



# PRE-EXPOSURE PROPHYLAXIS FOR HIV

---

Sean Kelly, MD

Vanderbilt Division of Infectious Diseases

February 6, 2020



# Disclosures

- None



# Objectives

- Background of PrEP
- Importance of PrEP in the Southeast
- Provider and patient barriers to PrEP
- PrEP eligibility
- Taking a sexual history
- PrEP prescribing
  - Counseling
  - Adverse effects
  - Lab monitoring
  - Financial aspects



# Post-Exposure Prophylaxis - PEP

- Intended to prevent the establishment of HIV infection AFTER exposure has occurred
- Occupational and non-occupational
- Must be started within 72 hours of exposure and continued for 28 days
- Can reduce risk of HIV infection by >80% after exposure



# PEP

- Regimen:
  - Truvada® (TDF/FTC) + raltegravir OR dolutegravir
  - Monitoring includes HIV screening at various intervals
    - Baseline
    - 28 days
    - 3 months
    - 6 months



**Table 1. Estimated per-act risk for acquiring human immunodeficiency virus (HIV) from an infected source, by exposure act<sup>a</sup>**

<b>Exposure type</b>	<b>Rate for HIV acquisition per 10,000 exposures</b>
<b>Parenteral</b>	
Blood transfusion	9,250
Needle sharing during injection drug use	63
Percutaneous (needlestick)	23
<b>Sexual</b>	
Receptive anal intercourse	138
Receptive penile-vaginal intercourse	8
Insertive anal intercourse	11
Insertive penile-vaginal intercourse	4
Receptive oral intercourse	Low
Insertive oral intercourse	Low
<b>Other<sup>b</sup></b>	
Biting	Negligible
Spitting	Negligible
Throwing body fluids (including semen or saliva)	Negligible
Sharing sex toys	Negligible
Source: <a href="http://www.cdc.gov/hiv/policies/law/risk.html">http://www.cdc.gov/hiv/policies/law/risk.html</a>	
<sup>a</sup> Factors that may increase the risk of HIV transmission include sexually transmitted diseases, acute and late-stage HIV infection, and high viral load. Factors that may decrease the risk include condom use, male circumcision, antiretroviral treatment, and preexposure prophylaxis. None of these factors are accounted for in the estimates presented in the table.	
<sup>b</sup> HIV transmission through these exposure routes is technically possible but unlikely and not well documented.	



# I. What is PrEP



# PrEP is primary prevention


It is intended to  
**PREVENT** the onset of a  
disease in those who are  
**AT RISK**

It is a concept, fulfilled by  
medication that has been FDA-  
approved for this purpose





# But what is PrEP, really?

- Truvada® 
  - Fixed dose combination of tenofovir disoproxil fumarate (TDF) 300mg/emtricitabine (FTC) 200mg
  - Developed by Gilead
  - FDA-approved for use as PrEP for adults on June 6, 2012
  - FDA-approved for use as PrEP for adolescents on May 15, 2018
- Generic TDF/FTC approved June 2017 (available September 2020)



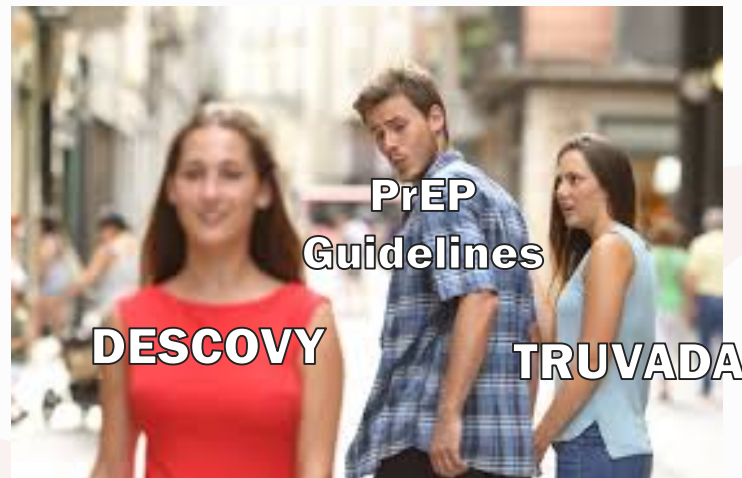
# And now also...

- Descovy®
  - Similar to Truvada®
    - Truvada® = tenofovir **disoproxil fumarate** (TDF) + emtricitabine
    - Descovy® = tenofovir **alafenamide** (TAF) + emtricitabine
  - Approved for PrEP October 2, 2019 for non-vaginal sex
  - TAF achieves high intracellular concentrations, but lower (>10-fold) plasma and tissue concentrations than TDF
    - Lower risk of BMD loss and reduced creatinine clearance
    - Can be used in chronic kidney disease (CrCl >30 mL/min)



# DISCOVER trial

- 5400 MSM and transgender women
- Randomized to Truvada® vs Descovy®
- Descovy® is non-inferior to Truvada® at 96 weeks
- Adverse events similar
- Descovy® achieved therapeutic levels faster and remained therapeutic longer after discontinuation.



Spinner CD, Brunetta J, Shalit P, et al. DISCOVER study for HIV pre-exposure prophylaxis (PrEP): F/TAF has a more rapid onset and longer sustained duration of HIV protection compared with F/TDF. 10th IAS Conference on HIV Science (IAS 2019), July 21-24, 2019, Mexico City.



## Please note:

- While either Descovy® or Truvada® may be used for patient patients, all current national guidelines pertain to Truvada®. For the sake of this talk, I will mainly discuss Truvada®.

{ noted. }



# Primary Prevention

	HIV	Myocardial infarction or Stroke
Assess risk	Take a sexual history	Take a past medical, family, social history, check cholesterol and screen for diabetes, calculate 10-year ASCVD risk by 2013 ACC/AHA guidelines
Laboratory evaluation	Serum creatinine, HIV screen	Comprehensive metabolic panel, cholesterol profile, hemoglobin a1c
Further risk reduction	Condom use, sexual health and substance use counseling, STI screening	Lifestyle and diet modification counseling, treat comorbid conditions (hypertension, diabetes), smoking cessation
Medication options	Truvada® Descovy®	Atorvastatin Rosuvastatin Pravastatin Pitavastatin Simvastatin Fluvastatin Aspirin



# Primary Prevention

	HIV	Myocardial Infarction
Assess risk	Take a sexual history	Take a family history, assess risk factors for the 10-year ASCVD risk by 2013 guidelines
Laboratory evaluation	Serum creatinine	Comprehensive metabolic panel, cholesterol profile, hemoglobin a1c
Further risk reduction	Counseling	Lifestyle and diet modification counseling, treat comorbid conditions (hypertension, diabetes), smoking cessation
Medication options	PrEP (e.g., Truvada®)	Atorvastatin Rosuvastatin Pravastatin Pitavastatin Simvastatin Fluvastatin Aspirin

**PREP IS EASY**



# PrEP is a PROGRAM

- Not only HIV prevention
- Involves comprehensive sexual healthcare
  - Screening and treatment for STIs
  - Hepatitis A and B vaccination
  - Counseling on STI prevention strategies





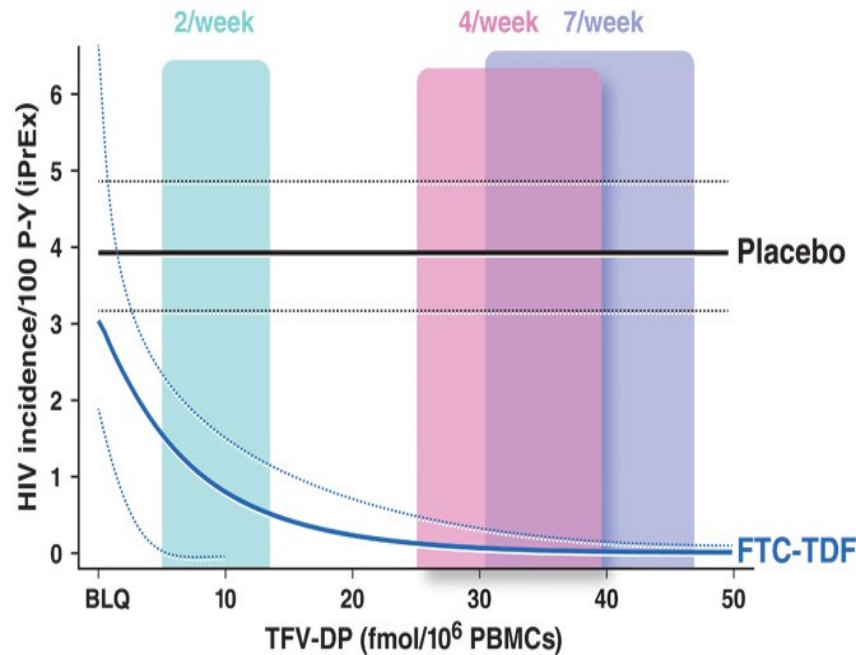
# Efficacy studies summary

Study	Population	Dosing	Risk Reduction
iPrEX	MSM	Daily	44% (92% with ideal adherence)
TDF2	Heterosexual men and women	Daily	62.2% (100% in open-label extension with regular follow-up)
Partners	Sero-discordant heterosexual couples	Daily	75% (90% with ideal adherence)
Bangkok Tenofovir Study Group	Intravenous drug users	Daily	48.9% (74% with ideal adherence)
IPERGAY	MSM	On-demand	86%





# Dosing matters



- Using drug concentrations in iPrEX and STRAND, pharmacokinetic models predict:
  - **76%** risk reduction with 2 doses/week
  - **96%** with 4 doses/week
  - **99%** with 7 doses/week.

Anderson PL, Glidden DV, Liu A, Buchbinder S, Lama JR, Guanira JV, et al. Sci Transl Med. 2012;4: 151ra125.

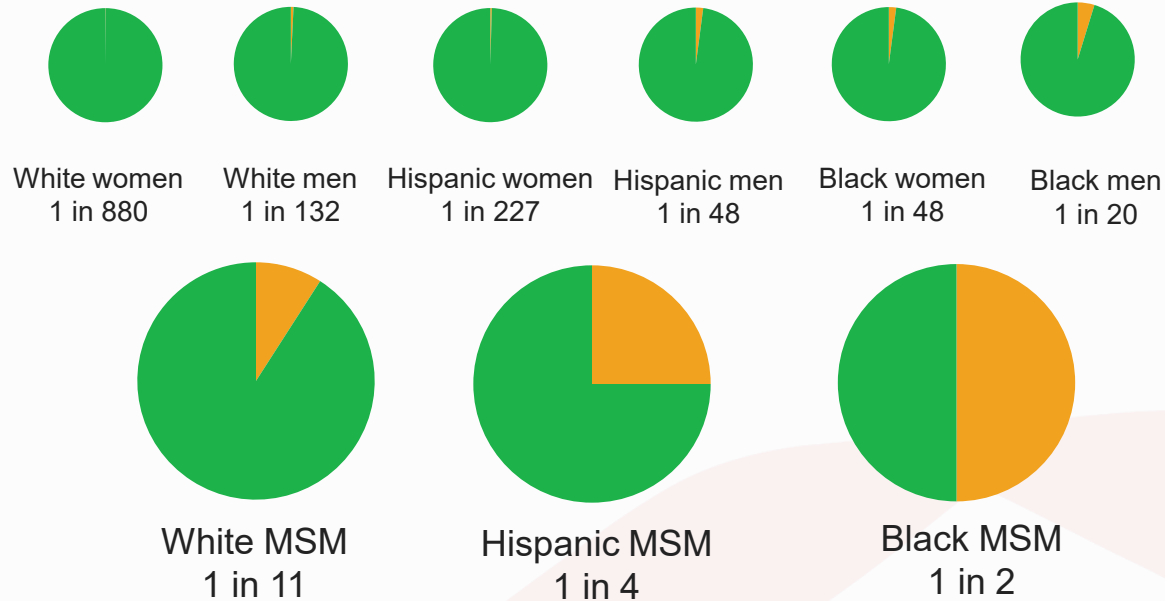


## II. Why PrEP Matters





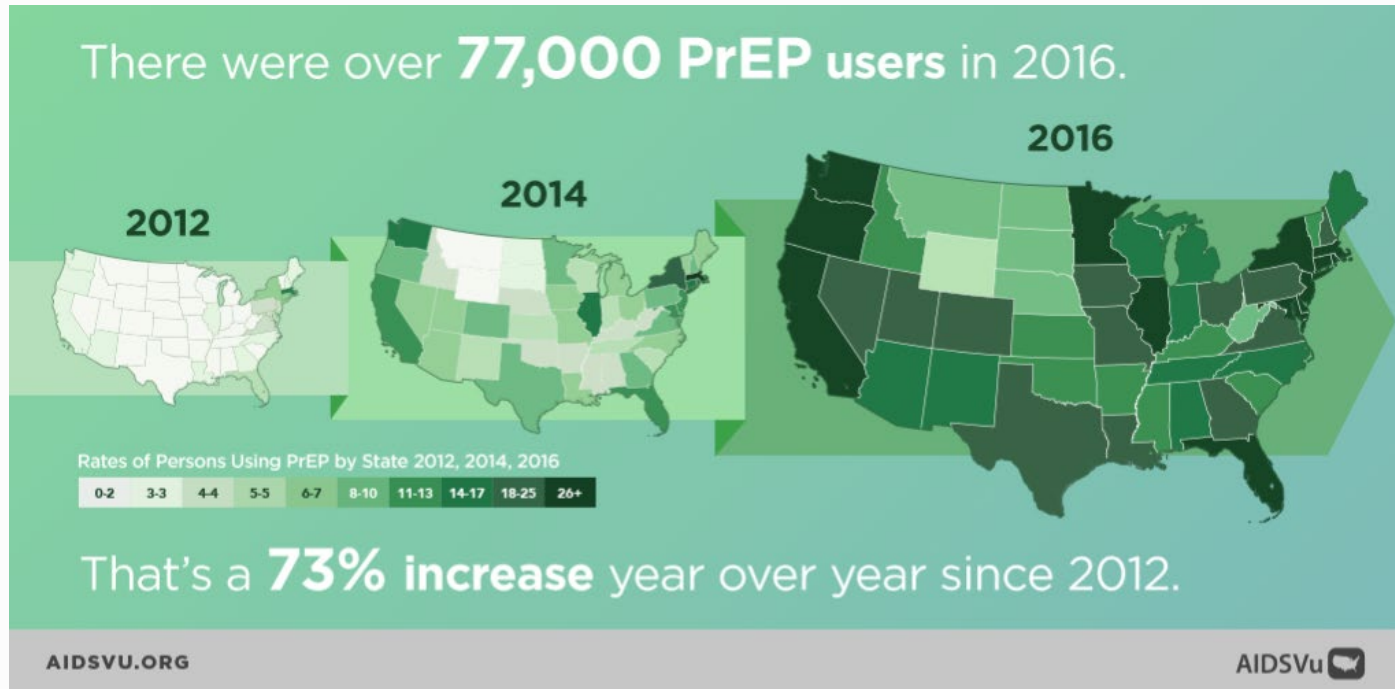
# HIV Risk by Race/Ethnicity and MSM



CDC, 23 Feb 2016: <http://www.cdc.gov/nchhstp/newsroom/2016/croi-press-release-risk.html>

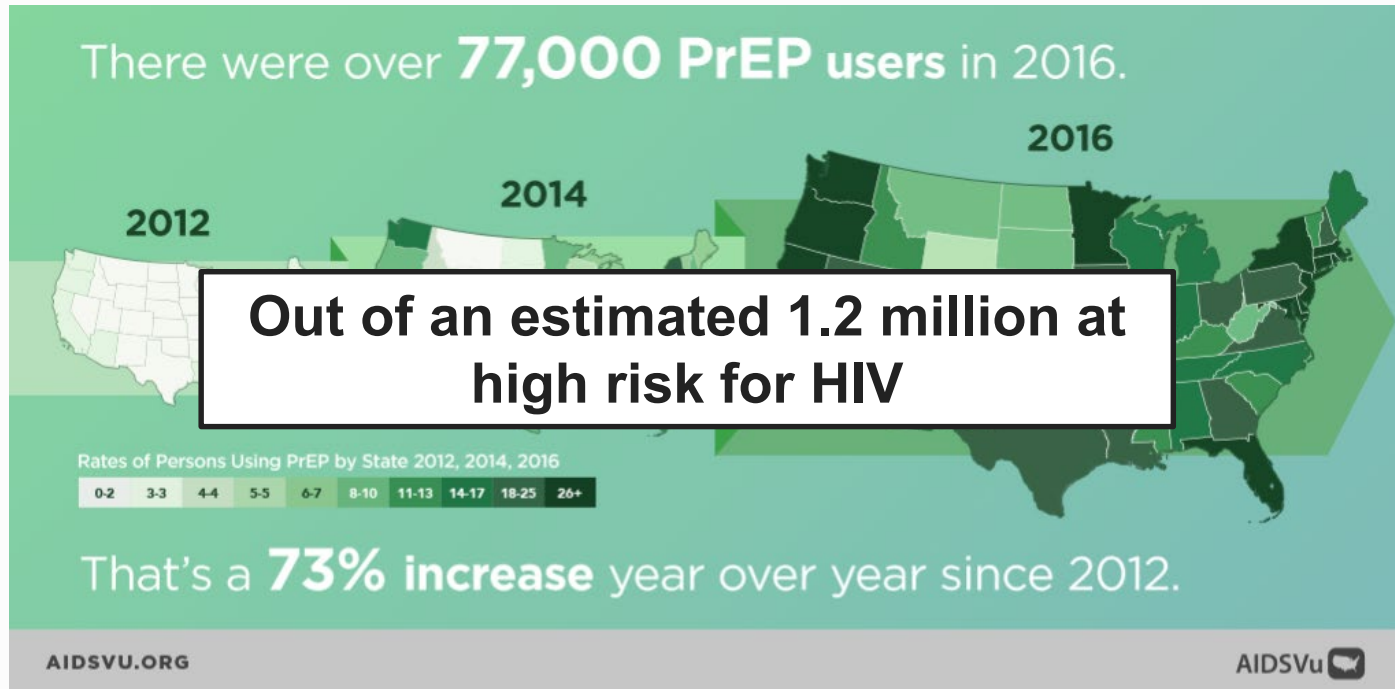


# PrEP use



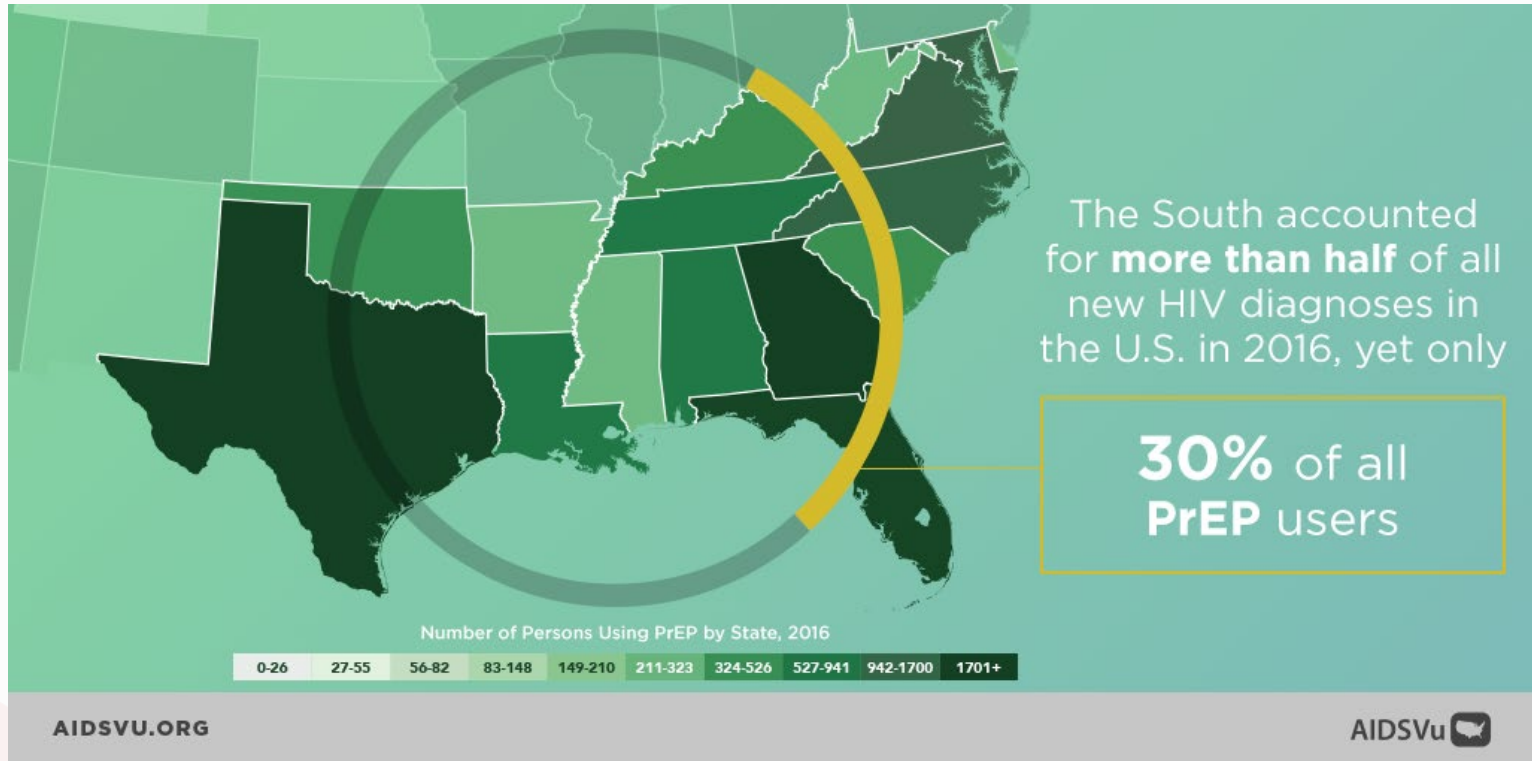


# PrEP use



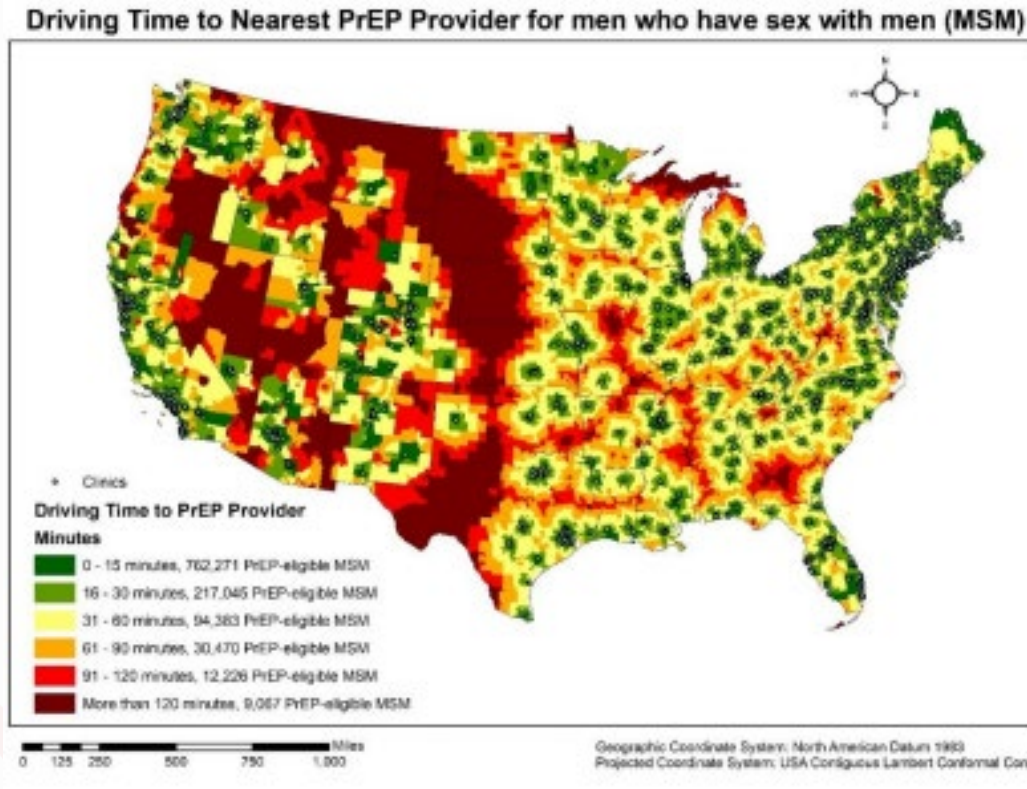


# PrEP use





# PrEP Deserts



- Most MSM with reduced geographic access to PrEP providers (“PrEP deserts”) reside in the South.
- Over 50% of MSM in the South must drive >60 minutes to a PrEP provider.
- PrEP deserts are generally non-urban areas.

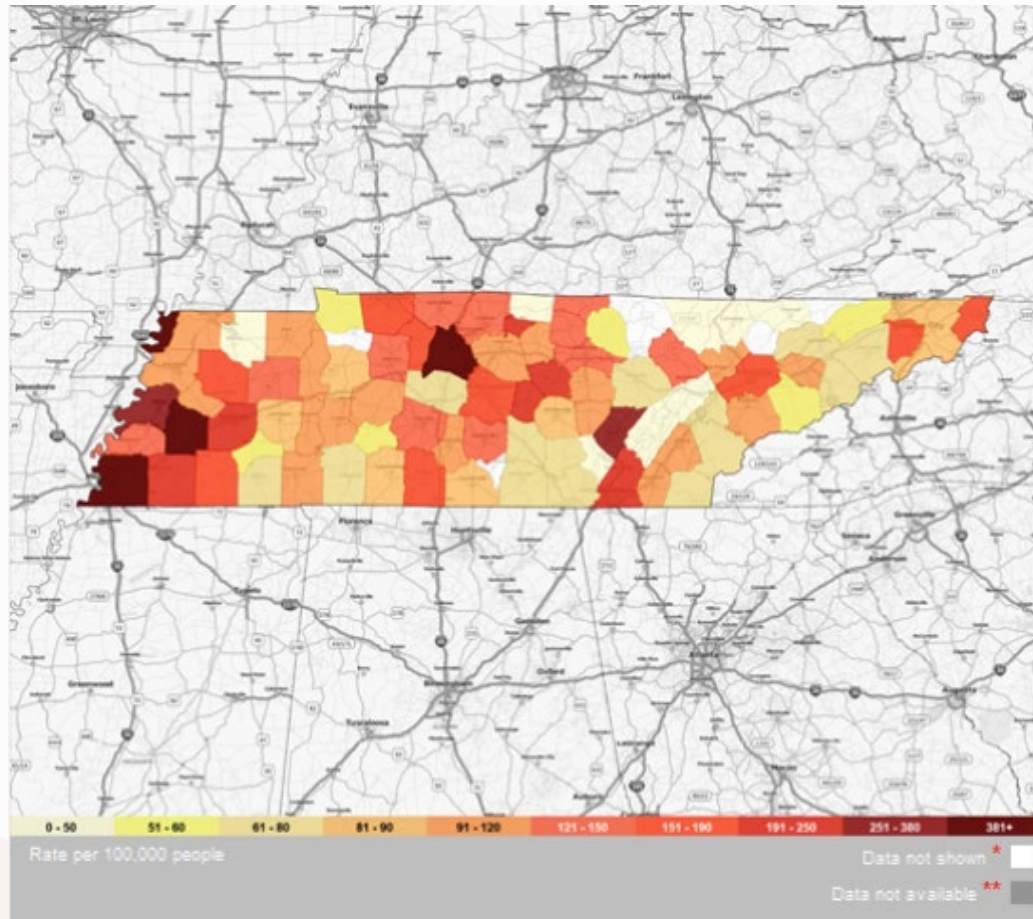
Weiss K, et al. Access to PrEP clinics among US MSM: documenting PrEP deserts. Conference on Retroviruses and Opportunistic Infections, Abstract 1006; March 4–7, 2018, Boston, Massachusetts





# Tennessee

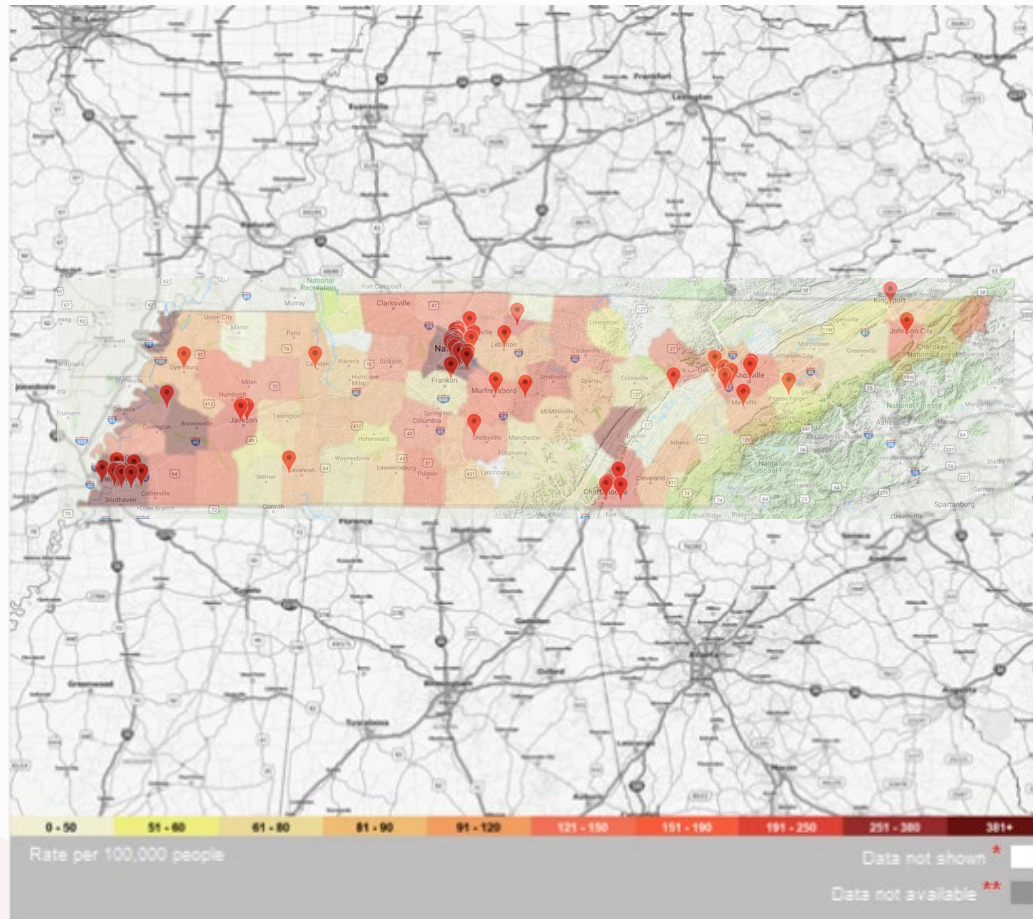
## HIV risk and location of PrEP providers





# Tennessee

## HIV risk and location of PrEP providers





# Barriers to PrEP



# PrEP sounds amazing!

So why aren't we using it?





# Stigma

A preventative measure against the consequences of sexual activity

... *condones* sexual activity

... *promotes* sexual activity

... *causes* sexual activity



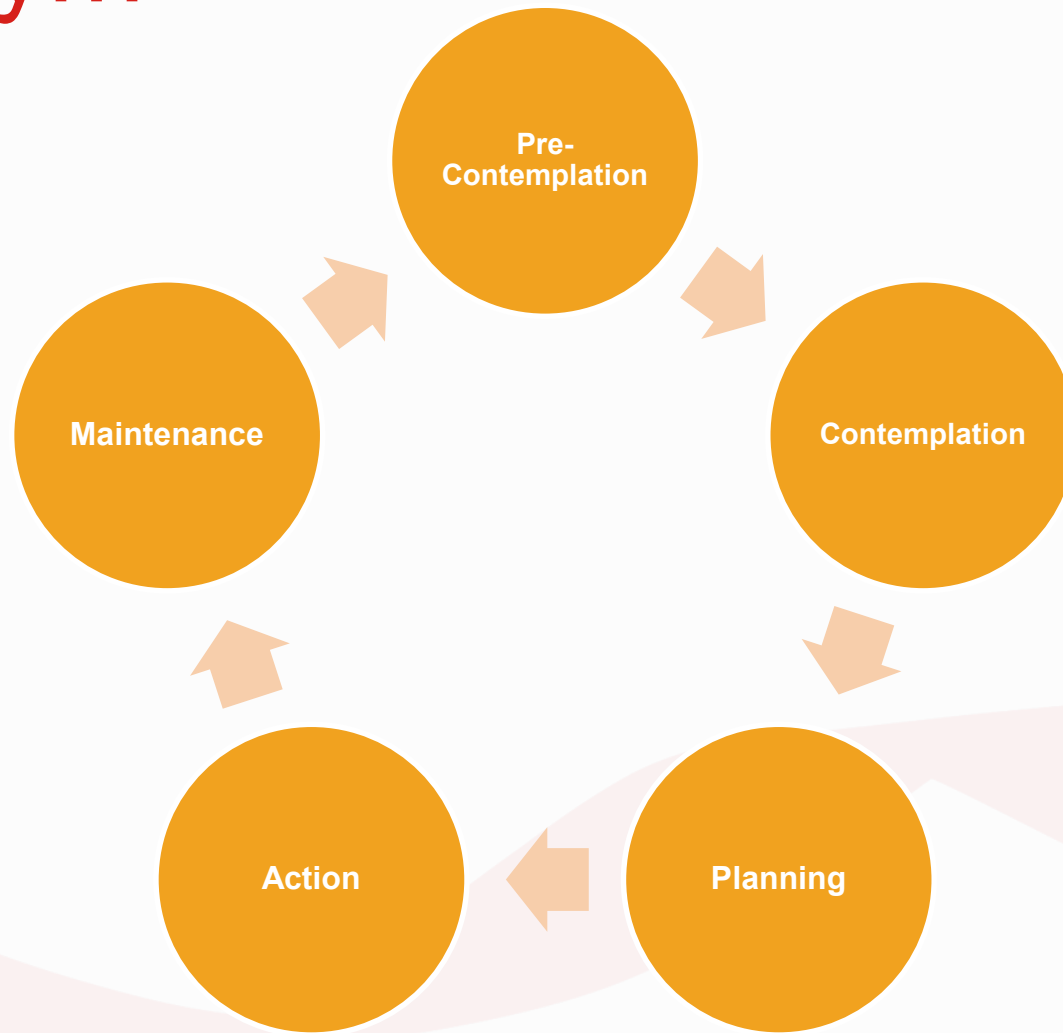


# Sexual risk compensation

- PrEP users will engage in higher risk sex than they previously had.
- This increased unsafe sex will undermine prevention efforts.
- Higher rates of bacterial STIs diagnosed among PrEP users may falsely support this.
  - PrEP users are screened for bacterial STIs frequently due to follow-up requirements.
- On a population level, sexual risk compensation is a fallacy.



# Actually...





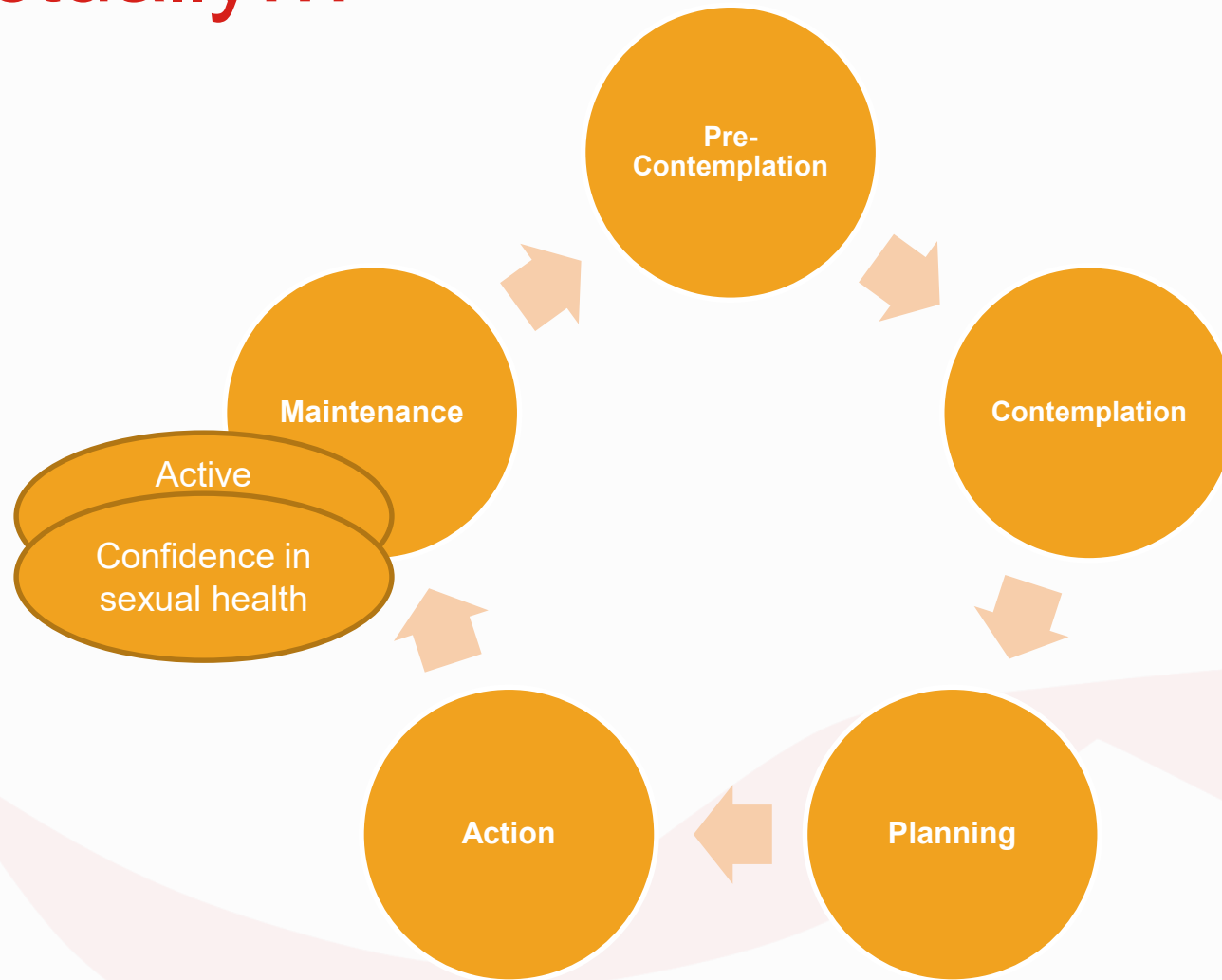
# Actually...







# Actually...



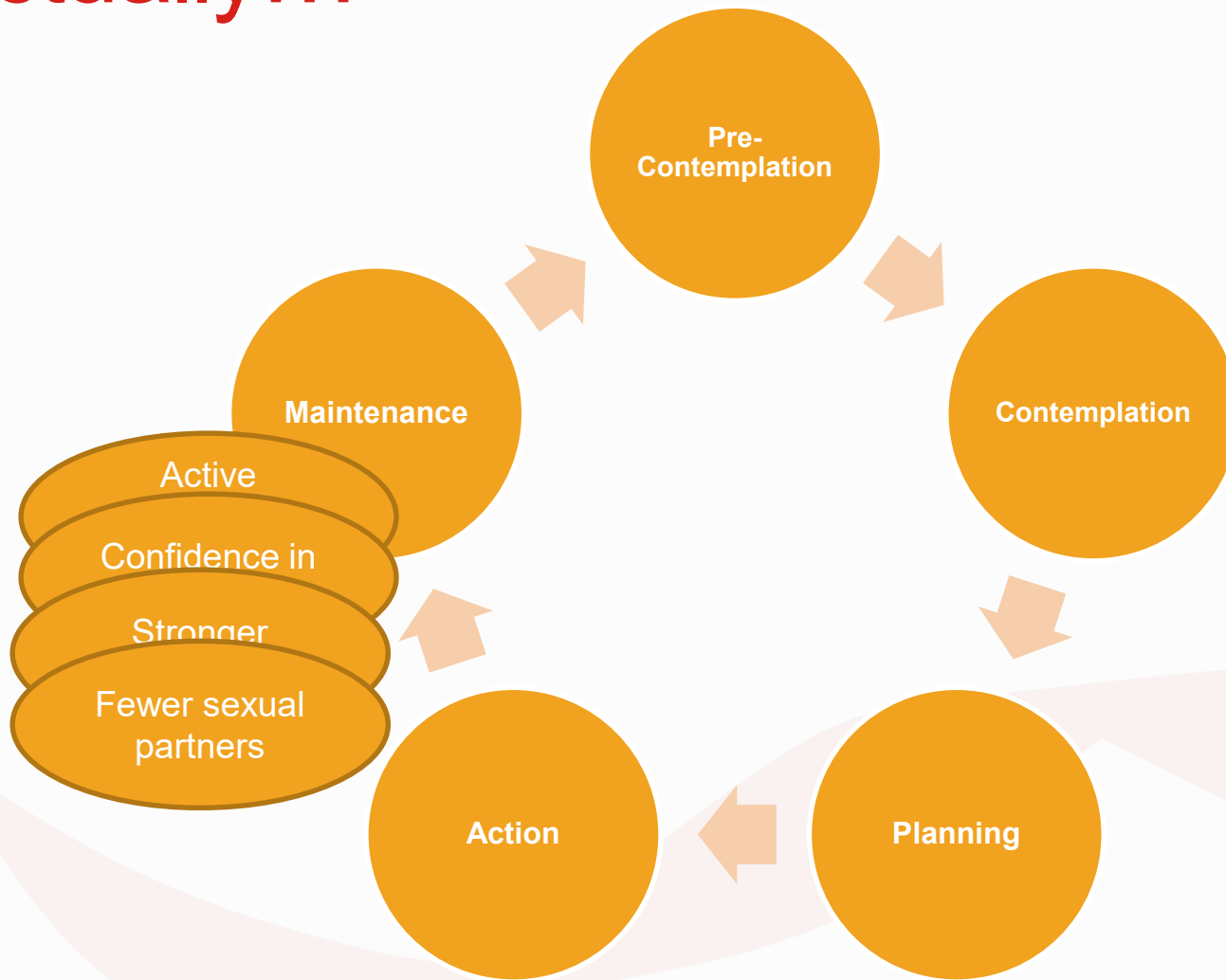


# Actually...





# Actually...





# Actually...





As a society, we treat HIV-related health care activities differently.

As healthcare providers, we need to accept our responsibility to protect our patients.



## III. PrEP eligibility



# PrEP eligibility

Summary of Guidance for PrEP Use			
	Men Who Have Sex With Men	Heterosexual Women and Men	Injection Drug Users
<b>Detecting substantial risk of acquiring HIV infection:</b>	<ul style="list-style-type: none"> <li>Sexual partner with HIV</li> <li>Recent bacterial STD</li> <li>High number of sex partners</li> <li>History of inconsistent or no condom use</li> <li>Commercial sex work</li> </ul>	<ul style="list-style-type: none"> <li>Sexual partner with HIV</li> <li>Recent bacterial STD</li> <li>High number of sex partners</li> <li>History of inconsistent or no condom use</li> <li>Commercial sex work</li> <li>Lives in high-prevalence area or network</li> </ul>	<ul style="list-style-type: none"> <li>HIV-positive injecting partner</li> <li>Sharing injection equipment</li> <li>Recent drug treatment (but currently injecting)</li> </ul>
<b>Clinically eligible:</b>	<ul style="list-style-type: none"> <li>Documented negative HIV test before prescribing PrEP</li> <li>No signs/symptoms of acute HIV infection</li> <li>Normal renal function, no contraindicated medications</li> <li>Documented hepatitis B virus infection and vaccination status</li> </ul>		
<b>Prescription</b>	Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90 day supply		
<b>Other services:</b>	<ul style="list-style-type: none"> <li>Follow-up visits at least every 3 months to provide:               <ul style="list-style-type: none"> <li>HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STD symptom assessment</li> </ul> </li> <li>At 3 months and every 6 months after, assess renal function</li> <li>Every 6 months test for bacterial STDs</li> </ul>		
	<ul style="list-style-type: none"> <li>Do oral/rectal STD testing</li> </ul>	<ul style="list-style-type: none"> <li>Assess pregnancy intent</li> <li>Pregnancy test every 3 months</li> </ul>	<ul style="list-style-type: none"> <li>Access to clean needles/syringes and drug treatment services</li> </ul>

Source: US Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States—2014: a clinical practice guideline.

<https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf>  
[http://www.gilead.com/~media/Files/pdfs/medicines/hiv/truvada/truvada\\_medication\\_guide.pdf](http://www.gilead.com/~media/Files/pdfs/medicines/hiv/truvada/truvada_medication_guide.pdf)



# PrEP eligibility

## Summary of Guidance for PrEP Use

	Men Who Have Sex With Men	Heterosexual Women and Men	Injection Drug Users										
<b>Detecting substantial risk of acquiring HIV infection:</b>	<ul style="list-style-type: none"> <li>Sexual p</li> <li>Recent b</li> <li>High nu</li> <li>partners</li> <li>History c</li> <li>no cond</li> <li>Commer</li> </ul>	<b>HIRI-MSM Risk Index*</b>											
<b>Clinically eligible:</b>	<ul style="list-style-type: none"> <li>Do</li> <li>No</li> <li>No</li> <li>Do</li> </ul>	1 How old are you today (yrs)? <table border="0"> <tr><td>&lt;18 years</td><td>score 0</td></tr> <tr><td>18–28 years</td><td>score 8</td></tr> <tr><td>29–40 years</td><td>score 5</td></tr> <tr><td>41–48 years</td><td>score 2</td></tr> <tr><td>≥49 years</td><td>score 0</td></tr> </table>	<18 years	score 0	18–28 years	score 8	29–40 years	score 5	41–48 years	score 2	≥49 years	score 0	
<18 years	score 0												
18–28 years	score 8												
29–40 years	score 5												
41–48 years	score 2												
≥49 years	score 0												
<b>Prescription</b>		2 How many men have you had sex with in the last 6 months? <table border="0"> <tr><td>&gt;10 male partners</td><td>score 7</td></tr> <tr><td>6–10 male partners</td><td>score 4</td></tr> <tr><td>0–5 male partners</td><td>score 0</td></tr> </table>	>10 male partners	score 7	6–10 male partners	score 4	0–5 male partners	score 0					
>10 male partners	score 7												
6–10 male partners	score 4												
0–5 male partners	score 0												
<b>Other services:</b>	<ul style="list-style-type: none"> <li>Fol</li> <li>HIV</li> <li>sid</li> <li>At 3</li> <li>Eve</li> <li>Do oral/re</li> </ul>	3 In the last 6 months, how many times did you have receptive anal sex (you were the bottom) with a man? <table border="0"> <tr><td>1 or more times</td><td>score 10</td></tr> <tr><td>0 times</td><td>score 0</td></tr> </table>	1 or more times	score 10	0 times	score 0							
1 or more times	score 10												
0 times	score 0												
		4 How many of your male sex partners were HIV positive? <table border="0"> <tr><td>&gt;1 positive partner</td><td>score 8</td></tr> <tr><td>1 positive partner</td><td>score 4</td></tr> <tr><td>&lt;1 positive partner</td><td>score 0</td></tr> </table>	>1 positive partner	score 8	1 positive partner	score 4	<1 positive partner	score 0					
>1 positive partner	score 8												
1 positive partner	score 4												
<1 positive partner	score 0												
		5 In the last 6 months, how many times did you have insertive anal sex (you were the top) with a man who was HIV positive? <table border="0"> <tr><td>5 or more times</td><td>score 6</td></tr> <tr><td>0 times</td><td>score 0</td></tr> </table>	5 or more times	score 6	0 times	score 0							
5 or more times	score 6												
0 times	score 0												
		6 In the last 6 months, have you used methamphetamines such as crystal or speed? <table border="0"> <tr><td>Yes</td><td>score 5</td></tr> <tr><td>No</td><td>score 0</td></tr> </table>	Yes	score 5	No	score 0							
Yes	score 5												
No	score 0												
		7 In the last 6 months, have you used poppers (amyl nitrate)? <table border="0"> <tr><td>Yes</td><td>score 3</td></tr> <tr><td>No</td><td>score 0</td></tr> </table>	Yes	score 3	No	score 0							
Yes	score 3												
No	score 0												
		Add down entries in right column to calculate total score <table border="0"> <tr><td><b>Total score†</b></td></tr> </table>	<b>Total score†</b>										
<b>Total score†</b>													
<p>*To identify sexually active MSM in their practice, we recommend clinicians ask all their male patients a routine question: "In the past (time) have you had sex? (if yes), with men, women, or both?"</p> <p>†If score is 10 or greater, evaluate for PrEP or other intensive HIV prevention services; If score is 9 or less, provide indicated standard HIV prevention services.</p>													

Source: US Public Health Service. Preexposure prophylaxis for HIV infection among men who have sex with men.

<https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf>

[http://www.gilead.com/~media/Files/pdfs/medicines/hiv/truvada/truvada\\_medication\\_guide.pdf](http://www.gilead.com/~media/Files/pdfs/medicines/hiv/truvada/truvada_medication_guide.pdf)





# PrEP eligibility

Summary of Guidance for PrEP Use			
	Men Who Have Sex With Men	Heterosexual Women and Men	Injection Drug Users
<b>Detecting substantial risk of acquiring HIV infection:</b>	<ul style="list-style-type: none"> <li>- Sexual p</li> <li>- Recent b</li> <li>- High nu</li> <li>- partners</li> <li>- History o</li> <li>- no cond</li> <li>- Commer</li> </ul>	<b>HIRI-MSM Risk Index*</b>	
		1 How old are you today	<18 years score 0
<b>Clinically eligible:</b>	<ul style="list-style-type: none"> <li>• Do</li> <li>• No</li> <li>• No</li> <li>• Do</li> </ul>	2 How many you have had sex with in the last 12 months	
<b>Prescription</b>		3 In the last 12 months, how many times did you have sex with a partner who has HIV or is taking PrEP	
<b>Other services:</b>	<ul style="list-style-type: none"> <li>• Fol</li> <li>• HIV</li> <li>• sid</li> <li>• At 3</li> <li>• Eve</li> </ul>	4 How many sex partners do you have (including those with HIV) in the last 12 months	
	<ul style="list-style-type: none"> <li>• Do oral/re</li> </ul>	5 In the last 12 months, how many times did you have sex (yourselves) with a partner who has HIV or is taking PrEP	
		6 In the last 12 months, how many times did you have sex with a partner who has HIV or is taking PrEP	
		7 In the last 12 months, how many times did you have sex with a partner who has HIV or is taking PrEP	
			<p><b>Medication Guide</b>  <b>TRUVADA® (tru-VAH-dah)</b>            (emtricitabine and tenofovir disoproxil fumarate) tablets</p> <p>Read this Medication Guide before you start taking TRUVADA and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.</p> <p>This Medication Guide provides information about two different ways that TRUVADA may be used (see the Medication Guide section <b>"What is TRUVADA?"</b> for important information about how TRUVADA may be used):</p> <ul style="list-style-type: none"> <li>• to treat Human Immunodeficiency Virus-1 (HIV-1) infection, and</li> <li>• to reduce the risk of getting HIV-1 infection in adults who are HIV-negative</li> </ul> <p>HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).</p> <p><b>What is the most important information I should know about TRUVADA?</b>  <b>If you also have hepatitis B virus (HBV) infection and take TRUVADA, your hepatitis B may become worse if you stop taking TRUVADA.</b></p> <ul style="list-style-type: none"> <li>• Do not stop taking TRUVADA without first talking to your healthcare provider.</li> <li>• Do not run out of TRUVADA. Refill your prescription or talk to your healthcare provider before your TRUVADA is all gone.</li> <li>• If your healthcare provider stops TRUVADA, your healthcare provider will need to watch you closely for several months to check your hepatitis B infection, or give you a medication to treat hepatitis B.</li> </ul> <p>Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking TRUVADA.</p> <p>For more information about side effects, see the section <b>"What are the possible side effects of TRUVADA?"</b> in this Medication Guide.</p> <p><b>Other important information for people who take TRUVADA to help reduce their risk of getting HIV-1 infection:</b>  <b>Before taking TRUVADA to reduce your risk of getting HIV-1 infection:</b></p> <ul style="list-style-type: none"> <li>• <b>You must be HIV-negative to start TRUVADA. You must get tested to make sure that you do not already have HIV-1 infection.</b></li> <li>• <b>Do not take TRUVADA to reduce the risk of getting HIV-1 unless you are confirmed to be HIV-negative.</b></li> <li>• Many HIV-1 tests can miss HIV-1 infection in a person who has recently become infected. If you have flu-like symptoms, you could have recently become infected with HIV-1. Tell your healthcare provider if you had a flu-like illness within the last month before starting TRUVADA or at any time while taking TRUVADA. Symptoms of new HIV-1 infection include:               <ul style="list-style-type: none"> <li>○ tiredness</li> <li>○ fever</li> <li>○ joint or muscle aches</li> <li>○ sore throat</li> <li>○ vomiting or diarrhea</li> <li>○ rash</li> </ul> </li> </ul>
			<p>*To identify their male partner, women, or injection drug users.</p> <p>†If score is 10 or greater, evaluate for PrEP or other intensive HIV prevention services; If score is 9 or less, provide indicated standard HIV prevention services.</p>

Source: US Public Health Service. Preexposure prophylaxis for HIV infection among men who have sex with men, women, and injection drug users.

<https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf>  
[http://www.gilead.com/~media/Files/pdfs/medicines/hiv/truvada/truvada\\_medication\\_guide.pdf](http://www.gilead.com/~media/Files/pdfs/medicines/hiv/truvada/truvada_medication_guide.pdf)



# PrEP eligibility

## Summary of Guidance for PrEP Use

	Men Who Have Sex With Men	Heterosexual Women and Men	Injection Drug Users
<b>Detecting substantial risk of acquiring HIV infection:</b>	<ul style="list-style-type: none"> <li>Sexual p</li> <li>Recent b</li> <li>High nu</li> <li>partners</li> <li>History o</li> <li>no cond</li> <li>Commer</li> </ul>		
<b>Clinically eligible:</b>	<ul style="list-style-type: none"> <li>Do</li> <li>No</li> <li>No</li> <li>Do</li> </ul>		
<b>Prescription</b>			
<b>Other services:</b>	<ul style="list-style-type: none"> <li>Foll</li> <li>HIV</li> <li>sid</li> <li>At</li> <li>Eve</li> </ul>		

Source: US Public Health Service. Preexposure proph

HIRI-MSM Risk Index*		
1	How old are you today	<18 years score 0
2	How many you have had in the last 12 months	
3	In the last 12 months, how many times did you have anal sex with a partner whose HIV status is unknown	
4	How many partners have you had sex with in the last 12 months	
5	In the last 12 months, how many times did you have sex with a partner whose HIV status is unknown	
6	In the last 12 months, how many times did you have sex with a partner whose HIV status is unknown	
7	In the last 12 months, how many times did you have sex with a partner whose HIV status is unknown	

**Medication Guide**  
**TRUVADA® (tru-VAH-dah)**  
 (emtricitabine and tenofovir disoproxil fumarate) tablets

Read this Medication Guide before you start taking TRUVADA and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

This Medication Guide provides information about two different ways that TRUVADA may be used (see the Medication Guide section **"What is TRUVADA?"** for important information about how TRUVADA may be used):

- to treat Human Immunodeficiency Virus-1 (HIV-1) infection, and
- to reduce the risk of getting HIV-1 infection in adults who are HIV-negative

HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

**What is the most important information I should know about TRUVADA?**  
 If you also have hepatitis B virus (HBV) infection and take TRUVADA, your hepatitis B may become worse if you stop taking TRUVADA.

The USPSTF recommends the following persons be considered for PrEP:

- Men who have sex with men, are sexually active, and have one of the following characteristics:
  - A serodiscordant sex partner (i.e., a sex partner living with HIV)
  - A recent sexually transmitted infection (STI) with syphilis, gonorrhea, or chlamydia
  - Inconsistent use of condoms during receptive or insertive anal sex
- Heterosexual women and men who are sexually active and have one of the following characteristics:
  - A serodiscordant sex partner (i.e., a sex partner living with HIV)
  - Inconsistent use of condoms during sex with a partner whose HIV status is unknown and who is at high risk (e.g., a person who injects drugs or bisexual partner)
  - A recent STI with syphilis or gonorrhea
- Persons who inject drugs and have one of the following characteristics:
  - Share drug injection equipment
  - Are at risk of sexual acquisition of HIV (see above)

\*To identify their male patients, women, or...  
 †If score is 10 or greater, consider PrEP services; If score is 9 or greater, consider PrEP services.

<https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf>  
[http://www.gilead.com/~media/Files/pdfs/medicines/hiv/truvada/truvada\\_medication\\_guide.pdf](http://www.gilead.com/~media/Files/pdfs/medicines/hiv/truvada/truvada_medication_guide.pdf)



# PrEP eligibility

Summary of Guidance for PrEP Use			
	Men Who Have Sex With Men	Heterosexual Women and Men	Injection Drug Users
Detecting substantial risk of acquiring HIV infection:	<ul style="list-style-type: none"> <li>- Sexual p</li> <li>- Recent b</li> <li>- High nu</li> <li>- partners</li> <li>- History o</li> <li>- no cond</li> <li>- Commer</li> </ul>	<b>HIRI-MSM Risk Index*</b>	
		1 How old are you today	<18 years score 0
		2 How many you have in the	
		<b>Medication Guide</b> TRUVADA® (tru-VAH-dah) (emtricitabine and tenofovir disoproxil fumarate) tablets <small>Read this Medication Guide before you start taking TRUVADA and each time you get a refill. There may be new</small>	

Anyone with high risk for HIV acquisition, as determined by the patient's and/or provider's assessment, in which the risk of Truvada® does not outweigh the benefit.

\*To identify their male partner, women, or  
†If score is 10 or greater; If score is 9 or less

Persons who inject drugs and have one of the following characteristics:

- A recent STI with syphilis or gonorrhea
- Share drug injection equipment
- Are at risk of sexual acquisition of HIV (see above)

<https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf>  
[http://www.gilead.com/~media/Files/pdfs/medicines/hiv/truvada/truvada\\_medication\\_guide.pdf](http://www.gilead.com/~media/Files/pdfs/medicines/hiv/truvada/truvada_medication_guide.pdf)



# What about U=U?





# U=U

- Those who have an undetectable viral load have effectively no risk of transmitting the virus.
- This is a consensus of HIV experts worldwide, CDC, NIH, IDSA/HIVMA, common knowledge in the medical community.
- Combined data from 4 studies (HPTN 052, OPPOSITES ATTRACT, PARTNER and PARTNER2)
  - Among sero-discordant couples where the partner living with HIV had a durably undetectable viral load:
    - zero transmission among over a hundred thousand condomless sex acts
    - Results similar in both male-female and male-male partnerships



# U=U

- Is PrEP necessary in this situation?
  - Consider *durable* viral suppression
    - Contributing factors include adherence, history of virologic failure, follow-up interval of the HIV-positive person
  - Consider non-monogamous sex
    - In U=U studies, HIV transmissions **DID** occur, but were linked to sex between HIV-negative participant and HIV-positive individual not involved in the study
  - Always weigh risks and benefits



# HIV risk is behavioral, individual, transitional

The only way to know is to ask (and listen)!



## IV. The sexual history

(Many providers don't do this, even though it is a crucial job requirement)





# Barriers to the Sexual History

- Lack of time
- Uneasiness of clinicians and patients with a difficult and sensitive subject
- Belief it is irrelevant
- Belief it is someone else's job
- Fear of offending the patient
- Medical/nursing school curricula design



# Barriers to the Sexual History

- What are your barriers to taking a sexual history?
- How can you overcome those barriers?

**As healthcare providers, we need to accept our responsibility to protect our patients.**



# Sexual History Misconceptions

- The problems with labeling
  - “Married persons do not acquire STIs”
  - “Persons who identify as “straight” only have sex with those of the opposite gender”
  - “Persons who identify as “gay” or “lesbian” only have sex with those of the same gender”
- Persons with an STI will have symptoms
- Persons will voice sexual concerns without prompting



# Effective Communication Skills

- Consider prefacing the sexual history with a short introduction.
- Start with open-ended questions
- Use closed-ended questions to elicit specific information



# The Sexual History

- Preface

- “The rates of sexually transmitted infections continue to increase, especially here in the South. In order to screen you correctly, prevent STIs and keep you healthy, it’s important for me to know how you have sex and with whom.”
- “Gonorrhea and chlamydia can also live in our rectums and throats, so it’s important for us to test anywhere you might have had an exposure.”



# The Sexual History

- “About how many partners have you had in the past 6 months?”
- “Do you have sex with men, women or both?”
- “Are you a top, bottom, or vers?”
  - Top = anal insertive
  - Bottom = anal receptive
  - Vers/versatile = both insertive and receptive
- “Do you have oral sex?”
- “What do you do to prevent STDs?”
- “Are you trying to prevent pregnancy? What do you use for contraception?”
- “Do you use condoms? What percentage of the time would you say you use condoms?”



# The Sexual History

- “Are any of your partners HIV-positive?”
  - If so, “do you know if they’re undetectable?”
- “Have any of your partners recently had an STD?”
- “Have you ever had an STD”
- “Have you ever had HIV or STD testing?”



# The Sexual History

- “Do you ever use drugs, like poppers or meth, when you have sex?”
- “Do any of your partners make you scared or feel unsafe?”
- “Do you ever have to use sex for things you need, like food or to pay pills?”





# The Sexual History

- Also a great time to discuss travel!
- Many people meet sexual partners, or have sex with partners other than long-term partner, during travel

MemphisChampionsAcademy3.6.20Patient  
Cases





# Interactive Cases!



# Case 1 - Mark

- 34-year-old man presenting for routine annual history and physical. He has been followed by this provider since he was 19.
- Fourth of seven children. Raised Baptist, participates in fundraising for his church.
- Originally from Johnson City, TN. Moved to Nashville for college, studied marketing at Belmont.
- Works in digital marketing for a healthcare start-up in Nashville.
- Travelled to Las Vegas for a bachelor party in September 2019, no other recent travel.
- Drinks 5-10 drinks/week (usually only on weekends), does not smoke cigarettes, smokes marijuana occasionally, no other recreational drugs.
- Identifies as heterosexual. Has had sex with both men and women. He has a girlfriend of two years, and has had sex with three different men (one time each) during the past two years (once without a condom). He met these partners on the dating app Grindr. He has had both anal insertive and receptive sex. He has not disclosed these other partners to anyone. He went a Walgreens walk-in clinic last year for STI testing, had negative urine gonorrhea/chlamydia, syphilis and HIV testing. He's otherwise never undergone STI testing.



# Case 2 - Elle

- 28-year-old woman presenting with dysuria, urinary urgency, and hesitancy consistent with urinary tract infection. This is her first visit to this provider.
- She has no siblings, has not spoken with her parents since she was 16.
- Her highest level of education is 10<sup>th</sup> grade.
- She has not recently travelled outside of Middle Tennessee.
- She does not drink alcohol, and smokes ½ pack per day.
- She has injected opioids and methamphetamines since she was 15. She has been to multiple intense outpatient rehabilitation programs and is usually able to maintain sobriety for 1-2 years after each program. She most recently relapsed 3 months ago and has been injecting heroin or taking prescription opiates daily since then. The injectable heroin is usually prepared for her, so she is not certain if the syringes had been previously used. She has traded sex for opiates, as well as a place to stay and money to pay her bills. She experienced intimate partner violence one month ago by the man she was living with who procures her opiates (who she considered her boyfriend), which resulted in a rib fracture. She now lives with her cousin but is afraid she will be kicked soon due to her opiate use.



# Case 3 - Ben

- 21-year-old man presenting for 3 days of urethral discharge. He established with this student health provider two years ago.
- He is a junior in college studying political science.
- No recent travel, but planning to go to Miami with friends on Spring Break.
- He drinks up to 15 drinks/week (usually on weekends). He has used cocaine, marijuana, and MDMA several times in the past 3 months. He does not smoke cigarettes.
- He identifies as gay. He has had seven male partners in the past 6 months. He knows most of these partners, and inquires about their HIV statuses. One of them is HIV-positive, engaged in care and undetectable, the rest are believed to be HIV-negative. His sexual debut was at age 18. He identifies as “vers” (anal insertive and receptive). He has a history of rectal gonorrhea last year and early syphilis two years ago. He uses condoms “80%” of the time. He typically undergoes HIV screening and STI testing every 6 months at the health department. He knows about PrEP but has financial concerns about starting it. He is on his parent’s insurance, so is worried that STI screening, treatment and PrEP-associated charges will be apparent on bills sent to his parent’s house. He worries that if his parents find out he is gay, he will be financially cut-off.



# IV. PrEP medication counseling



# PrEP Medication Counseling

- Dosing
  - One tab daily, with or without food
- Adherence, and its relationship to efficacy
- Time to effectiveness
  - 7-10 days for men, 21 days for women
  - Barrier protection especially needed during that time
- Adverse effects
  - Nausea, vomiting, diarrhea, loss of appetite, weight loss
  - Fatigue, headache
- Requirements for monitoring
- Refill process
  - “Call when you have 7-10 days left”



# Adverse Events

Table 2. Adverse Events, According to Treatment Group.\*

Adverse Event	TDF-FTC (N=611)		Placebo (N=608)		P Value†
	no. of participants (%)	no. of events	no. of participants (%)	no. of events	
Any	557 (91.2)	4357	536 (88.2)	4390	0.003
Any serious	63 (10.3)	68	66 (10.9)	79	0.90
Grade 3 or 4 only	19 (3.1)	21	29 (4.8)	32	0.17
At least possibly related to study drug	20 (3.3)	21	27 (4.4)	29	0.35
Upper respiratory tract infection	231 (37.8)	385	241 (39.6)	439	0.84
Headache	227 (37.2)	390	226 (37.2)	411	0.73
Dizziness	92 (15.1)	109	67 (11.0)	82	0.03
Abdominal pain	155 (25.4)	215	156 (25.7)	217	0.78
Nausea	113 (18.5)	132	43 (7.1)	48	<0.001
Vomiting	69 (11.3)	87	43 (7.1)	47	0.008
Diarrhea	76 (12.4)	93	65 (10.7)	76	0.22
≥5% Weight loss	75 (12.3)	113	61 (10.0)	72	0.13
Back pain	57 (9.3)	72	68 (11.2)	90	0.37
Rash	39 (6.4)	44	42 (6.9)	48	0.81
Fracture	7 (1.1)	7	6 (1.0)	8	0.74
Elevated creatinine	1 (0.2)	1	0	0	1.00
Hypophosphatemia	142 (23.2)	219	159 (26.2)	245	0.65
Hyperamylasemia	315 (51.6)	997	302 (49.7)	1017	0.45
Elevated AST	36 (5.9)	43	38 (6.2)	42	0.90
Elevated ALT	38 (6.2)	48	43 (7.1)	66	0.57
Death‡	2 (0.3)	2	4 (0.7)	4	0.45

\* ALT denotes alanine aminotransferase, and AST aspartate aminotransferase.

† All P values were calculated with the use of a time-to-first-event analysis (regression analysis of survival data on the basis of the Cox proportional-hazards model), with the exception of the P values for weight loss of 5% or more and death, which were calculated with the use of Fisher's exact test.

‡ The causes of death in the TDF-FTC group were motor vehicle accident (one participant) and suicide (one); the causes of death in the placebo group were motor vehicle accident (two), homicide (one), and cerebrovascular accident (one).





# Adverse Events

**Table 2. Adverse Events, According to Treatment Group.\***

Adverse Event	TDF-FTC (N = 611)		Placebo (N = 608)		P Value†
	no. of participants (%)	no. of events	no. of participants (%)	no. of events	
Any	557 (91.2)	4357	536 (88.2)	4390	0.003
Any serious	63 (10.3)	68	66 (10.9)	79	0.90
Grade 3 or 4 only	19 (3.1)	21	29 (4.8)	32	0.17
At least possibly related to study drug	20 (3.3)	21	27 (4.4)	29	0.35
Upper respiratory tract infection	231 (37.8)	385	241 (39.6)	439	0.84
Headache	227 (37.2)	300	226 (37.2)	411	0.73
Dizziness	92 (15.1)	109	67 (11.0)	82	0.03
Nausea	113 (18.5)	132	43 (7.1)	48	<0.001
Vomiting	69 (11.3)	87	43 (7.1)	47	0.008
Fracture	7 (1.1)	7	6 (1.0)	8	0.74
Elevated creatinine	1 (0.2)	1	0	0	1.00
Hypophosphatemia	142 (23.2)	219	159 (26.2)	245	0.65
Hyperamylasemia	315 (51.6)	997	302 (49.7)	1017	0.45
Elevated AST	36 (5.9)	43	38 (6.2)	42	0.90
Elevated ALT	38 (6.2)	48	43 (7.1)	66	0.57
Death‡	2 (0.3)	2	4 (0.7)	4	0.45

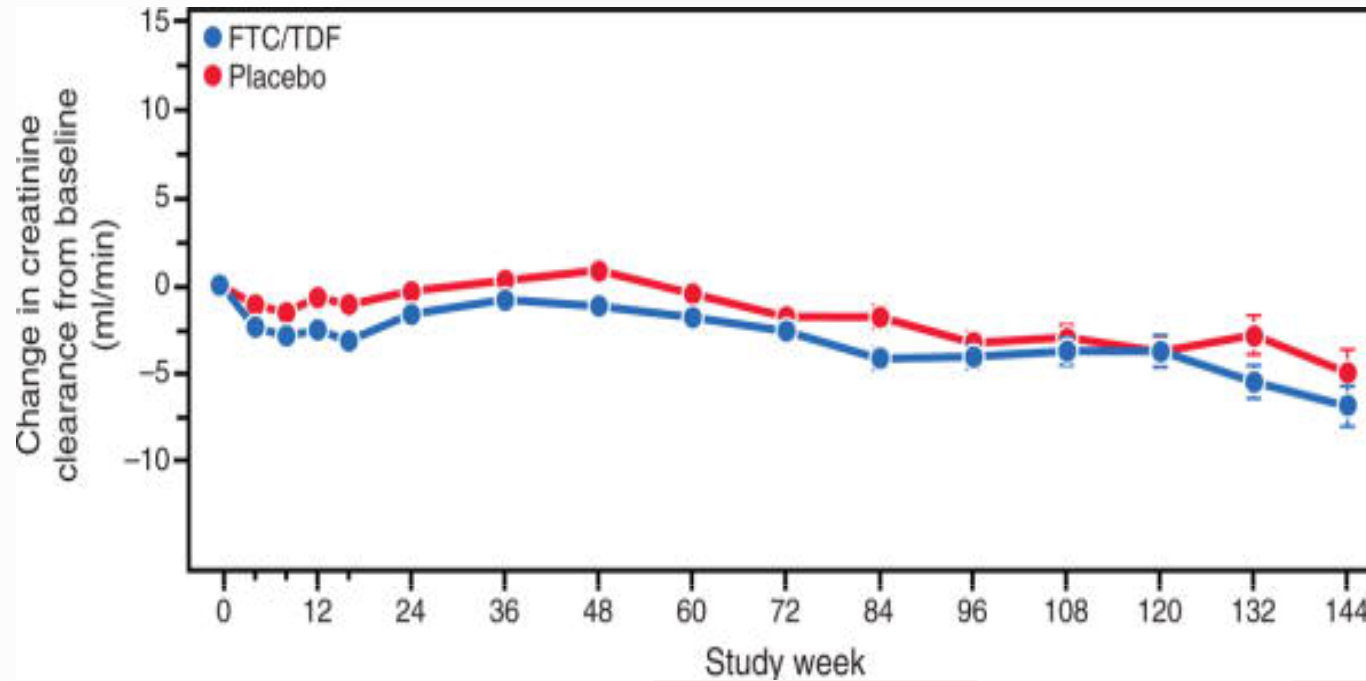
\* ALT denotes alanine aminotransferase, and AST aspartate aminotransferase.

† All P values were calculated with the use of a time-to-first-event analysis (regression analysis of survival data on the basis of the Cox proportional-hazards model), with the exception of the P values for weight loss of 5% or more and death, which were calculated with the use of Fisher's exact test.

‡ The causes of death in the TDF-FTC group were motor vehicle accident (one participant) and suicide (one); the causes of death in the placebo group were motor vehicle accident (two), homicide (one), and cerebrovascular accident (one).

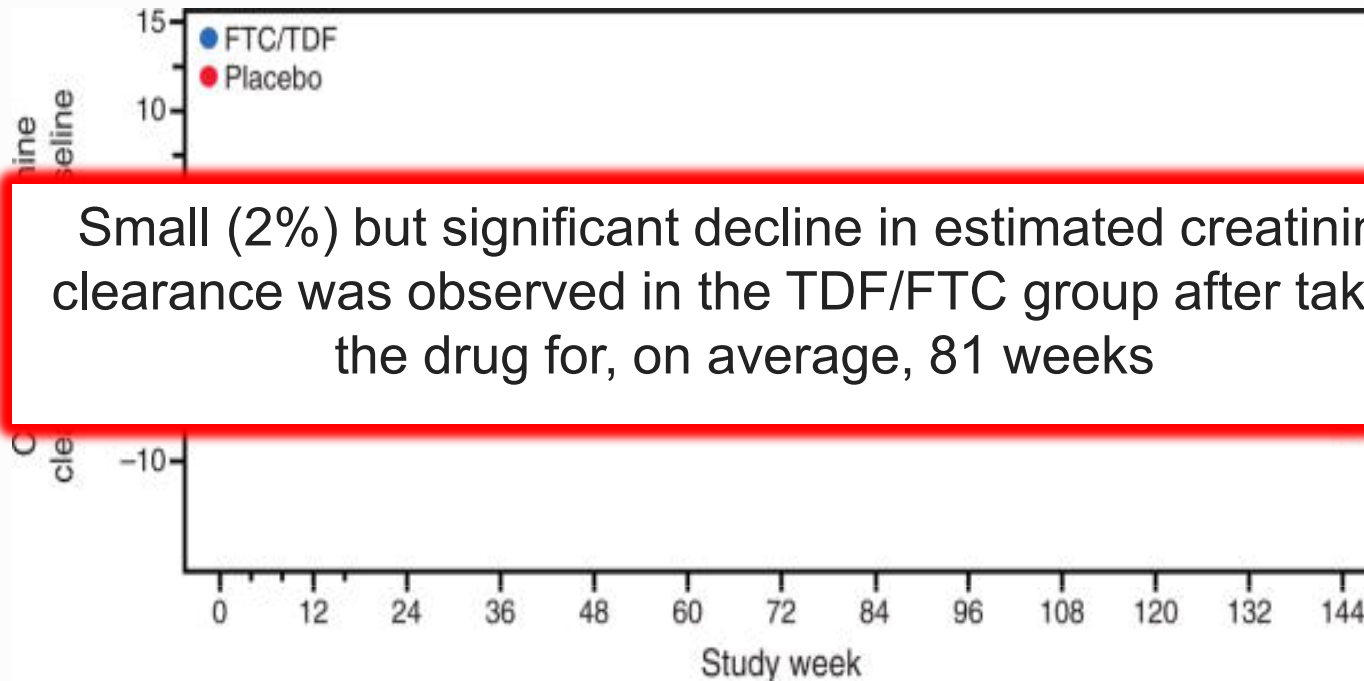


# Adverse Events





# Adverse Events



Small (2%) but significant decline in estimated creatinine clearance was observed in the TDF/FTC group after taking the drug for, on average, 81 weeks

# Adverse Events



**Table 3. Bone Mineral Density Scores.\***

Assessment	Forearm			Hip			Lumbar Spine		
	TDF-FTC (N=109)	Placebo (N=112)	P Value	TDF-FTC (N=109)	Placebo (N=112)	P Value	TDF-FTC (N=109)	Placebo (N=112)	P Value
<b>T score</b>			0.004			<0.001			<0.001
Enrollment	-0.75	-0.58		0.44	0.53		-0.72	-0.59	
6 mo	-0.77	-0.50		0.33	0.57		-0.84	-0.45	
12 mo	-0.79	-0.48		0.33	0.54		-0.77	-0.56	
18 mo	-0.93	-0.27		0.17	0.77		-0.92	-0.43	
24 mo	-0.92	-0.13		0.21	0.74		-1.11	-0.37	
<b>z Score</b>			0.004			<0.001			<0.001
Enrollment	-0.70	-0.54		0.45	0.54		-0.67	-0.54	
6 mo	-0.73	-0.45		0.35	0.58		-0.80	-0.41	
12 mo	-0.72	-0.42		0.34	0.55		-0.74	-0.53	
18 mo	-0.88	-0.21		0.18	0.78		-0.88	-0.41	
24 mo	-0.87	-0.13		0.20	0.76		-1.09	-0.28	

\* In the TDF-FTC group, 58 participants completed bone mineral density testing at the 6-month visit, 45 at the 12-month visit, 36 at the 18-month visit, and 23 at the 24-month visit. In the placebo group, 66 participants completed bone mineral density testing at the 6-month visit, 44 at the 12-month visit, 33 at the 18-month visit, and 35 at the 24-month visit.

# Adverse Events

**Table 3. Bone Mineral Density Scores.\***

Assessment	Forearm			Hip			Lumbar Spine		
	TDF-FTC (N=109)	Placebo (N=112)	P Value	TDF-FTC (N=109)	Placebo (N=112)	P Value	TDF-FTC (N=109)	Placebo (N=112)	P Value
T score			0.004			<0.001			<0.001
Enrollment	-0.75	-0.58		0.44	0.53		-0.72	-0.59	
6 mo	-0.77	-0.50		0.33	0.57		-0.84	-0.45	
12 mo	-0.73	-0.45		0.35	0.58		-0.80	-0.41	
18 mo	-0.72	-0.42		0.34	0.55		-0.74	-0.53	
24 mo	-0.88	-0.21		0.18	0.78		-0.88	-0.41	
24 mo	-0.87	-0.13		0.20	0.76		-1.09	-0.28	

Significant decline in T scores and z scores for BMD at the forearm, hip, and lumbar spine in participants who received TDF/FTC, as compared with those who received placebo

\* In the TDF-FTC group, 58 participants completed bone mineral density testing at the 6-month visit, 45 at the 12-month visit, 36 at the 18-month visit, and 23 at the 24-month visit. In the placebo group, 66 participants completed bone mineral density testing at the 6-month visit, 44 at the 12-month visit, 33 at the 18-month visit, and 35 at the 24-month visit.

# Adverse Events



**Table 3. Bone Mineral Density Scores.\***

Assessment	Forearm			Hip			Lumbar Spine		
	TDF-FTC (N=109)	Placebo (N=112)	P Value	TDF-FTC (N=109)	Placebo (N=112)	P Value	TDF-FTC (N=109)	Placebo (N=112)	P Value
T score			0.004			<0.001			<0.001

**BUT THIS CAN RECOVER!**

Bone mineral density recovered after 6 months of stopping TDF/FTC in both young and older adults.

24 mo	-0.87	-0.13	0.20	0.76	-1.09	-0.28
-------	-------	-------	------	------	-------	-------

\* In the TDF-FTC group, 58 participants completed bone mineral density testing at the 6-month visit, 45 at the 12-month visit, 36 at the 18-month visit, and 23 at the 24-month visit. In the placebo group, 66 participants completed bone mineral density testing at the 6-month visit, 44 at the 12-month visit, 33 at the 18-month visit, and 35 at the 24-month visit.



# V. PrEP laboratory monitoring



# The First Visit

- Labs:
  - HIV Ag/Ab (but if symptoms of acute HIV, get HIV RNA)
  - Basic Metabolic Panel
  - Hepatitis B sAg, sAb
  - Hepatitis C Ab
  - Treponemal IgG
  - Gonorrhea/chlamydia PCR (oral, rectal and urethral)
  - *Consider Hepatitis A IgM/IgG given recent outbreak*





# The Second Visit

- **Repeat HIV screen, repeat serum creatinine**
- Assess adherence
- Reassess eligibility
- Assess for side effects
- Provide behavioral risk reduction support
- STI screen, if necessary
- Assess pregnancy intention (test if could be pregnant)
- If HIV-negative and eligible, refill PrEP



# Every 3 months

- **HIV screen**
- **STI screen, if necessary**
- Assess adherence
- Reassess eligibility
- Assess for side effects
- Provide behavioral risk reduction support
- Assess pregnancy intention (test if could be pregnant)
- If HIV-negative and eligible, refill PrEP



# Every 6 months

- **Screen for other STIs**
- **Repeat serum creatinine**



# A year of PrEP

Encounter	To do
Month 0	<ul style="list-style-type: none"><li>• Screen for HIV</li><li>• Confirm HBV and HCV status</li><li>• Check serum creatinine</li><li>• Screen for STIs</li><li>• Counseling</li><li>• Prescribe</li></ul>
Month 3	<ul style="list-style-type: none"><li>• Screen for HIV</li><li>• Check serum creatinine</li><li>• Counseling</li><li>• Prescribe</li></ul>
Month 6	<ul style="list-style-type: none"><li>• Screen for HIV</li><li>• Screen for STIs</li><li>• Counseling</li><li>• Prescribe</li></ul>
Month 9	<ul style="list-style-type: none"><li>• Screen for HIV</li><li>• Check serum creatinine</li><li>• Counseling</li><li>• Prescribe</li></ul>
Month 12	<ul style="list-style-type: none"><li>• Screen for HIV</li><li>• Screen for STIs</li><li>• Counseling</li><li>• Prescribe</li></ul>

## Labs:

- HIV screen: 5
- Serum creatinine: 3
- STI screen: 3

Prescriptions/Refill authorizations: 5

Discussions: 5+



# Special considerations

- **Pregnant or breastfeeding women**
  - Pregnancy Category B (No known risk)
  - Minimally secreted in breastmilk, not contraindicated in breastfeeding
- **Chronic HBV**
  - TDF/TAF and FTC are active against HBV
  - Abrupt withdrawal could cause HBV flare
  - Stopping requires careful monitoring and observation
- **Chronic Renal Failure (CrCl <60mL/min)**
  - Don't use TDF/FTC; safety has not been adequately determined
  - Can use TAF/FTC for CrCl >30mL/min



# STOP PrEP

- The patient doesn't want it
- Behavior or life situations have changed that lower risk for HIV infection
- Intolerable adverse events/toxicities
- Nonadherence despite attempted interventions to improve
- HIV-infection





# VI. Financial aspects of PrEP



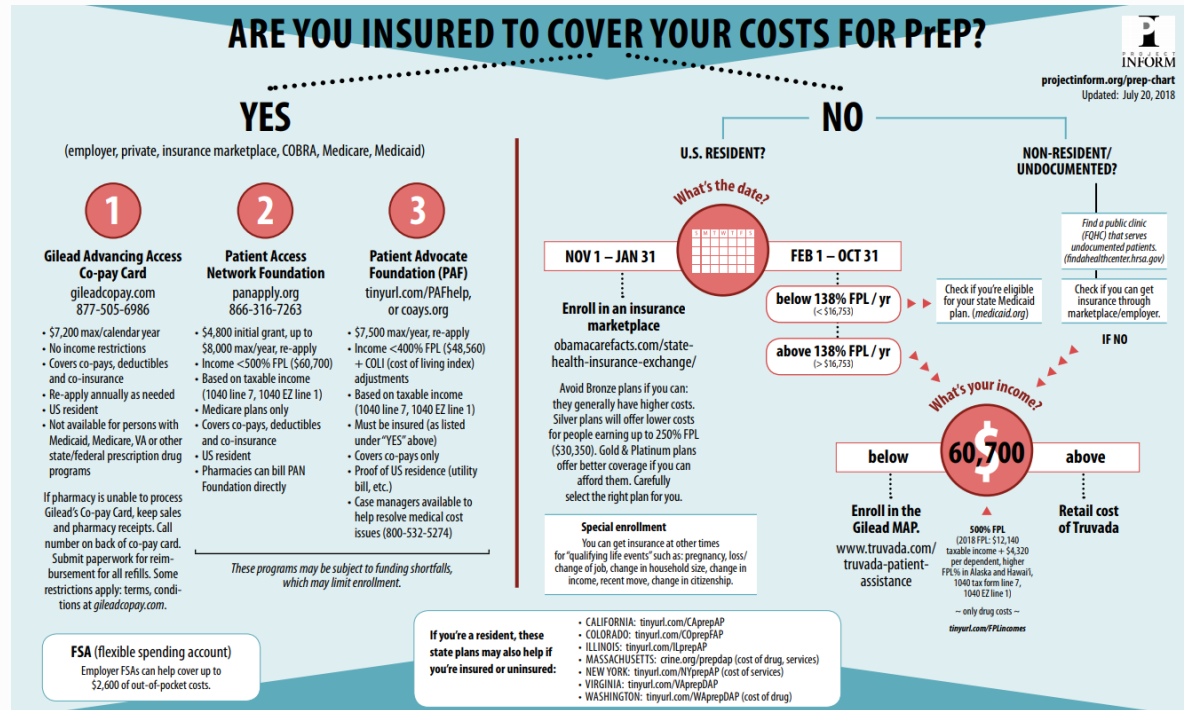
# Truvada® coverage

- Actually, Truvada® is very affordable for most patients
- All insurance plans cover TDF/FTC for the indication of HIV prevention
  - Variable copays
- Medicare/Medicaid cover TDF/FTC
- Gilead Advancing Access Program – Copay Assistance
  - \$7,200/calendar year of copay assistance
  - No income limitation
- Gilead Advancing Access Program – Medication Access
  - Full drug coverage if income <500% federal poverty level
  - Primary option for uninsured patients





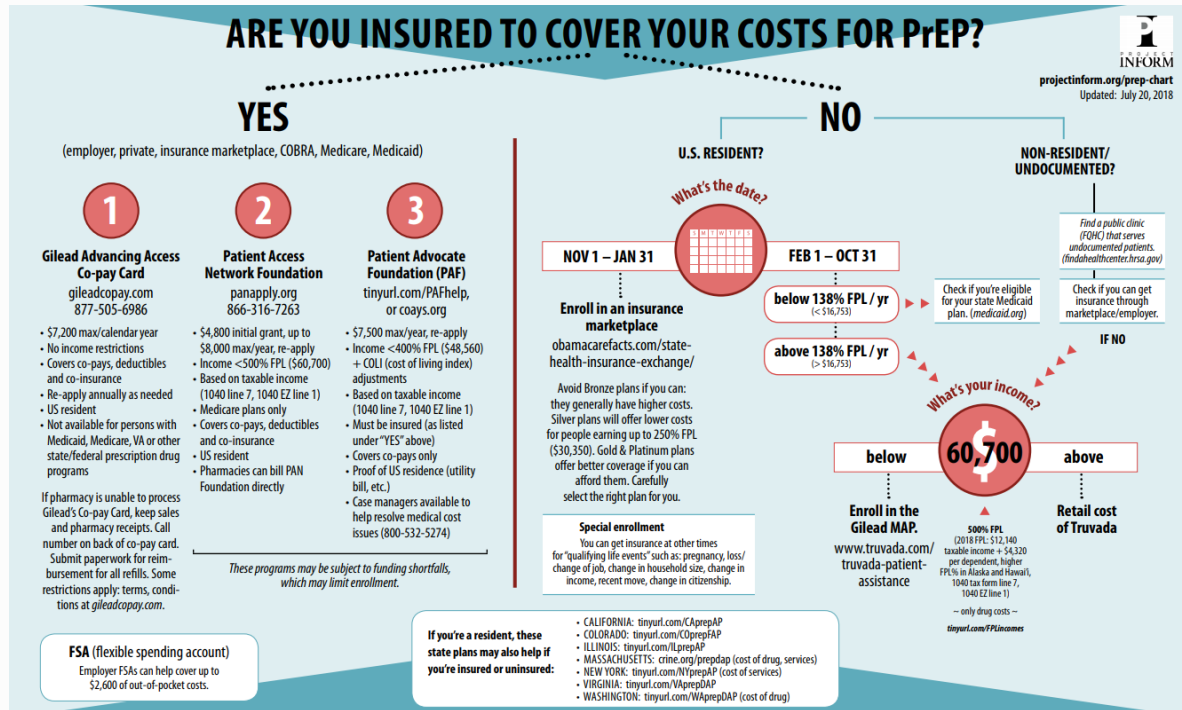
# Financial Assistance



www.projectinform.org



# Copay Assistance



www.projectinform.org



# Copay Assistance

**1**

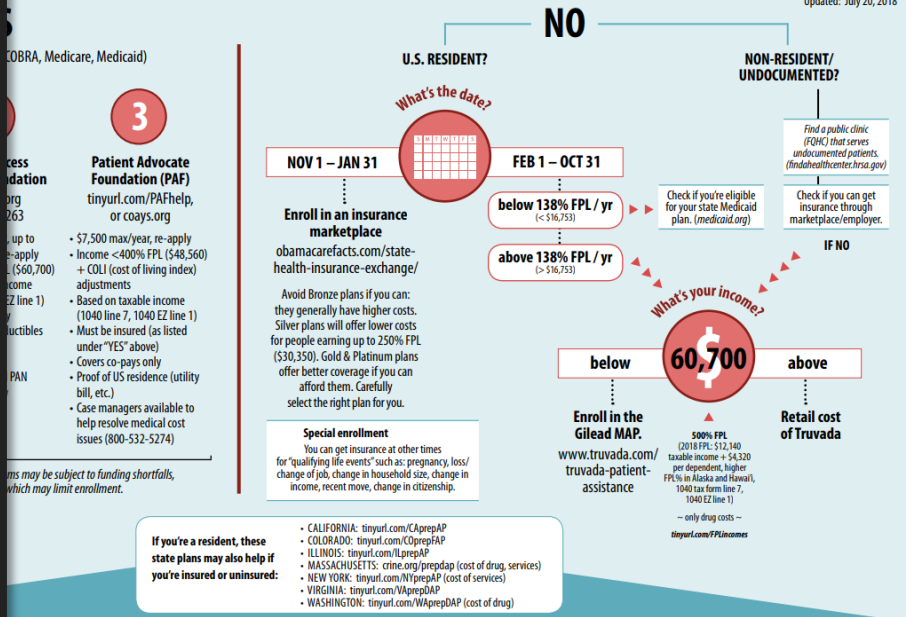
**Gilead Advancing Access Co-pay Card**  
 gileadcopay.com  
 877-505-6986

- \$7,200 max/calendar year
- No income restrictions
- Covers co-pays, deductibles and co-insurance
- Re-apply annually as needed
- US resident
- Not available for persons with Medicaid, Medicare, VA or other state/federal prescription drug programs

If pharmacy is unable to process Gilead's Co-pay Card, keep sales and pharmacy receipts. Call number on back of co-pay card. Submit paperwork for reimbursement for all refills. Some restrictions apply: terms, conditions at [gileadcopay.com](http://gileadcopay.com).

## YOU INSURED TO COVER YOUR COSTS FOR PrEP?



**INFORM**  
 projectinform.org/prep-chart  
 Updated: July 20, 2018



www.projectinform.org



# Copay Assistance

ADVANCING ACCESS <sup>®</sup>	FINANCIAL SUPPORT	INSURANCE SUPPORT
<h2 data-bbox="710 511 1136 639">Get Started with the Gilead Advancing Access<sup>®</sup> program</h2> <p data-bbox="710 672 1141 739">Advancing Access can provide you with information to help you find financial and insurance support every step of the way.</p> <div data-bbox="710 765 1112 862"><p><b>Support by Phone</b> Call <b>1-800-226-2056</b> to speak to an Advancing Access counselor directly. You can also leave a confidential message any time and day of the week. <b>Hours:</b> Monday-Friday / 9am to 8pm ET</p></div> <div data-bbox="710 891 1136 958"><p><b>Enroll Today</b> The form requires some information from your healthcare provider, so you may want to fill it out with them. <a href="#">Download the Advancing Access Enrollment Form</a> or <a href="#">Enroll Online</a></p></div>		



# Copay Assistance

ADVANCING ACCESS<sup>®</sup> FINANCIAL SUPPORT INSURANCE SUPPORT

Get Started with  
Gilead A  
pro

**GILEAD**  
 Rx/BIN: 610524  
 Rx/PCN: Loyalty  
 Rx/GRP: 50776283  
 ISSUER: (80840)  
 ID:

Not available for patients who are enrolled in  
 government healthcare programs (e.g.  
 Medicare, Medicaid, VA, etc.) or who are  
 on the list of excluded providers.  
 For terms and conditions, visit [www.GILEADACCESS.com](http://www.GILEADACCESS.com) for

Powered by:  
**MCKESSON**

**Co-Pay Coupon Card**

BICLENVY<sup>™</sup> (buprenorphine/naloxone) Advancing  
 BICLENVY<sup>™</sup> (buprenorphine/naloxone) Advancing  
 BICLENVY<sup>™</sup> (buprenorphine/naloxone) Advancing  
 STIBILD<sup>®</sup> (zalcitabine) Advancing  
 COMPLEXT<sup>™</sup> (zalcitabine) Advancing  
 TRUVADA<sup>™</sup> (emtricitabine/rilpivirine) Advancing  
 GILEAD<sup>™</sup> (emtricitabine/rilpivirine) Advancing  
 TRUVADA<sup>™</sup> (emtricitabine/rilpivirine) Advancing

Some information from your healthcare  
 provider may be needed to fill out with them. [Download](#)  
[the Advancing Access Enrollment Form](#) or [Enroll Online](#)



# Gilead Advancing Access Program

- \$7,200/calendar year benefit
  - Increased from \$3,600 to \$4,200 in January 2018
  - Increased from \$4,200 to \$7,200 in September 2018
- No income limitation
- Federal beneficiaries excluded
- Usually goes toward deductible
  - Beware of copay accumulator programs
    - Manufacturer copay assistance will no longer count toward deductible



# Copay Assistance

## ARE YOU INSURED TO COVER YOUR COSTS FOR PrEP?

**1**  
**Gilead Advancing Access Co-pay Card**  
gileadcopay.com  
877-505-6986

- \$7,200 max/calendar year
- No income restrictions
- Covers co-pays, deductibles and co-insurance
- Re-apply annually as needed
- US resident
- Not available for persons with Medicaid, Medicare, VA or other state/federal prescription drug programs

If pharmacy is unable to process Gilead's Co-pay Card, keep sales and pharmacy receipts. Call number on back of co-pay card. Submit paperwork for reimbursement for all refills. Some restrictions apply: terms, conditions at [gileadcopay.com](http://gileadcopay.com).

**FSA (flexible spending account)**  
Employer FSAs can help cover up to \$2,600 of out-of-pocket costs.

3

**Patient Advocate Foundation (PAF)**  
tinyurl.com/PAFhelp,  
or coays.org

- \$7,500 max/year, re-apply
- Income <400% FPL (\$48,560) + COLI (cost of living index) adjustments
- Based on taxable income (1040 line 7, 1040 EZ line 1)
- Must be insured (as listed under "YES" above)
- Covers co-pays only
- Proof of US residence (utility bill, etc.)
- Case managers available to help resolve medical cost issues (800-532-5274)

**2**  
**Patient Advocate Foundation (PAF)**  
panapply.org  
866-316-7777

- \$4,800 initial grant
- \$8,000 max/year
- Income <500% FPL
- Based on taxable income (1040 line 7, 1040 EZ line 1)
- Medicare plans only
- Covers co-pays, deductibles and co-insurance
- US resident
- Pharmacies can bill Foundation directly

These programs are available to patients who are uninsured (employer, private, insurance marketplace, or Medicaid).

**INFORM**  
projectinform.org/prep-chart  
Updated: July 20, 2018

NO

**U.S. RESIDENT?**

What's the date?

**NOV 1 – JAN 31**

**Enroll in an insurance marketplace**  
obamacarefacts.com/state-health-insurance-exchange/

Avoid Bronze plans if you can: they generally have higher costs. Silver plans will offer lower costs if people earning up to 250% FPL (\$30,350). Gold & Platinum plans offer better coverage if you can afford them. Carefully select the right plan for you.

**Special enrollment**  
You can get insurance at other times for "qualifying life events" such as: pregnancy, loss/change of job, change in household size, change in income, recent move, change in citizenship.

- CALIFORNIA: [tinyurl.com/CAprepAP](http://tinyurl.com/CAprepAP)
- COLORADO: [tinyurl.com/COprepFAP](http://tinyurl.com/COprepFAP)
- ILLINOIS: [tinyurl.com/ILprepAP](http://tinyurl.com/ILprepAP)
- MASSACHUSETTS: [crme.org/prepdap](http://crme.org/prepdap) (cost of drug, services)
- NEW YORK: [tinyurl.com/NYprepAP](http://tinyurl.com/NYprepAP) (cost of services)
- VIRGINIA: [tinyurl.com/VAprepDAP](http://tinyurl.com/VAprepDAP)
- WASHINGTON: [tinyurl.com/WAprepDAP](http://tinyurl.com/WAprepDAP) (cost of drug)

**FEB 1 – OCT 31**

**below 138% FPL / yr**  
(< \$16,753)

Check if you're eligible for your state Medicaid plan. ([medicaid.org](http://medicaid.org))

**above 138% FPL / yr**  
(> \$16,753)

What's your income?

**below**

**Enroll in the Gilead MAP.**  
[www.truvada.com/truvada-patient-assistance](http://www.truvada.com/truvada-patient-assistance)

**60,700**

500% FPL  
(2018 FPL: \$12,140 taxable income + \$4,320 per dependent, highest FPL% in Alaska and Hawaii, 1040 tax form line 7, 1040 EZ line 1)  
— only drug costs —  
[tinyurl.com/FPLnames](http://tinyurl.com/FPLnames)

**above**

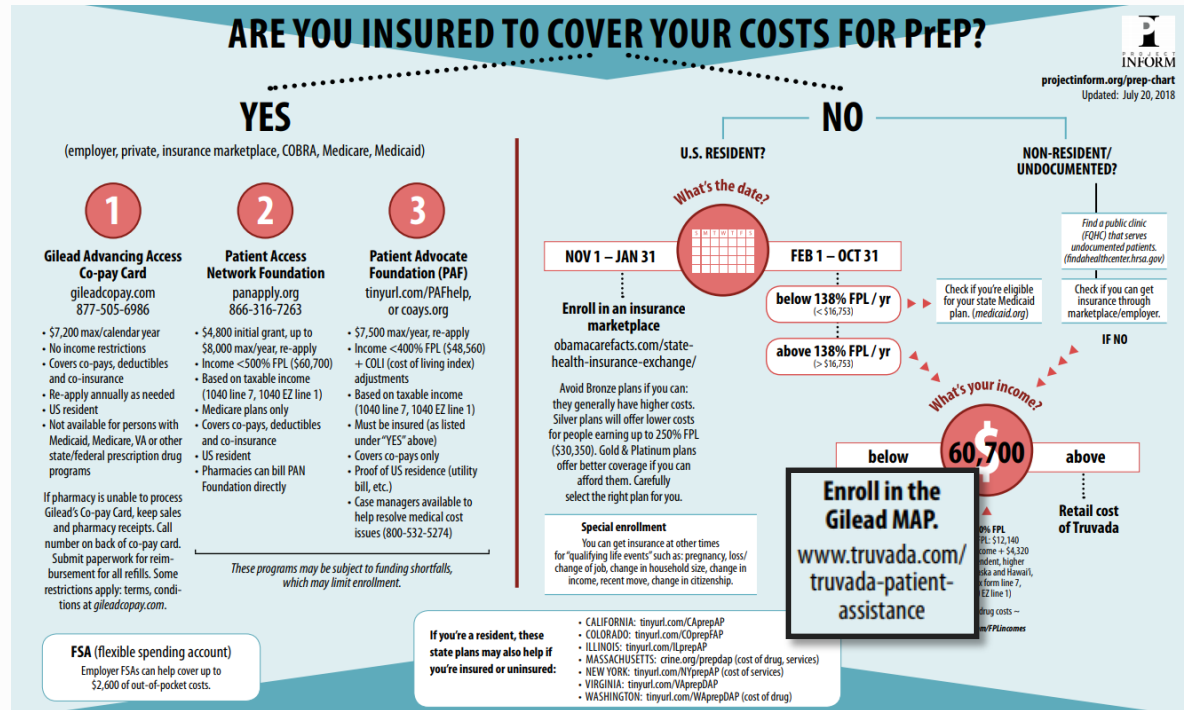
**Retail cost of Truvada**

www.projectinform.org

**AETC** AIDS Education & Training Center Program  
Southeast



# Medication Access Program







# Medication Assistance Program

The screenshot shows a web browser window with the URL <https://www.gileadadvancingaccess.com>. The page features the "ADVANCING ACCESS" logo in the top left, with navigation links for "FINANCIAL SUPPORT" and "INSURANCE SUPPORT" to its right. The main heading is "We're Here to Help", followed by the text: "The Gilead Advancing Access® program is committed to helping you afford your medication every step of the way." Below this text is an image of a white pill bottle with a large "Rx" symbol on it. To the right of the bottle, the heading "FINANCIAL SUPPORT" is displayed in red, followed by three menu items: "Co-pay Support", "Government Insurance Support", and "Uninsured Support", each with a right-pointing chevron. A red arrow points to the address bar in the browser window.



# Medication Assistance Program

The screenshot displays the Gilead Advancing Access website. The browser address bar shows <https://www.gileadadvancingaccess.com>. The page features a navigation menu with "FINANCIAL SUPPORT" and "INSURANCE SUPPORT". The main content area is titled "INSURANCE SUPPORT" and includes three links: "Help with Coverage & Benefits", "Help When Insurance & Coverage Changes", and "Understanding Insurance". Below this, there are three featured sections: "The Advancing Access CO-PAY COUPON PROGRAM", "The Advancing Access PATIENT SUPPORT PROGRAM", and "Advancing Access OVERVIEW". A red arrow points to the "PATIENT SUPPORT PROGRAM" link, which includes the text: "Financial and coverage support for your Gilead medication. Call 1-800-226-2000, download the Enrollment Form, or enroll online to get started." The footer contains the Gilead logo and links for "Terms of Use", "Privacy Policy", "Contact Us", and "Site Map".



# Medication Assistance Program

ADVANCING ACCESS		ENROLLMENT FORM		PAGE 1 OF 3	
		PHONE: 1-800-228-2056		FAX: 1-800-218-6857	
<b>1. REQUESTED PATIENT SUPPORT (REQUIRED)</b>				<b>CHECK ALL BOXES THAT APPLY</b>	
<input type="checkbox"/> Benefits Investigation		<input type="checkbox"/> Prior Authorization and Appeals Information		<input type="checkbox"/> Co-pay Coupon Program Enrollment	
<input type="checkbox"/> Patient Assistance Program (PAP) or Medication Assistance Program (MAP) Eligibility Screening					
<b>2. GLEAD MEDICATION PRESCRIBED (REQUIRED)</b>					
Product Name:		mg			
If requesting TRUVADA, please indicate for: <input type="checkbox"/> Treatment <input type="checkbox"/> PHEP/Prevention					
<b>3. PATIENT INFORMATION (REQUIRED)</b>					
First Name:		Last Name:		M.I.:	
Address:		Apt./Unit #:		City:	
State:		Zip Code:		Phone #:	
Email:		DOB:		SSNF (Last 4 digits)	
Alternate Contact Name:		Phone #:		Relationship:	
<b>CONTACT AUTHORIZATION</b>					
I authorize Advancing Access to leave a detailed message, including the name of my prescription, if I am unavailable when they call. <input type="checkbox"/> Yes <input type="checkbox"/> No					
<b>4. INSURANCE INFORMATION (REQUIRED)</b>				<b>PLEASE INCLUDE A COPY OF THE FRONT AND BACK OF INSURANCE CARDS</b>	
<input type="checkbox"/> Patient is insured (Please fill out all of the applicable insurance information below. Attach copy – front and back – of patient card)		<input type="checkbox"/> Patient is uninsured (no health insurance through any public or private payer) <b>SEE OFFICIAL "PATIENT FINANCIAL INFORMATION" SECTION BELOW</b>			
Primary Insurance: <input type="checkbox"/> Is this a Medicare Part D plan? <input type="checkbox"/> Yes <input type="checkbox"/> No					
Plan name:		Insurance Phone Number:			
Subscriber Name:		Policy Holder Name:		Policy Holder Relationship to Patient:	
Policy #:		Group #:		Rx Bin #:	
				Rx PCN #:	
<input type="checkbox"/> Check box if patient has secondary insurance coverage and fax a copy of insurance cards, if available.					
<b>5. PRESCRIBER INFORMATION (REQUIRED)</b>					
Prescriber Name:		Facility Name:			
Address:		City:			
State:		Zip Code:		Office Contact:	
Phone #:		Fax #:		NPI #:	
Tax ID #:		State License #:			
<b>6. DIAGNOSIS/MEDICAL INFORMATION</b> <b>MUST BE COMPLETED BY HEALTHCARE PROVIDER</b>					
Diagnosis (Please include ICD code):					
<b>7. PRESCRIBER CERTIFICATION AND STATEMENT OF MEDICAL NECESSITY</b>					
<p>By signing this form, I certify that I am prescribing Glead medication for the patient identified in Section 3. I certify that this prescription medication is medically necessary for the patient and that it will be used as directed, as long as the patient continues to qualify for the program. I will ensure that the appropriate information is provided to the patient and the patient's family. I will ensure that the patient's insurance coverage is verified and that the patient is not enrolled in any other government program or third-party insurance.</p> <p>If prescribing TRUVADA for PHEP, I certify that the patient has been tested for HIV infection and found to be HIV negative and regular HIV testing will be conducted as part of the patient's care plan. As part of my applicant's eligibility, I agree to periodically verify continued use of Glead medication and resultant current prescriptions.</p> <p>I certify that I have received the appropriate written authorization from the patient, or accordance with the Health Insurance Portability and Accountability Act of 1996, applicable state health information privacy laws, and any other applicable requirements, in order to release the patient's personal and medical information to Glead and its agents and contractors for the purposes of: 1) verifying the patient's insurance coverage and eligibility for benefits; 2) seeking prior authorization if needed on the patient's behalf; 3) providing financial assistance support, and referral support as needed; 4) facilitating the provision of the patient's prescription medication to the patient; 5) contacting the patient with educational materials about the patient's prescription medication or to evaluate the effectiveness of the Advancing Access Program under the TRUVADA and G for Glead's internal business purposes.</p>					
<b>PRESCRIBER SIGNATURE (REQUIRED)</b>				<b>DATE</b>	

© 2017 Glead Sciences, Inc. All rights reserved. ADMCD000 02/17



# Medication Assistance Program

ADVANCING ACCESS <sup>SM</sup>		ENROLLMENT FORM PAGE 1 OF 3 PHONE: 1-800-216-6857 FAX: 1-800-216-6857	
<b>1. REQUESTED PATIENT SUPPORT (REQUIRED)</b> <input type="checkbox"/> Benefits Investigation <input type="checkbox"/> Prior Authorization and <input type="checkbox"/> Patient Assistance Program (PAP) or Medication Assistance Program (MAP)		<b>ADVANCING ACCESS ENROLLMENT FORM</b> PHONE: 1-800-216-2056    FAX: 1-800-216-6857    PAGE 2 OF 3 PATIENT NAME: _____ DATE OF BIRTH: _____	
<b>2. GILEAD MEDICATION PRESCRIBED (REQUIRED)</b> Product Name: _____ If requesting TRUVADA, please indicate for:    Treatment    PHEP		<b>8. PATIENT AUTHORIZATION FOR USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION (REQUIRED)</b> I understand that I must complete this enrollment form before I can receive assistance through Gilead Sciences, Inc.'s Advancing Access ("Program") and the Patient Assistance Program/Medication Assistance Program ("PAP/MAP"). As part of this process, Gilead and its agents and contractors (collectively, "Gilead") will need to obtain, review, use and disclose my personal and medical information as described below. I hereby authorize my healthcare providers and health plans to disclose my personal and medical information as described below to Gilead in connection with the Program and/or the PAP/MAP, all in accordance with this authorization, and I authorize Gilead to use and disclose the information in accordance with the authorization. <b>Information to Be Disclosed:</b> Personal health information ("PHI"), including information about me (for example, my name, mailing address, financial information, and insurance information), my past, current and future medical condition (including information about my HIV-related status or treatment with this prescription medication and related medical condition), and all information provided on this enrollment form. <b>Persons Authorized to Disclose My Information:</b> My healthcare providers, including any pharmacy that fills my prescription medication, and any health plans or programs that provide me healthcare benefits. I understand that my pharmacy providers may receive remuneration for disclosing my PHI pursuant to this authorization. <b>Persons to Which My Information May Be Disclosed:</b> Gilead, including the third party administrator responsible for the administration of the Program and the PAP/MAP. <b>Purposes for Which the Disclosures Are to Be Made:</b> Disclosures of PHI may be made to Gilead so that Gilead may use and disclose the PHI for purposes of: 1) completing the enrollment process and verifying my enrollment form; 2) establishing my eligibility for benefits from my health plan or other programs; 3) providing financial assistance, support, and referral support, and communicating with my healthcare providers, including, but not limited to, facilitating the provision of my prescription medication to me; 4) contacting me to evaluate the effectiveness of the Program and/or the PAP/MAP; 5) for Gilead's internal business purposes, including quality control and support enhancing surveys; and 6) to send me marketing information, offers, and educational materials related to my treatment and/or my prescription medication, including the customer relationship marketing program (this use of my personal information is optional and by checking the box under the signatures below, I may opt in). I understand that once my PHI has been disclosed hereunder, federal privacy law may no longer restrict its use or disclosure. I understand further that I may refuse to sign this authorization and that if I refuse, my eligibility for health plan benefits or ability to obtain treatment from my healthcare providers will not change, but I will not have access to the support offered by Program and/or the PAP/MAP. I also understand that I may cancel this authorization at any time by notifying Gilead in writing at Advancing Access, PO Box 13185, La Jolla, CA 92039-3185. If I cancel, Gilead will stop using this authorization to obtain, use or disclose my PHI after the cancellation date, but the cancellation will not affect uses or disclosures of any PHI that have already been made pursuant to this authorization before the cancellation date. I am entitled to a copy of this signed authorization, which expires the earlier of two (2) years from the date it is signed by me or other time period required under the laws of the state in which I reside.	
<b>3. PATIENT INFORMATION (REQUIRED)</b> First Name: _____ Last Name: _____ Address: _____ Apt./Unit #: _____ State: _____ Zip Code: _____ Email: _____ Alternate Contact Name: _____		<b>9. PRESCRIBER INFORMATION (REQUIRED)</b> Prescriber Name: _____ FA Address: _____ CA State: _____ CA    Zip Code: _____ CA Phone #: _____ FA Tax ID #: _____ SK	
<b>CONTACT AUTHORIZATION</b> I authorize Advancing Access to leave a detailed message, including the name of _____		<input type="checkbox"/> By checking this box, I agree to receive marketing information, offers and educational materials related to my medical condition, treatment, and/or my prescription medication, including the customer relationship marketing program.	
<b>4. INSURANCE INFORMATION (REQUIRED) PLEASE</b> <input type="checkbox"/> Patient is insured (Please fill out all of the applicable insurance information below. Attach copy - front and back - of patient card)    YES Primary Insurance: _____ YES Plan name: _____ YES Subscriber Name: _____ Policy Holder Name: _____ Policy #: _____ Group #: _____ NO <input type="checkbox"/> Check box if patient has secondary insurance coverage and fax a copy of info		<b>SIGNATURE OF PATIENT OR PATIENT'S REPRESENTATIVE (REQUIRED)</b> DATE: _____ _____ <b>Patient Representative's Name (if signing for the patient)</b> _____ <b>Patient Representative's Relationship to Patient:</b> _____ <b>FAX COMPLETED FORM TO ADVANCING ACCESS AT 1-800-216-6857</b>	
<b>5. PRESCRIBER INFORMATION (REQUIRED)</b> Prescriber Name: _____ FA Address: _____ CA State: _____ CA    Zip Code: _____ CA Phone #: _____ FA Tax ID #: _____ SK		<b>6. DIAGNOSIS/MEDICAL INFORMATION</b> Diagnosis (Please include ICD code): _____	
<b>7. PRESCRIBER CERTIFICATION AND STATEMENT OF MEDICAL NECESSITY</b> By signing this form, I certify that I am prescribing Gilead medication for the patient identified on pages one and two or will be used as directed, as noted here and the supporting the patient's treatment Program ("PAP/MAP") from any government program or third-party insurer. If prescribing TRUVADA for PHEP, I certify that the applicant has been tested for HIV infection, applicant's care plan, as part of my applicant's eligibility, I agree to periodically verify continued eligibility that I have received the appropriate written authorization from the patient, or appropriate health information primary source, and any other applicable requirements, in order to release the patient's information to Gilead for the purpose of verifying the patient's insurance coverage and eligibility for benefits. (2) written support, and referral support as needed. (6) including the provision of the patient's prescription my patient's prescription medication or to evaluate the effectiveness of the Advancing Access Program.		<b>PRESCRIBER SIGNATURE (REQUIRED)</b> _____ <small>© 2017 Gilead Sciences, Inc. All rights reserved. ADMCD000 12/17</small>	
<small>© 2017 Gilead Sciences, Inc. All rights reserved. ADMCD000 12/17</small>		<small>© 2017 Gilead Sciences, Inc. All rights reserved. ADMCD000 12/17</small>	





# Advice to patients

- Find out your deductible
- Find out your Truvada® copay
- Find out your estimated costs of visits and labs
- If you need an insurance plan from the marketplace, avoid Bronze Plans due to high out-of-pocket expenses
- Use Flexible Spending Account to offset any out-of-pocket expenses



# Billing/coding

- While ICD-10 does not provide specific codes for PrEP, the following codes have been discussed with billing and used for PrEP visits:
  - Z20.6 “Contact with and (suspected) exposure to HIV ”
  - Z17.1 “Human immunodeficiency virus [HIV] counseling”
  - Z11.3 “Encounter for screening for infection with a predominantly sexual mode of transmission”
  - Z79.2 “Long-term (current) use of antibiotics”
  
- Not suggested
  - Z72.52 – High risk homosexual behavior



# Billing/coding

- While ICD-10 does not provide specific codes for PrEP, the following codes have been discussed with billing and used for PrEP visits:
  - Z20.6 “Contact with and (suspected) exposure to HIV ”
  - Z17.1 “Human immunodeficiency virus [HIV] counseling”
  - Z11.3 “Encounter for screening for infection with a predominantly sexual mode of transmission”
  - Z79.2 “Long-term (current) use of antibiotics”
- Not suggested:
  - Z72.52 – High risk heterosexual behavior






# PrEP Locator

PrEP Locator  Find Your Provider

[About Us](#) [About PrEP](#) [Locator Data](#) [FAQ](#) [Add Provider](#) [Add Locator To Your Site](#) [Contact](#)

Zip code or city & state, or full address 

PrEP for uninsured

PrEP access assistance

#### Vanderbilt Infectious Disease Clinic

1211 21st Avenue S  
Medical Arts Building  
Nashville, TN 37212  
615-936-1174

Distance from your location: 0.3 miles

#### Planned Parenthood Nashville Health Center

412 Dr. D.B. Todd Jr. Blvd  
Nashville, TN 37203  
615-321-7216

Distance from your location: 1.4 miles

#### Meharry Community Wellness Center

1005 Dr. D.B. Todd Jr Blvd  
Suite 333  
Nashville, TN 37209  
615-327-5788

Distance from your location: 2 miles

#### Middle Tennessee Internal Medicine Associates - Tracy Osbourne MD

510 Recovery Road  
Suite 201  
Nashville, TN 37212  
615-833-7080

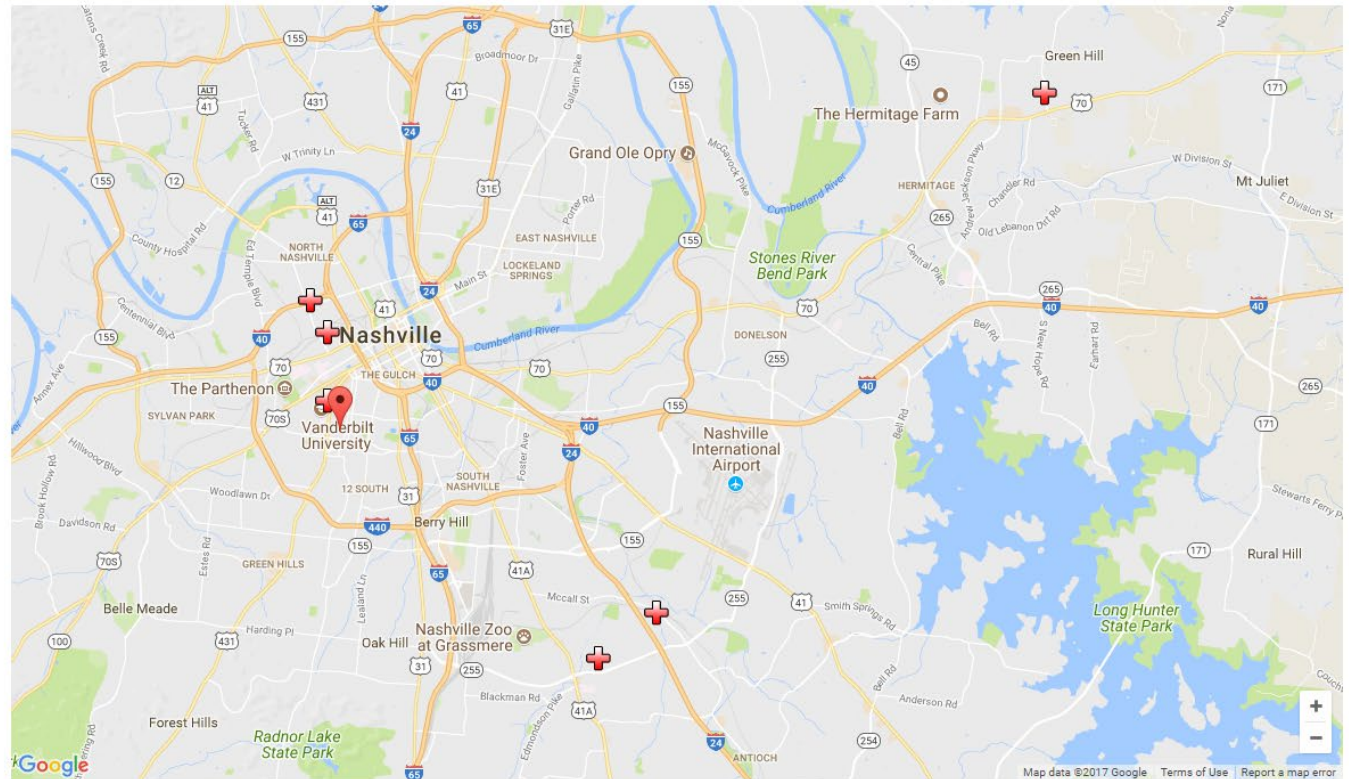
Distance from your location: 6 miles

#### Neighborhood Health @ MyHouse

42 Metroplex Drive  
Building 4  
Nashville, TN 37211

[Add PrEP Locator to Your Site](#)

[Suggest a provider for the directory](#)

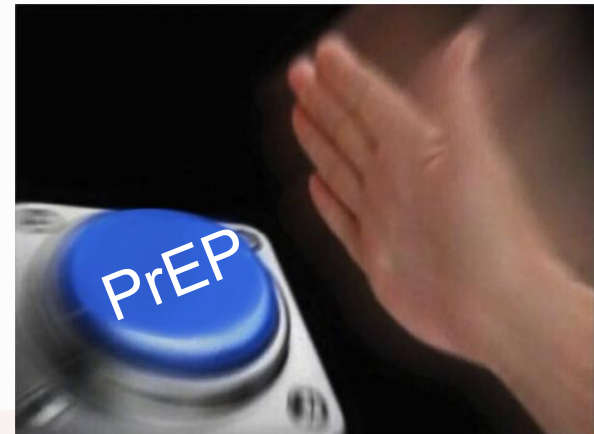


<https://prepolator.org>



# Conclusion

- PrEP is a component of primary care
- PrEP is an extremely effective preventive strategy for both HIV and STIs
- Understand PrEP prescribing guidelines
- PrEP is generally very well-tolerated
- Effective PrEP requires an ongoing patient-doctor relationship
- Sexual history is essential to comprehensive health care; care is incomplete without it.
- Ask for help! [sean.g.kelly@vumc.org](mailto:sean.g.kelly@vumc.org)





# Questions?

