



PrEP
PRE-EXPOSURE PROPHYLAXIS

A NEW OPTION FOR WOMEN FOR SAFER LOVING



a publication for women who have sex with men

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Using this booklet ...

Project Inform, SHERO, SisterLove and AVAC partnered to write this resource guide for women who have sexual relationships with men, because we all believe that every woman is beautiful and every woman deserves to have a sex life that is loving, consensual, passionate, pleasurable and free from concern about HIV and other sexually transmitted diseases (STDs). Because of that, we want to talk about a relatively new HIV prevention strategy that you might want to think about if you're sexually active or want to be. It's called *pre-exposure prophylaxis* (PrEP) and it means taking a pill daily that can be highly effective at reducing your risk of getting HIV.

You might already be thinking, "Why are you even talking about HIV with me? I'm not at risk!"

That might be true, but we believe in keeping it real, and the real truth is that many women who will become infected, don't think they are at risk. They may or may not know how HIV gets transmitted. In either case, it's just that understanding risk is a little different for women and there are a lot of factors that you might not have thought about before. As many as 1 in 30 black women will get HIV in their lifetime, and many would not have thought they were at risk in the first place.



HIV vulnerability: What do you see in the mirror?

Let's get the simple stuff out of the way first. HIV is a virus that attacks the immune system, and without treatment it is almost always fatal. It's spread through contact with blood, semen, breast milk and vaginal fluids.

You probably don't have much to worry about if you:

- don't have sex with anyone,
- are in a mutually monogamous relationship with one partner who you 100% know doesn't have HIV (perhaps because you got tested together recently), or
- always use a condom correctly for sex.

If your sex life is a bit more complicated than that, which is true for lots of women, there are some things we'd like you to think about.

On the next page is a drawing of a mirror. We're going to give you a long list of factors that make some women more vulnerable to HIV than other women.

We know that it isn't always possible or even desirable to use condoms. If a woman regularly uses condoms, then taking a pill to prevent HIV is unlikely to provide any more benefit. But for women who don't or can't always use condoms then PrEP might be helpful.

PrEP for HIV prevention means taking a pill every day that in the past was used (along with other medications) only to treat HIV. Because the pill is so potent against HIV, scientists began thinking it might also help prevent HIV-negative people from becoming infected. PrEP is recommended for some women, because at least two studies found that those who are able to take it regularly have high protection from HIV.

Here are some ways to think about HIV vulnerability and HIV risk

Read through these questions and see if any seem to apply to your situation.

- Do any of your sex partners have HIV? Plenty of women start relationships with HIV-positive men and many of these relationships are wonderful, loving and satisfying. In these cases, some women and men get to a place where a condom feels like it blunts intimacy. It's not about right and wrong ... because emotions are powerful. But just because you've been able to have condomless sex without getting infected so far, it doesn't mean that will always be the case.
- Do you find using condoms to be a challenge? Then there are at least a couple of things you can do to reduce your risk. If your HIV-positive partner is taking HIV medication and his virus levels are so low that they're undetectable, then your risk of HIV drops a lot. If your partner is not on meds, however, or if you don't know that his viral load is undetectable then PrEP may offer more protection.
- Does your partner refuse to use condoms with you? If he does, if you're in a new relationship, or if there's any chance he might have other sex partners then you are not alone. It could also be that he's never been tested or not tested for HIV recently. Lots of women have to deal with this, and unfortunately it places you at greater risk of HIV.



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- Are you African American or Latina? Sadly, women of color are generally at much higher risk of being infected with HIV in the US because there's more HIV in our communities and fewer people get into health services. That doesn't mean that white women never become infected, but it does mean that women of color might need to think more carefully about their other HIV risks and may especially benefit from PrEP.
- Do you live in a part of the country with very high rates of HIV? These include, but are not limited to, Washington DC, Baltimore, Atlanta and many other parts of the South, New York City, South East Los Angeles, and many other places. If you do, you probably need to re-consider your risk. Even if you don't live in one of those parts of the country, but have other vulnerabilities, you could still be at risk of HIV.
- Do you have more than one sex partner, even if it is only once in a while? This is true for many women and it might increase your vulnerability to HIV.
- Does your partner ever have other sex partners, or do you suspect he does? This is true for lots of women and it might increase your vulnerability to HIV.
- Have you or your partner(s) recently been treated for an STD such as syphilis, gonorrhea, chlamydia or herpes? This may be a sign that you are at increased risk for HIV.
- Have you experienced sexual or other types of violence in your life? Does your partner verbally threaten you or hit you or destroy your self-confidence? Nearly one in three women in the United States experiences this type of abuse at one point in their lives. Unfortunately, women who experience abuse as children or adults are much more likely to become infected with HIV. There are plenty of reasons for this, including

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the fact that abuse can make a woman more likely to use drugs or alcohol to numb her emotional pain and she may be less assertive at protecting herself sexually.

- Does your partner use injection drugs or did he ever use injection drugs? This could put him at higher risk of having HIV and that makes you more vulnerable too. However, PrEP can also help lower your risk for HIV if you share injection equipment.
- Has your partner ever been in jail or prison? This can also put him at higher risk of having HIV and that also makes you more vulnerable.
- Do you suffer from depression, very low self-esteem or anxiety? All of these can make you more vulnerable to HIV, because it may be harder for you to negotiate using condoms with your partner as well as you might if you felt better.
- Have you or your partners ever exchanged sex for money, drugs, housing or other kinds of assistance? These can increase your HIV vulnerability.

Once you've noted any of the factors that might place you at risk let's take a step back. How does it feel to look in that mirror? It might not feel good, but understanding your true vulnerability can actually be empowering, because it means you can do things to change your risk.

Having looked in the mirror, you can now decide what you want to do about your HIV vulnerability. Do you think you can now insist that your partners always use condoms with you? Are there other things you can do to reduce your risk? If so, then you might not need PrEP. However, if you can't make these kinds of changes, then PrEP might be a tool you can use to protect yourself from HIV, at least until you are able to make other changes.

What is PrEP and how can it help?



PrEP stands for PRE-exposure prophylaxis. Meaning that you take a medication before you are exposed to a disease so that you are less likely to get sick. In this case, an HIV-negative person who is particularly vulnerable to getting HIV would take the pill called Truvada every day to help reduce his or her risk of infection.

PrEP isn't just used to prevent HIV transmission though. Medications are used to prevent other diseases too and with other drugs. For instance, if you travel to certain parts of the world you might take a drug that helps prevent malaria. You'd start taking it before you travel, during your trip and for a little while afterward. That's also a kind of "PrEP".

Clinical studies show that HIV-negative heterosexual men and women who take Truvada for PrEP every day and who combine it with other prevention strategies may see their risk for HIV cut by up to 90%. Based on the evidence, the US Food and Drug Administration (FDA) approved daily Truvada for PrEP in July 2012 for adults at high risk for sexual transmission of HIV. They also recommended that PrEP be combined with condoms. Though other HIV drugs are being studied for PrEP, Truvada is the only drug currently approved for this purpose.

PrEP is not just about taking a pill every day. If you decide to take Truvada for PrEP, you'll need to see your medical provider at least every three months for routine care, monitoring and HIV

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testing. You'll need to talk about your current sexual activity, your level of risk, sexually transmitted infections (STDs), your routine test results and any side effects. This will mean more clinic visits and more attention to your HIV prevention plan.

**PrEP should only be taken by HIV-negative people.
That's why testing is so important.**

You should note that PrEP differs from PEP (POST-exposure prophylaxis), which means taking HIV medicines immediately **after** you think you are exposed to HIV. When a person takes PEP to prevent HIV, she takes two or more medicines for about a month after a high-risk exposure.

What is Truvada? How does it fight HIV?

Truvada is a pill made up of two HIV meds — Viread (tenofovir disoproxil fumarate) and Emtriva (emtricitabine). Truvada is normally used with other meds to treat HIV infection in HIV-positive people. The drugs in Truvada are also sometimes used to treat hepatitis B.

Truvada prevents HIV from reproducing in the body. If you're exposed to the semen or pre-cum from an HIV-positive man, then Truvada can help to keep the virus from causing a lasting infection. (Watch this video at www.whatisprep.org.)



PEP

HIV medications are also sometimes used after a person has a high-risk exposure to HIV, usually for about 28 days. This is called post-exposure prophylaxis, or PEP, as mentioned before.

How well does Truvada prevent HIV?

In clinical studies, when heterosexual men and women in mixed status couples (one partner was HIV-positive) took Truvada as close to every day as possible, the pill appeared to lower their risk for infection by up to 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. It just makes sense.

Below is a brief recap of studies that included women. PrEP was also found to be highly effective for heterosexual men and for gay, bi and other men or men who have sex with men.

The Partners PrEP study

In 2011, results from Partners PrEP study were released. The study, conducted in East Africa, included 4,758 heterosexual mixed-status couples where one partner was HIV-negative and the other HIV-positive. In some cases the man was HIV-positive and in other cases it was the woman. Overall, the study showed a 75% lower risk of infection when the HIV-negative partner in the couple took Truvada. When looking only at those people who took their pills every day, their risk was 90% lower than those who didn't take Truvada as PrEP.

The same team conducted another study looking at a more real-world scenario in mixed status couples. In this case, the HIV-positive man or woman started taking HIV medications to treat their disease and bring their virus levels down to undetectable. Doing this is not only good for the HIV-positive person. It also reduces the chance that they'll pass on HIV to their HIV-negative partners by at least 96%.

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Because it can take a few months for HIV levels to become undetectable, the HIV-negative person in each partnership took PrEP. Though the study is ongoing, there has only been one HIV transmission so far.

The TDF2 study

The TDF2 study conducted in Botswana had similar results. Women who were assigned to take Truvada were about 62% less likely to get HIV. When Truvada was measured in blood, women with detectable levels were less likely to get HIV than those with no drug (who didn't appear to take their Truvada).

The FEM-PrEP study

As you would expect, however, Truvada can't protect a woman if she doesn't take the drug. In another study conducted in young HIV-negative women in Africa, called FEM-PrEP, it was stopped early because there was no difference between those who took Truvada or a placebo (a fake Truvada pill). However, it was later found that almost 3 out of 4 women were not taking their pills.

The VOICE study

A second study called VOICE, which also included HIV-negative women in Africa, had a result similar to FEM-PrEP. Though women reported taking their medication, it turned out that only about one in three actually took the drug regularly. We know this because researchers checked the women's blood for the presence of the drugs in Truvada. Once again, with so few women actually taking the drug as directed, the women who were offered Truvada were just as likely to become infected with HIV as women who were offered a placebo. Some studies are underway to talk to the women in the studies to find out why they didn't use the drugs although they reported they were doing so.

Other studies are being planned to determine how to use PrEP in the "real world" outside of a clinical trial. Most of them will be done in Africa, but at least one is planned for the US.

Things you should know before starting

As with any medication, PrEP may not be right for you because of other medical concerns. Also, pretty much anything we put in our bodies has the potential to cause side effects. Even the simplest drugs such as aspirin, or even many herbal treatments, can cause side effects in some people. PrEP is no different and some side effects only show up on lab tests. Here's what you should know if you are considering PrEP.

PrEP is not for everyone

You should not use PrEP if:

- You don't think you can take a pill every day or nearly every day.
- You don't know your HIV status.
- You are HIV-positive (Truvada is not a full regimen for people with HIV though it may be used with other HIV medications).
- You have symptoms of acute HIV infection (symptoms similar to the flu). You may get tested for acute HIV on the day you are considering starting PrEP.
- Can't find a medical provider to provide regular HIV and STD testing and prevention counseling along with the medication. Taking someone else's medication without being monitored by a medical provider is not recommended.
- You haven't been tested to see whether you have hepatitis B. You will be tested for hepatitis B when you get evaluated for PrEP.
- You have kidney disease or reduced kidney health.

What are the potential side effects?

In studies of Truvada for PrEP, the main side effects were some short-term stomach upset. There were also very small changes in blood tests of bone and kidney health, but not to a degree that is believed to be harmful.

To judge how likely a woman might be to have a side effect we can look at the numbers from the studies. Based on those studies we would expect that if you gave Truvada to 100 women, about three of them would have an upset stomach or feel tired; but in the studies this lasted for only a few weeks and then went away.

In HIV-positive people who take Truvada with other drugs to treat their disease, we know that it can cause some loss of kidney function and bone health in small numbers of people and can sometimes be serious. However, HIV by itself can also cause these things so it's hard to know how much of the problem is caused by Truvada and how much by HIV or other factors.

In the studies of Truvada as PrEP, about 1 out of every 100 women had a mild change in their kidney function and this always went away as soon as the women stopped taking the pill. About 9 out of 100 women had very minor changes in bone health, but this was also true in women who were assigned to take a sugar pill (placebo).

There may be other problems for some people with Truvada and your health care provider should go over this information in detail before prescribing it. A health care provider should also monitor regularly to look out for side effects that might emerge later.

What are other risks to taking PrEP?



You may have heard that missed doses of Truvada may not be a concern, and this is certainly true when the primary risk is anal sex. However, drugs can concentrate at different levels in the vagina than the rectum, and this is also true for Truvada. In fact, vaginal tissue levels of one of Truvada's drugs (tenofovir) are not only lower, but they take longer to build up. This is why we warn that PrEP may not protect against vaginal transmission as quickly as it does for anal transmission. This is also why women may not be able to miss doses to remain protected

If you miss too many doses and become infected with HIV while taking PrEP, there's a chance that your virus could become resistant not only to Truvada, but also to other HIV drugs. Resistance is when strains of the virus develop that the drugs can't fight off anymore.

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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 may not be able to use these drugs later to control your HIV. Since Truvada is preferred over other HIV medications when starting HIV treatment, not being able to use it could limit your treatment choices.

There are 2 things you can do to help prevent drug resistance:

1 Make sure you're HIV-negative before starting PrEP.

If you are very recently infected (past few weeks), 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 a new or "acute" infection.

2 Get routinely tested for HIV every 3 months while on PrEP.

Also, let your provider know if you develop flu-like symptoms or unexplained rashes in between tests.

Both of the drugs in Truvada also work against hepatitis B. Therefore, it's important to know if you have hepatitis B before starting PrEP. If your provider finds that you're eligible for it, then get the hepatitis B vaccine.

If your hepatitis B test shows you do have active disease, then starting treatment for hepatitis B may be recommended. Discuss treatment options with your provider. 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 if for some reason you plan to stop PrEP and you also have hepatitis B disease.

What tests will you get before starting?

BEFORE YOU START PREP,

your medical provider should do the following tests and exams:

- A thorough talk about your sexual activity and level of HIV risk.
- An antibody or antibody/antigen test or possibly a test to detect HIV directly.
- Tests for hepatitis B, kidney function and STDs.
- A pregnancy test, especially if you haven't had your period in a while or if your periods aren't regular. We don't have full information yet on how Truvada may affect the fetus if you are taking the drug for PrEP but it does appear safe when taken by HIV-positive pregnant women.

What tests will you get while on PrEP?

WHILE YOU'RE TAKING PREP,

the following should be done:

- You should have regular visits to your medical provider every 3 months.
- Routine HIV tests (at least every 3 months) are needed to make sure you continue to be HIV-negative and don't develop drug resistance if you became HIV-positive while taking PrEP.
- Your medical provider should talk to you about side effects, adherence and sexual activity. You should also get STD tests done every 6 months or more often if your risk for STDs stays high.
- If you miss your period or if your periods are irregular you should find out if you might be pregnant.

Think about who should and shouldn't know that you are taking PrEP, and how you'll take it every day

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 it's used to treat HIV and assume you're HIV-positive. They may not be aware that it can be used as PrEP. And even if they know about PrEP, they may still think poorly about the people who take it.

Also, you need to think about how your sex partner or partners might feel about you taking PrEP if they find out. Some men could become upset or even violent, so thinking about where you keep the medications and whom you tell about them is important.

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. Also think about how to carry it around or remember to bring it with you if you sometimes stay away from your home. Some people won't find this to be an issue, but for others this may cause them some unnecessary social problems.



If you take PrEP, do you still have to use condoms?

In an ideal world, everyone would use condoms to prevent getting HIV and other STDs. 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 or 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.

Condoms are great. They are a cheap and reliable way to help avoid getting HIV, and they prevent most other STDs. However, PrEP is also great for some people, especially if you struggle with using condoms every time.

PrEP could be one of the best ways to prevent HIV while you work on those issues that keep you from using condoms every time you have sex to lower your risk.

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're trying to get pregnant ...

Men and women who are in mixed-status relationships (one is HIV-positive and the other HIV-negative) sometimes want to become parents. For some, there are assisted reproduction services, such as sperm washing and in vitro fertilization that can be used to ensure that HIV is not transmitted when women are trying to become pregnant. Unfortunately, these services are very expensive and not available everywhere.

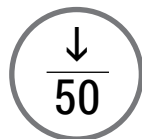
Another promising approach is to use PrEP for the HIV-negative woman combined with a full HIV regimen for the HIV-positive man. So far one small study shows that PrEP is effective at preventing transmission from the HIV-positive partner to the HIV-negative partner when couples are trying to have a baby, but more studies will be needed before PrEP can be widely recommended. Truvada appears safe when used by HIV-positive pregnant women, but it has not been studied well in HIV-negative women taking it while trying to get pregnant. Couples trying to have a baby should find a specialist with whom they can explore their options. If you can't find a specialist to help with the decision about taking PrEP or using other safer conception options while trying to get pregnant, your medical provider can call the National Perinatal HIV Hotline (1-888-448-8765) and get assistance and advice.



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There are a few points to consider before using PrEP when trying to become pregnant:

- Your HIV-positive male partner should be taking a full HIV regimen and ideally have undetectable HIV levels in his blood. If he can't get his HIV to undetectable or you can't get a procedure called sperm washing done, PrEP could be a good way to lower your HIV risks while trying to become pregnant.
- You may wish to time sex and only have sex without condoms on the days when you're most likely to conceive. This means during ovulation — the time of the month when your ovary releases an egg — usually about 2 weeks after your last period.
- You may want to test regularly for pregnancy. Discuss your HIV prevention options in case you do get pregnant. Although using Truvada for PrEP appears to be safe during pregnancy, you may want to stop it to reduce any possible harm to the fetus. In this case, start other prevention methods to protect yourself from HIV.
- You should see a medical provider who is familiar with using HIV drugs during pregnancy and with conception in mixed-status couples. If you cannot find one, your medical provider can call the National Perinatal HIV Hotline at 1-888-448-8765 and get assistance and advice.



PrEP requires a team approach

It's really important that you receive PrEP from a health care provider and other supportive social service providers who have learned how to use it safely, and how to support you in having the healthiest sex possible while taking PrEP.

Not all health care providers are totally on board with PrEP. Many don't know much about it at all. For this reason, if you think PrEP is right for you, but you don't have a provider who is comfortable offering it to you then you might need to find another provider who is.

Your provider can also get support and learn more about PrEP. Encourage them to look at the CDC PrEP guidelines (www.cdc.gov/hiv/prevention/research/prep/index.html) or the Truvada website (<http://start.truvada.com/hcp#>) for instructions on how to prescribe PrEP and monitor women who choose to take PrEP.

Things to ask your medical provider

- Are you informed, willing and ready to support me on PrEP?
- What is the result of my HIV antibody or antibody/antigen test? Do I need to test again later or have a viral load test done before starting PrEP because of recent high-risk sex?
- How often do you want me to test for HIV? (It should be every three months at a minimum.)
- Are you testing me for hepatitis B? Am I eligible for a hepatitis B vaccine? If I 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 my kidney health? Is it healthy enough to start PrEP?

How do you get PrEP? How much will it cost?

Since Truvada for PrEP is approved by the FDA, it is covered by health insurance. It should also be available through government programs like Medicaid. Because PrEP is a somewhat new HIV prevention strategy, a few insurers may decide not to cover it or make you jump through hurdles to get it.

If you have Medicaid, you should be able to get your medication and all your doctor's visits and lab tests with little money spent out of your own pocket. Some Medicais require your doctor to fill out a prior authorization form before you can get the medication, but this generally isn't an obstacle.

If you have private insurance, the costs you'll pay may vary quite a bit. Some people have relatively low co-pays. Truvada's maker, Gilead Sciences, covers up to \$3,600/year for co-pays (www.gileadadvancingaccess.com).

Some people have less generous insurance plans, especially those with bronze level plans through state insurance exchanges. For them there may be: 1) very high out-of-pocket costs for the drugs through deductibles that must be met in full before prescription benefits kick in, or 2) co-insurance that requires you pay a set percentage (maybe 30% or more) rather than a flat co-pay. Two programs can help with co-pays: Patient Advocate Foundation (<https://www.copays.org/diseases/hiv-aids-and-prevention>) and PAN Foundation (www.panfoundation.org).

For people without insurance who aren't eligible for Medicaid, or for people with insurance but without prescription coverage, Gilead's Medication Assistance Program offers free drugs to those with low to moderate incomes.

Read Project Inform's "Getting PrEPared for PrEP" flow chart for more information: www.projectinform.org/prep-chart.

Resources that may help you and your health provider

INFORMATION ON PrEP

Pre-Exposure Prophylaxis

www.projectinform.org/prep

My PrEP Experience

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

PrEP Facts

<http://prepfacts.org/>

What is PrEP?

www.whatisprep.org

PrEP Watch

www.prepwatch.org

The HIVE

(reproductive health & HIV)

www.hiveonline.org

Truvada for PrEP

(company website)

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

Truvada for PrEP

(company REMS website)

<https://www.truvadapreprems.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/>

RESOURCES FOR CLINICIANS

Truvada for a PrEP Indication

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

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

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

CDC Guidance on HIV PrEP for Various Populations

www.cdc.gov/hiv/prevention/research/prep/

Clinician Consultation Center

800-933-3413

<http://nccc.ucsf.edu/>

Clinical Studies Resources

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

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www.projectinform.org/prep