

PRE-EXPOSURE PROPHYLAXIS FOR HIV (EASIER THAN IT SOUNDS!)

Sean Kelly, MD

Vanderbilt Division of Infectious Diseases

August 10, 2018

Objectives

- Importance of PrEP in the Southeast
- Provider barriers for providing PrEP
- Becoming a PrEP provider
- Logistical considerations of a PrEP clinic
 - Visits
 - Labs
 - Truvada® access
 - Advertising

Have you provided PrEP?

- A. Yes
- B. No
- C. Wait, what's 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/emtracitabine (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 6/2017

Also approved in Australia, Canada, France, Norway, Belgium, Netherlands, Peru, Israel, Kenya, Botswana, Zimbabwe and South Africa

Coming soon in: Brazil, Nigeria, Zambia, Malawi, Uganda, India, Thailand, United Kingdom, Italy

This is different from PEP

- PrEP = Pre-Exposure Prophylaxis
 - HIV exposure has not yet occurred
 - indefinite duration if HIV risk persists
- PEP = Post-Exposure Prophylaxis
 - HIV exposure HAS occurred
 - Goal is to reduce incidence of established infection
 - THREE drugs required: Truvada® (TDF/FTC) + dolutegravir (or raltegravir)
 - Limited duration of 28 days

Primary Prevention

	HIV	Myocardial Infarction
Assess risk	Take a sexual history	Review medical history, family history, check cholesterol, screen for diabetes, calculate 10-year ASCVD risk using 2013 ACC/AHA guidelines
Laboratory evaluation	Serum creatinine	Comprehensive metabolic panel, cholesterol profile, hemoglobin a1c
Further risk reduction	Behavioral counseling, STI testing	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

Who benefits from PrEP

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"> Sexual partner Recent bacter High number partners History of inco no condom us Commercial se 	HIRI-MSM Risk Index*		
		1	How old are you today (yrs)?	<ul style="list-style-type: none"> <18 years score 0 18–28 years score 8 29–40 years score 5 41–48 years score 2 ≥49 years score 0
		2	How many men have you had sex with	<ul style="list-style-type: none"> >10 male partners score 7

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.

<p>*To identify sexually active MSM their male patients a routine question: men, women, or both?"</p> <p>†If score is 10 or greater, evaluate services; If score is 9 or less, provide</p>	<p>Medication Guide:</p> <p>Other important information for people who take TRUVADA to help reduce their risk of getting HIV-1 infection:</p> <p>Before taking TRUVADA to reduce your risk of getting HIV-1 infection:</p> <ul style="list-style-type: none"> You must be HIV-negative to start TRUVADA. You must get tested to make sure that you do not already have HIV-1 infection. Do not take TRUVADA to reduce the risk of getting HIV-1 unless you are confirmed to be HIV-negative. 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"> tiredness fever joint or muscle aches sore throat vomiting or diarrhea rash
--	---

How well does PrEP work?



iPrEX



The NEW ENGLAND JOURNAL of MEDICINE

[HOME](#)[ARTICLES & MULTIMEDIA ▾](#)[ISSUES ▾](#)[SPECIALTIES & TOPICS ▾](#)[FOR AUTHORS ▾](#)[CME >](#)

ORIGINAL ARTICLE

Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men

Robert M. Grant, M.D., M.P.H., Javier R. Lama, M.D., M.P.H., Peter L. Anderson, Pharm.D., Vanessa McMahan, B.S., Albert Y. Liu, M.D., M.P.H., Lorena Vargas, Pedro Goicochea, M.Sc., Martín Casapía, M.D., M.P.H., Juan Vicente Guanira-Carranza, M.D., M.P.H., Maria E. Ramirez-Cardich, M.D., Orlando Montoya-Herrera, M.Sc., Telmo Fernández, M.D., Valdilea G. Veloso, M.D., Ph.D., Susan P. Buchbinder, M.D., Suwat Chariyalertsak, M.D., Dr.P.H., Mauro Schechter, M.D., Ph.D., Linda-Gail Bekker, M.B., Ch.B., Ph.D., Kenneth H. Mayer, M.D., Esper Georges Kallás, M.D., Ph.D., K. Rivet Amico, Ph.D., Kathleen Mulligan, Ph.D., Lane R. Bushman, B.Chem., Robert J. Hance, A.A., Carmela Ganoza, M.D., Patricia Defechereux, Ph.D., Brian Postle, B.S., Furong Wang, M.D., J. Jeff McConnell, M.A., Jia-Hua Zheng, Ph.D., Jeanny Lee, B.S., James F. Rooney, M.D., Howard S. Jaffe, M.D., Ana I. Martinez, R.Ph., David N. Burns, M.D., M.P.H., and David V. Glidden, Ph.D., for the iPrEx Study Team*

N Engl J Med 2010; 363:2587-2599 | [December 30, 2010](#) | DOI: 10.1056/NEJMoa1011205

44% HIV risk reduction, but 92% risk reduction when taken consistently among MSM and transgender women

TDF2 Study Group



The NEW ENGLAND
JOURNAL of MEDICINE

HOME

ARTICLES & MULTIMEDIA ▾

ISSUES ▾

SPECIALTIES & TOPICS ▾

FOR AUTHORS ▾

CME ▶

ORIGINAL ARTICLE

Antiretroviral Preexposure Prophylaxis for Heterosexual HIV Transmission in Botswana

Michael C. Thigpen, M.D., Poloko M. Kebaabetswe, Ph.D., M.P.H., Lynn A. Paxton, M.D., M.P.H., Dawn K. Smith, M.D., M.P.H., Charles E. Rose, Ph.D., Tebogo M. Segolodi, M.Sc., Faith L. Henderson, M.P.H., Sonal R. Pathak, M.P.H., Fatma A. Soud, Ph.D., Kata L. Chillag, Ph.D., Rodreck Mutanhaurwa, M.B., Ch.B., Lovemore Ian Chirwa, M.B., Ch.B., M.Phil., Michael Kasonde, M.B., Ch.B., Daniel Abebe, M.D., Evans Buliva, M.B., Ch.B., Roman J. Gvetadze, M.D., M.S.P.H., Sandra Johnson, M.A., Thom Sukalac, Vasavi T. Thomas, M.P.H., R.Ph., Clyde Hart, Ph.D., Jeffrey A. Johnson, Ph.D., C. Kevin Malotte, Dr.P.H., Craig W. Hendrix, M.D., and John T. Brooks, M.D., for the TDF2 Study Group*

N Engl J Med 2012; 367:423-434 | August 2, 2012 | DOI: 10.1056/NEJMoa1110711

62.2% HIV risk reduction among
heterosexual men and women

Partners PrEP Study Team



The NEW ENGLAND
JOURNAL of MEDICINE

HOME

ARTICLES & MULTIMEDIA ▾

ISSUES ▾

SPECIALTIES & TOPICS ▾

FOR AUTHORS ▾

CME ▶

ORIGINAL ARTICLE

Antiretroviral Prophylaxis for HIV Prevention in Heterosexual Men and Women

Jared M. Baeten, M.D., Ph.D., Deborah Donnell, Ph.D., Patrick Ndase, M.B., Ch.B., M.P.H., Nelly R. Mugo, M.B., Ch.B., M.P.H., James D. Campbell, M.D., Jonathan Wangisi, M.B., Ch.B., Jordan W. Tappero, M.D., M.P.H., Elizabeth A. Bukusi, M.B., Ch.B., Ph.D., Craig R. Cohen, M.D., M.P.H., Elly Katabira, M.B., Ch.B., Allan Ronald, M.D., Elioda Tumwesigye, M.B., Ch.B., Edwin Were, M.B., Ch.B., M.P.H., Kenneth H. Fife, M.D., Ph.D., James Kiarie, M.B., Ch.B., M.P.H., Carey Farquhar, M.D., M.P.H., Grace John-Stewart, M.D., Ph.D., Aloysious Kakiya, M.B., Ch.B., Josephine Odoyo, M.P.H., Akasiima Mucunguzi, M.B., Ch.B., Edith Nakku-Joloba, M.B., Ch.B., Ph.D., Rogers Twesigye, M.B., Ch.B., M.P.H., Kenneth Ngunjiri, Ph.D., Cosmas Apaka, B.Sc., Harrison Tamoo, M.B., Ch.B., Fridah Gabona, M.B., Ch.B., Andrew Mujugira, M.B., Ch.B., Dana Panteleeff, B.S., Katherine K. Thomas, M.S., Lara Kidoguchi, M.P.H., Meighan Krows, B.A., Jennifer Revall, B.A., Susan Morrison, M.D., M.P.H., Harald Haugen, M.S., Mira Emmanuel-Ogier, B.A., Lisa Ondrejcek, M.A., Robert W. Coombs, M.D., Ph.D., Lisa Frenkel, M.D., Craig Hendrix, M.D., Namandjé N. Bumpus, Ph.D., David Bangsberg, M.D., M.P.H., Jessica E. Haberer, M.D., M.P.H., Wendy S. Stevens, M.D., F.C.Path., Jairam R. Lingappa, M.D., Ph.D., and Connie Celum, M.D., M.P.H., for the Partners PrEP Study Team*

N Engl J Med 2012; 367:399-410 | August 2, 2012 | DOI: 10.1056/NEJMoa1108524

75% HIV risk reduction among heterosexual sero-discordant couples, 90% among those with detectable drug levels

Bangkok Tenofovir Study Group



THE LANCET

Volume 381, Issue 9883, 15–21 June 2013, Pages 2083–2090



Articles

Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial

Kachit Choopanya, MD^a, Dr Michael Martin, MD^{b, c},  , Pravan Suntharasamai, MD^a, Udomsak Sangkum, MD^a, Philip A Mock, MAppStats^b, Manoj Leethochawalit, MD^d, Sithisat Chiamwongpaet, MD^d, Praphan Kitisin, MD^d, Pitinan Natrujirote, MD^d, Somyot Kittimunkong, MD^e, Rutt Chuachoowong, MD^b, Roman J Gvetadze, MD^e, Janet M McNicholl, MD^{b, c}, Lynn A Paxton, MD^c, Marcel E Curlin, MD^{b, c}, Craig W Hendrix, MD^f, Suphak Vanichseni, MD^a, for the Bangkok Tenofovir Study Group

48.9% risk reduction, but 74% HIV risk reduction when taken consistently, among IDUs (TDF only)

IPERGAY



The NEW ENGLAND JOURNAL of MEDICINE

[HOME](#)[ARTICLES & MULTIMEDIA ▾](#)[ISSUES ▾](#)[SPECIALTIES & TOPICS ▾](#)[FOR AUTHORS ▾](#)[CME ▶](#)

ORIGINAL ARTICLE

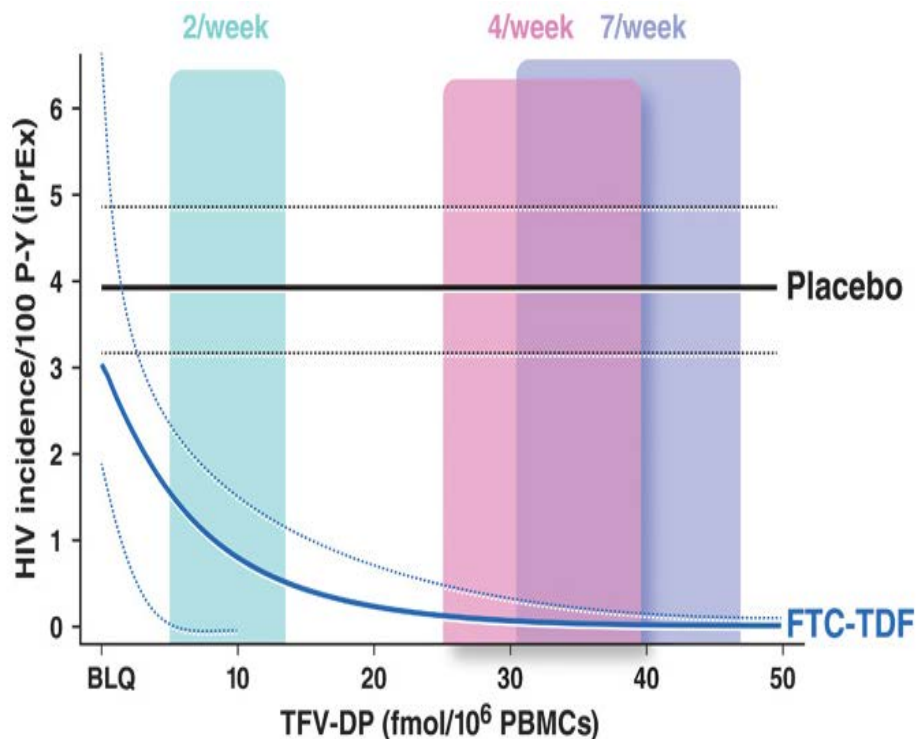
On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-1 Infection

Jean-Michel Molina, M.D., Catherine Capitant, M.D., Bruno Spire, M.D., Ph.D., Gilles Pialoux, M.D., Laurent Cotte, M.D., Isabelle Charreau, M.D., Cecile Tremblay, M.D., Jean-Marie Le Gall, Ph.D., Eric Cua, M.D., Armelle Pasquet, M.D., François Raffi, M.D., Claire Pintado, M.D., Christian Chidiac, M.D., Julie Chas, M.D., Pierre Charbonneau, M.D., Constance Delaugerre, Pharm.D., Ph.D., Marie Suzan-Monti, Ph.D., Benedicte Loze, B.S., Julien Fonsart, Pharm.D., Gilles Peytavin, Pharm.D., Antoine Cheret, M.D., Ph.D., Julie Timsit, M.D., Gabriel Girard, Ph.D., Nicolas Lorente, Ph.D., Marie Préau, Ph.D., James F. Rooney, M.D., Mark A. Wainberg, Ph.D., David Thompson, B.C.L., LL.B., Willy Rozenbaum, M.D., Veronique Doré, Ph.D., Lucie Marchand, B.S., Marie-Christine Simon, B.S., Nicolas Etien, B.S., Jean-Pierre Aboulker, M.D., Laurence Meyer, M.D., Ph.D., and Jean-François Delfraissy, M.D., for the ANRS IPERGAY Study Group*

N Engl J Med 2015; 373:2237-2246 | [December 3, 2015](#) | DOI: 10.1056/NEJMoa1506273

86% HIV risk reduction in MSM using on-demand
PrEP

Dosing matters

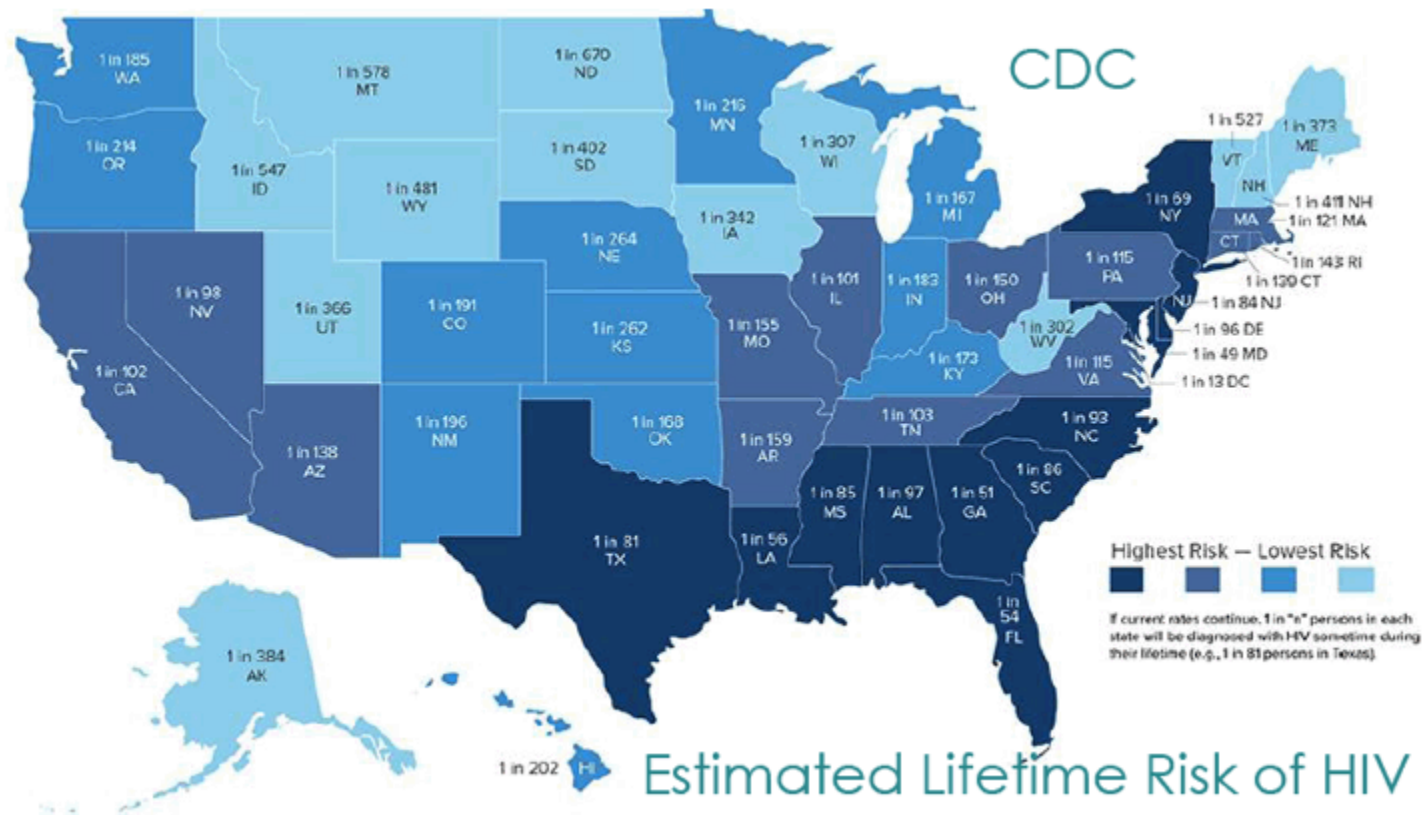


Using drug concentrations in iPrEX and STRAND, pharmacokinetic models predict **76%** risk reduction with 2 doses/week, **96%** with 4 doses/week, and **99%** with 7 doses/week.

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)
IPIRGAY	MSM	On-demand	86%

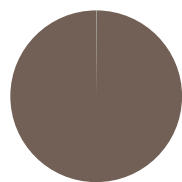
Why PrEP matters



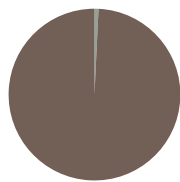
The Southeast remains the region with the highest HIV incidence, which can be markedly reduced with widespread use of pre-exposure prophylaxis (PrEP) among high-risk individuals.



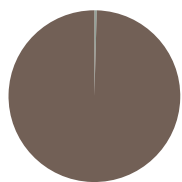
HIV Risk by Race/Ethnicity and MSM



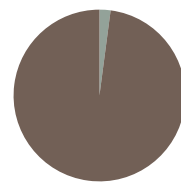
White women
1 in 880



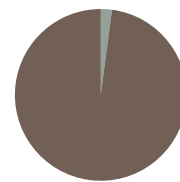
White men
1 in 132



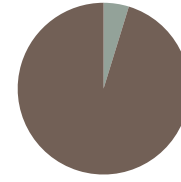
Hispanic women
1 in 227



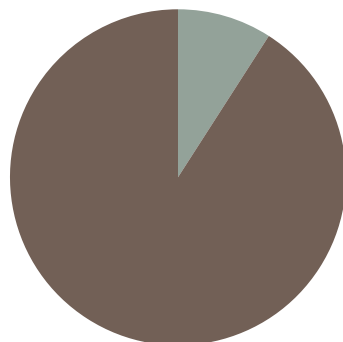
Hispanic men
1 in 48



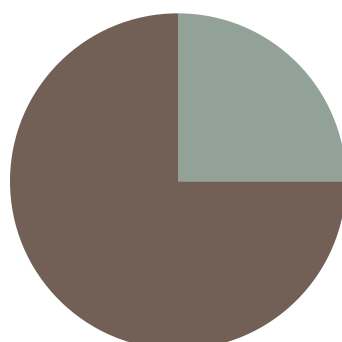
Black women
1 in 48



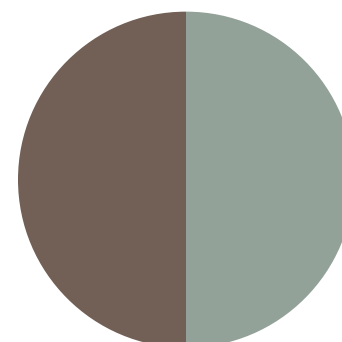
Black men
1 in 20



White MSM
1 in 11



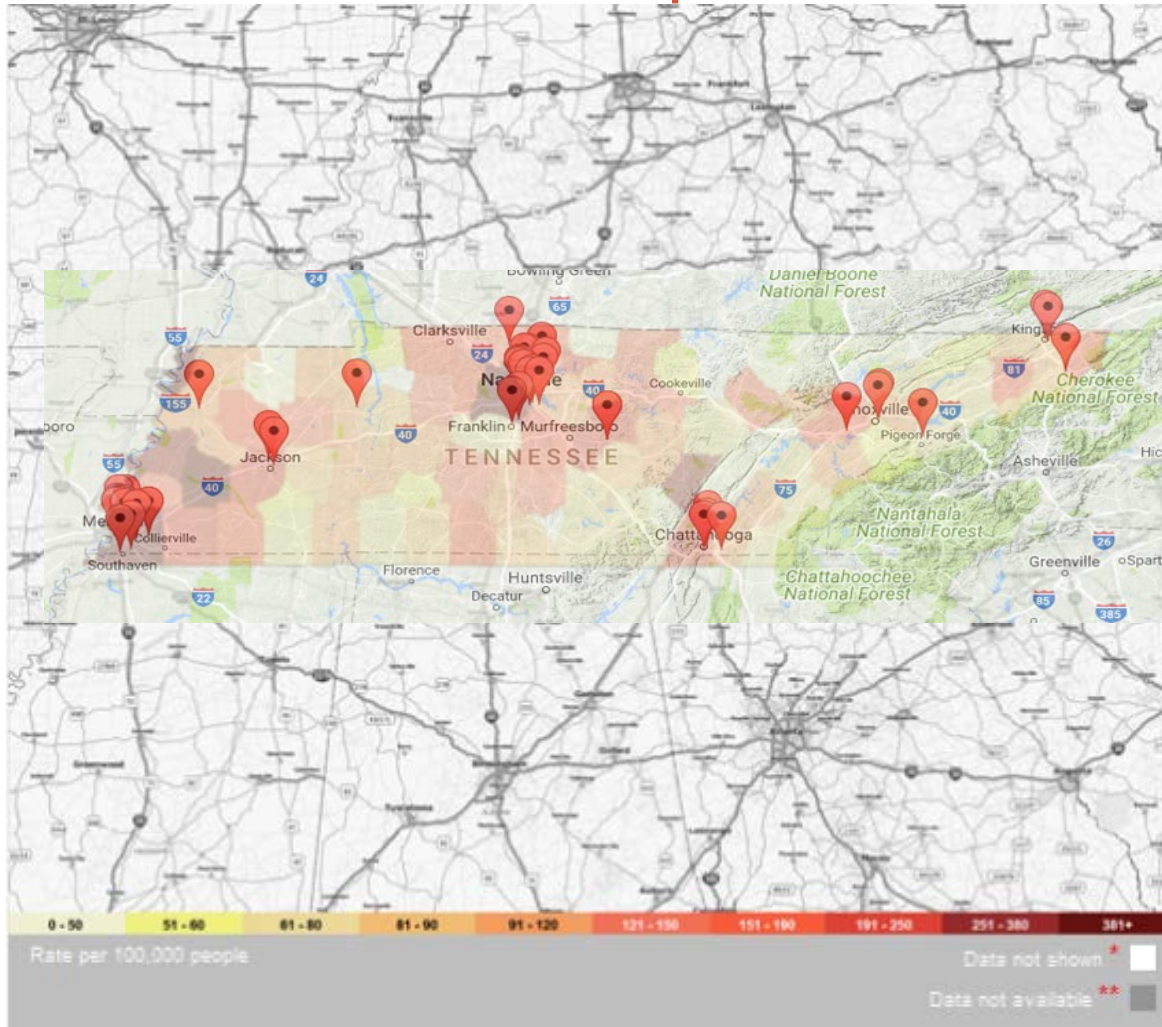
Hispanic MSM
1 in 4



Black MSM
1 in 2

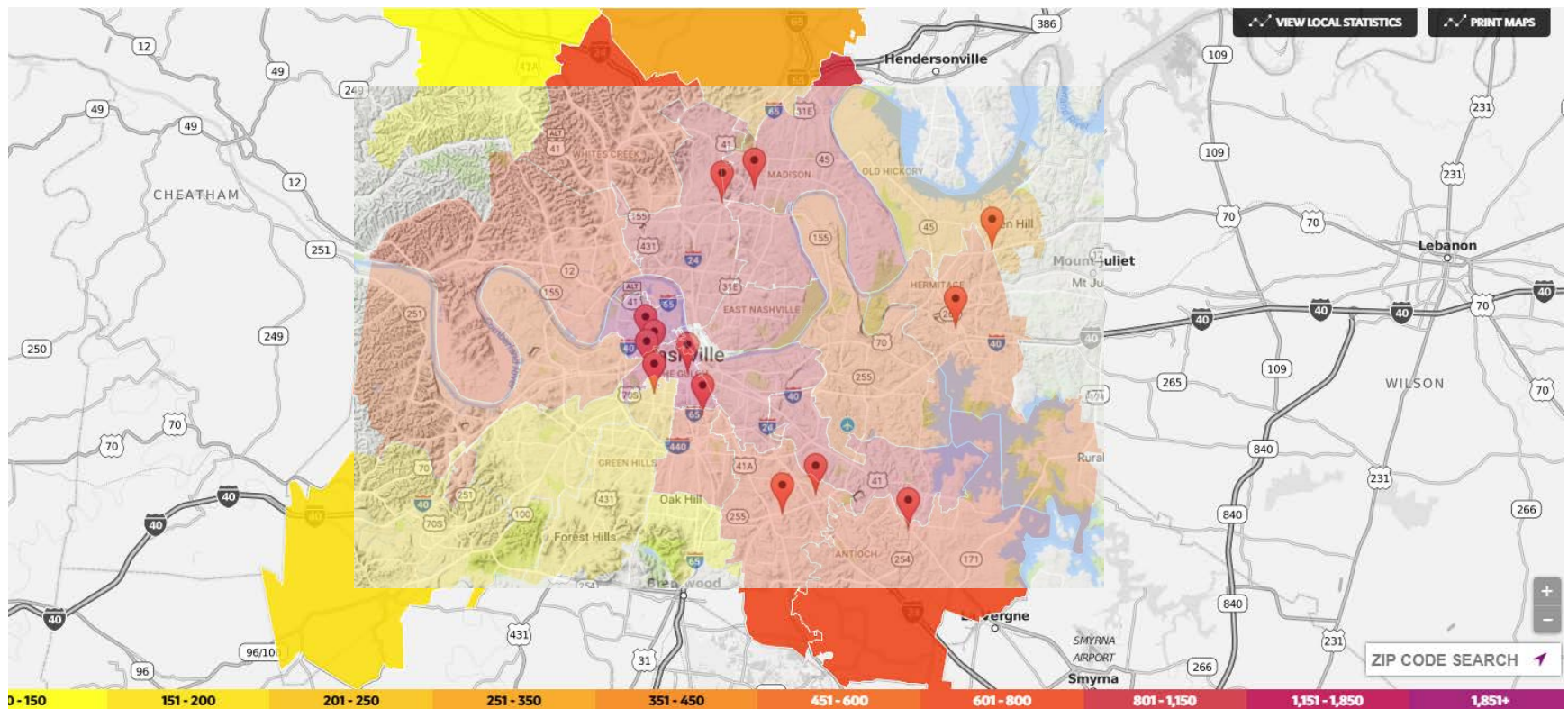
Tennessee

HIV risk and location of PrEP providers



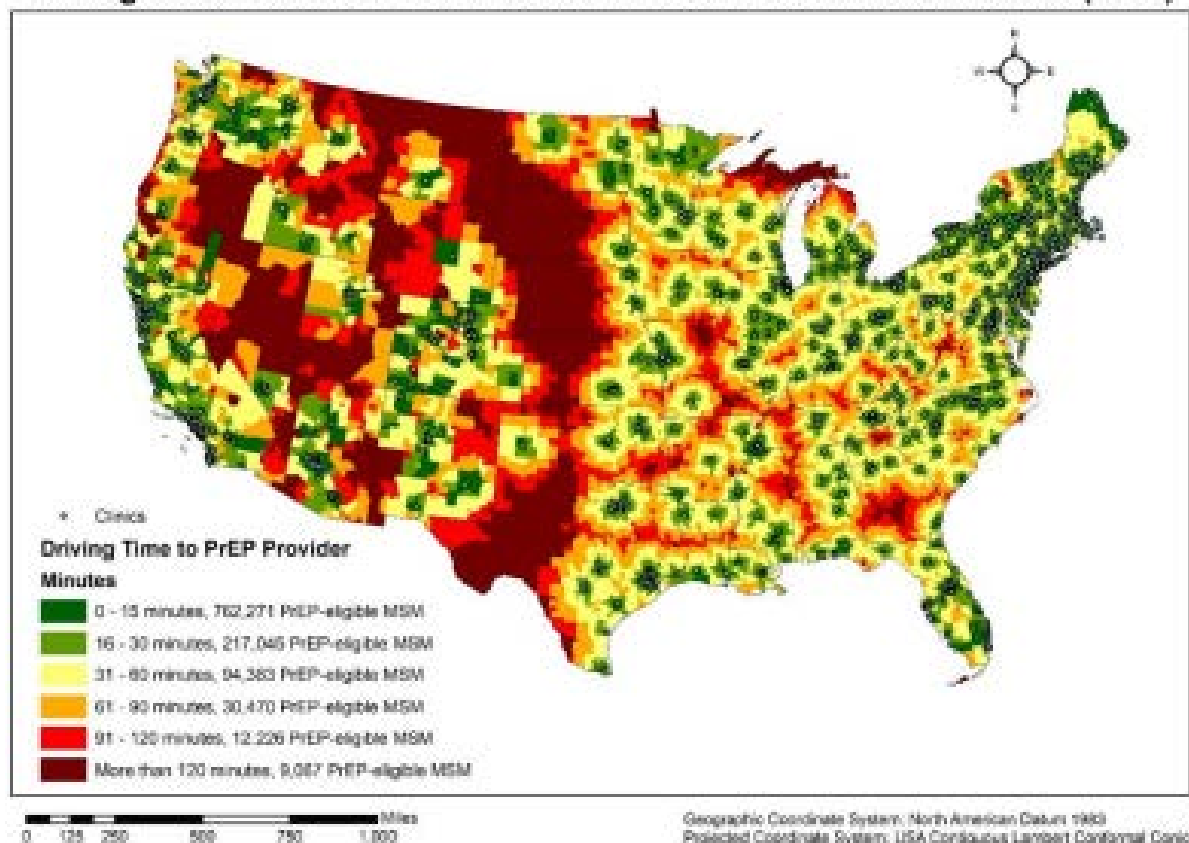
Nashville

HIV risk and location of PrEP providers



PrEP Deserts

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



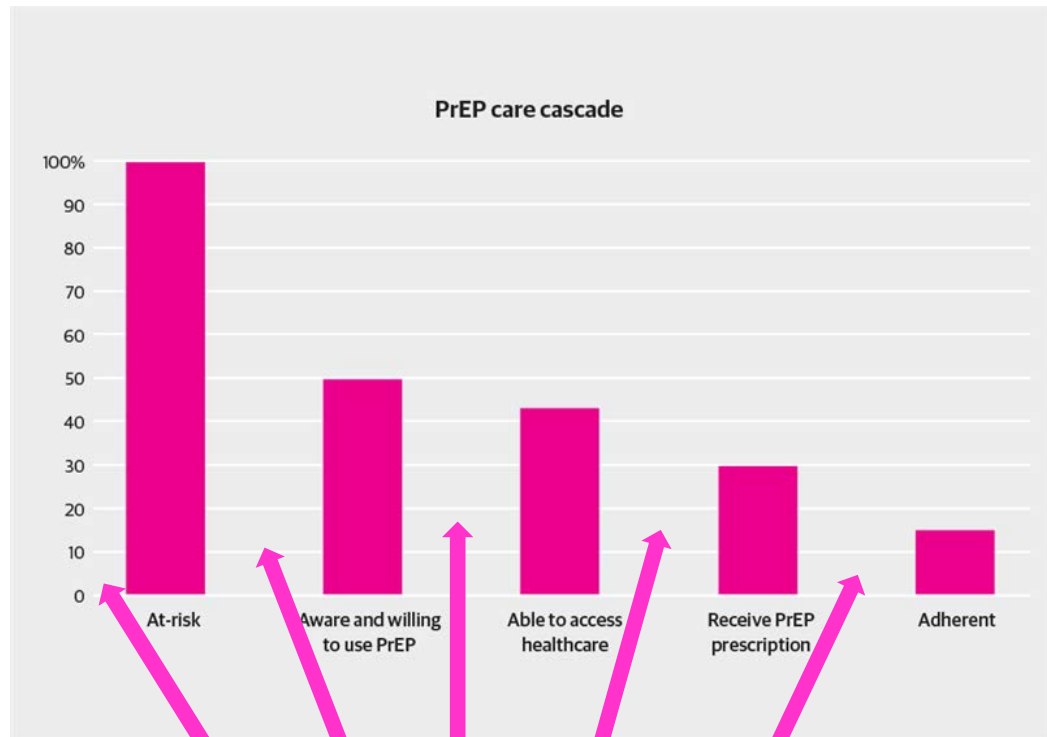
- Most MSM with reduced geographic access to PrEP providers (“PrEP deserts”) reside in the South.
- Over 50% of MSM in the South must drive >60 minutes to a PrEP provider.
- PrEP deserts are generally non-urban areas.

Low PrEP Uptake

- Among recent national surveys, low numbers of primary healthcare providers reported providing PrEP (9%-35%).

The PrEP Care Cascade

- Many barriers exist along the PrEP care cascade.
- Patient-related barriers have been well-characterized across many different populations.
- Provider-related barriers are relatively poorly characterized, though they also exist along the care continuum.

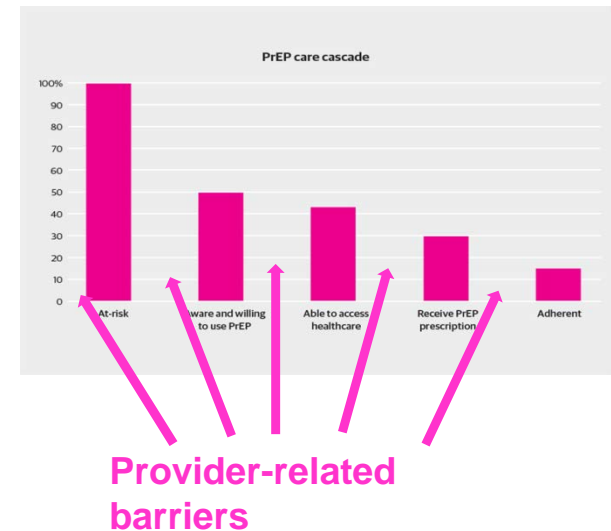


**Provider-related
barriers**

Provider barriers

Knowledge/Attitudes

- Insufficient evidence of efficacy (22%-81%)
- Inexperience with Truvada/lack of knowledge (60%-77.5%)
- PrEP is cost-prohibitive (29%-92%)
- PrEP is not a primary care activity (“not me”) (34%)
- Unfamiliarity with PrEP candidates; inability to assess high HIV risk (61%)

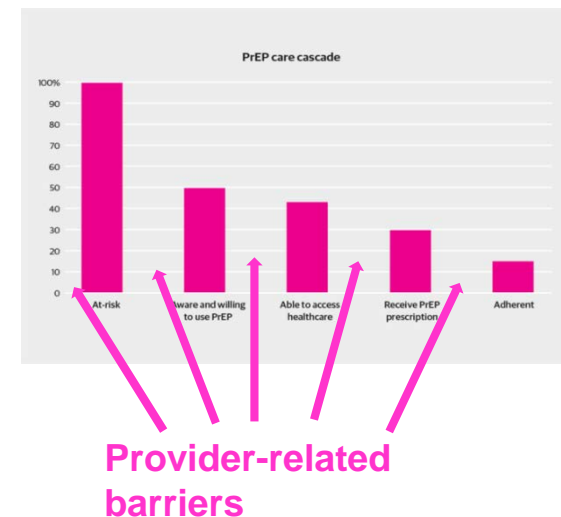


Blumenthal J, et al. *AIDS Behav* 2015;19:802-810.
Karris MY, et al. *Clin Infect Dis* 2014;58:704-712.
Sharma M, et al. *PLoS One* 2014;9:e105283.
Hakre S, et al. *Medicine (Baltimore)* 2016;95:e4511.
Clement ME, et al. *AIDS Care* 2017;1-6.
Martin J, et al. Abstract # 1447. IDWeek, San Diego, October 4-8, 2017.
Imp B, et al. Abstract # 879, IDWeek, San Diego, October 4-8, 2017.

Provider barriers

Knowledge/Attitudes

- Sexual risk compensation (that use of PrEP will lead to increased high-risk behavior) (33%)
- Discomfort using a drug with potential adverse effects in an otherwise healthy person (primary prevention vs. treatment) (67%)
- Patients perceived as non-adherent, and risk HIV resistance mutation development (40%-77%)
- Personal ideology

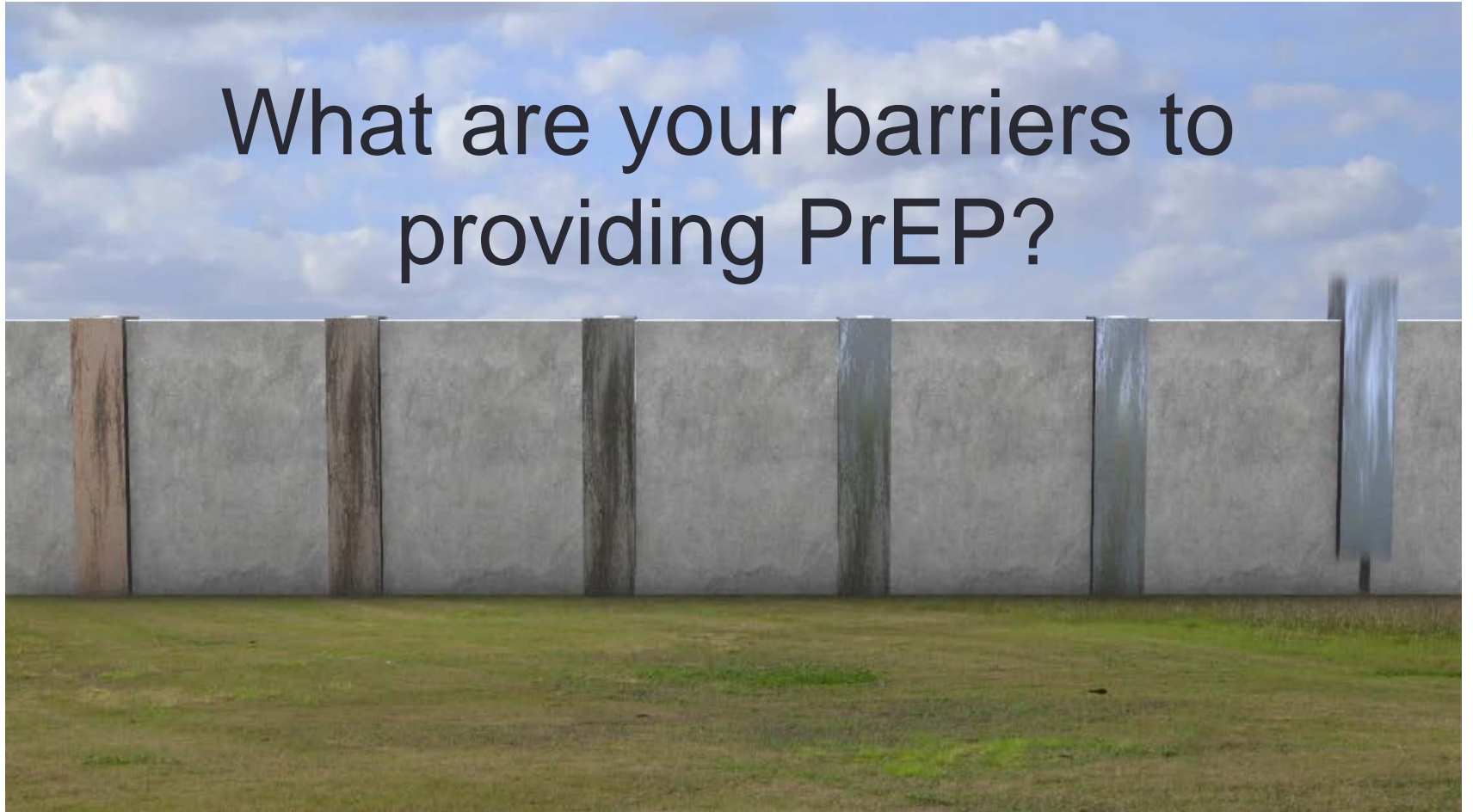


Provider Barriers

Needs for practice transformation

- Nursing support (92%)
- Social work support (90%)
- CME (90%)
- PrEP training event (OR 4.84, CI 1.77–13.21)

What are your barriers to providing PrEP?



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

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

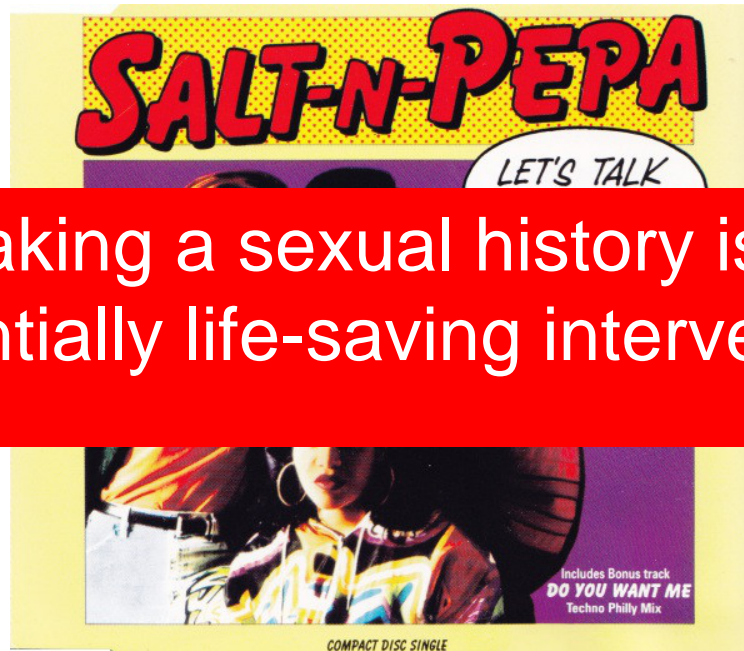
...Ready for it?

- Inquiring about a sexual history and sexual health counseling are part of primary care.
 - *We already do that!*
- The most important tool for assessing HIV risk is your clinical sense.
 - *We already have that!*
- Basic labs are required for Truvada® prescriptions.
 - *We already do that!*
- Most common medications, like Truvada®, require follow-up and monitoring.
 - *We already do that!*

Get comfortable!

- Patients have sex, *in lots of different ways*.
- Patients may not want to discuss this.
- Providers may not feel comfortable discussing this.

Taking a sexual history is a potentially life-saving intervention.



HIV risk is behavioral

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

Taking a sexual history promotes comprehensive STI risk reduction counseling



Condom use
Knowing HIV status
Knowing partner's HIV status
PrEP

Stigma

A preventative measure against the consequences of sexual activity

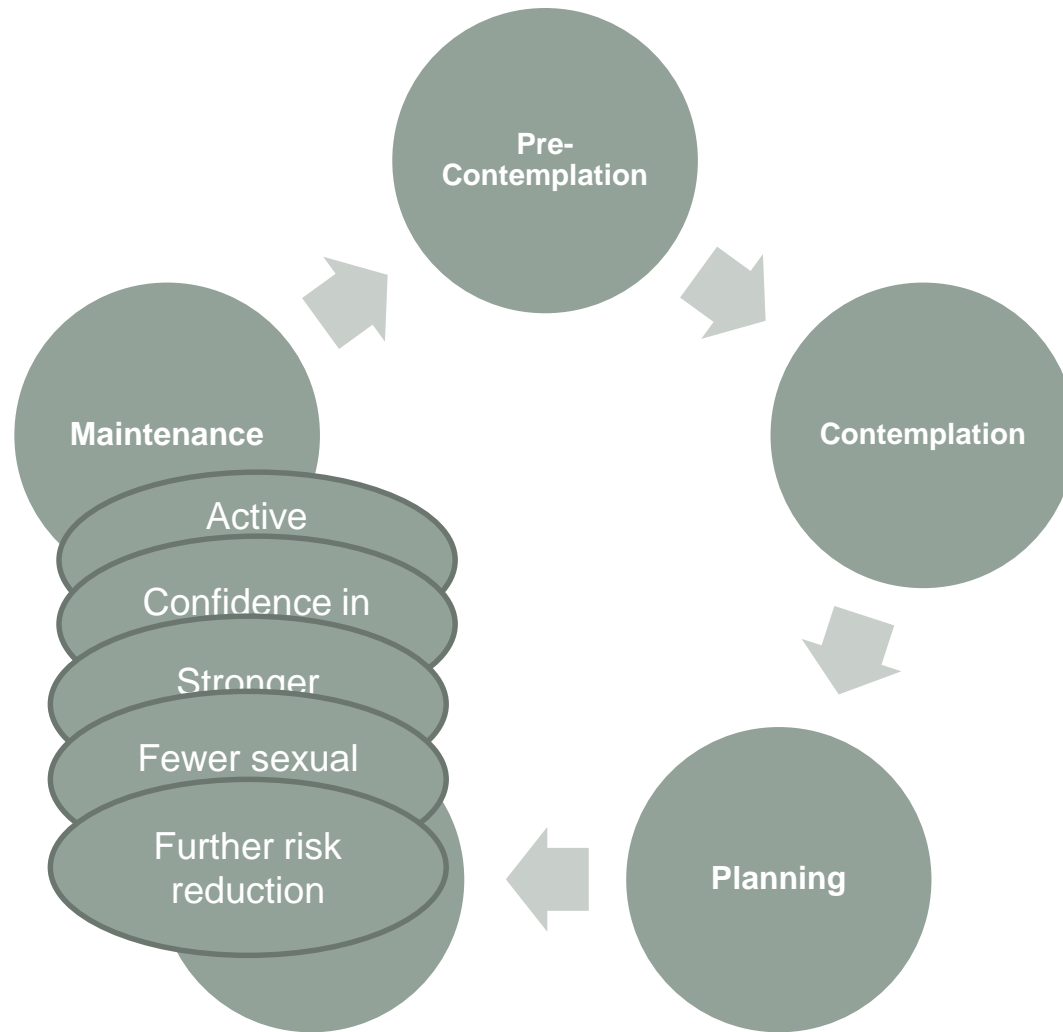
... *condones* sexual activity

... *promotes* sexual activity

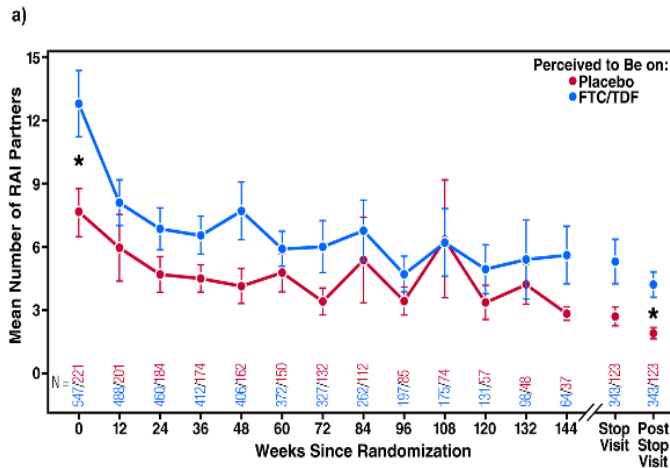
... *causes* sexual activity



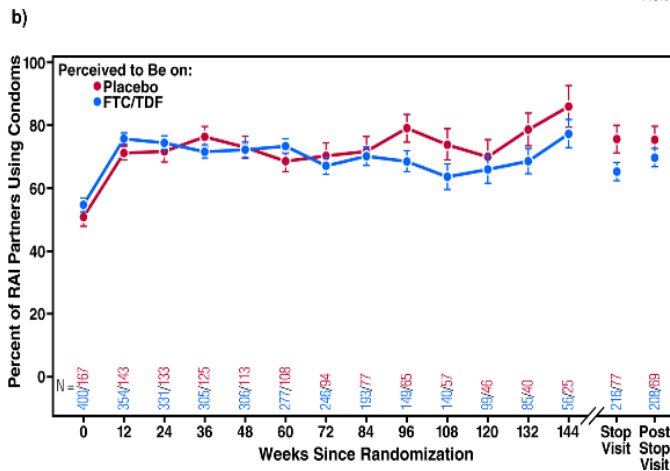
But actually...



No evidence of sexual risk compensation in the iPrEx trial of daily oral PrEP



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



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

Syphilis incidence also decreased in both study arms

Ready, set, PrEP!



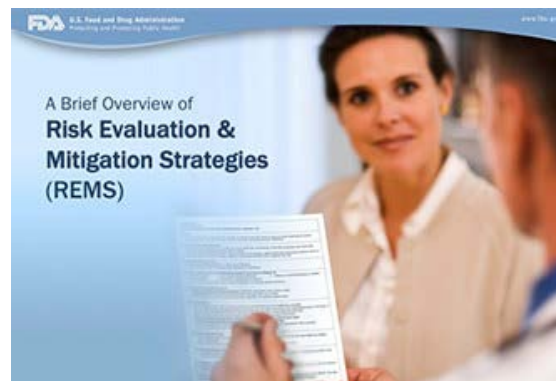


PrEP Clinic Needs

- Provider
- Nursing
 - Assistance in communicating with patient
 - Providing labs and other documents to pharmacy
 - Assisting in completing prior authorization
- Pharmacy
 - Specialty pharmacy partnership highly recommended
- Phlebotomy, blood draws
- Ability to provide treatment and counseling for STIs

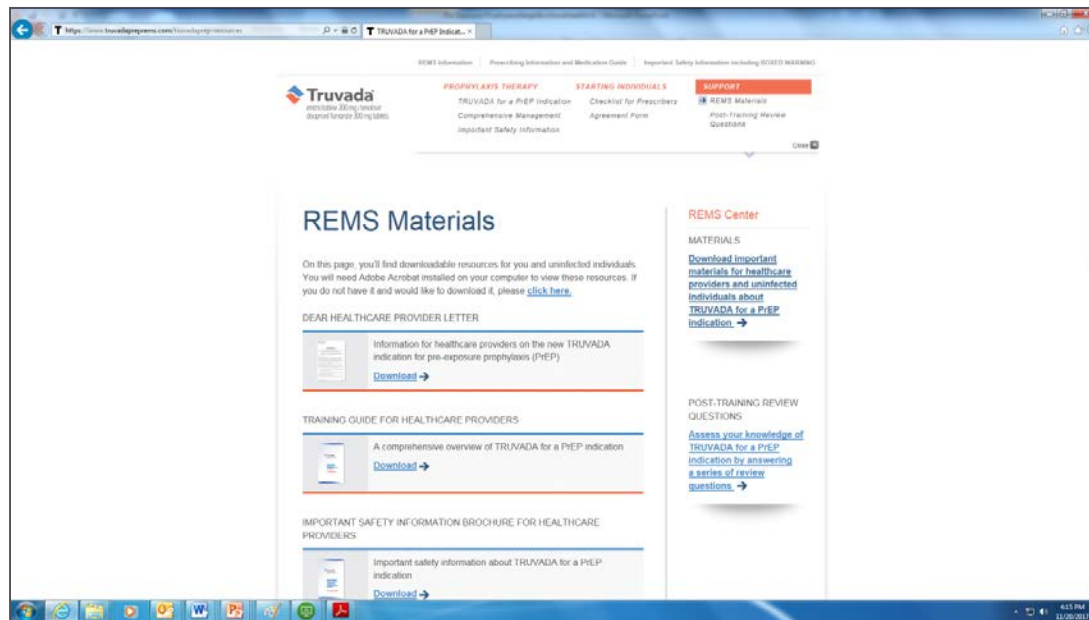
Before prescribing

- Risk Evaluation and Mitigation Strategies (REMS)
 - REMS is a safety strategy to manage risks associated with a drug and to enable continued access to the drug by managing its safe use.
 - REMS is a safety measure beyond the professional labeling to ensure the drug's benefits outweigh its risks.
 - REMS requirements are different for different drugs.



Before prescribing

- Risk Evaluation and Mitigation Strategies (REMS)



<https://www.truvadapreprems.com/truvadaprep-resources>

Before prescribing


Checklist for Prescribers: Initiation of Truvada® for Pre-exposure Prophylaxis (PrEP)

Individual Label


Instructions: Complete checklist at each visit and file in individual's medical record.

I have completed the following prior to prescribing TRUVADA for a pre-exposure prophylaxis (PrEP) indication for the individual who is about to start or is taking TRUVADA for a PrEP indication:

<p>Lab Tests/Evaluation</p> <ul style="list-style-type: none"><input type="checkbox"/> Completed high risk evaluation of uninfected individual<input type="checkbox"/> Confirmed a negative HIV-1 test immediately prior to initiating TRUVADA for a PrEP indication<ul style="list-style-type: none">* If clinical symptoms consistent with acute viral infection are present and recent (<1 month) exposure is suspected, delay starting PrEP for at least 1 month and reconfirm HIV-1 status or use a test approved by the FDA as an aid in the diagnosis of HIV-1 infection, including acute or primary HIV-1 infection. (Note: TRUVADA for a PrEP indication is contraindicated in individuals with unknown HIV-1 status or who are HIV-1 positive)<input type="checkbox"/> Performed HBV screening test<input type="checkbox"/> Confirmed estimated creatinine clearance (CrCl) >60 mL/min prior to initiation and periodically during treatment. In patients at risk for renal dysfunction, assess estimated CrCl, serum phosphorus, urine glucose, and urine protein before initiation of TRUVADA and periodically while TRUVADA is being used. If a decrease in estimated CrCl is observed in uninfected individuals while using TRUVADA for a PrEP indication, evaluate potential causes and reassess potential risks and benefits of continued use<input type="checkbox"/> Confirmed that the uninfected individual at high risk is not taking other HIV-1 medications or HBV medications<input type="checkbox"/> Evaluated risk/benefit for women who may be pregnant or may want to become pregnant	<p>Counseling/Follow-up</p> <ul style="list-style-type: none"><input type="checkbox"/> Discussed known safety risks with use of TRUVADA for a PrEP indication<input type="checkbox"/> Counseled on the importance of scheduled follow-up every 2 to 3 months, including regular HIV-1 screening tests (at least every 3 months), while taking TRUVADA for a PrEP indication to reconfirm HIV-1-negative status<input type="checkbox"/> Discussed the importance of discontinuing TRUVADA for a PrEP indication if seroconversion has occurred, to reduce the development of resistant HIV-1 variants<input type="checkbox"/> Counseled on the importance of adherence to daily dosing schedule<input type="checkbox"/> Counseled that TRUVADA for a PrEP indication should be used only as part of a comprehensive prevention strategy<input type="checkbox"/> Educated on practicing safer sex consistently and using condoms correctly<input type="checkbox"/> Discussed the importance of the individual knowing their HIV-1 status and, if possible, that of their partner(s)<input type="checkbox"/> Discussed the importance of and performed screening for sexually transmitted infections (STIs), such as syphilis and gonorrhea, that can facilitate HIV-1 transmission<input type="checkbox"/> Offered HBV vaccination as appropriate<input type="checkbox"/> Provided education on where information about TRUVADA for a PrEP indication can be accessed<input type="checkbox"/> Discussed potential adverse reactions<input type="checkbox"/> Reviewed the TRUVADA Medication Guide with the uninfected individual at high risk
--	---



Truvada
emtricitabine 200 mg/tenofovir
disoproxil fumarate 300 mg tablets



© 2017 Merck Sharp & Dohme
All rights reserved. 8086-TRV-0000 04/17

<https://www.truvadapreprems.com/truvadaprep-resources>

Patient Intake

- Most new PrEP patients will seek out PrEP
- Since many have no PCP, allow self-referrals
- Consider patient insurance status
 - Cost of medication
 - Cost of quarterly visits
 - Cost of labs
 - Cost of vaccination, parenteral antibiotics and their administrations if patient acquires bacterial STI

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.*

Adverse Event	FTC-TDF (N = 1251)		Placebo (N = 1248)		P Value†
	no. of patients (%)	no. of events	no. of patients (%)	no. of events	
Any adverse event	867 (69)	2630	877 (70)	2611	0.50
Any serious adverse event	60 (5)	76	67 (5)	87	0.57
Any grade 3 or 4 event	151 (12)	248	164 (13)	285	0.51
Grade 3 event	110 (9)	197	117 (9)	225	0.65
Grade 4 event	41 (3)	51	47 (4)	60	0.57
Elevated creatinine level	25 (2)	28	14 (1)	15	0.08
Headache	56 (4)	66	41 (3)	55	0.10
Nausea	20 (2)	22	9 (<1)	10	0.04
Unintentional weight loss (<5%)	27 (2)	34	14 (1)	19	0.04
Unintentional weight loss (≥5%)	27 (2)	34	14 (1)	19	0.04
Death	1 (<1)‡	1	4 (<1)	4	0.18
Discontinuation of study drug					
Permanently	25 (2)	26	27 (2)	33	0.82
Permanently or temporarily	79 (6)	99	72 (6)	92	0.49

* A listing of all laboratory abnormalities and clinical adverse events of grade 2 or higher that were reported in 25 or more subjects (1%) is provided in Tables S9 and S10 in the Supplementary Appendix. FTC-TDF denotes emtricitabine and tenofovir disoproxil fumarate.

† P values were calculated by the log-rank test.

‡ This death was due to a motorcycle accident.

Adverse Events

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

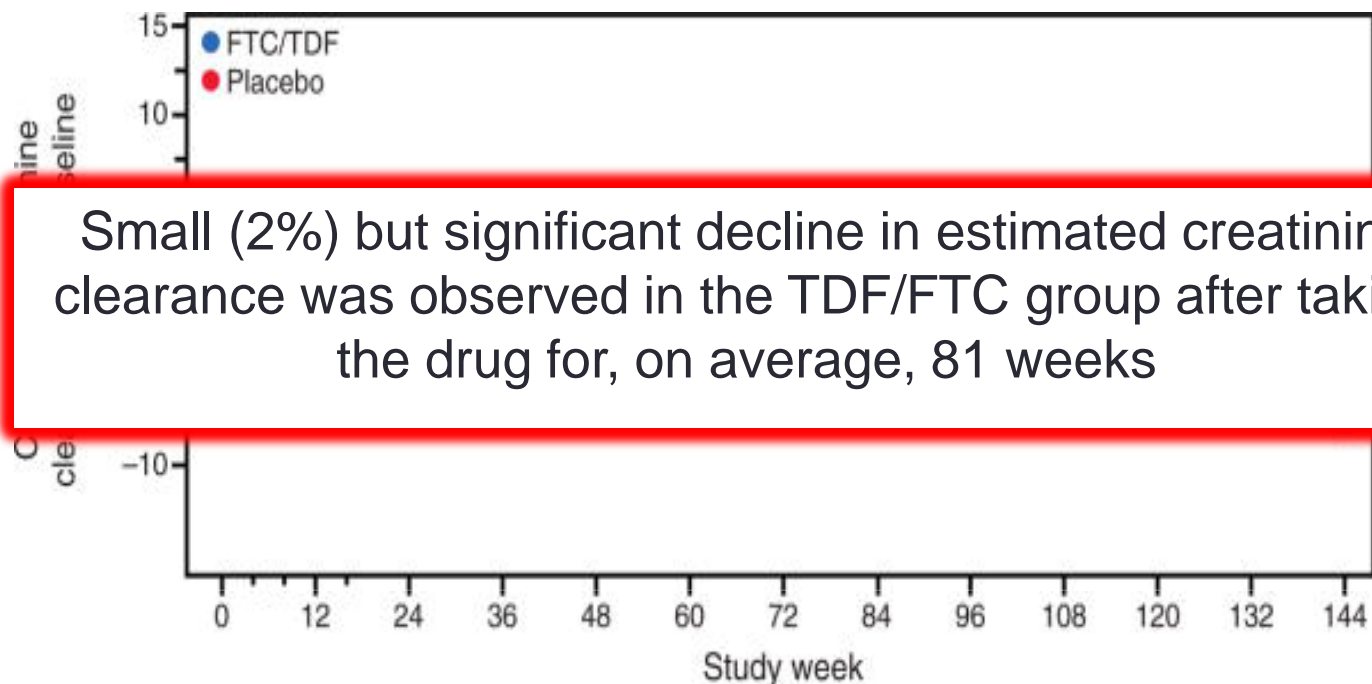
Adverse Event	TDF-FTC (N=611)		Placebo (N=608)		P Value†
	no. of participants (%)	no. of events	no. of participants (%)	no. of events	
Any	557 (91.2)	4357	536 (88.2)	4390	0.003
Any serious	63 (10.3)	68	66 (10.9)	79	0.90
Grade 3 or 4 only	19 (3.1)	21	29 (4.8)	32	0.17
At least possibly related to study 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
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
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



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
T score			0.004			<0.001			<0.001

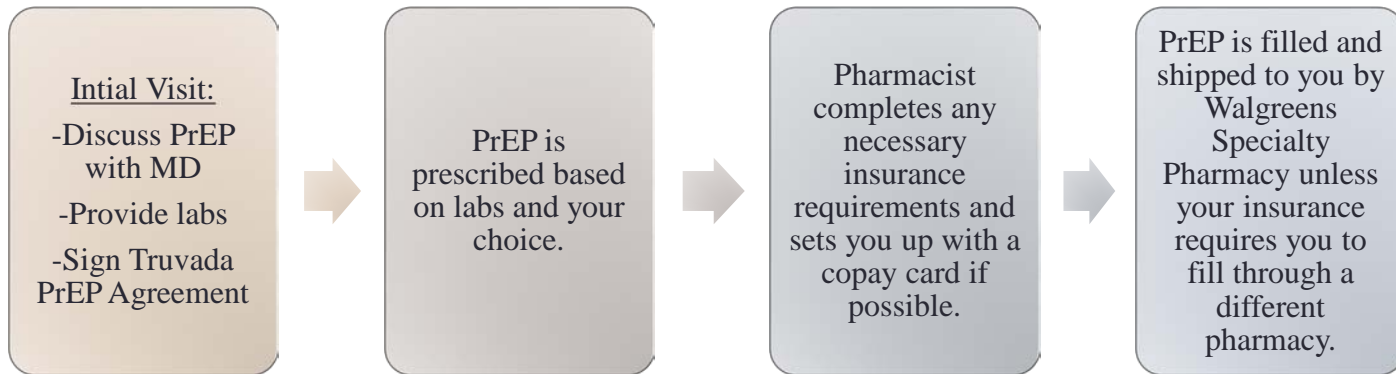
BUT THIS CAN RECOVER!

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.

The First Visit



The First Visit

Agreement Form

for Initiating Truvada® for
Pre-exposure Prophylaxis (PrEP)

Individual Label

Instructions:

Review form with an HIV-negative person who is about to start or is taking TRUVADA for a PrEP indication at each visit. File form in the person's medical record.

TRUVADA is indicated in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk. The following factors may help to identify individuals at high risk:

- Has partner(s) known to be HIV-1 infected, or
- Engages in sexual activity within a high prevalence area or social network and one or more of the following:
 - Inconsistent or no condom use
 - Diagnosis of sexually transmitted infections
 - Exchange of sex for commodities (such as money, shelter, food, or drugs)
 - Use of illicit drugs, alcohol dependence
 - Incarceration
 - Partner(s) of unknown HIV-1 status with any of the factors listed above

Healthcare Provider Agreement

By signing below, I signify my understanding of the risks and benefits of TRUVADA for a PrEP indication and my obligation as a prescriber to educate the HIV-negative person about these risks, counsel the person on risk reduction, monitor the person appropriately, and report adverse events. Specifically, I attest to having done the following:

- Confirmed the negative HIV-1 status of this person prior to starting TRUVADA for a PrEP indication
- Read the Prescribing Information, including the BOXED WARNING
- Discussed with the HIV-negative person the known safety risks with use of TRUVADA for a PrEP indication
- Reviewed the importance of adherence with a comprehensive prevention strategy, including practicing safer sex
- Discussed the importance of regular HIV-1 testing (at least every 3 months) while taking TRUVADA for a PrEP indication
- Reviewed the TRUVADA Medication Guide with the HIV-negative person at high risk prior to prescribing TRUVADA for a PrEP indication
- Completed the items on the Checklist for Prescribers: Initiation of TRUVADA for Pre-exposure Prophylaxis (PrEP)

HIV-Negative Person Agreement

By signing below, I acknowledge that I have talked with my healthcare provider about the risks and benefits of TRUVADA to reduce the risk of getting HIV-1 infection, and I understand them clearly. Specifically, I attest to the following:

- My healthcare provider talked with me about the importance of follow-up HIV-1 testing, and I agree to have repeat HIV-1 screening tests (at least every 3 months) as scheduled by my healthcare provider
- My healthcare provider talked with me about the safety risks involved with using TRUVADA to reduce the risk of getting HIV-1 infection
- My healthcare provider talked with me about a complete prevention strategy and always practicing safer sex by using condoms correctly
- I will talk with my healthcare provider if I have any questions
- I have read the TRUVADA Medication Guide

Healthcare Provider's Signature

Date

HIV-Negative Person's Signature

Date

 **Truvada**
emtricitabine 200 mg/tenofovir
disoproxil fumarate 300 mg tablets

 **GILEAD** © 2017 Gilead Sciences, Inc.
All rights reserved. 10245-170-0029 04/17

<https://www.truvadapreprems.com/truvadaprep-agreement-form#>

The First Visit

- Labs:
 - HIV Ag/Ab
 - Basic Metabolic Panel
 - Hepatitis B sAg, sAb
 - Hepatitis C Ab
 - Treponemal IgG
 - Gonorrhea/chlamydia PCR



The First Visit

- Tips

- If a specialty pharmacy will be used, make sure to document the patient's preferred pharmacy
 - Provides more efficient prescription for azithromycin if +chlamydia!
- Get contact information!
- Taking a sexual history is an excellent opportunity to discuss substance use
- High risk behavior often occurs during travel, so ASK!
- Use patient-friendly terms



PrEP resources for patients

- PrEP welcome packet
 1. Truvada® medication guide
 2. CDC PrEP medication information sheet for patients
 3. Patient/Provider Agreement
 4. PrEP Action Plan and Next Steps
 5. Walgreens Specialty Pharmacy contact information
 6. Additional PrEP resources

PrEP resources for patients

Page 1 of 2

About Truvada

Truvada (tenofovir and emtricitabine) is a medicine used to treat human immunodeficiency virus (HIV) and hepatitis B virus infection.

It is also used to prevent HIV infection. When you take Truvada to prevent HIV infection, this is called "pre-exposure prophylaxis" or "PrEP."

How does Truvada help prevent HIV infection?

If you take Truvada daily, it can sometimes stop the virus from spreading through your body. It does not work all the time, so you should still use condoms during sex to get the most protection from HIV infection.

How should Truvada be used?

- You must take one Truvada tablet by mouth every day.
- Follow the directions on your prescription label carefully. Ask your doctor or pharmacist to explain any part you do not understand.
- Do not stop taking Truvada without talking to your doctor. When you start to run low on your medicine, contact your doctor or pharmacist to get more.
- You may be at higher risk of getting infected with HIV if you miss doses or stop taking Truvada than if you take it every day.

HC 131 (04/2017)

Is there anything I should do before I start taking Truvada?

VANDERBILT UNIVERSITY MEDICAL CENTER

HIV Pre-Exposure Prophylaxis Action Plan

Welcome to the Comprehensive Care Center at Medical Center. Our dedicated team of physicians through getting started on Pre-Exposure Prophylaxis your risk of acquiring HIV. While you are on PrEP together to make sure you receive the best care and We are here to answer any questions or concerns

What's next?

Initial Visit:
-Discuss PrEP with MD
-Provide labs
-Sign Truvada PrEP Agreement

PrEP is prescribed based on labs and your choice.

Pharmacist completes insurance requirements and sets up your copy of PrEP.

Contact information:
Vanderbilt Comprehensive Care Center: (615) 875-5111
Walgreens Specialty Pharmacy: (615) 321-1808

Agreement Form for Initiating Truvada® for Pre-exposure Prophylaxis (PrEP)

Instructions:
Review form with an HIV-negative person who is about to start or is taking TRUVADA for a PrEP indication at each visit. File form in the person's medical record.

TRUVADA is indicated in prophylaxis (PrEP) to reduce risk. The following factors increase risk:

- Has partner(s) known to have HIV
- Engages in sexual activity and one or more of the following:
 - Inconsistent or no condom use
 - Diagnosis of sexually transmitted infection
 - Exchange of sex for money, drugs, or other favors
 - Incarceration
 - Partner(s) of unknown HIV status

Healthcare Provider Agreement

By signing below, I signify my understanding of the risks and benefits of TRUVADA for a PrEP indication and my obligation as a prescriber to educate the HIV-negative person about these risks, counsel the person on risk reduction, monitor the person appropriately, and report adverse events. Specifically, I attest to having done the following:

- Confirmed the negative HIV-1 status of this person prior to starting TRUVADA for a PrEP indication
- Read the Prescribing Information, including the BOXED WARNING
- Discussed with the HIV-negative person the known safety risks with use of TRUVADA for a PrEP indication
- Reviewed the importance of adherence with a comprehensive prevention strategy, including practicing safer sex
- Discussed the importance of regular HIV-1 testing (at least every 3 months) while taking TRUVADA for a PrEP indication
- Reviewed the TRUVADA Medication Guide with the HIV-negative person at high risk prior to prescribing TRUVADA for a PrEP indication
- Completed the items on the Checklist for Prescribers: Initiation of TRUVADA for Pre-exposure Prophylaxis (PrEP)

Healthcare Provider's Signature _____ Date _____

Individual Label

Learn More About PrEP

- AIDS.gov** – PrEP information page (<https://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/pre-exposure-prophylaxis/>)
- AIDSinfoNet** – Reliable, up-to-date treatment information (http://aidsinfo.net/infact_sheets/view/160)
- AVAC** – Global Advocacy for HIV Prevention (<http://www.avac.org/prevention-option/prep>)
- Avert** – AVERTing HIV and AIDS (<https://www.avert.org/hiv-transmission-prevention/prep>)
- CDC** – Questions and answers from the Centers for Disease Control and Prevention (<https://www.cdc.gov/hiv/basics/prep.html>)
- My PrEP Experience** – Real stories from real people who adopted PrEP for HIV prevention (<http://myprepexperience.blogspot.com/>)
- PrEP Facts** – San Francisco AIDS Foundation PrEP information in visual format for MSM and heterosexual individuals, with an option for Spanish (<https://prepfacts.org/>)
- PrEP Watch** – Interactive webpage with information and resources on gaining access to PrEP (<http://www.prepwatch.org/>)
- PrEParing for HIV** – An Epidemic Interventions Initiative by the University of California (<http://www.uctv.tv/prep/>)
- Project Inform** – Videos, publications and resources (<http://www.projectinform.org/prep/>)
- SFHVH** – City and County of San Francisco Department of Public Health's PrEP information page (<http://www.sfhv.org/resources/prep/>)
- Talk PrEP** – AIDS Action Committee's new PrEP campaign encouraging everyone to Do It Daily (<http://talkprep.org/>)
- Guidance for Use of PrEP in Practice and Research Settings**
WHO – World Health Organization (http://www.who.int/hiv/pub/guidance_prep/en/)
CDC – Centers for Disease Control and Prevention (<https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf>)
- From the Makers of Truvada**
start.truvada.com – Information about Truvada for PrEP for healthcare providers, consumers and educators
<http://www.truvadaprep.com/truvadaprep-resources> - Downloadable forms and resources for PrEP prescribers and users

Prescribing process

Specialty Pharmacy

- Specialty Pharmacy may complete all prior authorization and copay assistance requirements and connect with the patient
- May also send the prescription and prior authorizations to another pharmacy if the patient requests this



Prescribing process

Specialty Pharmacy

- Send prescription electronically to Specialty Pharmacy
 - 30 tabs, 2 refills (total 90-day supply)
- When HIV screen and serum creatinine are available, send message to clinic RN to fax lab results to pharmacy
- Pharmacy contacts patient for further counseling and to arrange PrEP delivery
- Pharmacy contacts patient intermittently over 6 months to assess tolerability and adherence

Prescribing Process

No Specialty Pharmacy

- Send prescription to pharmacy
- Follow HIV screen, serum creatinine
- Complete PA if required (VERY few insurance companies still require this)
 - Information requested: last date of screening and sometimes PrEP Agreement form
- Copay card
 - Gilead copay card: \$4800/year benefit
 - <https://www.gileadadvancingaccess.com/copay-coupon-card>
 - Federal beneficiaries not eligible

Prior Authorization

STEP 1: CLEARLY PRINT AND COMPLETE TO EXPEDITE PROCESSING	
Date: 02/28/2017	Prescriber First & Last Name: Sean Kelly
Patient First & Last Name:	Prescriber NPI: 1932477171
Patient Address:	Prescriber Address: 1211 21st Ave S Suite 102A Nashville TN 37232
Patient ID:	Prescriber Phone: 615-936-1174
Patient Date of Birth:	Prescriber Fax: 615-375-0666
STEP 2: COMPLETE REQUIRED CRITERIA: COMPLETE ONE OF THREE	
DIAGNOSIS A: Coverage for Human Immunodeficiency Virus (HIV) or Hepatitis B Virus (HBV) Infected patients (Approve for Lifetime) <input type="checkbox"/> Prescribed for the active treatment of HIV or HBV	
DIAGNOSIS B: Post-Exposure Prophylaxis (Approve for 1 Month) <input type="checkbox"/> Prescribed for post-exposure prophylaxis following suspected or confirmed Human Immunodeficiency Virus (HIV) exposure	
DIAGNOSIS C: Pre-Exposure Prophylaxis (Initial Coverage) (Approve for 3 Months) <input type="checkbox"/> Patient is at high risk for contracting Human Immunodeficiency Virus (HIV) due to sexual transmission and receiving TRUVADA for pre-exposure prophylaxis. If not due to sexual transmission, please explain other reason patient is at high risk for contracting HIV: _____ AND <input type="checkbox"/> Patient is \geq 18 years of age AND <input type="checkbox"/> Patient is HIV negative: Please provide date of last test: _____ AND <input type="checkbox"/> Prescriber has completed the REMS Prescriber Checklist: http://www.truvadapreprems.com/Content/pdf/Checklist_for_Prescribers.pdf AND <input type="checkbox"/> Patient and prescriber have signed the REMS Agreement Form and it is saved in the patient's medical chart: http://www.truvadapreprems.com/Content/pdf/Agreement_Form.pdf Please provide expected duration of treatment: _____	
DIAGNOSIS D: Pre-Exposure Prophylaxis (Continuing Coverage) (Approve for 3 Months) <input checked="" type="checkbox"/> Patient is Human Immunodeficiency Virus (HIV) negative Please provide date of last test: 12/30/2016	
STEP 3: SIGN AND FAX TO: NAVITUS PRIOR AUTHORIZATION AT: 855-668-8551	
Prescriber Signature: <u>Sean Kelly, MD</u>	Date: <u>2-28-17</u>
If patient meets criteria, allow 2 business days for processing	

Other Cost Options

ARE YOU INSURED TO COVER YOUR COSTS FOR PrEP?



projectinform.org/prep-chart
800-822-7422

YES

(employer, private, insurance marketplace, COBRA, Medicare, Medicaid)

1

Gilead Advancing Access Co-pay Card

gileadcopay.com
877-505-6986

- \$3,600 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.

2

Patient Access Network Foundation

panfoundation.org/hiv-treatment-and-prevention
866-316-7263

- \$8,000 max/year, re-apply
- Income <500% FPL (\$60,300)
- Based on taxable income (1040 line 7, 1040 EZ line 1)
- Must be insured (as listed under "YES" above)
- Covers co-pays, deductibles and co-insurance
- US resident
- Pharmacies can bill PAN Foundation directly

These programs may be subject to funding shortfalls, which may limit enrollment.

3

Patient Advocate Foundation (PAF)

<https://www.copays.org/diseases/hiv-aids-and-prevention>

- \$7,500 max/year, re-apply
- Income <400% FPL (\$48,240)
- 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)

FSA (flexible spending account)

If employer offers an FSA, it can help cover up to \$2,550 of out-of-pocket costs.

On Medicaid?

Medicaid should cover medical costs related to PrEP. If you encounter barriers to coverage, consult a legal advocate.

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 for people earning up to 250% FPL (\$30,150). Gold & Platinum plans offer better coverage if you can afford them. Carefully select the right plan for you.

Special enrollment

You can get insurance during the rest of the year for "qualifying life events" such as: pregnancy, loss or change of job, change in household size, change in income, recent move, change in citizenship.

FEB 1 – OCT 31

below 138% FPL / yr (< \$16,643)

above 138% FPL / yr (> \$16,643)

NON-RESIDENT/
UNDOCUMENTED?

To get care, find a public clinic (FQHC) that serves undocumented patients. (findahealthcenter.hrsa.gov)

Check if you can get an insurance plan through marketplace/employer.

IF NO

What's your income?

below

60,300

above

Enroll in the Gilead MAP.

www.truvada.com/truvada-patient-assistance

500% FPL (2017 FPL: \$12,060 taxable income → \$4,180 per dependent, higher FPL in Alaska and Hawaii, 1040 tax form line 7, 1040 EZ line 1)
— only drug costs —
<https://tinyurl.com/FPLIncomes>

Retail cost of Truvada

If you're a resident, these state plans may also help:

- COLORADO: <https://tinyurl.com/COprepAP>
- ILLINOIS: <https://tinyurl.com/ILprepAP>
- MASSACHUSETTS: <https://tinyurl.com/MAPrepDAP> (cost of drug, services)
- WASHINGTON: <http://tinyurl.com/WAprepDAP> (cost of drug)
- NEW YORK: <http://tinyurl.com/NYprepAP> (cost of services)

UPDATED AS OF
FEBRUARY 10, 2017

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”
- Note: Can also bill by time, >25 minutes = level 4
- Not coded
- Z72.52 – High risk homosexual behavior

The Second Visit

- Repeat HIV screen, repeat serum creatinine
- 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 3 months

- HIV screen
- 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

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



A year of PrEP

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

Labs:

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

Prescriptions/Refill authorizations: 5

Discussions: 5+

Advertise!

Pre-Exposure Prophylaxis (PrEP) at the Vanderbilt Comprehensive Care Center

If you have a partner who is not HIV-infected, the Vanderbilt Comprehensive Care Center now offers pre-exposure prophylaxis (PrEP) to reduce his or her risk of HIV infection.

PrEP is an HIV-prevention strategy. It is a pill taken once daily, containing some of the same drugs used to treat HIV. If taken by an individual at high risk of getting HIV, PrEP can reduce the risk of HIV infection by more than 90%.

If your partner is interested in PrEP, set up an appointment with a PrEP provider at the Vanderbilt Comprehensive Care Center PrEP program.



VANDERBILT
MEDICAL CENTER



PROTECT YOURSELF WITH PREP

How many people are at risk of HIV infection?

Newer studies have found a more effective tool at reducing HIV risk than pre-exposure prophylaxis ("PrEP"). PrEP is a daily medication for those who are at high risk of acquiring HIV. When taken as directed, it can reduce the risk of HIV by over 90%. Surprisingly, this medication is not particularly new, it was approved in 2010, but its use was somewhat slow to catch on, particularly in the South. The South, however, is the US region with the most new HIV infections. Throughout the US, the risk for HIV remains alarmingly high for certain groups. White men who have sex with men (MSM) have a higher risk of HIV infections of one in seven, and Black MSM have a higher HIV risk of one in two. PrEP is our best tool to keep people at such high risk uninfected, and

REPORTER

SEARCH

FOR MEDIA

Combination therapy PrEP offers effective way to prevent HIV infection

by Bill Snyder | Thursday, Sep. 7, 2017, 9:44 AM



Infectious disease experts Katie White, M.D., Ph.D., and Sean Kelly, M.D., are working to raise awareness of effective ways to prevent HIV infection, including the combination drug therapy called pre-exposure prophylaxis, or PrEP. (photo by Daniel Dubois)

Rates of new HIV infections in the United States are declining — except among men who have sex with men. Rates are particularly high among African-American and Hispanic men and especially in the South.



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

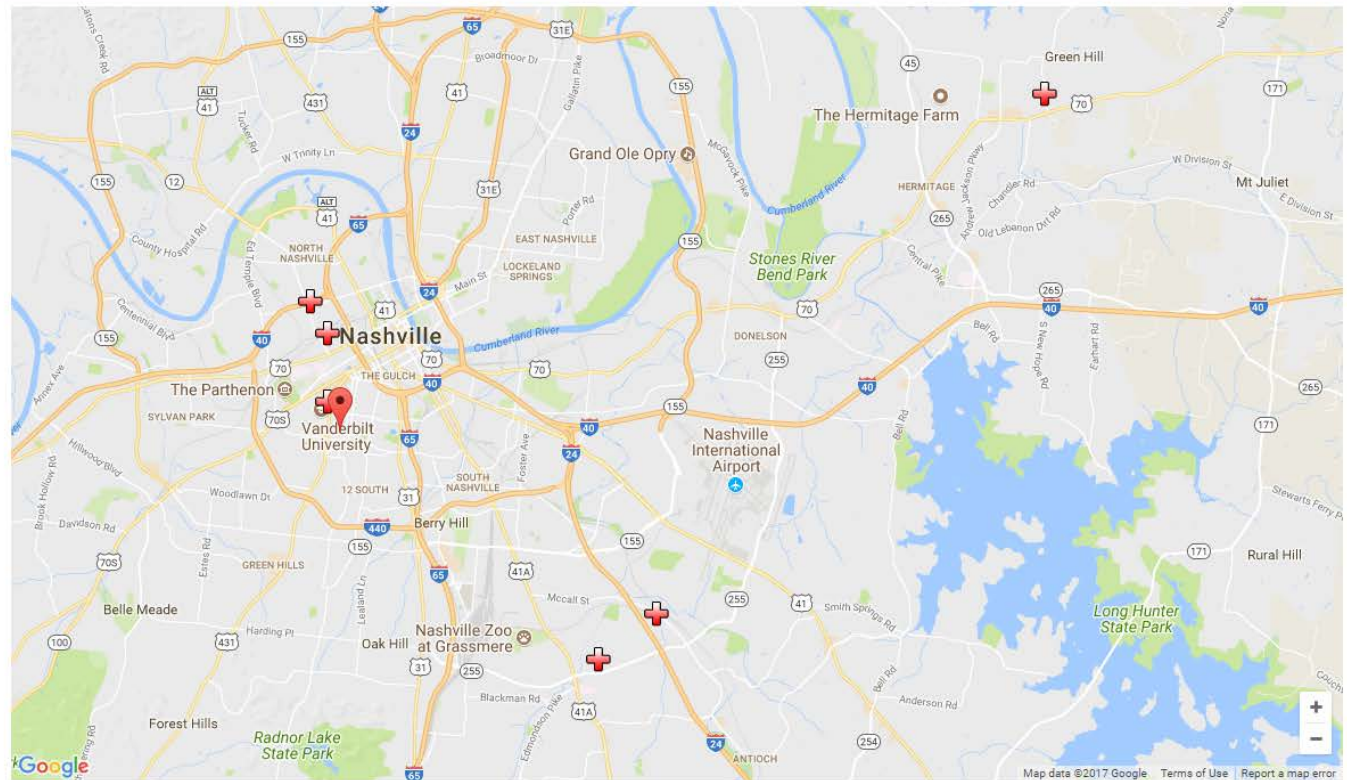
Distance from your location: 6 miles

Neighborhood Health @ MyHouse

42 Metroplex Drive
Building 4
Nashville, TN 37211

[Add PrEP Locator to Your Site](#)

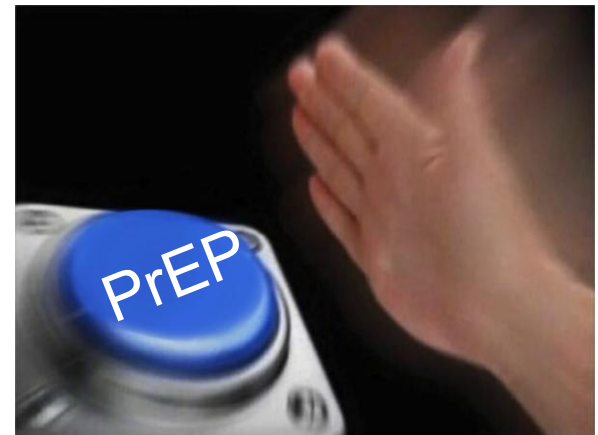
[Suggest a provider for the directory](#)



<https://preplocator.org>

Conclusion

- PrEP is an extremely effective preventive strategy
- Many PrEP barriers exist, but can *easily* be overcome
- Understand PrEP prescribing guidelines
- Evaluate individual clinic needs
- Identify individual beliefs and perceptions
- Ask for help!
sean.g.kelly@vanderbilt.edu



Questions?