



PrEPX & PrEPX-SA FAQs

What is HIV PrEP?

Pre-Exposure Prophylaxis (PrEP) is a medication used to HIV prevention in people who do not have HIV to reduce their risk of becoming infected with HIV. It is recommended that PrEP is taken every day to minimise the risk of HIV.

What is the drug that is used for PrEP?

PrEP contains two antiretroviral medicines, tenofovir 'TDF' and emtricitabine also known as 'FTC' (in combination known as 'TDF/FTC'). You may know this medicine by a brand name 'Truvada®', however there are generic forms of this co-formulated medicine containing the same active ingredients. Truvada® in combination with other medicines has been used to treat people living with HIV since August 2004.

How effective is PrEP at preventing HIV infection?

Current evidence shows that regular use of TDF/FTC for HIV PrEP by men who have sex with men provides the highest level of protection when compared to other HIV prevention strategies. In some of the early clinical trials PrEP was not highly effective at preventing HIV infection. For example in the first placebo-controlled study of gay men, PrEP only reduced HIV infection by 44% overall. However, when they looked at the individuals in this study who took PrEP every day, they saw a 99% reduction in HIV infections. In a more recent study where every study participant received PrEP, they saw a reduction in HIV infections of 86%. PrEP reduced HIV infection by 70% in studies of heterosexuals and by about 50% in people who inject drugs. The reason why PrEP's ability to prevent HIV infection varies quite a lot between these studies is mostly related to how well people in the studies were able to take (or adhere to) the study PrEP medication. In gay men and heterosexuals there is evidence that taking the PrEP tablets every day reduces HIV infection by 99%. Taking it only a few days weekly, or not at all will increase the risk of HIV infection. It is important to note that people who participated in these PrEP clinical trials were also using other HIV prevention strategies as much as possible, including using condoms and having regular tests for sexually transmitted infections and HIV.

Who will benefit from PrEP?

PrEP will benefit men who have sex with men, transgender people, heterosexuals and people who inject drugs who are at risk of HIV infection. Broadly, PrEP is an HIV prevention option that may be considered by anyone who is at high risk of acquiring HIV. Talk to your doctor about your individual circumstances.



Should I keep using condoms when taking PrEP?

The role of condoms in the setting of PrEP use is changing, but a few things haven't changed: condoms help prevent sexually transmitted infections and if a person has not been able to take their PrEP regularly then condoms still play an important role in preventing HIV infection. If you do take PrEP regularly but choose not use condoms, it is important to test regularly for STIs.

Are there any side effects?

Up to 20% of people starting PrEP may experience mild side-effects such as nausea, headaches and diarrhoea. If this occurs, symptoms mostly disappear after the first 4-12 weeks. A small number of people have experienced more severe side effects. If at any stage you are concerned that you may be experiencing side effects from taking PrEP, you should contact your clinician to discuss your options.

People with existing kidney, liver or bone problems such as osteoporosis, or people who are taking other medications will need to talk to a doctor about whether participating in this study is the right choice for them.

Can I just take PrEP when I need it?

There was a recent study that assessed taking PrEP intermittently, just before and after sex, and the study reported some promising early results. We suggest that you talk to your doctor about this option. However, the current PrEPX study is recommending that individuals take PrEP daily until more evidence becomes available to support intermittent dosing. Daily dosing of PrEP is in line with the current Australian PrEP guidelines and several international guidelines.

How long do I have to stay on PrEP?

People should stay on PrEP for as long as there is a high chance that they could become infected with HIV.

What is the PrEPX study?

Pre Exposure Prophylaxis eXpanded (PrEPX) is a new study that will expand the provision of PrEP to 3,200 Victorians who have a high chance of acquiring HIV. Alfred Health is responsible for conducting the study. Associate Professor Edwina Wright from the Department of Infectious Diseases Alfred Health, Monash University and The Burnet Institute will be the Chief Investigator of this study. The study is sponsored by the Victorian Department of Health and Human Services and, co-sponsored by Alfred Health and the Victorian AIDS Council. The chief research partners are The Burnet Institute and the Centre for Social Research in Health, UNSW. The aims of PrEPX are to:

- Reduce the incidence of new HIV infections in Victoria,
- Expand access to PrEP in Victoria, including rural and regional locations



- Build capacity in the Victorian Health Service system so that the use of PrEP will become a routine option for preventing HIV infection

What is the PrEPX-SA study?

PrEPX-SA is an expansion of PrEPX into South Australia. The study will provide 500 eligible South Australian people access to PrEP. This part of the study is funded through the Government of South Australia. The South Australian Health & Medical Research Institute (SAHMRI) will provide a leadership and coordination role for the project.

When do PrEPX and PrEPX-SA start and how long will they run?

PrEPX started enrolling people on 26th July 2016 and will run for at least 21 months. Currently PrEPX is fully enrolled (see below for how to go on a waiting list). PrEPX-SA is likely to start enrolling in mid April 2017 subject to research approvals and will run until the end of June 2018.

Where can I join the PrEPX and the PrEPX-SA study?

- Currently there are no available places for the PrEPX study in Victoria and there is a waiting list to join the study. Please visit www.alfredhealth.org.au and search for PrEPX.
- We have sites planned for South Australia and we are in the process of working with them to be ready to enrol once the study opens in South Australia. At this stage you can join the study registration list for information on when the clinics are open for enrolment. Visit the PrEPX-SA page on www.alfredhealth.org.au/prepxsa

Can I see my usual doctor to enrol in this study?

It may be possible for you to see your usual doctor while you are on the PrEPX study but you might need to visit a specific clinic or service that is participating in the PrEPX study. Initially, enrolment will be mostly at practices whose doctors are currently working in HIV, Gay Men's Health and Sexual Health Services.

Will I have to pay to be part of this study?

There is no cost to enrol in PrEPX but there will be a pharmacy charge associated with dispensing PrEP. During 2017 the current Pharmaceutical Benefits Scheme (PBS) equivalent co-payments of \$38.80 for non-concession holders and \$6.30 for concession holders will be charged for a three-month supply. These amounts will increase each year in line with the PBS scale. This approach will enable a smooth transition if the drugs are listed to the usual PBS model of care in the future. Standard GP consultation costs will also apply at each clinic and will vary across the study sites; when booking ask the clinic about their consultation fees.



How long can I get access to PrEP through this study?

We are hoping by December 2017 that ongoing arrangements will be in place for TDF/FTC to be available on the PBS for HIV prevention in Australia. This would mean that your doctor could simply write you a script and you could collect it from the pharmacy and pay your usual co-payment. PrEPX will provide study medication until at least the end of April 2018 in Victoria and until June 30th 2018 in South Australia.

Who is paying for this study?

The Victorian Government, Alfred Health and the Victorian AIDS Council are funding the study. PrEPX-SA is funded by The Government of South Australia.

Who is eligible for the study?

The study is for all people whose sexual activity or injecting drug use means that they have a high chance of acquiring HIV infection. This includes heterosexuals, transgender people and people who inject drugs.

Is generic PrEP safe and effective as TRUVADA®?

Yes. The generic PrEP that we are using is safe and has been approved by the World Health Organisation (WHO), the Federal Drug Administration (FDA) in the United States and is used in the US PEPFAR program for treatment of people with HIV infection. We have also received expert advice that the drug we are using in PrEPX has the same bioequivalence as Truvada®. In addition the generic PrEP that we are using in this study has now been registered by the Therapeutic Goods Administration for use to treat and prevent HIV infection.

I need PrEP now and can't wait, what should I do?

If you want to access PrEP before the PrEPX study starts, you can visit one of the GP clinics listed above to talk about your options, including importing PrEP online from overseas which is a legal option sanctioned by the TGA. If you do import PrEP then you can enrol into the PrEPX study once it opens and your imported PrEP supply has ended. If you have been exposed to HIV in the last 72 hours then you should urgently seek post-exposure prophylaxis (PEP)-

Victoria ring the PEP hotline 1800 889 887

South Australia ring the HIV PEP hotline 1800 022 226



I may have recently been exposed to HIV, can I still enrol in PrEPX?

Yes- it doesn't matter how recently you have had a possible exposure to HIV, you should come and be assessed for PrEP! If you think that you have been exposed to HIV in the past 72 hours, then your clinician could recommend that you take PEP for 28 days and then you can roll straight over on to PrEP.

How often are the appointments and blood taking visits for PrEPX?

You will have on visit at baseline, which is when you enrol into the study. Following this, you will have to attend for visit every 3 months. Sometimes you might have to attend more frequently, depending on your individual circumstances.

Who do I contact for further questions about PrEP, the PrEPX Study or PrEPX-SA?

You can call for SA and Victoria: PH: 03 90762940, m: 0429473138

South Australia:

Website: www.alfredhealth.org.au/prepxsa

Email: PrEPXSA@alfred.org.au

Victoria:

Website: www.alfredhealth.org.au/prepx

Email: PrEPX@alfred.org.au