GP Perspective about prescribing PEP & PrEP

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Disclosures

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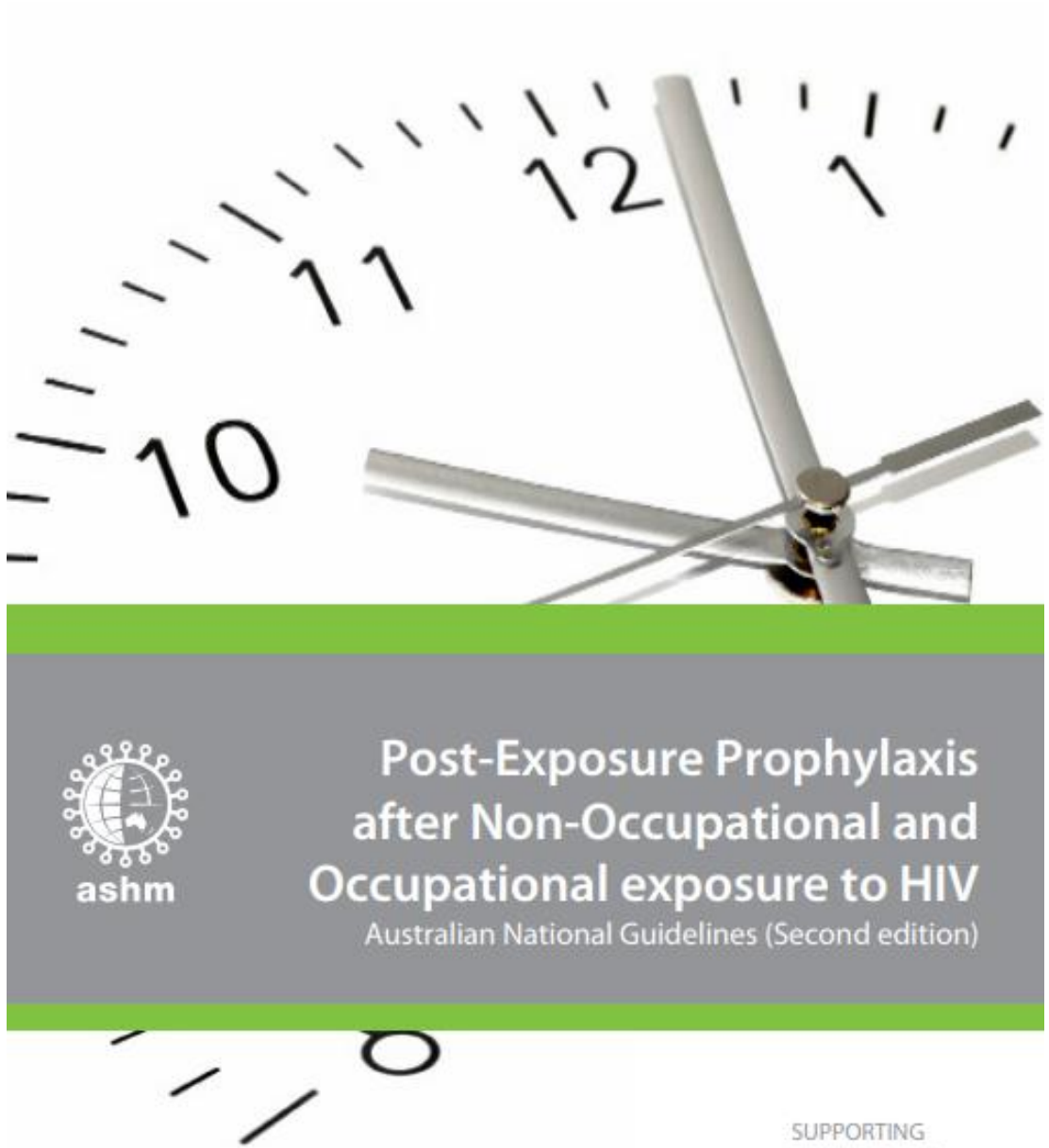

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Post-Exposure Prophylaxis after Non-Occupational and Occupational exposure to HIV

Australian National Guidelines (Second edition)

SUPPORTING
THE HIV, VIRAL
HEPATITIS AND
SEXUAL HEALTH
WORKFORCE

- Dr Karen Chung

About post-exposure prophylaxis for HIV (PEP)

Post-exposure prophylaxis (PEP) is the use of antiretroviral medications (ARVs) by HIV uninfected individuals to reduce the risk of acquiring HIV.

There is no data from randomised control trials of the use of PEP. Evidence for use has been extrapolated from animal data, mother to child transmission, and occupational exposure.

PEP Post exposure prophylaxis

- As a GP what I need to know is when should I seek advice and/or refer

- Key: risk greater than approx 1:1000

- U=U for sex only, not applicable to needles

Table 9. Estimates to quantify risk

Risk	Risk description
1/1 ≥ risk ≥ 1/10	Very high
1/10 > risk ≥ 1/100	High
1/100 > risk ≥ 1/1000	Moderate
1/1000 > risk ≥ 1/10,000	Low
1/10,000 > risk ≥ 1/100,000	Very low
1/100,000 > risk ≥ 1/1,000,000	Minimal
1/1,000,000 > risk ≥ 1 in 1 billion-trillion	Negligible

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

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

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

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

Table 4. PEP recommendations after NON-OCCUPATIONAL exposure to a source with UNKNOWN HIV status

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

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

† Based on estimated seroprevalence 1.0%.

‡ Based on estimated seroprevalence of 29%.

^ Based on estimated seroprevalence 0.1%.

HIV-positive source

Type of exposure with known HIV-positive source	Estimated risk of HIV transmission per exposure if source not on antiretroviral treatment	PEP recommendation	
		Source not on treatment or on treatment with detectable or UNKNOWN viral load	Source viral load KNOWN to be undetectable
NSI or other sharps exposure	1/440	3 drugs	Consider 2 drugs
Mucous membrane and non-intact skin exposure	< 1/1000	3 drugs	Consider 2 drugs

Table 6. Laboratory evaluation of individuals who are prescribed PEP

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

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

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

^ If clinically indicated.

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

Recommended PEP regimens:

2-drug regimens^:

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

OR

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

3-drug regimens:

Your preferred 2-drug regimen **PLUS**

dolutegravir 50mg (Daily)

OR

raltegravir 400mg (BD)

OR

rilpivirine 25mg (Daily)

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

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

Dolutegravir, raltegravir or rilpivirine as the 3rd drug:

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

6. Transitioning from PEP to PrEP

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

7. Renal disease

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

New Zealand

- Currently GP's may not prescribe PEP
- This may change when the price of the ARVs go down, and with appropriate credentialing and support from specialist colleagues
- Essential we are familiar with assessing relative risk, so we can explain the options, and to refer patients appropriately, if in doubt, pick up the phone.

PrEP

Pre Exposure Prophylaxis

First country in the world to publicly fund PrEP

- Approximately 850 patients access funded PrEP through Pharmac since the 1st March 2018
- Estimated at risk population is between 3000 to 6000

Resource being developed

To access the Auckland Regional Pathways:
When logged into Healthpoint, go directly to: http://aucklandregion.healthpathways.org.nz/
Otherwise, go to: http://aucklandregion.healthpathways.org.nz and use;
HealthPathways: **Username:** connected **Password:** healthcare

Pre-exposure Prophylaxis for HIV (PrEP)

Caution: This page is in development.

DRAFT PHASE
Second+ edits

region's changes
Streamliners' changes
queries

About pre-exposure prophylaxis for HIV (PrEP)

Assessment

1. Take a sexual history.
   - Explain that this is a common procedure for assessing STI risks and what tests might be needed.
   - Determine whether the patient is eligible for funded PrEP.
2. Check whether the patient has risk factors for renal disease.
3. Examination:
   - Take blood pressure.
   - Perform sexual health check. See pathways for male and female patients.

Search

- Infectious Mononucleosis
- Influenza
- Measles
- Meningococcal Disease
- Mumps
- Pertussis (Whooping Cough)
- Post-exposure Prophylaxis for HIV (PEP)
- Pre-exposure Prophylaxis for HIV (P
- Recurrent Staphylococcal Infection
- Rheumatic Fever
- Scabies
- Zika Virus
- Infectious Diseases Requests
- Nephrology
- Neurology
- Oncology
- Pain Management
- Palliative Care
- Respiratory
- Rheumatology
- Sexual Health
- Sleep
- Spinal Cord Impairment (SCI)

4. Arrange investigations:
    - Blood tests – HIV serology, syphilis serology, hepatitis A, hepatitis B, hepatitis C, creatinine, eGFR, LFTs
    - Urine protein/creatinine ratio
    - If the patient is a gay or bisexual man, multi-site STI testing – throat, urine, and rectal specimens.

Management

1. If the patient has been at risk of contracting HIV in the last 72 hours, seek infectious diseases advice or sexual health advice about considering non-occupational post-exposure prophylaxis for HIV (nPEP).
2. Review results:
    - Confirm the patient is HIV negative. If baseline HIV test is negative but the patient has been at risk within 4 weeks of testing, they may need to be re-tested earlier than 3 months.
    - Treat any STIs.
3. Offer vaccinations:
    - HAV and HBV if not immune.
    - HPV if eligible.
4. Discuss behavioural risk reducing strategies.
5. If not comfortable prescribing PrEP yourself, consider referring the patient to a suitable general practitioner via the PrEP map.

SAFE SEX

Find a doctor who knows about PrEP

If you're considering PrEP, you should discuss this with a doctor with experience in HIV and sexual health, to help decide if it is right for you.

Check out the map below to find a doctor near you who knows about PrEP.

If you are a clinician interested in learning more about PrEP, check out this information for PrEP prescribing clinicians by the New Zealand AIDS Foundation. If you're already prescribing PrEP and would like to be added to the doctor map, get in touch with us at hello@endinghiv.org.nz.

Enter a location

25

West Auckland Sexual Health Clinic

2nd Floor Westpac House 362 Great North Road Henderson

http://www.ashs.org.nz/sexual-health-clinics.html

0800 739432

Auckland Central Medical

Dr Garsing Wong. Appointment fees apply

326/28 College Hill Freemans Bay Auckland 1011

https://www.akcentralmedical.co.nz/

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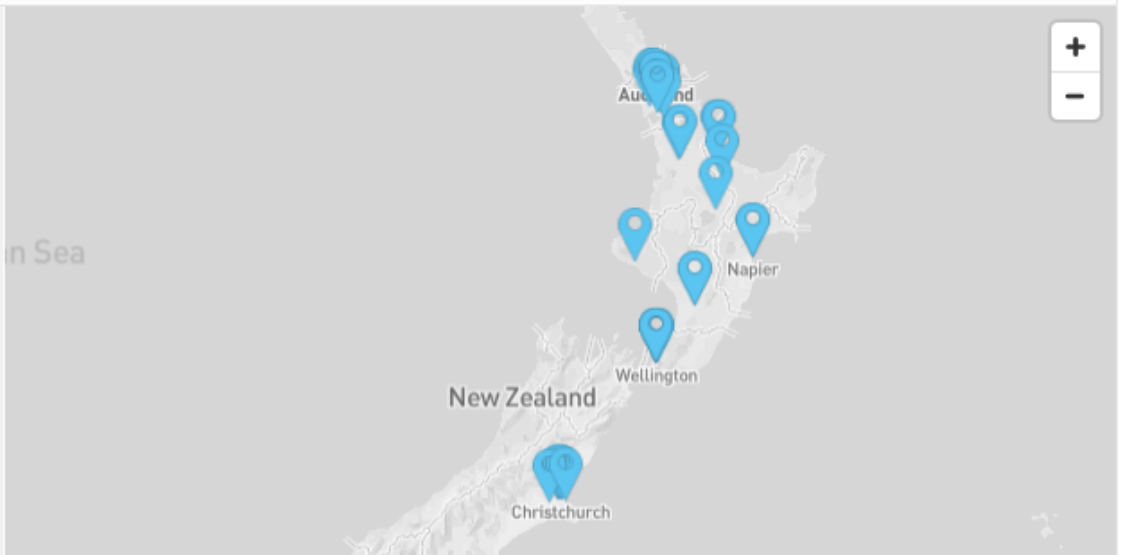

Search

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- Neurology
- Oncology
- Pain Management
- Palliative Care
- Respiratory
- Rheumatology
- Sexual Health
- Sleep
- Spinal Cord Impairment (SCI)
- Mental Health and Addiction
- Older Adults' Health
- Pharmacology
- Public Health
- Specific Populations
- Surgical
- Women's Health
- Our Health System
- Pathway Development Hub

Management if the patient is eligible for funded PrEP

1. Explain how to take PrEP and provide written instructions. Printed copies of PrEP Information for Patients can be ordered from the New Zealand AIDS foundation by emailing contact@nzaf.org.nz.
2. Advise the patient that they will need to be reviewed every 3 months to reassess eligibility for funded PrEP, for Special Authority renewal and for testing.
3. Request non-acute sexual health assessment. The first prescription must be written or approved by an HIV or sexual health specialist.
   - Consider using a referral template to ensure you have covered eligibility criteria, and attach relevant notes and results.
   - Renewal applications may be completed by any relevant practitioner every 3 months.
4. Consider using a template for documentation in general practitioner notes.
5. Arrange to review in 1 week, once Special Authority has been obtained.
6. Arrange follow-up every three months.

Follow-up

- At each follow-up appointment:
  - give advice regarding condom use and risk reduction strategies for HIV and STIs.
  - arrange tests:
    - HIV serology, syphilis serology, and full STI screens (including NAAT testing and rectal and throat swabs) must be completed within 2 weeks before re-application.
    - Renal function testing (including creatinine, eGFR, and urine protein/creatinine ratio) must be completed at least once a year, or more often if clinically indicated, e.g. older patient, risk factors for renal impairment.

Management if the patient is not eligible for funded PrEP

Template for consultation

Discussion

- - patient knowledge and awareness of HIV risk factors / practices
- - patient knowledge and awareness of HIV seroconversion symptoms
- - how to take PrEP, that it should ideally be taken every day for maximum effectiveness
- - common transient side effects - headache, nausea, flatulence, fatigue, diarrhoea.
- - signs or symptoms of renal injury and acute HIV infection - needs urgent review.
- - 2 more major adverse events - renal function (which will be monitored) and bone density (likely only 1-2% reversible decrease, consider DEXA if high risk).

Template for consultation

- FIRST VISIT FOR PrEP
-
- Eligibility:
- - Documented negative HIV test result using 4th-generation Ag/Ab test within 14 days of starting PrEP
- - No signs or symptoms of acute HIV infection
- - Normal renal function (eGFR >60mL/min)
- - No contraindicated medications (those that reduce renal function or compete for active tubular secretion may increase serum concentrations of tenofovir and emtricitabine: see Patients with chronic renal failure below)
- - When was last CLAI (condomless anal intercourse) - if <72 hours, consider PEP
- - Note that Hep B needs special consideration +/- discussion with specialist.

- Risk Assessment as per guideline:
- Any high risk factors (regular HIV +ve partner (excluding undetectable), at least one episode unprotected receptive anal intercourse with any casual HIV +ve (excluding undetectable) or unknown HIV status male partner, or any rectal gonorrhoea, rectal chlamydia, syphilis or methamphetamine use within the past 6 months):
- Any medium risk factors (unprotected insertive anal intercourse):

Initial Clinical Assessment

- Hep A/B status: Immune / Not Immune (—> vaccinate)
- Hep C status:
- HPV: (offer course of vaccination if not had this)
- Full STI screen including rectal CT/NG, pharyngeal CT/NG, urine first pass CT/NG. If anorectal symptoms, seek sexual health advice.
- Syphilis
- HIV status
- Creatinine / eGFR
- Random Urine Protein Creatinine Ratio
- LFTs
- Risk of renal disease (including diabetes, HTN, smoking, other medications, previous renal disease)
- PMHx, Allergies, Hgt, Wgt, BP, Genitalia, Anal region, DRE, Swabs

- Plan: (If importing) Script for PrEP initiated.
- Bloods within 7 days prior to starting PrEP.
- Recommend regular condom use from today until after 7 days of starting PrEP.
- See in 4 weeks for repeat blood test, and next prescription for PrEP (so always 2 months ahead).
- Write on the prescription “Medication is to be imported for personal use to prevent HIV under Section 51 of the Medicines Act 1981”
- This will mean that the medication should not be held at New Zealand Customs for further clarification with the prescribing doctor.

Plan: (If funded) Apply for SA for PrEP

- Given blood form to repeat kidney function and HIV in one month.
- See again in 10 weeks for follow up, earlier if needed.
- Give labtest form for bloods to be completed one week prior to coming in

Dear Sexual Health Consultant,

Thank you for considering applying for Special Authority for PrEP in my patient.

My patient is HIV negative and

Male or transgender
and has sex with men
and is likely to have multiple episodes of condomless anal intercourse in the next 3 months

AND:
had at least one episode of condomless receptive anal intercourse with one or more casual male partners

OR:
had a diagnosis of rectal chlamydia, rector gonorrhoea or infectious syphilis in the last 3 months

OR:
used methamphetamines in the last 3 months

XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

OR:
has a regular partner who has HIV infection
and their partner is either not on treatment or has had a detectable viral load
and condoms have not been consistently used

(strike non applicable)

Please find attached baseline tests.

Yours sincerely,

Follow up at 1/12 unfunded or 2/12 funded

- Side Effects:
- ?Vaccinations: Hep B, Hep A
- HIV test:
- BP:
- Next prescription and lab form
- Risk reduction, medication adherence, HIV risk assessment, any other risk factors

Ongoing followup

- Side Effects:
- ?Vaccinations: Hep B, Hep A, HPV
- HIV test:
- Renal function:
- BP:
- Next prescription and lab form
- Apply for renewed SA when HIV test to hand and if fulfils criteria
- STI check
- Risk reduction, medication adherence, HIV risk assessment, any other risk factors

How much time?

Initial consult 30min

Followup/subsequent consults 15min

Thank you

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