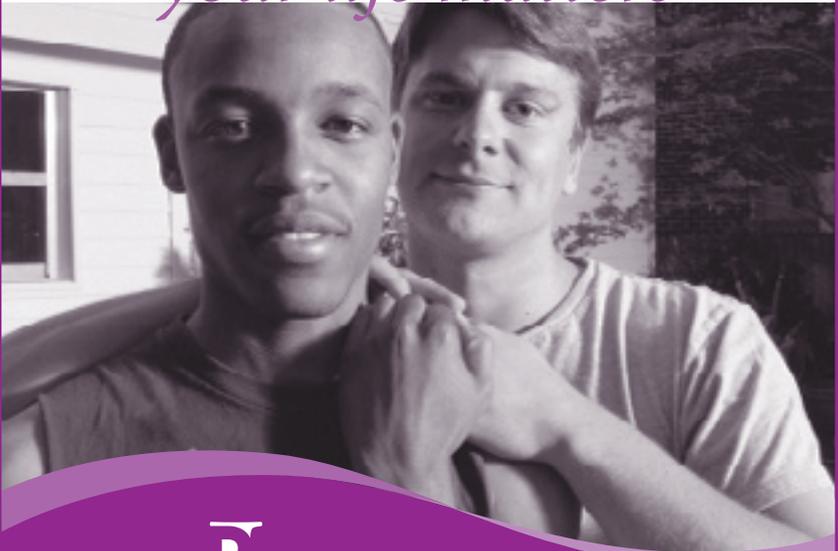


*A publication for men and
transgender women who have sex with men*

PRE-EXPOSURE PROPHYLAXIS

Is taking PrEP the
right choice for you?

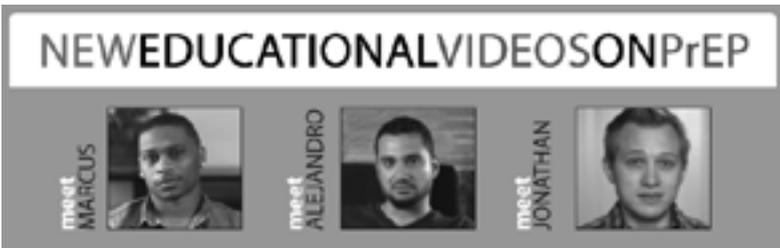
your life matters



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JUNE 2014

**Check out our four videos
on PrEP as well!**



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

Go to www.projectinform.org/prep.

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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 so you can make the best decision for yourself. PrEP is an exciting new prevention tool, but it's not for everyone. So 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, please read our other PrEP publication, *PrEP: A new option for women for safer loving*.

We also have a companion booklet called *How to get PrEP*, which explains how to talk to your medical provider about PrEP and how to deal with the possible barriers to getting it should you encounter any. And, Project Inform has developed 4 educational videos on PrEP for gay men, which are found at projectinform.org/prep.

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 prescribed by a health provider.
- Since PrEP was recently approved by the FDA, some providers may not know about it or may not be knowledgeable or comfortable discussing PrEP or your sexual health.
- 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 is highly effective at blocking HIV infection.



What is PrEP?

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

Three clinical studies show that HIV-negative people who take Truvada for PrEP every day — and who combine it with condoms (and other HIV prevention methods) — may see their risk for HIV cut by up to 92%. 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 provider 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*, or PEP. PEP means taking medicines after you were exposed to a virus or bacteria. When a person takes PEP to prevent HIV, s/he takes 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 provider.



- 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 an STD 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, drugs or alcohol or other needs; or, does your sex partner(s)?
- Has your partner ever threatened or forced you to have sex against your will?

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 complete regimen for people with HIV).
- Have symptoms of acute HIV infection (symptoms similar to the flu).
- Don't know whether you have hepatitis B or have been successfully vaccinated for it.
- Can't find a medical professional or clinic to provide regular HIV and STD testing and prevention counseling along with Truvada.
- Don't think you can take it every day.
- Just plan to take 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 pills 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 or blood from an HIV-positive person, then Truvada can help to keep the virus from causing an infection. (Watch this video at www.whatisprep.org.)

What are Truvada's side effects?

Most people who take Truvada don't experience side effects. In fact, some people have remarked that they wonder if the pill is working at all because they haven't felt side effects. You can trust the drugs are there doing their job even if you don't feel them.

With that said, the short-term side effects noted in PrEP studies included headaches, weight loss and stomach problems like nausea, diarrhea and stomach ache. These occurred in about 1 out of 10 people, and most subsided after the first few weeks of taking Truvada.

A few people have had minor problems with kidney health, which got better when Truvada was stopped. Minor bone loss also occurred. As for its long-term side effects, we don't yet know about them since these PrEP studies only followed HIV-negative 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 number of people who take it. Because HIV by itself can also cause this, it's difficult to know whether Truvada on its own causes kidney and bone disease. However, people with current kidney disease should not use PrEP. Those who use PrEP should have their kidney health checked regularly.

One "side effect" that's often not mentioned is that some people end up feeling less anxious about HIV. They have more time to organize their thoughts, which can eventually lead them to making better sexual choices. You may find that PrEP gives you the mental and emotional space to becoming more proactive around your sexual health.

How well does Truvada prevent HIV infection?

In clinical studies, when people took Truvada every day, the pill appeared to lower their risk for infection by at least 90%. In people who did not take it every day, it did not protect them as well. 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 PrEP study in men who have sex with men that the FDA reviewed when they approved Truvada for PrEP. In that study (called iPrEx, iprexnews.com) condoms, regular STD check-ups and other prevention education were offered along with the pills.

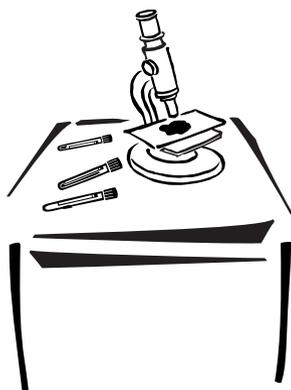
The study included 2,499 men and transgender women who have sex with men at high risk for HIV. Results were reported in November 2010. Overall, iPrEx showed a 44% lower risk of infection in those assigned to take Truvada compared to a placebo (fake pill). This 44% included people who took it every day as well as those who took it only now and then or who never took it. However, when looking only at those people who actually took Truvada every day, the drugs cut their HIV risk by up to 92%. In a separate look at the iPrEx data, researchers found that people with enough Truvada in their blood system equal to 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 condom use was the same in both the Truvada and placebo groups, it is highly likely that Truvada, and not just condoms, had a lot to do with how effective the pill prevented new infections.

What tests will you need to get?

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

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



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

- You should have regular medical visits every 2–3 months.
- Routine HIV tests (at least every 3 months) are needed to make sure you continue to be HIV-negative. Or, if you experience symptoms of early HIV infection in between scheduled visits, test again to rule out possible acute infection.
- Someone in your doctor's office or clinic should talk to you about side effects, how to take it every day and your risky sexual or drug use activity. You should also get STD tests done every 6 months or more often if your risk for STDs stays high.

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

Both of the drugs in Truvada also work against hepatitis B. Therefore, it's important to know if you have currently hepatitis B before starting PrEP. If that test shows that you haven't been exposed to hepatitis B, then get the routine vaccine. It's covered by most health insurance plans.



You can take PrEP at the same you're taking hepatitis B meds. In fact, you may be given Truvada to treat hepatitis B as well as prevent HIV. However, if you have active hepatitis B disease and stop PrEP suddenly, it can cause dangerous liver problems. Work with your medical provider on the safest way to stop PrEP if you also have hepatitis B disease.

What should you talk to your health care provider about?

- Is s/he knowledgeable, willing and ready to support you being on PrEP?
- What is the result of your most recent HIV antibody test? Do you need to test twice before starting PrEP because of recent high-risk sex?
- 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 you get tested for? How often should you get tested for them?
- What is your kidney health and is it safe for you to start PrEP?
- What kinds of drug interactions are possible with the other medications you take? (Such as testosterone, hormonal pills, heart medicine, etc.)



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 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 take it for a few months or years, stop for a period of time if they're not at risk, and then restart if that changes again. Making this decision — when to use PrEP as well as when not to use it — should be done with help from your provider.

As for stopping PrEP, if you find out that you're HIV-positive, you should stop it immediately! This is because Truvada is not strong enough to control HIV on its own 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 provider 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.

Why should you take PrEP every day?

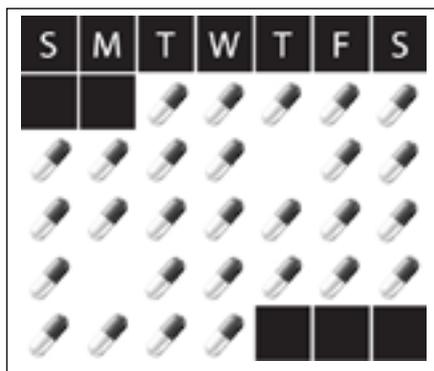
All of the PrEP studies so far clearly show that people who take Truvada every day have a much lower risk of HIV infection. Not taking it as prescribed can lower the drug's ability to prevent HIV infection.

Therefore, it's very important that you take PrEP as directed. Newer information shows that a missed pill every now and then may still leave you protected, however. If you start on PrEP, it's recommended that at least seven daily doses are taken first to establish the proper level of Truvada in rectal tissue.

Some people find it fairly easy to take pills every day, like taking a daily vitamin. This can be easier if you take the dose at the same time every day 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 messages 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. Paying extra attention to these types of issues can in turn help you keep up with your doses.



What if you get HIV while taking PrEP?

In order to control the virus, HIV-positive people take at least three meds altogether. Taking two meds, as with Truvada, is not strong enough to control HIV infection. Doing this can cause new strains of HIV to develop that the drugs could 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 as HIV treatment. 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 your body hasn’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.

What if my sex partner has HIV that's resistant to one or both drugs in Truvada?

If your partner has drug-resistant HIV, there are two important considerations. First, what is his or her viral load? Second, if their viral load is more than 50 copies (called *detectable*), to which drug(s) is his/her virus resistant?



The most important factor is your partner's viral load. One large study among mixed-status heterosexual couples found that when the positive partner's viral load was consistently undetectable (<50 copies), transmission to the negative partner was cut by >96%.

Therefore, even if your partner's virus has developed resistance to either drug in Truvada at some point in the past, transmission is far less likely as long as s/he continues to stay undetectable. In fact, if you are each monogamous and your partner's viral load is consistently undetectable, PrEP may not be necessary, but may still be taken for your added protection.

continued ...

What if my sex partner has HIV that's resistant to one or both drugs in Truvada?, *continued*

Truvada contains two drugs, tenofovir and emtricitabine. The main HIV mutation to tenofovir is called K65R; the main mutation to emtricitabine is M184V/I. In both cases, these mutations make HIV less easily transmitted, because they make the virus less strong. That doesn't mean that drug-resistant virus can't be transmitted. It can. However, transmission of K65R is very rare, perhaps less than 1% of all cases of drug-resistant transmission. M184V/I is a very common mutation, but is generally not well transmitted.

Also, in the Partners PrEP and Bangkok IDU studies only tenofovir was used, and in those who took it regularly it was effective at blocking infection. Therefore, if your partner's virus is not resistant to tenofovir, it's likely that taking Truvada as PrEP will work well provided you take it consistently.

If your partner's virus is higher than 50 copies and is resistant to tenofovir (carries the K65R mutation), then Truvada may not protect you.

Do you still have to use condoms?

Condoms work 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 to lower your risk (like knowing the status of your partner[s]).



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're 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 improved 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 getting HIV. It won't protect you from most other STDs, but it might strongly reduce your risk of HIV compared with not using it at all.

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 pill 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.

OUR BOTTOM LINE: if you're taking PrEP, then you're taking charge of your sexual health. You've carefully thought about it and are acting more responsibly at preventing HIV ... for yourself and your community. And that's something to be proud of. If you ever hear others disapproving of your choice to use PrEP, then it may provide you a chance to educate others if you want to go that route.

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

Since the prescription is approved by the FDA, it can 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 insurers have yet decided to cover it. Some may choose not to pay for it.

For people whose insurance covers PrEP, the major cost should only be the drug co-pay charged at the pharmacy and co-pays for medical visits and lab tests. It's worth asking your health provider to contact Gilead Sciences, who makes Truvada, as they offer co-pay cards which help cover all or some of the drug's co-pay costs. To access that program, go online at www.truvada.com/truvada-patient-assistance or fill out this form: http://start.truvada.com/Content/pdf/Medication_Assistance_Program.pdf.

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

Gilead can also provide vouchers for free condoms for those taking PrEP. Information about this can be found at <https://start.truvada.com/individual>.

If you're interested in taking PrEP, but don't have a health provider, contact your local health department's HIV or STD program. They may 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** take PrEP on your own. It should only be taken as prescribed from a health provider who can monitor your health and any possible side effects. You need specific initial and ongoing tests. If you don't know the results to these tests, your health could suffer.
- **DO NOT** occasionally take your PrEP pill. No 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, but results aren't expected until 2015. In the meantime, it's important to use PrEP daily.
- 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.
- Taking PrEP can be a major change in your life and can affect your sexual and other close relationship(s). Consider talking about PrEP (and other prevention methods) to your partner(s) to continue to promote open dialogue about the choices you make.



Resources that may help you and your health provider

PATIENT INFORMATION

Pre-Exposure Prophylaxis
www.projectinform.org/prep

Talking to Your Doctor
www.cdc.gov/hiv/pdf/risk_PrEP_TalkingtoDr_FINAL_cleared.pdf

My PrEP Experience
<http://myprepexperience.blogspot.com/>

PrEP Facts
<http://prepfacts.org/>

What is PrEP?
www.whatisprep.org

PrEP Watch
www.prepwatch.org

Truvada for PrEP
(company website)
<http://start.truvada.com/#>

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

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

RESOURCES FOR CLINICIANS

CDC/Federal PrEP Guidelines
www.cdc.gov/hiv/prevention/research/prep/

CDC Fact Sheet (PrEP: A New Tool for HIV Prevention)
www.cdc.gov/hiv/prep/pdf/PrEPfactsheet.pdf

Clinician Consultation Center
800-933-3413
<http://nccc.ucsf.edu/>

Truvada for a PrEP Indication
<https://start.truvada.com/>

*Our appreciation to the following providers
for their review of this booklet:*

Raphael Landovitz, MD, Los Angeles

W. David Hardy, MD, Los Angeles



273 Ninth Street
San Francisco, CA 94103

Check out our companion booklet, *How to get PrEP*, available at:
www.projectinform.org/prep/

Help us improve this material by telling us what you think!

www.projectinform.org/surveyprep/