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Australian National Guidelines for **Post-Exposure Prophylaxis (PEP)** after Non-Occupational and Occupational Exposure to HIV

(Fourth Edition) 2025

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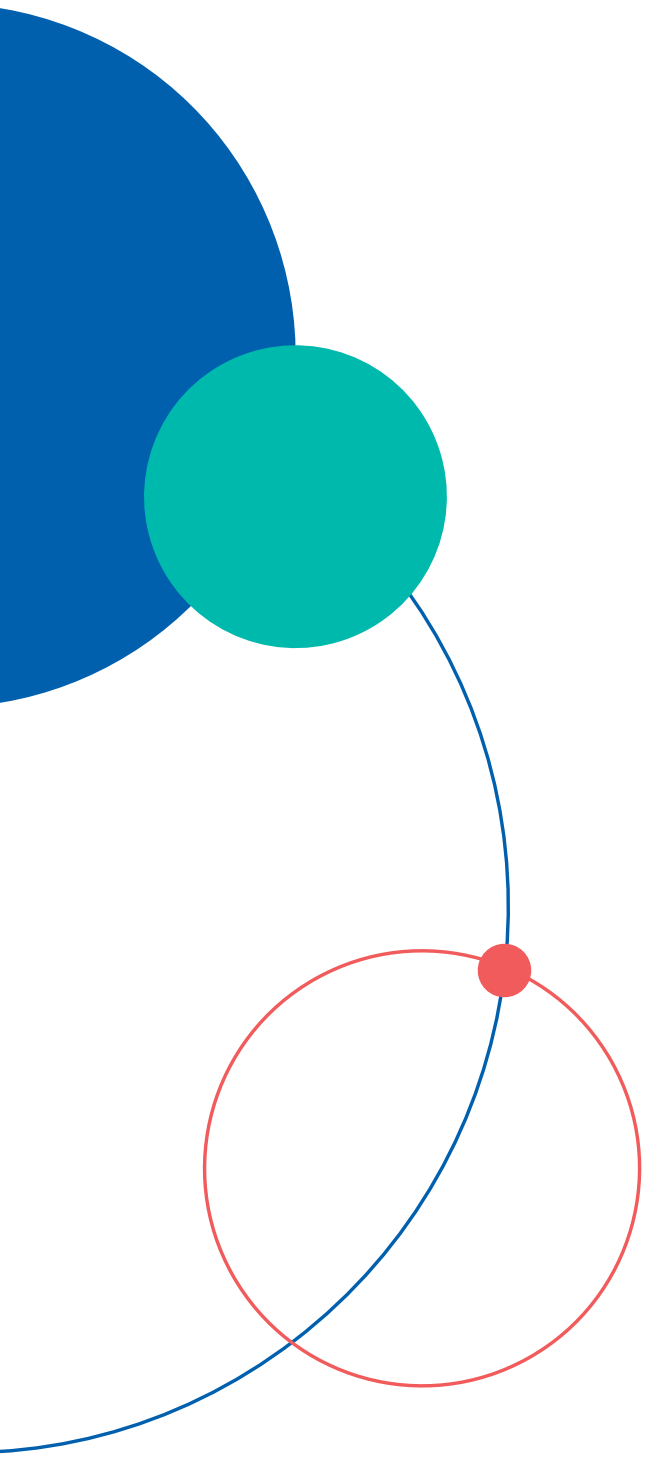

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Introduction

This is the fourth edition of the Australian National Guidelines for Post-Exposure Prophylaxis (PEP) after Non-Occupational and Occupational Exposure to HIV, which outline the management of individuals who have been exposed (or potentially exposed) to human immunodeficiency virus (HIV) in non-occupational and occupational settings. Risk of transmission, the timing of PEP, baseline assessment, preferred regimen and follow-up are outlined. Also included is the use of HIV PEP in the era of the Pharmaceutical Benefits Scheme (PBS)-subsidised HIV pre-exposure prophylaxis (PrEP).

There are no data from randomised controlled trials of the use of 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, the biomedical management of HIV exposures is largely based on expert opinion and limited data.

Every presentation for PEP should be assessed on a case-by-case basis, balancing the potential benefits against the potential risks of PEP recommendation.

Presenting for PEP and disclosing HIV risk behaviour can be a stressful experience and therefore it is important that clinicians are non-judgemental when conducting PEP assessments. A patient's negative experience when requesting PEP has resulted in failure to re-present for PEP, leading to subsequent HIV acquisition.[1,2]

Although recommended to be given within 72 hours to be effective, the earlier PEP is initiated after the exposure, the better. PEP is available through s100 and other PEP prescribing GPs, specialist nurse practitioners, sexual health clinics, emergency departments and some urgent care clinics. Unlike PrEP, PEP is not available on the PBS; however, now that affordable generic formulations for 2-drug PEP are available, all GPs are able to prescribe 2-drug PEP at a reasonable cost, using a private (non-PBS) prescription (see section "Prescribing PEP").

This fourth edition of the National PEP guidelines is:

- Revised from the third edition of the National guidelines for post-exposure prophylaxis after non-occupational and occupational exposure to HIV (2023).
- Produced by ASHM.
- Available as a website resource at www.pep.guidelines.org.au
- Supported by a clinical decision-making tool available at https://ashm.org.au/resources/decision-making-in-hiv-pep/
- Funded by the Commonwealth Department of Health (DoH).
- Will be reviewed regularly through ASHM, for advice to the DoH.

A note about source viral load

Although an estimated 87% of all PLHIV in Australia have undetectable viral load[3], this does not influence PEP prescribing. If the source VL is unknown, then the risk is still sufficient to prescribe PEP. If the source VL is undetectable, then PEP is not required.

A note about gender identity and history

It is acknowledged that language is ever evolving, and the term trans and gender diverse (TGD) used in this document is inclusive of both binary and non-binary TGD individuals.

Evidence for HIV prevalence and risk among TGD individuals in Australia is poor due to limitations with data collection and recording of TGD status.[4,5] Internationally, TGD individuals are often disproportionately affected by HIV.[6]

It is important for clinicians not to make assumptions about a patient's gender identity or the type of sex they have. Ask for and use preferred pronouns and names for anatomical sites (e.g. this could be front hole rather than vagina) and use open-ended questions when taking a sexual history. The focus of the PEP risk assessment needs to be the potential HIV risk of the source and type of exposure, rather than the individual's gender identity.

What's New (2025)

- **A Decision Making in HIV PEP tool now supplements the guidelines, providing a summary of the information required to prescribe PEP.**
- **Removal of the "very high prevalence population (MSM who inject drugs)" category from Table 2: PEP recommendations after NON-OCCUPATIONAL exposure.**
- **Removal of the "estimated HIV acquisition risk if source is viraemic, by population group" tables in Appendix B.**

Glossary

TERM	DEFINITION
AFP	Alpha fetoprotein
Ag/Ab	Antigen/antibody test
AIDS	Acquired immunodeficiency syndrome
AOD	Alcohol and other drugs
ART	Antiretroviral therapy
ARV	Antiretroviral
BBVs	Blood-borne viruses
CK	Creatine kinase
eGFR	Estimated glomerular filtration rate
EUC	Electrolytes, Urea, Creatinine
FBC	Full Blood Count
FTC	Emtricitabine
GP	General practitioner
HBV	Hepatitis B virus
hCG	Human chorionic gonadotropin
HCV	Hepatitis C virus
HCW	Healthcare worker
HIV	Human immunodeficiency virus
HPC	High-prevalence country
IAI	Insertive anal intercourse
iPrEx	Pre-Exposure Prophylaxis Initiative
IVI	Insertive vaginal intercourse
LFT	Liver Function Test
MSM	Men who have sex with men

TERM	DEFINITION
PBS	Pharmaceutical Benefits Scheme
urinary PCR	urine protein:creatinine ratio
PEP	Post-exposure prophylaxis
PrEP	Pre-exposure prophylaxis
PWID	People who inject drugs
RAI	Receptive anal intercourse
RVI	Receptive vaginal intercourse
s100	A section of the Pharmaceutical Benefits Scheme which provides access to highly specialised drugs
Source individual	A person whose blood or other bodily substance may be a source of HIV exposure
STI	Sexually transmissible infection
TAF	Tenofovir alafenamide
TD	Tenofovir disoproxil
TDF	tenofovir disoproxil fumarate
TGA	Therapeutic Goods Administration
TGD	Trans and gender diverse
U=U	Undetectable equals untransmissable
Viraemic	≥ 200 copies/ml of HIV detected on a blood test
VL	Viral load
WB	Western blot assay

Immediate Management of HIV Exposure

- 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.

PEP Efficacy: Background and Evidence

There is currently no data from randomised controlled trials that provide evidence of the efficacy of PEP in preventing HIV acquisition. Animal data have been particularly informative regarding the importance of starting PEP as early as possible following an exposure event, the 72-hour post-exposure window period for starting PEP and the 28-day duration of the course.[7-11]

Further evidence for the use of PEP has also been extrapolated from data from mother-to-child transmission[12-14] and following occupational exposures in health care workers,[15] where a retrospective case control study demonstrated that PEP users had an 81% reduction in HIV seroconversions compared to those who did not take PEP.[16]

The only clinical effectiveness study of PEP in humans was performed among 200 Brazilian high-risk HIV-negative men who have sex with men (MSM). Seroincidence in the cohort was very similar to that expected in the population. There was no difference in PEP efficacy, likely due to a lack of statistical power. However, HIV seroconversions were only 1/68 in the PEP group compared with 10/132 in the group not receiving PEP.[17]

Although PEP is likely to be highly effective when initiated in a timely manner and taken as prescribed, there have been documented HIV seroconversions following PEP after both sexual and occupational exposures. In Australian[18] and international[19,20] observational studies, seroconversions subsequent to a PEP course following sexual exposures, although rare, were most commonly associated with ongoing risk behaviours. Other reasons for seroconversion have included delays in PEP initiation,19,21 poor adherence to PEP[21,22] and already established HIV infection at the time of PEP initiation.[23]

The rare cases of PEP failure following occupational exposures were mostly reported over two decades ago.[16,24-26] Occupational PEP failures have been described due to resistance mutations in the virus of the source27 and possible early primary HIV infection in an Australian healthcare worker who seroconverted after sustaining a needlestick injury from a viraemic, treatment-experienced source, despite commencing PEP only two hours later.[28]

Notably, despite completing the 28-day course, the healthcare worker had stopped PEP for four days in the third week.

Completion of the 28-day PEP course has historically been low, ranging from 48% to 88%.[29] However, less tolerable older PEP regimens, particularly those containing zidovudine,[30,31] have been replaced by better-tolerated regimens in recent years, including the use of tenofovir disoproxil fumarate (TDF) as one component of the PEP backbone with an integrase inhibitor (versus a protease inhibitor) as a third drug, where required.[30,32,33]

Education on the importance of PEP adherence and seeking timely clinical review for PEP regimen modification if side-effects impact adherence remains a cornerstone of PEP management, along with appropriate post-PEP testing.

There is no evidence for greater efficacy of two or three-drug PEP regimens. (See **Appendix A**) Recommendations in international and national guidelines are based on transmission risk assessment, epidemiology (including co-factors), local prescribing practices and cost.

Assessing HIV Transmission Risk

U=U

Robust evidence has proven that HIV is untransmissible by sexual activity when the source is on treatment and has an undetectable viral load,[34-37] now referred to in global health promotion programs as 'undetectable = untransmissible' or U=U.38 However, source information is often unavailable in PEP decision-making. If doubt exists, PEP should be initiated as outlined in **Table 2**.

Where the source HIV status is unknown, 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 has HIV with a detectable viral load
- Any co-factors associated with the source and the exposed individual

Risk of HIV transmission

=

risk per exposure

x

risk of source having HIV with detectable viral load

What is the HIV transmission risk/exposure?

Table 1 outlines the estimated risks of HIV transmission per exposure to a source with HIV. Whilst these risk estimates are important at a population health level, they do not adequately estimate an individual's risk after a single exposure. HIV transmission may be increased by numerous factors, including viral load of the source, sexually transmitted infections (STI), breaches in mucosal barriers and circumcision status (see co-factors related to HIV transmission below). In addition, there is considerable genetic heterogeneity between individuals that affects HIV infectiousness and susceptibility.

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

Significant exposures are those where body fluids that potentially contain HIV come into contact with mucosal surfaces or non-intact skin. Body fluids that are infectious, potentially infectious and non-infectious are included in Appendix B.[51]

Table 1: Estimated risk of HIV transmission by exposure (source with HIV) [27,39-47]

EXPOSURE	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 • circumcised	 1/160 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. Estimates do not take into account the source viral load. If viral load is undetectable, there is no risk.

\# Worldwide, there have been no reported cases of HIV acquisition from a discarded needle in a public place.[48] Very rare transmission of HBV and HCV have occurred in this situation, so these infections need to be considered.

† Human bites and semen splash to the eye are extremely low risk.

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

Viral load (VL):

- When the source VL is undetectable (<200 copies/mL) there is no risk of sexual transmission of HIV (U=U)[33-37]
- Higher plasma VL (when seroconverting or with advanced disease) is associated with increased risk of HIV transmission[48]

Other factors that increase the risk of HIV transmission:

- Sexually transmitted infections (STI) in the source or exposed individual, especially genital ulcer disease and symptomatic gonococcal infections
- Source ejaculation during receptive anal, vaginal or oral intercourse
- Breach in genital mucosal integrity (e.g. trauma, genital piercing or genital tract infection)
- 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).

What is the HIV status of the source individual?

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

In the setting of non-occupational exposure, the HIV status of the source is often unknown. Previous guidelines have recommended that active attempts should be made to contact the source to request an urgent HIV test, however, this is often impractical and rarely occurs.

Therefore:

- If the source cannot be contacted, seroprevalence data (see below) will assist in determining the need for PEP.
- If the source is contactable and:
  - discloses they have HIV, seek consent to determine recent viral load results and antiretroviral treatment history.
  - is known to be taking HIV 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 the potential for PrEP 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 have HIV.

HIV seroprevalence in Australian populations

Overall, in Australia seroprevalence of HIV is very low at 0.14%, with the highest prevalence among gay, bisexual and other men who have sex with men (MSM) (9.2%)[49] The proportion of people with undiagnosed HIV in Australia is greatest in those born in Southeast Asia and Latin America. In people who inject drugs (PWID), seroprevalence is 1.5%, although this figure may be significantly higher than this in those who are also MSM[3,49]

HIV seroprevalence in overseas populations

HIV seroprevalence overseas varies widely. A high prevalence country (HPC) is defined as having an HIV prevalence of >1% in the general population. However, HIV varies greatly within countries and sub-populations, such as sex industry workers and people who inject drugs, often have higher HIV seroprevalence than the general population. For those exposed overseas, go to **https://aidsinfo.unaids.org/** for the most recent seroprevalence estimates.[50]

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). The results should be followed up on as soon as possible, preferably within 24 hours of the specimen being collected. If this result is positive, refer urgently to an HIV specialist.

When to prescribe PEP

PEP for Non-Occupational Exposure

Situations where non-occupational PEP should routinely be offered include:

- Anal or vaginal intercourse (either receptive or insertive) with a partner known to have HIV with an unknown or detectable viral load.
- Receptive anal intercourse with a source of unknown HIV serostatus from a high prevalence population (MSM, TGD or from HPC).
- Insertive anal intercourse where the exposed person is uncircumcised, with a source of unknown HIV serostatus from a high prevalence population (MSM, TGD or from HPC).
- Sharing needles/injecting equipment with a source who is known to have HIV with an unknown or detectable viral load.

Non-occupational PEP should NOT be routinely offered where:

- The source status is unknown and from a low HIV prevalence setting, such as the general Australian-born heterosexual population
- The source is a person living with HIV with a non-detectable (<200 copies/mL) HIV viral load
- The exposure itself poses negligible risk, such as a community needlestick injury or oral sex

Situations where there is greater uncertainty or complexity, such as known or suspected antiretroviral resistance in the source, pregnancy, breastfeeding or chronic hepatitis B and C, should be discussed with a physician experienced in this area.

There is no direct or compelling indirect evidence to support the greater efficacy of three-over two-drug regimens; rather, it has been extrapolated from evidence that a higher number of drugs or combination of drug classes have historically achieved better treatment outcomes for HIV. A summary of the evidence for three-drug versus two-drug PEP is provided in Appendix A.

See Tables 2 and 3 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. For very high-risk exposures (e.g. exposure to a source with a known high viral load), three-drug PEP may be considered after 72 hours as it can be continued as very early HIV treatment if seroconversion occurs.

Linkage to a specialist for discussion regarding PrEP should be considered where future HIV risk is likely and/or there have been multiple previous PEP presentations. See the Australian HIV PrEP guidelines for further guidance.

Table 2: PEP recommendations after NON-OCCUPATIONAL exposure

	SOURCE HIV STATUS UNKNOWN	SOURCE KNOWN TO HAVE HIV	
	High prevalence population (MSM, TGD or from HPC)	HIV VL undetectable	HIV VL detectable or VL unknown
Receptive anal sex with or without ejaculation	2 drugs	Not recommended	3 drugs
Insertive anal sex – uncircumcised	2 drugs	Not recommended	3 drugs
Insertive anal sex – circumcised	Consider 2 drugs*	Not recommended	3 drugs
Receptive vaginal sex	2 drugs	Not recommended	3 drugs
Insertive vaginal sex	2 drugs	Not recommended	3 drugs
Fellatio	Not recommended#	Not recommended	Not recommended#
Cunnilingus	Not recommended	Not recommended	Not recommended
Semen splash to the eye	Not recommended	Not recommended	Not recommended
Human bite†	Not recommended†	Not recommended	Not recommended†
Shared injecting equipment	2 drugs	Consider 2 drugs	3 drugs
Community needle-stick injury	Not recommended	Not applicable	Not applicable

* 2 drugs may be considered if there is a high likelihood of an STI, trauma or blood.

\# 2 drugs may be considered only for receptive fellatio WITH ejaculation AND significant visible oral mucosal trauma, or dental and gum disease.

† 2 drugs may be considered after a bite if: (a) the source (biter's) saliva or mouth had visible blood, AND (b) there was a high suspicion that the biter was known to have HIV and not taking ART AND (c) the bite has resulted in severe, deep or multiple tissue injuries.

In Table 2 above, the recommended 2-drug PEP regimen is tenofovir disoproxil/emtricitabine 300mg/200mg daily.

The recommended 3-drug PEP regimen is tenofovir disoproxil/emtricitabine 300mg/200mg daily plus dolutegravir 50mg daily.

See What to Prescribe for more detail, including alternative regimens

PEP for Occupational Exposure

In occupational settings, the source is usually able to be identified and tested for HIV. Consent for source testing must be obtained. When the source is incompetent, unconscious or deceased, approval to test the source must be obtained from an authorised person (e.g. Chief Health Officer), as directed in the state or territory legislation.

If the source is at high risk of having HIV and is unable to be tested immediately, the exposed worker should be commenced on PEP without waiting for the source's results. If the source is unable to be identified or tested, then the risk of the source having HIV 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 1. However, the risk is most likely significantly lower than this as these data predate effective antiretroviral therapy (ART). There have not been any reports of occupational HIV transmission in the UK since 1999, and only one in the USA since 1999.[26,52] This may be due to a number of factors, including changes in practices to reduce the risk of needlestick injury and a greater proportion of patients on treatment with undetectable viral load. As described above, there is no risk of sexual transmission of HIV when the source has an undetectable viral load (<200 copies/mL).[34-37] While it is likely that the same would apply for occupational exposures that most often involve exposure to blood, there is a lack of data to support this. It is reasonable to always offer PEP to a healthcare worker who has had a significant exposure to a source who has HIV, even if the source has an undetectable HIV viral load.

Table 3: PEP recommendations after OCCUPATIONAL exposure

	SOURCE HIV POSITIVE		SOURCE HIV STATUS UNKNOWN
	HIV VL detectable or VL unknown	HIV VL undetectable*	High prevalence population (MSM, TGD or from HPC)
Needlestick injury or other sharps exposure	3 drugs	Consider 2 drugs	Consider 2 drugs
Mucous membrane and non-intact skin exposure	3 drugs	Consider 2 drugs	Consider 2 drugs

* Co-factors that may influence decision-making following occupational exposures include deep trauma and bolus of blood injected. There is no current direct evidence that U=U is applicable to occupational exposures to blood

Clinical Assessment and Follow-up

In making a clinical assessment, health practitioners should consider the gender, culture, language and literacy level of the person seeking care, and their intellectual capacity. The following details should be discussed and documented in the patient's history:

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 cofactors
c. If the exposure occurred in a context that was consensual or involved coercion, force or lack of consent, as disclosed by the individual. If non-consensual, consider referral for forensic assessment based on patient preference and provide information for ongoing support.

Information about the source person

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

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

Information about the exposed person

a. Most recent HIV test and result
b. Other potential HIV exposures since the last negative HIV test
c. Previous use of PEP, including regimen, adherence and side effects
d. Current or previous use of PrEP (see Table 6 for interface between PEP and PrEP)
e. Current symptoms of an STI
f. Previous history of syphilis (to assist with interpretation of a positive syphilis result from baseline testing)
g. Hepatitis B status: if a patient is known to have chronic hepatitis B (HBV), they can be safely commenced on PEP with specialist advice sought before PEP is ceased (see section: Additional Clinical Management Issues).
h. Pregnancy risk, contraception and lactation (consider emergency contraception)
i. Medical history:
    - all medications and drug allergies
    - current and past medical history, including renal disease, psychiatric history and drug and alcohol history.

Information to provide to patients when initiating PEP

- 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 and what to do if a dose is missed (see Additional Clinical Management Issues).
- The symptoms of HIV seroconversion (fever, fatigue, myalgia, skin rash, headache, pharyngitis, cervical adenopathy, arthralgia, night sweats, and diarrhoea), with advice to urgently access specialist advice if these or any other symptoms occur.
- Recommendation to adopt risk-reduction practices (including condoms for vaginal and anal intercourse and sterile injecting paraphernalia) until final HIV testing is complete post PEP completion.
- Option for transitioning from PEP directly onto PrEP for those at ongoing risk of HIV acquisition.
- The recommended timing of follow-up HIV and other testing is outlined in Table 4 – Individuals with a positive or indeterminate HIV test on baseline testing, or during follow-up, require immediate referral to an HIV specialist.
- 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 4 sets out the recommended schedule of testing for individuals who are prescribed PEP.

Table 4: Laboratory evaluation of individuals who are prescribed PEP

TEST	BASELINE (WEEK 0)	WEEK 2	WEEK 6[A]	WEEK 12
HIV serology (HIV Ab/Ag)	X		X	X
Hepatitis B serology (HBsAg, Anti-HBs and Anti-HBc[B]	X			X
Hepatitis C serology (HCV Ab)[C]	X			X
STI screen[D]	X	X		X
Syphilis serology[D]	X		X	X
UEC	X[E]		X	
Pregnancy test[F]	X		X	

A. HIV testing is best performed at week 6, which is 2 weeks after cessation of PEP.
However, where a patient is directly transitioning onto PrEP, perform HIV testing at the end of the PEP course at week 4.
Patients who are not prescribed PEP do not need further HIV testing beyond week 6.[53]

B HBV surface antigen; HBV surface antibody; HBV core antibody.
PEP can be safely commenced in people with HBV (HBsAg positive).
Seek specialist consultation in regard to safely ceasing PEP in those with HBV https://ashm.org.au/initiatives/b-referred/
Individuals with evidence of prior immunity to HBV (Anti-HBs >10 mIU/mL) will require no further follow-up.
Non-immune individuals (Anti-HBs <10 mIU/mL) should be offered immunisation and follow-up to 6 months

C. Where HCV Ab positive, and reflex HCV PCR testing is not available, recall patient for HCV PCR testing.
Patients potentially at risk of HCV acquisition require baseline and follow-up testing for HCV.

D. Only required for sexual exposures. Conduct a full STI screen from all relevant sites as per Hx

E. Seek specialist input for recommendation of alternative PEP drugs if eGFR<60

F. If clinically indicated. Consider emergency contraception

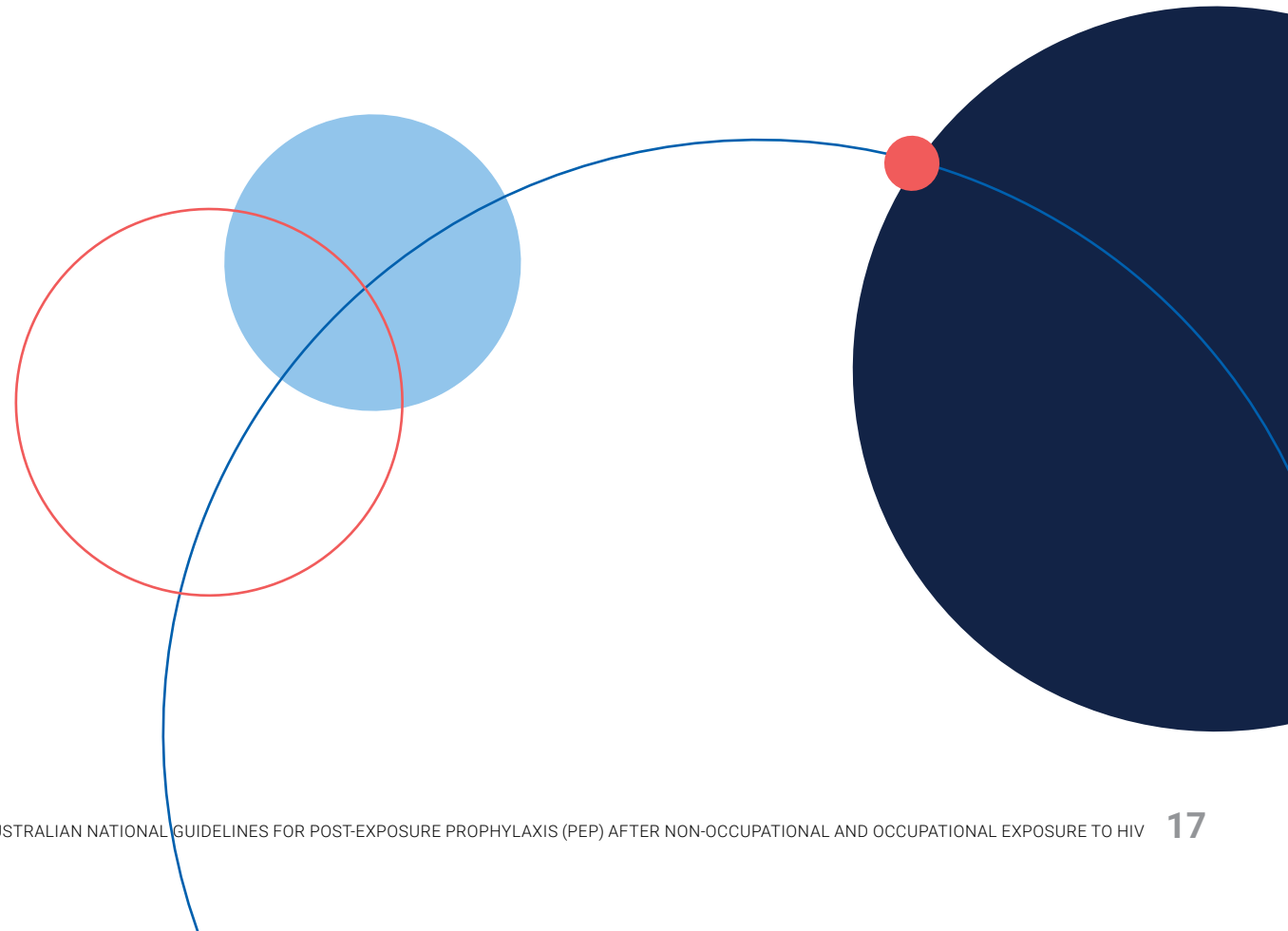
Follow-up of indeterminate HIV test results[54,55]

Although uncommon, indeterminate HIV test results may occur. This situation is complex and requires the input of a laboratory with expertise in HIV testing and may require additional or different tests.

When a baseline HIV Ag/Ab result is positive and confirmatory testing is delayed, or indeterminate, the clinician should recall the individual and:

- assess for HIV seroconversion symptoms (most commonly, in order of decreasing prevalence: fever, fatigue, myalgia, skin rash, headache, pharyngitis, cervical adenopathy, arthralgia, night sweats, and diarrhoea)[56]
- add the recommended third PEP drug to two-drug PEP regimens to minimise the risk of developing antiretroviral resistance
- continue three-drug PEP regimens
- seek immediate advice from, or refer to, an HIV specialist and/or discuss with the virologist or microbiologist at the testing laboratory
- advise the individual that they have a reactive initial test that still requires confirmation
- advise the individual that they may be at risk of transmitting HIV and provide advice on actions that can be taken to reduce the risk of onward transmission including condom use and sterile injecting paraphernalia.
- refer to or provide psychological support

Commencing antiretroviral therapy early during acute HIV infection has been found to delay the development of both positive HIV antibodies and HIV WB tests.[57] Therefore, a 28-day course of PEP also has the potential to delay seroconversion. In such situations, it is recommended to follow the advice of a specialist laboratory with regard to tests required to confirm a diagnosis of acute HIV.



Prescribing PEP

Important note for medical and nurse practitioners who have not previously prescribed HIV PEP

The availability of generic formulations of tenofovir disoproxil 300 mg /emtricitabine 200 mg, (TD/FTC) used for PrEP, now make it possible for any prescriber to provide a private prescription for TD/FTC as two-drug PEP at a reasonable cost (at the time of publication: approximately $40-50 for a one-month course). Traditionally the medication used for two-drug PEP (TD/FTC) has only been available at emergency departments, sexual health clinics, HIV specialists or other accredited HIV s100 prescribers, however, due to widespread uptake of PrEP, TD/FTC is now also available in many community pharmacies. The medications used are not Therapeutic Goods Administration (TGA) approved, or PBS listed for PEP, therefore, a private prescription for TD/FTC with no repeats needs to be written.

Please follow the guidelines outlined in this document to assess if your patient fits the recommendation for two-drug PEP and, if unsure, contact your local PEP telephone support line. If two-drug PEP is indicated and the individual is considering starting PrEP, as there are likely to be ongoing HIV exposures, a 3-month prescription for PrEP (TD/FTC 30 tabs with 2 repeats) can be offered, as PrEP and two-drug PEP are the same medication. Alternatively, write a private prescription for PEP (TD/FTC 30 tablets, no repeats) and arrange follow-up.

As PEP medication comes in 30-day supplies, prescriptions can be written for 30 days. Advise the individual to take 28 days and keep the remaining 2 tablets to allow immediate commencement of PEP should they have a future exposure.

As generic formulations are not currently available for dolutegravir, the current recommended third drug used for PEP, if the individual requires three-drug PEP, please consult your local PEP phone line for advice on where to access dolutegravir.

Local telephone support is available here for PEP prescribing in each Australian jurisdiction.

Provide the full course at first presentation

Previously, anecdotal reports suggested potential benefits of starter packs, including clinical review within the first week to ensure completed baseline pathology and to allow modification of inappropriate or poorly tolerated PEP regimens. However, a systematic review and meta-analysis of outcomes of PEP initiation using starter packs (versus dispensing the full 28-day course) suggested that starter packs do not improve acceptance and may negatively affect completion of PEP, with almost 30% of those provided with a starter pack not returning for follow-up.[30,58] PEP starter packs of 5-7 days remain an option for emergency department presentations, especially presentations in rural and remote and low PEP presentation settings, where timely specialist advice may not be available. In some settings, starter packs may contain all three drugs, with patients receiving either two or three drugs depending on the exposure.

If a three-drug PEP regimen is recommended and the third drug is not available, a two-drug regimen may be initially prescribed. Contact the PEP phoneline in your state or the closest PEP providing site for advice on where to obtain the third drug.

What to prescribe

The current recommended first-line two-drug regimen is co-formulated tenofovir disoproxil 300mg and emtricitabine 200mg (TD/FTC) taken once daily. This regimen is ideal for PEP because it is well tolerated with good anogenital tissue penetration.[59] In addition, TD/FTC is now available in affordable, generic forms.

Where a third drug is required, dolutegravir is recommended.

Recommended PEP regimens

2-drug regimen
Tenofovir disoproxil* 300mg /emtricitabine 200mg (daily) for 28 days

3-drug regimen
Tenofovir disoproxil* 300mg /emtricitabine 200mg (daily) for 28 days

PLUS

Dolutegravir 50mg (daily) for 28 days
If dolutegravir is unsuitable due to drug interactions use raltegravir 1200 mg daily (see Table 5)

* There are four salts of tenofovir disoproxil available with slightly different dosages, which are considered bioequivalent: maleate, phosphate, fumarate and succinate

In general, tenofovir disoproxil and emtricitabine with dolutegravir is well tolerated when taken as PEP.[22,29,30,32,33,60,61]

If a patient reports intolerable or serious side effects from a previous PEP course or has an e-GFR < 60mL/min:

- An alternative PEP regimen should ideally be prescribed (discuss with specialist or PEP phone line)
- In emergency (out-of-hours) situations (unless previously reported side-effects were serious), the available PEP regimen should be prescribed with urgent specialist follow-up arranged to monitor the PEP regimen.

Medications and cautions

Table 5: Specific medications and cautions

MEDICATION	COMMENTS AND CAUTIONS
Tenofovir disoproxil	• Use with caution or avoid in renal disease (eGFR <60), consult specialist for alternative (tenofovir alafenamide) if eGFR <60 • Avoid high doses of NSAIDS • Where tenofovir is directly contraindicated seek expert advice.
Dolutegravir	• Phenytoin, phenobarbital, rifampicin, St John's Wort, carbamazepine all reduce dolutegravir levels. If unable to cease above medications, use raltegravir 1200 mg daily • 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	• Small risk of rhabdomyolysis – inform patients about the potential for myalgia and the need to re-present if myalgia occurs. Caution patients who engage in heavy gym work about the increased risk of rhabdomyolysis, especially when anabolic steroids are used. • Check CK, renal function and urinary myoglobin in patients who report myalgia on raltegravir • Advise against the use of statins while on PEP containing raltegravir.

Adverse Events

Proximal renal tubular dysfunction (including Fanconi syndrome) has been reported among people with HIV on tenofovir disoproxil-containing therapy,[62] but has not been reported among patients prescribed a 28-day PEP course.

Myopathy or severe rhabdomyolysis has been reported, albeit rarely, with use of dolutegravir and raltegravir.[63-66] It is advised that:

- Patients on PEP should be monitored for symptoms
- Caution should be taken among those with a history of myopathy, or co-administration with medications such as statins,[67] which may also cause myopathy
- Creatine kinase (CK), renal function and urinary myoglobin should be checked in patients who report significant myalgia.

Potential Drug-Drug interactions can be checked using the **Liverpool HIV Drug interaction checker.**

Management of Co-Exposures

Sexually transmitted infections (STIs)

Individuals presenting for non-occupational PEP (NPEP) require appropriate targeted testing for chlamydia, gonorrhoea and syphilis as per Australian STI Management Guidelines at www.sti.guidelines.org.au

If symptoms of STI are present, further tests, empirical treatment and follow-up are required.

Hepatitis B (HBV)

All patients presenting for PEP should be assessed for HBV (see Table 4).

HBV-negative individuals

- Individuals with evidence of previous immunity to HBV (anti-HBs ≥ 10 mIU/mL) ever documented following a complete vaccination course, or past cleared infection who are immunocompetent) require no further follow-up
- Non-immune individuals (anti-HBs <10 mIU/mL and anti-HBc negative) require HBV immunisation and follow-up (as per Australian Immunisation Handbook)
- If the person is non-immune (anti-HBs <10 mIU/mL and anti-HBc negative) and the source is known to have chronic HBV (HBsAg positive), a single dose of hepatitis B immune globulin (HBIG) should be administered and hepatitis B vaccination commenced. They will also need follow-up for subsequent serology as per the Australian Immunisation Handbook guidelines.

Hepatitis C (HCV)

There is no current evidence to support any mode of PEP in preventing hepatitis C (HCV) acquisition following exposure to HCV.[68] People presenting for PEP who may be at risk of HCV, either from prior risk exposures or from the risk exposure which prompted the presentation for HIV PEP, include:

- people who have shared needles and other injecting paraphernalia[69]
- occupational needle-stick or other sharps injury[68]
- MSM[70]
- people who have been sexually assaulted[71]
- those currently or previously incarcerated.[69]

Patients potentially at risk of HCV acquisition require baseline and follow-up testing for HCV.

The incubation period for HCV ranges from two weeks to six months, and approximately 80% of people do not exhibit any symptoms. If symptoms develop, they may include fever, fatigue, decreased appetite, nausea, vomiting, abdominal pain, dark urine, pale faeces, joint pain and jaundice. Patients should be informed about these symptoms of acute HCV, with advice to seek specialist review if these occur.[69]

Highly effective antiviral treatments are available, and early treatment is recommended if HCV seroconversion is detected.[69] For further advice, see the National Hepatitis C Guidelines.

Tetanus

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

Additional Clinical Considerations

Pregnancy and breastfeeding

The risk of HIV acquisition is increased during pregnancy, and the viraemia that occurs during HIV seroconversion leads to an increased risk of intrauterine HIV transmission.[72]

- Antiretrovirals recommended for PEP can be safely used by people with HIV who are pregnant and/or breastfeeding and are recommended as first-line therapy.
- Antiretrovirals taken during lactation can enter breast milk and be ingested by the infant. Timely specialist consultation is recommended, however, PEP should not be delayed or withheld in people who are pregnant or breastfeeding. All patients with the potential to conceive presenting for PEP should:
  - have a contraceptive and reproductive history taken to assess risk of pregnancy
  - be offered pregnancy testing (ideally serum beta hCG)
  - be offered emergency contraception if indicated (refer to RACGP Australian Family Physician. Emergency contraception: oral and intrauterine options)[87]
  - when indicated, follow-up pregnancy testing should occur three to four weeks post-exposure

For further information on the use of antiretrovirals in pregnancy and lactation, refer to the **Australian Commentary on the US DHHS Guidelines for the use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents**.

Missed PEP doses

Recommendations on whether and when to discontinue PEP after missed doses is largely empirical, informed by the biological and pharmacological properties of each agent, as well as expert opinion. Advice provided to those who miss dose(s) will depend on both the time since the last dose, as well as the number of missed doses. Maintenance of therapeutic levels of PEP differ due to varying pharmacokinetic properties of each PEP agent[63,73,74]

What to advise patients who miss PEP dose(s):

- Take the missed dose as soon as possible, unless it is time for the next dose
- If it is time for the next dose, skip the missed dose and return to a regular schedule
- Do not take a double dose to make up for a forgotten dose
- If 72 hours or more have elapsed since the last dose, discontinue PEP
- If interruption of PEP (for less than 72 hours since the last missed dose) is related to side effects, seek urgent specialist advice
- Depending on the likelihood of which agent is most likely to be causing specific side-effects, advice may be to stop the third drug and continue two-drug PEP or consider alternative agents.

Individuals at risk of HIV acquisition who decline PEP

There may be several reasons that a patient declines PEP, including:

- Inaccurate personal risk assessment
- Concern about medication side effects or long-term toxicities
- Lack of awareness about the use and likely efficacy of PEP.

Clinicians should address concerns and, where the individual still declines PEP, advise of the maximum 72-hour window-period for starting a PEP should they later reconsider.

Patients with high-risk HIV exposures who decline PEP should be advised to:

- Have follow-up HIV testing at 6 weeks post-exposure
- Monitor for HIV seroconversion symptoms: most commonly (in order of decreasing prevalence): fever, fatigue, myalgia, skin rash, headache, pharyngitis, cervical adenopathy, arthralgia, night sweats, and diarrhoea.[75]
- Return for assessment if any symptoms are present

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. Caution should be taken not to immediately dismiss low-risk exposures, particularly from people from countries with high HIV prevalence or where punitive LGBTIQ and HIV related laws occur. The individual may be fearful of stigma and discrimination when disclosing risk.

Where the HIV risk is truly low, it is recommended not to prescribe PEP to alleviate HIV anxiety, as this may inadvertently reinforce the individual's belief that the exposure was high enough to warrant PEP and result in further HIV anxiety and presentations for similar low-risk exposures in the future.

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

People who re-present for PEP after completion of a PEP course

People who present for repeat PEP should be supported, with each presentation assessed on its merits in a non-judgemental manner. Disproportionately higher rates of HIV acquisition occur among people who have previously used PEP.[18-20] Unless the exposure is isolated (e.g. an isolated condom failure, high-risk sexual assault), transitioning immediately onto PrEP after the PEP course should be discussed and recommended.

People who re-present with additional high-risk exposure(s) while taking a PEP course

Two-drug PEP and PrEP consist of the same medication, and a subsequent exposure that occurs while someone is on a current course of PEP is similar to an exposure that occurs while taking PrEP. When used for PrEP, co-formulated tenofovir-disoproxil and emtricitabine is proven to prevent HIV acquisition.[76,77] From the ANRS Prévenir trial of daily versus on-demand PrEP, extending the PrEP treatment for 48 hours after the last exposure is now known to be highly efficacious for the prevention of HIV acquisition via sex in MSM.[78] The iPrEx PrEP trial enrolled the highest number of transgender women to date, and no HIV infections were

observed in transgender women whose blood levels were compatible with taking four or more doses of PrEP weekly.[79] However, on stratification, PrEP did not provide a benefit for transgender women compared to the overall reduction in HIV incidence in the active study arm. Tenofovir levels decline rapidly after cessation in the vagina and neovagina,[59,80,81] so PEP should be continued for seven days after the last high-risk exposure.

There is no empirical evidence to guide clinicians managing people who inject drugs who have a repeat HIV risk exposure whilst injecting drugs during the PEP course. Therefore, extending the PEP course by a further 28 days from repeat exposures is recommended in this situation.

We recommend clinicians follow this advice:
Continue PEP for 48 hours after the last high-risk anal sexual exposure, 7 days after the last high-risk vaginal/neovaginal/front hole exposure and 28 days after the last high-risk sharps or blood exposure.

Individuals who are on PrEP

People taking PrEP as prescribed would generally not be eligible for PEP. However, those at risk of HIV acquisition taking PrEP may present for PEP in the context of suboptimal adherence to PrEP.[82] Clinical[83] and pharmacokinetic data80,84,85 provide good evidence of levels of adherence to PrEP required to effectively prevent HIV acquisition via anal and vaginal sex. There is little data regarding front hole sex in trans men or neovaginal sex in trans women, but levels of adherence required can be extrapolated from protective tissue concentrations in peripheral blood mononuclear cells.[85] The time to protection of tenofovir disoproxil is shortest in lower gastrointestinal tract tissues, followed by peripheral blood mononuclear cells and then female genital tract tissues. Due to persistence of tenofovir and emtricitabine in rectal tissues, levels of PrEP adherence required for protection of HIV acquisition from anal sex are lower than those required for vaginal, front hole or neovaginal sex.

Evaluating the need for PEP involves an assessment of the:

a. site and nature of exposure
b. number and timing of PrEP doses taken in the seven days before the risk exposure
c. correct dosage and timing of on-demand PrEP taken before and after the exposure.

Refer to Table 6 for guidance

Switching from PrEP to PEP is only recommended if:

- The exposure risk warrants 3-drug PEP, AND
- The last exposure event occurred within the 72-hour PEP window, AND
- Adherence to PrEP has been sub-optimal in the 7 days prior to the exposure(s),

Sub-optimal PrEP adherence is:

- Less than 4 doses of PrEP in the last 7 days for anal, penile and oral exposures
- Less than 6 doses of PrEP in the last 7 days for receptive vaginal/neovaginal/front hole sex and sharps/blood exposures

Table 6: Switching from PrEP to PEP

ADHERENCE TO PREP	HIV EXPOSURE WHERE 3-DRUG PEP RECOMMENDED	HIV EXPOSURE WHERE 2-DRUG PEP RECOMMENDED
OPTIMAL ADHERENCE **Daily PrEP:** Has taken PrEP at least 4 days (anal, penile or oral sex) or at least 6 days (receptive vaginal/ neovaginal/front hole sex, sharps/blood exposures) in the 7 days prior to the exposure **On-demand PrEP:** Has taken 2 tablets 2–24 hours pre-exposure and 1 tablet 24- and 48-hours post-exposure	Nil action required. Continue PrEP as usual and provide education that when taken as prescribed, PrEP provides protection against HIV	Nil action required. Continue PrEP as usual and provide education that when taken as prescribed, PrEP provides protection against HIV
SUB-OPTIMAL ADHERENCE **Daily PrEP:** Has taken PrEP less than 4 days (anal, penile or oral sex) or less than 6 days (receptive vaginal/neovaginal/front hole sex, sharps/blood exposures) in the 7 days prior to the exposure **On-demand PrEP:** Exposure occurred less than 2 hours after loading dose, or missed doses at 24 and/or 48 hours post-exposure)	Transition to 3-drug PEP	Take PrEP daily for 28 days post exposure

Transitioning from PEP to PrEP

Many patients who present for PEP have ongoing risk factors for HIV acquisition and so should be recommended to commence PrEP on completion of PEP. Comprehensive information on patient assessment, the prescription of PrEP and follow-up is available in the https://ashm.org.au/resources/australian-prep-guidelines/ HIV PrEP Guidelines.

Briefly:

- PrEP can be prescribed by all medical practitioners and specialised nurse practitioners
- PrEP can be commenced immediately following completion of PEP
- HIV serology and recommended testing as per the Australian HIV PrEP Guidelines should be performed on transition from PEP to PrEP

Renal disease

All patients having PEP should be assessed for renal impairment. Tenofovir disoproxil should not be used if creatinine clearance is less than 60mL/min.[73] In this situation, tenofovir alafenamide (TAF) is an alternative that may be used. Seek specialist advice about prescribing, as this is not available as a generic formulation.

HBV-positive (HBsAg-positive) individuals

- People known to have or who are newly diagnosed with HBV infection on baseline testing can be safely commenced on HIV PEP
- Refer to **ASHM Decision Making in Hepatitis B tool**.
- As soon as possible after chronic HBV is identified, collect additional blood for:
  - HBeAg and anti-HBe
  - HBV DNA (viral load)
  - Full blood count
  - Liver function test (LFT)
- Refer to a clinician experienced in managing HBV as soon as possible (and before completion of the 28-day HIV PEP course) for a decision about treatment discontinuation and follow-up

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 ideally 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.

There is 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%.[87]

Assaults where there is potential risk of HIV acquisition include penile-anal or penile-vaginal penetration, where the person who committed the assault is known or reasonably believed to be from a region with high HIV prevalence or MSM, or where the assailant is known to have HIV and is not on antiretroviral therapy or is viraemic.

For male-to-male sexual assault PEP is always recommended. PEP is generally not recommended following heterosexual sexual assault; however, the decision to prescribe PEP should be made on a case-by-case basis. PEP is recommended where an assailant is from a region with high HIV prevalence.

Concerns have been raised that anogenital or oral injuries from a penile-vaginal sexual assault may further increase the risk of HIV acquisition. Given the very low risk of acquiring HIV from a receptive penile-vaginal assault from a heterosexual source in Australia, any additional increase in risk from anogenital injuries or other co-factors would not raise the risk estimate to that in which PEP would be considered.

Emergency contraception should always be offered for people able to conceive in this situation.

Children

All children and adolescents under 18 years of age presenting with 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. Clinicians should assess Gillick competency in all cases of underage presentations and determine if parents or guardians are required to be contacted. Children who are sexually assaulted should be assessed for the risk of acquiring other STIs and the possibility of pregnancy in children who are 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. Child safety should also be considered. When parental or legal guardian consent is determined necessary but cannot be obtained, 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 and that appropriate clinical support, follow-up, and emotional care are available throughout, particularly when the individual is a child or adolescent. Refer to **ANZPID guidelines** and seek specialist advice.

People incarcerated or working in correctional or detention facilities

People incarcerated or working 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 prevalence in Australian correctional facilities is estimated at below 0.1%[87], although this data is drawn from small and biased samples and should be used carefully. Timely disclosure of exposure is a limiting factor in these circumstances. The provision of assessment and treatment in correctional facilities should be available across all jurisdictions.

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 4. 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 person seeking care and should be carefully explained, and the individual reassured.

Aboriginal and Torres Strait Islander individuals

HIV prevalence is low (0.1%) in the Aboriginal and Torres Strait Islander population.[49] The mode of HIV acquisition differs from non-indigenous Australians, with a higher proportion of indigenous Australians acquiring HIV via heterosexual exposure and injecting drug use.

Provision of culturally safe services for Aboriginal and Torres Strait Islander patients is important in all areas of healthcare, and perhaps even more so for HIV and sexual health-related healthcare. Enquire if the individual has a preference for gender of the clinician conducting the PEP assessment.

Phone Support for Clinicians

Refer to the table below for relevant support on PEP prescribing in your jurisdiction.

REGION	CONTACT INFORMATION
ACT	**Canberra Sexual Health Centre: 02 5124 2184** Mon – Fri 8:30 am – 5 pm **Canberra Afterhours Locum Medical Service: 1300 422 567** Mon-Fri 6 pm – 8:30 am Weekends and Public Holidays, 24 hours
NSW	**NSW PEP hotline: 1800 737 669 (1800 PEP NOW)** 7 days, 24 hours
NT	**Clinic 34 sexual health services at** nt.gov.au Refer to your closest clinic Mon – Fri 8:30am – 4:30pm
QLD	Contact the public health unit closest to you Find your closest public health unit at health.qld.gov.au. Times will vary
SA	**South Australian HIV PEP Hotline: 1800 022 226** 7 days, 24 hours
TAS	**Sexual Health Service Tasmania: 03 6166 2672** Mon – Fri 8:30 am – 5 pm **Health Direct: 1800 022 222** Outside of business hours
VIC	**Victorian NPEP Service Phoneline: 1800 889 887** Mon – Fri 9 am – 5 pm
WA	https://www.health.wa.gov.au/~/media/Corp/Documents/Health-for/Communicable-Diseases/Guidelines/Guideline-for-NPEP-in-WA.pdf Guideline for Non-Occupational Post-Exposure Prophylaxis (NPEP) to Prevent HIV in Western Australia. See Appendix 2 - Page 26

Local information on PEP prescribing may be found on the health department websites in each jurisdiction. For information on PrEP, refer to the ASHM Australian HIV PrEP Guidelines.

Information for Patients

Patient information about PEP is available from HOME - Get PEP
Local AIDS councils and health departments can also provide further information.
Links to AIDS councils are available via Health Equity Matters (HEM - formerly AFAO).
Information on HIV and PEP is contained here in multiple languages.

Appendices

Appendix A: Evidence for three-drug versus two-drug PEP regimens

There is no direct or compelling indirect evidence to support the greater efficacy of three-drug over two-drug regimens; rather, it has been extrapolated from evidence that a higher number of drugs or combination of drug classes have historically achieved better treatment outcomes for HIV. In previous years, three-drug combinations were recommended for the treatment of HIV. However, more recently, dual HIV therapy including an integrase strand transfer inhibitor (INSTI), or a non-nucleoside reverse transcriptase inhibitor (NNRTI) has shown non-inferiority to previously recommended three-drug regimens.[86,87]

A systematic review and meta-analysis of animal PEP studies found no difference in efficacy between single-nucleoside/nucleotide reverse transcriptase inhibitor (NRTI) or INSTI PEP, dual NRTI PEP or triple NRTI and protease inhibitor (PI) PEP, although several of the included studies were not powered to detect a difference.[87]

For neonatal PEP, a large randomised controlled trial found similar reductions in intrapartum HIV transmission for two drugs (zidovudine and nevirapine) and three drugs (zidovudine, lamivudine and nelfinavir), although both multi-drug regimens further reduced intrapartum HIV transmission by 50% over zidovudine given alone.[13]

Appendix B: HIV and body fluids

INFECTIOUS	POTENTIALLY INFECTIOUS	NON-INFECTIOUS*
Blood	Cerebrospinal fluid	Faeces
Semen	Synovial fluid	Urine
Pre-seminal fluid (pre-cum)	Pleural fluid	Saliva
Vaginal secretions	Peritoneal fluid	Sputum
Anal secretions	Pericardial fluid	Nasal secretions
Breastmilk	Amniotic fluid	Gastric secretions
Other body fluids contaminated with visible blood		Vomit
		Sweat
		Tears

* Unless visibly contaminated with blood

Appendix C. Cost of PEP regimens

Table 6: Cost of PEP regimens[a]

REGIMEN	APPROXIMATE COST / 28-DAY COURSE (AUD $)
Tenofovir disoproxil (TD)/emtricitabine (FTC)	40
Tenofovir alafenamide (TAF)/FTC	700
Dolutegravir (DTG)	625
Raltegravir (RTG)	442
TD/FTC plus DTG	665
TD/FTC plus RTG	482
TAF/FTC plus DTG	1325
TAF/FTC plus RTG	1142

[a] costs correct as at 20 Jan 2025

Further information about pricing is available from the Pharmaceutical Benefits Scheme (PBS).

For more information on drug dosing and adverse events, please see
Adverse Effects of ARV Agents - HIV ARV Guidelines

Appendix D: Methods

A multidisciplinary Expert Reference Group (see **Acknowledgements**) was convened by ASHM in March 2022. The updated guideline is based on a comprehensive literature review conducted by a trained librarian from an Expert Reference Group member's Institution (Walter McGrath Library, St Vincent's Hospital, Sydney).

The search included dates from January 2015 to January 2022 and for literature in English. Databases searched were: the Cochrane Library, EMBASE (Ovid) and Medline 1996 - (Ovid). Public search engines such as Google were used to locate documents on the management of HIV exposures nationally and internationally. Keywords searched were 'post-exposure prophylaxis' or 'post exposure prophylaxis' or 'PEP' or 'nPEP' or 'oPEP' or 'occupational exposure and HIV' or 'nonoccupational exposure and HIV'.

The formal review process was further informed by searches of the reference lists from publications of interest; grey literature and citations were also reviewed. The grey literature included: conference presentations, project reports, government reports, policies and strategies, and healthcare organisation publications. PEP guidelines and reference lists from the UK (2021),[88] the US Centers for Disease Control (2016),[89] and the World Health Organisation (2014)[90] were also reviewed.

Final recommendations were developed following meetings and regular email correspondence between Expert Reference Group members on original drafts, comments and recommendations. David Templeton drafted the, *Introduction, Background: evidence supporting the efficacy of PEP in preventing HIV acquisition, Evidence for two-drug versus three-drug PEP regimens, Antiretroviral agents not generally recommended for PEP, Side-effects of recommended PEP medications, Drug-drug interactions with PEP medications, Management of possible exposure to other conditions: Pregnancy and lactation and Adult sexual assault (>16 years of age).* Charlie McLeod, Brendan McMullan and David Templeton drafted *Additional Clinical Management Issues: Children younger than 16 years of age. Anna Pierce drafted Management of possible exposure to other conditions: Hepatitis B and Hepatitis C.* Caroline Thng drafted *Specific clinical situations for PEP: People who re-present for PEP after completion of a PEP course, People who re-present with additional high-risk exposure(s) while taking a PEP course and People who are on PrEP.* Charlotte Bell drafted *Clinical assessment and Specific clinical situations for PEP: People at negligible risk of HIV transmission who request PEP. David Lee drafted Management of possible exposure to other conditions: Sexually transmissible infections*. Donna Tilley drafted *Laboratory testing for HIV PEP recipients, Prescribing PEP, Specific clinical situations for PEP: People at risk of HIV acquisition who decline PEP and People who are transitioning from PEP to PrEP.* John McAllister drafted *Assessment of the risk of HIV transmission and When to Prescribe PEP.* Louise Owen, Sarah Martin and Anna Pierce drafted *Important note for general practitioners who have not previously prescribed HIV PEP.* David Templeton was responsible for checking the accuracy of supporting references and writing the final version of the revised guideline.

In late 2024, after feedback from clinicians, a small working group (Dr Anna Pierce, Dr Louise Owen and Jude Armishaw, nurse practitioner) was convened by ASHM to streamline sections of guidance as part of a minor update to the Third Edition (2023) to improve clinical accuracy and usability which led to the Fourth Edition (2025) and the development of the Decision Making in HIV PEP.

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Footer

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