

*A publication for men and
transgender women who have sex with men*

PRE-EXPOSURE PROPHYLAXIS

Is taking PrEP the
right choice for you?

your life matters



PROJECT
INFORM

OCTOBER 2013

Check out our four videos
on PrEP as well!

NEW EDUCATIONAL VIDEOS ON PrEP

meet
MARCUS



meet
ALEJANDRO



meet
JONATHAN



- an overview of PrEP
- how PrEP fits into your life
- making decisions with your doctor
- PrEP and mixed status couples

Go to vimeo.com/prepvideos.

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Using this booklet ...

This publication provides a lot of information about PrEP, or *Pre-Exposure Prophylaxis*. Project Inform believes that you deserve to know as many facts as possible about this topic so you can make the best decision for yourself. PrEP is an exciting new prevention tool but it's not for everyone, so please take your time and read it at your own pace.

Is taking
this pill the right
thing for me
to do?



This document was written for gay, bisexual and other men who have sex with men — as well as transgender women — who want to learn about PrEP. If you are a heterosexual woman or man, please read our other PrEP publication.

Additionally, Project Inform has developed four educational videos on PrEP for men who have sex with men. These can be viewed at vimeo.com/prepvideos.

Quick facts about PrEP ...

- PrEP is a single pill called Truvada taken once daily to prevent HIV infection in people who are at high risk for it.
- PrEP is used along with other prevention methods, such as condoms.
- Do not take PrEP on your own. It must be done with the support of a health care provider.
- Since PrEP was recently approved by the FDA, some doctors may not know about it or may not be willing to discuss PrEP or sexual activities with you.
- Taking PrEP includes getting routine blood tests done.
- You may have side effects from taking PrEP.
- When taken as prescribed, and with other prevention options, PrEP may be up to 99% effective at blocking HIV infection.



What is PrEP?

PrEP means that you take a drug before you are exposed to a virus or bacteria to prevent becoming infected. In this case, an HIV-negative person at high risk for HIV would take the pill called Truvada to prevent infection.

Two clinical studies show that HIV-negative people who take Truvada for PrEP every day or nearly every day — and who combine it with condoms (and other HIV prevention methods) — may see their risk for HIV cut by up to 99%. This is true in both women and men and for both vaginal and anal sex. Based on these studies, the US Food and Drug Administration (FDA) approved Truvada for PrEP in July 2012 for adults at high risk for sexual transmission of HIV.

PrEP is not just about taking a pill every day. If you decide to take PrEP, you'll need to see your doctor at least every three months for routine care and testing. You'll need to talk about your current sexual activity, your level of risk, sexually transmitted diseases (STDs), your routine test results and any side effects. This means more doctor visits, refills, co-pays, and extra attention to your HIV prevention plan.

PrEP differs from *Post-Exposure Prophylaxis* (PEP). PEP means taking HIV medicines after you are exposed to a virus or bacteria. When a person takes PEP to prevent HIV, s/he takes two or more medicines for about a month after a high-risk exposure.

Is PrEP right for you?

If you're HIV-negative and are trying to stay that way, then PrEP might be right for you. Here are some questions to consider. If you answer “yes” to any of them then PrEP might be a good thing to discuss with your doctor.



- Is your main sexual partner HIV-positive? In other words, are you part of a mixed-status couple?
- Has a man — especially an HIV-positive man or a man whose status you're not sure about — penetrated you during anal sex (“topped” you) without a condom recently?
- Have you been treated recently for a sexually transmitted disease in your butt, such as rectal gonorrhea?
- Have you used PEP more than once in the past year?
- Have you or your partner(s) been in prison?
- Do you use alcohol and/or drugs heavily; or, does your sex partner(s)?
- Do you exchange sex for money, housing or other needs; or, does your sex partner(s)?
- Has your partner threatened you with violence or physically harmed you recently?

When is PrEP not right for you?

You should not use PrEP if you:

- Don't know your HIV status
- Are HIV-positive (Truvada is not a full regimen for people with HIV)
- Have symptoms of acute HIV infection (symptoms similar to the flu)
- Don't know whether you have hepatitis B
- Can't find a doctor to provide regular HIV and STD testing and prevention counseling along with the medication
- Don't think you can take the pill on time every day or nearly every day
- Want to use PrEP as “disco dosing”, or just taking it from time to time such as over a weekend of partying
- Have kidney disease or reduced kidney health



What is Truvada and how does it work?

Truvada is a pill made up of two HIV meds — Viread (tenofovir disoproxil fumarate) and Emtriva (emtricitabine). Currently, it's commonly used together with other meds to treat HIV infection in HIV-positive people. Viread is also used to treat hepatitis B.

Truvada prevents HIV from reproducing in the body. If you are exposed to the semen, pre-cum or vaginal fluids from an HIV-positive person, then Truvada can help to keep the virus from causing a lasting infection.

What are Truvada's side effects?

The short-term side effects that were seen in PrEP studies included headaches, weight loss and stomach problems like nausea, diarrhea and gut pain. Some people also had slightly poorer bone and kidney health, which got better when Truvada was stopped. As for Truvada's long-term side effects, we don't yet know about them since these PrEP studies only followed people for less than two years.

However, in HIV-positive people, over time Truvada can cause bone loss and can damage the kidneys in a very small proportion of people who take it. Because HIV by itself can also cause these problems, it's difficult to know how much Truvada on its own causes kidney and bone disease. People with current kidney disease (<60 mL/minute *creatinine clearance*) should not use PrEP. Those who use PrEP should have their kidney and bone health checked regularly.

How well does Truvada prevent HIV infection?

In clinical studies, when people took Truvada as close to every day as possible, the pill appeared to lower their risk for infection by at least 90%. It did not protect people as well who took it less often. As with any medicine, it can't work if you don't take it ... that just makes sense.

Below is a brief recap of a large study that the FDA reviewed when they approved Truvada for PrEP. In that study (called iPrEx) condoms and other prevention education were offered along with the pills.

Researchers included 2,499 high-risk men and transgender women who have sex with men. Results were reported in November 2010. Overall, iPrEx showed a 44% lower risk of infection in those assigned to take Truvada compared to a placebo (fake pill). However, when looking only at those people who actually took Truvada as close to every day as possible, the drugs cut their HIV risk by up to 90%. In a separate look at the iPrEx data, researchers found that people with enough Truvada in their blood to show daily use were 99% less likely to become infected with HIV.

Although everyone reported “bottoming” (receptive anal sex) in the previous 6 months without a condom, most people actually reported using condoms more often during the study. Given that high-risk sexual behaviors were still quite common, and given that use of condoms was the same in the Truvada group and the placebo group, it is highly likely that Truvada, and not just condoms, had a lot to do with how effective the drugs were at preventing new infections.

Why should you get tested for hepatitis B before starting PrEP?

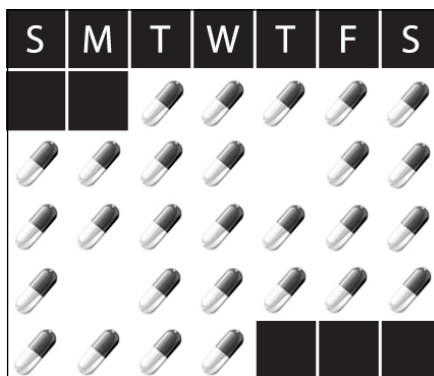
Both of the drugs in Truvada work against hepatitis B as well as HIV. Therefore, it's important to know if you have hepatitis B before starting PrEP. If your hepatitis B test shows that you don't have active disease, then get the hepatitis B vaccine.



If your hepatitis B test shows you have active disease, then starting treatment for hep B may be recommended. You can take PrEP at the same you're taking hepatitis B meds. However, if you have active hepatitis B disease and stop PrEP suddenly it can cause dangerous liver problems. Work with your doctor on the safest way to stop PrEP in this situation.

Why should you take PrEP every day?

All of the PrEP studies so far clearly show that people who take Truvada every day have a much lower risk of HIV infection. Not taking PrEP as prescribed can increase your risk for getting HIV. Therefore, it's



very important that you take PrEP as directed or as close to it as possible. Some newer information shows that a missed pill every now and then may still protect you, however.

Some people find it fairly easy to take pills every day, like taking a daily vitamin. This can be easier if taking the dose happens at the same time that a routine activity occurs, like shaving or eating breakfast or brushing your teeth before you go to sleep at night.

It can also help if the pill bottle is in plain view like on a night stand or bathroom shelf. Some people use gadgets like a cell phone, or a texting service that sends message or email reminders to help them to take their pills on time.

Things that might make it harder for you to take your Truvada include: depression, drinking or using drugs, having a busy daily schedule, or having a schedule that changes often. Correcting these types of issues can in turn help you keep up with your doses.

When do you start/stop taking PrEP?

It depends.

Generally speaking, people should use PrEP over a period of time when they are at a high risk for getting HIV. Some people may be able to quickly adopt safer behaviors and will only need to use PrEP for a few months. Others may find the need to take it over years. Still others may want to start for awhile, stop for some time, and then re-start for another period. Making this type of decision — when to use PrEP as well as when not to use it — should be done with help from your doctor.

As for stopping PrEP, if you find out that you've become infected with HIV, you should stop it very quickly! This is because Truvada on its own is not enough to control HIV once you are infected. The virus could become resistant to the drugs in Truvada. If that happens, it would limit your treatment options. This is a key reason to get tested often for HIV while you're on PrEP.

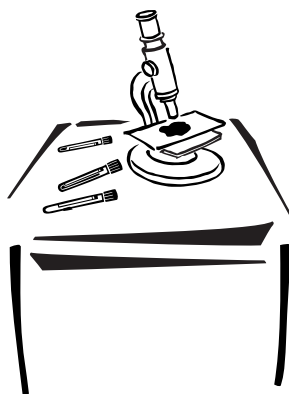
It's also OK to stop for other reasons. One might be that you simply want to stop. You may find that your risk for HIV has changed, or that you don't like the side effects, or you have trouble taking the pill every day. Whatever your reason, it's important to talk to your doctor or an HIV counselor before you stop to make sure you're doing whatever else you can to prevent getting HIV.

One very important thing to remember is that if you have hepatitis B, you should stop PrEP very carefully. This will help avoid having a “flare up” in your liver, which can occur when Truvada is stopped all at once.

What tests will you need to get?

Before you start PrEP, the following tests and exams should be done by your doctor:

- A thorough and honest talk about your sexual activity and level of HIV risk
- An HIV antibody test and possibly a test to detect HIV directly
- A test for hepatitis B, kidney function and STDs



While you're taking PrEP, the following should be done:

- You should have regular doctor visits every two to three months.
- Routine HIV tests (at least every three months) are needed to make sure you continue to be HIV-negative.
- Someone in your doctor's office should talk to you about side effects, adherence and risky activity. You should also get STD tests done every 6 months or more often if your risk for STDs stays high.

Do you still have to use condoms?

Condoms are great. They are the cheapest and easiest way to avoid getting HIV. However, PrEP is also great for some people, especially if you struggle with using condoms. PrEP could be one of the best ways to prevent HIV while you work on those issues that keep you from using condoms or doing other things that lower your risk (like having sex with fewer people).



In an ideal world, everyone would use condoms and other risk-reduction behaviors to prevent getting HIV. This is not always possible for everyone. Your partner(s) might refuse to use condoms. If you are depressed or using alcohol or drugs heavily, condoms may seem impossible. You and your partner might see using condoms as a sign that you don't trust one another or that you love each other less. Plenty of people struggle with condom use, so you should not feel ashamed if you have trouble with this.

In the PrEP studies so far, people stated that their condom use got a little bit better while they were on PrEP. This means that in the best-case scenario people would use condoms as much as possible while taking PrEP.

If you rarely — or never — use regular or female condoms for riskier sex, PrEP is still a really great option to lower your risk for HIV. It won't protect you from most other STDs, but it might strongly reduce your risk of HIV compared to not using it at all.

What should you talk to your health care provider about?

- Is s/he informed, willing and ready to oversee you being on PrEP?
- What is the result of your HIV antibody test? Do you need to test twice before starting PrEP because of high-risk sex within the past 6 weeks?
- How often does s/he want you to test for HIV? (It should be at least every 3 months.)
- Is your provider testing you for hepatitis B? If you don't have active disease, then can you get vaccinated for it? If you have active disease, then what's the right treatment for it?
- What STDs should I get tested for? How often should I get tested for them?
- What is your kidney health? Is your *creatinine clearance* >60 mL/minute so you can start PrEP?
- What kinds of drug interactions are possible with the other medications you take? (Such as testosterone, hormonal pills, heart medicine, etc.)



What if you get HIV while taking PrEP?

In order to control the virus over time, HIV-positive people take at least three meds altogether. Taking two meds, as with Truvada, is not strong enough to control long-term HIV. Doing this would cause new strains of HIV to develop that the drugs can no longer control. In other words, the virus becomes “resistant” to those meds.

Therefore, if you get HIV while on PrEP and don't realize it until resistance has developed to both of the drugs in Truvada, then you wouldn't be able to use these drugs later to control your HIV. Since Truvada is preferred over some other HIV medications, not being able to use it could really limit your treatment choices.

There are two things you can do to help prevent drug resistance:

- **Before starting PrEP**, make sure you're HIV-negative. If you are very recently infected, your antibody test could say that you're HIV-negative when in fact you're HIV-positive. This is because you haven't developed enough antibodies to HIV to show up on that test. For this reason, report any flu-like symptoms or rashes to your provider before starting PrEP as they could be symptoms of early infection.
- **While on PrEP**, get routinely tested for HIV every 3 months. Also, let your provider know if you develop flu-like symptoms or unexplained rashes in between tests.

Should I keep it a secret that I'm taking PrEP?

One of the things that you may not think about before starting PrEP is what might happen if anyone finds out that you're taking Truvada. Some of your friends or family may know what that drug is used for and may



assume you're HIV-positive. They may not be aware that it can be used as PrEP. Even if they know about PrEP, they may still have a negative opinion about it.

Take some time and think about how you'll take your pill every day, where you'll store it, and who may be around to see you. Some people won't find this to be an issue, but for others this may cause them some unnecessary social problems.

Where do you get PrEP and how much will it cost?

Since PrEP is approved by the FDA, the prescription should be covered by health insurance if you have it. It should also be available through government insurance programs like Medicaid. Because PrEP is an entirely new HIV prevention strategy, not all insurance companies or state insurance programs have yet decided to cover it. Some may choose not to pay for it.

For people whose insurance does cover PrEP, the major cost should only be the drug co-pay charged at the pharmacy and co-pays for doctor visits and lab tests. Gilead Sciences, who makes Truvada, will cover the co-pays for the drugs. To access that program, go online at www.truvada.com and look for the button describing the Truvada co-pay assistance program or call 888-358-0398. Gilead won't cover co-pays for Medicaid or Medicare or for people living in MA.

For people without insurance, or whose insurance won't cover PrEP, Gilead has agreed to help those with lower incomes. To learn more about this program, go online at <https://start.truvada.com>.

Gilead has also agreed to provide vouchers for free HIV tests and free condoms for those taking PrEP. Information about this can also be found at <https://start.truvada.com>.

If you're interested in PrEP, but don't have a provider, contact your local health department's HIV or STD program. They should be able to let you know about clinics or hospitals offering PrEP or about PrEP demonstration projects — which study how to provide PrEP in the real world — that are taking place in your city.

What else should you know?

- DO NOT try to take PrEP on your own. It should only be done with the support of your doctor. You need specific initial and ongoing tests. If you don't know the results to these tests, your health could suffer.
- DO NOT disco-dose your PrEP pill. No clinical study has shown that taking Truvada every now and then works at preventing HIV. Doing so could cause the drug level in your bloodstream to be too low to prevent infection. It could actually increase your risk of having resistant HIV. One study is looking at how effective less than daily dosing of Truvada might be. Results aren't expected until 2013 or 2014. In the meantime, it's important to use PrEP daily.
- Taking PrEP can be a major change in your life and can affect the sexual relationship(s) you have. Consider talking about PrEP (and other prevention methods) to your partner(s) to continue to promote open dialogue about the choices you make.



What else should you know?, *continued*

- Some people do not want their doctors to test them for HIV. Some fear that a positive test result could jeopardize their health insurance. However, part of getting PrEP is that your doctor tests you for HIV and writes those results in your medical record. If this is an issue for you, think about it before you decide to take PrEP.
- Although other HIV drugs are currently being studied, no other HIV pill besides Truvada and Viread has been shown to prevent HIV infection. Therefore, you should not use any other HIV pill in place of Truvada.

Online resources that may help

INFORMATION ON PrEP

Pre-Exposure Prophylaxis

www.projectinform.org/prep/

My PrEP Experience

<http://myprepexperience.blogspot.com/>

PrEP Facts

<http://prepfacts.org/>

Truvada for PrEP

(company website)

<http://start.truvada.com/#>

Truvada for PrEP

(company REMS website)

<https://www.truvadapreprems.com/#>

ARTICLES

The Math and Morality of PrEP

www.frontiersla.com/Blog/PositiveFrontiers/blogentry.aspx?BlogEntryID=10474103

Ask a Guinea Pig:

What Do I Need to Know Before Joining a PrEP Trial?

<http://betablog.org/ask-a-guinea-pig-what-do-i-need-to-know-before-joining-a-prep-trial/>

Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men (clinical study data)

www.nejm.org/doi/pdf/10.1056/NEJMoa1011205

APPLICATION FORM

Medication Assistance Program

(for uninsured people to cover the cost of Truvada, work with doctor to fill it out)

https://start.truvada.com/Content/pdf/Medication_Assistance_Program.pdf

WEBSITES FOR CLINICIANS

Truvada for a PrEP Indication

<https://start.truvada.com/>

Clinical Studies Resources

www.avac.org/ht/d/sp/i/262/pid/262

CDC Fact Sheet (PrEP: A New Tool for HIV Prevention)

www.cdc.gov/hiv/prep/pdf/PrEPfactsheet.pdf

CDC Interim Guidance on HIV PrEP for Men Who Have Sex with Men

www.cdc.gov/nchhstp/newsroom/images/CDC-Interim-PrEP-Guidance.jpg

Interim Guidance for Clinicians Considering the Use of PrEP for the Prevention of HIV Infection in Heterosexually Active Adults

www.cdc.gov/mmwr/preview/mmwrhtml/mm6131a2.htm?s_cid=mm6131a2_w



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