



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

Australian National Guidelines (Second edition)

SUPPORTING
THE HIV, VIRAL
HEPATITIS AND
SEXUAL HEALTH
WORKFORCE



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

(Second edition)

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Contents

| | |
|--|-----------|
| Introduction | 4 |
| New to the guidelines | 5 |
| Before you begin | 5 |
| Assessment of the risk of HIV transmission | 6 |
| 1. What is the HIV transmission risk/exposure? | 6 |
| 2. What is the HIV status of the source individual? | 7 |
| 3. What is the HIV status of the exposed individual? | 8 |
| When to Prescribe PEP | 9 |
| PEP recommendations after occupational exposure | 11 |
| Immediate management of an individual with known or suspected exposure to HIV | 11 |
| Clinical assessment and follow-up | 12 |
| Laboratory assessment and follow-up | 13 |
| Prescribing PEP | 14 |
| Recommended PEP regimens | 14 |
| Medications and cautions | 15 |
| Management of possible exposure to other conditions | 16 |
| 1. Hepatitis B | 16 |
| 2. Sexually transmissible infections | 16 |
| 3. Hepatitis C | 16 |
| 4. Pregnancy and breastfeeding | 16 |
| 5. Tetanus | 16 |
| Additional clinical management issues | 17 |
| 1. Preventive behaviours while being managed for HIV exposure | 17 |
| 2. Individuals at risk of HIV acquisition who decline PEP | 17 |
| 3. Individuals at negligible risk of HIV transmission who request PEP | 17 |
| 4. Individuals who re-present for NPEP | 17 |
| 5. Individuals who are on PrEP | 17 |
| 6. Transitioning from PEP to PrEP | 18 |
| 7. Renal disease | 18 |
| 8. Gender identity and history | 18 |
| 9. Individuals who have been sexually assaulted | 18 |
| 10. Children | 19 |
| 11. Prisoners and detainees | 20 |
| 12. Individuals who commenced PEP overseas | 20 |
| 13. Risk communication: understanding the risk of exposure | 20 |
| References | 21 |
| Information for clinicians | 22 |
| Information for patients | 22 |
| Appendix 1: Drugs commonly prescribed in PEP regimens | 22 |
| Further information | 22 |

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 non-occupational and occupational settings. There are currently no data from randomised controlled trials of the use of post-exposure prophylaxis (PEP) and evidence for use has been extrapolated from animal data, mother to child transmission, occupational exposure and small prospective studies of PEP regimens in HIV-negative men. 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.

This second edition of the National PEP guidelines is:

- revised from the first National PEP guidelines released in 2013, which replaced the National guidelines for Non-Occupational Post-Exposure Prophylaxis to HIV (DoH 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, Viral Hepatitis and Sexual Health Medicine (ASHM)
- available as a website resource at www.pep.guidelines.org.au
- also located at www.ashm.org.au/pep-guidelines
- funded by the Commonwealth Department of Health (DoH)
- to be reviewed regularly through ASHM, for advice to the DoH
- supported by a Literature Review¹ and other documents also available at the above websites.

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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.

New to the guidelines

- PEP is no longer routinely recommended for non-occupational exposure when an HIV-positive source has an undetectable viral load
- Tenofovir and emtricitabine or tenofovir and lamivudine are recommended as the preferred 2-drug PEP regimen
- Dolutegravir or raltegravir or rilpivirine are recommended as the preferred third agent for 3-drug PEP
- The PEP course should be extended by 28 days from the last HIV exposure risk
- PEP is discussed in the context of pre-exposure prophylaxis (PrEP)
- Routine monitoring of blood tests at week 1 is no longer recommended
- Advice has been added regarding:
 - PEP and children
 - renal disease
 - gender identity and history.

Before you begin

The experience of presenting for PEP can be stressful in itself. Research has documented cases where people stated they did not re-present for PEP due to a previous negative experience and then later seroconverted.² Therefore, it is important that clinicians respond to each presentation in a non-judgemental way, using non-stigmatising language.

To be effective, initiation of PEP needs to occur within 72 hours, the earlier the better. Emergency Departments (ED) are busy environments with competing demands. People requiring PEP during business hours should be encouraged to present to the existing options of s100 prescribing GPs or sexual health clinics with levels of staffing able to meet this ad hoc demand where this is available. In geographical areas where these options are not available, or in cases that require attention outside of business hours, people should present to their nearest hospital ED. Training for ED staff should include the necessity to triage, assess and treat these patients with the appropriate priority.

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.

| |
|--|
| <p>Risk of HIV transmission = risk per exposure x risk of source being HIV positive</p> |
|--|

1. What is the HIV transmission risk/exposure?

All sexual risk estimations are for condomless 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 who is NOT on antiretroviral treatment.

See Literature Review¹ section 'Transmission risks associated with different exposures' for further information.

| Type of exposure with known HIV-positive source who is NOT on antiretroviral treatment | Estimated risk of HIV transmission/exposure* |
|--|--|
| Receptive anal intercourse (RAI) – ejaculation – withdrawal | 1/70 1/155 |
| Shared needles and other injecting equipment | 1/125 |
| Insertive anal intercourse (IAI) uncircumcised | 1/160 |
| Insertive anal intercourse (IAI) circumcised | 1/900 |
| Receptive vaginal intercourse (RVI) | 1/1250 |
| Insertive vaginal intercourse (IVI) | 1/2500 |
| 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 |

* These estimates are based on prospective studies, not cross-sectional data or figures derived from modelling. These estimates do not take into account source viral load, which if undetectable markedly reduces risk estimates.

† Human bites are extremely low risk.

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

Viral load (VL):

- Higher plasma VL (when seroconverting or with advanced disease) is associated with increased risk of HIV transmission³
- Preliminary data shows no transmissions have occurred within male homosexual⁴ or heterosexual⁵ couples, from a partner with an undetectable VL.⁶

Undetectable viral load is defined in these guidelines as less than 50 copies/mL, consistent with the Seventh National HIV Strategy.⁷

Other factors that increase the risk of HIV transmission:

- a sexually transmissible infection (STI) in the source or exposed individual, especially genital ulcer disease and symptomatic gonococcal infections
- source ejaculation during receptive anal or vaginal intercourse
- a breach in genital mucosal integrity (e.g. 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 insertive anal intercourse (IAI) or insertive vaginal intercourse (IVI).

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.

Therefore:

- If the source cannot be contacted, the seroprevalence data (see **Table 2**) will assist in determining the need for PEP.
- If the source is contactable and:
 - discloses they are HIV positive, consent should be gained to seek treatment details from their doctor. It is useful to know if they are on treatment or not, and if their viral load is undetectable.
 - is known to be taking PrEP (Pre-Exposure Prophylaxis), PEP is generally not required. Decisions to prescribe PEP should still be considered on a case-by-case basis due to potential for non-adherence of the source.
 - chooses not to disclose their HIV status or have an HIV test, it should be assumed (for the purposes of PEP prescription) that they are HIV positive.

Table 2. HIV seroprevalence in Australian populations

See Literature Review¹ section '*HIV status of the source individual*' for further information.

| Community group | HIV seroprevalence (%) |
|--|---|
| Men who have sex with men (MSM) ⁸⁻¹³ <ul style="list-style-type: none"> • ACT • Adelaide • Queensland • Melbourne • Perth • Sydney Actual seroprevalence may be higher than reported seroprevalence ¹⁴ | 8.3 7.4 11.2 9.5 4.2 8.5 |
| People who inject drugs in Australia ¹⁵ <ul style="list-style-type: none"> • MSM • all others | 30.0 0.5 |
| Heterosexuals in Australia ¹⁶ <ul style="list-style-type: none"> • new blood donors (% donations) • sexual health clinic attendees | <0.003 <0.5 |
| Female commercial sex workers (Australia) ¹⁵ | <0.1 |
| Overall Australian seroprevalence ¹⁵ | 0.14 |

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 26%) and in people who inject drugs in South East Asia (up to 40% in Thailand and Indonesia). For seroprevalence for individual countries go to <http://aidsinfo.unaids.org/>

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

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

All candidates for PEP require baseline HIV testing (4th-generation Ag/Ab tests). Where possible, the results should be followed up within 24 hours of the specimen being collected.

When to prescribe 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, such as known or suspected antiretroviral resistance in the source, pregnancy, breastfeeding or chronic hepatitis B or C, should be discussed with a physician experienced in this area.

As for the number of drugs recommended for treatment, there is no direct evidence to support the greater or lesser efficacy of three over two-drug preventative regimens. It is an extrapolation of any possible benefit conferred by increased numbers/classes of drugs for HIV treatment while also taking into account potential side effects, toxicity, adherence and cost-effectiveness of adding a third drug. See **Tables 3, 4** and **5** for PEP recommendations.

Where PEP is recommended, it should be prescribed and started as soon as possible after the exposure and within 72 hours.

PEP should generally not be prescribed after 72 hours, but may be considered on a case-by-case basis in consultation with a specialist.

Linkage to a specialist for discussion regarding PrEP should be considered. See the PrEP guidelines for further guidance at http://arv.ashm.org.au/images/Australian_National_PrEP_Guidelines.PDF

Table 3. PEP recommendations after NON-OCCUPATIONAL exposure to a KNOWN HIV status source

| Type of exposure with known HIV positive source | Estimated risk of HIV transmission per exposure if source NOT on antiretroviral treatment | PEP recommendation | |
|---|---|--|---|
| | | Source not on treatment or on treatment with detectable or <u>UNKNOWN</u> viral load | Source viral load <u>KNOWN</u> to be undetectable |
| Receptive anal intercourse (RAI) - ejaculation - withdrawal | 1/70 1/155 | 3 drugs | Not recommended* |
| Shared needles and other injecting equipment | 1/125 | 3 drugs | Not recommended* |
| Insertive anal intercourse (IAI) (uncircumcised) | 1/160 | 3 drugs | Not recommended* |
| Insertive anal intercourse (IAI) (circumcised) | 1/900 | 3 drugs | Not recommended* |
| Receptive vaginal intercourse (RVI) | 1/1250 | 3 drugs | Not recommended* |
| Insertive vaginal intercourse (IVI) | 1/2500 | 3 drugs | Not recommended* |
| Receptive or insertive oral intercourse | Not measurable | Not recommended [†] | Not recommended |
| Mucous membrane and non-intact skin exposure | < 1/1000 | 3 drugs | Not recommended |

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

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

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 needles and other injecting equipment | 1/12,500 [†] (1/1250 – 1/415 [‡] if source MSM) | 2 drugs if source MSM or from HPC |
| Insertive anal intercourse (IAI) (uncircumcised) | 1/1600* | 2 drugs if source MSM or from HPC |
| Insertive anal intercourse (IAI) (circumcised) | 1/9000* | Consider 2 drugs if source MSM or from HPC, particularly if concurrent STI, trauma or blood |
| Receptive vaginal intercourse (RVI) | 1/1,250,000 [^] | Not recommended Consider 2 drugs if source MSM or from HPC |
| Insertive vaginal intercourse (IVI) | 1/2,500,000 [^] | Not recommended Consider 2 drugs if source from 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%.

PEP recommendations after occupational exposure

In the occupational setting, the source is usually able to be identified and tested for HIV, and PEP is usually only prescribed or continued for those who have definitely been exposed to HIV. If the source is unable to be tested immediately, the exposed healthcare worker should be commenced on PEP without waiting for the results if the source is at high risk of being HIV positive. If the source is unable to be identified or tested, then the risk of the source being HIV positive must be assessed from any epidemiological or other information available. The use of PEP should be decided on a case-by-case basis, and it is recommended that an expert is always consulted in this situation.

The risks carried by exposures that occur in the occupational setting are outlined in **Table 5**. However, the risk is most likely significantly lower than this as these data predate effective antiretroviral therapy (ART). There has only been one confirmed case of occupational HIV transmission in the United States since 1999.¹⁷ This may be due to a number of factors, including change in practices to reduce the risk of needlestick injury and a greater proportion of patients on treatment with undetectable viral load. There is now strong evidence that the risk of sexual transmission of HIV is significantly reduced when the source has undetectable viral load.¹⁸ It is presumed that the same applies for percutaneous transmission; however, this will never be able to be studied.

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

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 if source not on antiretroviral treatment | PEP recommendation | |
|---|---|---|--|
| | | Source not on treatment or on treatment with detectable or UNKNOWN viral load | Source viral load KNOWN to be undetectable |
| NSI or other sharps exposure | 1/440 | 3 drugs | Consider 2 drugs |
| Mucous membrane and non-intact skin exposure | < 1/1000 | 3 drugs | Consider 2 drugs |

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 mouth with water.
- Wash wounds and skin sites that have been in contact with blood or body fluids with soap and water.
- Irrigate mucous membranes and eyes (remove contact lenses) with water or saline.
- Do not inject antiseptics or disinfectants into wounds.

Clinical assessment and follow-up

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

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

1. Information about the exposure

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

2. Information about the exposed person

- a. Most recent HIV test and result
- b. Potential exposures within the last three months (or earlier if last HIV test longer than three months ago)
- c. Previous use of PEP or PrEP
- d. Evaluation of current STIs
- e. Hepatitis B (HBV) and C (HCV) infection

If a patient is known to be HBV or HCV positive, specialist advice should be sought before PEP is commenced.*

- f. Pregnancy risk, contraception and lactation (consider emergency contraception)
- g. Medical history:
 - all medications and drug allergies
 - current and past medical history, e.g. renal disease
 - psychiatric history
 - drug and alcohol history.

3. Information about the source person

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

- a. HIV status if known
- b. Demographics factors, e.g. gender, country of origin
- c. If HIV positive:
 - plasma viral load, date of last test, medication adherence
 - antiretroviral treatment history (has resistance been an issue, if so with which drugs?)
 - recent HIV resistance testing
- d. Current STIs; hepatitis B and C status
- e. Whether the source is known to be taking PrEP.

4. PEP discussion

An explanation of PEP and its indications, effectiveness, risks and benefits, potential side effects, potential drug interactions, the importance of 100% adherence to dosing and regimen completion, what to do if a dose is missed.

5. HIV discussion

HIV risk assessment and HIV pre-test information (see National HIV Testing Policy¹⁶).

6. Pre-Exposure Prophylaxis (PrEP) discussion

A brief explanation of PrEP for patient consideration and further discussion with a specialist.

*Patients who have already commenced PEP whose baseline serology is consistent with chronic/active hepatitis B and who are on a regimen containing lamivudine, tenofovir or emtricitabine should have LFTs +/- viral load monitored. Advice from a specialist in the management of viral hepatitis should be sought.

7. Follow-up

The recommended timing of follow-up HIV and other testing is outlined in **Table 6** – Individuals found to be HIV positive or indeterminate on baseline testing, or during follow-up, require immediate referral to an HIV specialist.

8. Prescribing and other details

The time of the assessment, regimen prescribed and time of first dose, referral to mental health, risk-reduction counselling or alcohol and other drug (AOD) services if indicated.

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).

Table 6 sets out the recommended schedule of testing for individuals who are prescribed PEP. Follow-up HIV testing is no longer recommended at six months. The management of an exposed patient who seroconverts is not included. The symptoms of seroconversion should be explained to all patients, with advice to present if these or any other symptoms occur.

Table 6. Laboratory evaluation of individuals who are prescribed PEP

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

* Individuals with evidence of previous immunity to hepatitis B (HBsAb positive) will require no further follow-up. Non-immune individuals require immunisation and follow-up (to 6 months). See also section 'Management of possible exposure to other conditions' for more information.

[†] Depends upon mode of exposure and mode of follow up. See also section 'Management of possible exposure to other conditions'.

[^] If clinically indicated.

Prescribing PEP

Adverse effects caused by antiretrovirals and their impact on adherence are well recognised. Drug choice is determined by: safety, tolerability, ease of dosing, HIV resistance patterns in the local infected population, the medical history of the exposed person, and cost. When known, source information concerning antiretroviral treatment history and the results of past HIV resistance testing may also determine the choice of drugs for PEP.

We now have PEP regimens that are well tolerated, with minimal side effects, drug–drug interactions, dosing requirements and pill burden.

Clinicians must inform patients who are prescribed PEP about the following:

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

PEP should generally not be prescribed after 72 hours, but may be considered on a case-by-case basis in consultation with a specialist.

Linkage to a specialist for discussion regarding PrEP should be considered.

See the PrEP guidelines for further guidance at

http://arv.ashm.org.au/images/Australian_National_PrEP_Guidelines.PDF

A 28-day course of PEP is recommended. Patients presenting to emergency departments should receive a 5–7 days starter pack and be provided with a referral for a follow-up appointment with a specialist PEP provider. Patients presenting to sexual health clinics, HIV clinics or s100 prescriber GPs may be given a prescription for the entire 28 days.¹⁹

Recommended PEP regimens:

2-drug regimens[^]:

Tenofovir disoproxil fumarate 300mg with lamivudine 300mg (Daily)*

OR

Tenofovir disoproxil fumarate/emtricitabine 300mg/200mg (Daily)

3-drug regimens:

Your preferred 2-drug regimen **PLUS**

dolutegravir 50mg (Daily)

OR

raltegravir 400mg (BD)

OR

rilpivirine 25mg (Daily)

[^] Zidovudine, in combination with lamivudine, can be used in two-drug PEP combinations. The benefits of cheaper zidovudine cost are offset by the need for a twice-daily treatment regimen, higher incidences of gastrointestinal side effects, myalgia and headaches in comparison to the recommended regimens.

* TGA-approved generic lamivudine may be used to reduce cost.

Dolutegravir, raltegravir or rilpivirine as the 3rd drug:

The current guidelines recommend dolutegravir or raltegravir or rilpivirine as the 3rd drug in PEP. Using three drugs for PEP increases the likelihood of an adverse event e.g. drug–drug interactions and the potential for rhabdomyolysis with raltegravir. See **Table 7** for further details.

See Appendix 1 for the comparative cost of different PEP regimens.

Medications and cautions

Table 7. Specific medications and cautions

| Medication | Comments and cautions |
|--|--|
| Tenofovir | <ul style="list-style-type: none"> • Daily dosing. Tenofovir disoproxil fumarate/emtricitabine or tenofovir with lamivudine have superior tolerability when compared to zidovudine/lamivudine or stavudine with lamivudine. • Use with caution or avoid in renal disease (eGFR <60), dose reduction required in renal impairment. • Use zidovudine/lamivudine where tenofovir is directly contraindicated and seek expert advice. |
| Dolutegravir | <ul style="list-style-type: none"> • Daily dosing. Well tolerated when used in PEP with high rates of adherence and regimen completion rates. <p>Drugs that are contraindicated</p> <ul style="list-style-type: none"> • Dofetilide (not available in Australia). <p>Drugs that should be used with caution</p> <ul style="list-style-type: none"> • Phenytoin, phenobarbital, rifampicin, St John's Wort, carbamazepine - increase dolutegravir dose to 50mg BD or stop St. John's Wort. • Antacids containing polyvalent cations e.g. Mg or Al – use at least 2 hours before or 6 hours after the dolutegravir dose. • Products containing calcium or iron – use at least 2 hours before or 6 hours after the dolutegravir dose OR dose concomitantly with food. • Metformin – increase monitoring of glycaemic control, adjustment in metformin dose may be required. |
| Raltegravir | <ul style="list-style-type: none"> • BD dosing. Well tolerated when used in PEP with high rates of adherence and regimen completion rates. • Small risk of rhabdomyolysis – inform patients about the potential for myalgia and the need to re-present if myalgia occurs. • Advise against the use of statins while on PEP containing raltegravir. • Caution patients who engage in heavy gym work about the increased risk of rhabdomyolysis, especially when anabolic steroids are used. • Consider switching to dolutegravir or rilpivirine (see below) in patients who report myalgia on raltegravir. • Check CK, renal function and urinary myoglobin in patients who report myalgia on raltegravir. |
| Rilpivirine | <ul style="list-style-type: none"> • Daily dosing. Well tolerated when used in PEP with high rates of adherence and regimen completion rates. • MUST be taken with food. Rilpivirine taken without food results in at least a 40% drop in drug exposure. <p>Drugs that are contraindicated</p> <ul style="list-style-type: none"> • Carbamazepine, oxcarbazepine, phenobarbital, phenytoin • Rifabutin, rifampicin, rifapentine • Dexamethasone • Omeprazole, lansoprazole, pantoprazole, esomeprazole • St. John's Wort. <p>Drugs that should be used with caution</p> <ul style="list-style-type: none"> • Famotidine, cimetidine, nizatidine, ranitidine – administer at least 4 hours after rilpivirine dose. • Aluminium or magnesium hydroxide, calcium carbonate – administer 2 hours before or 4 hours after rilpivirine dose. |
| Zidovudine | BD dosing. Frequent side effects. Not recommended as a first-line agent. |
| Efavirenz, Nevirapine, Abacavir, Didanosine (or in combination with Stavudine) | Are not recommended due to excessive toxicity and/or life-threatening hypersensitivity reaction. ^{20,21} |
| Protease inhibitors | Should be avoided because of high rates of potential drug interactions with other commonly used licit and illicit medications as well as the high rates of gastrointestinal side effects and regimen discontinuation. ²² |

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 within 72 hours of the exposure and hepatitis B immunisation commenced. For further advice go to www.HepatitisB.org.au

2. Sexually transmissible infections

Individuals presenting for non-occupational PEP (NPEP) require appropriate targeted screening for chlamydia, gonorrhoea and syphilis as recommended by local guidelines. If symptoms of STI are present, further tests, empiric treatment and follow-up are required. For further advice see the Australian STI Management Guidelines at www.sti.guidelines.org.au

3. Hepatitis C

Individuals who are potentially at risk of hepatitis C infection (e.g. people who have shared needles and other injecting equipment, or who have had a needlestick injury, or men who have sex with men that have engaged in mucosally traumatic condomless anal sex) require baseline and follow-up testing for hepatitis C.²³ Referral may be required if hepatitis C seroconversion is detected. Patients should be informed about the symptoms of acute hepatitis, with advice to present if these occur. New, highly effective antiviral treatments are available. For further advice, see <http://www.ashm.org.au/HCV/management-hepc>

4. Pregnancy and breastfeeding

All women who have the potential to be pregnant at the time of presentation for PEP should be offered pregnancy testing. Emergency contraception is offered to women presenting for PEP within 72 hours, who are at risk of pregnancy. Follow-up pregnancy tests should be offered at 3-4 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 risk-reduction practices until their seronegative status is confirmed at follow-up. This includes safer sexual and injecting behaviour as well as preventing exposing others to their body fluids through other means such as accidents or body tissue donation. Women should be counselled about pregnancy, the risk of mother-to-child transmission, contraception, and offered emergency contraception if indicated.

2. Individuals at risk of HIV acquisition who decline PEP

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

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

This response may relate to anxiety and fear about an apparently negligible exposure or to undisclosed more serious risk behaviours.

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

4. Individuals who re-present for NPEP

People who present for repeat NPEP should be supported, with each presentation assessed on its merits in a non-judgemental manner. It may be necessary to consider extension to an existing PEP course and this should be by a full 28 days from the last HIV exposure risk.²⁴

Repeat presentation(s) and extension of PEP courses warrant careful assessment of the context of risk behaviour and should prompt consideration for PrEP, referral to mental health, risk-reduction counselling and/or AOD services (see the National HIV Testing Policy at <http://testingportal.ashm.org.au/hiv>). Safer sex information should be an integral part of the consultation.

5. Individuals who are on PrEP

Switching from PrEP to PEP is only recommended if:

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

See **Table 8** for guidance. If switching from PrEP to PEP occurs in an emergency department, expert advice should be sought and the individual referred back to their PrEP prescriber as a matter of urgency.

If the individual is presenting for PrEP and they have had a possible exposure within the last 72 hours, they should be offered PEP and can then be transitioned to PrEP once confirmed to be HIV-negative.

Table 8. Switching from PrEP to PEP

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

6. Transitioning from PEP to PrEP

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

7. Renal disease

All patients having PEP should be assessed for renal impairment. Tenofovir should not be used if creatinine clearance is less than 60mL/min. Zidovudine with lamivudine with both doses adjusted to degree of renal function is recommended as a 2-drug regimen with a third agent as indicated.²⁵

8. Gender identity and history

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

9. Individuals who have been sexually assaulted

Those who present due to sexual assault should be assessed for their need for PEP as early as possible after the event. This is usually best done in a specialist sexual assault centre (where specialist counselling and forensic testing can also occur). However, PEP, if indicated, should not be delayed pending referral. Male-to-male sexual assault clients should always be offered PEP. There are no data on HIV prevalence for convicted sexual assailants in Australia; however, from studies on HIV point prevalence in Australian correctional services it ranges between 0 to 0.6%, with most jurisdictions reporting below 0.1%. Given that the risk of exposure is low, PEP is generally not recommended following heterosexual sexual assault; however, the decision to prescribe PEP should be made on a case-by-case basis. Factors such as multiple assailants, trauma or an assailant who is from a high prevalence country may increase the exposure risk. Emergency contraception should always be offered for women or trans men in this situation.

10. Children

All minors presenting following a potential risk of HIV exposure should be immediately considered for PEP. In the case of sexual assault, evaluation and treatment should be managed by a multidisciplinary team that is experienced in addressing the medical, psychosocial, and legal issues of such an offence. Parents or legal guardians should be notified unless the adolescent is ≥ 15 years and deemed legally competent to request that their guardians are not notified. Children who are sexually assaulted should be assessed for the risk of acquiring other STIs and the possibility of pregnancy for girls post-menarche. Emergency contraception should always be offered. The clinician should discuss key issues about PEP with the family and child as soon as possible. When parental or legal guardian consent cannot be obtained to initiate PEP, treatment may be initiated, with consent strongly recommended to continue PEP beyond the first hours/days. If PEP is prescribed, ensure sufficient medication is supplied to complete a full 28-day course.

Recommended dosage*:

| | |
|---|--|
| Weight 35kg or more | |
| Preferred option: Tenofovir + Emtricitabine PLUS Raltegravir Secondary options: 1) Zidovudine + Lamivudine PLUS Raltegravir; 2) Zidovudine + Lamivudine PLUS Lopinavir + Ritonavir | |
| Formulations | |
| Tenofovir disoproxil fumarate 300mg + Emtricitabine 200mg (ONE co-formulated tab once daily) Do not use in renal impairment | |
| Raltegravir 400mg tablet (ONE tab BD) | |
| Tab: Zidovudine 300mg + Lamivudine 150mg (ONE co-formulated tab BD) | |
| Tab: Adult Lopinavir 200mg + Ritonavir 50mg (TWO co-formulated tabs BD) Note strength of tablet | |
| Weight under 35kg | |
| <3 years | Preferred option: Zidovudine + Lamivudine PLUS Lopinavir + Ritonavir |
| ≥ 3 years | Preferred option: Zidovudine + Lamivudine PLUS Raltegravir (if chewable available) Secondary option: Zidovudine + Lamivudine PLUS Lopinavir + Ritonavir |
| Formulations | |
| Zidovudine Cap: 100mg or 250mg (180mg/m ² /dose BD) OR Liquid: 10mg/ml (Max: 250mg BD) | |
| Lamivudine Tab: 100mg or 150mg (4mg/kg/dose BD) OR Liquid: 10mg/ml (Max: 150mg BD) | |
| Liquid: Lopinavir 80mg/ml + Ritonavir 20mg/ml (Co-formulated 300mg/m ² /dose BD) (Max: 400mg BD Dose based on Lopinavir) OR | |
| Tab: Paediatric Lopinavir 100mg + Ritonavir 25mg (Co-formulated) Note strength of tablet Surface area (m ²): $\frac{\text{Weight(Kg)} \times \text{Height (cm)}}{\sqrt{3600}}$ | Weight banded dosing using 100/25mg tablets: 15–25kg: TWO tablets BD 25–35kg: THREE tablets BD > 35kg: FOUR tablets BD |
| Raltegravir 25mg or 100mg CHEWABLE tablets These tablets are NOT bioequivalent to the 400mg Raltegravir tablet | CHEWABLE tablet: 11–14kg 75mg BD 14–20kg 100mg BD 20–28kg 150mg BD 28–40kg 200mg BD > 40kg 300mg BD If >25kg and can swallow tablets: 400mg tablet BD |
| * Determined in consultation with the ANZPID Guidelines for post-exposure prophylaxis (PEP) after non-occupational exposure to blood borne viruses in children (2016). | |

11. Prisoners and detainees

People living in correctional or detention facilities who are potentially exposed to HIV sexually, through injecting drug use or other means require assessment for PEP as soon as possible after exposure. HIV point prevalence in Australian correctional facilities is estimated at below 0.1%²⁶, 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.

12. Individuals who commenced PEP overseas

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

13. Risk communication: understanding the risk of exposure

Communicating the risk of an action or consequence can be very difficult. **Table 9** presents an approach to this that may be useful with patients.

Table 9. Estimates to quantify risk

| Risk | Risk description |
|---|------------------|
| $1/1 \geq \text{risk} \geq 1/10$ | Very high |
| $1/10 > \text{risk} \geq 1/100$ | High |
| $1/100 > \text{risk} \geq 1/1000$ | Moderate |
| $1/1000 > \text{risk} \geq 1/10,000$ | Low |
| $1/10,000 > \text{risk} \geq 1/100,000$ | Very low |
| $1/100,000 > \text{risk} \geq 1/1,000,000$ | Minimal |
| $1/1,000,000 > \text{risk} \geq 1 \text{ in } 1 \text{ billion-trillion}$ | Negligible |

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Information for clinicians

Further information about PEP and antiretroviral prescribing is available via the ASHM website at <http://ashm.org.au/pep-guidelines>

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

Information for patients

Further information about PEP is available from <http://getpep.info/>

Local AIDS councils and health departments can also provide further information. Links are available via the Australian Federation of AIDS Organisations (AFAO) at <http://www.afao.org.au/about-hiv/links/australian-links/state-based-organisations>

Appendix 1. Drugs commonly prescribed in PEP regimens

| Regimen | Cost/28-day course* (AUD) |
|--|---------------------------|
| Tenofovir disoproxil fumarate 300mg (TDF) with lamivudine 300mg (3TC) | \$568.80 |
| Tenofovir disoproxil fumarate/emtricitabine 300mg/200mg (Truvada® (TVD)) | \$700.30 |
| TDF with 3TC and dolutegravir (DTG) | \$1,211.90 |
| TDF with 3TC and raltegravir (RAL) | \$1,180.80 |
| TDF with 3TC and rilpivirine (RPV) | \$1,102.60 |
| TVD with DTG | \$1,343.40 |
| TVD with RAL | \$1,312.30 |
| TVD with RPV | \$1,234.10 |
| TVD/RPV (Eviplera®) | \$953.80 |
| Lamivudine and zidovudine (Combivir®) | \$149.10 |

*Correct as of 28 July 2016, Pharmaceutical Benefits Scheme list prices.

Further information

Further information about pricing is available from www.pbs.gov.au/pbs/home

For more information on drug dosing and adverse events, please see <http://arv.ashm.org.au>



