

Clinical Zoom

HIV PrEP

Sexual Health Questions and Answers with Dr Jane Morgan

July 2022

Topics we will cover

- HIV pre and post exposure
- Q and A with Dr Jane Morgan

Resources

ASHM prep guidelines (https://www.ashm.org.au/hiv/prep/)

BPAC guideline (https://bpac.org.nz/2019/prep.aspx)

Goodfellow webinar (https://www.goodfellowunit.org/events/hiv-prep-update-primary-care)

Burnett Foundation (https://www.burnettfoundation.org.nz/learn/staying-safe/prep/prep-information-for-clinicians/)

Health Navigator (https://www.healthnavigator.org.nz/medicines/p/pre-exposure-prophylaxis-prep/)

Dynamed (https://www.dynamed.com/prevention/preexposure-prophylaxis-prep-for-hiv)





HIV update PrEP changes

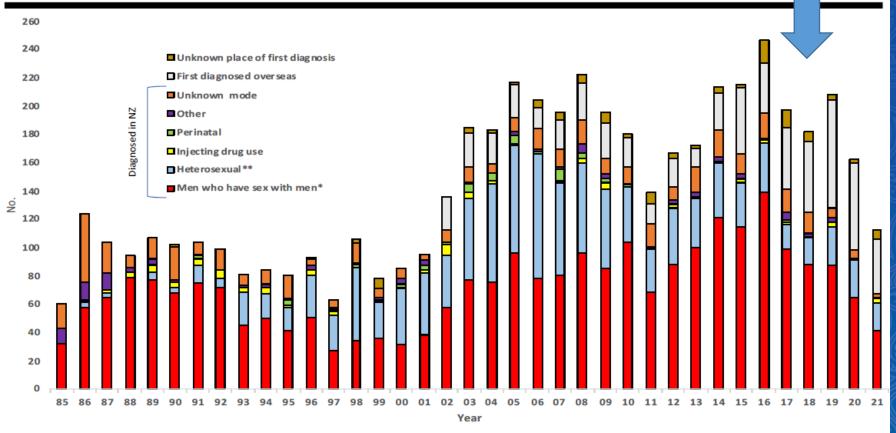


Figure 1. Number of people diagnosed with HIV in New Zealand by year of diagnosis and means of acquisition of HIV and, since 2002, the number of people first diagnosed overseas. (Infection may have occurred a number of years prior to diagnosis)
*Includes MSM & injecting drug use (IDU) **Includes Heterosexual & IDU



78% of those newly diagnosed with HIV with a known mode of transmission were men who had sex with men (MSM), 19% contracted HIV heterosexually, 0.7% acquired HIV through injecting drug use (IDU), 0.7% were perinatal (overseas) 2% obtained the infection through other means. Around 1.7% were transgender.

MSM are estimated to be 187 times more likely to be living with diagnosed HIV than heterosexual men and women.

No deaths from AIDS were reported in 2021 (Figure 5). It is possible, however, that this number could rise due to delayed reports.

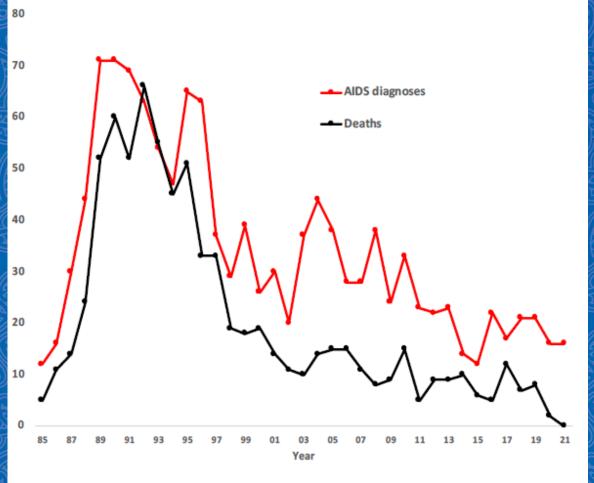


Figure 5. Annual number of diagnoses of AIDS and deaths among people notified with AIDS (The number of notifications and deaths for 2021 are expected to rise due to delayed reports)



An estimated 2964 living with HIV in NZ currently.

Equity

- Among Māori, the majority of HIV diagnoses occur among takatāpui (Māori MSM).
- Evidence from 2011 suggests Māori MSM have the same prevalence of HIV as other NZ MSM, although it is less frequently diagnosed.
- The proportion of new HIV diagnoses among MSM who were Māori has remained relatively stable at around 10%,
- Surveillance data shows Māori MSM are more likely than other NZ MSM to present with advanced HIV disease (CD4 < 200 cells/μL).
- There has been a doubling over time in the proportion of MSM newly diagnosed with HIV reporting an Asian ethnicity.



Not a panacea

Box 3.1 Priority actions from the Consensus Statement.¹⁰ Adapted from Saxton et al. 2015¹¹

Action	Purpose
(1) Sophisticated promotion of condoms to protect against HIV and STIs during anal and vaginal intercourse, and continuation of needle and syringe exchange programs	To interrupt HIV and STI transmission
(2) Timely, more frequent and widespread HIV testing by improving access to testing services in clinical and community settings	To reduce the number with undiagnosed HIV infection
(3) HIV antiretroviral treatment to be offered following diagnosis, and ongoing retention in health care, to achieve and maintain an undetectable viral load	To minimise transmission and maximise personal wellbeing of people with confirmed HIV infection
(4) Pre-exposure prophylaxis (PrEP) and quarterly STI screening to be made available to people without HIV at high risk and unable to sustain behavioural risk reduction	To target the most vulnerable people who also play a disproportionate role in onward HIV transmission
(5) Improved access to comprehensive STI vaccination, screening and treatment	To control resurgent STI epidemics which synergise with HIV control
(6) Ongoing surveillance and research into HIV and STI infections and risk behaviours	To enable evidence-based decision making, evaluate progress and prompt agile responses



PrEP – pre exposure prophylaxis for HIV

tenofovir disoproxil with emtricitabine (TD/FTC)

New Criteria:

- confirm that the patient is HIV negative,
- consider the patient is at elevated risk of HIV exposure and
- use of PrEP is clinically appropriate



Who is at risk?

Risk factor	HIV incidence per 100 person years (95% CI)
All gay and bisexual men regardless of behavioural practices	0.78 (0.59-1.02)
A regular sexual partner of an HIV-positive man with whom condoms were not consistently used in the last 6 months	5.36 (2.78-10.25)
At least one episode of receptive, unprotected anal intercourse with any casual male partner with HIV infection or a male partner of unknown HIV status during the last 6 months	2.31 (1.48-3.63)
Rectal gonorrhoea diagnosis in last 6 months	7.01 (2.26-21.74)
Rectal chlamydia diagnosis in last 6 months	3.57 (1.34-9.52)
Methamphetamine use in last 6 months	1.89 (1.25-2.84)
More than one episode of anal intercourse during the last 3 months when proper condom use was not achieved (e.g. condoms slipped off or broke)	1.30 (0.95-1.77)
A regular sexual partner of CLAI or having at least one episode of insertive CLAI where the serostatus of partner is not known or is HIV positive	0.94 (0.35-2.52)
In uncircumcised men having at least one episode of insertive CLAI where the serostatus of partner is not known or is HIV positive	1.73 (0.43-6.90)
In circumcised men (comparison group, low risk, PrEP not recommended)	0.65 (0.16-2.61)

Table 3.1 Factors associated with elevated risk of HIV acquisition among men who have sex with men in the Health in Men (HIM) study, Australia, 2001–2007¹⁷

Note that while the HIM study uses the terminology of 'gay and bisexual men', this guideline uses 'men who have sex with men' to focus on behaviour rather than identity

CI: confidence interval;

CLAI: condomless anal intercourse;

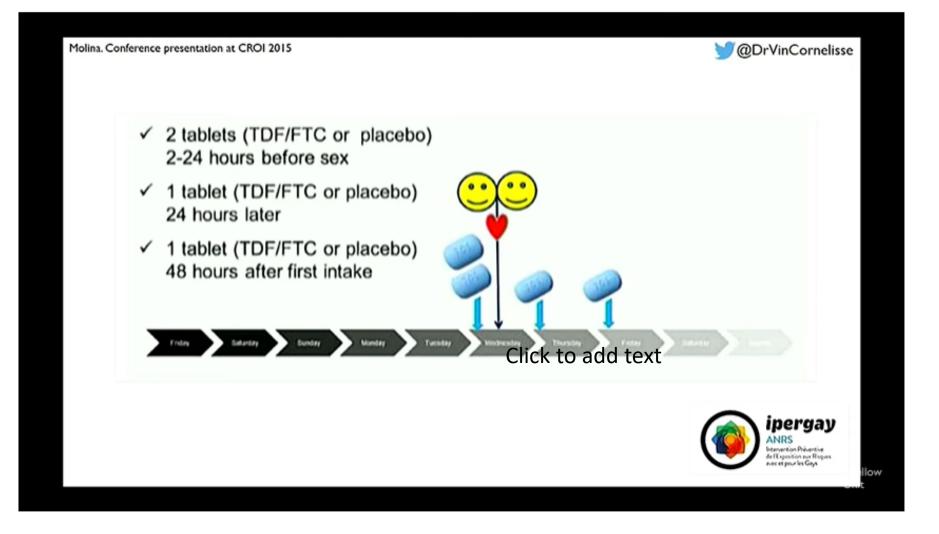
HIV: human immunodeficiency virus;

PrEP: pre-exposure prophylaxis

Event driven vs daily PrEP

- Daily use of TD/FTC is highly efficacious at preventing HIV transmission in MSM, heterosexuals, transgender women and people who inject drugs in the setting of high medication adherence.
- Event-driven PrEP involves taking 2 tablets of TD/FTC 2–24 hours before
 a potential sexual exposure to HIV, followed by a third tablet 24 hours after
 the first dose and a fourth tablet 48 hours after the first dose.
- This regimen is referred to as The 2 + 1 + 1 dosing of PrEP.





If sex continues for several days, people take one tablet of TD/FTC daily until the last sex act, following which one dose 24 hours later and again at 48 hours are taken after the last episode of sex.



Recommendations

Daily TD/FTC dosing for all populations suitable for PrEP.

Event driven on-demand PrEP should only be offered to cis-gender MSM.

- -when this preference is expressed,
- when the person has at-risk sex less than twice a week and
- when sex can be delayed for 2 hours.

Daily PrEP is the only suitable regimen for cis-gender MSM with chronic hepatitis B infection.



Ongoing monitoring

mL/min/1.73 m2

Test		3 months after initiation	Every 3 months while on PrEP	Every 6 months while on PrEP	Annually
HIV testing		✓	✓		
Hepatitis C serology					✓
STI screen	Syphilis serology	✓	✓		
Ensure all applicable	Gonorrhoea	✓	✓		
sites tested (pharyngeal, rectal, and urine NAT)	Chlamydia	√	✓		
Complete Blood Count (CBC)				✓	
Liver Function Tests (LFT's)				✓	
*Phosphate		✓			✓
HbA1c		✓			✓
"eGFR and protein/creatinine ratio (urinary)		✓		✓	
Pregnancy test		✓	✓		

Testing for HIV, syphilis, and a full STI screen needs to have occurred in the previous two weeks
Hep B if not immune.

Renal function testing (creatinine, phosphate, and urine protein creatinine ratio) within the previous 3 months

Baseline blood pressure reading, urinalysis, full blood count and liver function tests





Side Effects

- Generally mild and transient.
- Gastrointestinal symptoms, e.g. nausea, vomiting, abdominal pain, flatulence, diarrhoea, and headache are most frequently experienced.
- These are most likely to be reported in the first month of treatment.
- There is an increased risk of hepatic adverse effects in patients with chronic hepatitis.
- Renal toxicity
- The bone density of patients taking PrEP may be reduced slightly
- HIV partial treatment (inc risk of multidrug resistant HIV)
- HepB flare





PRESCRIBING HIV PRE-EXPOSURE **PROPHYLAXIS (PrEP) IN NEW ZEALAND**

Confirm HIV status and review medical history

including renal function

HIV Negative

But recent HIV exposure

(within 72 hours)

Immediately seek advice

discuss with a local ID

physician on the need

for 3-drug nPEP. If 2-drug

nPEP is recommended.

prescribe PrEP with

advice for immediate

start.

Plan to commence PrEP

upon completion of nPEP

course.





BEHAVIOURAL ELIGIBILITY

Patient requests PrEP Patient unsure whether

to start PrEP

HIV risk identified during consultation

Refer to HIV risks listed overleaf (Table 1)

HIV risk

Low or no HIV risk

Proceed to Step 2

Discuss condoms & other risk reduction methods

Consider self-funded PREP

2 CLINICAL ELIGIBLITY

HIV Negative

(tested within last 14 days)

Assess clinically for

acute HIV infection

(e.g. fever, night sweats,

fatigue, myalgia,

arthralgia, rash, headache,

pharyngitis, generalised

lymphadenopathy,

diarrhoea)

Confirm normal renal

function

(eGFR > 60 mL/min)

Exclude use of

nephrotoxic medication

(e.g. high-dose NSAIDS)

or medications that

interact with PrEP

www.hiv-druginteractions.org

Note: Steps 1.2. 3 & 4 are usually completed at the same visit

Positive

Not for

PrEP

Refer to

a local Id

or sexual

health

physician

3 OTHER TESTING

Assess for STIs, viral hepatitis and other conditions. See Table 2 (overleaf)

STI testing as per the New Zealand STI Management Guidelines www.nzshs.org/guidelines

Hepatitis B serology (HBsAg, Anti-HBs, Anti-HBc) Vaccinate if not immune If HBsAg+ve, refer to gastroenterologist or ID physician as per local pathway

Hepatitis C serology (anti-HCV; followed by HCV RNA if anti-HCV +ve) If HCV RNA+ve, then treat.

www.hepatitisfoundation.org.nz

Proceed to Step 4

Daily continuous PrEP

PRESCRIBING

4 PRES

Suitable for anyone with an ongoing risk of HIV.

1 pill daily of tenofovir/emtricitabine. Start 7 days before HIV risk.

Proceed to Step 5

Event driven PrEP (2-1-1 method)

Suitable only for cis-gender men who have sex with men whose HIV risk is from anal sex rather than injecting drug use. For info on effectiveness, see full ASHM guidelines.

Tenofovir/Emtricitabine:

- · 2 pills at least 2h before sex (up to 24h before sex)
- 1 pill 24h later
- · 1 pill 48h after first dose If repeated sexual activity, then continue with 1 pill daily until 48h after last sexual contact.

ONGOING MONITORING

Ongoing monitoring See Table 2 (overleaf)

Patient education

Discuss how PrEP works. frequency, missed dose protocol, continued condom use. See Box 1 (overleaf)

BOX 1: PATIENT EDUCATION

- Discuss the role of condoms to prevent HIV and STIs, and emphasize role of regular STI testing.
- Discuss safer injecting practices, if applicable.
- Discuss PrEP adherence at every
- Ongoing monitoring every 3 months is required, also for event driven
- Discuss potential side effects, early (e.g. headache, nausea) and longer term (e.g. renal toxicity, lowered bone density).
- Ask about nephrotoxic medications. eg NSAIDs.

STOPPING PrEP

- Only cis-gender men who have sex with men (MSM) taking daily or on-demand PrEP can stop 48 hours after last exposure.
- Non-MSM patients on daily PrEP should continue PrEP for 28 days after last exposure.
- Patients who stop PrEP need a plan to re-start PrEP if their HIV risk increases again.

Proceed to Step 3

Repeat Step 2

Making an HIV diagnosis

Refer patient to local DHB infectious diseases or sexual health service. Peer support and counselling available from community organisations www.bodypositive.org.nz and www.nzaf.org.nz















TABLE 1: HIV RISK					
Men who have sex with men (MSM) Trans & gender diverse people		Heterosexual people	People who inject drugs		
High risk of HIV and eligible for funded PFEP 1. Likely to have multiple events of CLAI in the next 3 months; And having any one of the following: At least one episode of receptive CLAI with one or more casual male partners in the last 3 months; Rectal genorrhoea, rectal chlamydia or infectious syphilis diagnosis during the last 3 months; Methamphetamine use in the last 3 months OR 2. CLI with a regular HIV+ partner who is not on treatment and/or has a detectable viral load.		High risk of HIV and eligible for funded PrEP CLI with a regular HIV+ partner who is not on treatment and/or has a detectable viral load.			
Not eligible for funded PrEP; could consider self-funded PrEP Insertive CLAI with any casual male partner (in last 3 months or expected in next 3 months) Travelling to a high-HIV prevalence country and anticipates risk		Not eligible for funded PrEP; could consider self-funded PrEP Receptive CLI with any casual MSM partner (in last 3 months or expected in next 3 months) Travelling to a high-HIV prevalence country and anticipates risk	Not eligible for funded PrEP; could consider self-funded PrEP Shared injecting equipment with an HIV+ individual or with MSM of unknown HIV status (in last 3 months or expected in next 3 months)		

Notes on prescribing PrEP:

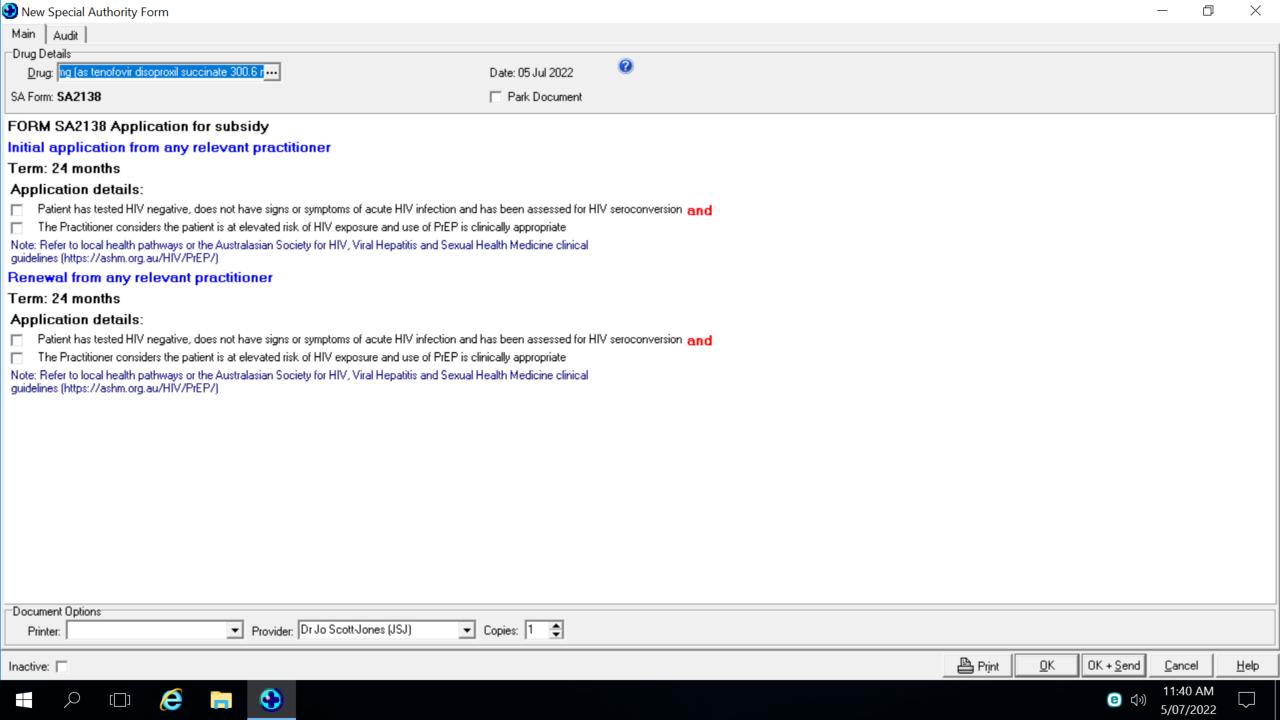
- Prescribe: Tenofovir 300mg + Emtricitabine 200mg (coformulated); 1 tablet daily for 90 days.
- Patient to be advised to commence PrEP within 14 days of negative HIV test. If there is no recent HIV test result, PrEP can be prescribed on the same day as an HIV test and patient advised to only start PrEP once informed the test is negative
- Apply for special authority, search for HIV prophylaxis on: https://www.pharmac.govt.nz
- Patients not eligible for PHARMAC funded PrEP can self-fund from a NZ pharmacy or can self import PrEP under the self importation scheme: www.endinghiv.org.nz/stay-safe/prep.

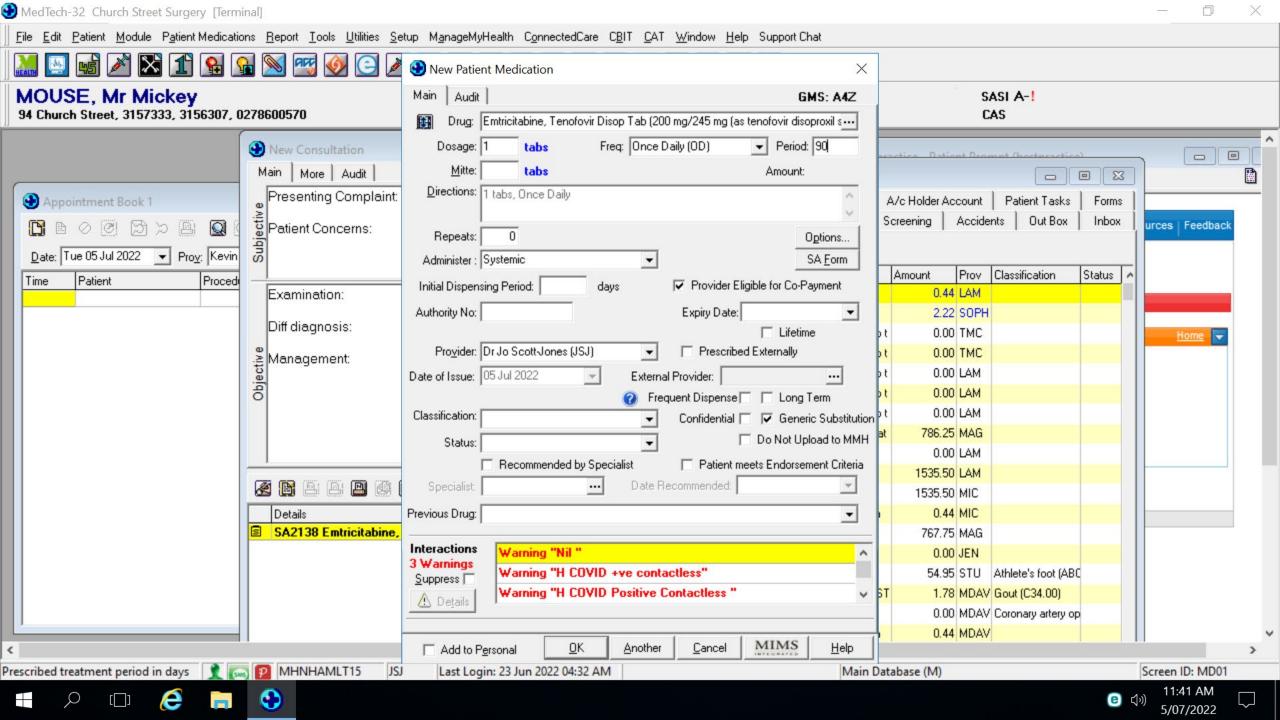
CLI: Condomiess intercourse; MSM: Men who have sex with men; els men: assigned male at birth; CLAI: condomiess anal intercourse

TABLE 2: LABORATORY EVALUATION AND CLINICAL FOLLOW-UP OF INDIVIDUALS WHO ARE PRESCRIBED PreP

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	Υ	Y Retest HIV if any doubt about window period for baseline HIV test. Can be done by giving client a lab form to do this and does not require a visit.	Y	Y	N
Full blood count	Υ	N	N	N	N .
Phosphate	Y	N	N	N	Y Every 12 months
Urine analysis	Υ	N	N	N	N .
Assess side-effects	N	Υ	Υ	Υ	N .
Hepatitis A serology. Vaccinate if non-immune.	Υ	N	N	N	N .
Hepatitis B serology. Vaccinate if non-immune.	Υ	N	Y (if not immune)	Y (if not immune)	Y If patient required hep B vaccine at baseline, confirm immune response to vaccination 1 month after last vaccine dose
Hepatitis C serology	Y	N	N	N	Y Every 12 months, or more frequently if ongoing risk e.g. non-sterile injecting drug use and MSM with sexual practices that predispose to anal trauma
Liver function tests	Y	N	N	N	Y Every 6 months
STI (i.e. syphilis, gonorrhoea, chlamydia) as per www.nzshs.org/guidelines	Y	N	Y	Υ	N .
eGFR at 3 months and then every 6 months	Υ	N	Υ	N	Y At least every 6 months or according to risk of chronic kidney disease
Urine protein:creatinine ratio (PCR) baseline	Υ	N	Υ	N	Y At least every 6 months
Pregnancy test (for people who may become pregnant)	Υ	Υ	Υ	Υ	N .









Q and A with Dr Jane Morgan