

the**well**project

# PrEP for Women

*Together, we can change the course of the HIV epidemic...one woman at a time.*

#onewomanatatime

[www.thewellproject.org](http://www.thewellproject.org)

#thewellproject



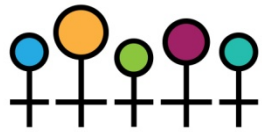
thewellproject

# What Is PrEP?

*PrEP* stands for  
**Pre-**  
**Exposure**  
**Prophylaxis:**



*Prophylaxis:* Taking medicine ***before*** being exposed to something, to prevent yourself from getting a disease or condition



thewellproject

# What Is PrEP?

We use *several kinds of medicine* this way:

- ***Taking anti-malaria medication*** when we travel to areas where we might be bitten by mosquitoes that carry malaria
  - When medicine is in a person's body before getting a mosquito bite, (s)he is much less likely to get malaria when bitten
- For women, ***taking birth control pills (contraceptives)***
  - Chances of pregnancy greatly reduced when contraceptives are already in a woman's body when exposed to semen during sex
- PrEP in connection to HIV and women: HIV-negative individuals ***taking HIV drugs to reduce their risk of becoming HIV positive*** if exposed to the virus



thewellproject

# How Does PrEP Prevent the Spread of HIV?

- CD4 cells infected with HIV become little factories that make thousands of new viruses each day
  - HIV drugs work by blocking HIV from making copies of itself
- If an HIV-negative woman already has HIV drugs in her bloodstream when she is exposed to HIV during sex without condoms:
  - Medicine might be able to keep the HIV from making enough copies of itself to "take hold"
  - May prevent her from becoming HIV positive



thewellproject

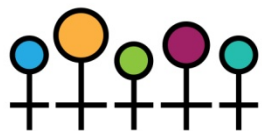
# Approval for Daily Oral PrEP

**July 2012:** U.S. Food and Drug Administration (FDA) approved daily Truvada (tenofovir disoproxil fumarate + emtricitabine, or TDF/FTC) as PrEP for sexually active adults at risk of HIV

- Truvada often used as part of combination HIV drug treatment
- First time FDA has approved any drugs for prevention of HIV

**June 2016:** World Health Organization (WHO) releases updated guidelines recommending daily oral PrEP be offered as additional prevention method for all people at substantial risk of HIV

- WHO approves either Viread (tenofovir/TDF) or Truvada for daily oral PrEP



thewellproject

# Has PrEP Been Shown to Be Effective?

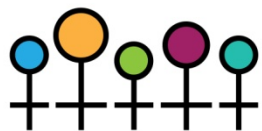
- **Efficacy shown**

- *iPrex, TDF2, Partners* studies tested **Truvada**

- Conducted among men who MSM and transwomen in U.S. and Latin America
- Among heterosexual women, men in several African countries
- Effectiveness varied from 44 – 73% additional protection against HIV

- Study in Bangkok tested *tenofovir (Viread)* as PrEP

- Among >2,400 HIV-negative women and men who inject drugs
- Reduced risk of getting HIV by almost half



the**well**project

# Has PrEP Been Shown to Be Effective?

- **Efficacy shown: Partners Demonstration Project**
  - Nearly eliminated HIV transmission among >1,000 serodifferent heterosexual couples in Kenya, Uganda
  - Tested PrEP + treatment as prevention, with PrEP as a “bridge”
    - HIV-negative partner took PrEP while partner living with HIV took first 6 months of ARVs
  - Completed in December 2016; only 1 new infection noted in primary results through July 2014
    - 96% reduction in new HIV cases
  - Applies to all new infections, including those from someone other than one's regular sexual partner



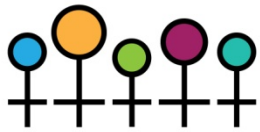
thewellproject

# Has PrEP Been Shown to Be Effective?

Other studies have found PrEP *not to be effective*

- **FemPrEP** study
  - Tested Truvada in Kenyan, Tanzanian, South African women at high risk for HIV
  - Stopped early – did not seem to help in preventing HIV transmission
- **VOICE** study
  - >5,000 women in South Africa, Zimbabwe, Uganda
  - Tested:
    - Oral daily tenofovir
    - Oral daily Truvada
    - 1% tenofovir vaginal gel
  - Found all **three methods ineffective** in preventing HIV transmission





thewellproject

# Why Are Some Research Findings Unclear?

For HIV prevention tools (condoms, PrEP, etc.) to work, they ***have to be used – correctly and consistently***

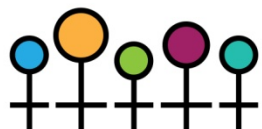
- **Adherence** was the key factor for success in PrEP studies
- FemPrEP and VOICE studies:
  - Low levels of adherence; fewer than 1 in 3 women took drug regularly
  - Many women in FemPrEP study did not consider themselves at risk for HIV
- Studies that showed benefit had ***much higher rates of adherence***
  - People who took PrEP as prescribed were much less likely to become HIV positive
  - CDC says that in people at high risk for HIV who take PrEP consistently, risk can be reduced by 92%



the**well**project

# Why Are the Research Findings Unclear?

- Reasons why people – especially women – had low levels of adherence to oral PrEP is not yet fully understood
- Very important to do more research looking at what issues might affect women's interest in or ability to take a drug for HIV prevention
- Also important for women to know about and take part in future research that will look at unanswered questions about PrEP



thewellproject

# CDC Guidelines for PrEP Use

**May 2014:** CDC released updated guidelines for PrEP use in U.S.

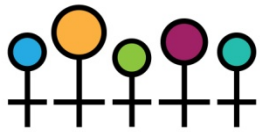
- Recommend PrEP with daily, oral Truvada be ***considered for HIV-negative people who are at substantial risk for HIV***, including people who:
  - Are in a sexual relationship with a partner living with HIV
  - Don't regularly use condoms/don't know HIV status of sexual partner(s)
  - Have high number of sexual partners
  - Are engaged in commercial sex work
  - Have had recent bacterial sexually transmitted disease
  - Use injections drugs and
    - Share drug equipment, *or*
    - Were recently in a drug treatment program



the**well**project

# CDC Guidelines for PrEP Use

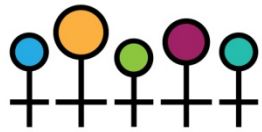
- Some reasons ***PrEP is not recommended***; having
  - Unknown HIV status (it's important that only people who test negative for HIV take PrEP)
  - Signs or symptoms of acute HIV infection
  - Decreased kidney function
  - Unknown hepatitis B status and/or vaccination status
- Guidelines suggest providers consider PrEP for people in areas or personal networks where HIV is more common, offer tools to help providers identify these areas



the**well**project

# CDC/WHO PrEP Guidelines

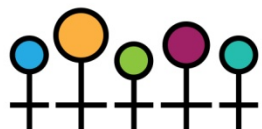
- To ***provide high-level protection***, PrEP needs to be
  - Taken for 7 days before anal sex; up to 20 days before vaginal sex
  - Used with other HIV prevention strategies (condoms, safer injecting practices)
    - Not intended to be used alone
    - Not proven 100 percent effective
- Everyone prescribed Truvada as PrEP have negative HIV test
  - CDC recommends people on PrEP be tested every 3 months to make sure they remain HIV-negative
- WHO recommends tenofovir or Truvada be offered to all people at substantial risk of HIV



thewellproject

# PrEP and Pregnancy

- **CDC** : HIV-negative women who are pregnant/trying to become pregnant should talk with providers about risks and benefits of PrEP
- **U.S. Public Health Service**: providers should discuss PrEP as option to protect HIV-negative partners in serodifferent couples interested in getting pregnant
- Both Viread and Truvada appear safe in early pregnancy when used as PrEP
  - Partners PrEP study showed no negative effect on babies conceived when mother taking PrEP
  - Women living with HIV have been taking these drugs safely during pregnancy for many years



thewellproject

# The PrEP Debate

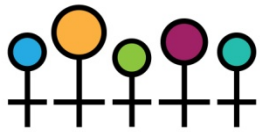
- You may have heard debate about PrEP – while many believe it's a good addition to the prevention toolbox, others disagree
- Following are several of the arguments against PrEP and response to those arguments

## **Concerns about PrEP**

- HIV-negative people may not adhere; PrEP won't be effective
- PrEP will be used in place of condoms or other safer sex measures

## **Advantages of PrEP**

- PrEP can be taken without agreement or knowledge of one's sex partner
- Research has not shown that using PrEP has reduced use of condoms/other safer sex methods



thewellproject

# The PrEP Debate

## Concerns about PrEP

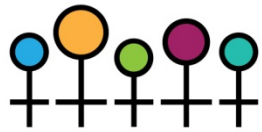
- Possible side effects
  - Most common: nausea and vomiting
- Occasional serious effects of Truvada (bone, kidney or liver problems, lactic acidosis, lipodystrophy, etc)

## Advantages of PrEP

- Most effects occur among people taking new HIV drug; often go away quickly
- No serious side effects found during PrEP studies
  - Small decrease in bone mineral density in men and transgender women in recent PrEP study

**Many national and international guidelines recommend PrEP as a prevention tool, though others are still seeking more information and research.**



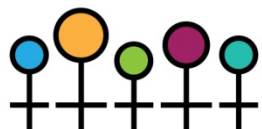


the**well**project

# What Does PrEP Mean for Women?

We now have evidence that PrEP works in preventing HIV if taken as prescribed, but ***much more work needs to be done*** before PrEP can be widely used and accepted

- ***Improving health care systems*** so people can access and afford PrEP
- Making HIV testing ***more widely available***
  - Only people who know they are HIV-negative can use PrEP safely
  - If HIV-negative people taking PrEP become HIV positive, don't know it, and continue taking Truvada, they are much more likely to develop drug-resistant HIV



thewellproject

# What Does PrEP Mean for Women?

PrEP is a promising tool that women can use to ***prevent HIV without their partners' cooperation***

- Many questions remain:
  - How will taking PrEP affect pregnancy and breastfeeding?
  - How will women get tested, especially if their partners won't?
    - Will they be able to get PrEP if they don't know their partners' status?
  - Will men refuse condoms if they know their partner is on PrEP?
  - Will women be able to keep PrEP drugs given to them?
    - Some women worry drugs given to them might be taken away, given to another family member who "needs them more"
- These and other questions are currently being explored in ***research and advocacy efforts*** in the U.S. and worldwide



thewellproject

# Considering Taking Truvada as PrEP?

## *Questions to discuss with your provider:*

- How often—and for how long—do I need to take PrEP?
- What happens if I miss a dose/several doses?
- What are Truvada's likely side effects and how will I manage them?
- How often will I need to be tested for HIV?
- How much will the drug cost me?
  - Will it be covered by my insurance?
  - Will HIV tests also be covered by my insurance?

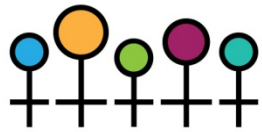


thewellproject

# Considering Taking Truvada as PrEP?

## ***More questions to discuss with your provider:***

- Do any of my current medical conditions make Truvada a less-good choice?
- Do any of my other prescription medications, OTC drugs, street drugs, herbs, vitamins, supplements have interactions with Truvada?
- What should I do if I become pregnant while on PrEP?
- Pros and cons of PrEP compared to other safer sex techniques?

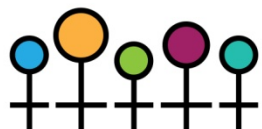


thewellproject

# New Developments in the PrEP Arena

## ***Tenofovir alafenamide (TAF):***

- Can be given at lower doses than TDF (the form in Viread and Truvada)
- Less bone loss; less reduction in kidney function
  - FDA approved TAF + emtricitabine (Descovy) for HIV treatment in April 2016; study of TAF as PrEP ongoing



the**well**project

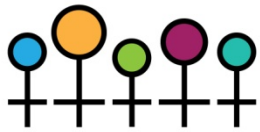
# New Developments in the PrEP Arena

## ***Long-acting injectable PrEP:***

- Cabotegravir (integrase inhibitor)
- Shots found safe and tolerable in ÉCLAIR study
- May reduce burden of adherence to daily pill

## ***Maraviroc (Selzentry):***

- Safe and well tolerated as PrEP in small study of US women; fewer bone and kidney effects



thewellproject

## Learn More!

- To learn more, and for links to fact sheet featuring more details, please read the full fact sheet :
  - [PrEP for Women](#)
- For more fact sheets and to connect to our community of women living with HIV, visit:
  - [www.thewellproject.org](http://www.thewellproject.org)
  - [www.facebook.com/thewellproject](https://www.facebook.com/thewellproject)
  - [www.twitter.com/thewellproject](https://www.twitter.com/thewellproject)