

## **HIV Testing**

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#### Continuing Education Disclosure

No disclosures



#### **Session Objectives**

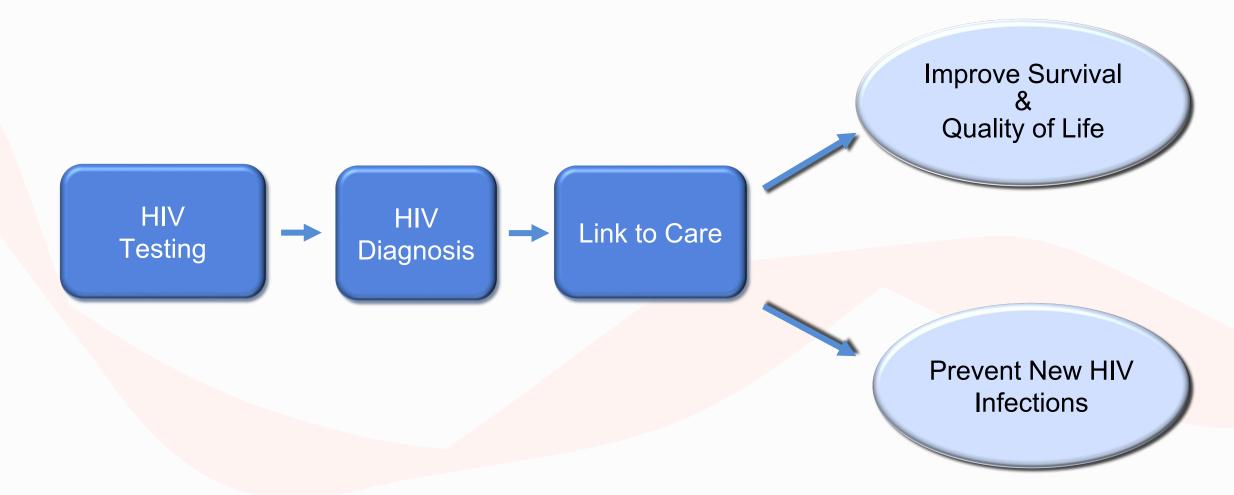
At the end of this session, participants will be able to

- Describe principles of routine testing for HIV infection
- Interpret HIV test results using the current 4<sup>th</sup> Generation Ag/Ab assay algorithm





#### Goals of Routine Testing for HIV

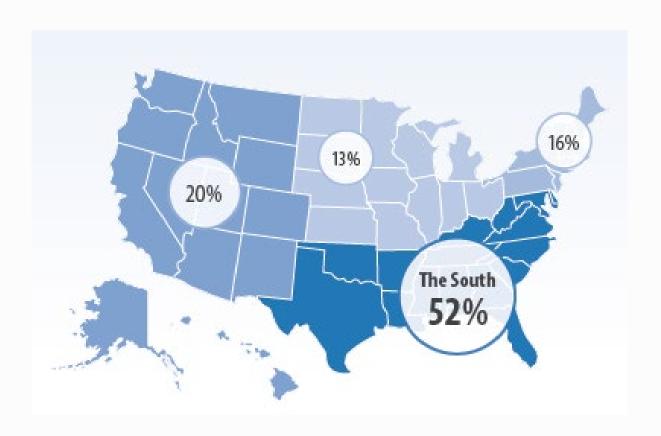






#### HIV in the United States

Over 1.1 million people are living with HIV in the US



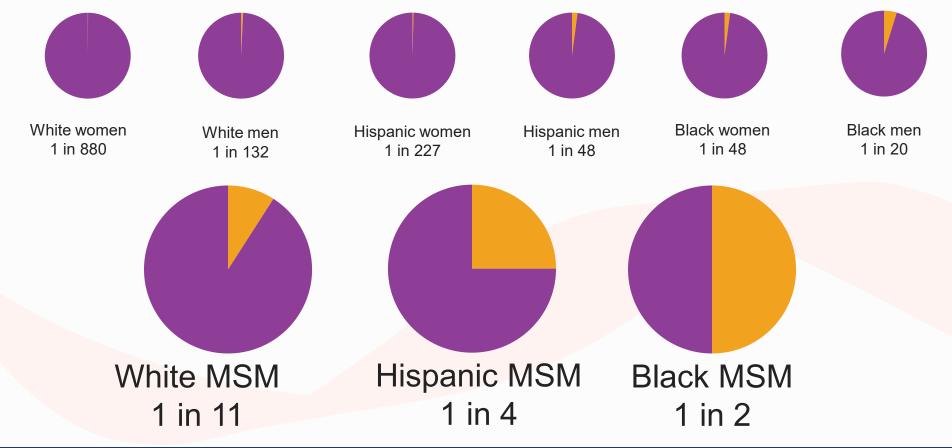


One in seven are unaware of their infection

https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-info-sheet-diagnoses-of-HIV-infection-2016.pdf http://www.floridahealth.gov/diseases-and-conditions/aids/surveillance/epi-slide-sets.html



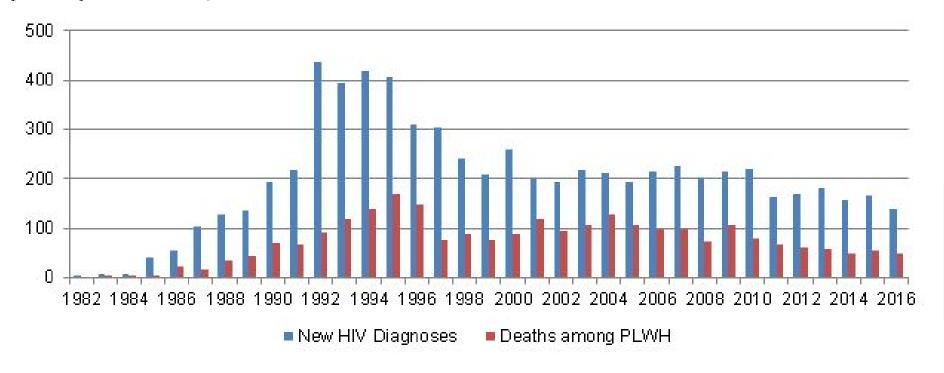
## HIV Risk by Race/Ethnicity and MSM





#### HIV in Nashville

Figure 1. Number of New HIV Diagnoses and Deaths among People Living with HIV (PLWH) – Nashville, 1982-2016



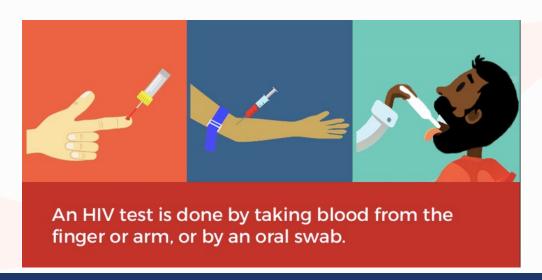
Source: Tennessee enhanced HIV/AIDS Reporting System (eHARS), accessed June 30, 2017.





#### Who Should We Screen? CDC 2006

- Routinely screen all patients aged 13-64 for HIV infection after notifying them that testing will be performed unless declined
- Prevention counseling should not be required with HIV diagnostic testing or as part of HIV screening programs in health-care settings







#### **Screening Based on Risk**

- Screen all patients
  - Starting treatment for tuberculosis
  - Seeking treatment for STDs during each visit for a new complaint
- Screen at least annually
  - Intravenous drug users and their sex partners
  - People who exchange sex for money or drugs
  - Sex partners of people with HIV infection
  - Men who have sex with men (MSM) or heterosexuals who have or who their sex partners have had more than one sex partner since their most recent HIV test



CDC. MMWR 2006;55(RR14;1-17)



#### Screening Based on Risk

- Screen all patients
- Screen at least annually
- Se Also anyone you suspect may have HIV in a given encounter!

  Mer nave sex with men (MSM) or heterosexuals who have or who their sex partners have had more than one sex partner since their most recent HIV test



CDC. MMWR 2006;55(RR14;1-17)

pmplaint



#### HIV Screening in Pregnant Women

- Universal Opt-out screening
- Address reasons for declining test
  - Document declinations in the medical records
- Timing of HIV test
  - Early during pregnancy
  - Repeat in third trimester, ideally < 36 weeks gestation</li>
  - Rapid testing at time of delivery if indicated



## Benefits of Knowing HIV Status

- HIV negative
  - Safer sex and needle practices
  - Assess if candidate for pre-exposure prophylaxis (PrEP)
- HIV Positive
  - Safer sex and needle practices
  - Antiretroviral use for individual patient health
  - Treatment as prevention, U=U
  - Prophylaxis to prevent opportunistic infections, if indicated



# Disproportionate Transmission of HIV By People Unaware of HIV Infection Status

Awareness of HIV Infection **New HIV Infections** 25% Unaware 54% 75% **Aware** 46%







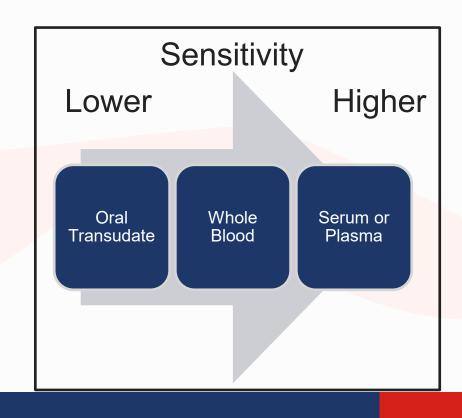
#### U=U

- 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



## Options for HIV Testing

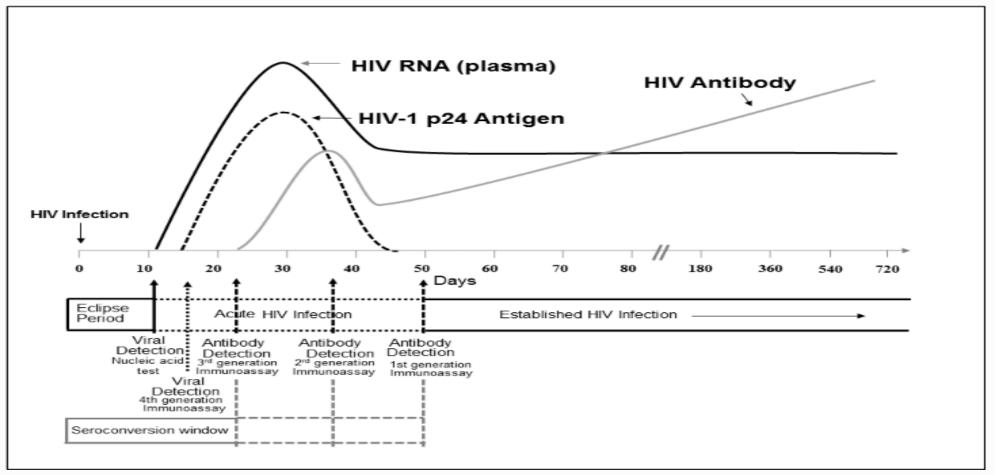
- HIV Antigen/Antibody Test (4<sup>th</sup> generation testing)
  - Can detect acute HIV infection
- HIV Antibody Test (3<sup>rd</sup> generation)
- Rapid HIV Test
  - Blood or saliva
  - Requires confirmation
- HIV viral load
  - Can detect acute HIV infection







# Sequence of Appearance of Lab Markers of HIV-1 Infection

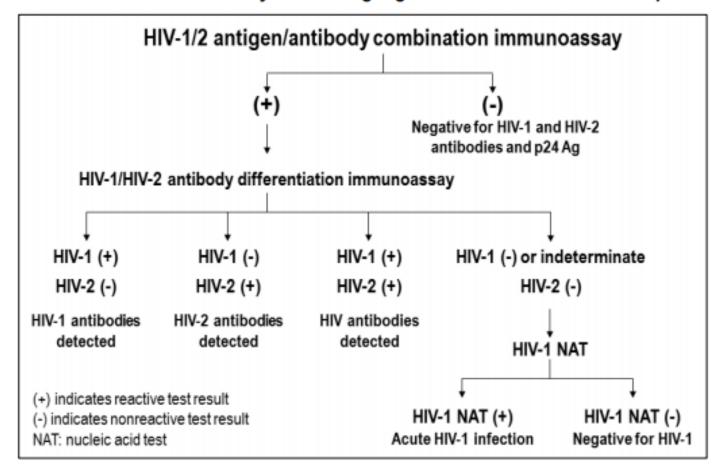


Branson BM, et al. Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations. CDC.gov. June 27, 2014. Available at http://stacks.cdc.gov/view/cdc/23446..



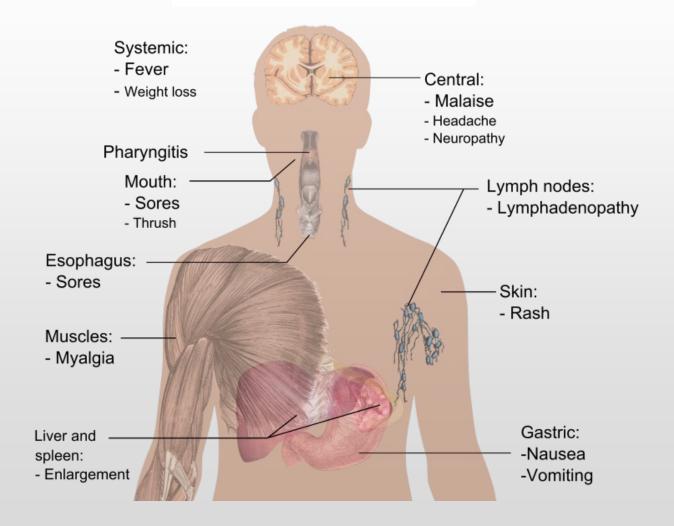
## **HIV Diagnosis**

Box 1. Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens





#### Symptoms of Acute HIV



#### **Acute HIV**

- Consider any time you see a febrile patient with a mononucleosistype presentation who may be at risk:
  - College student
  - Person who injects drugs
  - Person with multiple partners of unknown HIV status
- Clinical clues to acute HIV
  - Fever, malaise, pharyngitis, rash
  - Lymphadenopathy
  - Cytopenia
  - CD4 count can decline <200 cells/uL, OI can occur</li>





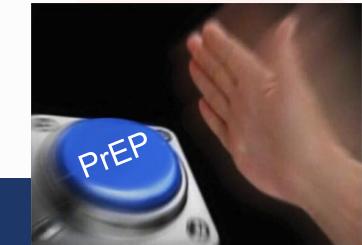
## What happens if the test is positive?

- Positive rapid tests require confirmation
  - Component of 4<sup>th</sup> generation testing algorithm
- Results should be communicated confidentially through personal contact
- Provide counseling
  - HIV is a manageable disease
  - Discuss HIV risk reduction
  - Discuss ways to handle the emotional consequences of a positive result
- Inform the patient that they might be contacted by health department staff



### What if the test is negative?

- Reinforce safer sex and needle sharing practices
- Recommend additional testing if indicated
  - Concern for acute HIV?
  - Consider HIV Pre-exposure prophylaxis (PrEP)





Phil is a 29-year-old man who is in a long-term relationship with Aaron. They recently returned from a Caribbean cruise where they both had multiple anonymous sex partners. They did not use condoms regularly.



- Phil presented a week after his return home with diffuse papular, erythematous rash.
- Other symptoms included: fever, diarrhea, right upper quadrant abdominal discomfort and 7-pound weight loss
- Labs revealed new thrombocytopenia (plt 101, was 164 prior to trip), AST 85 (nl 0-37) and ALT 196 (nl 0-41)
- Syphilis and tri-compartment GC/chlamydia screens negative



- HIV Testing
  - HIV Ag/Ab screen positive
  - HIV antibody differentiation assay negative
  - HIV RNA 4,024,146 copies/mL



Alexandra is a 32-year-old woman who presents to labor and delivery with rupture of membranes at 37 weeks of gestation.

- No prenatal care
- What should be done about HIV testing?



## Case 2 (continued)

- HIV Test results
  - HIV Ag/Ab screen positive
  - HIV antibody differentiation assay negative
  - HIV RNA negative



## Case 2 (continued)

- False-positive HIV screen
  - Consider ALL possibilities
    - Very early infection?
    - HIV-2?
      - It's possible this could be a very early HIV-2 infection, in which case the antibody is not present, and HIV RNA PCR does not detect HIV-2
  - Gather more history
  - Repeat testing (or additional testing) will likely be indicated
  - Talk to the laboratory



### Summary

- HIV testing should be done on all patients aged 13-64 regardless of risk
- Some patients require more frequent screening based on risks or concomitant diagnoses
- Be aware of symptoms and signs that suggest acute HIV infection
  - Is the test you are using able to identify acute HIV?
  - Do you need to add on an HIV viral load or repeat testing later?



## The sexual history

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



- To learn about the patient's sexual health
  - This is more than just ascribing HIV/STI risk
    - People tend to underestimate/not believe their own risks
- To help the patient achieve the goals in their sexual health
  - Emphasizes benefits over risk



## Sexual History Misconceptions

- 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 will an STI will have symptoms



- Give a preamble/preface
- Offer opt-out HIV testing
- Ask open-ended questions
- Listen for relevant information, and ask more pointed questions to fill in the blanks
- Suggest a course of action

VS

5Ps (partners, practices, protection from STI, past history of STI, prevention of pregnancy)



- Preamble
  - "I talk to all of my patients about sexual health, because it's such an important part of overall health. Some of my patients have questions or concerns about their sexual health, so I want to make sure I understand what your questions or concerns might be and provide whatever information or other help you might need."
  - "Gonorrhea and chlamydia can also live in our rectums and throats, so it's important for me to test anywhere you might have had an exposure."



- "Tell me about your sex life."
- "About how many partners have you had in the past 6 months?"
  - OR "Tell me about your sexual partners"
- "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?"
- "How do you prevent pregnancy?"
- "Do you use condoms? What percentage of the time would you say you use condoms?"



- "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







#### Pre-Exposure Prophylaxis for HIV

Sean Kelly, MD Vanderbilt Division of Infectious Diseases October 30, 2020

### 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
- PrEP options in Nashville



### Secondary Objectives

- Increase your confidence in providing PrEP!
- Provide PrEP!





### 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® (701)
  - 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 (now available! Starting 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)

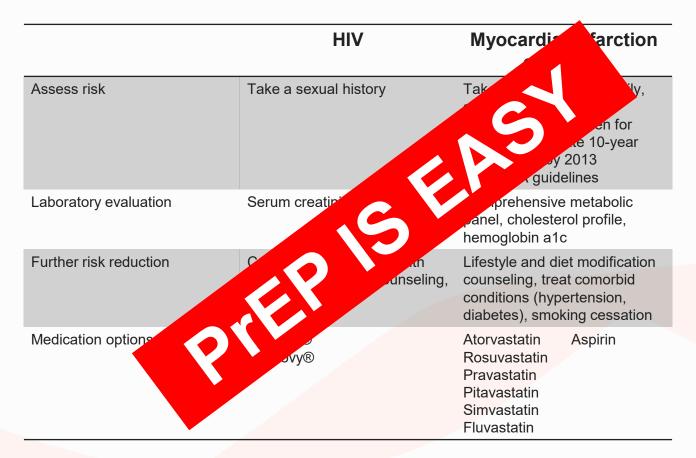


# **Primary Prevention**

	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 Aspirin Rosuvastatin Pravastatin Pitavastatin Simvastatin Fluvastatin



### **Primary Prevention**





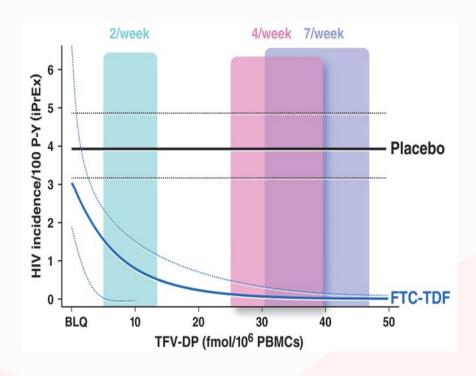
# Efficacy studies summary

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

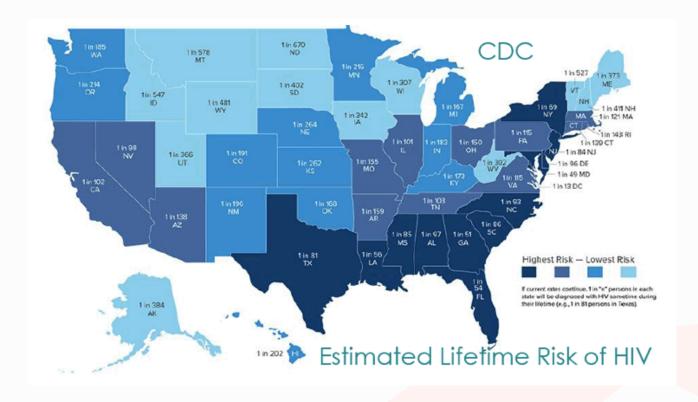


- Using drug concentrations in iPrEX and STRAND, pharmacokinetic models predict:
  - 76% risk reduction with 2 doses/week
  - 96% with 4 doses/week
  - 99% with 7 doses/week.



# Why PrEP Matters



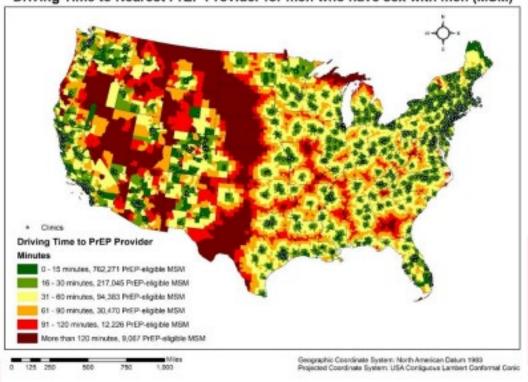


The Southeast remains the region with the highest HIV incidence, which can be markedly reduced with widespread use of pre-exposure prophylaxis (PrEP) among high-risk individuals.



### PrEP Deserts

#### Driving Time to Nearest PrEP Provider for men who have sex with men (MSM)



- 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



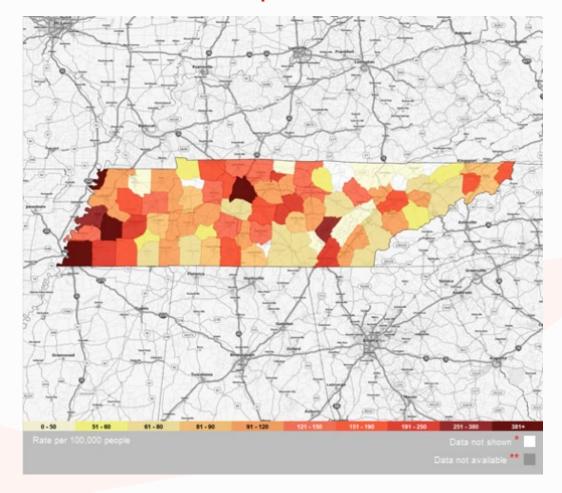
### PrEP use





### Tennessee

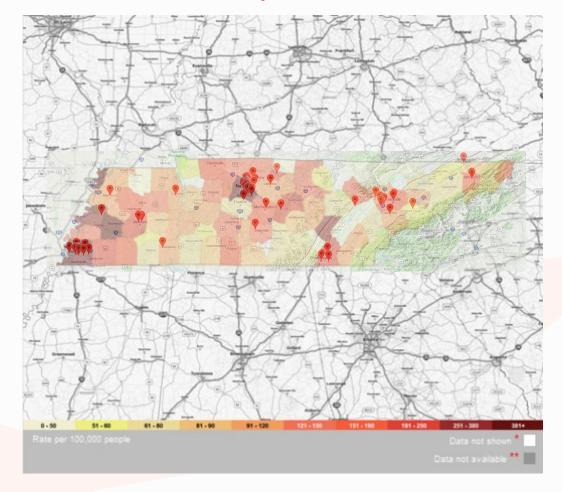
#### HIV risk and location of PrEP providers





### Tennessee

#### HIV risk and location of PrEP providers





### Barriers to PrEP



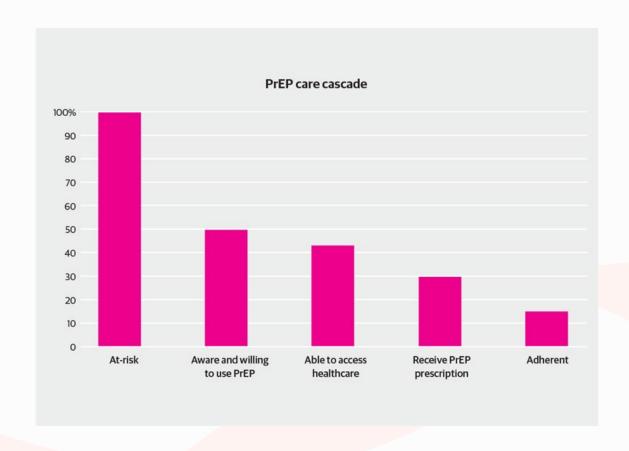
### PrEP sounds amazing!

So why aren't we using it?





### PrEP barriers





# Stigma

A preventative measure against the consequences of sexual activity

```
... condones sexual activity ... promotes sexual activity ... causes sexual activity
```







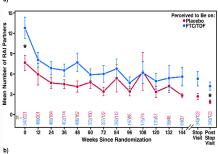
### Sexual risk compensation

- 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.



#### Sexual Risk Compensation

#### **iPrex**



For patients believing they were on PrEP, the number of receptive anal intercourse partners decreased.

Syphilis incidence also decreased in both study arms

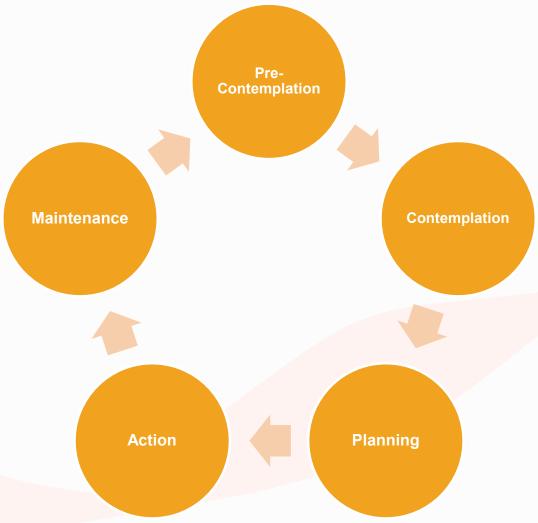
For patients believing they were on PrEP, condom use increased.

#### **PROUD**

- Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection
  - UK randomized, open-label study
    - 275 MSM to start TDF/FTC immediately
    - 269 MSM to start TDF/FTC after 1 year
  - 86% HIV risk reduction
  - No difference between groups in STI incidence



Actually...





Actually... Pre-Contemplation Maintenance Contemplation Active **Planning Action** 



Actually... Pre-Contemplation Maintenance Contemplation Active Confidence in sexual health **Planning Action** 



Actually... Pre-Contemplation Maintenance Contemplation Active Confidence in Stronger relationships **Planning Action** 



Actually... Pre-Contemplation Maintenance Contemplation Active Confidence in Stronger Fewer sexual partners **Action Planning** 



Actually... Pre-Contemplation Maintenance Contemplation Active Confidence in Stronger Fewer sexual Further risk reduction **Action Planning** 



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

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



### PrEP barriers – Providers

- Insufficient evidence of efficacy
- Too harmful/risk of adverse events
- Inexperience with Truvada/lack of knowledge
- PrEP is cost-prohibitive
- PrEP is not a primary care activity ("not me")

- Unfamiliarity with PrEP candidates; inability to assess high HIV risk
- Sexual risk compensation
- Patients perceived as nonadherent, and risk HIV resistance mutation development
- Personal ideology

Blumenthal J, et al. *AIDS Behav* 2015,19:802-810.
Karris MY, et al. *Clin Infect Dis* 2014,58:704-712.
Sharma M, et al. *PLoS One* 2014,9:e105283.
Hakre S, et al. *Medicine (Baltimore)* 2016,95:e4511.
Clement ME, et al. *AIDS Care* 2017:1-6.

Martin J, et al. Abstract # 1447. IDWeek, San Diego, October 4-8, 2017. Imp B, et al. Abstract # 879, IDWeek, San Diego, October 4-8, 2017. Blackstock OJ, eta al. *J Gen Intern Med* 2017,32:62-70.

Moore E, et al. Healthcare Provider Attitudes and Knowledge Around Pre-Exposure Prophylaxis (PrEP) for the Prevention of HIV-Infection in Tennessee. IDWeek 2019



### PrEP barriers in TN – Providers

- Barriers cited by providers (prescribers vs nonprescribers)
  - Cost (26% vs 51%)
  - Need for administrative support (26% vs 49%)
  - Sexual risk compensation (22% vs 25%)
  - Suboptimal adherence (17% vs 27%)
  - Serious adverse events (0% vs 8%)



# PrEP eligibility





# 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:	Sexual partner with HIV Recent bacterial STD High number of sex partners History of inconsistent or no condom use Commercial sex work	Sexual partner with HIV Recent bacterial STD High number of sex partners History of inconsistent or no condom use Commercial sex work Lives in high-prevalence area or network	HIV-positive injecting partner     Sharing injection equipment     Recent drug treatment (but currently injecting)		
Clinically eligible:	Documented negative HIV test before prescribing PrEP     No signs/symptoms of acute HIV infection     Normal renal function, no contraindicated medications     Documented hepatitis B virus infection and vaccination status				
Prescription	Daily, continuing, oral doeses of TDF/FTC (Truvada), ≤90 day supply				
Other services:	<ul> <li>Follow-up visits at least every 3 months to provide:</li> <li>HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STD symptom assessment</li> <li>At 3 months and every 6 months after, assess renal function</li> <li>Every 6 months test for bacterial STDs</li> </ul>				
	Do oral/rectal STD testing	Assess pregnancy intent     Pregnancy test every 3 months	Access to clean needles/ syringes and drug treatment services		

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





	Men Who Have Sex With Men	Heterosexual Women and Men	Injection Drug Users	
Detecting substantial risk	Sexual p	HIRI-MSM		
of acquiring HIV infection:	• Recent b	How old are you	<18 years	score 0
or acquiring rite infection.	High nur	today (yrs)?	18–28 years	score 8
	partners	1044) (315).	29–40 years	score 5
	- History d		41–48 years	score 2
	no cond - Commer		≥49 years	score 0
	2	How many men have	>10 male partners	score 7
		you had sex with	6–10 male partners	score 4
Clinically eligible:	• Do	in the last 6 months?	0–10 male partners	score 0
Clinically eligible:	• No 3	In the last 6 months,	1 or more times	score 10
	• Noi	how many times	0 times	score 0
	- Do	did you have receptive	0 times	score o
Prescription		anal sex (you were the bottom) with a man?		
Other services:	• Foll 4	How many of your male	>1 positive partner	score 8
	- HIV	sex partners were	1 positive partner	score 4
	side	HIV positive?	<1 positive partner	score 0
	• At 3 • Eve 5	In the last 6 months,	5 or more times	score 6
	- Eve	how many times did	0 times	score 0
	- Do oral/re	you have insertive anal sex (you were the top) with a man who was HIV positive?		
ource: US Public Health Service. Pr	reexposure proph 6	In the last 6 months, have	Yes	score 5
		you used methamphetamines such as crystal or speed?	No	score 0
	7	In the last 6 months,	Yes	score 3
		have you used poppers (amyl nitrate)?	No	score 0
			Add down entries in right column to calculate total score	Total score

men, women, or both?"

their male patients a routine question: "In the past (time) have you had sex? (if yes), with

†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.





	Sum	mary of Gu	idance fo	r PrEP Use			
	Men Who Hav	e Sex With Men	Heterosexu	ial Women and Men	Injection Drug Users	5	1
Detecting substantial risk	Sexual p	50		HIRI-MSM	1 Risk Index*		
of acquiring HIV infection:	Recent b     High nur     partners	1	How old a today	re you	<18 years	score 0	
	History of no conde     Commer	2	How ma		TRUVADA* (emtricitabine and ten	tion Guide  (tru-VAH-dah) ofovir disoproxil fumarate)	
Clinically eligible:	- Doc - No - No - Doc	3	In the lathow ridid you anal s	information. This information your treatment. This Medication Guide pro Guide section "What is TF	le before you start taking TRUVA	ing to your healthcare prov rent ways that TRUVADA r tion about how TRUVADA	ider about your medical condition or nay be used (see the Medication
Other services:	• Foll • HIV side • At 3 • Eve	5	the bo How ma sex pa HIV p In the lan how n	HIV is the virus that cause: What is the most importa If you also have hepatitis stop taking TRUVADA  Do not stop taking TRU	A. UVADA without first talking to you	ency Syndrome).  about TRUVADA?  ike TRUVADA, your hepa  ur healthcare provider.	titis B may become worse if you
	• Do oral/re		you h sex (y with a HIV p	gone.  • If your healthcare provimonths to check your lealthcare providing the second	VADA. Refill your prescription or rider stops TRUVADA, your health hepatitis B infection, or give you a fer about any new or unusual synusus it side effects, see the section "W	hcare provider will need to a medication to treat hepati nptoms you may have after	itis B. you stop taking TRUVADA.
ource: US Public Health Service. P	reexposure proph	7	In the lar you u such a In the lar have y (amyl	Medication Guide.  Other important informat Before taking TRUVADA  You must be HIV-neg HIV-1 infection.  Do not take TRUVAD  Many HIV-1 tests can symptoms, you could I illness within the last in infection include:	tion for people who take TRUV, to reduce your risk of getting It pative to start TRUVADA. You not a to reduce the risk of getting miss HIV-1 infection in a person whave recently become infected with the property of the results of the risk of the	ADA to help reduce their HIV-1 infection: nust get tested to make s HIV-1 unless you are con who has recently become i tith HIV-1. Tell your healthcor or at any time while taking	risk of getting HIV-1 infection: ure that you do not already have firmed to be HIV-negative. nfected. If you have flu-like
		me			o von	ve HIV prevention	





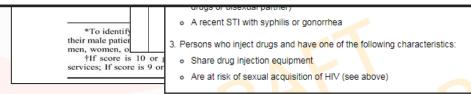
	Summary of (	Guid	lance for	PrE	EP Use
	Men Who Have Sex With M	en l	Heterosexua	al Wo	omen and Men Injection Drug Users
Detecting substantial risk	Sexual p	100			HIRI-MSM Risk Index*
of acquiring HIV infection:	Recent b     High nur     partners     History c	1 1	How old are today	e you	ou <18 years score 0
	no condi - Commer	2 1	How ma		Medication Guide  TRUVADA* (tru-VAH-dah)  (emtricitabine and tenofovir disoproxil fumarate)
		2 1	you h		(emunchabine and tendrovii disoproxii dimarate) tablets
Clinically eligible:	· Doc · No · No	3 1	in the	info	and this Medication Guide before you start taking TRUVADA and each time you get a refill. There may be new ormation. This information does not take the place of talking to your healthcare provider about your medical condition or ur treatment.  is Medication Guide provides information about two different ways that TRUVADA may be used (see the Medication
Prescription	• Do		did yo anal s	Guid •	to treat Human Immunodeficiency Virus-1 (HIV-1) infection, and
Other services:	1011	4 1	How ma		to reduce the risk of getting HIV-1 infection in adults who are HIV-negative  V is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).
	• HIV side • At 3	5 1	sex pa HIV r	If yo	hat is the most important information I should know about TRUVADA? you also have hepatitis B virus (HBV) infection and take TRUVADA, your hepatitis B may become worse if you stop taking TRUVADA.
	• Eve		how r you h sex (y with a		The USPSTF recommends the following persons be considered for PrEP:  1. 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)
ource: US Public Health Service. P	reexposure proph	6 1	HIV p In the last you u	For Med Oth	A recent sexually transmitted infection (STI) with syphilis, gonorrhea, or chlamydia
		7 1	such a In the las	Bef	2. Heterosexual women and men who are sexually active and have one of the following characteristics:
			(amyl	:	<ul> <li>A serodiscordant sex partner (i.e., a sex partner living with HIV)</li> <li>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 injectives or bisexual partner)</li> </ul>
			To identify		A recent STI with syphilis or gonorrhea
		men, v	nale patier women, o		3. Persons who inject drugs and have one of the following characteristics:
			f score is 10 es; If score is		





	Summary	Summary of Guidance for PrEP Use						
	Men Who Have Sex Wit	h Men	Heterosexual Women and Men	Injection Drug Users				
Detecting substantial risk	Sexual p	1.0	HIRI-M	SM Risk Index*				
of acquiring HIV infection:	Recent b     High nur     partners	1	How old are you today	<18 years	score 0			
	History d     no conde     Commer			Medication C TRUVADA® (tru-\				
		2	How ma you h	(emtricitabine and tenofovir tablets				
Cliniantha alimible.	0-		in the Read this Medication (	Guide before you start taking TRLIVADA ar		refill There may be new		

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.





## Recommendation comparisons

- 300 high risk young, black MSM (age 16-29) in Chicago
- 33 HIV acquisitions over 3 years
  - 52% met CDC eligibility for PrEP
  - 85% met HIRI-MSM eligibility for PrEP
  - 94% met drug company eligibility for PrEP
  - CDC guidelines: Low sensitivity, specificity (52%)
  - Drug company guidelines: High sensitivity, low specificity (15%)

Lancki N et al. AIDS 2018



## 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)</p>
  - Don't use TDF/FTC; safety has not been adequately determined
  - Can use TAF/FTC for CrCl >30mL/min



## 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 Event	TDF-FT0 (N=611			Placebo (N = 608)		
	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	

<sup>\*</sup> ALT denotes alanine aminotransferase, and AST aspartate aminotransferase.



<sup>†</sup> 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.

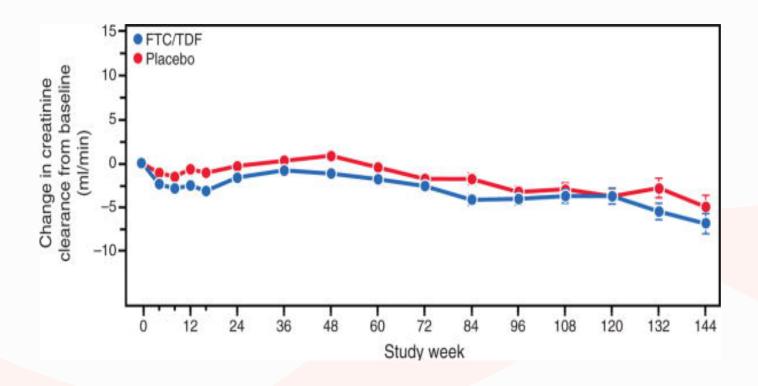
<sup>‡</sup>The causes of death in the TDF–FTC group were motor vehicle accident (one participant) and suicide (one); the causes of death in the placebo group were motor vehicle accident (two), homicide (one), and cerebrovascular accident (one).

	Table 2. Adverse Events, According to Treatm	ent Group.*						
	Adverse Event	TDF-FT0 (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		
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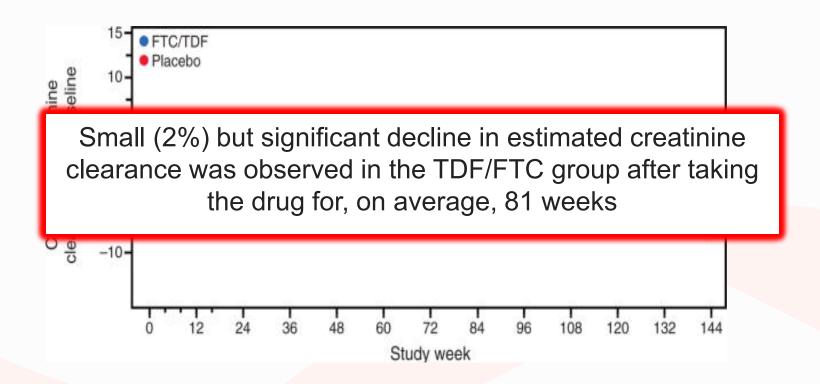






Table 3. Bone Mine	eral Density Sco	res.*							
Assessment		Forearm			Hip		L	umbar Spine	
	TDF-FTC (N=109)	Placebo (N=112)	P Value	TDF-FTC (N=109)	Placebo (N = 112)	P Value	TDF-FTC (N=109)	Placebo (N=112)	P Value
T score			0.004			<0.001			<0.001
Enrollment	-0.75	-0.58		0.44	0.53		-0.72	-0.59	
6 mo	-0.77	-0.50		0.33	0.57		-0.84	-0.45	
12 mo	-0.79	-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	
z Score			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	

<sup>\*</sup> 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.





Table 3. Bone Mine	eral Density Sco	res.*							
Assessment		Forearm			Hip		Lu	ımbar 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	

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

24 mo	-0.87	-0.13	0.20	0.76	-1.09	-0.28	
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<sup>\*</sup> 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.





Table 3. Bone Min	eral Density Sco	res.*							
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.

VISIT, 44 at the 14-month visit, 53 at the 16-month visit, and 55 at the 44-month visit,



### 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



## 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



# A year of PrEP

Encounter	To do
Month 0	<ul> <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><li>Screen for HIV</li><li>Check serum creatinine</li><li>Counseling</li><li>Prescribe</li></ul>
Month 6	<ul><li>Screen for HIV</li><li>Screen for STIs</li><li>Counseling</li><li>Prescribe</li></ul>
Month 9	<ul><li>Screen for HIV</li><li>Check serum creatinine</li><li>Counseling</li><li>Prescribe</li></ul>
Month 12	<ul><li>Screen for HIV</li><li>Screen for STIs</li><li>Counseling</li><li>Prescribe</li></ul>

#### Labs:

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

Prescriptions/Refill authorizations: 5

Discussions: 5+



## Financial aspects of PrEP

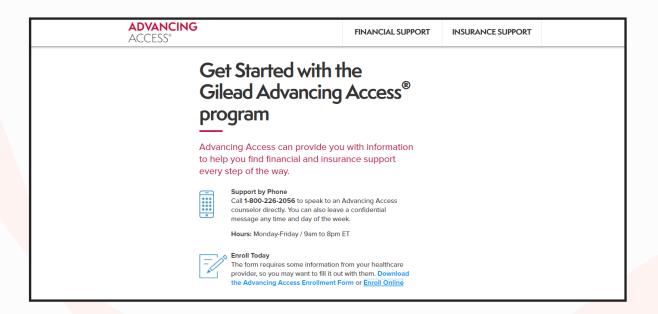


## PrEP coverage

- Actually, Truvada® and Descovy® are very affordable for most patients
- All insurance plans cover TDF/FTC, most cover TAF/FTC
  - Variable copays
- Medicare/Medicaid cover PrEP
- 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</li>
  - Primary option for uninsured patients



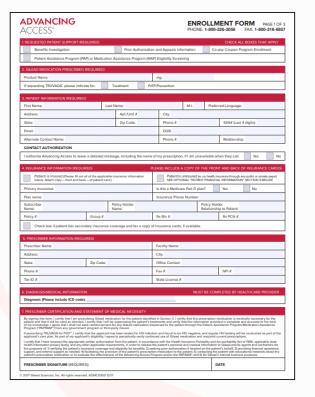
## Copay Assistance







# Medication Assistance Program



ADVANCING ACCESS ENROLLMENT FORM PHO		DATE OF BURTO	PAGE
PATIENT NAME:		DATE OF BIRTH:	
8. PATIENT AUTHORIZATION FOR USE AND DISCLOSE	URE OF PERSONAL HEALTH INFORMATIO	IN (REQUIRED)	
I understand that I must complete this enro Advancing Access ("Program") and the Pati of this process, Gilead and its agents and co my personal and medical information as de disclose my personal and medical informat PAP/MAP, all in accordance with this authori with the authorization.	ient Assistance Program/Medicat ontractors (collectively, "Gilead") v escribed below. I hereby authoriz tion as described below to Gilead	ion Assistance Program ("Pr will need to obtain, review, te my healthcare providers d in connection with the Pro	AP/MAP*). As p use and disclo- and health pla- gram and/or th
Information to Be Disclosed: Personal healt name, mailing address, financial informatio (including information about my HIV-relate condition), and all information provided on	on, and insurance information), red status or treatment with this p	my past, current and future	medical condit
Persons Authorized to Disclose My Informat medication, and any health plans or progra providers may receive remuneration for dis	tion: My healthcare providers, in ims that provide me healthcare b	penefits. I understand that r	fills my prescri my pharmacy
Persons to Which My Information May Be D administration of the Program and the PAP	Disclosed: Gilead, including the t		sponsible for th
Purposes for Which the Disclosures Are to B disclose the PHT for purpose of '1) comple my eligibility for benefits from my health p support, and communicating with my healt prescription medication to me; 4) contactin Gilead's internal business purposes, includi information, offers, and educational materi customer relationship marketing program the signatures below, I may opt in).	ting the enrollment process and lan or other programs; 3) provide thcare providers, including, but r 19 me to evaluate the effectivene ing quality control and support e lals related to my treatment and (this use of my personal informa	verifying my enrollment foing financial assistance, sug- ont limited to, facilitating the ss of the Program and/or the enhancing surveys; and 6) to or my prescription medicat tion is optional and by checons.	orm; 2) establist oport, and refer e provision of r ne PAP/MAP; 5) to send me mar ion, including t cking the box u
I understand that once my PHI has been di understand further that I may refuse to sig ability to obtain treatment from my healthch by Program and/or the PAP/MAP. I also und writing at Advancing Acces, PO Box 13185 to obtain, use or disclose my PHI after the ca PHI that have already been made pursuant signed authorization, which expires the ear under the laws of the state in which I reside under the laws of the state in which I reside	on this authorization and that if I are providers will not change, bu lerstand that I may cancel this au b, La Jolla, CA 92039-3185. If I ca ancellation date, but the cancella to this authorization before the c dier of two (2) years from the date	refuse, my eligibility for he, at I will not have access to the thorization at any time by m ncel, Gilead will stop using ation will not affect uses or a cancellation date. I am enti	alth plan benef ne support offen notifying Gilead this authorizati disclosures of a tled to a copy o
By checking this box, I agree to receive marketi prescription medication, including the customer		terials related to my medical condition	on, treatment, and/o
SIGNATURE of PATIENT or PATIENT'S REPRESENTA	ITIVE (REQUIRED):	DATE:	
Patient Representative's Name (if signing for the patie	ient):		
Patient Representative's Relationship to Patient:			

ATIENT NAME:				DATE OF BIRTH:
9. PATIENT FINANCIAL INFORMATION REQUIRED ONLY IF APPLYIN	G FOR	THEF	ATIENT A	SSISTANCE PROGRAM/MEDICATION ASSISTANCE PROGRAM (PAPIMAP)
Current Annual Household Income: \$				
Number of People in Household supported by above income		1	2	3 4 5 6 Other:
Please submit current documentation for all sources of income (eg. tax ret if there is no household income, indicate how the patient/household is being			2 pay stub	, etc.).
ADDITIONAL INSURANCE INFORMATION				
Social Security Number:				
Has the patient applied for ADAP?	W.	bs.	No	If Yes, date of application:
Has the patient applied for Medicaid?	W Y	bs	No	If Yes, date of application:
Is the patient eligible for Medicaid?	N W	bs.	No	If No, state reason:
Is the patient eligible for VA benefits?	W W	bs.	No	If Yes, has the patient tried to obtain the medication through the VA?
Has the patient applied for an insurance plan offered through a state insurance marketplace (also known as an exchange)?	W W	bs	No	If Yes, date of application:
is the patient eligible for an insurance plan offered through a state insurance marketplace (also known as an exchange)?	W W	bs	No	If No, state reason:
will terminate if Advancing Access becomes aware of any false or completing this application does not ensure that I will qualify for p	r inaccu patient	urate i assist	information	IR THE PARIMAP)  we, is complete and accurate, I understand that program assistance on or if this medication is no longer prescribed for me. I understand that exceive the product through the PAPIMAP, I contrib that I will not seek to monate if I am a member of a Medicace Part I beats will not seek
will terminate if Advancing Access becomes aware of any fatise or completing this application down of names that will wailiguility for completing this application down of names that will wailing this property of the proper	r inaccu patient i ith plan ounted i ntinue t spensin fit repor	urate i assist i, or g as par this pr g pha et abo	informatic lance. If I i overnmen it of my or rogram, o irmacy on out me to	me, is complete and accurate. I understand that program assistance in or if this medication is no longer prescribed for me. I understand that



## Ready, Set, PrEP

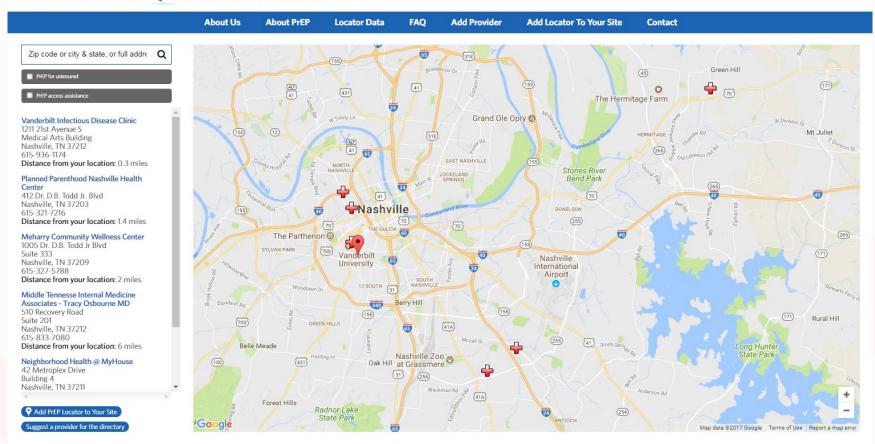
- US Dept. of Health and Human Services Program
  - No-cost PrEP provider if the patient:
    - Tests negative for HIV;
    - Has a valid prescription
    - Does not have health insurance coverage for outpatient prescription drugs
  - Does not cover costs of visits or labs
- Easy to apply:
  - Online: GetYourPrEP.com
  - By phone: 855.447.8410





### **PrEP Locator**



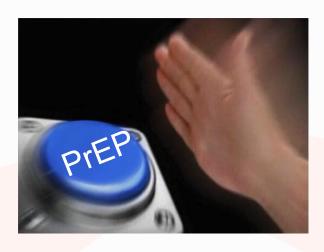


https://preplocator.org



### Conclusion

- PrEP is a component of primary care
- PrEP is an extremely effective preventive strategy for both HIV and STIs
- Understand PrEP prescribing guidelines
- There are some adverse effects, but PrEP is generally very well-tolerated
- PrEP requires an ongoing patientdoctor relationship
- Sexual history is essential to comprehensive health care
- Ask for help! <u>sean.g.kelly@vumc.org</u>





## Questions?

