.org/en/dataanalysis/datatools/aidsinfo/

3. What is the HIV status of the exposed individual?

All candidates for PEP require baseline HIV antibody testing. Where possible, the results should be followed up within 24 hours of the specimen being collected. Urgent testing should be made available to individuals who are identified as at high risk for HIV.*

Initiation of PEP should not be delayed while determining the HIV status of the exposed individual.

* It is recognised that not all areas can provide test results within 24 hours.

Prescribing PEP

Ultimately, the decision to prescribe PEP needs to be made on a case-by-case basis considering all the variables. These guidelines are not prescriptive, but put forward cases where PEP is recommended and the benefit of treatment is likely to exceed harm. Situations where there is greater uncertainty or complexity should be discussed with a physician experienced in this area.

PEP should be prescribed as soon as possible after the exposure and within 72 hours.

Adverse effects caused by antiretrovirals and their impact on adherence are well recognised, Individuals receiving PEP should be informed of the potential adverse effects of treatment and possible drug interactions; particularly if protease inhibitors are prescribed. Drug choice is determined by considering antiretroviral treatment history, viral load and resistance patterns of the source case and the medical history of the exposed individual.

As for the number of drugs recommended for treatment, there is no direct evidence to support the greater or lesser efficacy of 3 over 2 drug preventative regimens. It is an extrapolation of any possible benefit conferred by increased numbers/classes of drugs for HIV treatment whilst also taking into account potential side effects, toxicity, adherence and cost effectiveness of adding a third drug.

Table 3. PEP recommendations after non-occupational exposure to a known HIV positive source

Type of exposure with known HIV positive source	Estimated risk of HIV transmission per exposure	PEP recommendation	
		Source viral load undetectable	Source not on treatment or on treatment with detectable viral load
Receptive anal intercourse (RAI) - ejaculation - withdrawal	1/70 1/155	2 drugs	3 drugs
Contaminated injecting equipment	1/125	2 drugs	3 drugs
Insertive anal intercourse (IAI) (uncircumcised)	1/160	2 drugs	3 drugs
Insertive anal intercourse (IAI) (circumcised)	1/900	Consider 2 drugs (if STI, trauma or blood)	3 drugs
Receptive vaginal intercourse (RVI)	1/1250	Not recommended*	3 drugs
Insertive vaginal intercourse (IVI)	1/2500	Not recommended*	3 drugs
Receptive or insertive oral intercourse	Not Measurable	Not recommended	Not recommended†
Mucous membrane and non-intact skin exposure	< 1/1000	Not recommended	3 drugs

* Provided source is compliant with medication, attends regular follow-up and has 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.

Table 4. PEP recommendations after non-occupational exposure to a source with unknown HIV status

Type of exposure to source with unknown HIV status	Estimated risk of HIV transmission per exposure	PEP recommendation
Receptive anal intercourse (RAI) - ejaculation - withdrawal	1/700* 1/1550*	2 drugs if source MSM or from high prevalence country (HPC)
Shared injecting equipment	1/12,500† (1/1250 – 1/415‡ if source MSM)	2 drugs if source MSM or from high prevalence country (HPC)
Insertive anal intercourse (IAI) - uncircumcised - circumcised	1/1600* 1/9000*	2 drugs if uncircumcised Consider 2 drugs if circumcised and STI, trauma, blood
Receptive vaginal intercourse (RVI)	1/1,250,000^	Not recommended Consider 2 drugs if source MSM or from high prevalence country (HPC)
Insertive vaginal intercourse (IVI)	1/2,500,000^	Not recommended Consider 2 drugs if source from high prevalence country (HPC)
Receptive or insertive oral intercourse	Not measurable	Not recommended
Mucous membrane and non-intact skin exposure	< 1/10,000* (MSM exposure)	Not recommended
Needlestick injury (NSI) from a discarded needle in community	Not measurable	Not recommended

* Based on estimated seroprevalence 10% (9.6%) in MSM

† Based on estimated seroprevalence 1.0%

‡ Based on estimated seroprevalence of 29%

^ Based on estimated seroprevalence 0.1%

Table 5. PEP recommendations after occupational exposure to a known HIV positive source

Type of exposure with known HIV positive source	Estimated risk of HIV transmission per exposure	PEP recommendation	
		Source viral load undetectable	Source not on treatment or on treatment with detectable viral load
Needlestick injury (NSI) or other sharps exposure	1/440*	2 drugs	3 drugs
Mucous membrane and non-intact skin exposure	< 1/1000	Consider 2 drugs	3 drugs

* PEP may be recommended if needle and syringe contained fresh blood and sufficiently penetrated the skin

PEP recommendations after occupational exposure to a source with unknown HIV status

In the occupational setting, the source is usually able to be identified and tested for HIV, and PEP is usually only prescribed for those who have definitely been exposed to HIV. The risks carried by exposures that occur in the occupational setting are outlined in the Table 5. If the source is unable to be identified or tested, then the risk of the source being HIV positive must be assessed from any epidemiological or other information available. When the source is unknown, the use of PEP should be decided on a case-by-case basis, and it is recommended that an expert always be consulted in this situation.

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.

Clinical assessment and follow-up

In making a clinical assessment health practitioners should consider the gender, culture, behaviour, language and literacy level of the patient, and their intellectual capacity.

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

1. **The time of the assessment and first dose, if prescribed**
2. **Details of the exposure (when, with whom, what, and where)**
   a. time of exposure
   b. details of source
   c. exact mode and details of exposure (including contributory factors) blood or body fluid involved, trauma, first aid measures applied.
   d. place of exposure
3. **Information about the exposed person**
   a. most recent HIV test and result
   b. potential exposures within the last 3 months (and earlier as indicated)
   c. previous post-exposure prophylaxis and history of this treatment
   d. evaluation of current STIs; hepatitis B* and C infection
   e. pregnancy risk, contraception and lactation, consider emergency contraception
   f. medical history, all medications and drug allergies
   g. psychiatric history
   h. drug and alcohol history
   i. their knowledge of the source (if unavailable for interview)
4. **Information about the source**

   Provision of PEP should not be delayed whilst obtaining this information.
   a. HIV status and other relevant demographic features
   b. if HIV positive:
      (i) plasma viral load and CD4
      (ii) antiretroviral treatment history (has resistance been an issue, if so with which drugs?)
      (iii) recent HIV resistance genotyping
   c. current or past STIs; hepatitis B and C status
5. **PEP discussion**

   An explanation of PEP and its indications and effectiveness, risks and benefits are provided to all potential candidates. Discussion of HIV, including risk assessment, is part of clinical assessment *(see 2011 National HIV testing policy[10])*.
6. **Follow-up**

   Individuals found to be HIV positive or indeterminate on baseline testing, or during follow-up, require immediate referral. PEP should be ceased if the baseline test is positive.

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* Patients with serology consistent with chronic/active hepatitis B and on a regimen containing lamivudine, tenofovir or emtricitabine should have hepatitis B viral load measured. Advice from a specialist in the management of viral hepatitis should be sought when the PEP course is completed.

Laboratory assessment and follow-up

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

The table below sets out the recommended schedule of testing for individuals who are prescribed PEP (adapted from 2005 CDC guidelines[11]). Follow-up HIV testing is no longer recommended at 6 months. The management of an exposed patient who seroconverts is not included. The symptoms of seroconversion should be explained to all patients, with advice to present if these, or any other symptoms occur.

Table 6: Laboratory evaluation of individuals who are prescribed PEP

Test	Baseline (Week 0)	Week 1–2	Week 4–6	Month 3
HIV antibody	E		E	E
Hepatitis B serology[a]	E			E
Hepatitis C serology[b]	E			E
STI screen[b]	E	E[c]	E[d]	E[d]
FBE, LFT, EUC[e], CK[f]	E	E[f]		
Pregnancy test[b,e]	E	E		

E = exposed individual

[a] 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 also section *Management of possible exposure to other conditions* for more information.

[b] Depends upon mode of exposure.

[c] Repeat testing for chlamydia and gonorrhoea.

[d] Repeat syphilis serology after sexual exposure.

[e] Baseline and where clinically indicated.

[f] If raltegravir prescribed there should be a baseline measurement of serum creatine kinase with at least one other measurement during the course of treatment if myalgias or weakness develop along with clinical examination for proximal muscle weakness.

Which regimen?

Clinicians must inform patients who are prescribed PEP, of the uncertain efficacy of this intervention, the importance of adherence and the potential adverse effects associated with a 28-day course of antiretrovirals. Other key information includes preventive measures and description of seroconversion symptoms.

1. Time to initiation

Early initiation of PEP, as soon as possible after exposure, is strongly urged. PEP should NOT be offered more than 72 hours after exposure.

2. Duration of treatment

A 28-day course of PEP is recommended. A proactive approach to managing side effects and emphasising adherence will assist patients to complete their treatment.

3. Period and frequency of follow-up

HIV antibody testing is conducted at baseline, and at 4 to 6 weeks and 3 months after exposure. If there is a possibility of co-infection (with hepatitis B or C, for example), expert advice should be sought.

4. 2 vs 3 drugs

There is no direct evidence to support the greater or lesser efficacy of 3 over 2 drug preventive regimens. The recommendation for the number of antiretroviral drugs is based on an extrapolation of the possible benefit conferred by increased numbers/classes of drugs for HIV treatment.

5. Which drugs?

Apart from zidovudine (AZT), there is no evidence to support the use of one drug or class of drug over another. Factors to consider include the presence of co-morbidities, simplicity of the dosing regimen, minimisation of side effects and drug interactions. PEP starter packs encourage follow-up, support adherence and minimise drug waste if the course is not finished. Co-formulated preparations reduce pill burden and improve adherence.

See Appendix 1 for commonly prescribed regimens

Acceptable:

2-drug regimens:

2 nucleoside reverse transcriptase inhibitors (NRTI)

or

an NRTI plus a nucleotide reverse transcriptase inhibitor (NtRTI)

3-drug regimens:

2 NRTIs plus an NtRTI

or

2 NRTIs (may include an NtRTI) plus a protease inhibitor (PI)

Use with caution:

1. Raltegravir

   Although there is limited data or experience in its use, the integrase inhibitor raltegravir may be considered as an alternative third drug particularly when concern exists about resistant virus in an HIV positive source.

   Because of potential muscle toxicity, inquiry should be made concerning concomitant use of medications associated with rhabdomyolysis e.g. statins. Patients should be educated about a possible link between rhabdomyolysis, exercise and PEP containing raltegravir and patients should be asked to report and providers should ask about myalgia.

Do not use:

1. The non-nucleoside reverse transcriptase inhibitors (NNRTIs) family, such as nevirapine, efavirenz or delavirdine
2. Abacavir (or abacavir-containing formulation), didanosine (ddI) or the combination of stavudine (d4T) and ddI

If in any doubt at all, expert advice should be sought about suitable treatment regimens.

Management of possible exposure to other conditions

1. Hepatitis B

All individuals presenting for PEP 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 HBIG should be administered along with subsequent immunisation and follow-up (to 6 months).

2. Sexually transmissible infections

Individuals presenting for non-occupational post-exposure prophylaxis (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.

3. 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.

4. Pregnancy

All women who have the potential to be pregnant on presentation for PEP should be offered pregnancy testing. Emergency contraception is offered to women presenting for PEP 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 PEP and are pregnant or breastfeeding.

5. Tetanus

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

Additional clinical management issues

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 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 and contraception.

2. Individuals at risk of HIV transmission who decline PEP

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 3 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 risks of infection.

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

4. Individuals who re-present for non-occupational PEP (NPEP)

Those who present for repeat NPEP should be supported, with each presentation assessed on its merits. Such presentations show a need for education and counselling and assessment of predisposing medical, psychological and social factors (see 2011 National HIV testing policy). Pre-exposure prophylaxis (PrEP) is not currently available in Australia, and there are no guidelines for its use.

5. Individuals who have been sexually assaulted

Complaints of sexual assault should be assessed for their need for NPEP as early as possible after the event. Male-to-male sexual assault should always receive NPEP. There are no data on HIV prevalence for convicted sexual assailants in Australia; however, from studies on HIV point prevalence in Australian jails it ranges between 0 to 0.6%, with most jurisdictions reporting below 0.1%. Therefore, for non-complex male-to-female sexual assault, NPEP is not generally recommended. However, sexual assaults may involve multiple assailants, trauma or an assailant who is from an HPC. Whilst the risk of exposure generally still remains low, these factors may modify the risk, leaving the decision to prescribe PEP outside of simple sexual assault at the clinicians' discretion.

6. Prisoners and detainees

Inmates 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 jails 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. Responses should be tailored to the circumstances of the jurisdictional correctional health services.

7. Risk communication: understanding the risk of exposure

Communicating the risk of an action or consequence can be very difficult. Table 7 presents an approach to this that may be useful with patients.

Table 7: 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

Information for clinicians

Further information about PEP and antiretroviral prescribing is available on the ASHM website at www.ashm.org.au/HIVguidelines

Local information may be found on the health department websites in each jurisdiction.

Information for patients

Further information about PEP is available from local AIDS councils and health departments. Links are available at www.ashm.org.au/pep-guidelines-patient

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Appendix 1:
Drugs commonly prescribed in PEP regimens

Drug class	Drug name	Cost/28-day course* (A$)
NRTI	zidovudine 250mg (AZT) lamivudine 300mg (3TC) stavudine 40mg (d4T, Zerit®) emtricitabine (FTC)	$296 $221 $434 $263
NtRTI	tenofovir (Viread®)	$472
PI	lopinavir with ritonavir (Kaletra®)	$639
Co-formulations	lamivudine and zidovudine (Combivir®) emtricitabine and tenofovir (Truvada®)	$497 $736

* At May 2013.

	Combination	Examples	Cost/28-day course* (A$)
3-drug regimens	2 NRTIs plus 1 NtRTI	Combivir® plus Viread® or Truvada® plus Zerit®	$969 $1170
	1 NtRTI plus 1 NRTI plus 1 PI	Truvada® plus Kaletra®	$1375
2-drug regimens	2 NRTIs	Combivir®	$497
	1 NRTI plus NtRTI	Truvada®	$736

* At May 2013.

Use with caution:

1. Raltegravir

   Although there is limited data or experience in its use, the integrase inhibitor raltegravir may be considered as an alternative third drug particularly when concern exists about resistant virus in an HIV positive source.

   Because of potential muscle toxicity, inquiry should be made concerning concomitant use of medications associated with rhabdomyolysis e.g. statins. Patients should be educated about a possible link between rhabdomyolysis, exercise and PEP containing raltegravir and patients should be asked to report and providers should ask about myalgia.

Do not use:

1. The non-nucleoside reverse transcriptase inhibitors (NNRTIs) family, such as nevirapine, efavirenz or delavirdine
2. Abacavir (or abacavir-containing formulation), didanosine (ddI) or the combination of stavudine (d4T) and ddI

If in any doubt at all, expert advice should be sought about suitable treatment regimens.

Further information

Further information about pricing is available from www.pbs.gov.au/pbs/home
For more information or drug dosing and adverse events, please see arv.ashm.org.au

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Supporting the HIV, Viral Hepatitis and Sexual Health Workforce