

# From Challenge to Opportunity: Practical SRH & HIV Hot Topics for GPs

## PrEP and DoxyPEP

### How to incorporate into your practice?

Dr Rachel Burdon

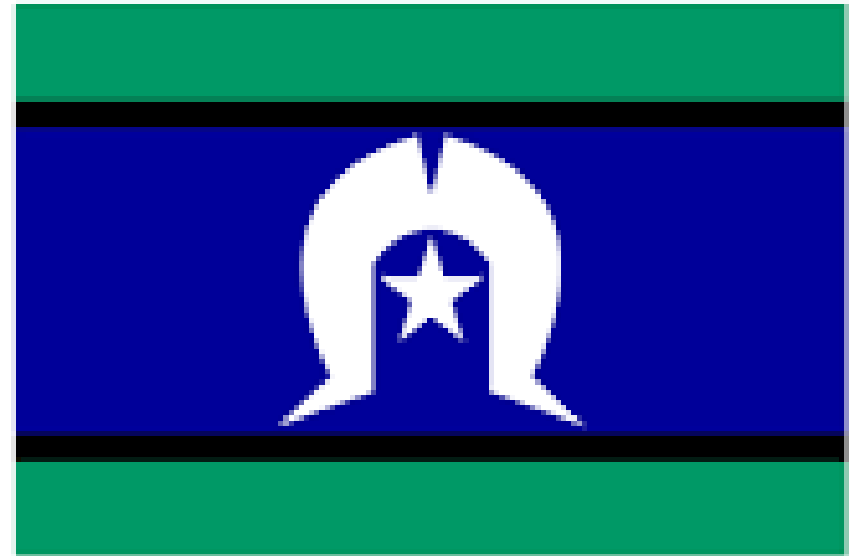
Senior Staff Specialist

Deputy Head of Department

RPA Sexual Health

# Acknowledgement of Country

- I would like to begin by acknowledging the Traditional Owners of the land on which we meet today, the Kurna People and pay my respects to Elders past, present and emerging and celebrate the diversity of Aboriginal peoples and their ongoing cultures and connections to the lands and waters of Australia.
- I also acknowledge and pay my respects to our Aboriginal and Torres Strait Islander people/colleagues joining us today.



# Presentation outline



1: Why do we need to integrate PrEP and DoxyPEP into our practice

- HIV and STI trends in Australia

2: PrEP

- What is it and who potentially needs it
- Different ways of taking oral PREP
- How to prescribe and monitor

3: DoxyPEP

- What is it and who potentially needs it
- How to prescribe and monitor

4: Discussion

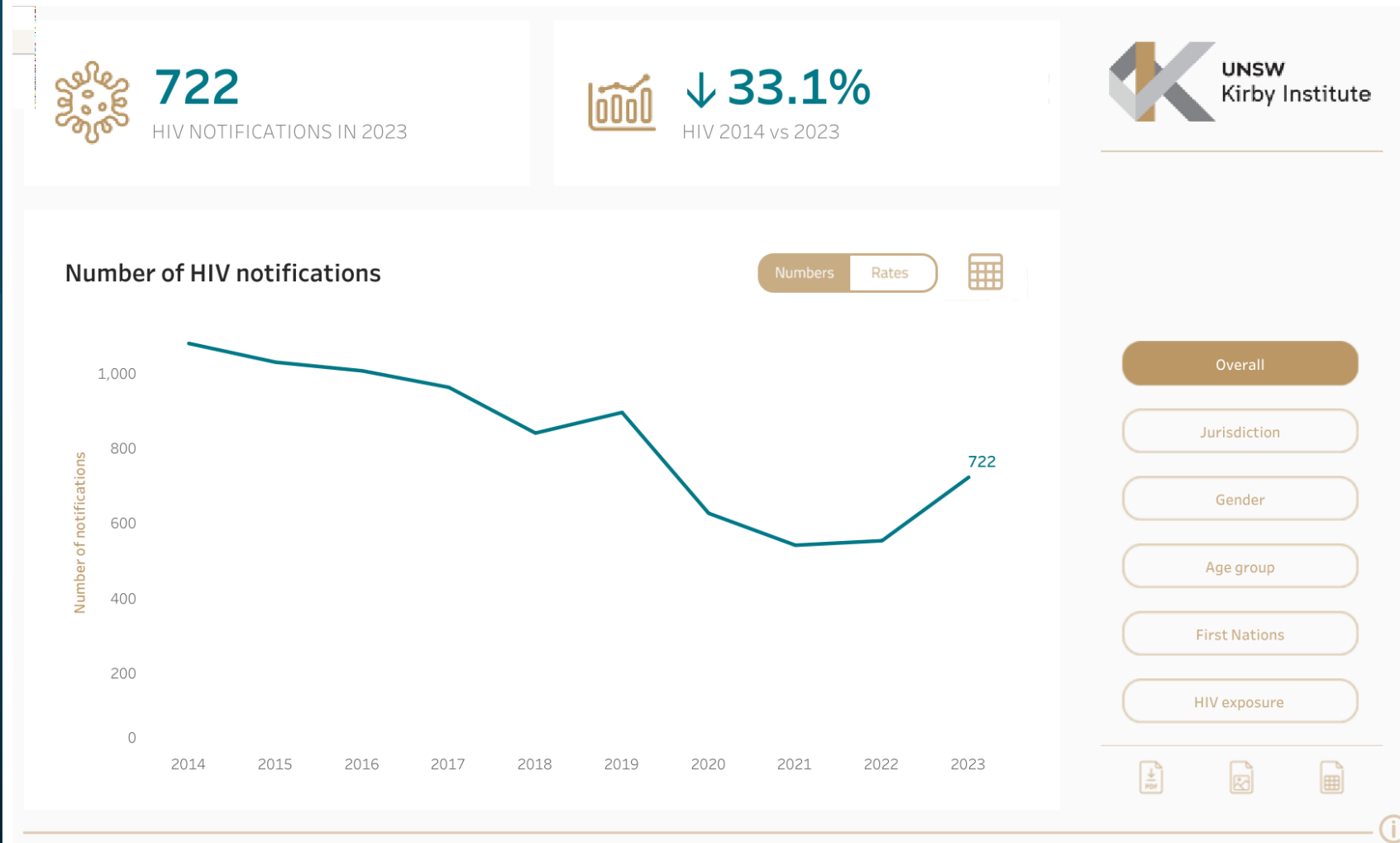
How many people are already prescribing PREP ??

Has anyone prescribed DoxyPEP ??

HERE'S WHAT YOU  
NEED TO KNOW  
ABOUT DOXY-PEP



# HIV Epidemiology: Australia



<https://www.data.kirby.unsw.edu.au/hiv>

# What is PrEP (Pre exposure prophylaxis) ?

- Use of antiretroviral drugs by HIV uninfected individuals to reduce HIV acquisition risk.
- Highly effective in preventing sexual transmission of HIV from sexual activity in high-risk groups
  - almost 100% effective with optimal adherence
- Estimated to be  $\geq 74\%$  effective in preventing transmission in PWID (poorly studied)
- Most commonly used medication is oral tenofovir disoproxil fumarate 300mg/emtricitabine 200mg
  - - PBS since April 2018
- Alternative is tenofovir alafenamide 25mg/emtricitabine 200mg (TGA but not PBS approved)
- It is generally safe and well tolerated
- Generic alternatives available reducing the cost
- A few different ways of taking oral PrEP available



## Effectiveness of PrEP

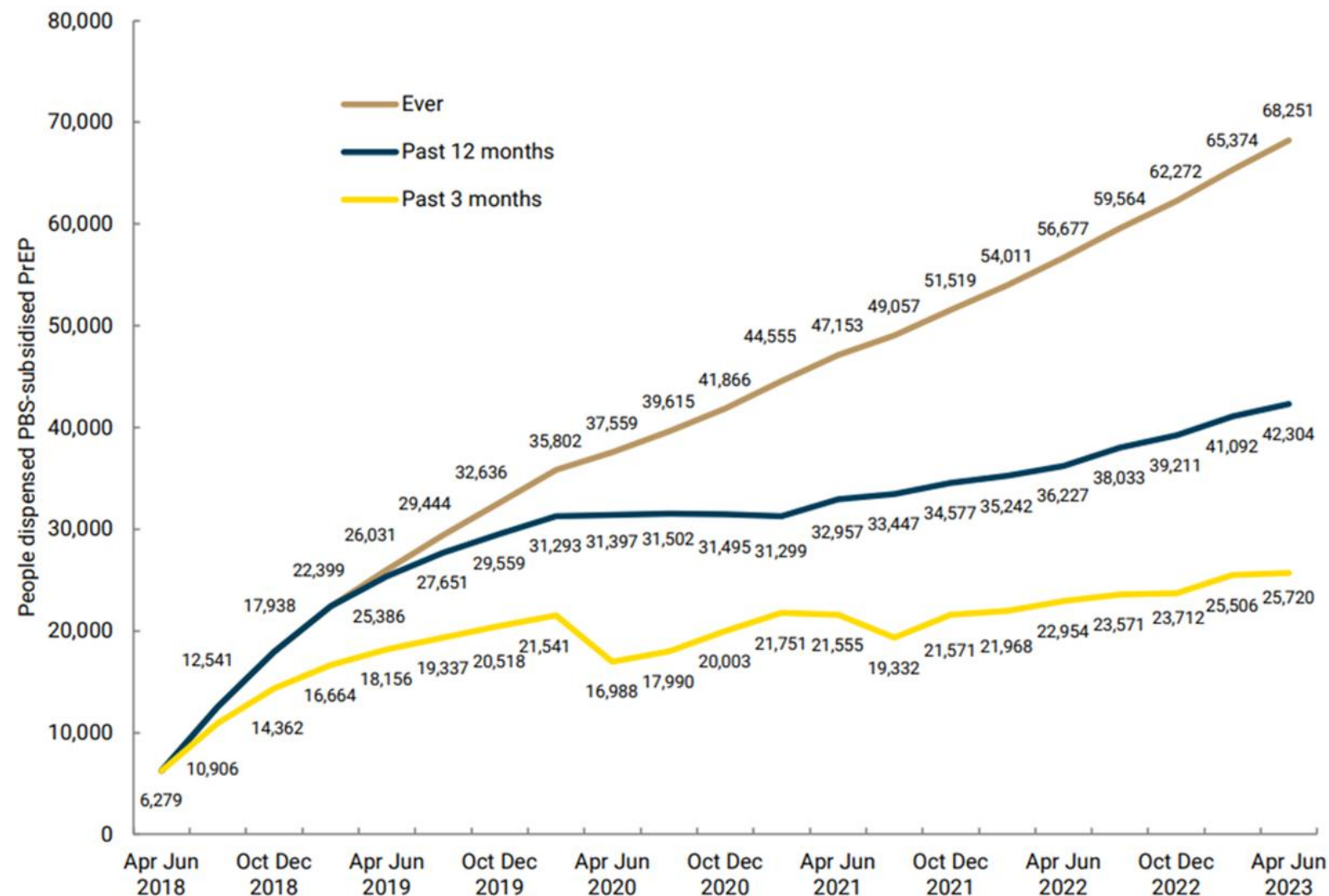
Population	Effectiveness Estimate	Source
Men who have sex with men (MSM)	~99%	Grant, 2014 Liu, 2015 McCormack, 2015 Volk, 2015 Marcus, 2017
Heterosexual Men and Women	~99%	N/A
Persons Who Inject Drugs (PWIDs)	74 – 84%	Choopanya, 2013 Martin, 2015

<https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html>



# PrEP Uptake in Australia: 2018-2023

Figure 1: Number of people ever and recently dispensed PBS-subsidised PrEP.

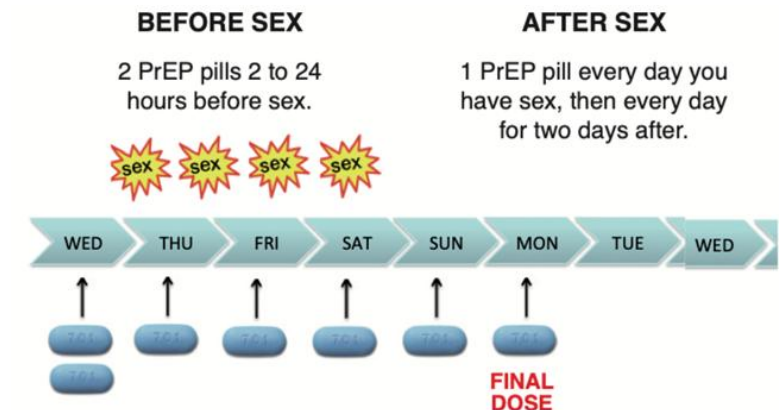
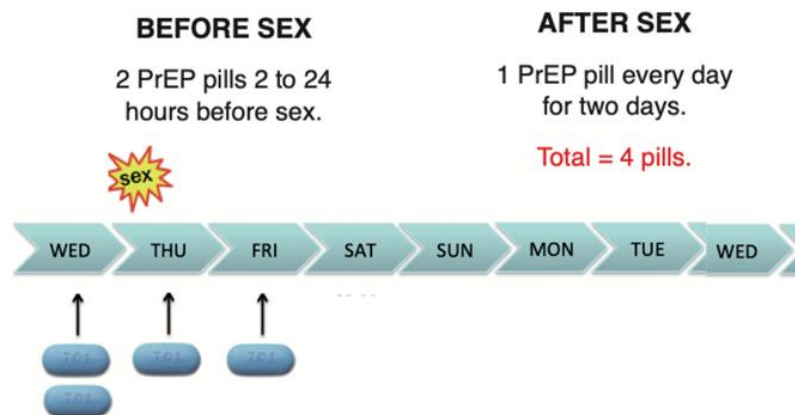


<https://www.data.kirby.unsw.edu.au/hiv>



# PrEP dosing: Daily vs On-Demand

- PrEP can be taken daily or on demand
- On-demand PrEP or 'disco dosing' (off-label in Australia) has been found to be non inferior to daily PrEP (IPERGAY 97% effective)
- Data available only for Tenofovir Disoproxil 300mg/Emtricitabine 200 mg
- Only indicated for cis-gender men who have sex with men
  - who do not inject drugs and do not have Hep B
  - who have sex no more than once per week - MUST be able to plan ahead
- Daily PrEP is more forgiving
  - a person can miss 1-2 doses a week with minimal impact on efficacy but missing doses of on-demand PrEP, reduces effectiveness dramatically
- Cautious with adolescents and those don't plan sexual activity



# Prescribing PrEP in General Practice: 5 Simple Steps

PrEP is PBS listed as a s85 drug = General schedule drug

Any GP can prescribe

## 1 BEHAVIOURAL SUITABILITY

## 2 CLINICAL SUITABILITY

## 3 OTHER TESTING

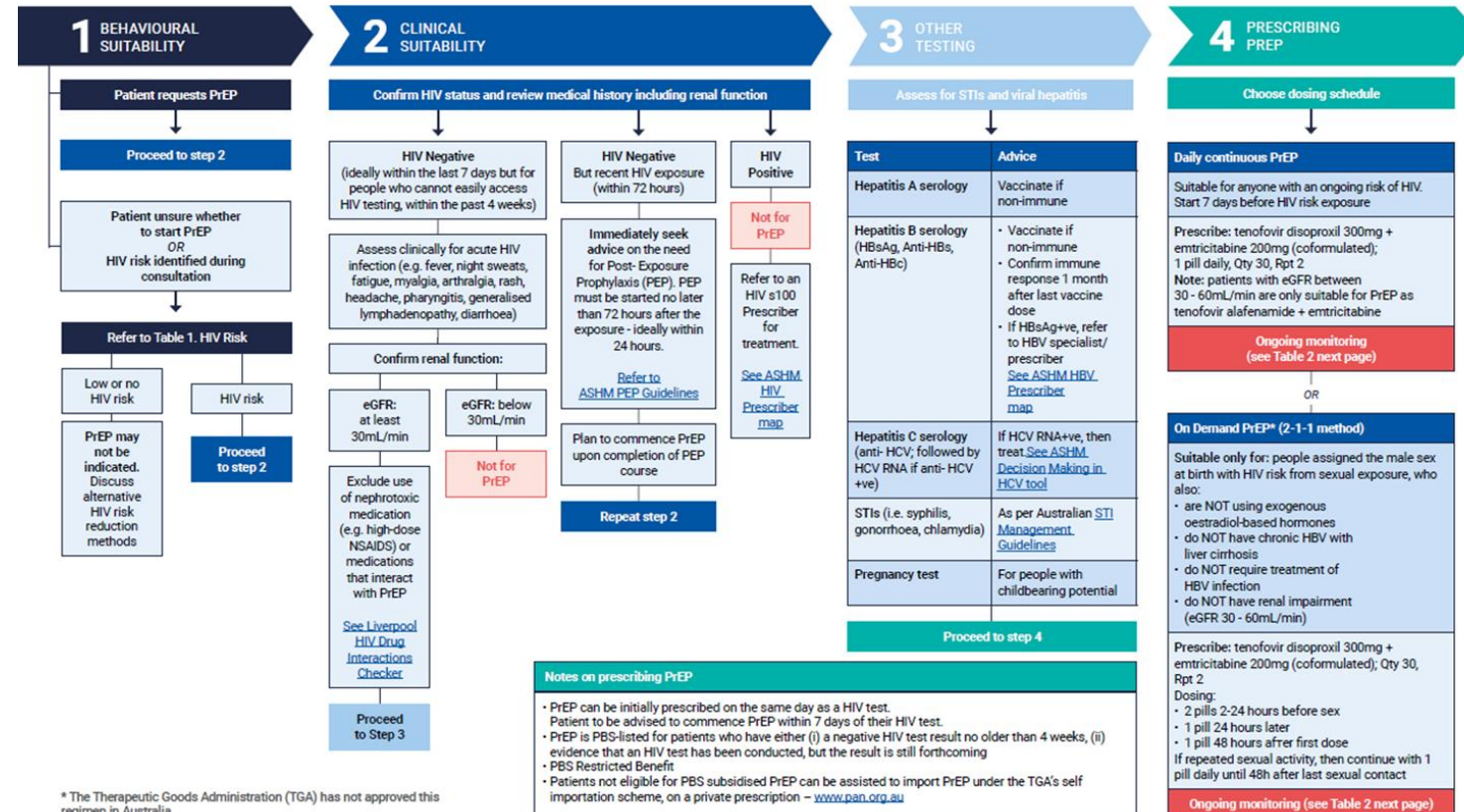
## 4 PRESCRIBING PREP

ONGOING MONITORING  
TABLE 2: CLINICAL FOLLOW-UP OF PATIENTS WHO ARE PRESCRIBED PREP

## Prescribing Oral HIV Pre-Exposure Prophylaxis (PrEP) in Australia

© HIV

PrEP can be prescribed by all medical practitioners and nurse practitioners using PBS scripts. No specialist training is required.



\* The Therapeutic Goods Administration (TGA) has not approved this regimen in Australia.



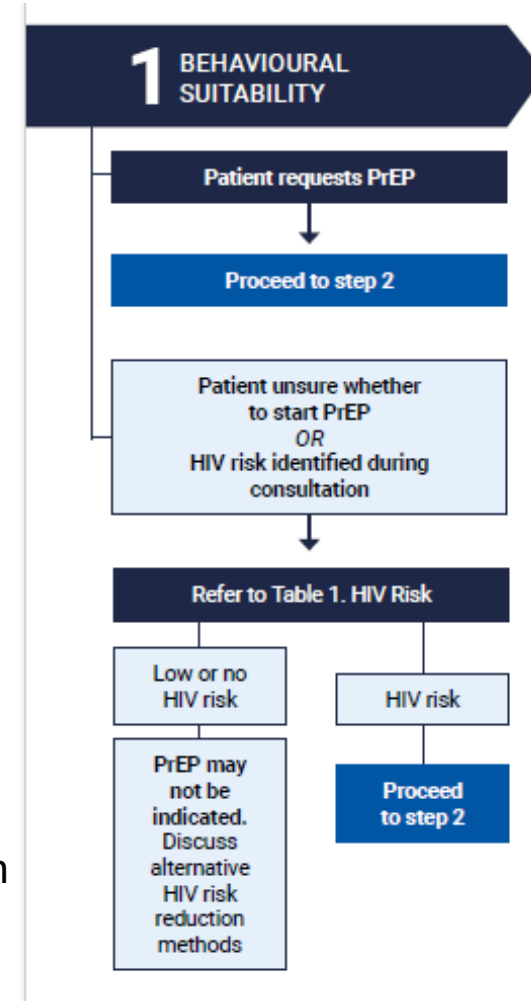
# Step 1: Behavioural Suitability -PrEP

There is no eligibility criteria – however suitable for :

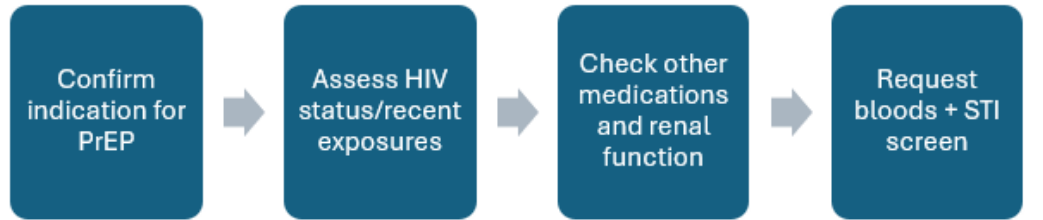
TABLE 1: HIV RISK			
Men who have sex with men (MSM)	Trans & gender diverse people	Heterosexual people	People who inject drugs
<ul style="list-style-type: none"><li>• Receptive CLI with any casual male partner.</li><li>• Rectal gonorrhoea, rectal chlamydia or infectious syphilis.</li><li>• Methamphetamine use.</li><li>• CLI with a regular HIV+ partner who is not on treatment and/or has a detectable viral load.</li></ul>	<ul style="list-style-type: none"><li>• Receptive CLI with any casual male partner.</li><li>• Rectal or vaginal gonorrhoea, chlamydia or infectious syphilis.</li><li>• Methamphetamine use.</li><li>• CLI with a regular HIV+ partner who is not on treatment and/or has a detectable viral load.</li></ul>	<ul style="list-style-type: none"><li>• Receptive CLI with any casual MSM partner.</li><li>• A woman in a serodiscordant heterosexual relationship, who is planning natural conception in the next 3 months.</li><li>• CLI with a regular HIV+ partner who is not on treatment and/or has a detectable viral load.</li></ul>	<ul style="list-style-type: none"><li>• Shared injecting equipment with an HIV+ individual or with MSM of unknown HIV status.</li></ul>

## In Your Practice this could mean discussing PrEP with anyone

- Who has needed Post Exposure Prophylaxis (PEP) recently/in the past
- GBMSM/TG individual who has had condomless sex with GBMSM/TG
- Who has a sexual partner LHIV who is off treatment/ detectable
- GBMSM/TG individual with history of rectal STIs
- Anyone who partakes in Chem sex
- Cis women who are having sex with GBSMSM or whose male partners are having sex with men
- Identifies future risk: Travel/ Incarceration
- Sex workers who consider themselves at risk
- Anyone who asks for it

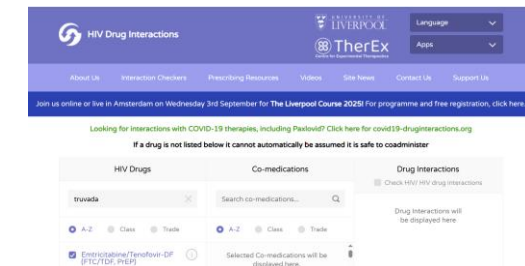
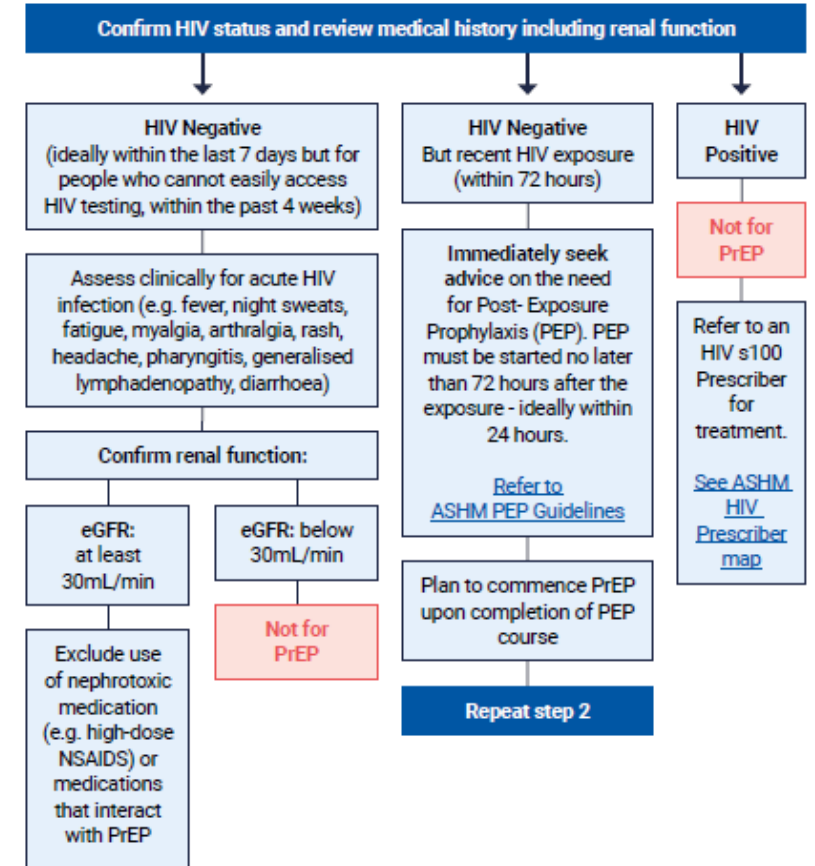


## 2. Clinical Suitability



- Confirm HIV negative and any recent HIV risk exposure
- Assess acute HIV infection
- Confirm normal renal function (eGFR > 60 mL/min)
- Review drug interactions and nephrotoxic medications
- Weight > 35 kg
- Safe in pregnancy when benefit outweigh risk –B1

### 2 CLINICAL SUITABILITY



**Remember to consider PEP in any patient had had a risk in the past 72 hours**

# Step 3. Other Testing

## 3 OTHER TESTING

Assess for STIs and viral hepatitis

Test	Advice
Hepatitis A serology	Vaccinate if non-immune
Hepatitis B serology (HBsAg, Anti-HBs, Anti-HBc)	<ul style="list-style-type: none"> <li>Vaccinate if non-immune</li> <li>Confirm immune response 1 month after last vaccine dose</li> <li>If HBsAg+ve, refer to HBV specialist/prescriber</li> </ul> <a href="#">See ASHM HBV Prescriber map</a>
Hepatitis C serology (anti-HCV; followed by HCV RNA if anti-HCV +ve)	If HCV RNA+ve, then treat. <a href="#">See ASHM Decision Making in HCV tool</a>
STIs (i.e. syphilis, gonorrhoea, chlamydia)	As per Australian <a href="#">STI Management Guidelines</a>
Pregnancy test	For people with childbearing potential

Proceed to step 4

Test	Baseline (Week 0)
HIV testing and assessment for signs or symptoms of acute infection	✓
Assess side effects	✗
Hepatitis A serology Vaccinate if non-immune	✓
Hepatitis B serology Vaccinate if non-immune	✓
Hepatitis C serology	✓
STI (i.e. syphilis, gonorrhoea, chlamydia) as per <a href="#">Australian STI Management Guidelines</a> *	✓
eGFR at 3 months and then every 6 months	✓
Urine protein creatinine ratio (PCR) baseline	✓
Pregnancy test (for women of child-bearing age)	✓

Use these guidelines



# Step 4. Prescribing PrEP

**No renal impairment, Daily or On Demand PrEP**

Prescribe Tenofovir Disoproxil 300 mg  
+Emtricitabine 200 mg (co-formulated),  
1 tablet daily, Qty 30, Rpt x 2 (**PBS**)



## 4 PRESCRIBING PREP

Choose dosing schedule

### Daily continuous PrEP

Suitable for anyone with an ongoing risk of HIV.  
Start 7 days before HIV risk exposure

Prescribe: tenofovir disoproxil 300mg +  
emtricitabine 200mg (coformulated);  
1 pill daily, Qty 30, Rpt 2

Note: patients with eGFR between  
30 - 60mL/min are only suitable for PrEP as  
tenofovir alafenamide + emtricitabine

Ongoing monitoring  
(see Table 2 next page)

OR

### On Demand PrEP\* (2-1-1 method)

Suitable only for: people assigned the male sex  
at birth with HIV risk from sexual exposure, who  
also:

- are NOT using exogenous oestradiol-based hormones
- do NOT have chronic HBV with liver cirrhosis
- do NOT require treatment of HBV infection
- do NOT have renal impairment (eGFR 30 - 60mL/min)

Prescribe: tenofovir disoproxil 300mg +  
emtricitabine 200mg (coformulated); Qty 30,  
Rpt 2

Dosing:

- 2 pills 2-24 hours before sex
- 1 pill 24 hours later
- 1 pill 48 hours after first dose

If repeated sexual activity, then continue with 1  
pill daily until 48h after last sexual contact

**Current ways to access PrEP in Australia:**  
**PBS script/ Private script/Online Importation with script**

### Tenofovir Disoproxil/Emtricitabine (300mg/200mg)

- Can be used people who eligible for daily/on demand PrEP (eGFR >60)
- Only regime for cis women, TG women on GAHT, TG men having vaginal sex, IDU
- Available on PBS \$30/month Or \$7.20 (HCC)
  - Similar cost for non-Medicare at some chemists
  - Access at reasonable cost online ([www.pan.org.au](http://www.pan.org.au))

### Tenofovir Alafenamide/Emtricitabine (25mg/200mg)

- Not suitable for cis women whose HIV risk is vaginal sex
- Should not be used for on demand PrEP
- TGA approved but not available on PBS
- Can be accessed online at @PAN for \$30/month

**eGFR 30-60 , Daily PrEP only**

Prescribe Tenofovir Alafenamide 25 mg  
+Emtricitabine 200 mg (co-formulated),  
1 tablet daily, Qty 30, Rpt x 2 (**non-PBS**)



**PAN**  
PrEPaccessNOW

# Prescribing PrEP in GP: Best Practice

New Rx

☒ Product name ☐ Therapeutic class ☐ Custom ☐ Favourites

Search for:

Available formulations: ☐ Show PBS/RPBS listed only

Product name	Quantity	Rpts	Restriction	BPP	TGP/S
Tenofovir /Emtricitabine 25mg;200mg Ta...	60	5	S100 (Community ac...	\$ 0.00	\$ 0.00
<b>Tenofovir /Emtricitabine 300mg;200mg T...</b>	<b>30</b>	<b>2</b>	<b>PBS/RPBS RB</b>	<b>\$ 0.00</b>	<b>\$ 0.00</b>
Tenofovir /Emtricitabine 300mg;200mg T...	60	5	S100 (Community ac...	\$ 0.00	\$ 0.00
Tenofovir /Emtricitabine 300mg;200mg T...	60	5	S100 (Community ac...	\$ 0.00	\$ 0.00
Tenofovir /Emtricitabine 301mg;200mg T...	30	2	PBS/RPBS RB	\$ 0.00	\$ 0.00
Tenofovir /Emtricitabine 301mg;200mg T...	60	5	S100 (Community ac...	\$ 0.00	\$ 0.00

**Tenofovir /Emtricitabine 300mg;200mg Tablet**  
Generic name: Tenofovir, Emtricitabine 300mg;200mg

Schedule: NSW: 4, QLD: 4, VIC: 4, SA: 4, WA: 4, TAS: 4, ACT: 4, NT: 4  
PBS Listing: PBS/RPBS Restricted benefit - 30 and 2 repeats  
Restriction: Pre-exposure prophylaxis (PrEP) against human immunodeficiency virus (HIV) infection  
Clinical criteria:  
\* Patient must have at least one of the following prior to having the latest PBS-subsidised prescription issued:  
(i) a negative HIV test result no older than 4 weeks,  
(ii) evidence that an HIV test has been conducted, but the result is still forthcoming.  
Notes:

Add to favourites

No allergy/adverse drug reaction information has been recorded!

Same drug class Equivalent products Product Information  
NPS RADAR Allergies/Reactions CMI

< Back Next > Cancel

New Rx - Tenofovir /Emtricitabine 300mg;200mg Tablet

Availability:

Quantity	Repeats	Restriction	BPP	TGP/SPC
30	2	PBS/RPBS RB	\$ 0.00	\$ 0.00
60	5	S100 (Community access)	\$ 0.00	\$ 0.00
60	5	S100 (Community access)	\$ 0.00	\$ 0.00

Quantity:  Repeats:  ☐ Regulation 49

Interval between repeats (days):

Prescribe as: ☒ PBS ☐ Private ☐ Urgent supply (Owing script)

☐ Print brand name on scripts ☐ Allow brand substitution

PBS Listing: ☒ Consent to upload to ASL ☐ Dosing Point ☐ Staged Supply ☐ Repeat on File ☐ Direction

PBS/RPBS Restricted benefit  
Restriction: Pre-exposure prophylaxis (PrEP) against human immunodeficiency virus (HIV) infection  
Clinical criteria:  
\* Patient must have at least one of the following prior to having the latest PBS-subsidised prescription issued:  
(i) a negative HIV test result no older than 4 weeks, (ii) evidence that an HIV test has been conducted, but the result is still forthcoming.  
Notes:

Generate note:

Medication prescribed  
Medication started in hospital  
Medication started by specialist  
Medication started by patient  
Medication started elsewhere

☒ Mark for printing ☐ Mark as printed

☐ Once only prescription ☒ Long term medication

Product Information CMI

< Back Next > Cancel



# Step 5: Monitoring PrEP

- Review every 3 months
- Ask about new medications, change in risk, side effects, adherence
- Important to check knowledge and use around on demand PrEP
- Monitoring schedule as per below

Test	Baseline (Week 0)	About day 30 after initiating PrEP (optional but recommended in some jurisdictions)	90 days after initiating PrEP	Every subsequent 90 days on PrEP	Other frequency
HIV testing and assessment for signs or symptoms of acute infection	✓	✓	✓	✓	✗
Assess side effects	✗	✓	✓	✓	✗
Hepatitis A serology Vaccinate if non-immune	✓	✗	✗	✗	✗
Hepatitis B serology Vaccinate if non-immune	✓	✗	✗	✗	✓ If patient required hepatitis B vaccine at baseline, confirm immune response to vaccination 1 month after last vaccine dose
Hepatitis C serology	✓	✗	✗	✗	✓ 12 monthly but, more frequently if ongoing risk e.g. non-sterile injection drug use and MSM with sexual practices that pre-dispose to anal trauma
STI (i.e. syphilis, gonorrhoea, chlamydia) as per <a href="#">Australian STI Management Guidelines</a> *	✓	✗	✓	✓	✗
eGFR at 3 months and then every 6 months	✓	✗	✓	✗	✓ At least every 6 months or according to risk of CKD
Urine protein creatinine ratio (PCR) baseline	✓	✗	✓	✗	✓ Every 6 months
Pregnancy test (for women of child-bearing age)	✓	✗	✓	✓	✗

# Stopping PrEP

- Important to regularly advise people using PrEP on how to discontinue it safely
- Cis-gender MSM can safely cease daily PrEP by taking a dose of PrEP 24 and 48 hours after their last at-risk sexual exposure
- For all other individuals PrEP should be continued for 28 days after the last at-risk sexual exposure



# Situations requiring consultation/referral with specialist services

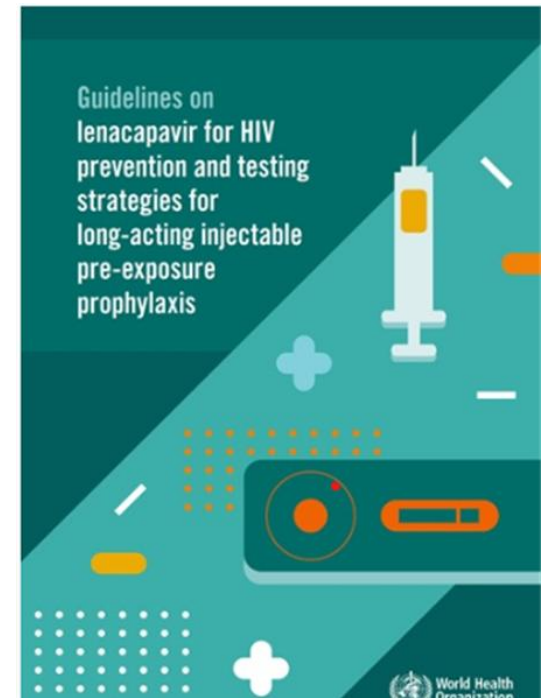
- Individuals with chronic Hepatitis B infection should be referred to specialist services before starting PrEP
  - Be aware that an individual with chronic Hepatitis B who ceases PrEP is at risk of an acute flare of viral hepatitis
- Individuals with renal disease
- Those with chronic GIT disease or any risk of malabsorption
- Individuals with increased risk of osteoporosis
- Unexpected increase in Creatinine/reduced eGFR
  - Remember eGFR is calculated using a formula including serum creatinine, age, and gender
  - Gym supplements that include creatinine don't negatively impact renal function but do make the eGFR reduce (Ok to take them as long as true renal function is OK)
  - Minor - Ensure well hydrated, no gym supplements week prior to testing, no recent heavy exercise, not fasting and repeat UEC
  - Major – Cease and refer



# Exciting alternative options for HIV prevention

Science has proven flexible choices that include injectable PrEP reduces HIV transmission

- Dapivirine vaginal ring inserted for 28 days for PrEP
  - WHO recommended – primarily used in Africa
  - Not available in Australia
- Cabotegravir: Two monthly antiretroviral injection used for PrEP
  - TGA but not PBS approved and currently available in Australia on special access
  - ViiV healthcare seeking extension to re-establish price negotiations
- Lenacapavir: 6 monthly antiretroviral injection used for PrEP
  - Approved by WHO , European US FDA
  - Submitted for consideration with Australian TGA April 2025
  - ASHM supporting development guidelines for Australia
- MK8527 is a nucleoside reverse transcriptase translocation inhibitor (NRTTI) taken once/month for HIV prevention





# STI Epidemiology: Australia

Why do we need to implement DoxyPEP?



# Syphilis in Australia

## What's the latest data on infectious syphilis?

In 2022, there were:



**6,036**  
notifications



**1,063**  
in females



**4,943**  
in males

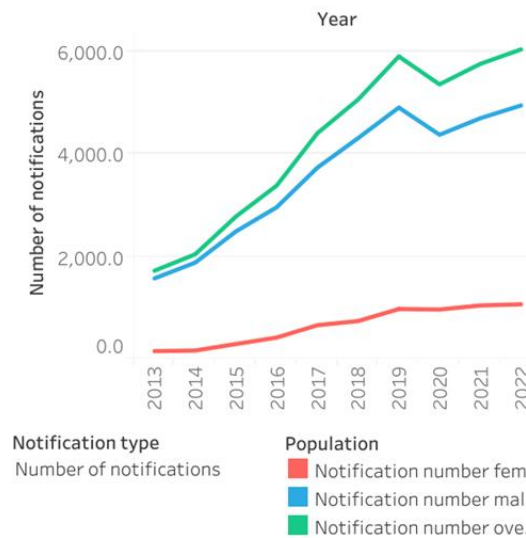


**↑ 351%**  
increase in the  
last 10 years

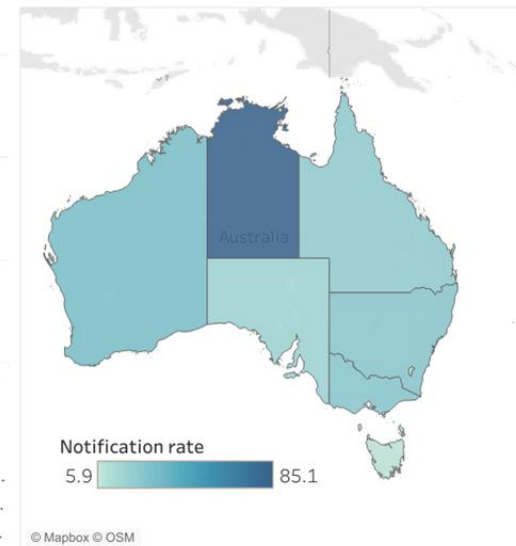


**x5 more cases**  
among Aboriginal and  
Torres Strait Islander  
peoples than  
non-Indigenous people

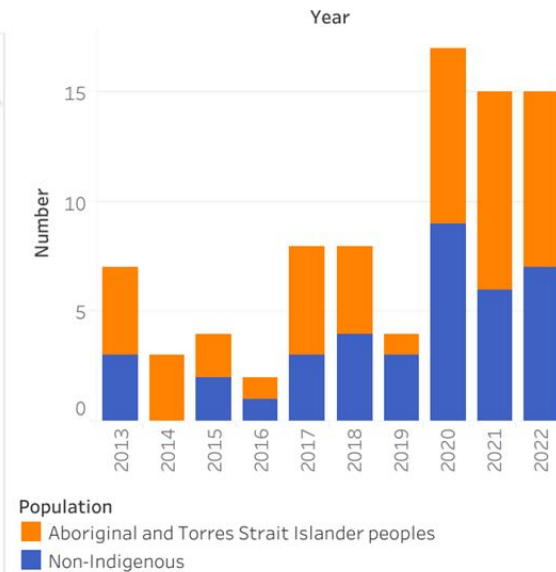
### What are the trends in syphilis in Australia?



### What do syphilis notification rates look like across Australia?



### Congenital syphilis notifications per year



### Notification rates versus number of notifications

**Notification rates** are the number of notifications per 100,000 people. **Numbers of notifications** are the numbers of new diagnoses notified to the relevant health authorit..

<https://www.data.kirby.unsw.edu.au>

# Chlamydia in Australia

## What's the latest data on chlamydia?

In 2022, there were:



**93,777**  
notifications



**46,465**  
in females



**46,973**  
in males

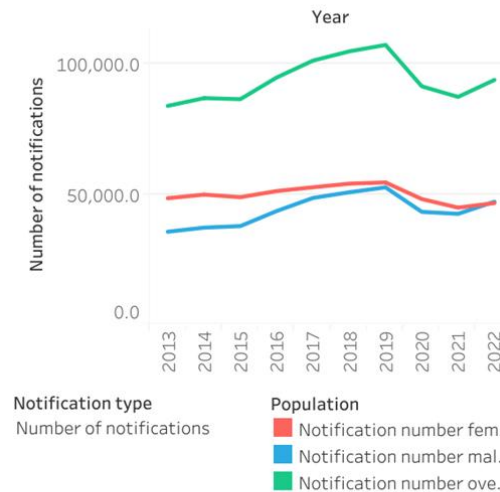


**↑ 12%**  
increase in the  
last 10 years

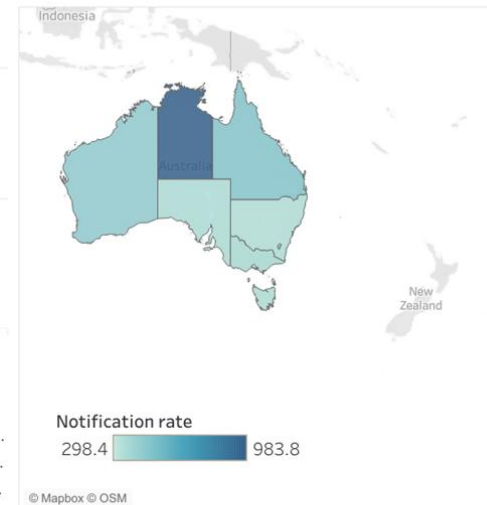


**x2 more cases**  
among Aboriginal and  
Torres Strait Islander  
peoples than  
non-Indigenous people

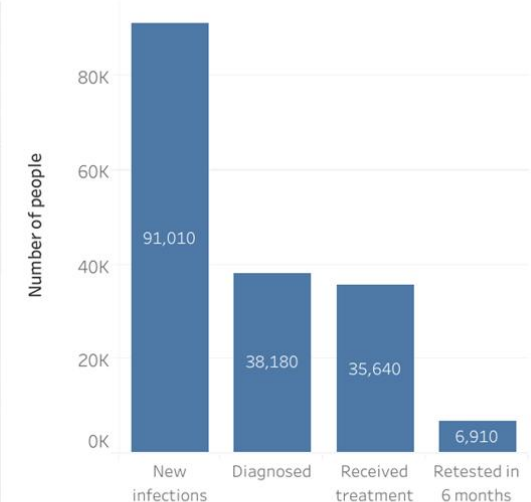
### What are the trends in chlamydia in Australia?



### What do chlamydia notification rates look like across Australia?



### The chlamydia diagnosis and care cascade



### Notification rates versus number of notifications

**Notification rates** are the number of notifications per 100,000 people. **Numbers of notifications** are the numbers of new diagnoses notified to the relevant health authority.

<https://www.data.kirby.unsw.edu.au>

# Gonorrhoea in Australia

## What's the latest data on gonorrhoea?

In 2022, there were:



**32,877**  
notifications



**9,518**  
in females



**23,206**  
in males

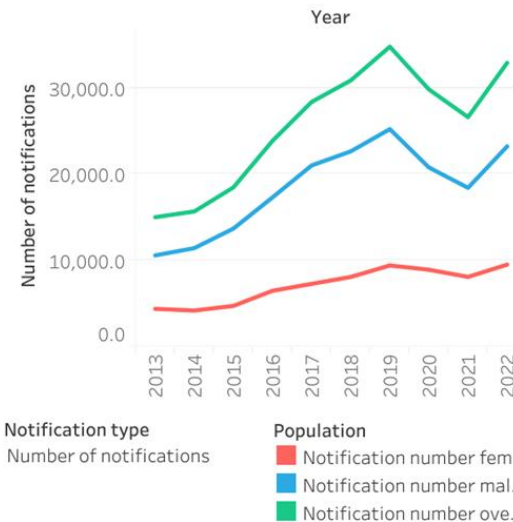


**120%**  
increase in the  
last 10 years

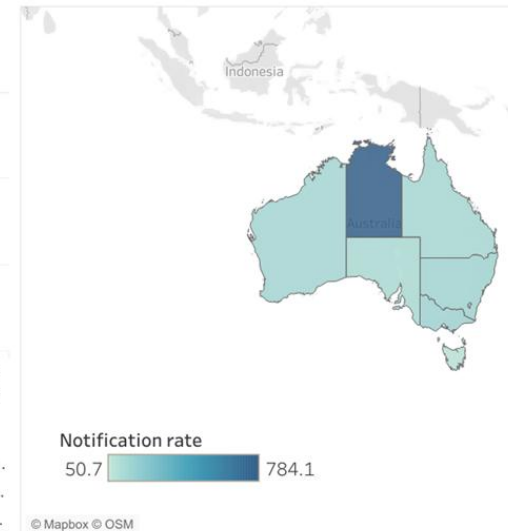


**x5 more cases**  
among Aboriginal and  
Torres Strait Islander  
peoples than  
non-Indigenous people

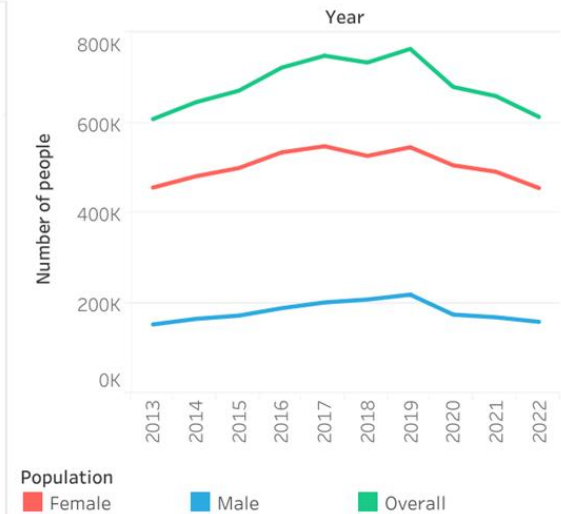
### What are the trends in gonorrhoea in Australia?



### What do gonorrhoea notification rates look like across Australia?



### How many people have been tested for gonorrhoea?

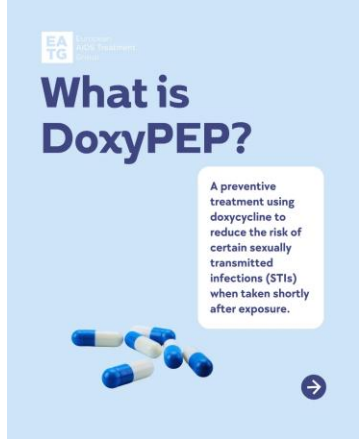


### Notification rates versus number of notifications

**Notification rates** are the number of notifications per 100,000 people. **Numbers of notifications** are the numbers of new diagnoses notified to the relevant health authorit..

<https://www.data.kirby.unsw.edu.au>

# What is DoxyPEP



- Involves taking 200mg doxycycline within 24 hours (up to 72 hours) after sexual intercourse
  - In Australia indicated for gay or bisexual men or trans women to reduce **syphilis**
  - No more than two doses a week
- DoxyPEP has been shown to reduce STI incidence among GBMSS and transgender women in series of randomized, open-label trials <sup>1,2</sup>
  - Syphilis (by 70–80%)
  - Chlamydia (by 70–90%),
  - Gonorrhoea (0 to 50–55% due to varying levels of tetracycline resistance in gonococcal isolates in different populations).


1:ASHM DoxyPEP Consensus statement 2023

2: European AIDS treatment group –Jan 2025

# DoxyPEP –How to Take

## *Doxy PEP – How to Take*

**Two 100 mg pills of doxycycline ideally within 24 hours but no later than 72 hours after condomless oral, anal or vaginal sex**

 = sex without a condom including oral sex

Example: Sex on Sat; take dose of doxy by Tues



Example: Sex on Thursday; take dose of doxy by Sunday

In Australia guidelines recommend no more than two doses/week



# Who is DoxyPEP recommended for

- GBMSM/trans women with a syphilis diagnosis in previous 6 – 12 months, or 2 or more other bacterial STI diagnoses within the past 6 – 12 months.
- GBMSM/trans women who identify an upcoming period of heightened STI risk
- GBMSM/trans women with concurrent sexual partners with a uterus
- + No contraindications to Doxycycline

## **Our clinic SOPs also recommend:**

- PLHIV are on ART/undetectable viral load
- On PREP (daily or on demand)

HERE'S WHAT YOU  
NEED TO KNOW  
ABOUT DOXY-PEP



# How to Prescribe Doxy-PEP in Primary Care

## Four Simple Steps

### 1. Suitability



### 2. Assessment and Testing



### 3. Prescribing Doxy-PEP



### 4. Ongoing Monitoring



## Doxy-PEP Decision Making Tool

Doxy-PEP is 200mg of doxycycline taken after sexual contact by gay or bisexual men, or trans women to reduce risk of syphilis



### 1. Suitability



Gay and bisexual men and trans women<sup>1</sup> who

- Are at increased risk of syphilis (See below), or
- Are at increased risk of serious consequences of chlamydia<sup>2</sup> or syphilis, e.g.
  - Psychosocial consequences
  - Transmission to women (or person with a uterus).

#### And

- Have no contraindications to taking doxycycline<sup>3</sup>
- Makes an informed decision after considering risks and benefits to take doxy-PEP.

#### Population Risk Factors

Markers of syphilis/STI risk in gay and bisexual men and trans women to consider for doxy-PEP

- Recent diagnosis (e.g. within the last year) of infectious/early syphilis (e.g. primary, secondary or evidence of acquisition within two years)
- Recent diagnoses (e.g. two or more within 12 months) of other bacterial STIs (e.g. gonorrhoea, chlamydia)
- Periods of increased risk (e.g. sex parties, chemsex, holidays)
- At risk-patients who have both cis male and partner/s with a uterus, to protect their partners from syphilis and chlamydia.

Opportunities to discuss risk and consider Doxy-PEP if:

- Starting or continuing HIV PrEP<sup>4</sup>
- Seeking STI testing because of risk<sup>5</sup>

### 2. Assessment and Testing



Part of a holistic and comprehensive sexual health approach including STI, HIV and blood-borne virus testing and vaccination which should include:

- [Assess and offer HIV pre-exposure prophylaxis \(PrEP\)](#) if there is an identified risk of HIV
- Provide referrals to HIV care for people living with HIV and encourage sustained engagement where appropriate
- Conduct testing for STIs and blood-borne viruses in line with the [Australian STI Management Guidelines](#)
- [Offer vaccinations as indicated](#) (mpox, hepatitis A and B, HPV)
- Patient education (See Box 1).

### 3. Prescribing Doxy-PEP



#### Explain dosing

200mg (2x100mg) tablets within 24 hours and no later than 72 hours after sexual contact. Doxy-PEP should be taken within 72 hours of sexual encounter(s), with a maximum dose of 200mg every 72 hours (See Box 1 over page).

#### Prescribe

Doxycycline 100mg tablet, 2 tablets PO, (200mg) within 24 hours (up to 72 hours), max 200mg/72 hours.

#### Quantity

- Only 7 tablets + 1 repeat are PBS subsidised (unrestricted)
- Estimate quantity based on expected frequency of use, patient wishes and duration of next review (e.g. median 10 tablets/month in studies, patient prefers enough to last until expected 6 month review = 60 tablets)
- Larger quantities can be prescribed as a private prescription for total quantity or for 28 tablets plus sufficient repeats.

### 4. Ongoing Monitoring



- [Ongoing/regular STI testing](#) (gonorrhoea, chlamydia, syphilis and HIV if not already HIV positive)
- No specific additional monitoring for those taking doxy-PEP (e.g. renal or liver) is required
- Review ongoing need for doxy-PEP and patient preferences. Consider duration of review for ongoing prescriptions (e.g. 6 months)

# Step 1: Suitability

## 1. Suitability



Gay and bisexual men and trans women<sup>1</sup> who

- Are at increased risk of syphilis (See below), or
- Are at increased risk of serious consequences of chlamydia<sup>2</sup> or syphilis, e.g.
  - Psychosocial consequences
  - Transmission to women (or person with a uterus).

### And

- Have no contraindications to taking doxycycline<sup>3</sup>
- Makes an informed decision after considering risks and benefits to take doxy-PEP.

### Population Risk Factors

Markers of syphilis/STI risk in gay and bisexual men and trans women to consider for doxy-PEP

- Recent diagnosis (e.g. within the last year) of infectious/early syphilis (e.g. primary, secondary or evidence of acquisition within two years)
- Recent diagnoses (e.g. two or more within 12 months) of other bacterial STIs (e.g. gonorrhoea, chlamydia)
- Periods of increased risk (e.g. sex parties, chemsex, holidays)
- At risk-patients who have both cis male and partner/s with a uterus, to protect their partners from syphilis and chlamydia.

Opportunities to discuss risk and consider Doxy-PEP if:

- Starting or continuing HIV PrEP<sup>4</sup>
- Seeking STI testing because of risk<sup>5</sup>

## Box 1: Patient Education



- Doxy-PEP is not 100% effective: approximately 80% for syphilis and chlamydia, and much less or not effective against gonorrhoea. Continue to test for STIs, particularly syphilis and HIV.
- Clinical need for, and ideal frequency of, testing for asymptomatic gonorrhoea and chlamydia is not known
- HIV and syphilis blood testing have important clinical and public health benefits
- [Side effects and how to manage them](#) (e.g. reflux, nausea, rash/photosensitivity).

### Antimicrobial resistance

- Normal body bacteria (skin, intestines) may develop resistance – the health impact is not known.
- Similar to other ongoing use indication for tetracyclines, taking doxy-PEP may contribute to overall antibiotic resistance in the community.

## Assess contraindications and drug interactions

Contraindications,  
drug-drug interactions,  
and dose adjustments

- Doxy-PEP should not be used concurrently with other doxycycline therapy (or any other tetracycline-class antibiotic) for treatment or prevention of a health condition (e.g., acne, rosacea, malaria prophylaxis).
- No significant drug-drug interactions exist between doxycycline and ARVs used for HIV treatment or PrEP.
- No known drug reactions exist between doxycycline and gender-affirming hormone therapies.
- No doxycycline dose adjustments are indicated for patients with renal dysfunction.
- Doxycycline is generally contraindicated during pregnancy because of potential adverse effects on the fetus.

Note – drug interaction between Roaccutane and Doxycycline  
Potential increased risk of intracranial hypertension

# Step 2: Assessment and Testing

## 2. Assessment and Testing



Part of a holistic and comprehensive sexual health approach including STI, HIV and blood-borne virus testing and vaccination which should include:

- [Assess and offer HIV pre-exposure prophylaxis \(PrEP\)](#) if there is an identified risk of HIV
- Provide referrals to HIV care for people living with HIV and encourage sustained engagement where appropriate
- Conduct testing for STIs and blood-borne viruses in line with the [Australian STI Management Guidelines](#)
- [Offer vaccinations as indicated](#) (mpox, hepatitis A and B, HPV)
- Patient education (See Box 1).

Use These Guidelines



## STI results and diagnosis

Interpreting STI results and diagnosis and management of concurrent STIs:

**No change with doxy-PEP**

- Syphilis serology interpretation – [as per guidelines](#)
- Sexual contacts of syphilis – [treat as per guidelines](#)
- Test and manage sexual contacts of other bacterial STIs according to [guidelines](#), and wait for results in most cases, except when there has been recent contact with gonorrhoea.
- Anyone diagnosed with gonorrhoea should have a swab collected for gonococcal culture prior to the administration of antibiotics.
- Risk or sexual contact with HIV: [post-exposure prophylaxis \(PEP\)](#) and [pre-exposure prophylaxis \(PrEP\)](#) as per guidelines.

# Step 3: Prescribing DoxyPEP

## 3. Prescribing Doxy-PEP



### Explain dosing

200mg (2x100mg) tablets within 24 hours and no later than 72 hours after sexual contact. Doxy-PEP should be taken within 72 hours of sexual encounter(s), with a maximum dose of 200mg every 72 hours (See Box 1 over page).

### Prescribe

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### Quantity

- Only 7 tablets + 1 repeat are PBS subsidised (unrestricted)
- Estimate quantity based on expected frequency of use, patient wishes and duration of next review (e.g. median 10 tablets/month in studies, patient prefers enough to last until expected 6 month review = 60 tablets)
- Larger quantities can be prescribed as a private prescription for total quantity or for 28 tablets plus sufficient repeats.

- 200 mg of doxycycline should ideally be taken within 24 hours after condomless sex, up to 72 hours maximum.
- No more than 2 doses of 200 mg of doxycycline should be taken in a 7-day period.
- Milk and vitamins containing positive cations (e.g., calcium, zinc, magnesium) should be avoided within 2 hours of taking doxycycline
  - Interfere with doxycycline absorption and may lower doxycycline levels, potentially reducing efficacy.

## Counsel re cautions and adverse effects

### Adverse effects

- GI adverse effects are common; taking doxycycline with food may help alleviate nausea or GI upset. Symptoms including nausea, vomiting, and reflux can be severe enough to require cessation of doxycycline.
- Esophageal injury and irritation can occur. Doxycycline should be taken with an 8-oz glass of [water](#) and the individual should remain upright for 30 minutes to 1 hour after dosing.
- Skin photosensitivity and phototoxicity can occur; wearing sunscreen, limiting sun exposure, and avoiding tanning beds can help prevent sunburn and other skin injury.
- Intracranial hypertension is a rare but serious adverse effect. Refractory headaches or vision changes should be evaluated promptly by a clinician.
- Doxycycline use may select for antibiotic-resistant organisms, which can cause infections in some circumstances and can disrupt the microbiome.



# Ongoing Monitoring

## 4. Ongoing Monitoring

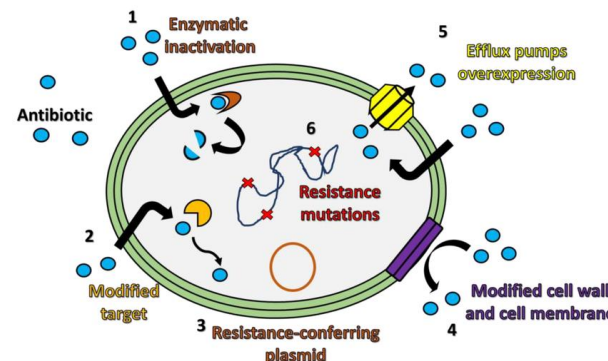


- Ongoing/regular STI testing (gonorrhoea, chlamydia, syphilis and HIV if not already HIV positive)
- No specific additional monitoring for those taking doxy-PEP (e.g. renal or liver) is required
- Review ongoing need for doxy-PEP and patient preferences. Consider duration of review for ongoing prescriptions (e.g. 6 months)

# DoxyPEP and Anti-Microbial resistance



- Concerns regarding impact of scale up DoxyPEP on individual and population level antimicrobial resistance (AMR)
- To date there are no reported cases of tetracycline resistance in chlamydia and syphilis
- Rates of gonorrhoea resistant to tetracyclines ranges from country to country and population to population (12-90%)
- Evidence that DoxyPEP use is resulting in increased tetracycline resistance in gonorrhoea (? Significance of this)
- Also concerns re impact on the microbiome and off-target effects (GAS and S.aureus)



# Summary DoxyPEP

## Benefits

- Evidence of marked reduction of syphilis and chlamydia incidence with no immediate threat for resistance
- Well tolerated and shown to be highly acceptable with good adherence

## HOWEVER

- Ongoing monitoring and research for AMR is needed
  - Selection and dissemination resistant NG
  - Impact on microbiome and other commensals

## **\*Recent recommendations to consider to safely scale up DoxyPEP**

- Limit dose of DoxyPEP to once per week ?
- Don't use Doxycycline to treat RTIs/other infections in people taking DoxyPEP
- Continue active surveillance

\*Not in guidelines yet



Vs



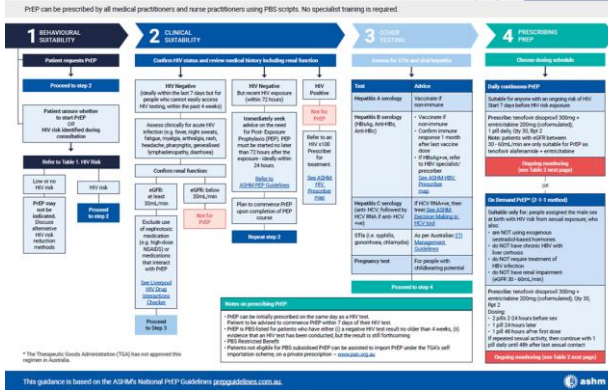


# Questions and Discussion

## PAN PrEPaccessNOW



Prescribing Oral HIV Pre-Exposure Prophylaxis (PrEP) in Australia



NOW OFFERING

## DOXYCYCLINE AS STI PEP

A NEW TOOL TO HELP PREVENT THE SPREAD OF SEXUALLY TRANSMITTED INFECTIONS

TALK TO YOUR PROVIDER TO SEE IF DOXY AS STI PEP IS RIGHT FOR YOU!

## AusDoc.

Home Articles CPD Events Order Samples

Find out how GPs are striving to deliver a better experience for patients and staff. [Read here](#)

6 minutes News

### Morning-after antibiotics may help curb STIs

A common antibiotic reduced the chance of contracting chlamydia or syphilis in men who have sex with men: study

HealthDay News

13 March 2023 Save

Using doxycycline about 72 hours after unprotected sex prevented chlamydia and syphilis cases in high risk groups, researchers have reported.

The findings looked at the effect of the antibiotic on men who have sex with men and in transgender women, and were presented last month at the Conference on Retroviruses and Opportunistic Infection.

The antibiotic had been slightly less effective for gonorrhoea, but treatment with a meningitis vaccine has already cut those cases in half, *The New York Times* reported.

### Doxy-PEP Decision Making Tool

Doxy-PEP is 200mg of doxycycline taken after sexual contact by gay or bisexual men, or trans women to reduce risk of syphilis

#### 1. Suitability

Gay and bisexual men and trans women who

- Are at increased risk of syphilis (See below), or
- Are at increased risk of serious consequences of chlamydia or syphilis, e.g.
  - Psychosocial consequences
  - Transmission to women (or person with a uterus).

**And**

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**Population Risk Factors**

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#### 3. Prescribing Doxy-PEP

**Explain dosing**

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