

I'M ENDING HIV

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MI-EPIC

INFORMATION
FOR
PARTICIPANTS

MI-EPIC

V1.0. dated 8 April 2019

epic-nswstudy.org.au

THIS BOOKLET AIMS TO ASSIST YOU WITH INFORMATION ABOUT A STUDY CALLED MI-EPIC

EPIC-PIN:

CLIENT_ID:

CONTACT INFORMATION FOR CLINICAL SITE:

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WHAT IS PREP?

PrEP stands for Pre-Exposure Prophylaxis. Prophylaxis meaning — To prevent or control the spread of an infection or disease.

PrEP is the use of HIV medication, one pill, once a day to keep HIV negative people from contracting HIV

PrEP contains two antiretroviral medicines that are also used to treat people who already have HIV infection, tenofovir disoproxil fumarate also known as “TDF” and emtricitabine also known as FTC (in combination known as TDF/FTC).

These are the same drugs used to suppress the virus in people living with HIV. You may know this medicine by a brand name Truvada, however there are generic forms of the drug with the same active ingredients.

We recommend that PrEP be taken every day in order to maximise effectiveness. If doses are missed it may reduce the effectiveness of the medication.

In terms of HIV prevention, you can think about PrEP in a similar way to condoms. When condoms are used correctly and consistently they provide a high degree of protection against HIV, but if they are not used consistently your risk of contracting HIV increases dramatically. Condoms – like PrEP – can’t protect you if they’re not being used! PrEP is not a vaccine and only provides protection from HIV so long as you continue to take it as prescribed. However, unlike condoms, PrEP does not protect you against other sexually transmitted infections.

MI-EPIC

MI-EPIC stands for Medicare Ineligible – Expanded PrEP Implementation in Communities

MI-EPIC is a study run by the Kirby Institute and funded by the NSW Government, in collaboration with a number of partners such as sexual health services and clinics. MI-EPIC aims to provide extended study PrEP access and identify the barriers and challenges of overseas-born Medicare ineligible individuals and at high-risk of HIV infection to starting and continuing PrEP. PrEP was listed on the Pharmaceutical Benefits Scheme (PBS) on 1st April 2018 and is now subsidised by the Australian Government for individuals at risk to HIV infection if they are eligible for Medicare.

The study is a follow-on study of EPIC-NSW study, which

enrolled more than 9,700 participants between 1 March 2016 to 30 April 2018.

The study has sufficient study drug to enrol more than 1,000 overseas-born and Medicare ineligible individuals at high-risk of acquiring HIV. Participation is up to 12 months.

MI-EPIC is a criteria-based access program – which means eligibility for the study will be determined on the basis of HIV risk criteria. The aim is to rapidly enrol eligible people and follow them for up to 12 months while they take PrEP.

Partners involved in the study include the Kirby Institute, UNSW (leading the study), NSW Health and Local Health Districts, ACON, Positive Life NSW,

the Australasian Society for HIV Medicine (Australia's HIV professional organisation for clinicians) General Practitioners who specialise in HIV, NSW publicly funded sexual health clinics and private practices.

It is important to note that this study is not evaluating the effectiveness of PrEP itself, as this has already been demonstrated in a number of studies.

Rather this study is investigating how it is best to reach the overseas-born Medicare ineligible population and assist them to access PrEP.

The study has Human Research Ethics approval from the St Vincent's Hospital Sydney Human Research Ethics Committee and from ACON's Ethics Committee.

WHO WILL BENEFIT FROM PREP?

PrEP is a HIV prevention option that may be considered by anyone who is at risk of acquiring HIV. However, 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 and heterosexual people with an HIV positive partner who does not have an undetectable viral load.

Guidelines for PrEP use have been developed for NSW and Australia and are based on the US Guidelines. The Australian Guidelines have been endorsed by ASHM, the peak body representing and supporting HIV clinicians. Your clinician may refer to those Guidelines when discussing whether PrEP will be of benefit to you.

If you do not fall within the recommended Guidelines but feel that you would benefit from accessing PrEP, you can discuss this with your clinician. There are alternative options to access PrEP such as self-importation via the Therapeutic Goods Administration (TGA) process, and more information can be found at: endinghiv.org.au or call PrEP Info Service **1800 451 624**.

WHO IS ELIGIBLE FOR THE MI-EPIC STUDY?

Eligibility for MI-EPIC is based on the NSW Guidance on PrEP and these are described below (see pages 11 and 12). The guidelines are based on HIV risk and are split between sexual risks involving sex between men, and sex between men and women.

To be eligible, you will also need to be Medicare ineligible.

For more info on the study go to:
epic-nswstudy.org.au/

SEX BETWEEN MEN

The guidance in NSW for clinicians to prescribe daily PrEP is related to being at high risk of acquiring HIV. Therefore, PrEP is recommended if the individual acknowledges:

being likely to have multiple events of condomless anal intercourse, with or without sharing intravenous drug use (IDU), in the next 3 months (indicating sustained risk)

And having any of the following:

- Regular sexual partner of an HIV-infected man with whom condoms were not consistently used in the last 3 months (HIV positive partner is not on treatment and/or has detectable viral load);
- At least one episode of receptive condomless anal intercourse with any casual HIV-infected male partner or a male partner of unknown HIV status in the last 3 months;
- Rectal gonorrhoea, rectal chlamydia or infectious syphilis diagnosis during the last 3 months or at screening;
- Methamphetamine use in the last 3 months

SEX BETWEEN MEN AND WOMEN

The guidance in NSW for clinicians to prescribe daily PrEP is related to being at high risk of acquiring HIV. Therefore PrEP is recommended if the individual acknowledges:

being likely to have multiple events of condomless anal or vaginal intercourse, with or without sharing IDU, in the next 3 months (indicating sustained risk)

And

- Being a regular sexual partner of an HIV-infected man or woman with whom condoms were not consistently used in the last 3 months (HIV positive partner is not on treatment and/or has detectable viral load);

Transgender people who are at high risk of acquiring HIV are eligible to participate in MI-EPIC.

If you are not eligible to participate in MI-EPIC but would still like to access PrEP, speak to a clinician, contact ACON or the PrEP Info Service (details at the end of this resource).

WHO WILL DECIDE WHO PARTICIPATES IN THE STUDY?

People seeking to participate in MI-EPIC study will be assessed against the eligibility criteria by clinicians at participating sites across NSW. Enrolment into MI-EPIC will be on the condition that the clinician prescribing PrEP has assessed you are at high risk of acquiring HIV, based on the NSW PrEP Guidelines described earlier.

HOW WILL I FIND OUT ABOUT WHICH SITES ARE PARTICIPATING?

To find out which sites are recruiting for MI-EPIC, visit epic-nswstudy.org.au or contact ACON on 9206 2000 or the NSW PrEP Infoline 1800 451 624. Sites will be available across Sydney and in some regional centres of NSW.

WHAT HAPPENS WHEN I START ON THE STUDY?

If you are eligible to participate in the study and choose to take part, there are a number of steps to get you started. The three month follow up appointment will be continued on a quarterly basis for the duration of your participation in MI-EPIC.

<p>INITIAL APPOINTMENT</p>	<ul style="list-style-type: none"> • Run through participant information and consent forms • HIV, STI and other health tests • Receive prescription for one month
<p>ONE MONTH FOLLOWUP</p>	<ul style="list-style-type: none"> • HIV, STI and other health monitoring • Receive prescription for two months
<p>THREE MONTH FOLLOWUP (regular monitoring appointments for duration of study)</p>	<ul style="list-style-type: none"> • HIV, STI and other health monitoring • Receive prescription for three months

You will have a study number given to you when you enrol and this will be used while participating in the study. It is important to bring this with you to every visit about MI-EPIC to ensure your clinician knows you are part of the study, particularly if you change doctors or pharmacies.

You will be able to pick up your PrEP from certain designated public hospital pharmacies and public sexual health clinics while you are in the MI-EPIC study. Discuss with your clinician the closest pharmacy. A full list of participating pharmacies is available on the EPIC-NSW website epic-nswstudy.org.au

WHAT IF I STOP/WITHDRAW FROM THE STUDY?

You can withdraw from the MI-EPIC study at any time and this will not affect the care that you receive from your clinician. If you decide to withdraw from this study and do not want to take PrEP any longer please let your study doctor or study nurse know before you stop. PrEP should be continued for 30 days after the last potential HIV exposure in order to have maximum protective effect. Talking to your clinician will allow you to find out about any other possible health risks or special requirements before you stop.

If you no longer wish to take part in this study but still want to access PrEP, speak with your clinician or you can contact ACON on **9206 2000**.

THE PREP PROGRAM

Going on PrEP isn't just about taking a pill every day. It should be considered a health program that you are taking on in partnership with a clinician.

HIV STATUS

Firstly and most importantly, it is essential that you are tested for HIV before you start PrEP.

Starting PrEP when you are already HIV positive could lead to the virus becoming resistant to antiretroviral treatments, which may reduce your treatment options into the future.

When you have your HIV test, discuss with your clinician when your last potential exposure was so that you can both be confident that you are not in the window period (the time between when an infection occurs and it is detectable by an HIV test). Before commencing PrEP and during PrEP it is important to inform your team looking after you, if you have any symptoms which are consistent with HIV seroconversion such as sweats, fevers or other flu-like symptoms.

WORKING WITH A CLINICIAN

Forming a good relationship with your clinician is one of the most important things that you can do for your health. When it comes to PrEP, you are potentially going to be having some detailed discussions about your sexual practices and other relevant issues such as alcohol and other drug use. All sites participating in the MI-EPIC study are staffed by experienced clinicians and you should feel comfortable about having detailed discussions about your sexual practices with them.

Most clinicians who prescribe PrEP are doctors who have specialist qualifications in treating HIV at hospitals, sexual health clinics and some private GP practices.

SEXUAL HEALTH CHECKS

As part of the PrEP program, regular check-ups for HIV and sexually transmissible infections (STIs) should be part of your routine.

It is recommended that anyone taking PrEP has a full sexual health check every three months.

If you are taking part in MI-EPIC, you will need to see your clinician quarterly for comprehensive sexual health testing and new scripts for PrEP.

It is important to know if you have an STI and testing is the only way to be sure, as many STIs can have no symptoms. When left untreated, STIs can cause health complications and you may be passing them on to your sexual partners.

A sexual health check is easy. You should have STI tests of your urine, vagina, throat, anus and blood, including a test for HIV, for a complete sexual health check, depending on your sexual risk and sexual practices. Your clinician will advise you as to what specific testing regime is right

for you. If you do get an STI, a clinician can assist you with contacting your previous sexual partners so that they can get tested as well.

Both the active drugs in PrEP (TDF/FTC) work to treat Hepatitis B, so you will be tested to know if you have active Hepatitis B. This will allow a clinician to recommend you an appropriate treatment. Additionally, if you have not yet been vaccinated for Hepatitis A and B, this is something to discuss with your clinician.

OTHER MONITORING

In addition to regular sexual health checks, there are other aspects of your health that your clinician will be monitoring. PrEP has been associated with some side effects in a small proportion of people receiving it. Your clinician will monitor you for these side effects with blood tests of kidney function. For more information on the potential side effects of taking PrEP see page 25.

TYPE OF PREP USED IN MI-EPIC

The MI-EPIC study use tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) manufactured by Mylan Laboratories Ltd and purchased by the NSW Government. TDF/FTC is a generic version of Truvada® which was approved to be used as PrEP by the TGA in May 2016. TDF/FTC has the same active ingredients as Truvada® and is as effective as Truvada®.

TDF/FTC has been widely used for many years to treat HIV with other HIV medicines.

The participants in MI-EPIC will receive TDF/FTC (as a single tablet) free of charge. There is no placebo arm in this study; all participants will be taking the actual drug.

HOW DOES PREP WORK?

When taking PrEP, the medication will build up in your system to the point where it is effective in breaking the replication cycle of the virus, which will reduce the chance that it will take hold in your body.

For more information on how PrEP works and to watch a 5 minute video that explains it all, visit: whatisprep.org/

HOW SOON DOES IT START WORKING?

It takes time for PrEP to build up to levels in your body that are considered protective. The exact length of time is still not clear and is being investigated.

Studies have shown that protection is achieved after 7 days for rectal tissue, however for full protection to be achieved in blood and vaginal tissue it will take 20 days.

To be on the safe side you should assume that you aren't getting maximum protection until at least 20 days after you begin taking PrEP, if you take it consistently without missing any pills. This is recommended for all people taking PrEP.

HOW DO I TAKE IT?

PrEP is a pill that has been shown to be most effective when taken once daily. You should try to take it at the same time each day – whenever is convenient for you.

This might be during a regular activity, such as taking it with breakfast each morning or when brushing your teeth before bed at night. You might like to set reminders on your phone to ensure you remember to take it each day. If you have a busy or unpredictable schedule, you may want to plan other ways to make sure you take PrEP consistently. It is important to remember to take your PrEP with you when you travel or plan to be away from home for a few days. Your clinician might be able to help you to come up with strategies that are right for you.

WHAT IF I DON'T TAKE IT EVERY DAY?

If you miss a dose of PrEP, don't panic. Resume taking your pills as soon as you remember. It is not recommended to double dose PrEP. If you consistently miss doses, you may lose some of the protective benefit of taking PrEP.

If remembering to take your pills is a problem, you should speak with your clinician and friends who regularly take medications to discuss strategies to ensure you can take PrEP consistently.

TIPS ON PREP USE

- Here are some quick and helpful hints on how to give yourself the best chance to take your pills daily as prescribed so you get the maximum benefit from the treatment you take, whatever your circumstance.
- Reminders, either in your phone or a beeper which you can get from a pharmacy, can be your little nudge to remember. These are easy to set and a great way to help you remember to take your pills.
- Pill boxes can also help you keep track of when you have taken your meds. A seven day a week pill box can easily help you track if and when you have taken your pills and can also be purchased in most pharmacies.
- Keep pills in a convenient place. Having your pills close by and convenient will make taking them easy. They should be stored at room temperature and away from sunlight. The Pills SHOULD NOT be stored in the fridge or in a car.
- Plan ahead. If you are having a night out or travelling take 5 minutes to plan what that might mean to you taking your pills. It is usually easy to find a discrete place to take them with a drink. If travelling overseas, work out the best time to take them and be sure to pack some in your carry-on luggage.
- If you drink or use drugs, remembering might be a little tricky. Carry your next dose with you and do your best to take it close enough to the time you normally would.
- Practice with things like vitamins, supplements or even with something as simple as a tic tac to get you in the habit of taking a pill regularly.
- Most importantly, get into a routine. The easiest way to remember to take your medications is by doing it regularly at the same time each day or as near to as possible.

SHOULD I KEEP USING CONDOMS?

When PrEP is taken daily it is highly effective in preventing HIV transmission and gives protection against HIV transmission that is comparable to condoms, although it is not a guarantee against infection. Using condoms will be a choice for you and your sexual partners. It is important to remember that PrEP does not prevent the transmission of other STIs. If you do not use condoms, it is important to test regularly and treat STIs if you acquire them.

NEGOTIATING SEX AND DISCLOSURE OF PREP USE

Depending on what other risk reduction practices you use, including condoms, you may find yourself negotiating sex and risk where your PrEP status becomes relevant.

How this is negotiated will depend on whether you are with a regular or casual sexual partner. If you talk about PrEP with your sexual partners, friends and family, you may find yourself becoming an educator in certain situations. Sometimes this may be a welcome opportunity, while at other times it may become a more difficult task. This type of informal community education is something that many people with HIV have been dealing with for some time, so if you have any HIV positive friends, it might be worth asking them about the strategies they use.

If you want to refer people to more information, this booklet is available online at: endinghiv.org.au/prep

PrEP is now more widely used compared to a few years ago but it may not be well understood across the community. Often a frank and open discussion or referring to accurate information can help educate and reassure people. It is important to remember that taking PrEP is a responsible step that someone takes to reduce the risk of acquiring HIV.

The Public Health Act no longer requires the disclosure of HIV status prior to sexual intercourse. The law does require, however, someone who knows that they have HIV to take **reasonable precautions** against transmitting the virus to others. Reasonable precautions may include having an HIV viral load of less than 200 copies/ml, usually resulting from being on effective treatment; or seeking and receiving confirmation from a sexual partner that they are taking HIV pre-exposure prophylaxis (PrEP).

For more information, you can go to halc.org.au/publications/guides-to-hiv-and-the-law/

Living Positive Victoria, in partnership with the Victorian AIDS Council, has developed a guide for people with HIV on how to talk about PrEP with their HIV negative friends and partners and this can be accessed at:

livingpositivevictoria.org.au/living-with-hiv/pep-and-prep

PEP OR PREP?

Post-exposure prophylaxis (PEP) has been in use since 1996 and consists of a 28-day course of two or three antiretroviral drugs like TDF/FTC that must be started within the first 72 hours after exposure to HIV. PEP is intended to prevent HIV if exposure events are not-frequent or just happened one time. If you have taken multiple courses of PEP in a short time, you should think about PrEP, as it works better for people who are potentially exposed to HIV on a regular basis. PrEP, if taken daily and consistently alongside other prevention measures such as condoms, is a more suitable option.

SIDE EFFECTS

TDF/FTC has been used to treat HIV at exactly the same dose for more than 15 years and use as PrEP in more than 15,000 people in PrEP clinical trials in Australia. PrEP is generally very well tolerated and most of the potential side effects are quite mild. A minority (up to 20%) of people may experience mild symptoms such as nausea, headaches and diarrhoea. If this occurs, symptoms mostly disappear after the first few weeks or month. In a minority of cases, some 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.

If you have existing kidney, liver or bone problems such as osteoporosis, or are taking any other medications, speak to your clinician about whether participating in this study is the right choice for you.

If you are undertaking hormone treatments, discuss this with your clinician prior to starting taking PrEP, however there do not appear to be any interactions.

PREP, PREGNANCY AND BREASTFEEDING

For women trying to become pregnant while using PrEP it is recommended that you start taking daily doses of PrEP one month before a conception attempt and continue until one month after the last attempt to conceive. It is strongly recommended that you speak with your clinician if you are trying to conceive while taking PrEP.

As the effects of taking PrEP are unknown on new born babies, you will not be able to enrol in MI-EPIC if you are breastfeeding. If you are accessing PrEP through importation and you are breastfeeding or planning to breastfeed, raise this with your clinician immediately.

WHAT ABOUT PREP AND ITS INTERACTION WITH THE CONTRACEPTIVE PILL?

In some cases there is evidence to suggest that taking antiretroviral (ART) medicines, such as those used for PrEP, may decrease the effectiveness of the oral contraceptive pill. However what we know about the interaction between ART and oral contraceptive pills is quite limited. If you are on the oral contraceptive pill at the time of starting PrEP, speak with your clinician before commencing.

CONSENT AND FURTHER INFORMATION

As part of the process for enrolling you in the MI-EPIC study, you will go through a detailed consent and information form. Through this process you will have an opportunity to find out more detailed information about the personal information or data that will be collected through the study, and also have any questions you may have answered. This process is not intended to be very time-consuming but is important to ensure you fully understand everything that is involved in your participation in the study.

WHAT HAPPEN WHEN THE STUDY IS OVER

The MI-EPIC study looks at enrolling individuals with high-risk of HIV and ineligible to Medicare. The study drugs are purchased by the NSW Government.

Study participants will receive at least 3 months of PrEP and continue to receive 3-monthly PrEP until:

- the extension study finished or
- all study drug has been allocated

Your participation will be up to 12 months but can be as little as 3 months depending on when you join the MI-EPIC study. At the end of the study, your clinician will assist you to obtain PrEP outside the study if you wish to continue on taking PrEP.

REFERRALS TO OTHER INFORMATION AND RESOURCES

PrEP has been available for use in the United States since 2012 and in Australia since 2016, and a number of organisations and individuals have been providing information about PrEP and the experience taking it.

Please note that some of the information contained in these websites is specific to the US.

These are intended to supplement your knowledge about PrEP but the best way to find out more about using PrEP in NSW is to talk to your clinician.

The following websites contain more info and the experiences of people taking PrEP:

endinghiv.org.au/prep

men.prepfacts.org

whatisprep.org/

betablog.org/tag/prep

truvada.com/

For more information about MI-EPIC

visit: epic-nswstudy.org.au
or call the
PREP Info Service **1800 451 62**

