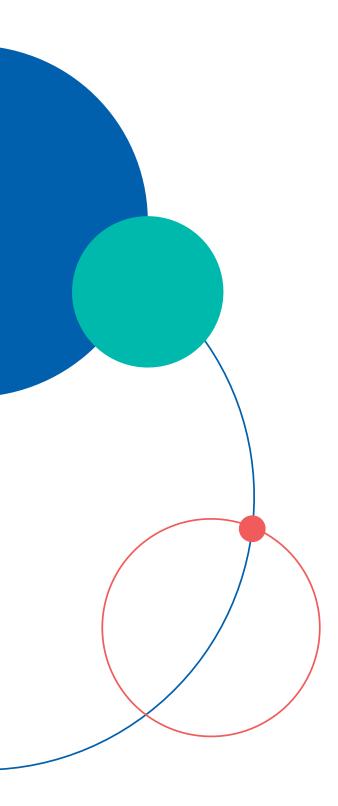


Australian National
Guidelines for PostExposure Prophylaxis (PEP)
after Non-Occupational and
Occupational Exposure to
HIV

(Fourth Edition) 2025



#### **Endorsement**

These guidelines have been endorsed by the Blood Borne Viruses and Sexually Transmitted Infections Standing Committee (BBVSS).

#### **Funding**

The Australian National Guidelines for Post-Exposure Prophylaxis (PEP) after Non-Occupational and Occupational Exposure to HIV are funded by the Australian Government Department of Health, Disability and Ageing.

#### **Disclaimer**

Whilst the Australian Government Department of Health, Disability and Ageing provides financial assistance to ASHM, the material contained in this resource produced by ASHM should not be taken to represent the views of the Australian Department of Health. The content of this resource is the sole responsibility of ASHM.

Last udpated: October 2025

www.ashm.org.au

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

(Fourth Edition) 2025

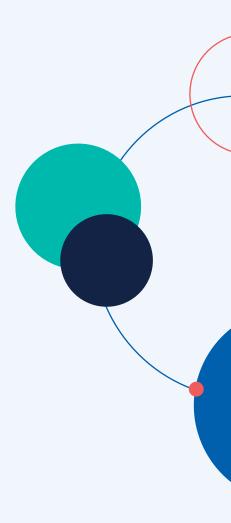
# Acknowledgements

#### **EXPERT REFERENCE GROUP MEMBERS**

MEMBER	REPRESENTING	POSITION
Anna Pierce	Australasian Society for Infectious Diseases	Infectious Diseases Physician, The Alfred Hospital Victoria
Jude Armishaw	VIC HIV Prevention Service	Nurse Practitioner, The Alfred Hospital Victoria
Louise Owen	BBVs and STIs Standing Committee TAS	Sexual Health Physician, Sexual Health Services Tasmania; Director, Tasmanian Statewide Sexual Health Service
Sohileh Aran	The Society of Hospital Pharmacists of Australia	Specialist Clinical Pharmacist, Royal Prince Alfred Hospital
David Baker	ASHM	HIV Clinical Advisor, ASHM;H IV s100 General Practitioner, East Sydney Doctors
Charlotte Bell	SA state-wide Health Directors of Sexual Health	Consultant Sexual Health Physician, Department of Health, SA
Judith Bevan	BBVs and STIs Standing Committee WA	Senior Policy and Planning Officer, Sexual Health & BBVs Program, WA Department of Health
Shawn Clackett	BBVs and STIs Standing Committee NSW	Senior Policy Analyst, HIV and STI Policy Unit, NSW Health
Christine Dykstra	WA state-wide Health Directors of Sexual Health	Sexual Health Consultant, Royal Perth Hospital Sexual Health Clinic
Fellon Gaida	BBVs and STIs Standing Committee ACT	Assistant Director, Sexual Health and BBVs, ACT Health
James Gray	Australasian College for Emergency Medicine	Manager, Policy and Advocacy, Australasian College for Emergency Medicine
Manoji Gunathilake	NT Health	Manager, Policy and Advocacy, Australasian College for Emergency Medicine
Azra Hadzic	Blood Borne Viruses and Sexually Transmissible Infections Standing Committee QLD	Senior Program Officer, Sexually Transmissible Infection and Blood Borne Virus Section, QLD Health
Mihaela Ivan	BBVs and STIs Standing Committee VIC	Senior Medical Advisor, Public Health Division, Department of Health VIC
Andi Kippling (Observer)	Australian Government Department of Health, Disability and Ageing	Assistant Director, BBVs and STIs, and Torres Strait Health Policy Section
David Lee	Australian College of Nurse Practitioners	Nurse Practitioner, Melbourne Sexual Health Centre
Sarah Martin	ACT PEP Providers	Sexual Health Physician, Director, Canberra Sexual Health Centre
John McAllister	NSW NPEP Service	Nurse Practitioner, HIV/Immunology unit, St Vincent's Hospital
Charlie McLeod	Australian and New Zealand Paediatric Infectious Diseases Group (ANZPID)	Infectious Diseases Paediatrician, Perth Children's Hospital, WA; Deputy Director, Wesfarmers Centre of Vaccines and Infectious Diseases
Brendan McMullan	Australian and New Zealand Paediatric Infectious Diseases Group (ANZPID)	Paediatric Infectious Diseases Specialist and Microbiologist, Sydney Children's Hospital, Randwick; Senior Research Fellow, Faculty of Medicine and Health, Discipline of Paediatrics, UNSW
Justin Salerno	Health Equity Matters	Project Officer, Health Equity Matters
Holley Skene	BBVs and STIs Standing Committee SA	Senior Project Officer, STIs and BBVs Section, SA Health
Alexander Rack	Australasian College for Emergency Medicine	Emergency Specialist, RNS and Gosford Hospitals; EHITH Staff Specialist, Royal Prince Alfred Hospital
Nathan Ryder	The Australasian Sexual and Reproductive Health Alliance	Chair of The Australasian Sexual and Reproductive Health Alliance; Clinical Director, Pacific Clinic – Newcastle Sexual Health
David Templeton	NSW Sexual Health Medical Directors Committee	Professor and Head of Department, Sexual Health Medicine and Sexual Assault Medical Service, Community Health, Sydney Local Health District
Caroline Thng	Gold Coast Sexual Health Service, QLD	Sexual Health Staff specialist, Gold Coast Sexual Health Service; Co- chair, QLD Sexual Health Clinical Network
Donna Tilley	The Australasian Sexual Health and HIV Nurses Association	Quality and Service Improvement Coordinator/Nurse Practitioner, Sexual Health and Blood Borne Virus Services, South Eastern Sydney Local Health District
Donna Mak	WA Department of Health	Senior Medical Advisor and Public Health Physician, CDCD, WA Department of Health
Paula Carter	WA Department of Health	A/Principal Policy Officer, CDCD, WA Department of Health
Emma Knowland	The Australasian Sexual Health and HIV Nurses Association	Nurse Practitioner, West Moreton Health
Ben Wilcock	Health Equity Matters	Manager, National Programs, Health Equity Matters
Molly Stannard	ASHM	Senior Project Officer
Carrie Griffith	ASHM	Project Officer
Zoe Sever	ASHM	HIV Program Manager

# **Contents**

Acknowledgements	2
Introduction What's New (2025)	<b>4</b>
Glossary	6
Immediate Management of HIV Exposure	6
PEP Efficacy: Background and Evidence	7
Assessing HIV Transmission Risk	8
What is the HIV transmission risk/exposure?	8
Factors modifying HIV transmission	9
What is the HIV status of the source individual? What is the HIV status of the exposed individual?	10 10
When to prescribe PEP	11
PEP for Non-Occupational Exposure	11
PEP for Occupational Exposure	13
Clinical Assessment and Follow-up	14
Information about the exposure Information about the source person	14 14
Information about the source person	15
Information to provide to patients when initiating PEP	15
Laboratory Assessment and Follow-up	16
Prescribing PEP	18
What to prescribe	19
Recommended PEP regimens	19
Medications and cautions Adverse Events	20 20
Management of Co-Exposures	21
Sexually transmissible infections (STIs)	21
Hepatitis B (HBV)	21
Hepatitis C (HCV)	21
Tetanus	21
Additional Clinical Considerations	22
Pregnancy and breastfeeding	22
Missed PEP doses Individuals at risk of HIV acquisition who decline PEP	22 23
Individuals at negligible risk of HIV transmission who request PEP	23
People who re-present for PEP after completion of a PEP course	23
People who re-present with additional high-risk exposure(s) while taking a PEP course Individuals who are on PrEP	23 24
Transitioning from PEP to PrEP	25
Renal disease	26
HBV-positive (HBsAg-positive) individuals	26
Individuals who have been sexually assaulted Children	26 27
People incarcerated or working in correctional or detention facilities	27
Individuals who commenced PEP overseas	27
Aboriginal and Torres Strait Islander individuals	27
Phone Support for Clinicians	28
Information for Patients	29
Appendices	30
Appendix A: Evidence for three-drug versus two-drug PEP regimens	30
Appendix C: Coct of PEP regimens	30
Appendix C. Cost of PEP regimens Appendix D: Methods	31 32
References	33



# Introduction

This is the fourth edition of the Australian National Guidelines for Post-Exposure Prophylaxis (PEP) after Non-Occupational and Occupational Exposure to HIV. It outlines the management of individuals who have been exposed (or potentially exposed) to human immunodeficiency virus (HIV) in both non-occupational and occupational settings. Risk of transmission, the timing of PEP, baseline assessment, preferred regimen, and follow-up care 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 is no data from randomised controlled trials (RCTs) 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. Therefore, it is important that clinicians are non-judgemental when conducting PEP assessments. Negative experiences when requesting PEP have resulted in failure to re-present for PEP, leading to subsequent HIV acquisition.<sup>1,2</sup>

While it is recommended that PEP is started 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 general practitioners (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 nonoccupational 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 ashm.org.au/resources/decision-making-in-hiv-pep/
- Funded by the Australian Government Department of Health, Disability and Ageing.

This guideline will be reviewed regularly through ASHM, for advice to the Department of Health, Disability and Ageing.

#### A note about source viral load

Although an estimated 87% of all people living with HIV (PLHIV) in Australia have an undetectable viral load (VL), 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.<sup>3,4</sup> Internationally, TGD individuals are often disproportionately affected by HIV.5

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 A.

# **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
СК	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
НРС	High-prevalence country
IAI	Insertive anal intercourse
iPrEx	Pre-Exposure Prophylaxis Initiative
IVI	Insertive vaginal intercourse
LFT	Liver function tests
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 untransmissible	
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. 6,7,8,9,10

Further evidence for the use of PEP has been extrapolated from data on mother-to-child transmission<sup>11,12,13</sup> and following occupational exposures in healthcare workers, 14 where a retrospective case control study demonstrated that PEP users had an 81% reduction in HIV seroconversion compared to those who did not take PEP.15

The only clinical effectiveness study of PEP in humans was performed among 200 Brazilian high-risk, HIVnegative 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.16

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<sup>17</sup> and international<sup>18,19</sup> 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, 18,20 poor adherence to PEP,20,21 and already established HIV infection at the time of PEP initiation.<sup>22</sup>

The rare cases of PEP failure following occupational exposures were mostly reported over two decades ago. 15, <sup>23,24,25</sup> Occupational PEP failures have been described due to resistance mutations in the virus of the source<sup>26</sup> 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.27

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%.<sup>28</sup> However, less tolerable, older PEP regimens, particularly those containing zidovudine,<sup>29,30</sup> have been replaced by bettertolerated 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. 29,31,32

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 3-drug over 2-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. 33,34,35,36 This is now referred to in global health promotion programs as 'undetectable = untransmissible' or U=U.37 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

Х

risk of source having HIV with detectable viral load

# What is the HIV transmission risk/exposure?

Table 1 outlines the estimated risk of HIV transmission per exposure to a source with HIV. While 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 transmissible infections (STIs), breaches in mucosal barriers, and circumcision status (see co-factors related to HIV transmission below). In addition, the considerable genetic heterogeneity between individuals 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**.

Table 1: Estimated risk of HIV transmission by exposure (source with HIV) 26,38,39,40,41,42,43,44,45,46

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 <sup>†</sup>	< 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.<sup>47</sup> 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.

# **Factors modifying HIV transmission**

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:

- · STIs 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
- If the source is contactable and:
  - discloses they have HIV, seek consent to determine recent viral load results and antiretroviral treatment history.
  - o 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 nonadherence of the source
  - o 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 MSM (9.2%).<sup>49</sup> The greatest proportion of people with undiagnosed HIV in Australia is among those born in Southeast Asia and Latin America. Among people who inject drugs (PWID), HIV seroprevalence is 1.5%, although this figure may be significantly higher in those who are also MSM.<sup>49,50</sup>

#### HIV seroprevalence in overseas populations

HIV seroprevalence overseas varies widely. A high prevalence country (HPC) is defined as having an HIV prevalence of more than 1% in the general population. However, HIV seroprevalence varies greatly within countries and sub-populations. Sex industry workers and PWID often have higher HIV seroprevalence than the general population. For those exposed overseas, go to aidsinfo.unaids.org for the most recent seroprevalence estimates.51

# 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:

- 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 a 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 a 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</li>
- 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 3-drug over 2-drug PEP 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 3-drug versus 2-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), 3-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

EXPOSURE	SOURCE HIV STATUS UNKNOWN SOURCE K		NOWN 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 <sup>†</sup>	Not recommended <sup>†</sup>	Not recommended	Not recommended <sup>†</sup>	
Shared injecting equipment	2 drugs	Consider 2 drugs	3 drugs	
Community needle-stick injury	Not recommended	Not applicable	Not applicable	

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

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.

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

<sup>† 2</sup> 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.

### **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 healthcare 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 the data predates effective antiretroviral therapy (ART). There have not been any reports of occupational HIV transmission in the UK since 1999, and only one case has been reported in the USA since 1999. 25,53 This may be due to a number of factors, including changes in practices to reduce the risk of needlestick injuries and a greater proportion of people with living HIV on treatment with an 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)<sup>33-36</sup> 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

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

<sup>\*</sup> Cofactors 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, as well as their intellectual capacity. The following details should be discussed and documented in the patient's history.

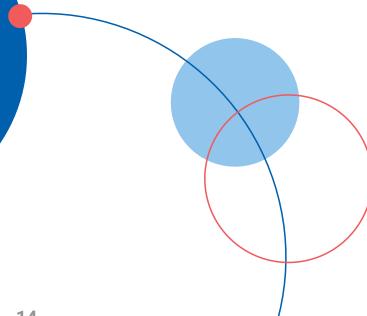
### Information about the exposure

- 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, including gender, sexual identity, and 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 Considerations**)
- 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, including:
  - its indications
  - effectiveness
  - orisks and benefits
  - o potential side effects
  - potential drug interactions
  - o the importance of 100% adherence to dosing
  - o regimen completion and what to do if a dose is missed (see section Additional Clinical Management Considerations).
- 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 service, 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 the 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 <sup>A</sup>	WEEK 12
HIV serology (HIV Ab/Ag)	Х		Х	Х
Hepatitis B serology (HBsAg, Anti-HBs and Anti-HBc) <sup>B</sup>	X			Х
Hepatitis C serology (HCV Ab) <sup>c</sup>	X			Х
STI screen <sup>D</sup>	Х	Х		Х
Syphilis serology <sup>D</sup>	X		X	Х
UEC	Χ <sup>ε</sup>		X	
Pregnancy test <sup>F</sup>	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 6.54
- 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 history.
- E. Seek specialist input for recommendation of alternative PEP drugs if eGFR<60mL/min
- F. If clinically indicated. Consider emergency contraception.

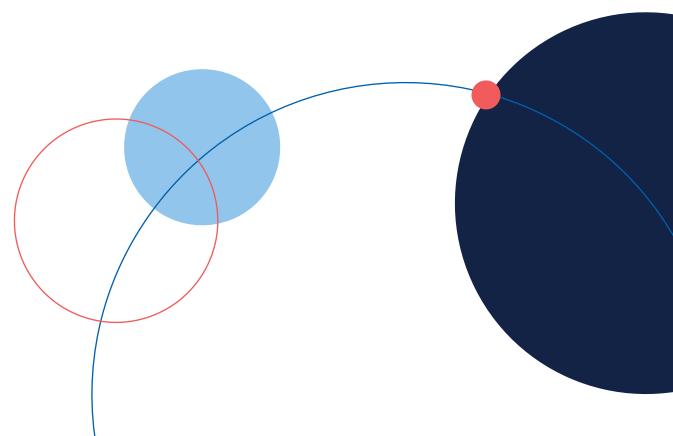
### Follow up of indeterminate HIV test results<sup>55,56</sup>

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

When a baseline HIV Ag/Ab result is positive and confirmatory testing is delayed or indeterminate, the clinician should recall the individual. The following actions should be taken:

- 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).<sup>57</sup>
- Add the recommended third PEP drug to 2-drug PEP regimens to minimise the risk of developing antiretroviral resistance
- Continue 3-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 person that they may be at risk of transmitting HIV and provide information on risk-reduction practices, including condom use and sterile injecting paraphernalia
- Refer to a mental health service 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 Western Blot (WB) tests.58 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.





#### Important note for healthcare workers who have not previously prescribed HIV PEP

Traditionally, the medication used for 2-drug PEP - tenofovir disoproxil 300mg /emtricitabine 200mg (TD/FTC) - was only available from emergency departments, sexual health clinics, HIV specialists, or other accredited HIV s100 prescribers. However, due to the widespread uptake of PrEP, generic formulations of TD/FTC are now also available in many community pharmacies. This makes it possible for any prescriber to provide a private prescription for TD/FTC as 2-drug PEP at a reasonable cost. (At the time of publication, approximately \$40-\$50 for a one-month course). 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 must written.

Please follow the guidelines outlined in this document to assess if your patient fits the recommendation for 2-drug PEP and, if unsure, contact your local PEP telephone support line. If 2-drug PEP is indicated and the individual is considering starting PrEP for likely ongoing HIV exposures, a 3-month prescription for PrEP (TD/FTC 30 tablets with two repeats) can be offered, as PrEP and 2-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 the medication for 28 days and keep the remaining two tablets. This allows for the immediate commencement of PEP should they have a future exposure.

Generic formulations are not currently available for dolutegravir, the current recommended third drug used for PEP. If the individual requires 3-drug PEP, please consult your local PEP phone line for advice on where to access dolutegravir.

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

#### Provide the full course at first presentation

Previously, anecdotal reports suggested potential benefits with the use 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.<sup>29,59</sup>

PEP starter packs for five to seven 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 3-drug PEP is recommended and the third drug is not available, 2-drug PEP 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 2-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.<sup>60</sup> 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 1200mg 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. 21,28,29,31,32,61,62

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	<ul> <li>Use with caution or avoid in renal disease (eGFR &lt;60), consult specialist for alternative (tenofovir alafenamide) if eGFR &lt;60</li> <li>Avoid high doses of non-steroidal anti-inflammatory drugs (NSAIDs) during use.</li> <li>Where tenofovir is directly contraindicated, seek expert advice.</li> </ul>
Dolutegravir	<ul> <li>Phenytoin, phenobarbital, rifampicin, St John's Wort, and carbamazepine all reduce dolutegravir levels. If unable to cease above medications, use raltegravir 1200mg daily</li> <li>If taking antacids containing polyvalent cations (e.g. magnesium or aluminium), take the antacid at least 2 hours before or 6 hours after the dolutegravir dose</li> <li>Products containing calcium or iron should be taken at least 2 hours before or 6 hours after the dolutegravir dose OR dose concomitantly with food</li> <li>If taking metformin, increase monitoring of glycaemic control - an adjustment of metformin dose may be required.</li> </ul>
Raltegravir	<ul> <li>There is a 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</li> <li>Check creatine kinase (CK), renal function, and urinary myoglobin in patients who report myalgia on raltegravir</li> <li>Advise against the use of statins while on PEP containing raltegravir.</li> </ul>

#### **Adverse Events**

Proximal renal tubular dysfunction (including Fanconi syndrome) has been reported among people with HIV on tenofovir disoproxil-containing therapy,63 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. 64,65,66,67 It is advised that:

- · Patients on PEP should be monitored for symptoms
- · Caution should be taken among those with a history of myopathy, or with co-administration with medications such as statins,68 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 transmissible 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 STIs 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 those with 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</li> 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.69 People presenting for PEP who may be at risk of HCV, either from prior risk exposures or from the risk exposure that prompted the presentation for HIV PEP, include:

- people who have shared needles and other injecting paraphernalia<sup>70</sup>
- occupational needle-stick or other sharps injury<sup>69</sup>
- MSM<sup>71</sup>
- people who have been sexually assaulted<sup>72</sup>
- those currently or previously incarcerated. 70

Patients potentially at risk of HCV acquisition require baseline and follow-up testing for HCV (see Table 4).

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.70

Highly effective antiviral treatments are available, and early treatment is recommended if HCV seroconversion is detected.<sup>70</sup> 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.73

- Antiretrovirals recommended for PEP can be safely used by people 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, but, 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:
  - o have a contraceptive and reproductive history taken to assess the 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
  - o have follow-up pregnancy testing 3 to 4 weeks post-exposure, when indicated.

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 Infected Adults and Adolescents with HIV.

#### 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 the varying pharmacokinetic properties of each PEP agent. 63,74,75

#### 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 2-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 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<sup>76</sup>
- 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 who are from countries with high HIV prevalence or where punitive LGBTIQA+ 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 followup 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.<sup>17-19</sup> 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

2-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.77,78 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.79 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.80 Tenofovir levels decline rapidly after cessation in the vagina and neovagina,60,81,82 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 while 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.83

Clinical<sup>84</sup> and pharmacokinetic data<sup>81,85,86</sup> 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.86 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 7 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 two tablets 2–24 hours pre-exposure and one tablet at 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 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.74 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 HBV infection, or those who are newly diagnosed via baseline testing, can be safely commenced on HIV PEP. Refer to the ASHM Decision Making in Hepatitis B tool.

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)
- o 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, if PEP is indicated, it should not be delayed pending referral.

There is no data on HIV prevalence among convicted sexual assailants in Australia. However, studies on HIV point prevalence in Australian correctional services have shown it ranges between 0 to 0.6%, with most jurisdictions reporting below 0.1%.87

Assaults where there is a 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, but 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 to 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

People started on PEP while overseas may have been prescribed antiretroviral drugs that are not recommended in Australia. Frequently, these people have not had all the baseline tests and STI/blood-borne virus (BBV) evaluations recommended in Table 4.

In these cases, the recommended tests should be completed as soon as possible, and the PEP course should be completed using an Australian-recommended PEP regimen. This can cause some anxiety to the person seeking care, and careful explanations and reassurance should be provided.

# **Aboriginal and Torres Strait Islander individuals**

HIV prevalence is low (0.1%) in the Aboriginal and Torres Strait Islander population.<sup>49</sup> 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	<b>NSW PEP hotline: 1800 737 669 (1800 PEP NOW)</b> 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
	PEP Information 13 HEALTH (13 43 25 84) 7 days, 24 hours
SA	South Australian HIV PEP Hotline: 1800 022 226 7 days, 24 hours
TAS	Sexual Health Service Tasmania: 1800 675 859  Mon-Fri 8:30 am-5 pm
	Health Direct: 1800 022 222  Outside of business hours (advise you are calling from Tasmania about PEP)
VIC	Victorian NPEP Service Phoneline: 1800 889 887 Mon-Fri 9 am-5 pm
	PEP Phoneline: 1800 889 887
WA	Guideline for Non-Occupational Post-Exposure Prophylaxis (NPEP) to Prevent HIV in Western Australia.  See Appendix 2 - Page 26
	<b>PEP Line: 1300 767 161</b> 24 hours a day, 7 days a week

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 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 in multiple languages is available from the Multicultural HIV and Hepatitis Service.

# **Appendices**

### **Appendix A: Evidence for 3-drug versus 2-drug PEP regimens**

There is no direct or compelling indirect evidence to support the greater efficacy of 3-drug over 2-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, 3-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 noninferiority to previously recommended 3-drug regimens.<sup>88,89</sup>

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.<sup>77</sup>

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. 12

### 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		Vomit
with visible blood		Sweat
		Tears

<sup>\*</sup> Unless visibly contaminated with blood

# **Appendix C: Cost of PEP regimens**

Table 6: Cost of PEP regimens<sup>a</sup>

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

<sup>&</sup>lt;sup>a</sup> 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),90 the US Centers for Disease Control (2016),91 and the World Health Organisation (2014)<sup>92</sup> 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 Considerations: 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.

# References

- Gianacas C, Down I, Ellard J, et al. Experiences of HIV: The Seroconversion Study Final Report 2007-2015. Monograph, The Kirby Institute, UNSW Australia, Sydney, Australia. (https://www.kirby.unsw.edu.au/sites/default/files/ documents/Experiences-of-HIV-Seroconversion-Study-Final-Report.pdf).
- Palich R, Martin-Blondel G, Cuzin L, et al. Experiences of HIV postexposure prophylaxis (PEP) among highly exposed men who have sex with men (MSM). Sex Transm Infect 2017;93(7):493-498. DOI: 10.1136/ sextrans-2016-052901.
- Callander D, Wiggins J, Rosenberg S, et al. The 2018 Australian Trans and Gender Diverse Sexual Health Survey: Report of Findings. Sydney, NSW: The Kirby Institute, UNSW Sydney. (https://www.kirby.unsw.edu.au/sites/ default/files/documents/ATGD-Sexual-Health-Survey-Report\_2018.pdf).
- Freestone J, Mooney-Somers J, Hudson S. The sector is ready, and the community needs Australian alcohol and other drug treatment services to ask about sexuality and gender identity. Drug Alcohol Rev 2022;41(1):39-42. DOI: 10.1111/dar.13367.
- Costa AB, Viscardi LH, Feijo M, Fontanari AMV. HIV Voluntary Counseling and Testing (VCT-HIV) effectiveness for sexual risk-reduction among key populations: A systematic review and meta-analysis. EClinicalMedicine 2022;52:101612. DOI: 10.1016/j.eclinm.2022.101612.
- Bourry O, Brochard P, Souquiere S, et al. Prevention of vaginal simian immunodeficiency virus transmission in macaques by postexposure prophylaxis with zidovudine, lamivudine and indinavir. AIDS 2009;23(4):447-54. DOI: 10.1097/QAD.0b013e328321302d.
- Irvine C, Egan KJ, Shubber Z, Van Rompay KK, Beanland RL, Ford N. Efficacy of HIV Postexposure Prophylaxis: Systematic Review and Meta-analysis of Nonhuman Primate Studies. Clin Infect Dis 2015;60 Suppl 3:S165-9. DOI: 10.1093/cid/civ069.
- 8 Le Grand R, Vaslin B, Larghero J, et al. Post-exposure prophylaxis with highly active antiretroviral therapy could not protect macaques from infection with SIV/HIV chimera. AIDS 2000;14(12):1864-6. DOI: 10.1097/00002030-200008180-00029.
- Otten RA, Smith DK, Adams DR, et al. Efficacy of postexposure prophylaxis after intravaginal exposure of pigtailed macaques to a human-derived retrovirus (human immunodeficiency virus type 2). J Virol 2000;74(20):9771-5. DOI: 10.1128/jvi.74.20.9771-9775.2000.
- Tsai CC, Emau P, Follis KE, et al. Effectiveness of postinoculation (R)-9-(2-phosphonylmethoxypropyl) adenine treatment for prevention of persistent simian immunodeficiency virus SIVmne infection depends critically on timing of initiation and duration of treatment. J Virol 1998;72(5):4265-73. DOI: 10.1128/JVI.72.5.4265-4273.1998.
- Gray GE, Urban M, Chersich MF, et al. A randomized trial of two postexposure prophylaxis regimens to reduce mother-to-child HIV-1 transmission in infants of untreated mothers. AIDS 2005;19(12):1289-97. DOI: 10.1097/01. aids.0000180100.42770.a7.
- Nielsen-Saines K, Watts DH, Veloso VG, et al. Three postpartum antiretroviral regimens to prevent intrapartum HIV infection. N Engl J Med 2012;366(25):2368-79. DOI: 10.1056/NEJMoa1108275.
- Wade NA, Birkhead GS, Warren BL, et al. Abbreviated regimens of zidovudine prophylaxis and perinatal transmission of the human immunodeficiency virus. N Engl J Med 1998;339(20):1409-14. DOI: 10.1056/ NEJM199811123392001
- Tomkins S, Ncube F. Occupationally acquired HIV: international reports to December 2002. Euro Surveill 2005;10(3):E050310 2. DOI: 10.2807/esw.10.10.02660-en.
- 15 Cardo DM, Culver DH, Ciesielski CA, et al. A case-control study of HIV seroconversion in health care workers after percutaneous exposure. Centers for Disease Control and Prevention Needlestick Surveillance Group. N Engl J Med 1997;337(21):1485-90. DOI: 10.1056/NEJM199711203372101.
- Schechter M, do Lago RF, Mendelsohn AB, et al. Behavioral impact, acceptability, and HIV incidence among homosexual men with access to postexposure chemoprophylaxis for HIV. J Acquir Immune Defic Syndr 2004;35(5):519-25. DOI: 10.1097/00126334-200404150-00010.
- Poynten IM, Jin F, Mao L, et al. Nonoccupational postexposure prophylaxis, subsequent risk behaviour and HIV incidence in a cohort of Australian homosexual men. AIDS 2009;23(9):1119-26. DOI: 10.1097/QAD.0b013e32832c1776.
- Beymer MR, Kofron RM, Tseng CH, et al. Results from the post-exposure prophylaxis pilot program (P-QUAD) demonstration project in Los Angeles County. Int J STD AIDS 2018;29(6):557-562. DOI: 10.1177/0956462417743158.
- Mitchell H, Furegato M, Hughes G, Field N, Nardone A. What are the characteristics of, and clinical outcomes in men who have sex with men prescribed HIV postexposure prophylaxis following sexual exposure (PEPSE) at sexual health clinics in England? Sex Transm Infect 2017;93(3):207-213. DOI: 10.1136/sextrans-2016-052806.

- 20 Roland ME, Neilands TB, Krone MR, et al. Seroconversion following nonoccupational postexposure prophylaxis against HIV. Clin Infect Dis 2005;41(10):1507-13. DOI: 10.1086/497268.
- 21 Mayer KH, Mimiaga MJ, Cohen D, et al. Tenofovir DF plus lamivudine or emtricitabine for nonoccupational postexposure prophylaxis (NPEP) in a Boston Community Health Center. J Acquir Immune Defic Syndr 2008;47(4):494-9. DOI: 10.1097/QAI.0b013e318162afcb.
- Johnson KA, Chen MJ, Kohn R, et al. Acute HIV at the Time of Initiation of Pre-exposure or Post-exposure Prophylaxis: Impact on Drug Resistance and Clinical Outcomes. J Acquir Immune Defic Syndr 2021;87(2):818-825. DOI: 10.1097/QAI.0000000000002638.
- Do AN, Ciesielski CA, Metler RP, Hammett TA, Li J, Fleming PL. Occupationally acquired human immunodeficiency virus (HIV) infection: national case surveillance data during 20 years of the HIV epidemic in the United States. Infect Control Hosp Epidemiol 2003;24(2):86-96. DOI: 10.1086/502178.
- Hawkins DA, Asboe D, Barlow K, Evans B. Seroconversion to HIV-1 following a needlestick injury despite combination post-exposure prophylaxis. J Infect 2001;43(1):12-5. DOI: 10.1053/jinf.2001.0811.
- Woode OM, Wellington E, Rice B, Gill ON, Ncube F, contributers a. Eye of the Needle United Kingdom Surveillance of Significant Occupational Exposures to Bloodborne Viruses in Healthcare Workers: data to end 2013. December 2014. Public Health England, London. (https://assets.publishing.service.gov.uk/media/5a7ee6c1e5274a2e87db29f4/EoN\_2014\_-\_FINAL\_CT\_3\_sig\_occ.pdf).
- Beltrami EM, Luo CC, de la Torre N, Cardo DM. Transmission of drug-resistant HIV after an occupational exposure despite postexposure prophylaxis with a combination drug regimen. Infect Control Hosp Epidemiol 2002;23(6):345-8. DOI: 10.1086/502065.
- Kijak GH, Kim JH. Timing, adherence, resistance, and ... persistence? new insight into the mechanisms of failure of HIV type 1 postexposure prophylaxis. J Infect Dis 2013;208(10):1542-4. DOI: 10.1093/infdis/jit486.
- Jain S, Mayer KH. Practical guidance for nonoccupational postexposure prophylaxis to prevent HIV infection: an editorial review. AIDS 2014;28(11):1545-54. DOI: 10.1097/QAD.00000000000301.
- Ford N, Shubber Z, Calmy A, et al. Choice of antiretroviral drugs for postexposure prophylaxis for adults and adolescents: a systematic review. Clin Infect Dis 2015;60 Suppl 3:S170-6. DOI: 10.1093/cid/civ/092.
- Parkin JM, Murphy M, Anderson J, El-Gadi S, Forster G, Pinching AJ. Tolerability and side-effects of post-exposure prophylaxis for HIV infection. Lancet 2000;355(9205):722-3. DOI: 10.1016/s0140-6736(99)05005-9.
- Mayer KH, Mimiaga MJ, Gelman M, Grasso C. Raltegravir, tenofovir DF, and emtricitabine for postexposure prophylaxis to prevent the sexual transmission of HIV: safety, tolerability, and adherence. J Acquir Immune Defic Syndr 2012;59(4):354-9. DOI: 10.1097/QAI.0b013e31824a03b8.
- McAllister J, Read P, McNulty A, Tong WW, Ingersoll A, Carr A. Raltegravir-emtricitabine-tenofovir as HIV nonoccupational post-exposure prophylaxis in men who have sex with men: safety, tolerability and adherence. HIV Med 2014;15(1):13-22. DOI: 10.1111/hiv.12075.
- Bavinton BR, Pinto AN, Phanuphak N, et al. Viral suppression and HIV transmission in serodiscordant male couples: an international, prospective, observational, cohort study. Lancet HIV 2018;5(8):e438-e447. DOI: 10.1016/S2352-3018(18)30132-2
- Cohen MS, Chen YQ, McCauley M, et al. Antiretroviral Therapy for the Prevention of HIV-1 Transmission. N Engl J Med 2016;375(9):830-9. DOI: 10.1056/NEJMoa1600693.
- Rodger AJ, Cambiano V, Bruun T, et al. Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study. Lancet 2019;393(10189):2428-2438. DOI: 10.1016/S0140-6736(19)30418-0.
- Rodger AJ, Cambiano V, Bruun T, et al. Sexual Activity Without Condoms and Risk of HIV Transmission in Serodifferent Couples When the HIV-Positive Partner Is Using Suppressive Antiretroviral Therapy. JAMA 2016;316(2):171-81. DOI: 10.1001/jama.2016.5148.
- 37 Prevention Access Campaign. Risk of sexual transmission of HIV from a person living with HIV who has an undectable viral load messaging primer and consensus statement. (https://preventionaccess.org/wp-content/uploads/2021/07/UU-Consensus-Statement.pdf).
- Baggaley RF, Owen BN, Silhol R, et al. Does per-act HIV-1 transmission risk through anal sex vary by gender? An updated systematic review and meta-analysis. Am J Reprod Immunol 2018;80(5):e13039. DOI: 10.1111/aji.13039.
- 39 Boily MC, Baggaley RF, Wang L, et al. Heterosexual risk of HIV-1 infection per sexual act: systematic review

and meta-analysis of observational studies. Lancet Infect Dis 2009;9(2):118-29. DOI: 10.1016/S1473-3099(09)70021-0.

- 40 Cresswell FV, Ellis J, Hartley J, Sabin CA, Orkin C, Churchill DR. A systematic review of risk of HIV transmission through biting or spitting: implications for policy. HIV Med 2018;19(8):532-40. DOI: 10.1111/hiv.12625.
- del Romero J, Marincovich B, Castilla J, et al. Evaluating the risk of HIV transmission through unprotected orogenital sex. AIDS 2002;16(9):1296-7. DOI: 10.1097/00002030-200206140-00017.
- 42 Ippolito G, Puro V, De Carli G. The risk of occupational human immunodeficiency virus infection in health care workers. Italian Multicenter Study. The Italian Study Group on Occupational Risk of HIV infection. Arch Intern Med 1993;153(12):1451-8. (https://www.ncbi.nlm.nih.gov/pubmed/8512436).
- Jin F, Jansson J, Law M, et al. Per-contact probability of HIV transmission in homosexual men in Sydney in the era of HAART. AIDS 2010;24(6):907-13. DOI: 10.1097/QAD.0b013e3283372d90.
- Peterman TA, Stoneburner RL, Allen JR, Jaffe HW, Curran JW. Risk of human immunodeficiency virus transmission from heterosexual adults with transfusion-associated infections. JAMA 1988;259(1):55-8. (https://www.ncbi.nlm.nih.gov/pubmed/3334772).
- Richman KM, Rickman LS. The potential for transmission of human immunodeficiency virus through human bites. J Acquir Immune Defic Syndr (1988) 1993;6(4):402-6. (https://www.ncbi.nlm.nih.gov/pubmed/8455145).
- Rothenberg RB, Scarlett M, del Rio C, Reznik D, O'Daniels C. Oral transmission of HIV. AIDS 1998;12(16):2095-105. DOI: 10.1097/00002030-199816000-00004.
- Webb R. Needlestick injuries, discarded needles and the risk of HIV transmission. A research briefing. aidsmap June 2019. (https://www.aidsmap.com/about-hiv/needlestick-injuries-discarded-needles-and-risk-hiv-transmission).
- Baggaley RF, White RG, Boily MC. HIV transmission risk through anal intercourse: systematic review, metaanalysis and implications for HIV prevention. Int J Epidemiol 2010;39(4):1048-63. DOI: 10.1093/ije/dyq057.
- 49 Health Equity Matters. HIV in Australia 2023. (https://assets.healthequitymatters.org.au/wp-content/uploads/2022/11/16053027/hiv-in-australia-2023.pdf).
- King J, Kwon J, McManus H, Gray R, McGregor S. HIV, viral hepatitis and sexually transmissible infections in Australia: Annual surveillance report 2024, The Kirby Institute, UNSW Sydney, Sydney, Australia. The Kirby Institute, UNSW Sydney. (https://www.kirby.unsw.edu.au/sites/default/files/documents/Annual-Surveillance-Report-2024\_HIV\_0.pdf).
- 51 UNAIDS. AIDSinfo. Global data on HIV epidemiology and response. (https://aidsinfo.unaids.org/).
- 52
- 53 Centres for Disease Control and Prevention. HIV and Occupational Exposure. (https://www.cdc.gov/hiv/workplace/healthcareworkers.html).
- Williams E, Moso M, Lim C, et al. Laboratory diagnosis of HIV: a contemporary overview in the Australian context. Pathology 2023;55(5):610-620. DOI: 10.1016/j.pathol.2023.04.001.
- 55 (WHO) World Health Organisation. Delivering HIV Test Results and Messages for Re-Testing and Counselling in Adults. WHO.
- 56 Smith DK, Switzer WM, Peters P, et al. A Strategy for PrEP Clinicians to Manage Ambiguous HIV Test Results During Follow-up Visits. Open Forum Infect Dis 2018;5(8):ofy180. DOI: 10.1093/ofid/ofy180.
- 57 Daar ES, Pilcher CD, Hecht FM. Clinical presentation and diagnosis of primary HIV-1 infection. Curr Opin HIV AIDS 2008;3(1):10-5. DOI: 10.1097/COH.0b013e3282f2e295.
- de Souza MS, Pinyakorn S, Akapirat S, et al. Initiation of Antiretroviral Therapy During Acute HIV-1 Infection Leads to a High Rate of Nonreactive HIV Serology. Clin Infect Dis 2016;63(4):555-61. DOI: 10.1093/cid/ciw365.
- Ford N, Venter F, Irvine C, Beanland RL, Shubber Z. Starter packs versus full prescription of antiretroviral drugs for postexposure prophylaxis: a systematic review. Clin Infect Dis 2015;60 Suppl 3:S182-6. DOI: 10.1093/cid/civ093.
- Patterson KB, Prince HA, Kraft E, et al. Penetration of tenofovir and emtricitabine in mucosal tissues: implications for prevention of HIV-1 transmission. Sci Transl Med 2011;3(112):112re4. DOI: 10.1126/scitranslmed.3003174.
- 61 McAllister JW, Towns JM, McNulty A, et al. Dolutegravir with tenofovir disoproxil fumarate-emtricitabine as HIV postexposure prophylaxis in gay and bisexual men. AIDS 2017;31(9):1291-1295. DOI: 10.1097/

#### QAD.000000000001447.

- Mulka L, Annandale D, Richardson C, Fisher M, Richardson D. Raltegravir-based HIV postexposure prophylaxis (PEP) in a real-life clinical setting: fewer drug-drug interactions (DDIs) with improved adherence and tolerability. Sex Transm Infect 2016;92(2):107. DOI: 10.1136/sextrans-2015-052262.
- 63 Hughes C. Renal adverse drug reactions. Curr Opin HIV AIDS 2021;16(6):303-308. DOI: 10.1097/COH.0000000000000703.
- 64 (TGA) Therapeutic Goods Administration. Australian product information for TIVICAY (dolutegravir) film-coated tablets and TIVICAY PD (dolutegravir) dispersible tablets (https://www.tga.gov.au/sites/default/files/2022-08/auspar-tivicay-tivicay-pd-220705-pi.pdf).
- $(TGA)\ The rapeutic\ Goods\ Administration.\ Australian\ product\ information\ for\ ISENTRESS\ and\ ISENTRESS\ HD\ (raltegravir\ potassium)\ tablets.\ (https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-PI-03893-3&d=20250107172310101).$
- Saad M, Casado-Castillo F, Kelly P. Case report of Triumeq (abacavir/dolutegravir/lamivudine) associated rhabdomyolysis in a human immunodeficiency virus (HIV) infected patient. Medicine (Baltimore) 2019;98(17):e15149. DOI: 10.1097/MD.000000000015149.
- Tsai WJ, Lee SS, Tsai HC, et al. Rapid onset of rhabdomyolysis after switching to a raltegravir-based antiretroviral regimen. J Microbiol Immunol Infect 2016;49(2):286-8. DOI: 10.1016/j.jmii.2013.02.008
- Attardo S, Musumeci O, Velardo D, Toscano A. Statins Neuromuscular Adverse Effects. Int J Mol Sci 2022;23(15). DOI: 10.3390/ijms23158364.
- Moorman AC, de Perio MA, Goldschmidt R, et al. Testing and Clinical Management of Health Care Personnel Potentially Exposed to Hepatitis C Virus CDC Guidance, United States, 2020. MMWR Recomm Rep 2020;69(6):1-8. DOI: 10.15585/mmwr.rr6906a1.
- 70 Spearman CW, Dusheiko GM, Hellard M, Sonderup M. Hepatitis C. Lancet 2019;394(10207):1451-1466. DOI: 10.1016/S0140-6736(19)32320-7.
- Lockart I, Matthews GV, Danta M. Sexually transmitted hepatitis C infection: the evolving epidemic in HIV-positive and HIV-negative MSM. Curr Opin Infect Dis 2019;32(1):31-37. DOI: 10.1097/QCO.000000000000515.
- Ward E, Carlisle N, Williams E, Heath SL, Meloun K, Walter LA. Prevalence of hepatitis C in sexual assault survivors presenting to a SANE clinic: A descriptive analysis. J Viral Hepat 2022;29(6):487-492. DOI: 10.1111/jvh.13675.
- 73 Thomson KA, Hughes J, Baeten JM, et al. Increased Risk of HIV Acquisition Among Women Throughout Pregnancy and During the Postpartum Period: A Prospective Per-Coital-Act Analysis Among Women With HIV-Infected Partners. J Infect Dis 2018;218(1):16-25. DOI: 10.1093/infdis/jiy113.
- 74 (TGA) Therapeutic Goods Administration. Australian product information for Truvada® (tenofovir disoproxil fumarate and emtricitabine) tablets. (https://www.tga.gov.au/sites/default/files/auspar-tenofovir-disoproxil-fumarate-161110-pi.pdf).
- 75 Krishna R, Rizk ML, Larson P, Schulz V, Kesisoglou F, Pop R. Single- and Multiple-Dose Pharmacokinetics of Once-Daily Formulations of Raltegravir. Clin Pharmacol Drug Dev 2018;7(2):196-206. DOI: 10.1002/cpdd.358.
- Tindall B, Barker S, Donovan B, et al. Characterization of the acute clinical illness associated with human immunodeficiency virus infection. Arch Intern Med 1988;148(4):945-9. (https://www.ncbi.nlm.nih.gov/pubmed/3258508).
- 77 Grulich AE, Bavinton BR. Scaling up preexposure prophylaxis to maximize HIV prevention impact. Curr Opin HIV AIDS 2022;17(4):173-178. DOI: 10.1097/COH.000000000000739.
- Grulich AE, Jin F, Bavinton BR, et al. Long-term protection from HIV infection with oral HIV pre-exposure prophylaxis in gay and bisexual men: findings from the expanded and extended EPIC-NSW prospective implementation study. Lancet HIV 2021;8(8):e486-e494. DOI: 10.1016/S2352-3018(21)00074-6.
- Molina JM, Ghosn J, Assoumou L, et al. Daily and on-demand HIV pre-exposure prophylaxis with emtricitabine and tenofovir disoproxil (ANRS PREVENIR): a prospective observational cohort study. Lancet HIV 2022;9(8):e554-e562. DOI: 10.1016/S2352-3018(22)00133-3.
- Deutsch MB, Glidden DV, Sevelius J, et al. HIV pre-exposure prophylaxis in transgender women: a subgroup analysis of the iPrEx trial. Lancet HIV 2015;2(12):e512-9. DOI: 10.1016/S2352-3018(15)00206-4.
- Cottrell ML, Yang KH, Prince HM, et al. A Translational Pharmacology Approach to Predicting Outcomes of Preexposure Prophylaxis Against HIV in Men and Women Using Tenofovir Disoproxil Fumarate With or Without Emtricitabine. J Infect Dis 2016;214(1):55-64. DOI: 10.1093/infdis/jiw077.

- Louissaint NA, Cao YJ, Skipper PL, et al. Single dose pharmacokinetics of oral tenofovir in plasma, peripheral blood mononuclear cells, colonic tissue, and vaginal tissue. AIDS Res Hum Retroviruses 2013;29(11):1443-50. DOI: 10.1089/aid.2013.0044.
- McCormack S, Dunn DT, Desai M, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial. Lancet 2016;387(10013):53-60. DOI: 10.1016/S0140-6736(15)00056-2.
- Molina JM, Capitant C, Spire B, et al. On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-1 Infection. N Engl J Med 2015;373(23):2237-46. DOI: 10.1056/NEJMoa1506273.
- Anderson PL, Glidden DV, Liu A, et al. Emtricitabine-tenofovir concentrations and pre-exposure prophylaxis efficacy in men who have sex with men. Sci Transl Med 2012;4(151):151ra125. DOI: 10.1126/scitranslmed.3004006.
- Hendrix CW, Andrade A, Bumpus NN, et al. Dose Frequency Ranging Pharmacokinetic Study of Tenofovir-Emtricitabine After Directly Observed Dosing in Healthy Volunteers to Establish Adherence Benchmarks (HPTN 066). AIDS Res Hum Retroviruses 2016;32(1):32-43. DOI: 10.1089/AID.2015.0182.
- 87 Simpson PL, Gardoll B, White L, Butler T. HIV policies in Australian prisons: a structured review assessing compliance with international guidelines. Lancet Reg Health West Pac 2023;41:100813. DOI: 10.1016/j. lanwpc.2023.100813.
- Cahn P, Madero JS, Arribas JR, et al. Dolutegravir plus lamivudine versus dolutegravir plus tenofovir disoproxil fumarate and emtricitabine in antiretroviral-naive adults with HIV-1 infection (GEMINI-1 and GEMINI-2): week 48 results from two multicentre, double-blind, randomised, non-inferiority, phase 3 trials. Lancet 2019;393(10167):143-155. DOI: 10.1016/S0140-6736(18)32462-0.
- 89 Llibre JM, Hung CC, Brinson C, et al. Efficacy, safety, and tolerability of dolutegravir-rilpivirine for the maintenance of virological suppression in adults with HIV-1: phase 3, randomised, non-inferiority SWORD-1 and SWORD-2 studies. Lancet 2018;391(10123):839-849. DOI: 10.1016/S0140-6736(17)33095-7.
- 90 (BASHH) British Association for Sexual Health and HIV . UK guideline for the use of HIV post exposure prophylaxis 2021. (https://bhiva.org/wp-content/uploads/2024/10/PEP-guidelines.pdf).
- Dominguez KL, Smith DK, Thomas V, et al. Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016. (https://stacks.cdc.gov/view/cdc/38856).
- (WHO) World Health Organisation. Guidelines on post-exposure prophylaxis for HIV-related infections among adults, adolescents and children: recommendations for a public health approach: December 2014 supplement to the 2013 consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. (https://iris.who.int/bitstream/handle/10665/145719/9789241508193\_eng.pdf?sequence=1).

