

PrEP: the other blue pill

Thursday 29 November 2018

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The Royal Australian College of General Practitioners



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Acknowledgement of Country

We recognise the traditional custodians of the land and sea on which we live and work.

We pay our respects to Elders past and present.



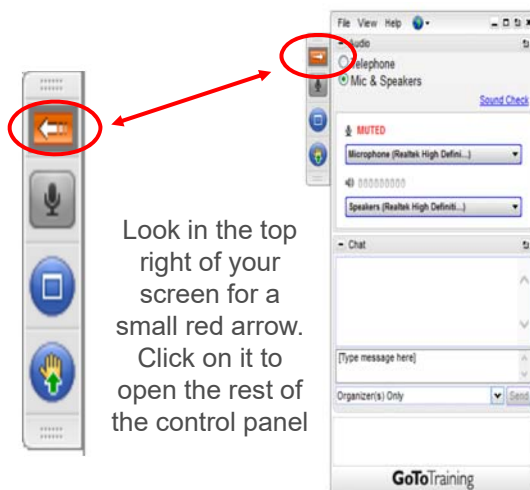
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Where is my control panel?



Look in the top right of your screen for a small red arrow. Click on it to open the rest of the control panel



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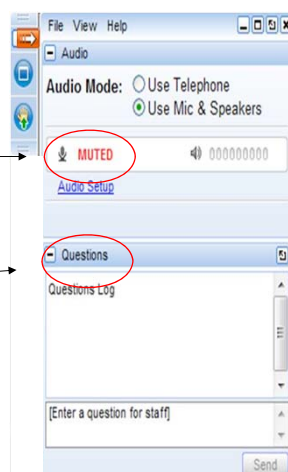
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Listen only mode

You have been placed on "mute" to optimise the learning experience for you and your peers

Use the question box function to talk to us.



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Conflict of interest

- Speaker's fees and conference assistance from Gilead Sciences
- Speaker's fees from Merck Sharp & Dohme
- Advisory board fees from ViiV Healthcare.
- Co-investigator on VicPrEP trial, with study drug supplied by Gilead.
- Co-investigator on PrEPX trial, with study drug supplied by Mylan



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Learning Objectives



Describe HIV epidemiology



Confidently identify eligible patients for PrEP



Understand the steps required to prescribe PrEP



Confidently manage patients on PrEP



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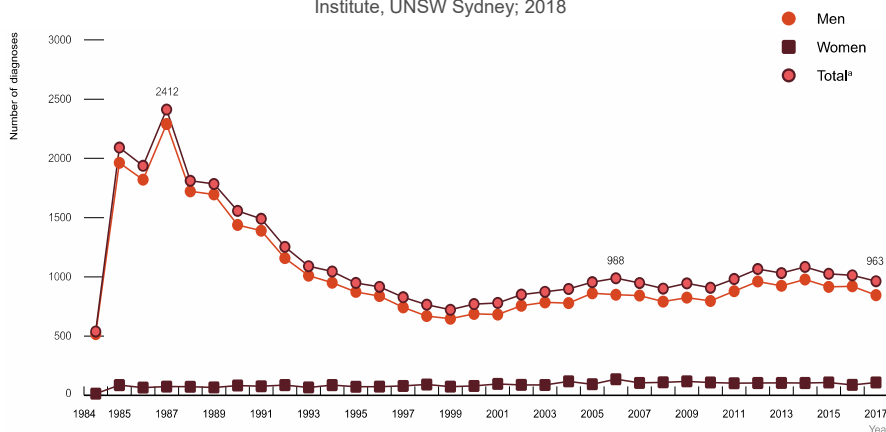


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New HIV Diagnoses in Aust., 1984–2017, By Sex

Kirby Institute. HIV in Australia: annual surveillance short report 2018. Sydney: Kirby Institute, UNSW Sydney; 2018



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HIV Epidemiology

The following data is from 2017:

Kirby Institute. HIV in Australia: annual surveillance short report 2018. Sydney: Kirby Institute, UNSW Sydney; 2018



27 545
estimated
living with
HIV in
Australia



963
new HIV
diagnoses in
Australia
in 2017



Annual
number of
new HIV
diagnoses
has
remained
stable over
the past 4
years



63%
of new
diagnoses in
MSM



Estimated
11% people
remain
undiagnosed



HIV
prevalence
extremely
low among
women
involved in
sex work –
incidence of
0.03 per 100
persons



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Why PrEP.... Why Now?

- Annual number of new HIV diagnoses has remained stable over the past 4 years
- Something different needed
- Studies internationally and in Australia have demonstrated the efficacy (randomised trials) and effectiveness (cohort studies) of PrEP in preventing HIV infections
- Increasing data of falling HIV infections (impact) in San Francisco and other cities after the introduction of PrEP
- Australia currently being recognized internationally for the success of their studies and rolling out PrEP en masse and quickly



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What is PrEP?

- Pre-Exposure Prophylaxis against HIV acquisition
- Prevents HIV infection from establishing itself if acquired
- Involves taking one co-formulated tablet of two antiretroviral drugs (ARVs: tenofovir DF and emtricitabine; or TDF+FTC) every day or, in some cases, intermittently (to be discussed).
- On the PBS since April 1st 2018 (Authority 30+2, streamlined 7580)
- Can be prescribed by any medical practitioner or, in some States, by a Nurse Practitioner.



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How do we know PrEP works?

- The efficacy of ARVs as continuous daily PrEP has been established in clinical trials among various risk groups including:
 - men who have sex with men (iPrEx, iPERGAY, Proud studies),
 - heterosexual adults (Partners PrEP and TDF2), and
 - Injecting drug users (Bangkok Tenofovir study)
- Transgendered people have not been well represented in PrEP studies, but data from iPrEx suggests that PrEP is effective in transgender people if taken correctly
- For participants who took their PrEP every day (100% adherence), PrEP was 95-99% effective.

Pooled efficacy data across PrEP trials suggest up to a 99% reduction in HIV acquisition



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Global estimate ~300-350,000 cumulative to date



Cohen, Science, March 2018 & WHO



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How many Australians are on PrEP already?

- Around 15,000 moderate-to-high-risk individuals
- Numbers are expected to grow
- Early reports suggest a drop in new HIV infections since PrEP rolled out, but precise national data are awaited



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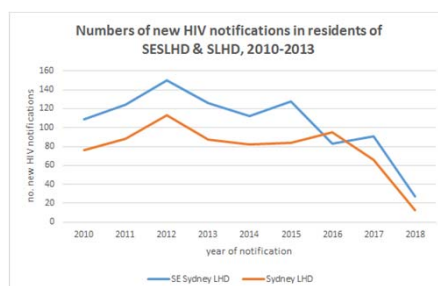


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Number of new HIV diagnoses in residents of Sydney and Southeast Sydney LHDs, 2010-Q1 2018

LHD	2010	2011	2012	2013	2014	2015	2016	2017	2018
SE Sydney	109	124	150	126	112	128	83	91	27
Sydney	76	88	113	87	82	84	95	66	13



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PrEP safety

- Long term key safety concerns mainly related to Tenofovir (tenofovir disoproxil fumarate)
- Key safety considerations include:
 - renal dysfunction/Fanconi syndrome
 - reduced bone mineral density (BMD)
 - safety for use in patients with chronic hepatitis B
 - HAART resistance in those who seroconvert
(**RARE** if adherent)



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When might you recommend or institute PrEP?

Patient requests

- Assess eligibility

Clinician suggests

- Initiate discussion

Why might the patient request?

- Actual risk
- Perceived risk
- Future risk

Why might the clinician suggest?

- Eliciting a history of high-risk behaviours



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Who are the Populations for HIV Testing

Priority populations for testing are outlined in the Seventh National HIV Strategy 2014-2017 (next strategy currently in draft)

Priority populations identified in this Strategy are:

- Gay men and other men who have sex with men
- Aboriginal and Torres Strait Islander people
- People from high HIV prevalence countries and their partners
- Travellers and mobile workers
- Sex workers
- People who inject drugs
- People in custodial settings

All of the above groups should potentially be assessed for suitability for PrEP



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Exposure and transmission risk/exposure with known HIV positive source who is NOT on antiretroviral treatment

Type of exposure with known HIV positive source	Estimated risk of HIV transmission per exposure if source NOT on antiretroviral treatment
Receptive anal intercourse (RAI) - ejaculation - withdrawal	1/70 1/155
Shared needles and other injecting equipment	1/125
Insertive anal intercourse (IAI) (uncircumcised)	1/160
Insertive anal intercourse (IAI) (circumcised)	1/900
Receptive vaginal intercourse (RVI)	1/1250
Insertive vaginal intercourse (IVI)	1/2550
Receptive or insertive oral intercourse	Not measurable
Mucous membrane and non-intact skin exposure	< 1/1000

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



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Talking about sexual health history

- Establish **trust**, make the patient feel **comfortable**
- **Normalise**
- Explain **rationale** for questions
- Be **prepared & comfortable** discussing topics
- **Don't assume** heterosexuality
- Address the **whole person** and relationships, not just STIs
- **Does not need to be extensive** – most important information is determining whether they have sexual contact with men, women or both



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Key points to remember

- Begin with **general** or **presenting issues** (less threatening)
- **Progress to more detailed** and specific questioning
- **Non-judgmental** attitude / neutral
- **Privacy** (see patient alone)
- Assure **confidentiality** (note exceptions)
- Explanation of the **goals** of the interview
- Consider the **cultural appropriateness** of sexual history taking



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The steps in prescribing PrEP

<https://www.ashm.org.au/products/product/3000100092>



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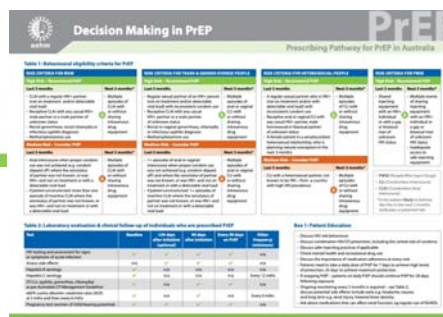
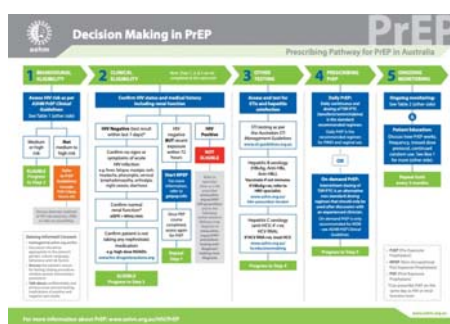


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ASHM Decision Making in PrEP Tool

<https://www.ashm.org.au/products/product/3000100092>



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The steps in prescribing PrEP

1 BEHAVIOURAL ELIGIBILITY

- Assess HIV risk as per ASHM PrEP Clinical Guidelines
- High risk groups to consider for PrEP:
 1. Men who have sex with men (MSM)
 2. Trans and Gender Diverse People
 3. Heterosexual People
 4. People who inject drugs
- Need to be classified as **MEDIUM** or **HIGH** risk to be eligible for PBS-subsidised PrEP.



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Practical Application

1 BEHAVIOURAL ELIGIBILITY

Answer **yes** or **no** to the following example:

Receptive condomless anal intercourse (CLAI) with a male partner of unknown status

&

Multiple episodes of CLAI in the next three months



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Answer



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Practical Application

1 BEHAVIOURAL ELIGIBILITY

Answer **yes** or **no** to the following example:

Shared injecting equipment with a gay or bisexual man of unknown status

&

Multiple events of sharing with a gay or bisexual man of unknown status over the next 3 months



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Answer



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Practical Application

1 BEHAVIOURAL ELIGIBILITY

Answer **yes** or **no** to the following example:

Condomless intercourse with a heterosexual partner, not known to be
HIV –ve, from a country with high HIV prevalence
&
Multiple episodes with condomless intercourse over the next three
months



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Answer



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Practical Application

1 BEHAVIOURAL ELIGIBILITY

Answer **yes** or **no** to the following example:

Male having protected intercourse with a sex worker in Australia
&
Multiple episodes of condomless oral sex with a sex worker in Australia



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Answer



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1 BEHAVIOURAL ELIGIBILITY

Answer **yes** or **no** to the following example:

Male having condomless sex with a HIV positive man who has a sustained undetectable viral load



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Answer



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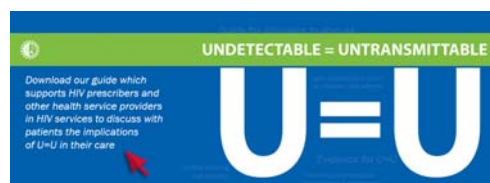
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Undetectable = Untransmittable U=U

HIV treatment as prevention

An undetectable viral load means that ART has been effective in suppressing viral replication.

There is effectively no risk of sexually transmitting the virus to a HIV-negative partner.



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The steps in prescribing PrEP

1 BEHAVIOURAL ELIGIBILITY

2 CLINICAL ELIGIBILITY

- Confirm the following prior to prescribing:
 - Patients HIV status
 - No signs of symptoms of acute HIV infection
 - Normal renal function
 - Not taking any nephrotoxic medication
- NOTE – if patient HIV negative BUT recent exposure within 72hrs refer patient for nPEP (non-occupational Post Exposure Prophylaxis)



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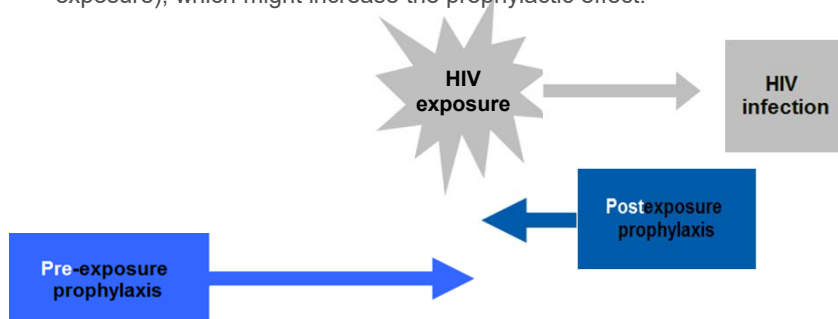


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Pre- vs Post-exposure Prophylaxis

After exposure to HIV, infection may become established. Post-exposure prophylaxis (PEP - initiated soon after exposure) reduces the chance of infection. Pre-exposure prophylaxis (PrEP) begins treatment earlier (before exposure), which might increase the prophylactic effect.



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When was last at risk episode?

1 BEHAVIOURAL ELIGIBILITY

2 CLINICAL ELIGIBILITY

- Within the last 72 hours?
- **SOONER is better**
- Can seamlessly transition PEP to PrEP
- PEP no longer routinely recommended for non-occupational exposure when an HIV-positive source has an undetectable viral load



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The steps in prescribing PrEP

1 BEHAVIOURAL ELIGIBILITY

2 CLINICAL ELIGIBILITY

If a patient requires NPEP?

- Q. Where do patients access NPEP?
- **A. Any hospital Emergency Department or any s100 prescriber**
- Q. What is the timeframe they need to access NPEP in?
- **A. 72 hours**



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The steps in prescribing PrEP

1 BEHAVIOURAL
ELIGIBILITY

2 CLINICAL
ELIGIBILITY

PEP Hotlines

- NSW PEP Hotline 1800 PEP NOW (1800 737 669)
- SA Hotline 1800 022 226
- WA AIDS Council 1300 767 161
- QLD Positive People 1800 636 214
- Victorian NPEP Service 1800 889 887



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The steps in prescribing PrEP

1 BEHAVIOURAL
ELIGIBILITY

2 CLINICAL
ELIGIBILITY

If a patient tests positive for HIV?

- Most HIV diagnoses are made in the general practice setting
- Some states and territories have specific programs in place to assist practitioners who have just made a new diagnosis
- ASHM provides practical resources to support clinicians making a new diagnosis
- Some concern in the community that some GPs are advising newly-diagnosed HIV+ patients to report to the police.

<https://www.ashm.org.au/HIV/prevention-testing-and-diagnosis/making-new-diagnosis/>



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Practical Application

1 BEHAVIOURAL
ELIGIBILITY

2 CLINICAL
ELIGIBILITY

- What HIV test do you order?
HIV Ag/Ab
- What is the window period for HIV to show up positive in a test?
Australian labs are using the fourth generation HIV test (antigen/antibody combination test) which becomes positive 2-6 weeks after exposure. Given the small window period with the fourth generation HIV test, it is recommended to test patients at their initial presentation and 3 months later.



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Practical Application

1 BEHAVIOURAL
ELIGIBILITY

2 CLINICAL
ELIGIBILITY

Confirming no signs or symptoms of acute HIV infection:

What specifically might you be looking for here in a patient?
Fever, fatigue, myalgia, rash, headache, pharyngitis, cervical lymphadenopathy, arthralgia, night sweats, diarrhoea



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Practical Application

1 BEHAVIOURAL ELIGIBILITY

2 CLINICAL ELIGIBILITY

Confirming your patient's renal function and whether they are taking any nephrotoxic medication:

1. What is the minimum eGFR that a patient must have to be eligible for PrEP?

Confirm normal renal function*

eGFR > 60mL/min

1. What are some examples of nephrotoxic medications?

- Acyclovir/valacyclovir
- High dose or multiple NSAIDs
- Aspirin
- Aminoglycosides



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The steps in prescribing PrEP

1 BEHAVIOURAL ELIGIBILITY

2 CLINICAL ELIGIBILITY

3 OTHER TESTING

Assess and test for **STIs** and **hepatitis** coinfection

- Hepatitis B
- Hepatitis C
- Sexually Transmitted Infections:
test as per the Australian STI Management Guidelines



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Practical Application

- 1 BEHAVIOURAL ELIGIBILITY 2 CLINICAL ELIGIBILITY 3 OTHER TESTING

Confirming a patient's Hepatitis B status:

1. What test/s would you order to do this?
Order HBsAg, Anti-HBs, Anti-HBc
1. If the patient was not immune would you vaccinate?
Yes
1. If the patient is HBsAg +ve what would your next step be?
If HBsAg +ve, refer to HBV specialist



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Practical Application

- 1 BEHAVIOURAL ELIGIBILITY 2 CLINICAL ELIGIBILITY 3 OTHER TESTING

Confirming a patient's Hepatitis C status:

1. What test/s would you order to do this?
Order HCV RNA if anti-HCV +ve
1. If the patient is HCV RNA +ve what would your next step be?
HCV RNA +ve treat HCV



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PrEP and Hepatitis B

1 BEHAVIOURAL ELIGIBILITY 2 CLINICAL ELIGIBILITY 3 OTHER TESTING

- Tenofovir is a HBV treatment option
- Involvement of someone who manages Hep B is recommended
- Most often not going to delay PrEP start
- Starting PrEP
 - Assessment for decompensated liver disease
 - Adherence even more important
- On demand PrEP contraindicated
- Discontinuing PrEP
 - Hepatic Flares possible



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PrEP regimens

1 BEHAVIOURAL ELIGIBILITY 2 CLINICAL ELIGIBILITY 3 OTHER TESTING 4 PRESCRIBING PrEP

Daily PrEP [recommended]

Daily PrEP should be recommended to people who have ongoing high or medium risk of acquiring HIV. In Australia, TDF/FTC has been registered for use as a daily medication.

On-demand PrEP [only in consultation with experienced clinician]

- If exposure happens only for relatively short periods of time (e.g. during travel)
- Irregular event-based exposure
- It may also suit those who have adverse events, such as nausea and diarrhoea, or changes in their kidney function, due to previous use of daily PrEP
- Only for MSM and Transwomen



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PrEP regimens



On-demand PrEP

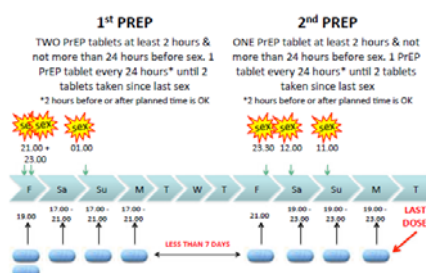
- Less effective than daily PrEP (Ipergay trial reported 86% efficacy)
- Adherence can vary
- Four or more doses per week may be sufficient (iPrEx Study)



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One pill, many uses can increase confusion

• Truvada [Gilead]

tenofovir disoproxil fumarate 300mg /
emtricitabine 200mg

• Mylan

Tenofovir disoproxil maleate 300mg /
emtricitabine 200mg

• Generic Health

Tenofovir disoproxil phosphate 291mg
/emtricitabine 200mg

Reverse transcriptase
inhibitors prevent HIV
replication through blocking
viral RNA incorporation into
host DNA



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TD-FTC Same medication different uses

- Back bone of many successful anti-retroviral HIV treatment regimes
 - Single tablet, low side effect combinations
- Post Exposure Prophylaxis (PEP)
 - Used as 2 drug single tablet or in combination with a 3rd agent (often dolutegravir, raltegravir, rilpivavine)
 - Some PrEP prescribed as PEP to PrEP likely
- Pre-exposure Prophylaxis (PrEP)
 - Only available as tenofovir/emtricitabine combination



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PrEP has PBS listing 1st April



streamlined 7580

TENOFOVIR + EMTRICITABINE

Source: General Schedule
Body System: ANTINEOPLASTIC FOR SYSTEMIC USE > ANTINEOPLASTIC FOR SYSTEMIC USE > DIRECT ACTING ANTINEOPLASTIC

Note

Authority Required (STREAMLINED)

T250

Pre-exposure prophylaxis (PrEP) against human immunodeficiency virus (HIV) infection.

Clinical criteria:

- The treatment must be for patients at medium to high risk of HIV infection, as defined by the Australian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM) Guidelines.

AND

- Patient must have a negative HIV test result prior to treatment with PBS subsidised therapy with this drug.

Population criteria:

- Patient must be 18 years or older.

Code & Name	Medical Product Pack (Name, form & strength and pack size)	Max qty pack/s	Max qty units	No. of repeats (PBS)	Max Safety Net	General Patient Price
T250L	TENOFOVIR + EMTRICITABINE tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30 (P, CWS)	1	30	2	\$240.00	\$35.00

Prescriber details

LEGEND

Brand equivalent Medical Practitioner Nurse Practitioner

Department of Health | PBS INFORMATION | BROWSE THE PBS | FOR HEALTH PROFESSIONALS | FOR INDUSTRY

About the PBS | New, amended and deleted | For more information | How to List on the PBS



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Prescribing PrEP - Personal Importation Scheme



- pan.org.au and prepdforchange.com have extensive information
- From \$23/month
- Can import up to 3 months at one time
- No medicare required
- Requires script for customs
- Be conscious about delivery time



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The steps in prescribing PrEP



Test	Baseline	±30 days after initiation (optional)	90 days after initiation	Every 90 days on PrEP	Other frequency (minimum)
HIV testing + assessment for acute infection	✓	✓	✓	✓	n/a
Assess side effects	n/a	✓	✓	✓	n/a
Hepatitis B	✓	n/a	n/a	n/a	n/a
Hepatitis C	✓	n/a	n/a	n/a	Every 12 Months
STI Testing	✓	n/a	✓	✓	n/a
eGFR +/- urine protein: creatinine ration	✓	n/a	✓	n/a	Every 6 months
Pregnancy test	✓	✓	✓	✓	n/a

The steps in prescribing PrEP



Also includes ongoing patient education

- Combination HIV/STI prevention
- Safer injecting practices if applicable
- Importance of adherence and ongoing monitoring
- When they will be protected (7 days) and when stopping PrEP how long they will be protected for (28 days)
- Medications that can affect renal function
- Mental health and recreational drug use
- Side effects



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Initial side effects are common



Reports 10-30% of patients

Limited to first month generally

- Nausea
- Diarrhoea
- Headache
- Fatigue
- Flatulence

Supportive measures to progress through period



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Medication interactions



Minimal issues

Liverpool App: www.hiv-druginteractions.org.au

Concern is cumulative effects of nephrotoxic agents

Most common issues revolve around NSAIDs, protein powders and gym supplements.



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Long-term Issues - Renal



- Patients with an eGFR of 60 mL/min/1.73 m² should not be prescribed PrEP
- Monitor 3-6 monthly eGFR, PCR
- Care with nephrotoxic drugs e.g. NSAIDs
- Creatine supplementation can cause false creatinine elevation



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Long-term Issues - Bone



- Generally not a significant issue in most
 - Small but significant reduction in BMD
 - Reverses on stopping PrEP
 - Biggest concern would be in those with high risk for osteoporosis
 - need monitoring



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PrEP and Pregnancy



- Risk of HIV acquisition vs TD*/FTC risk to infant
- Data primarily from ARV use in HIV+ mothers
- Pregnancy
 - Slight drop BMD in newborns
- Breast feeding
 - Secreted in breast milk
 - <2% of infant HIV treatment dose



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Adherence is key



- Most reports of PrEP failures related to adherence issues, only a handful of treatment resistant failures.
- “If you don’t take it, it doesn’t work!”
- Need to take PrEP at least 4 days a weeks for efficacy in men but more Rx., more protection



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How to Stop / Restart PrEP



- Need to discuss at initiation
- Need to consider any risk exposures in the last 28 days **BEFORE** stopping
- Need to be **very clear** of need to retest HIV prior to restarting



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Ongoing 3 monthly reviews



- Tolerance
- Adherence
- Health changes / new treatment or OTC
- Risk reassessment (last 3 months, next 3 months)
 - Sexual behaviours
 - Recreational drugs
 - STIs
- Consider need for harm minimisation strategy
- Review results of tests done prior to visit



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Staying Safe on PrEP



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PrEP and PEP guidelines

PrEP and PEP guidelines

<https://ashm.org.au/HIV/PrEP/>

<https://www.ashm.org.au/HIV/PEP/>



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Cases



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Case Study #1: Mark

1 BEHAVIOURAL ELIGIBILITY

- 34 yo man identifies as gay
 - Heard about PrEP from friends
 - Regularly 'bottoms' with casual partners he meets on Grindr
 - 'Pretty good' at using condoms most of the time but has had some 'slip ups'
 - Wants to 'bareback'
- Does he meet the behavioural eligibility criteria?



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Case Study #1: Mark

1 BEHAVIOURAL ELIGIBILITY

High Risk – Recommend PrEP	
Last 3 months	Next 3 months*
<ul style="list-style-type: none"> • QIAI with a regular HIV+ partner (not on treatment and/or detectable viral load) • Receptive QIAI with any casual HIV+ male partner or a male partner of unknown status • Rectal gonorrhoea, rectal chlamydia or infectious syphilis diagnosis • Methamphetamine use 	<ul style="list-style-type: none"> • Multiple episodes of QIAI with or without sharing intravenous drug equipment

&



What is your next step?



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Case Study #1: Mark

1 BEHAVIOURAL ELIGIBILITY

2 CLINICAL ELIGIBILITY

- No signs or symptoms of acute HIV infection
- No high risk exposures in the last 72 hours
- No medical history, nil medications/OTC/supplements
- You discuss PrEP in detail including dosing, side effects and follow-up
- What is your next step?



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Case Study #1: Mark

1 BEHAVIOURAL ELIGIBILITY

2 CLINICAL ELIGIBILITY

3 OTHER TESTING

- You order baseline testing
 - HIV Ag/Ab
 - eGFR & urine ACR
 - HBV/HCV/syphilis serology
 - Gonorrhea & chlamydia PCR (throat, anal, urine)
- You give him a prescription for 3 months of TD*/FTC 1 tablet daily and ask him not to start the medication until you have notified him of his results



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Case Study #1: Mark



- You receive Mark's results the following day
 - HIV Ag/Ab NEGATIVE
 - eGFR >90mL/min, nil microalbuminuria
 - HBV/HCV/syphilis serology and STI PCR's NEGATIVE
- You advise him he can start PrEP and remind him that protective levels require 7 days of dosing and he should continue for 28 days after any potential exposure to HIV if he wishes to cease PrEP
- When do you ask him to return for review?



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Case Study #1: Mark



- You see Mark 3 months after commencing PrEP
- Mild headache for a few days after starting and no current STI symptoms
- You discuss HIV-risk behaviour, STI prevention, recreational drug use, adherence, stopping protocol & nephrotoxic medications
- You prescribe 3 months of daily TD*/FTC and order routine tests
 - HIV Ag/Ab
 - eGFR
 - STI testing



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Case Study #2: Steve

1 BEHAVIOURAL ELIGIBILITY

- 43 years old
- Having sex with women only
- Attending your clinic for travel vaccinations as travelling to Thailand for his annual three week holiday
- Does Steve need to consider PrEP?



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Case Study #2: Steve

1 BEHAVIOURAL ELIGIBILITY

- How might you broach the topic of high risk behaviours he might engage in while in Thailand?
- What STI testing might you offer Steve (refer to the Australian STI Management Guidelines)?
- What PrEP regime might be considered for Steve and why?



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Case Study #2: Steve

1 BEHAVIOURAL ELIGIBILITY

Medium Risk – Consider PrEP

Last 3 months

- CLI with a heterosexual partner, not known to be HIV-, from -a country with high HIV prevalence

Next 3 months*

- Multiple episodes of CLI with or without sharing intravenous drug equipment

&



- You refer to the PrEP guidelines and decide that Steve meets the behavioural eligibility criteria given his likely future risk
- He is keen to commence PrEP and asks how long he needs to take it for
- What is your response?



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Case Study #2: Steve

1 BEHAVIOURAL ELIGIBILITY

- You discuss that he needs to commence PrEP within 7 days of his negative HIV test and least 7 days before his holiday
- He needs to continue for 28 days after any potential exposure to HIV
- You complete your routine PrEP workup and prescribe daily TD*/FTC
- You ask him not to start the medication until you notify him of his results



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Case Study #3: Sharon

1 BEHAVIOURAL ELIGIBILITY

- 28 years old
- Attending your clinic due to persistent cough
- Has attended your clinic for last 5 years for methadone prescriptions as Sharon has a history of injecting drug use and continues to inject



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Case Study #3: Sharon

1 BEHAVIOURAL ELIGIBILITY

2 CLINICAL ELIGIBILITY

3 OTHER TESTING

4 PRESCRIBING PrEP

5 ONGOING MONITORING

- What questions will you ask Sharon to determine whether Sharon might need to be considered for PrEP?
- What STI tests would you offer Sharon (refer to the Australian STI Management Guidelines)?
- If Sharon is commenced on PrEP outline your ongoing monitoring management plan for her



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Case Study #4: Tim

1 BEHAVIOURAL ELIGIBILITY

- 45 year old gay man
- Books in on Monday morning for an urgent appointment
- Upset as he has had insertive condomless anal sex with a casual partner at a club the previous night
- Has previously taken PEP (post exposure prophylaxis) and thinks he needs PEP again
- Tim says that he has been having regular insertive condomless anal sex over the last few months in clubs but no receptive anal sex
- What do you do?



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Case Study #4: Tim

1 BEHAVIOURAL ELIGIBILITY

2 CLINICAL ELIGIBILITY

- Tim meets the behavioural eligibility criteria for PrEP
- You think he needs PEP and PrEP
- As you are not sure about what to do you ring the PEP hotline



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Case Study #4: Tim

They calculate his HIV risk at 1/1600 (uncircumcised) to 1/9000 (circumcised) and recommend 2 drug PEP for 28 days

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

Type of exposure with unknown HIV positive source	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)	1/1,250,000 [*]	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%.

Case Study #4: Tim



- You discuss this with Tim
- He says that he has been thinking about PrEP for a while and thinks now is a good time to start
- You perform the standard screening tests
- You prescribe PEP / PrEP for immediate start today – the local chemist has stock



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Case Study #5: Sam

1 BEHAVIOURAL ELIGIBILITY

- 32 year old gay man from Vietnam, now permanent resident of Australia
- Presents seeking PrEP
- No regular partners, casuals through Grindr does have condomless anal sex
- Fit and healthy, No Rx., No smoking, No alcohol
- **Anything else you want to know?**
- **Are you going to support his PrEP decision?**



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Case Study #5: Sam

1 BEHAVIOURAL ELIGIBILITY

2 CLINICAL ELIGIBILITY

3 OTHER TESTING

- HIV Ag/Ab: Not detected
- Creatinine 93, eGFR >90
- TPTA (treponemal serology): not detected
- Hep A Ab: not detected
- Hep B: sAg pos, sAb neg, cAb pos
- Hep C Ab: not detected
- PCR CT/ NG : negative
- **Where to from here?**



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Case Study #5: Sam



FBC: **normal**
 LFTs: **ALT 22**
 Hep B e Ag/Ab status: **e Ag pos, eAb neg**
 HBV DNA: **>170 million IU/ml**
 Physical Exam: **normal**
 Coags: **normal**
 AFP: **normal**
 HDV serology: **not detected**
Where to from here?



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Case Study #5: Sam



- Start PrEP?
- Refer to Hepatology?
- Any other considerations?
 - On demand PrEP
 - Adherence
 - Flares – When might you get them?
 - Stopping PrEP



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Case Study #6: Ben



- Ben presents for his 9 month follow-up
- His HIV & STI testing were NAD.
- His eGFR is 58
- What are the points you wish to cover at this follow-up visit?

Date:	03/07/18	16/04/18	22/01/18		
Coll. Time:	07:50	17:50	18:40		
Lab Number:	7915001	6459325	3455051		
Sodium	143	142	139	(135 - 145)	mmol/L
Potassium	4.1	4.8	4.1	(3.5 - 5.2)	mmol/L
Chloride	103	108	103	(95 - 110)	mmol/L
Bicarbonate	32	28	28	(22 - 32)	mmol/L
Urea	7.0	6.7	6.1	(2.5 - 8.5)	mmol/L
Creatinine	* 124	102	95	(60 - 110)	umol/L
eGFR	* 58	73	80	(> 59)	mL/min/1.73m2

Case Study #6: Ben



- Ongoing risk evaluation
 - Sexual
 - Party drugs
 - STIs
- Harm minimisation needs
- Adherence
- New medications or OTC
- Renal review
- Script and follow-up blood form



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Take Home Message

- PrEP is effective, safe, well tolerated and easy!
- Important to follow ASHM's 5 steps for safe care
 - Behavioural eligibility – assess for medium/high risk
 - Clinical eligibility – ensure HIV negative and no renal issues
 - Other testing – beware hepatitis B infection
 - Prescribing – ensure 7 day cover with initiation
 - Ongoing monitoring – ensure 28 day cover with cessation
- You can always ask for help from an experienced prescriber



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Resources

PrEP

- ashm.org.au/HIV/PrEP/
- pan.org.au
- prepdforchange.com

PrEP decision making tool:

- <https://www.ashm.org.au/products/product/3000100092>

PrEP patient information:

- <https://ashm.org.au/products/product/prep-patient-information>

PEP

- ashm.org.au/HIV/PEP/
- getpep.info
- NPEP hotline (Mon-Fri, 9-5): 1800 889 887

Undetectable = Untransmittable: A guide for clinicians to discuss:

- <https://ashm.org.au/products/product/UequalsU>



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References

- Kirby Institute. HIV in Australia: annual surveillance short report 2018. Sydney: Kirby Institute, UNSW Sydney; 2018
- Cohen, J. Concern as HIV prevention strategy languishes. *Science* 2018; 359(6381).
- Wright, E., Grulich, A et al., 2018, 'Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine HIV pre-exposure prophylaxis: clinical guidelines. Update 2018', *Journal of Virus Eradication*, vol. 4, pp. 143 – 159.
- Calabrese, S., Magnus, M., et al., 2016, 'Putting PrEP into Practice: Lessons Learned from Early-Adopting U.S. Providers' Firsthand Experiences Providing HIV Pre-Exposure Prophylaxis and Associated Care', *PLOS One*, <viewed 3 May 2018 <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0157324>>
- Krakower, D. & Mayer, K., 2016, 'The role of healthcare providers in the roll out of pre-exposure prophylaxis', *Current Opinion in HIV AIDS*, vol. 1, pp 41-48.
- Saberi, P., Berrean, B., et al., 2018, 'Simple Pre-Exposure Prophylaxis (PrEP) Optimization Intervention for Health Care Providers Prescribing PrEP: Pilot Study', *Journal of Medical Internet Research*, <viewed 3 May 2018 <https://formative.jmir.org/2018/1/e2/>>
- The Department of Health Seventh National HIV Strategy 2014-2017, <viewed 28 May 2018 <http://www.health.gov.au/internet/main/publishing.nsf/content/ohp-bbvs-hiv>>
- Victorian HIV Strategy 2017-2020, <viewed 1 Nov 2018 <https://www2.health.vic.gov.au/about/publications/policiesandguidelines/victorian-hiv-strategy-2017-2020>>



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