



PrEPX FAQs version 1

This document will be published on the Alfred Health PrEPX webpage and as a printed hand out for potential study participants.

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 disoproxil fumarate also known as '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 Truvada® for HIV PrEP by men who have sex with men provides the highest level of protection when compared to other HIV prevention strategies.. There is evidence that if individuals take PrEP daily that they may reduce their chance of HIV infection by up to 99%. However in some studies PrEP has been less effective at preventing HIV infection. For example in one study of gay men, PrEP only reduced HIV infection by 44% although it reduced HIV by 86% in a different, more recent study. 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 ?

Some groups of people have been identified as benefiting the most from PrEP due to being at high risk of HIV infection. These groups include gay men and other men who have sex with men, transgender people, heterosexuals and people who inject drugs who are at risk of HIV. Broadly, PrEP is an HIV prevention option that may be considered by anyone who is at 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 few 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 2,600 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:



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- 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

When does PrEPX start and how long will it run?

PrEPX will start enrolling people on 26th July 2016 and run for 21 months. You will not be able to access the study prior to that date.

Where can I join the PrEPX study?

Initially, it is planned PrEPX study will enrol participants through the following sites:

- The Alfred Hospital HIV Integrated Prevention (HIP) Clinic
- The Alfred Hospital, PrEPX Study Clinic
- Centre Clinic
- PRONTO!
- Prahran Market Clinic
- Northside Clinic
- Melbourne Sexual Health Centre - HIV Integrated Prevention (HIP) Clinic

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 2016 the current Pharmaceutical Benefits Scheme (PBS) equivalent co-payments of \$38.30 for non-concession holders and \$6.20 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?



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We plan to offer individuals up to 21 months of PrEP in this study. We are hoping by December 2017 that ongoing arrangements will be in place for Truvada® to be used to prevent HIV infection 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.

Who is paying for this study?

The Victorian Government, Alfred Health and the Victorian AIDS Council are funding the study.

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®.

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)- ring the PEP hotline 1800 889 887.

I am in the VicPrEP Study. What will happen to me? You will be able to stay in the VicPrEP study until you reach the end of the study, which will be your month 30 visit. Following this you can roll over into the PrEPX study. Let your GP know that you plan to enrol in PrEPX once VicPrEP ends.

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 to PrEP.

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

You will have one visit at baseline, which is when you enrol into the study. Following this, you will have to attend for a 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, or the PrEPX study?

You can call 0429473138 or email: PrEPX@alfred.org.au