

Oral pre-exposure prophylaxis (PrEP)

Frequently asked questions

Based on the *Updated Guidelines for the provision of oral pre-exposure prophylaxis (PrEP) to persons at substantial risk of HIV infection*, published October 2021, National Department of Health, South Africa

What is PrEP?

Pre-exposure prophylaxis (PrEP) is an effective option for HIV-negative people to prevent contracting HIV **before** potential exposure. The HIV-negative person takes a fixed dose combination of two antiretrovirals – tenofovir (TDF) and emtricitabine (FTC) – on a daily basis.

Who should be considered for PrEP?

Any person requesting or requiring PrEP, even if the healthcare worker does not perceive this person to be at risk.

People considered to be high-risk for HIV include:

- men who have sex with men (MSM)
- sex workers
- adolescents and young women and men
- migrant workers
- pregnant and breastfeeding women
- people who have more than one sexual partner
- people who inject drugs
- people with a recent history of STI(s)
- people who recognise their own risk and request PrEP
- serodiscordant couples, if the HIV-positive partner's viral load is not suppressed

How long before PrEP is active?

When first starting PrEP, it needs to be taken consistently for 7 days before it provides its full protection. Clients should be advised to avoid having sex or to use condoms during this period.

Who cannot use PrEP?

- People who are HIV-positive
- People with poor kidney function (Table 1):
 - * Adults and adolescents ≥ 16 years: eGFR < 50 mL/min
 - * Adolescents ≥ 10 and < 16 years: eGFR < 80 mL/min
 - * Pregnant clients: serum creatinine (sCr) > 85 $\mu\text{mol/L}$

If the client has symptoms or signs of acute HIV infection, PrEP should be postponed until symptoms subside and a repeat rapid HIV test after 4 weeks remains negative.

PrEP in pregnancy and breastfeeding?

The choice to start, continue or discontinue PrEP during pregnancy and breastfeeding, should be made by the client, following a discussion of the risks and benefits with the healthcare provider.

The key message for risk/benefit counselling for pregnant and breastfeeding clients:

the benefits of taking PrEP during pregnancy and when breastfeeding for an HIV-negative client, far outweighs the risk of any possible harm to the mother and baby. The WHO recommends that PrEP is safe for use in pregnant or breastfeeding clients at substantial risk of HIV infection.

How are clients on PrEP monitored?

Routine creatinine monitoring is not required in all populations (Table 1). Monitoring includes HIV testing, hepatitis B surface antigen screen (at baseline), STI syndromic screening, pregnancy screen and creatinine monitoring/eGFR in some populations (Table 2). Clients with acute or chronic hepatitis B may need liver function tests done.

Table 1: Assessing renal function

Age/pregnant	Measurement used	Acceptable level for PrEP use
≥ 10 and < 16 years	eGFR using Counahan Barratt formula (below)	> 80 mL/min/1.73m ²
≥ 16 years	eGFR	> 50 mL/min/1.73m ²
Pregnant	Serum creatinine	< 85 $\mu\text{mol/L}$
Criteria for and frequency of eGFR and sCr monitoring		
Age/pregnant	Co-morbidity	When to do creatinine
< 30 Years	None	Not required
≥ 30 Years	None	Baseline
All (except pregnancy)	Diabetes and/or hypertension	Baseline and annually
Pregnancy	N/A	Baseline, 3 and 6 months

The Counahan Barratt formula:

$$\text{eGFR (mL/min/1.73 m}^2\text{)} = \frac{\text{height (cm)} \times 40}{\text{Creatinine } (\mu\text{mol/L)}}$$

Table 2: Baseline investigations and monitoring

Investigation	Action to be taken
HIV Test (use algorithm in National HTS guidelines)	If client is HIV-positive, initiate on ART. If client is HIV-negative, screen for PrEP. Repeat HIV test after 1 month of PrEP initiation, then 3-monthly thereafter.
Hepatitis B surface antigen (HBsAg)	If HbsAg negative : start PrEP and assess eligibility for vaccination, if available and not already vaccinated. If HbsAg positive : start PrEP and refer to a doctor for liver function monitoring and management of Hepatitis B infection. Clients with acute or chronic hepatitis B infection can be safely initiated on PrEP but require liver function monitoring.
Syndromic STI screening	Treat STI if present. Repeat at every visit.
Pregnancy screening	As per WHO guidance, PrEP may be offered to pregnant client at substantial risk of HIV. If the client is not pregnant, offer contraception.
Renal function (eGFR and sCr)	See Table 1, above.

Safety of PrEP

The use of TDF and FTC is safe, with minimal side-effects in most users. Some individuals may report minor side effects in the first month of PrEP use, such as nausea, diarrhoea, abdominal pain and headache. More serious side-effects are rare and may include kidney damage and a decrease in bone mineral density.

What happens if the PrEP user tests HIV-positive?

Offer lifelong antiretroviral treatment if the PrEP user tests HIV-positive. Complete the *Oral PrEP seroconversion reporting form* (see *NDoH 2021 Updated PrEP Guidelines*).

Switching from PEP (post-exposure prophylaxis) to PrEP

After completing PEP (28 days), a client can be moved to PrEP if counselling reveals that they will be at continued risk for HIV after PEP is completed. The client can start TDF + FTC immediately after PEP is completed.

Signs of acute HIV Infection

Signs and symptoms include, but are not limited to:

- a general feeling of discomfort or illness
- loss of appetite
- body aches
- headache
- sore throat
- rash
- fever
- sweating
- swollen and sore glands

Advise the PrEP user to report immediately to their healthcare provider if they are experiencing any of the symptoms of acute HIV infection. Postpone initiation of PrEP in persons who are showing symptoms that may indicate HIV infection until their symptoms resolve and a repeat rapid HIV test after 4 weeks remains negative.

What if a dose of PrEP is missed?

The PrEP user should take their medicine as soon as they remember and continue to take daily, as before.

Can the PrEP user interrupt/stop PrEP?

Yes. PrEP can be stopped if the PrEP user is no longer at risk of HIV infection. PrEP should, however, be continued for at least 7 days after the last exposure. PrEP users with chronic hepatitis B should be carefully monitored when they discontinue PrEP. PrEP can be restarted if the person's risk of being infected with HIV changes.

PrEP should be stopped if there are safety concerns where the risks of PrEP outweigh potential benefits, or if the client:

- Tests HIV-positive
- Has persistently low eGFR or high sCr levels (in pregnancy)
- Is non-adherent to PrEP
- No longer needs or wants PrEP

What if the PrEP user is infected with hepatitis B?

TDF and FTC both have hepatitis B antiviral activity. PrEP users with chronic hepatitis B should be carefully monitored when they discontinue PrEP as discontinuation may cause serious liver damage resulting from reactivation of hepatitis B virus. These patients, in consultation with their healthcare provider, may decide to continue using TDF to control their hepatitis.

Should I advise the PrEP user to continue using condoms?

Yes. If PrEP is taken daily, it offers protection against HIV only. PrEP does not protect against other sexually transmitted infections (STIs) or pregnancy.

The best protection against HIV, STIs and pregnancy is to take PrEP every day, together with consistent and correct use of condoms.

How can a PrEP user further decrease their risk?

- Avoid having unprotected sex: use condoms correctly with every exposure.
- Knowing their and their partner's HIV status is extremely important. Ensure the PrEP user and partner come for regular HIV testing.
- If the partner is HIV-positive, confirm that the partner is on ARVs and virologically suppressed.
- Avoid recreational or injectable drugs.
- For males, consider medical circumcision.
- Avoid sex under the influence of alcohol and/or drugs.
- Advise your client to always seek medical attention if they have had unprotected sex and they are not taking PrEP. Post-exposure prophylaxis (PEP) should be taken as soon as possible but within 72 hours if a client is exposed to HIV. The client can be transitioned to PrEP immediately after completing 28 days of PEP. PrEP users do NOT need PEP if they take their PrEP correctly.

NEED HELP?

Contact the TOLL-FREE National HIV & TB Health Care Worker Hotline

0800 212 506 / 021 406 6782

Alternatively "WhatsApp" or send an SMS or

"Please Call Me"

to 071 840 1572

www.mic.uct.ac.za



This publication was supported under funding provided by the Global Fund to Fight AIDS, Tuberculosis and Malaria through the National Department of Health of South Africa and the NDoH Pharmacovigilance Centre for Public Health Programmes. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Global Fund or the National Department of Health of South Africa