

# PrEP in Heterosexual Couples/ PrEP For Pregnancy

SOUTH CAROLINA HIV PrEP INITIATIVE



HIV PRE-EXPOSURE PROPHYLAXIS (PrEP)  
EDUCATION TRAINING CONSULTATIVE SUPPORT CO-MANAGEMENT



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# Disclosures and Objectives

- ▣ No disclosures
  
- ▣ Objectives
  1. PrEP during COVID-19
  2. Discuss how to identify and engage at risk heterosexual people
  3. Understand the utility of PrEP for pregnancy in sero-discordant couples
  4. Describe the safety of PrEP during Pregnancy

# HIV PrEP Option #1

- Daily oral PrEP with the fixed-dose combination of tenofovir disoproxil fumarate (TDF) 300 mg + emtricitabine (FTC) 200 mg has been shown to be **safe and effective** in reducing the risk of HIV acquisition in at risk adults(AI)<sup>1</sup>
  - Truvada® (FDA approved) pts with eCrCl of  $\geq 60$  ml/min
  - FDA approved for adolescents over 35 kgs(2018)



The American College of  
Obstetricians and Gynecologists  
WOMEN'S HEALTH CARE PHYSICIANS

## COMMITTEE OPINION

Number 595 • May 2014  
(Reaffirmed 2017)

### Committee on Gynecologic Practice

*This Committee Opinion was developed with the assistance of the HIV Expert Work Group. This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. This information should not be construed as dictating an exclusive course of treatment or procedure to be followed.*

Preexposure Prophylaxis for the Prevention of Human  
Immunodeficiency Virus



Release Date: June 2019

Recommendation Summary		
Population	Recommendation	Grade (What's This?)
Persons at high risk of HIV acquisition	The USPSTF recommends that clinicians offer preexposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition.	<b>A</b>



# PrEP: An Alternative to TDF/FTC

Tenofovir disoproxil fumarate (TDF) only



- Considered an alternative in certain populations
  - Heterosexually active men and women
  - People who inject drugs
- Lack of data: MSM, transgender

US Public Health Service

**PREEXPOSURE PROPHYLAXIS FOR  
THE PREVENTION OF HIV  
INFECTION IN THE UNITED STATES  
– 2017 UPDATE**

A CLINICAL PRACTICE GUIDELINE

# PrEP: Option #2

1. TAF/FTC –FDA approved for at-risk adults and adolescents ( $\geq 35$  kg), excluding individuals at risk from receptive vaginal sex. (October 2019)
  - Not yet incorporated into guidelines
  - eCrCl  $> 30$  mL/min



Not an option  
for  
Cis Women  
Trans men(vaginal sex)

# PrEP: Who Needs It?

MSM	Heterosexual Men and Women	Injection Drug Users	Transgender People
<ul style="list-style-type: none"> <li>Commercial sex workers</li> <li>HIV+ partner</li> <li>Recent STI</li> <li>Multiple partners</li> <li>Inconsistent/No condoms</li> </ul>	<ul style="list-style-type: none"> <li>Commercial sex workers</li> <li>HIV+ partner</li> <li>Recent STI</li> <li>Multiple partners</li> <li>Inconsistent/No condom use</li> <li>High prevalence area</li> </ul>	<ul style="list-style-type: none"> <li>HIV positive injecting partner</li> <li>Sharing needles/injection equipment</li> </ul>	<p>Trans women of color<sup>2</sup> (National HIV/AIDS Strategy 2010, 2015)</p>

US Public Health Service

**PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2017 UPDATE**

A CLINICAL PRACTICE GUIDELINE

GUIDANCE ON PRE-EXPOSURE ORAL PROPHYLAXIS (PrEP) FOR SERODISCORDANT COUPLES, MEN AND TRANSGENDER WOMEN WHO HAVE SEX WITH MEN AT HIGH RISK OF HIV: Recommendations for use in the context of demonstration projects

July 2012



- <https://www.cdc.gov/hiv/risk/prep/index.html> (2017 guidelines)
- Herbst JH, Jacobs ED, Finlayson TJ, et al. Estimating HIV prevalence and risk behaviors of transgender persons in US. AIDS Behav 2008
- [https://www.cdc.gov/mmwr/volumes/68/wr/mm6827a1.htm?s\\_cid=mm6827a1\\_](https://www.cdc.gov/mmwr/volumes/68/wr/mm6827a1.htm?s_cid=mm6827a1_)

# PrEP Workflow



Time  
management

Palmetto Health USC  
MEDICAL GROUP

## HIV PrEP Implementation Toolkit

1 vs 2 visits

**Bolded items  
mandatory**

### PrEP Orientation Visit:

- Discuss PrEP use
- Review insurance coverage/med. assistance
- Perform baseline laboratory tests:
  - **HIV Ab/Ag screen<sup>^</sup> (4<sup>th</sup> generation)**
  - **Cr**
  - **Hepatitis Bs Ag/Ab** and cAb
  - Hepatitis C Antibody
  - RPR/Trep Ab
  - Triple site GC/CH testing- Urine, Rectal, Oral (based on exposure)
  - **Pregnancy test** (if female)

### Initial Provider Visit:

- Discuss PrEP use ( 7 day interval before adequate levels in rectal tissue and 20 days for vaginal tissue/blood; compliance; SE)
- Risk reduction counselling, condoms
- PrEP Clinic Questionnaire(initial)
- Provider visit
- Symptom history to r/o acute HIV
- 30-day supply of PrEP (**start within 7 days of HIV screen**)

# PrEP Workflow

## Every visit(Q 3mths)

- Provide condoms
- HIV Ag/Ab → refills
- Assess adherence
- Risk reduction counseling

Decide who sees the person

**Bolded items mandatory**

### PrEP Orientation Visit:

- Discuss PrEP use
- Review insurance coverage/med. assistance
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- Provider visit
- Symptom history to r/o acute HIV
- 30-day supply of PrEP (**start within 7 days of HIV screen**)

### 30-day visit:

- Adherence review with nurse/ PharmD, risk reduction counselling, assess side effects
- Cr

Optional UA

60-day supply of PrEP

### 3-month visit:

- PrEP Clinic Questionnaire (short)
- Provider visit, risk reduction counselling, condoms
- **HIV Ab/Ag Test, Pregnancy test,** STI screen in MSM^ ( RPR/Trep Ab, GC/CH( triple site))

90-day supply of PrEP

### 6-month visit/ 12 month visit:

- PrEP Clinic Questionnaire (long)
- Provider visit, risk reduction counselling, condoms
- **HIV Ab/Ag, Pregnancy test, Cr,** RPR/Trep Ab, GC/CH( triple site), Hep C ab annually

90-day supply of PrEP

### 9-month visit:

- PrEP Clinic Questionnaire (short)
- Provider visit , risk reduction counselling, condoms
- **HIV Ab/Ag,** STI screen in MSM( RPR/Trep Ab, GC/CH( triple site))

90-day supply of PrEP

### After the 12 month visit: (Re-evaluation of need for continuing PrEP)

Q 3 monthly visit with Adherence nurse/ Pharm D, risk reduction counselling, , condoms.

- PrEP Clinic Questionnaire (short)
- **HIV ab/ab q 3 monthly** and STI screen q 3 monthly in MSM
- 90 day supply of PrEP

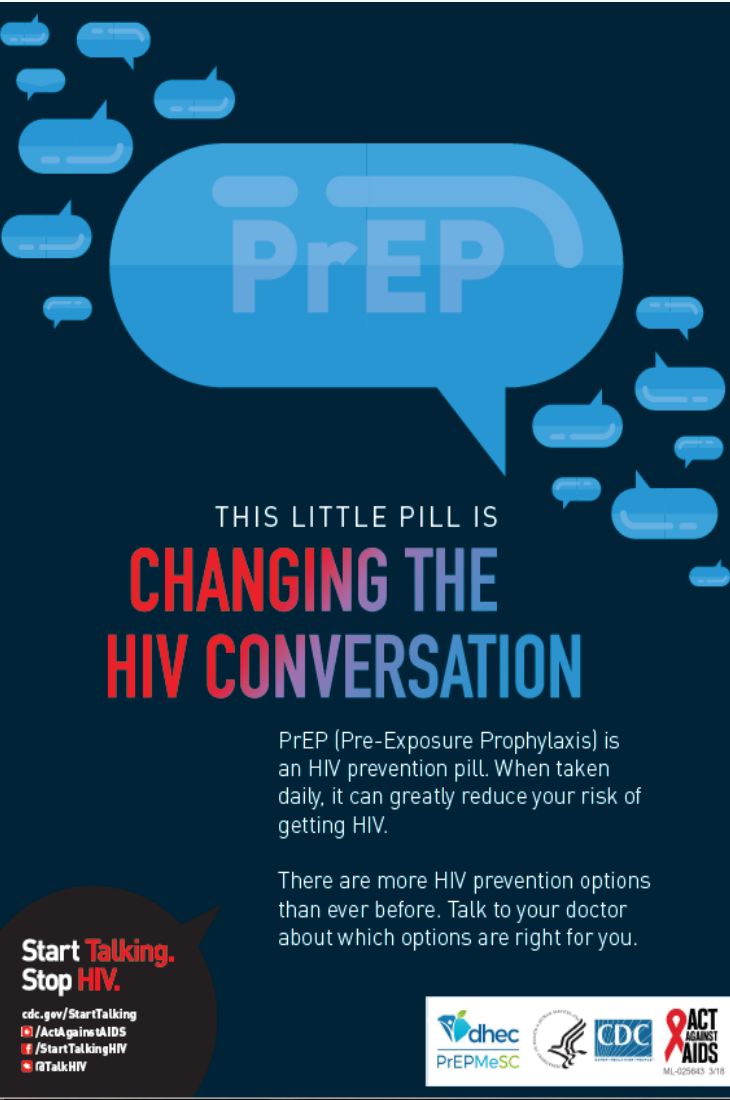
Q 6 monthly visit with Provider

- Pregnancy test, Cr, RPR/Trep Ab, GC/CH( triple site) ,Hep C
- 90-day supply of PrEP, condoms



# PrEP in setting of COVID-19

- Virtual visit
  - Phone visit
  - Video visit – various platform
- Labs
  - By appointments
    - Everyone with mask
      - To prevent transmission if +
    - Wait in car then come in
    - Labs at car



**PrEP**




THIS LITTLE PILL IS  
**CHANGING THE  
HIV CONVERSATION**

PrEP (Pre-Exposure Prophylaxis) is an HIV prevention pill. When taken daily, it can greatly reduce your risk of getting HIV.

There are more HIV prevention options than ever before. Talk to your doctor about which options are right for you.

**Start Talking.  
Stop HIV.**

[cdc.gov/StartTalking](http://cdc.gov/StartTalking)  
[/ActAgainstAIDS](#)  
[/StartTalkingHIV](#)  
[@TalkHIV](#)

ML-020443 3/18

# PrEP Workflow (During COVID 19)

## Lab visit

- HIV Ag/Ab Q3 month
  - Cr @ month 6
  - Self swabs
- Provide condoms

## Phone/Video visit

Day 0

Day 30

Week 12

Week 24

- Assess adherence
- Risk reduction counseling

**Bolded items mandatory**

### PrEP Orientation Visit:

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60-day supply of PrEP

### 3-month visit:

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90-day supply of PrEP

### 6-month visit/ 12 month visit:

- PrEP Clinic Questionnaire (long)
- **Provider visit, risk reduction counselling, condoms**
- **HIV Ab/Ag, Pregnancy test, Cr, RPR/Trep Ab, GC/CH( triple site), Hep C ab annually**

90-day supply of PrEP

### 9-month visit:

- PrEP Clinic Questionnaire (short)
- Provider visit , risk reduction counselling, condoms
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90-day supply of PrEP

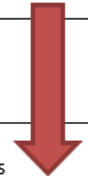
### After the 12 month visit: (Re-evaluation of need for continuing PrEP)

Q 3 monthly visit with Adherence nurse/ Pharm D, risk reduction counselling, , condoms.

- PrEP Clinic Questionnaire (short)
- **HIV ab/ab q 3 monthly** and STI screen q 3 monthly in MSM
- 90 day supply of PrEP

Q 6 monthly visit with Provider

- Pregnancy test, Cr, RPR/Trep Ab, GC/CH( triple site) ,Hep C
- 90-day supply of PrEP, condoms





# Virtual visit: Adherence



<https://www.caringvillage.com/2018/02/09/the-top-five-medication-management-apps/>  
<https://www.ripplephx.org/?p=5234>

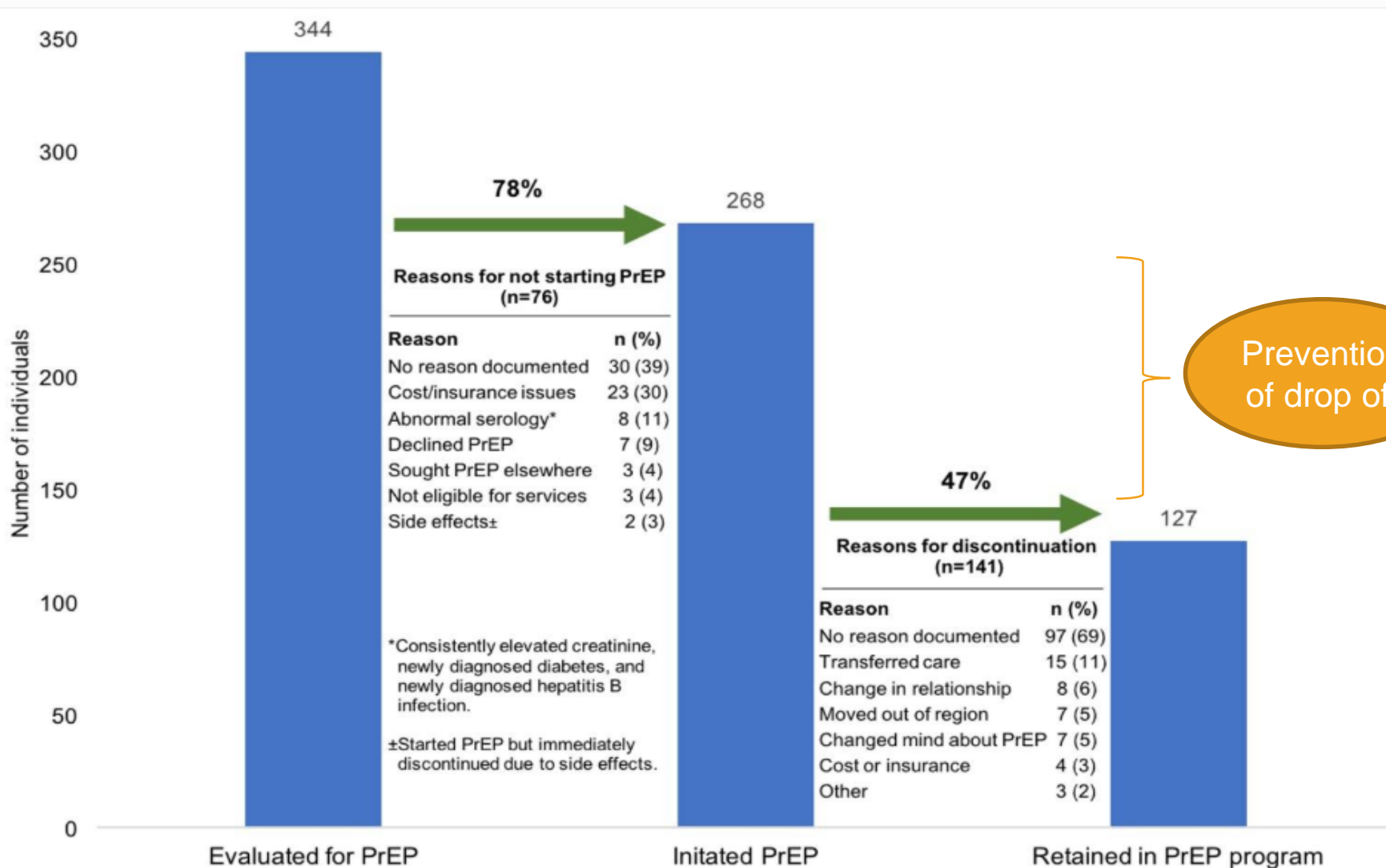


TAF/FTC – 30  
day Blister pack

# Virtual Visit Support

- Retention/adherence rates varies – higher in multidisciplinary scenarios 75%- 90%<sup>1,3</sup>
  - **Pharmacist**<sup>1</sup> and **nurse models**<sup>4</sup>
- **Text messaging**<sup>2</sup> service or PrEPmate(**app**)<sup>5</sup>
  - Those who opted for text; more likely to remain in clinic (76% vs. 53%)<sup>2</sup>
  - App had better adherence to visits/ therapeutic levels (56 vs 40% @ 36 wks)
- Brief **behavioral intervention** (sexual health or adherence)→ < missed pills/higher drug levels (96.6 vs 84%; p=0.02 )- NYC<sup>3</sup>

# Virtual visit: Reason for Adherence



# Case 1

- 29 y/o heterosexual male come to office after ED visit for follow up.
  - Presented there with ‘drips’
  - Got treated with ceftriaxone IM and azithro
  - Urine GC was sent
  
- In addition to asking about symptoms, what other information is needed ?
  - Possible PrEP Candidate

# PrEP for Heterosexual Persons

## Identifying persons at risk

- Talk Sexual Health
- Sexually hx usually deferred by various groups
  - Primary care<sup>1</sup>
  - STI care<sup>2</sup>
  - HIV care<sup>3-5</sup>

**ARE YOU READY FOR PrEP?**  
PrEP 101

**PrEP Basics**

PrEP stands for **Pre-Exposure Prophylaxis**. The word "prophylaxis" means to prevent or control the spread of an infection or disease.

PrEP is an HIV prevention option that works by taking **one pill every day**.

PrEP can help prevent you from getting HIV if you are exposed to the virus.

**How Does It Work?**

In several studies of PrEP, the risk of getting HIV infection was much lower — up to 92% lower — for those who took the medicines consistently than for those who didn't take the pill.

Some of the same medicines prescribed for the treatment of HIV can also be prescribed for its prevention.

When taken every day, PrEP can provide a high level of protection against HIV, and is even more effective when it is combined with condoms and other prevention tools.

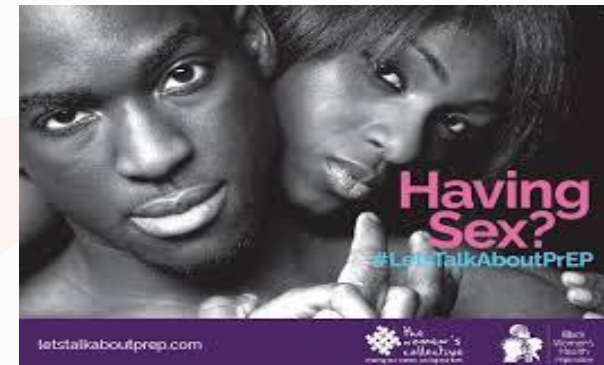
People who use PrEP must take the medicine every day, and return to their health care provider every 3 months for follow-up and prescription refills.

**92% LOWER RISK**

Some people in clinical studies of PrEP had early side effects such as an upset stomach or loss of appetite, but these went away and usually went away in the first month. Some people also had a mild headache. No serious side effects were observed. You should tell your health care provider if these or other symptoms become severe or do not go away.

**Start Talking. Stop HIV.**

Follow us online at [facebook.com/StartTalkingPrEP](https://www.facebook.com/StartTalkingPrEP) and [Instagram](https://www.instagram.com/StartTalkingPrEP)



- 1 Wimberly YH et al. Sexual history-taking among primary care physicians. *J Natl Med Assoc.* 2006
- 2 Kurth AE. A national survey of clinic sexual histories for sexually transmitted infection and HIV screening. *STD 2005*
- 3 Laws MB. Discussion of sexual risk behavior in HIV care is infrequent and appears ineffectual. *AIDS Behav.* 2011
- 4 Metsch LR., Delivery of HIV prevention counseling by physicians at HIV medical care settings. *Am J Public Health.* 2004
- 5 Duffus WA. Effect of physician specialty on counseling practices /referral patterns among physicians caring for disadvantaged HIV populations. *CID* 2003

# PrEP for Heterosexual Persons

## Sexual Health: Identifying Persons at risk

In the past 6 mth:(Heterosexual men and women)

- Have you had sex with men, women, or both?  
(if opposite sex or both sexes) How many men/women have you had sex with?
- How many times did you have vaginal or anal sex when neither you nor your partner wore a condom?
- How many of your sex partners were HIV-positive?  
(if any positive) With these HIV +partners, how many times did you have vaginal or anal sex without a condom?

The five “P”s stand for:

- **Partners**
- **Practices**
- **Protection from STDs**
- **Past history of STDs**
- **Prevention of pregnancy**



# Case 1

- Male
- Heterosexual
- Female partners mainly, sometimes insertive anal sex
  - No condoms
  - Dates online
  - Unsure of partners HIV status
- HIV test negative, CrCL >60

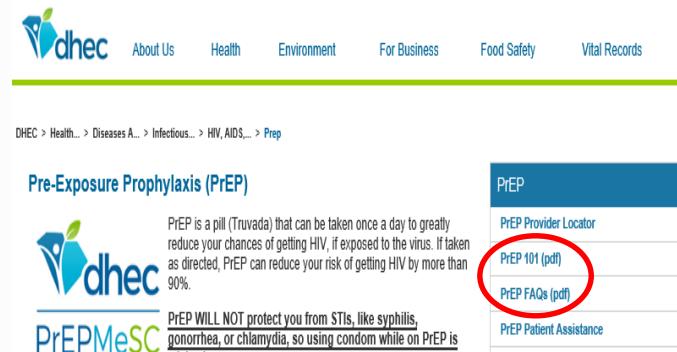
# Case 1: PrEP options for him ?

1. Daily TDF/FTC (Truvada®)
2. Daily TAF/FTC (Descovy®)
3. Defer PrEP since not MSM

# Adherence Counselling

## What to expect

- Symptoms
  - Flatulence, nausea / GI upset
  - Headache and rash
  - Arthralgia
- This start up syndrome resolves within first 4-6 wks , for most
  - Use OTC medications
- Uncommon
  - Drop in bone density(TDF)
  - Renal dysfunction (subclinical), rare Fanconi syndrome
  - Lactic acidosis
  - Transaminitis



The screenshot shows the dhcc website navigation menu at the top: dhcc, About Us, Health, Environment, For Business, Food Safety, Vital Records. Below the navigation is a breadcrumb trail: DHCC > Health... > Diseases A... > Infectious... > HIV, AIDS... > PrEP. The main heading is 'Pre-Exposure Prophylaxis (PrEP)'. To the right is a table of links under the heading 'PrEP':

PrEP	
<a href="#">PrEP Provider Locator</a>	
<a href="#">PrEP 101 (pdf)</a>	
<a href="#">PrEP FAQs (pdf)</a>	
<a href="#">PrEP Patient Assistance</a>	

The 'PrEP 101 (pdf)' link is circled in red. Below the table, there is a paragraph of text: 'PrEP is a pill (Truvada) that can be taken once a day to greatly reduce your chances of getting HIV, if exposed to the virus. If taken as directed, PrEP can reduce your risk of getting HIV by more than 90%.' Below this is another paragraph: 'PrEP WILL NOT protect you from STIs, like syphilis, gonorrhea, or chlamydia, so using condom while on PrEP is'.

# Adherence Counselling

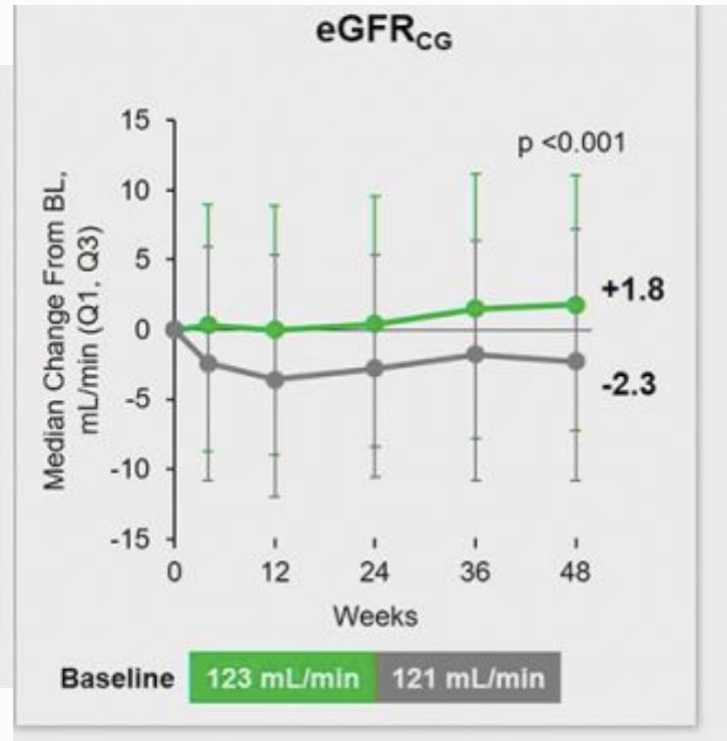
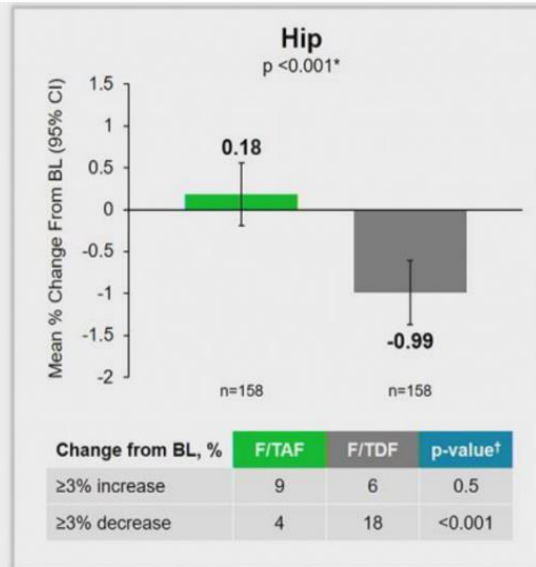
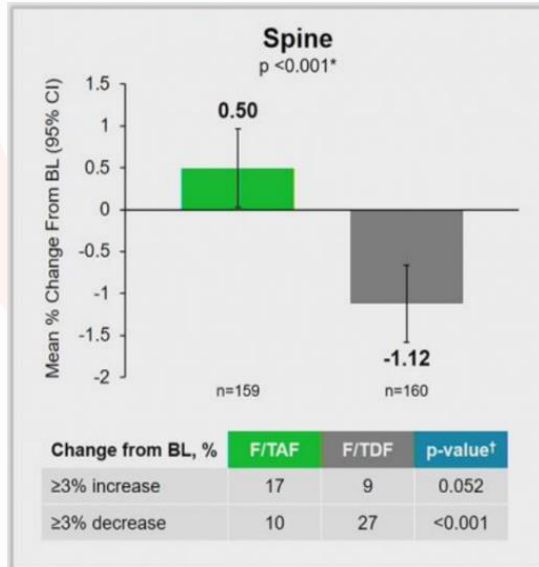
## Bone Health ( TDF)



- Small (~1%) decline in BMD occurred in first few months → either stabilized or returned to normal <sup>1,2</sup>
  - iPrEx trial (TDF/FTC) & CDC PrEP safety trial in MSM
  - No increase in fragility (atraumatic) fractures over the 1-2 years
- DEXA scans or other assessments are NOT recommended

# Adherence Counselling Bone/Kidney Health

- RCT of Truvada<sup>®</sup> versus Descovy<sup>®</sup> for PrEP
  - MSM and TGW (Enrolled ~6000: 74 TGW) ; followed 96 wks
  - 22 HIV transmission (7 TAF and 15 TDF)



\*p-values from analysis of variance model with baseline F/TDF for PrEP and treatment as fixed effects; †p-value was based on a dichotomized response (ie, ≥3% vs <3%) from Cochran-Mantel-Haenszel test for nominal data (general association statistic) adjusting for baseline F/TDF for PrEP. BL, baseline.

# Case 2

- 25 y/o cis-woman visits your office with rash
- 1 male partner , condomless sex
- No new lotions or soaps, No meds
- WBC normal

Think  
Syphilis !!!

- PHx
  - Abnormal PAP in 2019 with GC positive in 2018
- Is PrEP an option for her?

# PrEP for Women

## Missed Opportunities to Prescribe PrEP

- 885 new HIV+ pts had 4029 healthcare visits in the months prior to diagnosis (SC 2013-2016)
- 2/3<sup>rd</sup> had missed opportunities for PrEP engagement
- **Women, Black race and younger** individuals were more likely to have had missed opportunity
- Location
  - 84% of missed opportunities occurred in the ED
  - 10% occurred in outpatient clinics

# Engaging Cis-Women



- Why are women at risk for HIV
  - **Unaware of their male partner's risks** (IVDU or MSM) → No condoms (93% of HIV-negative high-risk women had vaginal sex without a condom; 26% anal sex without condom<sup>2</sup>)
    - “Southern women are sometimes too polite to ask” -TC
  - **At higher risk for getting HIV during vaginal/anal sex** than their sex partners
  - HIV **testing rates lower** among women (20% with anal sex tested<sup>3</sup>)
  - **STI** (gonorrhea, syphilis) greatly increase the likelihood of HIV transmission
  - Women s/p sexual abuse more likely to **engage in sexual risk behaviors** - sex for drugs, multiple partners, or sex without condom



# PrEP for Women




The CDC estimates **468,000** U.S. WOMEN are eligible for PrEP

Women's health care providers are uniquely positioned to screen, counsel about, and offer PrEP

NCHRPSTP - National Center for HIV/AIDS, Viral Hepatitis, STD, TB Prevention

Women account for **1 in 5** new HIV diagnoses.<sup>1</sup>



African American/black women have a disproportionately higher lifetime risk of infection (1 in 54 black women compared to 1 in 256 Hispanic/Latina women and 1 in 941 white women).<sup>2</sup> Although PrEP is a highly effective, woman-controlled prevention option for HIV-negative women, PrEP use among women has been very low (especially among black women).<sup>3</sup>

CDC invited subject matter experts involved in HIV prevention efforts for women to participate in a web-based series to discuss barriers to PrEP implementation.

## Summary of Key Findings\*

### Barriers

- Women's lack of knowledge about PrEP, HIV-related health literacy, and HIV risk perception
- Challenges identifying women who might benefit from HIV prevention with PrEP and assessing women's risk of acquiring HIV
- Healthcare provider bias based on a woman's race, social class, or sexual behavior that might hinder effective communication about HIV risk and PrEP
- High costs associated with PrEP
- Lack of resources and infrastructure to provide PrEP for women in settings and venues they frequently use for healthcare

### Suggested Activities

- Develop and disseminate gender and culturally appropriate materials for women and clinicians to:
  - » Increase women's knowledge/awareness of PrEP and HIV risk
  - » Increase clinicians' PrEP knowledge and clinical skills, including providing PrEP care and effectively assessing HIV risk
  - » Equip clinicians with the skills to cultivate respectful patient-provider interactions that enable shared decision making
- Conduct research to identify:
  - » Best practices for identifying women who might benefit from PrEP
  - » Effective PrEP implementation models

**Disclaimer:** This is a summary of the discussion series held November 2016 through May 2017. It reflects ideas and thoughts shared by individual participants, and is not intended to represent the collective view of participants.

### Conclusions

Increasing PrEP uptake will require careful attention to personal, social, and structural barriers to PrEP awareness, access, and utilization. Potential actions to consider include:

- Creating/revising PrEP materials to be overtly inclusive of women (e.g., language, images).
- Conducting or supporting health services research to address barriers.
- Developing or strengthening existing partnerships to promote PrEP implementation for women.

### References

<sup>1</sup>CDC 2017. HIV surveillance report, 2016. <https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>; <sup>2</sup>Yassir et al. 2017. <https://doi.org/10.1016/j.amepre.2017.02.003>; <sup>3</sup>Bush et al. 2016. [https://www.aidshealth.org/wp-content/uploads/2016/07/GLD\\_Bush-PrEP-Place-Utilization-est-June-2016.pdf](https://www.aidshealth.org/wp-content/uploads/2016/07/GLD_Bush-PrEP-Place-Utilization-est-June-2016.pdf)



U.S. Department of Health and Human Services  
Centers for Disease Control and Prevention

#PrEPForHer

**DOMINATE** your sex life

PrEP is a safe, daily pill that helps prevent HIV.



**I'M DOING IT**  
Testing for HIV

*"I've lost too many people to AIDS because of ignorance. Not knowing your status will hold you back from staying healthy and strong. Get tested today."*  
— Anna Marie Horsford, Actress

#DoingIt

Testing is Fast, Free, and Confidential. [cdc.gov/DoingIt](http://cdc.gov/DoingIt)

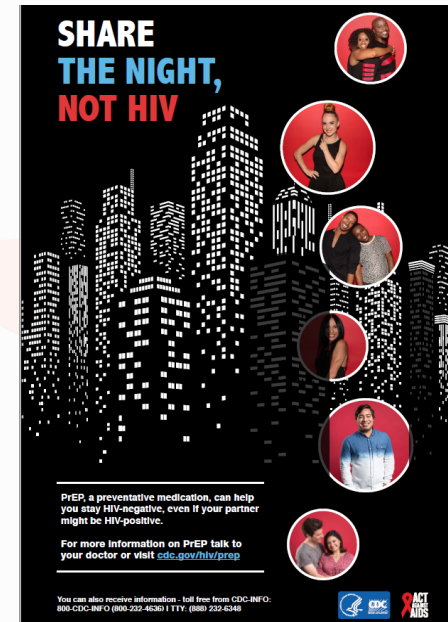


**SHARE THE NIGHT, NOT HIV**

PrEP, a preventative medication, can help you stay HIV-negative, even if your partner might be HIV-positive.

For more information on PrEP talk to your doctor or visit [cdc.gov/hiv/prep](http://cdc.gov/hiv/prep)

You can also receive information - toll free from CDC: 800. CDC-888 (800.232.4636) | TTY: (888) 232-6348



# Case 2- PrEP options for her?

1. Daily TDF/FTC (Truvada®)
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3. Defer PrEP since not MSM

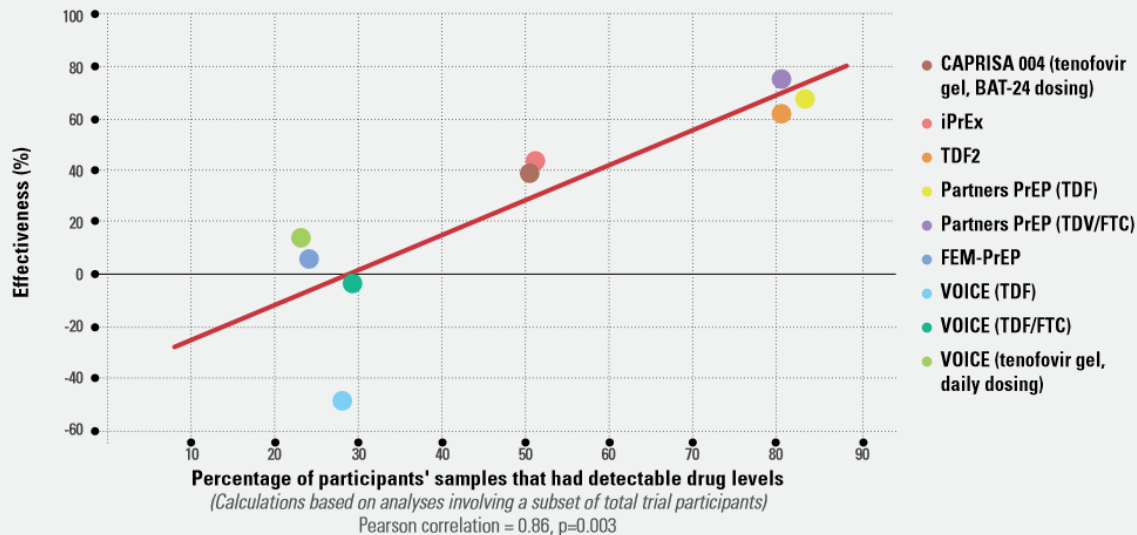
# PrEP: Does it Work for women?

Trial	Where	Who	What	Efficacy
1. iPrEx n=2499	SA, US, South Africa, Thailand	MSM high risk	TDF-FTC or placebo	44% TDF-FTC
<b>2. Partners PrEP n=4747</b>	<b>Kenya, Uganda</b>	<b>Discordant hetero couples</b>	<b>TDF, TDF-FTC or placebo</b>	<b>67 -75% (TDF, TDF/FTC)</b> •Men 84% •Women 66%
3. US MSM safety Trial, n=400	US	MSM	TDF or placebo Early vs delay	Not reported ; 0 infections on TDF
<b>4. TDF2 n=1219</b>	<b>Botswana</b>	<b>Hetero men or women</b>	<b>TDF-FTC or placebo</b>	<b>62.2% all</b> •80% men •49% women (NS)
<b>5. FEM-PrEP n=2120</b>	<b>Kenya, South Africa, Tanzania</b>	<b>Women</b>	<b>TDF-FTC or placebo</b>	<b>Stopped early due to lack of efficacy</b>
<b>6. VOICE n=5021</b>	<b>Uganda, South Africa, Zimb.</b>	<b>Heterosexual women</b>	<b>TDF gel, placebo gel, TDF, TDF-FTC, placebo</b>	<b>TDF gel/pill stopped, lack of efficacy</b>
<b>7. West African Trial n=859</b>	<b>West Africa</b>	<b>Hetero women</b>	<b>TDF vs placebo</b>	<b>65% ( NS, stopped early)</b>
8. Bangkok TDF n=2413	Thailand	IVDU	TDF or placebo	49% TDF

# PrEP: Efficacy and Adherence

- If drug detected in blood, effectiveness of PrEP = 90-92%
  - 92-100% if levels equivalent to daily use<sup>2</sup> (Post Hoc iPrEx)
  - 0 conversions if at least 4 doses taken<sup>3</sup>

## Effectiveness and Adherence in Trials of Oral and Topical Tenofovir-Based Prevention



Trials of oral and topical tenofovir-based PrEP show that these strategies reduce risk of HIV infection if they are used correctly and consistently. Higher adherence is directly linked to greater levels of protection.

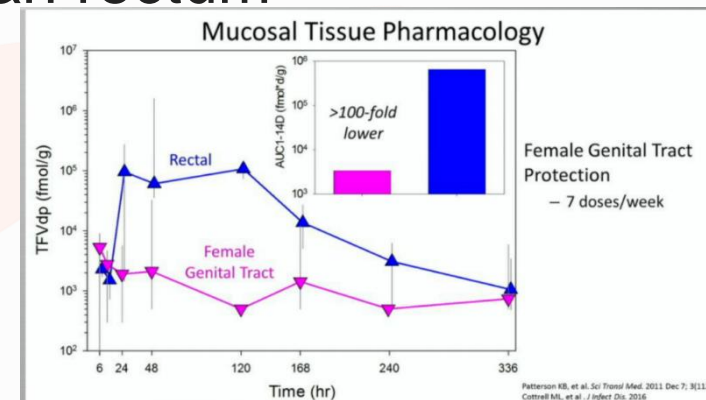
Source: Salim S. Abdool Karim, CAPRISA

Adherence=  
Efficacy

# PrEP in Women: Why didn't it work?

- 2 large studies (FEM-PrEP and VOICE trials), PrEP was not effective in preventing HIV<sup>1,2</sup>
  - Non-adherence was a major factor in study failure
    - Overall adherence <30%
    - More common in young women <25 yo
  - Differences in vaginal concentrations of drug plausible role in lack of efficacy- > 100 fold lower than rectum

- Women have to work harder
- Focus counselling efforts on cultural/social barriers



# PrEP: Reminder

1. TAF/FTC –FDA approved for at-risk adults and adolescents ( $\geq 35$  kg), excluding individuals at risk from receptive vaginal sex. (October 2019)
2. Dec 2019 – Company statement: agreed with the FDA on the framework of an innovative trial design to conduct a study evaluating Descovy for PrEP in cisgender women and adolescent females



Not a current option  
for  
Cis Women

# PrEP Continuum of Care - Retaining Clients



# Engagement/Retention

## Welcoming Environment

- Non judgmental
- Understand stigma/ fear of health care system
- Engage patients /language
  - Staff
  - Posters

**SHARE THE NIGHT, NOT HIV**

medication, can help  
e, even if your partner  
e.

on PrEP talk to  
[cdc.gov/hiv/prep](http://cdc.gov/hiv/prep)

nation - toll free from CDC-INFO:  
(866) 524-6348 | TTY: (888) 232-6348

**Having Sex?**  
#LetTalkAboutPrEP

letstalkaboutprep.com

### TREATMENT AND PREVENTION

#### Antiretroviral Therapy

The use of medications to treat HIV is called Antiretroviral Therapy (ART). ART decreases the amount of HIV in the body. ART also stops HIV from multiplying. Though ART does not cure HIV, it can help people living with HIV continue to lead healthy lives, and also reduce the likelihood of transmitting HIV. This is called having an undetectable viral load, or U=U (undetectable=untransmittable).

#### Condom Use

HIV is spread through contact with blood or bodily fluids, so the way in which the spread of HIV can be prevented is by limiting contact with these fluids. Condom use during vaginal or anal sex is a very effective way of preventing HIV.

#### PrEP

There is also a daily pill called PrEP (Pre-Exposure Prophylaxis) that can prevent HIV by 92% in women. If you are HIV positive, treatment can lower your viral load, to a point where the virus is undetectable and therefore untransmittable. If your partner is HIV negative, PrEP can help in decreasing the chances of your partner acquiring HIV. Also, there is a series of pills called PEP which can be taken if you believe you have come in contact with the HIV virus.

#### Regular Testing

Getting tested for other STIs regularly is also an important tool in preventing the spread of HIV, as HIV is more transmittable when in the company of other STIs.

#### Payment Assistance

Since the passage of the Affordable Care Act, most job-

### ADDITIONAL RESOURCES

#### General Information

[www.blackaids.org](http://www.blackaids.org)  
[www.plannedparenthood.org/learn/itds-hiv-safer-sex/hiv-aids](http://www.plannedparenthood.org/learn/itds-hiv-safer-sex/hiv-aids)  
[www.beeonline.org](http://www.beeonline.org)  
[www.cdc.gov/hiv/basics/index.html](http://www.cdc.gov/hiv/basics/index.html)  
[www.cdc.gov/hiv/group/safer/hiv/africanamericans/index.html](http://www.cdc.gov/hiv/group/safer/hiv/africanamericans/index.html)  
[www.pwn-usa.org](http://www.pwn-usa.org)  
[www.thewellproject.org](http://www.thewellproject.org)

#### General Information on PrEP

[www.blackaids.org/news-and-events/black-women-prep](http://www.blackaids.org/news-and-events/black-women-prep)  
[www.letstalkaboutprep.com](http://www.letstalkaboutprep.com)  
[www.hivonline.org/jsp/documents](http://www.hivonline.org/jsp/documents)  
[www.projectinform.org/pdf/prep\\_women.pdf](http://www.projectinform.org/pdf/prep_women.pdf)

#### Payment Assistance Programs

[www.gileadadvancingaccess.com](http://www.gileadadvancingaccess.com)  
[www.copays.org/issues/hiv-aids-and-prevention](http://www.copays.org/issues/hiv-aids-and-prevention)  
[www.hiv.gov/hiv-basics/staying-in-hiv-care/hiv-treatment-paying-for-hiv-care-and-treatment](http://www.hiv.gov/hiv-basics/staying-in-hiv-care/hiv-treatment-paying-for-hiv-care-and-treatment)  
<https://hub.hrsa.gov/get-care/state-healthy-hotlines>

#### Your Rights and HIV

[www.pwn-usa.org/issues/know-your-rights/guide/Guidance-for-People-Living-with-HIV-Who-Are-Threatened-with-or-Are-Facing-Criminal-Prosecution-for-HIV-NonDisclosure-or-Exposure](http://www.pwn-usa.org/issues/know-your-rights/guide/Guidance-for-People-Living-with-HIV-Who-Are-Threatened-with-or-Are-Facing-Criminal-Prosecution-for-HIV-NonDisclosure-or-Exposure); The Center for HIV Law & Policy, Positive Justice Project  
[www.thewellproject.org/hiv-information/hiv-criminalization-and-women](http://www.thewellproject.org/hiv-information/hiv-criminalization-and-women)



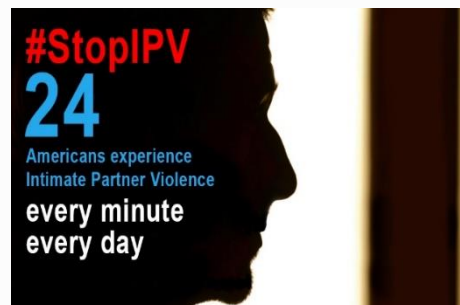
### BLACK AIDS INSTITUTE BLACK WOMEN AND HIV





# PrEP and Adherence

## - Intimate Partner Violence



### Intimate Partner Violence (IPV) and PrEP<sup>3,4,5</sup>

- Recent IPV (3 mths) associated with a lower adherence
- Women reported taking pills and pill counts (unused) pills suggested they took their PrEP (VOICES trial )
  - BUT serum drug levels undetectable
- Themes of stigma, fear, relationship conflict and lack of understanding

# Engagement/Retention

## Rural clients

The Initiative will target our resources to the 48 highest burden counties, Washington, D.C., San Juan, Puerto Rico, and 7 states with a substantial rural HIV burden.



**Geographical Selection:**  
Data on burden of HIV in the US shows areas where HIV transmission occurs more frequently. More than 50% of new HIV diagnoses\* occurred in only 48 counties, Washington, D.C., and San Juan, Puerto Rico. In addition, 7 states have a substantial rural burden—with over 75 cases and 10% or more of their diagnoses in rural areas.

Ending  
the  
HIV

[www.HIV.gov](http://www.HIV.gov)

- Rural residence -risk factor for late HIV diagnosis
  - Less likely to **obtain HIV testing** and Rx
- Challenges of rural pts with HIV (Can extrapolate to PrEP care):
  - Stigma and social isolation
  - Long travel distances to care
  - Lack of transportation
  - Lack of providers with “HIV” expertise
    - 95% of rural counties lack “HIV” providers compared to 69% of urban counties



# Case 3

- 26 y/o woman presents inquiring about PrEP
- 7 weeks gestation
- Her HIV ab/ag test= negative
- Male Partner HIV positive
  - HIV Viral load unknown, non compliance with ART
  - Continue to have unprotected sex with partner

# Case 3

- If she is HIV negative, should PrEP be offered to her?
  1. No; because she is already pregnant
  2. Yes; PrEP is safe in pregnancy and she has ongoing risk
  3. No; PrEP is not safe in pregnancy
  4. Unsure

# PrEP in Pregnancy

- TDF and FTC - FDA Pregnancy Category B medication<sup>1</sup>
- Risks and available information should be discussed
  - Risk of mother to child HIV transmission goes up if HIV acquired during pregnancy
  - In-utero studies with only low concentration of drug getting to umbilical cord<sup>2,3</sup>

Concentration of Tenofovir In Vivo

First Author	Sample Size	Tenofovir Dose, mg	Concentration in Maternal Serum, ng/mL	Concentration in Umbilical Cord, ng/mL
Flynn [14]	13	600	234	76
	15	900	456	68
Hirt [15]	38	300	310	100

# PrEP:

## Effects on Infants

## PrEP and Breastfeeding

- Infants of women on tenofovir while pregnant followed
  - Infants at 6 months- No effects on their weight, length and head circumference<sup>3</sup>
- Also minimal excretion in breastmilk <sup>5</sup>
  - Median amount of tenofovir ingested would be 0.03% of the recommended neonatal dose

### 1. Ehrhardt Breastfeeding While Taking 3TC or TDF CID 2015

2. Mofenso Tenofovir PrEP for Pregnant and Breastfeeding Women at Risk of HIV Infection PLOS 2015

3. CROI 2017 # 584 - Jourdain TDF TO PREVENT PERINATAL HEPATITIS B TRANSMISSION - RCT

4. Gibb Pregnancy and infant outcomes among HIV-infected women taking long-term ART with and without tenofovir in the DART trial *PLoS Med* 2012

5. Benaboud Concentrations of tenofovir and emtricitabine in breast milk of HIV-1-infected women in Abidjan, Cote d'Ivoire, in the ANRS 12109 TEmAA study, step 2 *Antimicrob Agents Chemother* 2011

# Case 3

If yes to PrEP, which agent

1. Daily TDF/FTC (Truvada®)
2. Daily TAF/FTC (Descovy®)

# PrEP: Reminder

1. TAF/FTC –FDA approved; excluding individuals at risk from receptive vaginal sex. (October 2019)
2. Study evaluating Descovy® for PrEP in cisgender women and adolescent females- will start in near future
3. **TAF/FTC (Descovy®) in Pregnancy= limited/no data**



Not a current option  
for  
Cis Women



# Case 4

- HIV positive male brings his HIV negative female partner to his well visit
- He has an undetectable viral load for the last 2 years and claims 100% compliant
- They would like to have children
- How do you advice?

# PrEP: For Pregnancy

**Reproductive Options for Couples in Which One or Both Partners are Living with HIV** (Last updated December 7, 2018; last reviewed December 7, 2018)

## Panel's Recommendations

For Couples Who Want to Conceive When One or Both Partners are Living with HIV:

- Expert consultation is recommended to tailor guidance to couples' specific needs (AIII).
- Partners should be screened and treated for genital tract infections before attempting to conceive (AII).
- Partners living with HIV should attain maximum viral suppression before attempting conception to prevent HIV sexual transmission (AI) and, for women living with HIV, to minimize the risk of HIV transmission to the infant (AII).
- For couples with differing HIV statuses, when the partner living with HIV is on ART and has achieved sustained viral suppression, sexual intercourse without a condom limited to the 2 to 3 days before and the day of ovulation (peak fertility) is an approach to conception with **effectively no risk** of sexual HIV transmission to the partner without HIV (BII).
- For couples with differing HIV statuses who attempt conception via sexual intercourse without a condom (despite counseling) when the partner living with HIV has not been able to achieve viral suppression or when the viral suppression status is not known, administration of antiretroviral pre-exposure prophylaxis (PrEP) to the partner without HIV is recommended to reduce the risk of sexual transmission of HIV (AI). Couples should still be counseled to limit sex (without condoms) to the period of peak fertility (AIII).
- When the woman is living with HIV, assisted insemination at home or in a provider's office with semen **from a partner without HIV** during the periovulatory period is **an option for** conception that eliminates the risk of HIV transmission to the partner without HIV (AIII).
- When the man is living with HIV, the use of donor sperm from a man without HIV **is an option for** conception that eliminates the risk of HIV transmission to the partner without HIV (BIII).
- For couples with differing HIV statuses who attempt conception (sexual intercourse without a condom limited to peak fertility) when the partner living with HIV has achieved viral suppression, it is unclear whether administering PrEP to the partner without HIV further reduces the risk of sexual transmission (CIII).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

# PrEP: For Pregnancy

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For discordant couples:

- HIV+ partner should be on ART and attain suppression of VL (AI)
- Once suppression of VL, Peri-ovulatory sex without condom, an option with effectively no risk of HIV transmission (BII)
  - (based on U=U data)
- Unclear if PrEP further reduced risk
  - But.....

# Case 5

- What is the positive partner is the woman
  - She is undetectable and has been for years
- New spouse is HIV negative and the couple would like to have a baby
  - How would you advise?

# PrEP: For Pregnancy

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**Additional measures after virologic suppression:**

If woman is HIV positive: At home or in office insemination in the peri ovulatory period is an option (AIII)

If man is HIV positive: Could use a sperm donor

Alternative options to unprotected sex = cost

- Artificial insemination can cost per cycle - \$1,500 to \$4,000
- Cheap method of insemination
- Sperm washing - \$100-300
- Semen analysis \$85-135

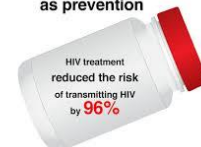


# Case 5

- Discuss U=U
- Could still offer PrEP



Treatment as prevention



U=U campaign  
Joined by CDC  
10/2017

# PrEP: For Pregnancy, Support Data Treatment as Prevention

Trial	When	Who (sero-Discordant)	What	Efficacy
1. Observational	1989-2008-Madrid Spain	424 heterosexual couples . 83% male+	20,000 acts of intercourse w/out condoms	0 transmission if +partner on ART Risk: 1 in 2000 exposure
2. HPTN 052	9 countries	1763 couples (homosexual + heterosexual)		0 transmission if the + partner were suppressed
3. Partners	14 countries Europe	1166 couples (homosexual + heterosexual)	58 000 instances of unprotected sex	0 of the 11 who converted were linked to their partners
4. Opposites Attract (1.7yrs)	3 countries (Aust, tia, Bra)	358 HIV+ homosexual men	17 000 acts of sex	3 new cases, 0 linked 0 within couple trans
5. Timed, peri ovulatory sex with PrEP	2005-2008	53 couples	244 unprotected intercourse Preg. rate: 75%	0 sero- conversions
6. Timed, peri ovulatory sex with PrEP	HIV+ suppressed 08-16 (China)	91 couples (43 with men living with HIV)	196 unprotected intercourse, 97 live births	0 seroconversion

# Counselling

## U=U: Believe the Science and Say What You Mean

### Language Matters

"From a practical standpoint, *the risk is zero.*"  
(Dr. Anthony Fauci, NIAID)



Be **clear** and **consistent** about risk.

#### Say:

Can't pass it on  
Can't transmit  
Effectively no risk

No risk  
Zero risk

Prevents HIV

Eliminates onward transmission

VS.

#### Don't say:

Greatly reduces  
Extremely unlikely  
Nearly impossible

Almost no risk  
Close to zero  
Helps prevent

Makes it hard to transmit

- U=U is about sex not breastfeeding or needle sharing
- U=U prevents HIV not other STI



IUPUI  
SCHOOL OF LIBERAL ARTS



# Case 6

- 30 y/o female seeing you for primary care
- HIV negative today
- HTN
- Her partner is HIV positive
  - She is unaware of his VL and if he takes his meds regularly
- They are actively trying to have children
  
- How do you advice ?

# PrEP: For Pregnancy

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### For discordant couples:

- HIV + partner should be undetectable before conception
- If HIV+ partner not suppressed or VL unknown:
  - PrEP (AI) to reduce the risk of sexual transmission and limit sex without condom in peri-ovulatory period (AIII)

Case 5  
Offer PrEP

# PrEP for Pregnancy

## When does protection start (Counselling)

- Time to maximal protection is unknown
- TDF/FTC concentrations vary by tissue
- Time to achieve maximal intracellular concentrations after daily TDF
  - Blood: ~ 20 days
  - Cervico-vaginal tissues: 20 days
  - Penile tissues: no data

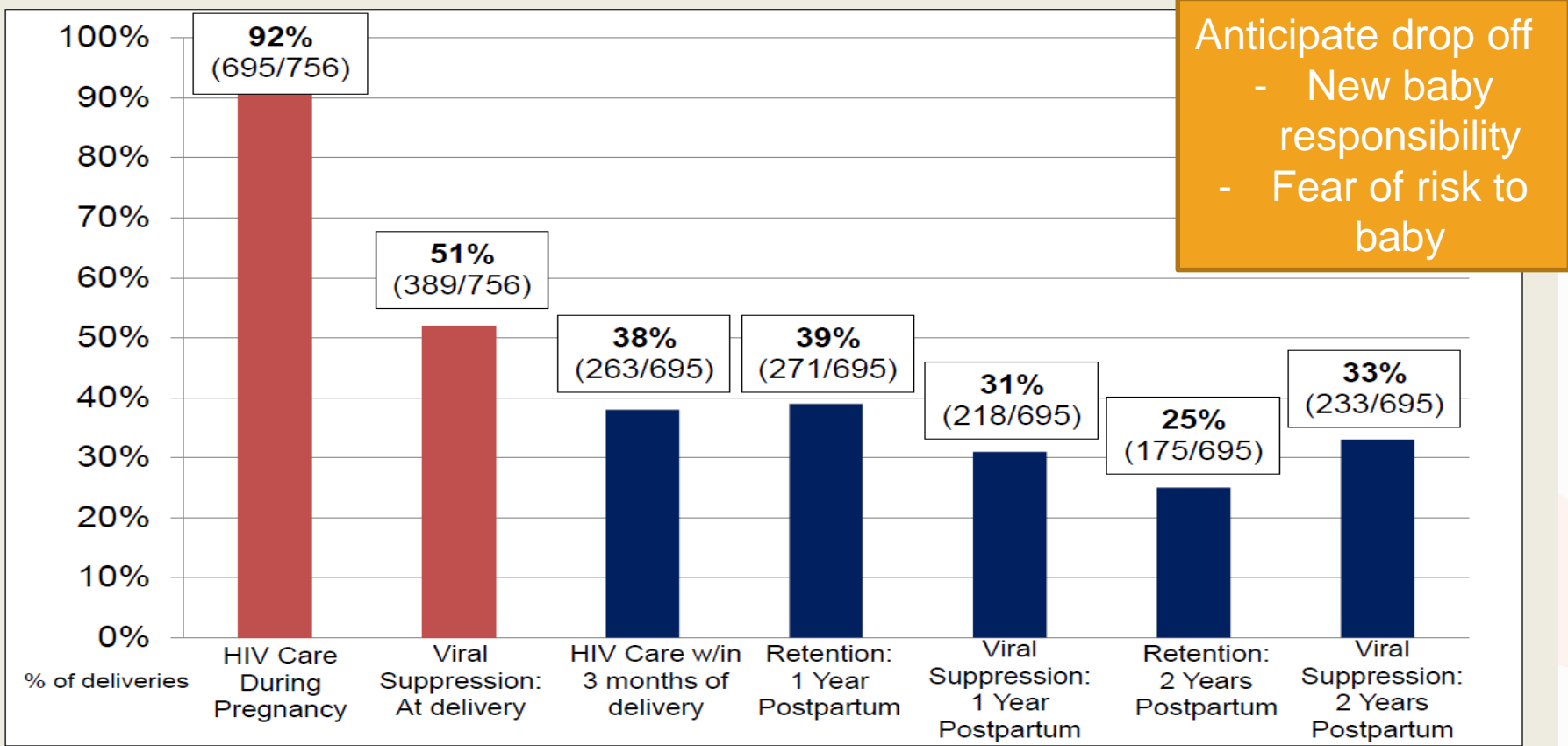
Wait 4 weeks before trying to get pregnant

- Ensure compliance: pill box, alarms, couple meds
- Tolerability

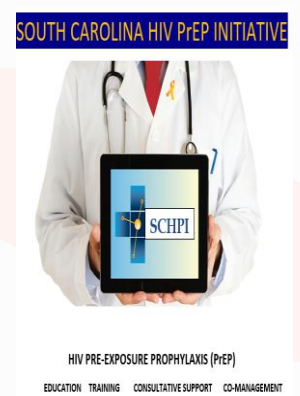
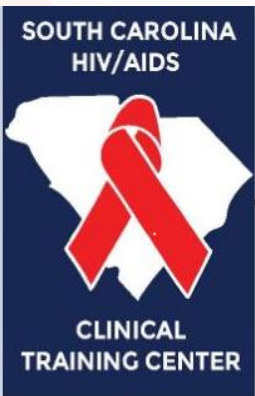
# What happens to PrEP after delivery

## Extrapolated from Postpartum HIV care

HIV Care Continuum for Postpartum Women in Philadelphia: 2005-2011  
**Figure 1. HIV Care Engagement During Pregnancy and for Two Years Postpartum for 598 HIV-Infected Women (n=756 deliveries)**



# PrEP in Heterosexual Couples/ PrEP For Pregnancy



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