Queensland Health

Initiating post-exposure prophylaxis after non-occupational and occupational exposure to HIV

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Queensland Government

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An electronic version of this document is available at https://www.health.qld.gov.au/system-governance/policies-standards/guidelines

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1 Statement

Queensland Health is working towards the virtual elimination of new Human immunodeficiency virus (HIV) transmissions, including an evidence-based approach to accessing HIV medication as a preventive measure.

2 Purpose

The *Initiating post-exposure prophylaxis after non-occupational and occupational exposure to HIV Guideline* (Queensland Guideline) provides direction for prescribing post-exposure prophylaxis (PEP) following incidents involving potential exposure to HIV infection in either occupational or non-occupational contexts.

3 Scope

This guideline is intended to guide PEP initiation and should be read in conjunction with the *Post Exposure Prophylaxis after non-occupational and occupational exposure to HIV: Australian National Guidelines (Third Edition)* (National PEP Guideline) that outlines a complete PEP management plan, including baseline testing and follow up.

The Queensland Guideline applies to all prescribers in Queensland and is not intended to be prescriptive or replace specialist advice in the provision of post-exposure prophylaxis (PEP). Each presentation for PEP should be assessed on a case-by-case basis.

Compliance with this guideline is not mandatory, but sound reasoning should exist for departing from the recommended principles.

4 National PEP risk assessment and recommendations

The National PEP Guideline states the risk of HIV transmission through a single exposure is determined by:

- the nature of exposure with its estimated risk per exposure (Table 1)
- if the source is known to be HIV positive and viraemic (Table 2)
- the risk the source is HIV positive and viraemic if their status is unknown (Table 2) **Note:** For information on estimated HIV acquisition risk if source is viraemic by population group, see Appendix A in the National guidelines
- additional factors which likely or potentially increase the risk of HIV transmission (outlined in footnotes of Table 2).

The decision to initiate PEP should be based upon a risk/benefit analysis weighing up the risk of acquiring HIV and the potential for harm due to PEP.

Table 1 Estimated risk of transmission by exposure

Exposure	Risk
Receptive anal intercourse (RAI) • With ejaculate • With withdrawal	 1:70 1:155
Insertive anal intercourse (IAI) • Index uncircumcised • Index circumcised	 1:160 1:900
Receptive vaginal intercourse (RVI)	1:1250
Insertive vaginal intercourse (IVI)	1:2500
Fellatio	Negligible
Cunnilingus	Negligible
Mucous membrane/non intact skin	1:1000
Intact skin exposure	Negligible
Human bite	Negligible
Shared injecting equipment	1:125
Occupational needle stick injury	1:440
Community needle stick injury from a discarded needle	Negligible*
Blood transfusion	1:1

*Worldwide, there have been no reported cases of HIV acquisition from a discarded needle in a public place. Rare transmission of HBV and HCV have occurred in this situation, so these infections need to be considered.
NOTE: These figures are estimates derived from cohort and modelling studies, where HIV status, treatment status and HIV viral load of source or sexual partners were either self-reported or unknown. All sexual risk estimations are for condomless sexual contact. It is assumed a similar risk is incurred when the condom fails.

Source: Post-Exposure Prophylaxis after non-occupational and occupational exposure to HIV; Australian National Guidelines (Third Edition).

The HIV status of the source individual is key to determining the risk of acquisition for the person exposed, and whether PEP is indicated. If it is not possible to determine the HIV status and treatment history of the source individual, assumptions about their HIV risk must be made based on demographic characteristics.

When a source individual is known to have HIV, knowledge of their treatment status, last viral load (VL) and history of any antiretroviral resistance can be useful in determining whether PEP is indicated and whether a non-standard PEP regimen is required due to previous detection or suspicion of antiretroviral resistance mutations. When this information is unavailable or the source is not contactable, the guidance for specific exposures in Table 2 under *Source of unknown HIV status* should be followed.

In non-occupational exposure where the source status is unknown, ideally an attempt should be made to contact the source to request an urgent HIV test. This procedure should not delay the commencement of PEP and, again, recommendations for *Source of unknown HIV status* outlined in Table 2 should be followed.

Provision of PEP should not be delayed while establishing the source HIV status. Informed consent should be sought from the source when performing an HIV test. It is important to note the sensitivity of gathering information on an individual's HIV status and ensure the source individual's privacy and confidentiality.

If the source is contactable and

- discloses they are HIV positive:
  - consent should be requested to seek further information from their treating physician
  - information requested should include source treatment status, last HIV viral load and history and suspicion of any antiretroviral resistance
- is HIV negative and confirmed to be taking HIV PrEP as prescribed:
  - PEP is not indicated
- chooses not to disclose their HIV status or have an HIV test:
  - PEP should be considered based on the risk exposure outlined in Table 2 under *Source of unknown HIV status.*

Table 2 Recommendations for PEP

NOTE: PEP is not recommended for any exposure when source is from a low prevalence population* or where source is taking HIV pre-exposure prophylaxis (PrEP).

	Source[1] known HIV positive (refer to National Guideline)		Source[1] of unknown HIV status (refer to National Guideline)	
	HIV VL unknown or detectable	HIV VL undetectable	**Very high** prevalence population[2] (MSM who share injecting equipment	**High** prevalence population[2] (MSM or from HPC)
Sexual exposure[3,4]				
Receptive anal sex	3-drug	NR	3-drug	2-drug
Insertive anal sex (uncircumcised)	3-drug	NR	3-drug	2-drug
Insertive anal sex (circumcised)	3-drug	NR	3-drug	NR
Receptive vaginal sex	3-drug	NR	N/A	NR
Insertive vaginal sex	3-drug	NR	3-drug	NR
Fellatio	NR#	NR	NR#	NR#
Cunnilingus	NR	NR	NR	NR
Semen splashed into eye	NR	NR	NR	NR
Occupational and other exposures[5]				
Shared injecting equipment	3-drug	Consider 2-drug	3-drug	2-drug
Occupational needle-stick injury	3-drug	Consider 2-drug	3-drug	NR
Mucosal exposure/splash injury to infectious fluids	3-drug	NR	3-drug	NR
Human bite[6]	NR	NR	NR	NR
Community needle-stick injury	NR	NR	NR	NR

* a low prevalence population is defined as a population or specific subgroup of the population with an HIV prevalence below 1% (e.g., men other than MSM, general population of Australia who do not inject drugs.

consider 2-drug PEP only where receptive fellatio WITH ejaculation AND significant visible oral mucosal trauma, or dental and gum disease.

[1] The person whose blood or other bodily substance may be a source of HIV exposure.

[2] Very high and high prevalence populations are those with a significant likelihood the source is HIV positive and may be viraemic. In Australia, this is principally MSM who inject drugs, MSM who do not inject drugs, people who inject drugs from high-risk countries especially from Central Asia and Eastern Europe and migrants from areas of high prevalence, particularly sub-Saharan Africa.

[3] Sexual exposure assumes no condom use or condom failure. Sexual exposures also include those in female and male sex work in Australia. Rates of HIV infection and viraemia in these people are similar to the populations they belong to. **NOTE:** The rates of HIV infection and viraemia in female sex workers in other parts of the world (for example Southeast Asia) may be significantly higher, and PEP may be considered.

[4] Co-factors that may influence decision-making following sexual exposures: (a) breaches in the mucosal barrier such as genital ulcer disease and anal or vaginal trauma following sexual assault or first intercourse; (b) multiple episodes of exposure within a short period of time e.g., group sex; (c) a sexually transmissible infection (STI) in either partner.

[5] Co-factors that may influence decision-making following occupational exposures: (a) deep trauma; (b) bolus of blood injected.

[6] PEP should only be considered after a bite if: (a) the biter's saliva or mouth had visible blood, AND (b) there was a high suspicion that the biter was viraemic and not on treatment, AND (c) the bite has resulted in severe, deep, or multiple tissue injuries.

NOTE: All children younger than 16 years who qualify for HIV PEP are recommended to receive combination therapy with 3 drugs.

Definitions

3-drug: 3-drug PEP recommended

2-drug: 2-drug PEP recommended

Consider 2-drug PEP: the benefits of PEP are less clear and should be balanced against the risks, including consideration of co-factors (see footnote of Table 1) which may increase risk of HIV acquisition.

NR: PEP not recommended

HPC: high prevalence country (defined as population prevalence above 1%)

MSM: men who have sex with men

VL: HIV viral load

Source: Adapted from Post-Exposure Prophylaxis after non-occupational and occupational exposure to HIV; Australian National Guidelines (Third Edition).

5 Prescribing PEP in Queensland

5.1 Starter packs

Anti-retroviral treatment administered within 72 hours after exposure may reduce the risk of acquiring HIV infection. PEP should be initiated as soon as possible and started no later than 72 hours after the exposure, ideally within 24 hours. Due to the urgency of initiating treatment, some of these treatments are prescribed in the emergency department by a non-HIV specialist. Therefore, PEP starter packs may be used to facilitate rapid initiation of PEP until a visit to an HIV specialist can occur.

Queensland prescribers are encouraged to consider the primary purpose of the starter pack – to promote early access in multiple sites, provide follow-up care and opportunities to modify poorly tolerated regimens.

The National PEP Guideline recommends a 28-day course of anti-retroviral therapy (ART) within 72 hours of exposure to HIV, following evidence toward improved completion rates for people prescribed the 28-day course at initiation. Hence, when initiating PEP, prescribers are encouraged to seek advice from a HIV specialist (e.g. on call ID clinicians or Sexual Health services if available) so a full 28-day course may be provided at initiation.

Three to six day starter packs are recommended when a full 28-day course cannot be provided at the initial consultation. A longer term starter pack may be provided at the discretion of the clinician.

If 3–6 day starter packs are provided, it is important to:

- organise referral for follow up and continuation of PEP
- ensure sufficient PEP has been dispensed to support adherence until follow up appointment
- emphasise a complete 28-day course of PEP is required to achieve effectiveness and that follow up is necessary.

The potential benefits of providing PEP 3–6 day starter packs include:

- facilitating rapid initiation of PEP by non-HIV specialists
- PEP requests over a weekend can be met with immediate provision
- the opportunity to modify poorly tolerated PEP regimens at a subsequent visit
- when a 28-day script is not clinically indicated (negligible risk), the patient may return for 28-day script if suspected exposure or high-risk source is confirmed
- reduction in drug wastage if, upon review by a HIV specialist, PEP is no longer required.

5.2 Recommended PEP regimens

The recommended first-line 2-drug regimen for Queensland Health Services is co-formulated tenofovir disoproxil and emtricitabine. Please refer to Table 3 for 2 vs 3-drug PEP recommendations.

The National PEP Guideline recommends 3-drug regimens in certain situations, such as if the source's HIV status is positive or unknown and from a very high prevalence population, i.e., men who have sex with men who inject drugs.

Note: There is no direct nor compelling indirect evidence to support the greater efficacy of 3-over 2-drug regimens (ASHM, June 2023).

Table 3 Recommended PEP regimens

2-drug regimen	3-drug regimen	Children <6 years or weighing less than 25kg	Children >6 years
Tenofovir disoproxil*/emtricitabine 200mg 1 tablet orally, daily	Tenofovir disoproxil* /emtricitabine 200mg 1 tablet orally, daily **PLUS** Dolutegravir 50mg (1 tablet orally, daily) **OR** (alternative) Raltegravir 1200mg (2x 600mg tablets orally, daily)	Lamuvidine/ zidovudine **PLUS** Dolutegravir 50mg (1 tablet orally, daily) **OR** (alternative) Raltegravir 1200mg (2x 600mg tablets orally, daily)	If weighing < 35kg Tenofovir disoproxil*/emtricitabine **PLUS** Dolutegravir **OR** (alternative) Raltegravir **If weighing > 25kg** Biktarvy®

Source: Adapted from Post-Exposure Prophylaxis after non-occupational and occupational exposure to HIV; Australian National Guidelines (Third Edition).

5.3 General practitioners who have not previously prescribed HIV PEP

The availability of generic formulations of tenofovir disoproxil 300mg and emtricitabine 200mg now make it possible for any prescriber to provide a private prescription for 2-drug PEP at a reasonable cost.

If an individual fits the recommendation for 2-drug PEP (and if unsure, contact the public health unit), a private prescription for generic co-formulated tenofovir disoproxil 300mg and emtricitabine 200mg may be written and follow-up with a specialist arranged.

Considerations if prescribing generic TDF/FTC for PEP:

- availability and access at community pharmacies (PEP must be commenced within 72 hours of exposure, with evidence of increased efficacy within 24 hours)
- cost to the patient
- a full 28-day course should be prescribed.

Generic formulations are not available for 3-drug PEP therefore, if required, consult your local public hospital specialists (infectious disease, sexual health physicians or immunology) for advice.

Children (aged <16 years)

The National PEP Guidelines generally apply to people aged 14 years or older. For paediatric PEP prescribing guidance, refer to the section: Children younger than 16 years of age in the *National PEP Guidelines* and the *Children's Health Queensland Post-Exposure Prophylaxis for HIV guideline.*

Immediately assess all children presenting following a potential HIV exposure for PEP, ideally in conjunction with a paediatric infectious disease specialist.

The National PEP Guideline recommends all children younger than 16 years who qualify for PEP receive combination therapy with 3-drugs at appropriate doses:

- The full 28-day PEP course should be provided at the time of the initial presentation.
- In children younger than 6 years or weighing less than 25kg, the preferred PEP regimen is:
  - lamuvidine + zidovudine + dolutegravir or raltegravir.
- In children older than 6-years, the preferred regimen is:
  - if weighing more than 35kg, emtricitabine + tenofovir disoproxil + dolutegravir or raltegravir
  - if weighing more than 25kg, Biktarvy®.

5.4 Rural and remote settings

Rural and remote settings where timely specialist advice is unavailable and the clinician cannot determine if, or how many, PEP drugs to prescribe, patients should ideally be prescribed a 3-drug starter pack. If 3-drug starter-packs are unavailable, prescribe a 2-drug starter pack and seek urgent specialist review.

People receiving a starter pack should be provided with a referral for a follow-up appointment with a specialist PEP provider or sexual health service. Clinicians may also seek advice from their local Public Health Unit where specialist HIV services are not available.

Glossary

Term	Definition
Durable viral suppression (DVS)	no formal definition: for the purposes of this document, plasma HIV-1 RNA less than 200 copies/mL sustained for a full six month period
Source individual	a person whose blood or other bodily substance may be a source of HIV exposure
Undetectable viral load (UDVL)	defined as viral suppression in the plasma with antiretroviral therapy to below the lower limit of detection of a specified assay (typically HIV-1 RNA <20 copies/mL) NB. Most guidance around 'undetectable' refers to the threshold of HIV-1 RNA 200 c/mL – treatment as prevention studies provide robust evidence to demonstrate there is no risk of HIV transmission through sexual contact if HIV viral load is maintained at <200 copies/mL (REF: PARTNER 1 and 2, Opposites Attract, HPTN-052)
Viraemic	≥ 200 copies/ml of HIV detected on a blood test
Viral suppression (VS)	defined as a quantitative measure of plasma HIV-1 RNA <200 copies/mL

Version Control

Version	Date	Comments
0.1	17 November 2023	CDB final draft for internal consultation
0.2	20 November 2023	CDB final draft for external consultation
0.3	12 April 2024	CDB draft consultation updates
0.4	1 October 2024	CDB draft for approval
1.0	7 November 2024	Final

Approval and implementation

Policy Custodian	Policy Contact Details	Approval Date	Approver
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