

PRE-EXPOSURE PROPHYLAXIS AND THE SEXUAL HISTORY

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Vanderbilt Division of Infectious Diseases

April 12, 2019

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
- Future directions of PrEP

Secondary Objectives

- Increase your confidence in providing PrEP!
- Improve your ability to take a sexual history!




PrEP is primary prevention

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

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

But what is PrEP, really?

- Truvada® 
 - Fixed dose combination of tenofovir disoproxil fumarate (TDF) 300mg/emtricitabine (FTC) 200mg
 - Developed by Gilead
 - FDA-approved for use as PrEP for adults on June 6, 2012
 - FDA-approved for use as PrEP for adolescents on May 15, 2018
- Generic TDF/FTC approved June 2017 (but not yet available)

For this talk: PrEP = Truvada® = TDF/FTC

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®	Atorvastatin Rosuvastatin Pravastatin Pitavastatin Simvastatin Fluvastatin Aspirin

Primary Prevention

	HIV	Myocardial Infarction
Assess risk	Take a sexual history	Review medical history, family, 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

How well does PrEP work?

(spoiler alert: very well)

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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



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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



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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., Aloysius Kakia, 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



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ORIGINAL ARTICLE

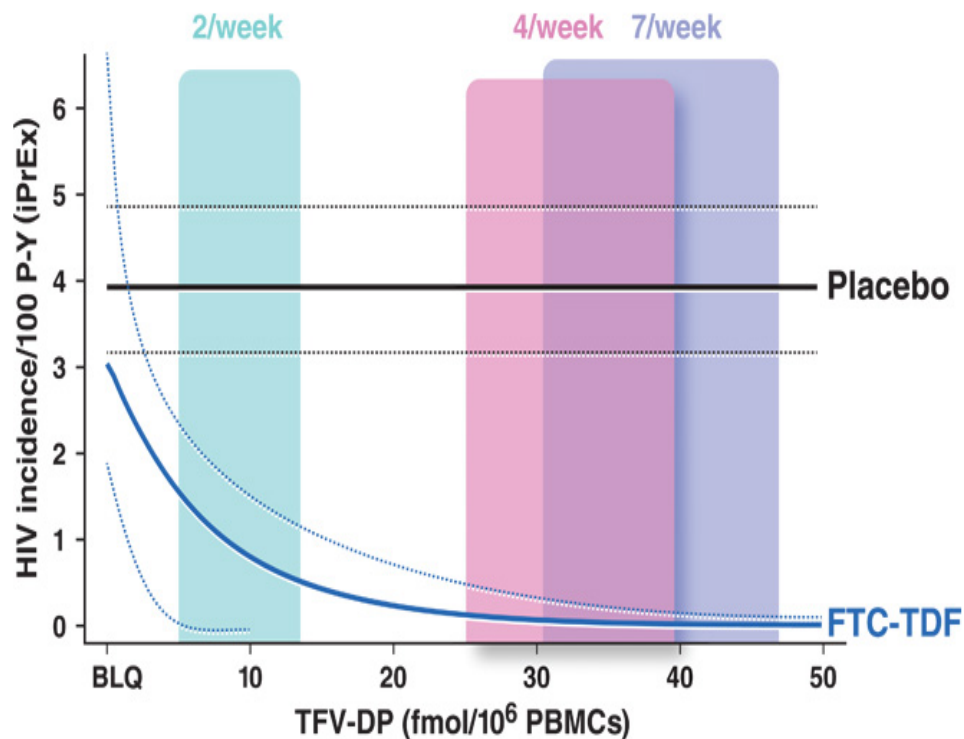
On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-1 Infection

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%

PrEP and adolescents

- Adolescent Trial Network
 - 78 HIV-negative MSM, ages 15-17, who reported HIV risk behavior during the previous 6 months received daily PrEP
 - Follow-up monthly for 12 weeks, then quarterly for the remainder of 48-week study
 - Adherence was high during monthly follow-up
 - 95% with detectable TDF drug levels at 12 weeks
 - After 12 weeks, adherence dropped dramatically (by more than half)
 - 32 discontinued before the end of the study
 - HIV acquisition rate: 3 new infections, 6.4 per 100 person-years

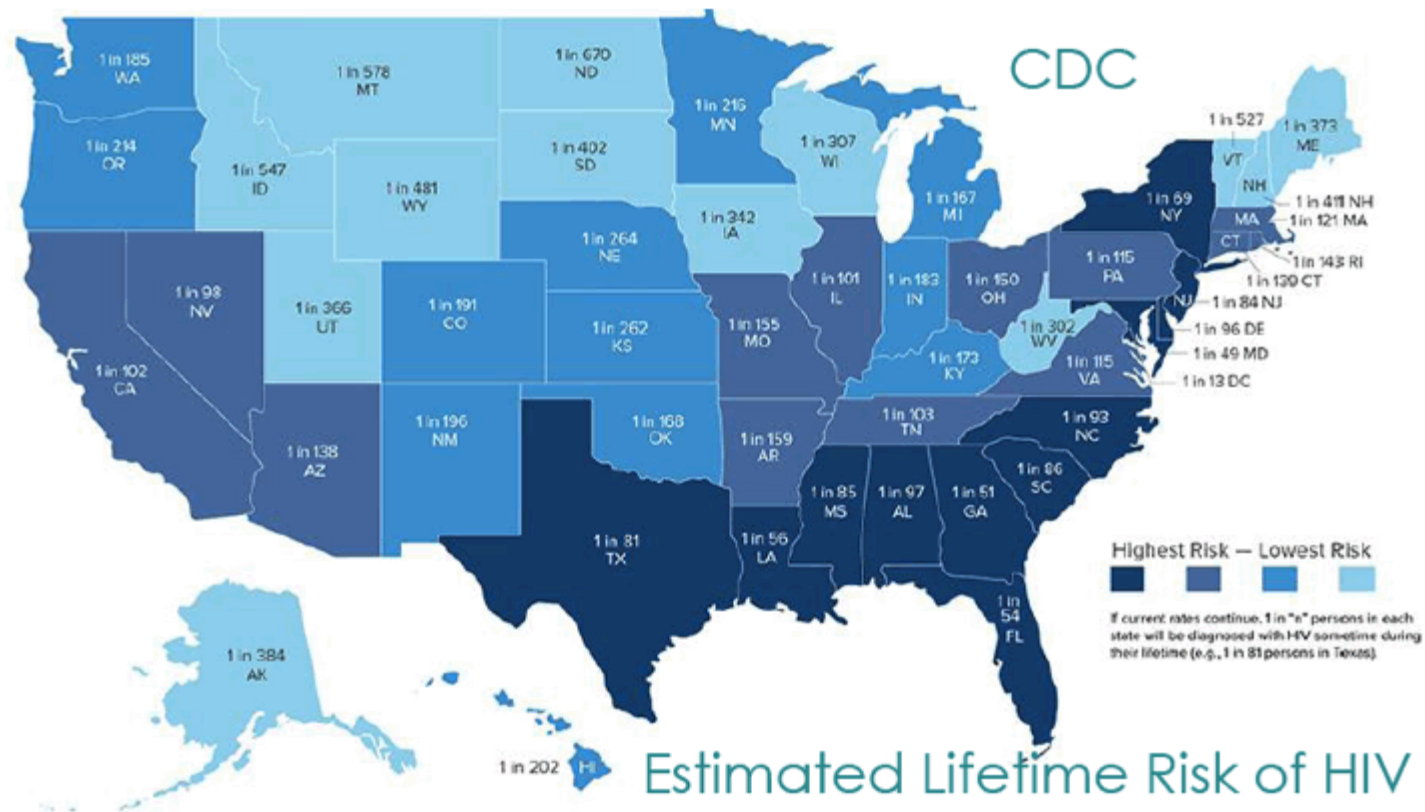
Adolescent Trials Network

- Safety and acceptability
 - PrEP was well-tolerated
 - No discontinuations due to adverse effects
 - BMD increased during treatment (as expected for age-appropriate increases in BMD)
 - Slight decline in z-score suggests BMD increase was lower than expected
 - Unclear if due to TDF or small sample size

Adolescent Trials Network

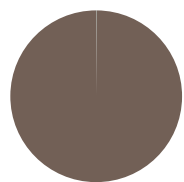
- Why the poor adherence?
 - Those without detectable TDF drug levels were:
 - More likely to endorse the statement, “I worry others will see me taking pills and think I am HIV-positive”
 - More likely to report missing doses due to:
 - Not being at home
 - Being too busy
 - Forgetting
 - Acceptability of pill size and taste decreased after 12 weeks
 - Those with seroconversion had absent TDF levels

Why PrEP matters

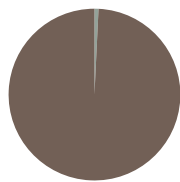


The Southeast remains the region with the highest HIV incidence, which can be markedly reduced with widespread use of pre-exposure prophylaxis (PrEP) among high-risk individuals.

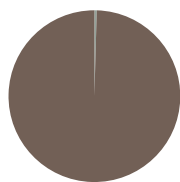
HIV Risk by Race/Ethnicity and MSM



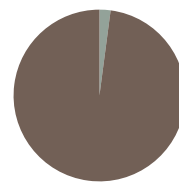
White women
1 in 880



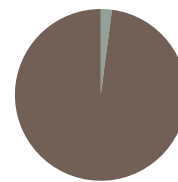
White men
1 in 132



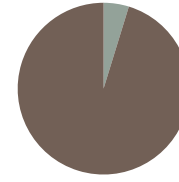
Hispanic women
1 in 227



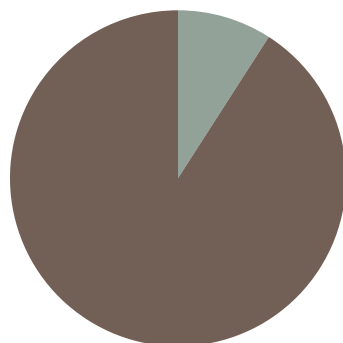
Hispanic men
1 in 48



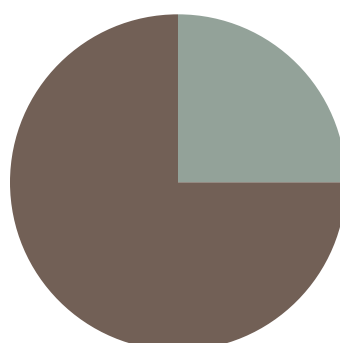
Black women
1 in 48



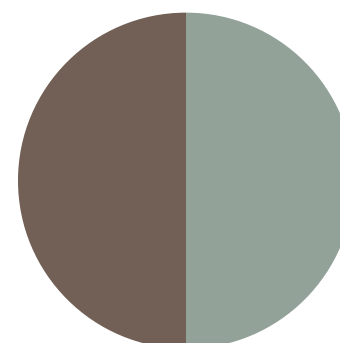
Black men
1 in 20



White MSM
1 in 11



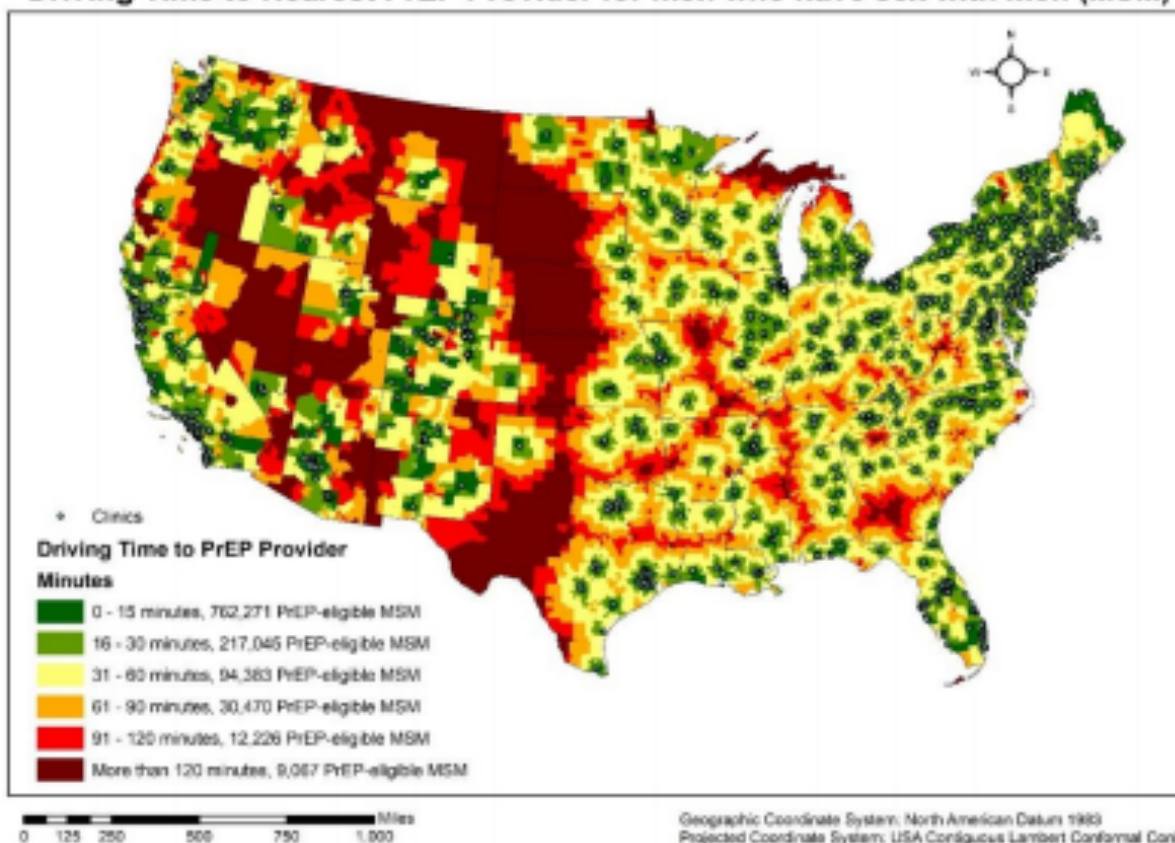
Hispanic MSM
1 in 4



Black MSM
1 in 2

PrEP Deserts

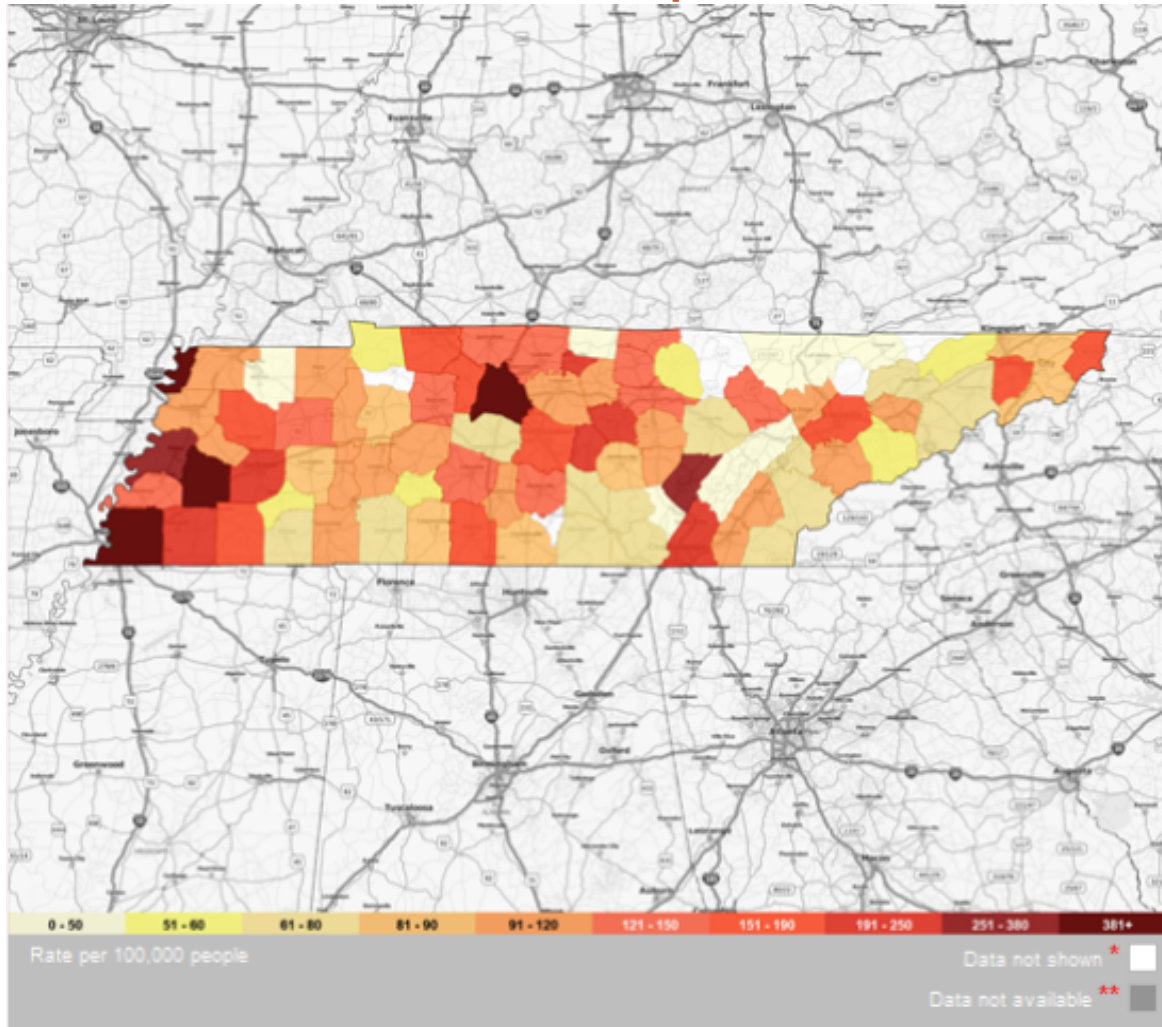
Driving Time to Nearest PrEP Provider for men who have sex with men (MSM)



- 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.

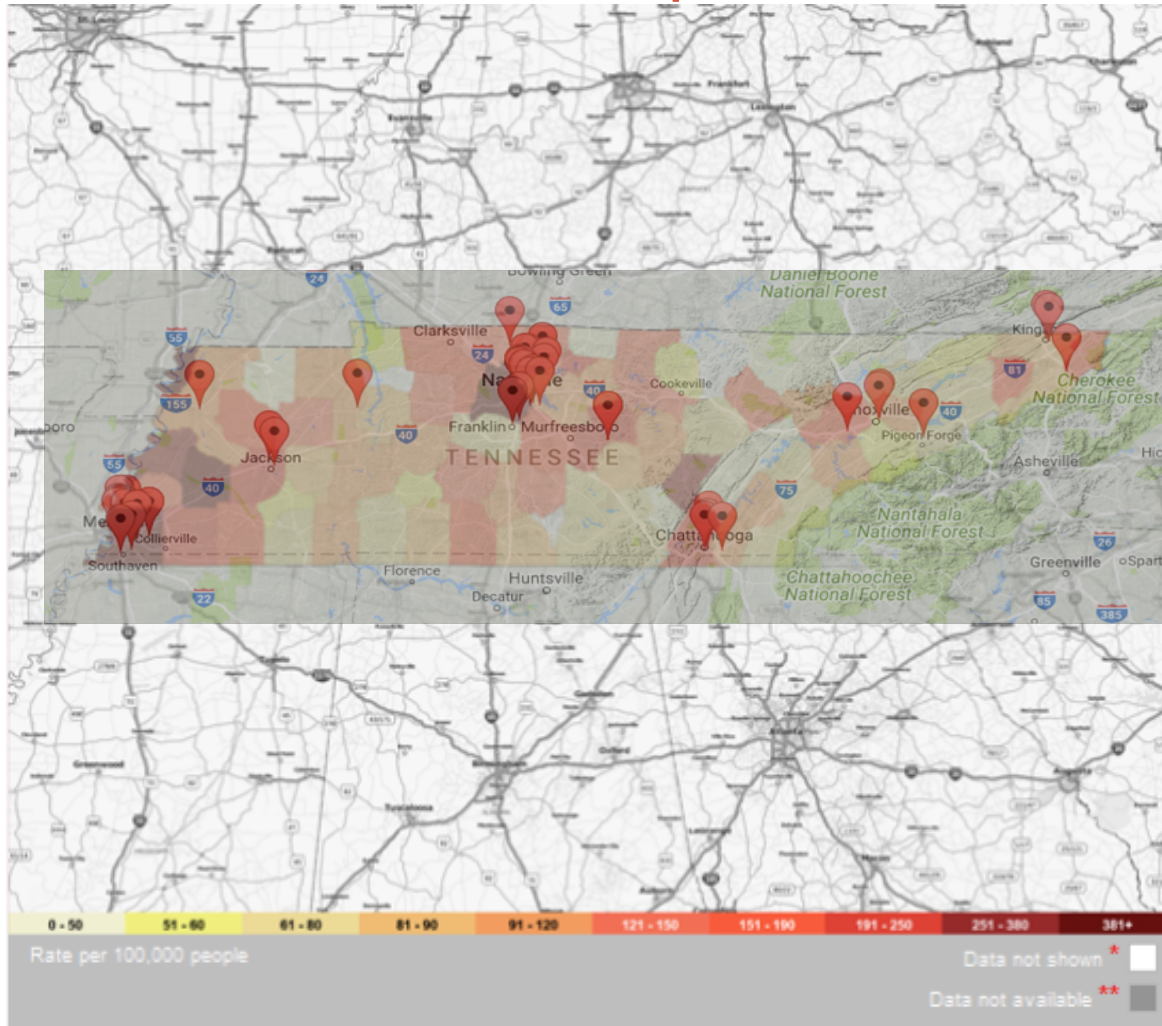
Tennessee

HIV risk and location of PrEP providers



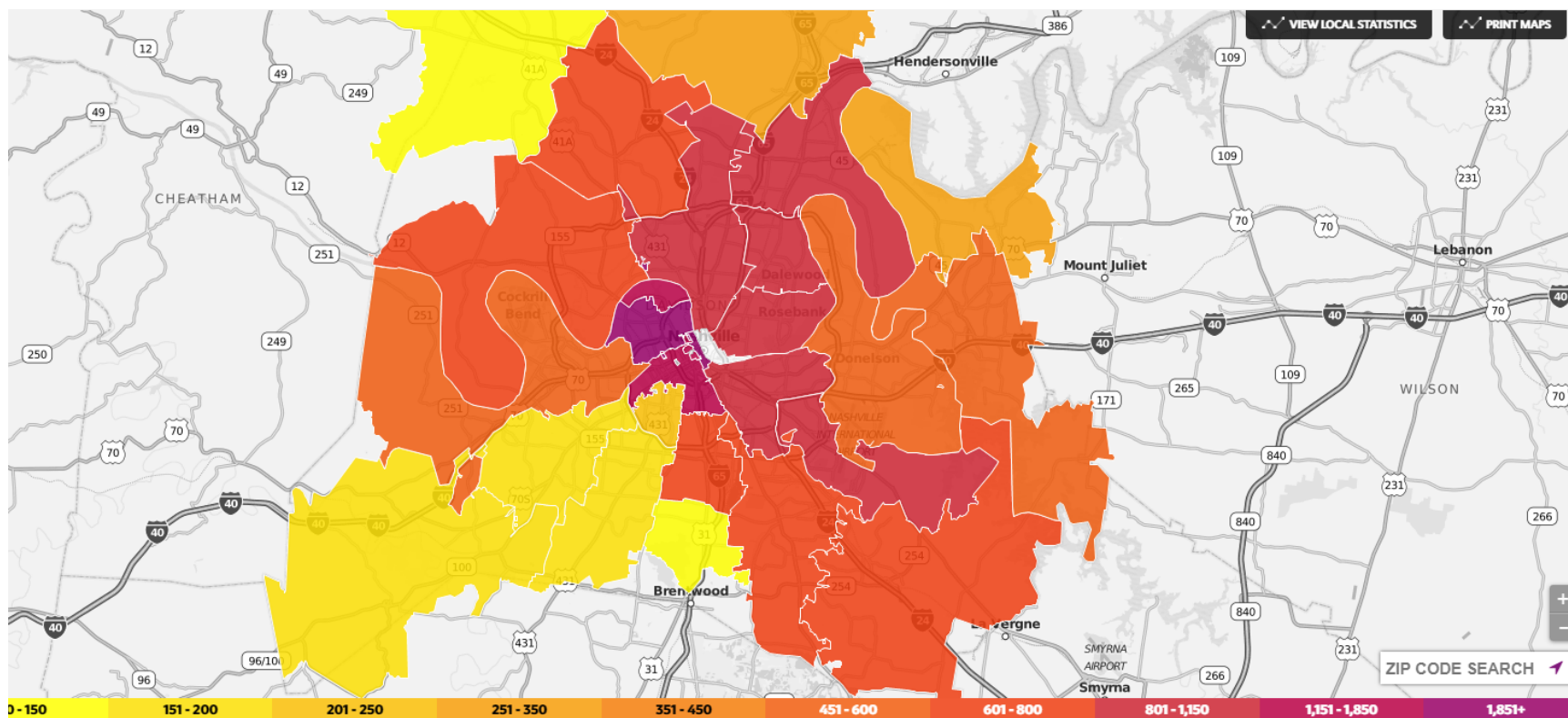
Tennessee

HIV risk and location of PrEP providers



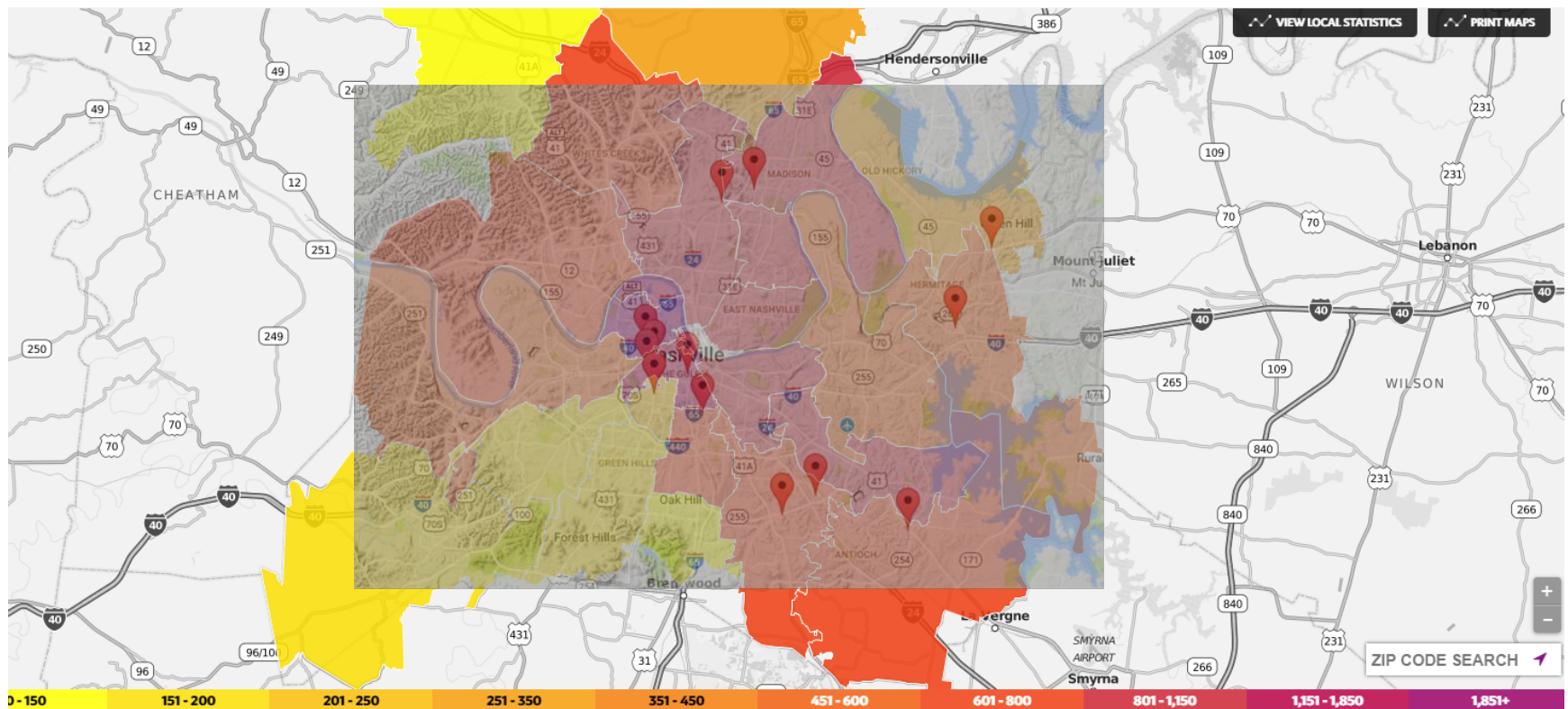
Nashville

HIV risk and location of PrEP providers



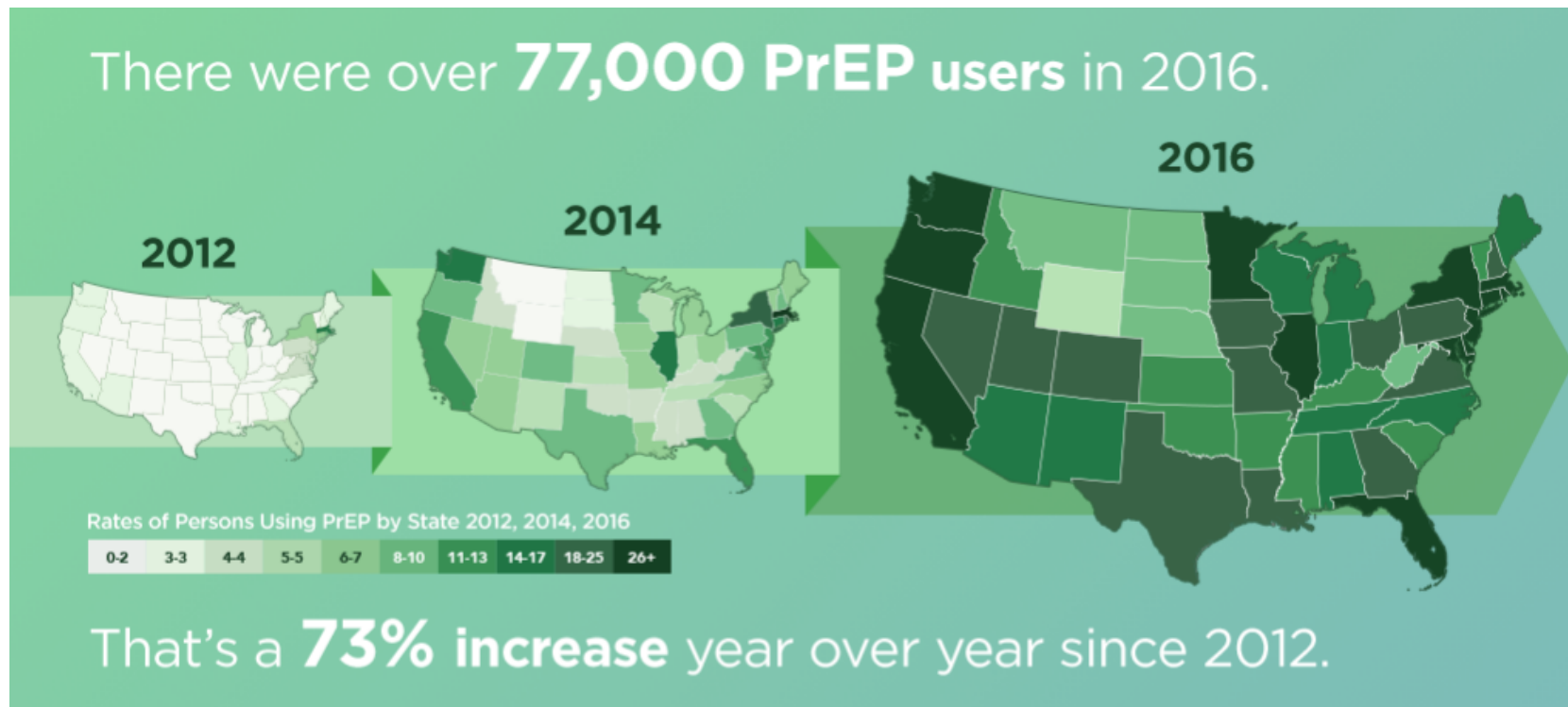
Nashville

HIV risk and location of PrEP providers



PrEP use

There were over **77,000 PrEP users** in 2016.



That's a **73% increase** year over year since 2012.

PrEP use

There were over **77,000 PrEP users** in 2016.

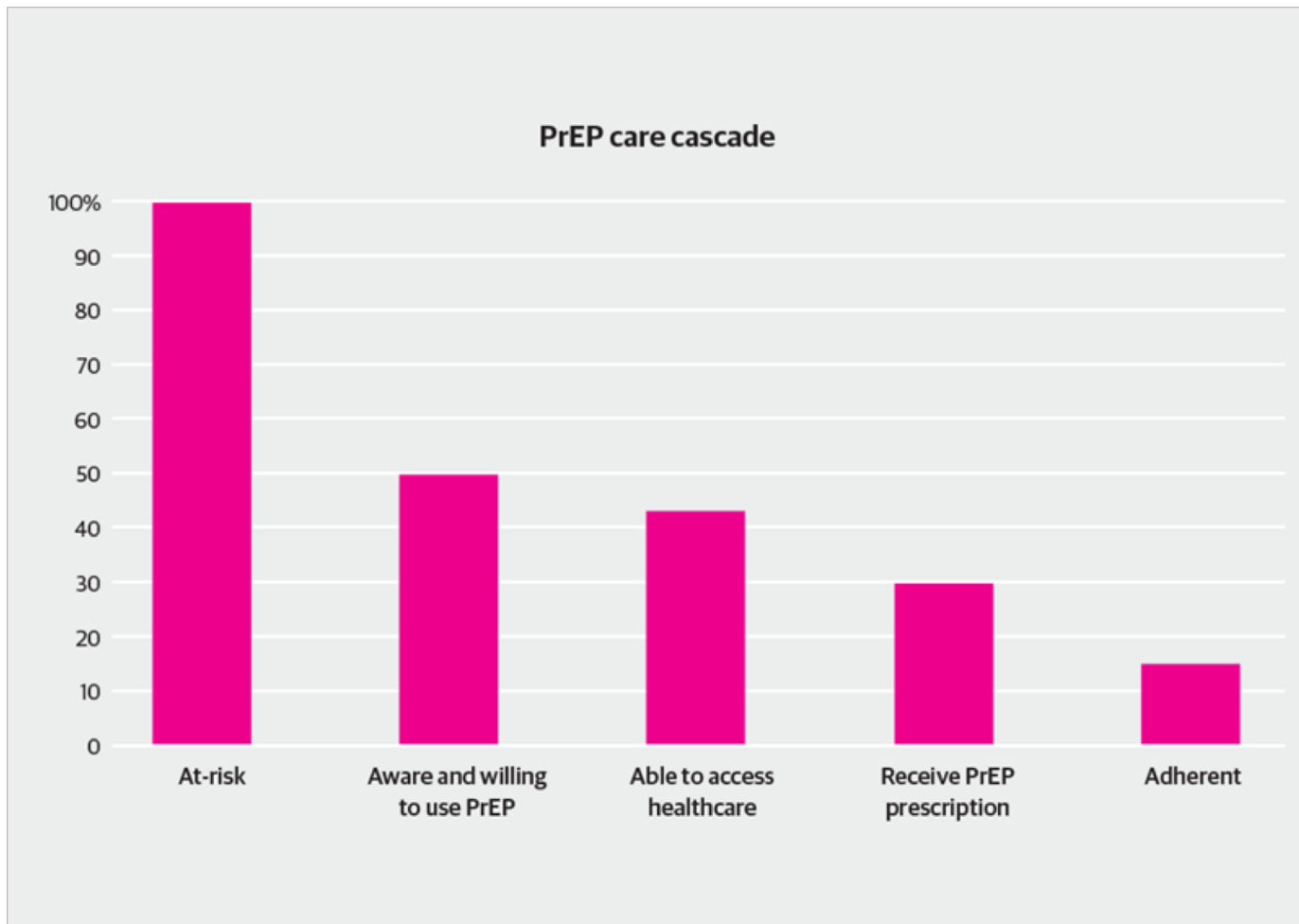
2016

Out of an estimated 1.2 million at high risk for HIV

The Southern U.S: 30% of all PrEP users, but 52% of all new HIV diagnoses in 2016

That's a **73% increase** year over year since 2012.

PrEP barriers



Stigma

A preventative measure against the consequences of sexual activity

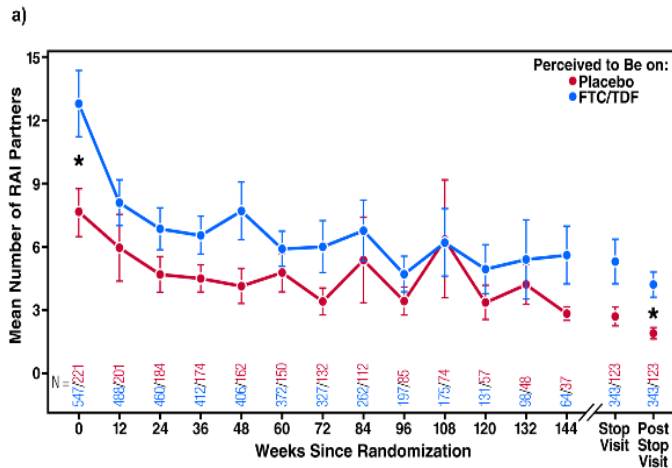
... *condones* sexual activity

... *promotes* sexual activity

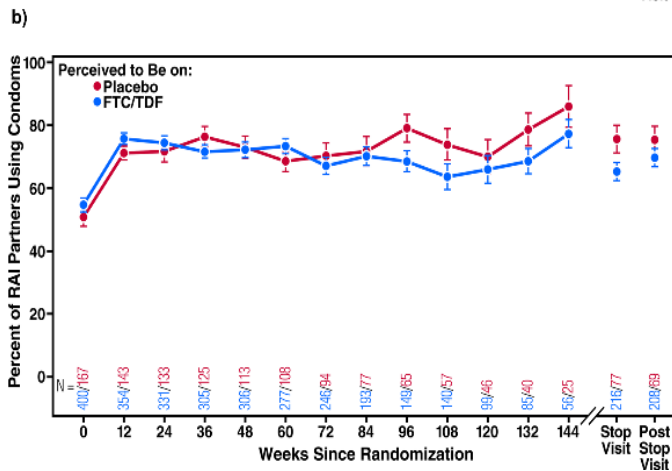
... *causes* sexual activity



Sexual Risk Compensation



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



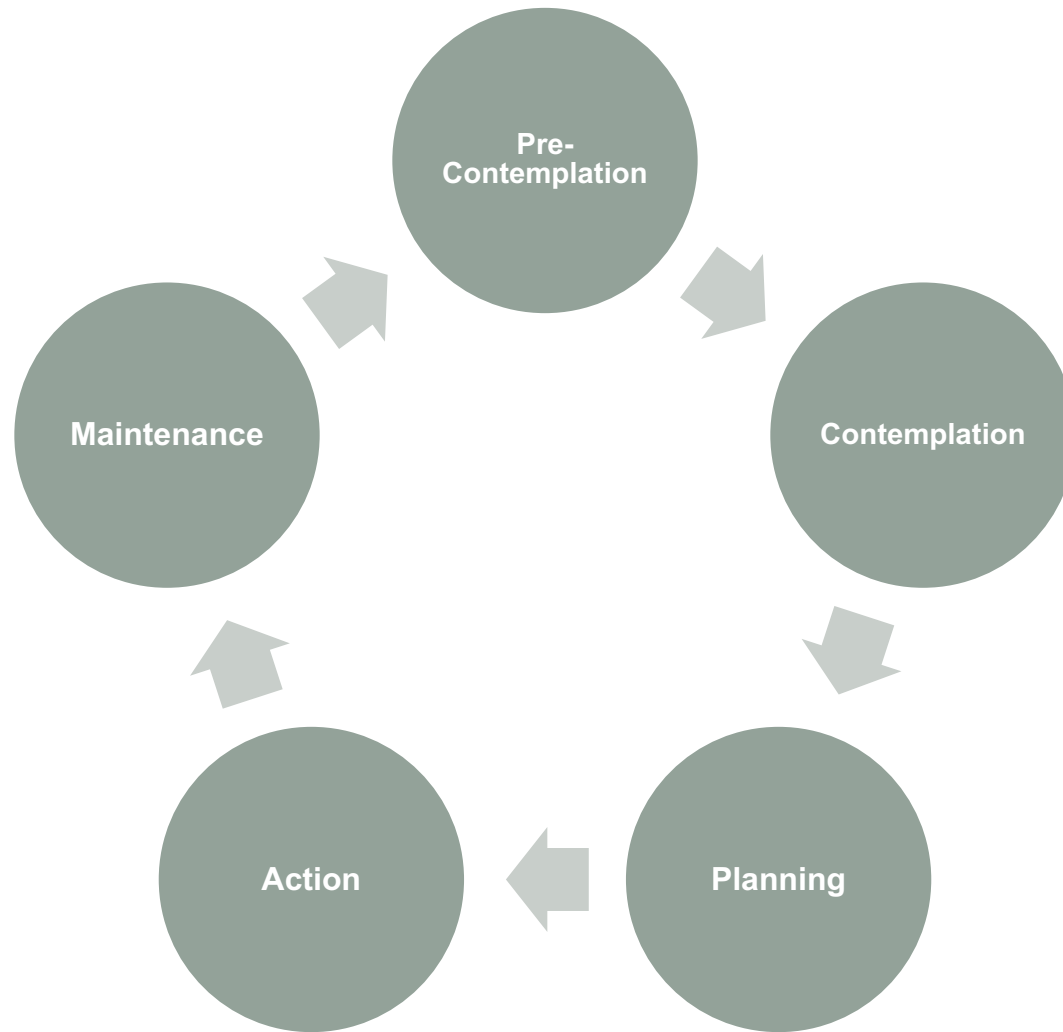
For patients believing they were on PrEP, condom use increased.

Syphilis incidence also decreased in both study arms

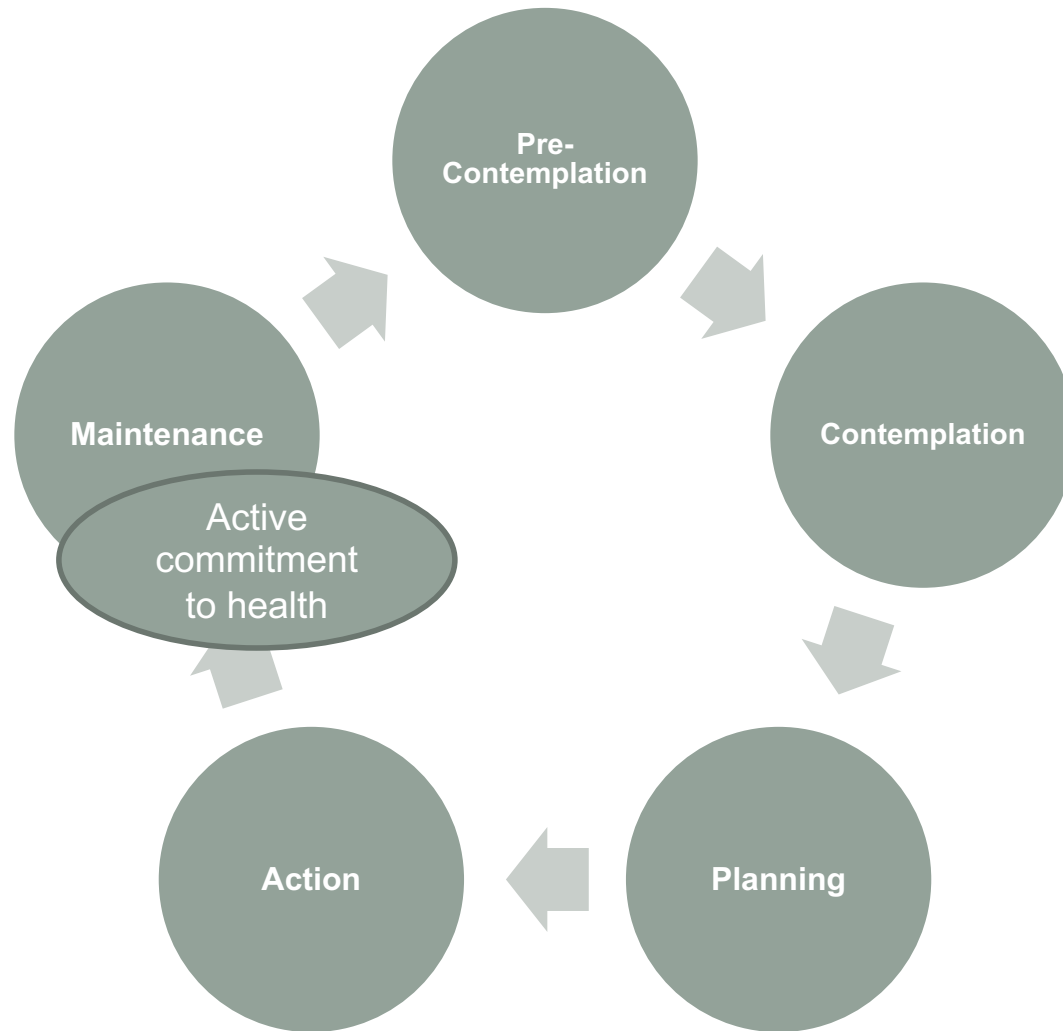
Sexual Risk Compensation

- Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD)
 - 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

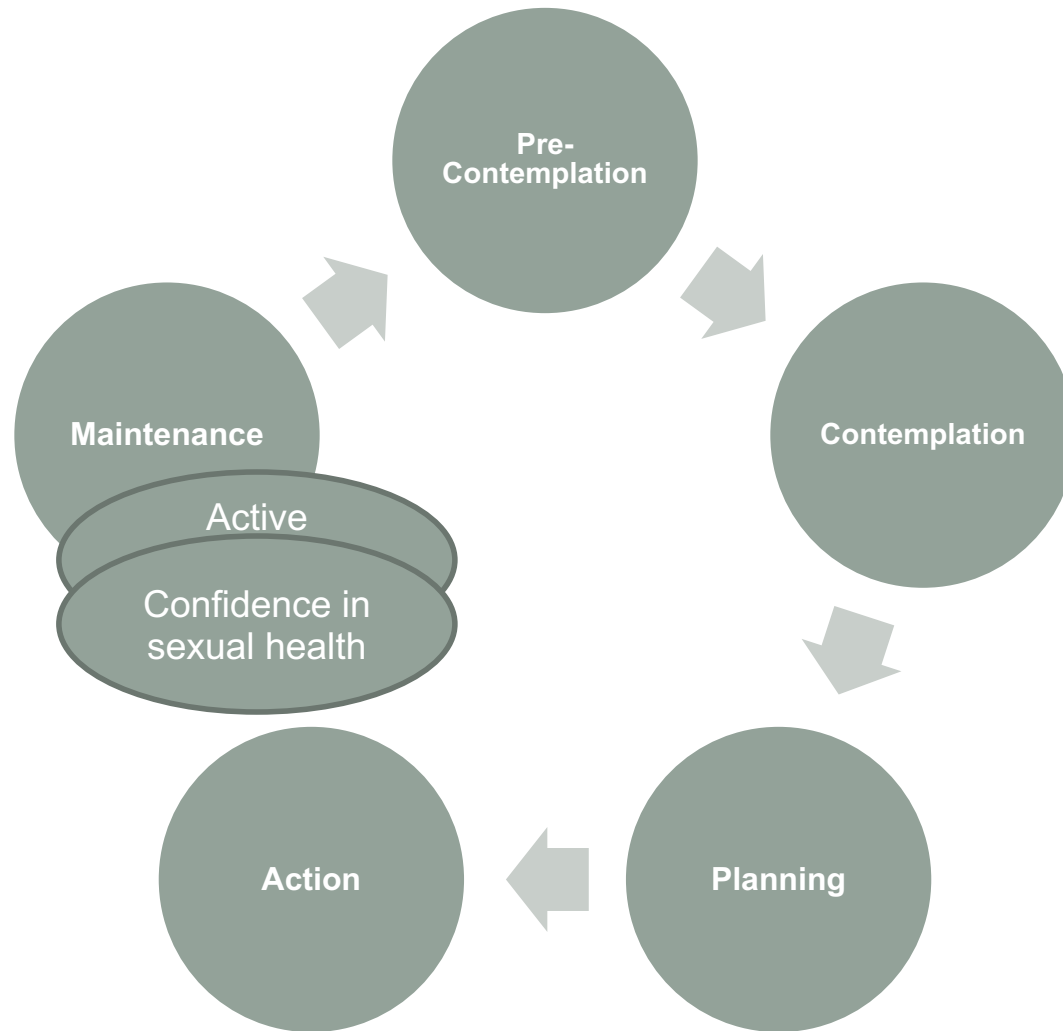
Actually...



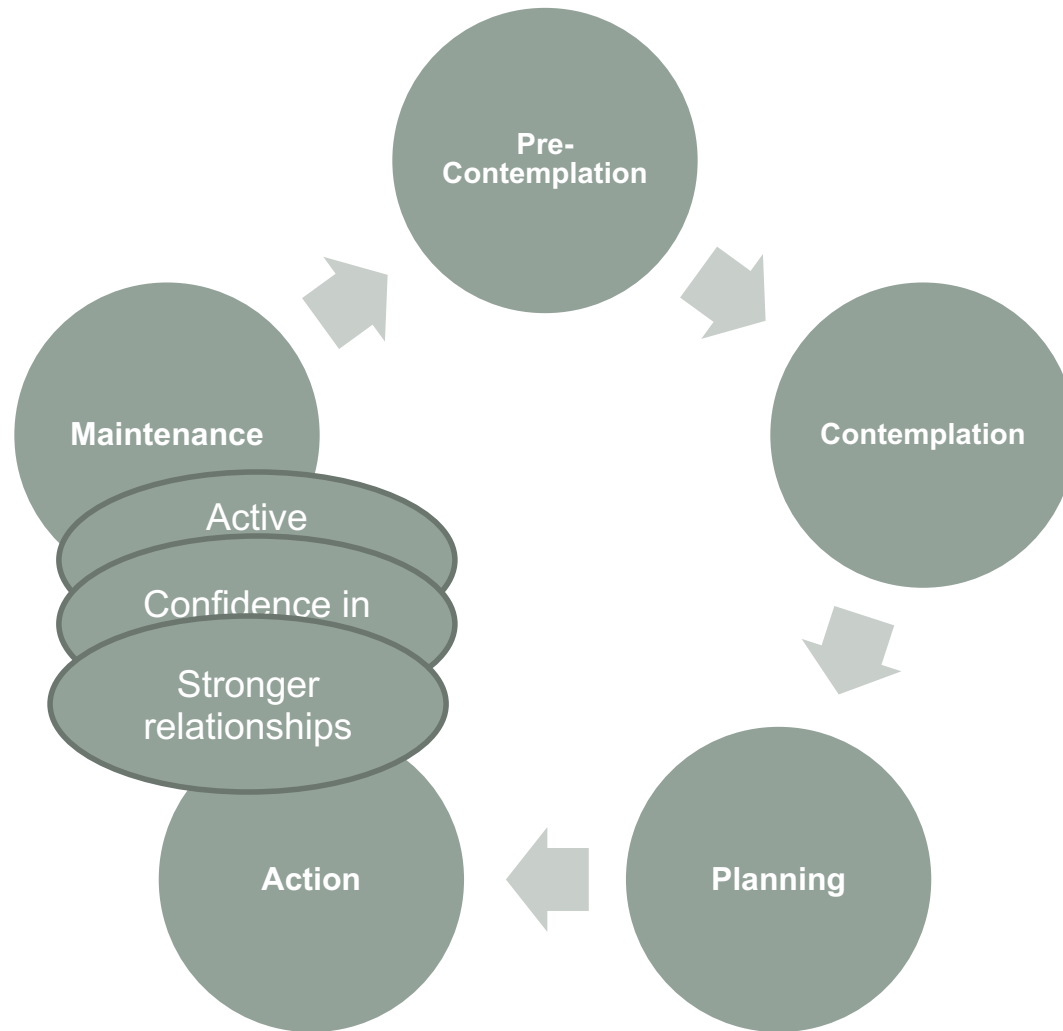
Actually...



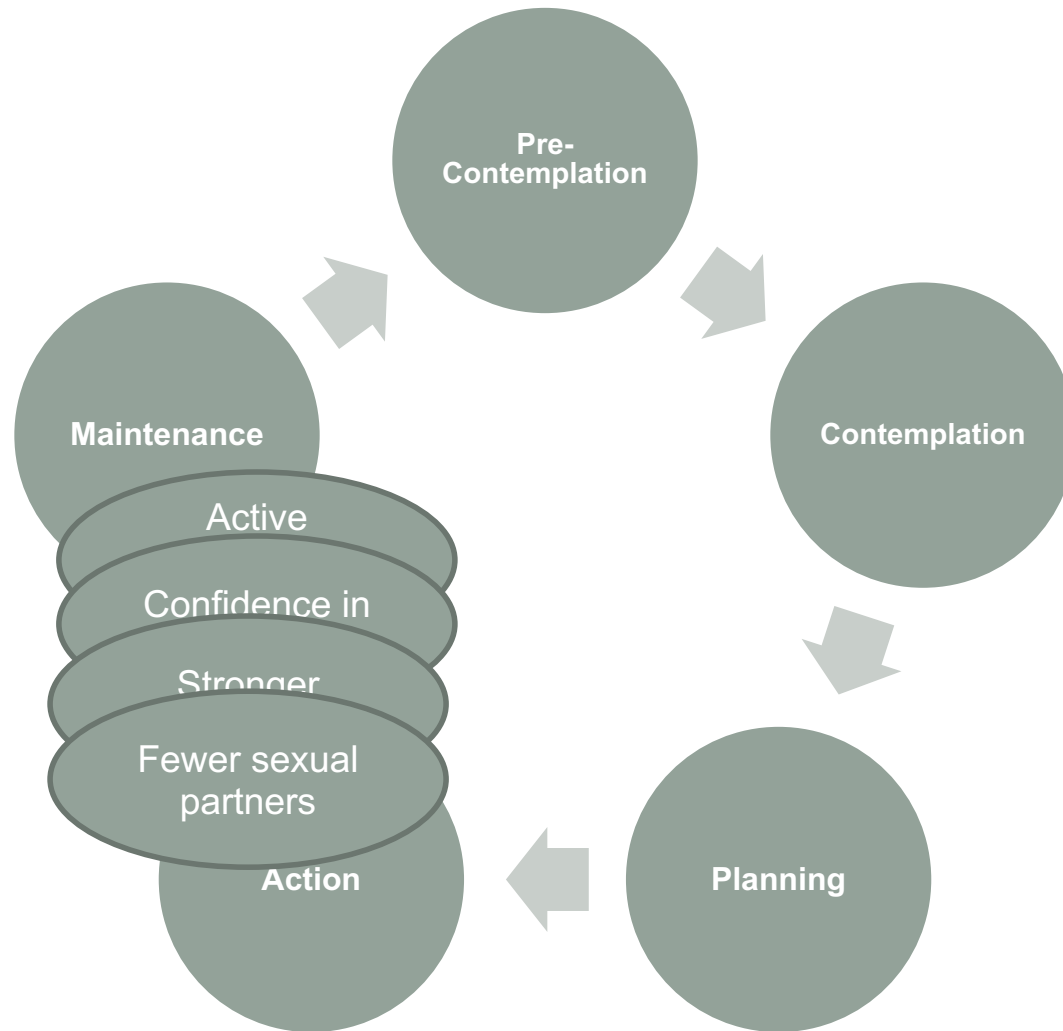
Actually...



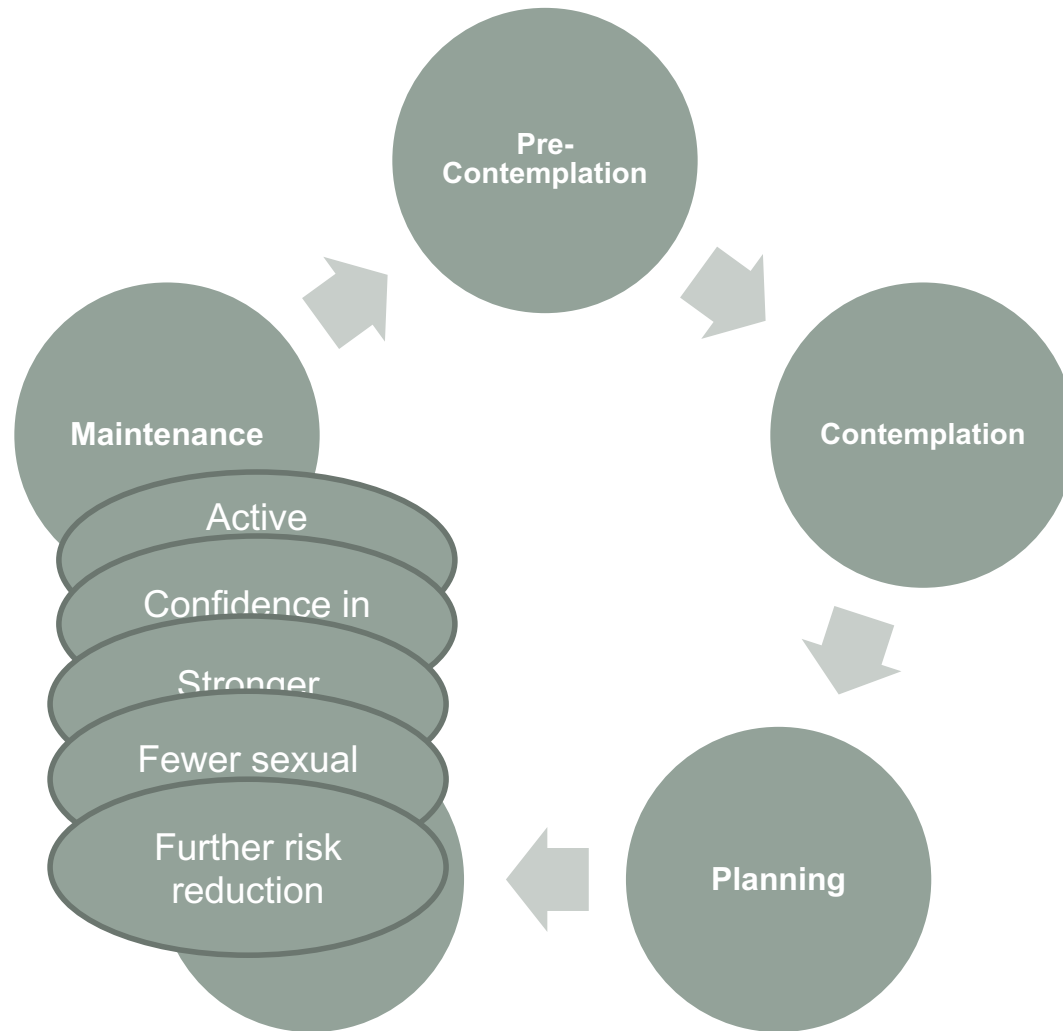
Actually...



Actually...



Actually...



PrEP barriers - Providers

- Insufficient evidence of efficacy
- 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 (that use of PrEP will lead to increased high-risk behavior)
- Discomfort using a drug with potential adverse effects in an otherwise healthy person (primary prevention vs. treatment)
- Patients perceived as non-adherent, 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.

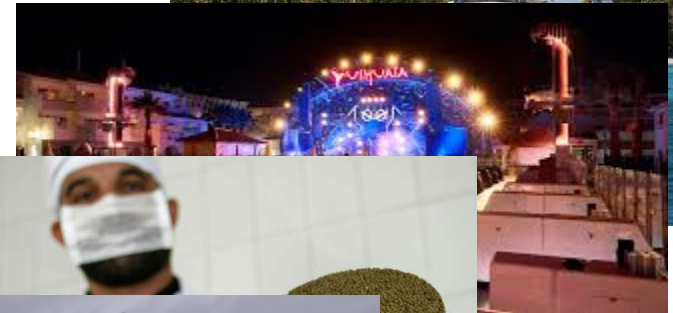
Blackstock OJ, et al. *J Gen Intern Med* 2017,32:62-70.

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

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

The “cost” of Truvada®

- Out-of-pocket cost of TDF/FTC*
 - Per pill: \$67.03
 - Per month: \$1,876.84
 - Per year: \$24,465.95



*Average Wholesale Price

Truvada® coverage

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

Financial Assistance

ARE YOU INSURED TO COVER YOUR COSTS FOR PrEP?



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

YES

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

1

Gilead Advancing Access Co-pay Card

gileadcopay.com
877-505-6986

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

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

2

Patient Access Network Foundation

panapply.org
866-316-7263

- \$4,800 initial grant, up to \$8,000 max/year, re-apply
- Income <500% FPL (\$60,700)
- Based on taxable income (1040 line 7, 1040 EZ line 1)
- Medicare plans only
- Covers co-pays, deductibles and co-insurance
- US resident
- Pharmacies can bill PAN Foundation directly

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

3

Patient Advocate Foundation (PAF)

tinyurl.com/PAFhelp,
or coays.org

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

FSA (flexible spending account)

Employer FSAs can help cover up to \$2,600 of out-of-pocket costs.

If you're a resident, these state plans may also help if you're insured or uninsured:

- CALIFORNIA: tinyurl.com/CAPrepAP
- COLORADO: tinyurl.com/COprepFAP
- ILLINOIS: tinyurl.com/ILprepAP
- MASSACHUSETTS: crine.org/prepdap (cost of drug, services)
- NEW YORK: tinyurl.com/NYprepAP (cost of services)
- VIRGINIA: tinyurl.com/VAPrepDAP
- WASHINGTON: tinyurl.com/WAprepDAP (cost of drug)

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 (\$30,350). Gold & Platinum plans offer better coverage if you can afford them. Carefully select the right plan for you.

Special enrollment

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

FEB 1 – OCT 31

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

Check if you're eligible for your state Medicaid plan. (medicaid.org)

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

NON-RESIDENT/
UNDOCUMENTED?

Find a public clinic (FQHC) that serves undocumented patients. (findahealthcenter.hrsa.gov)

Check if you can get insurance through marketplace/employer.

IF NO

What's your income?

below

60,700

above

Enroll in the Gilead MAP.
www.truvada.com/truvada-patient-assistance

500% FPL (2018 FPL: \$12,140 taxable income + \$4,320 per dependent, higher FPL% in Alaska and Hawaii, 1040 tax form line 7, 1040 EZ line 1)

~ only drug costs ~
tinyurl.com/FPLincomes

Retail cost of Truvada

Co-pay Assistance

1

Gilead Advancing Access Co-pay Card

gileadcopy.com
877-505-6986

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

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

ARE YOU INSURED TO COVER YOUR COSTS FOR PrEP?



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

NO

U.S. RESIDENT?

NON-RESIDENT/
UNDOCUMENTED?

What's the date?

NOV 1 – JAN 31

FEB 1 – OCT 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 (\$30,350). Gold & Platinum plans offer better coverage if you can afford them. Carefully select the right plan for you.

Special enrollment

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

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

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Retail cost of Truvada

~ only drug costs ~
tinyurl.com/FPLIncomes

3

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

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

Plans may be subject to funding shortfalls, which may limit enrollment.

If you're a resident, these state plans may also help if you're insured or uninsured:

- CALIFORNIA: tinyurl.com/CAPrepAP
- COLORADO: tinyurl.com/COprepAP
- ILLINOIS: tinyurl.com/ILprepAP
- MASSACHUSETTS: crine.org/prepdap (cost of drug, services)
- NEW YORK: tinyurl.com/NYprepAP (cost of services)
- VIRGINIA: tinyurl.com/VAPrepDAP
- WASHINGTON: tinyurl.com/WAprepDAP (cost of drug)

Copay Assistance

ADVANCING
ACCESS®

FINANCIAL SUPPORT

INSURANCE SUPPORT

Get Started with the Gilead Advancing Access® program

Advancing Access can provide you with information to help you find financial and insurance support every step of the way.



Support by Phone

Call **1-800-226-2056** to speak to an Advancing Access counselor directly. You can also leave a confidential message any time and day of the week.

Hours: Monday-Friday / 9am to 8pm ET



Enroll Today

The form requires some information from your healthcare provider, so you may want to fill it out with them. [Download the Advancing Access Enrollment Form](#) or [Enroll Online](#)

Copay Assistance

ADVANCING ACCESS® FINANCIAL SUPPORT INSURANCE SUPPORT

Get Started with Gilead Advancing Access Program

Co-Pay Coupon Card

GILEAD
RxBIN: 610524
RxPCN: Loyalty
RxGRP: 50776283
ISSUER: (80840)
ID:

Not available for patients who are enrolled in government healthcare programs (e.g. Medicare Part D, Medicaid, VA, DSH, or TICare). Visit www.GILEADACCESS.com for full terms and conditions.

Powered by **MCKESSON**

Includes some information from your healthcare provider, so you may want to fill it out with them. [Download](#) the [Advancing Access Enrollment Form](#) or [Enroll Online](#)

Gilead Advancing Access Program

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

Copay Assistance

ARE YOU INSURED TO COVER YOUR COSTS FOR PrEP?



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

(employer, private)

1

Gilead Advancing Co-pay Card
gileadcopay.com
877-505-6982

- \$7,200 max/calendar year
- No income restriction
- Covers co-pays, deductibles and co-insurance
- Re-apply annually as of 1/1
- US resident
- Not available for persons on Medicaid, Medicare, Veterans Affairs, or state/federal prescription drug programs

If pharmacy is unable to accept Gilead's Co-pay Card, you and pharmacy receive a number on back of card. Submit paperwork for reimbursement for all restrictions apply: terms and conditions at gileadcopay.com

FSA (flexible spending account)

Employer FSAs can help cover up to \$2,600 of out-of-pocket costs.

2

Patient Access Network Foundation
panapply.org
866-316-7263

- \$4,800 initial grant, up to \$8,000 max/year, re-apply annually
- Income <500% FPL (\$60,700)
- Based on taxable income (1040 line 7, 1040 EZ line 1)
- Medicare plans only
- Covers co-pays, deductibles and co-insurance
- US resident
- Pharmacies can bill PAN Foundation directly

3

Patient Advocate Foundation (PAF)
patientadvocate.com/PAFhelpdays.org

- Re-apply annually as of 1/1
- 100% FPL (<\$48,560) of living index
- Taxable income (1040 EZ line 1)
- Insured (as listed above)
- US resident only
- US residence (utility bills)
- No other persons available to pay medical cost (\$32-5274)

shortfalls,

If you're a resident, these state plans may also help if you're insured or uninsured:

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

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 (\$30,350). Gold & Platinum plans offer better coverage if you can afford them. Carefully select the right plan for you.

Special enrollment

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

FEB 1 – OCT 31

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

Check if you're eligible for your state Medicaid plan. (medicaid.org)

NON-RESIDENT/
UNDOCUMENTED?

Find a public clinic (FQHC) that serves undocumented patients. (findahealthcenter.hrsa.gov)

Check if you can get insurance through marketplace/employer.

IF NO

What's your income?

below

60,700

above

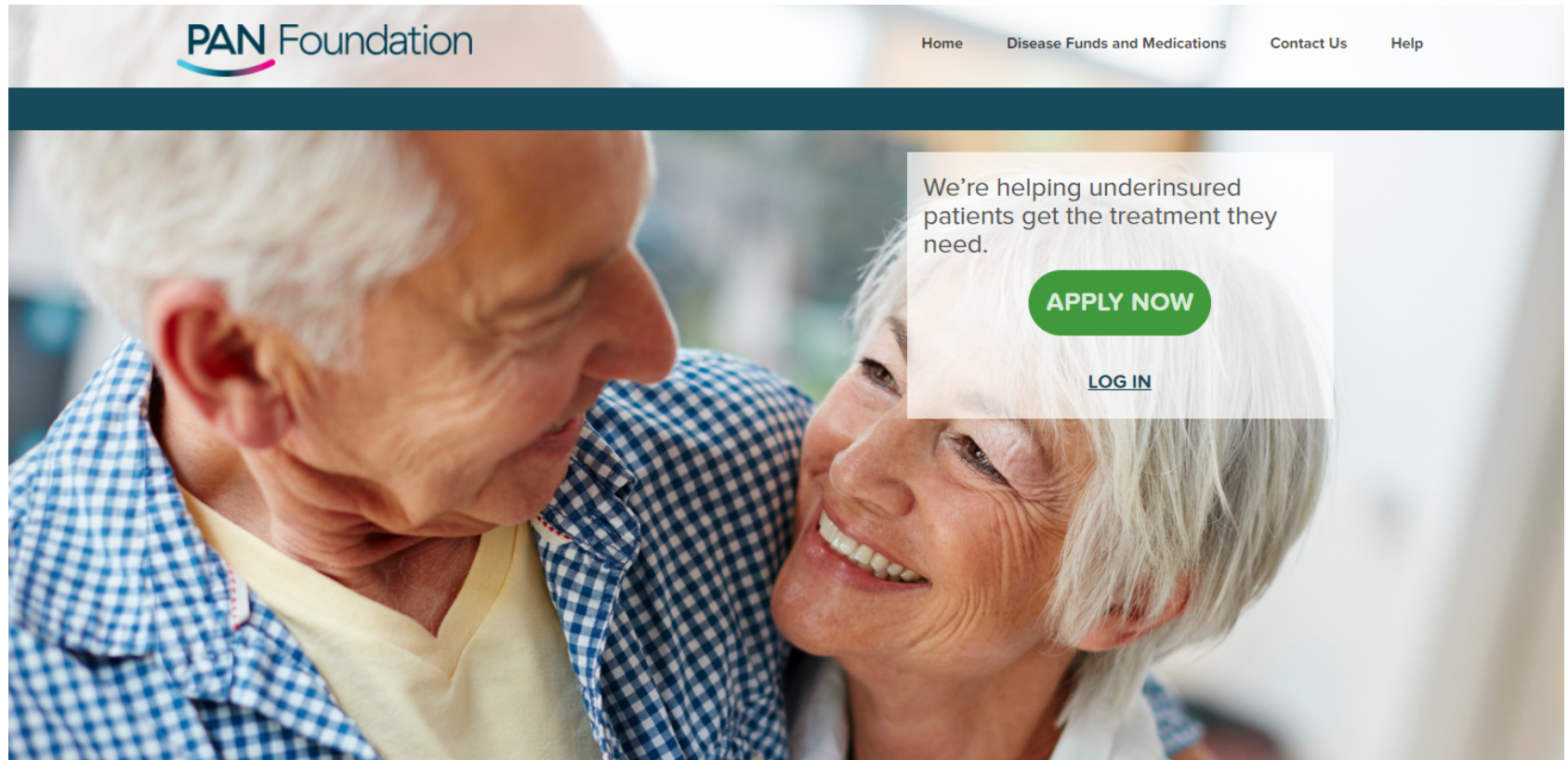
Enroll in the Gilead MAP.
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~ only drug costs ~
tinyurl.com/FPLincomes

Retail cost of Truvada

Copay Assistance



PAN Foundation

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[Disease Funds and Medications](#)

[Contact Us](#)

[Help](#)

We're helping underinsured patients get the treatment they need.

[APPLY NOW](#)

[LOG IN](#)

Copay Assistance



Copay Assistance

ARE YOU INSURED TO COVER YOUR COSTS FOR PrEP?



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

YES

1 (employer, private, insurance marketplace, or FSA)

2 (Medicaid, Medicare, VA, or other state/federal prescription drug programs)

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

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

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

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

Patient Advocate Foundation (PAF) Network Four
panapply.com
866-316-7888

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

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.

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

NO

U.S. RESIDENT?

What's the date?

NOV 1 – JAN 31
Enroll in an insurance marketplace
obamacarefacts.com/state-health-insurance-exchange/

FEB 1 – OCT 31
below 138% FPL / yr (< \$16,753)
above 138% FPL / yr (> \$16,753)

Check if you're eligible for your state Medicaid plan. (medicaid.org)

Check if you can get insurance through marketplace/employer.

NON-RESIDENT/ UNDOCUMENTED?

Find a public clinic (FQHC) that serves undocumented patients. (findahealthcenter.hrsa.gov)

IF NO

What's your income?

below **60,700** above

Enroll in the Gilead MAP.
www.truvada.com/truvada-patient-assistance

Retail cost of Truvada

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

Special enrollment
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- COLORADO: tinyurl.com/COprepAP
- ILLINOIS: tinyurl.com/ILprepAP
- MASSACHUSETTS: crine.org/prepdap (cost of drug, services)
- NEW YORK: tinyurl.com/NYprepAP (cost of services)
- VIRGINIA: tinyurl.com/VAprepDAP
- WASHINGTON: tinyurl.com/WAprepDAP (cost of drug)

Copay Assistance



Providing Critical Financial Support for Patients Nationwide Since 2004

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[Online Application](#)

ELIGIBILITY REQUIREMENTS

Do I qualify for financial assistance?

HOW TO APPLY ONLINE

[Patient, Provider and Pharmacy Instructions](#)

PATIENT TESTIMONIALS

What our patients are saying about CPR...



WELCOME TO PATIENT ADVOCATE FOUNDATION'S CO-PAY RELIEF

What is the Patient Advocate Foundation Co-Pay Relief Program?

PAF Co-Pay Relief (CPR) provides direct financial assistance to qualified patients, assisting them with prescription drug co-payments their insurance requires relative to their diagnosis. CPR call counselors work directly with the patient as well as with the provider of care to obtain necessary medical, insurance and income information to advance the application in an expeditious manner. Upon approval, payments are made.

COMPANY NEWS ANNOUNCEMENTS

Email Address *

First Name *

Last Name *

Send me messages about these PAF topics

PAF News, Patient Resources & Disease

Medication Access Program

ARE YOU INSURED TO COVER YOUR COSTS FOR PrEP?



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

YES

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

1

Gilead Advancing Access Co-pay Card

gileadcopay.com
877-505-6986

- \$7,200 max/calendar year
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2

Patient Access Network Foundation

panapply.org
866-316-7263

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- Income <500% FPL (\$60,700)
- Based on taxable income (1040 line 7, 1040 EZ line 1)
- Medicare plans only
- Covers co-pays, deductibles and co-insurance
- US resident
- Pharmacies can bill PAN Foundation directly

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

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Patient Advocate Foundation (PAF)

tinyurl.com/PAFhelp,
or coays.org

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- Income <400% FPL (\$48,560) + COLI (cost of living index) adjustments
- Based on taxable income (1040 line 7, 1040 EZ line 1)
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- Covers co-pays only
- Proof of US residence (utility bill, etc.)
- Case managers available to help resolve medical cost issues (800-532-5274)

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- ILLINOIS: tinyurl.com/ILprepAP
- MASSACHUSETTS: crine.org/prepdap (cost of drug, services)
- NEW YORK: tinyurl.com/NYprepAP (cost of services)
- VIRGINIA: tinyurl.com/VAPrepDAP
- WASHINGTON: tinyurl.com/WAprepDAP (cost of drug)

NO

U.S. RESIDENT?

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www.truvada.com/truvada-patient-assistance

100% FPL
FPL: \$12,140
Income + \$4,320
resident, higher
Alaska and Hawaii,
EZ line 7,
EZ line 1)
drug costs –
FPL incomes

Retail cost of Truvada

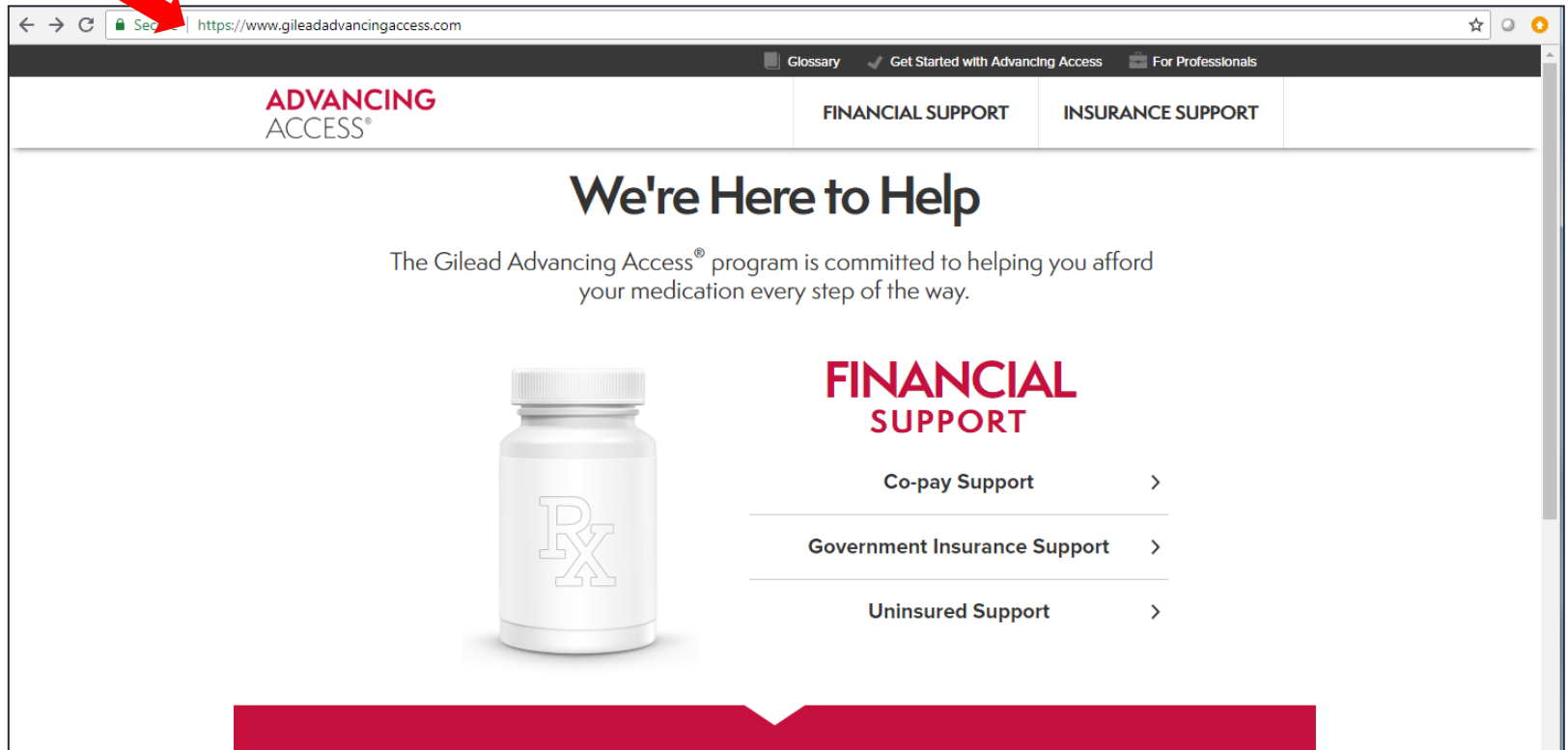
NON-RESIDENT/
UNDOCUMENTED?

Find a public clinic (FQHC) that serves undocumented patients. (findahealthcenter.hrsa.gov)

Check if you can get insurance through marketplace/employer.

IF NO

Medication Assistance Program




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

ADVANCING ACCESS

FINANCIAL SUPPORT INSURANCE SUPPORT

We're Here to Help

The Gilead Advancing Access® program is committed to helping you afford your medication every step of the way.



FINANCIAL SUPPORT

- Co-pay Support >
- Government Insurance Support >
- Uninsured Support >

Medication Assistance Program

The screenshot displays the Gilead Advancing Access website. At the top, the navigation bar includes the Gilead logo, "ADVANCING ACCESS", and menu items for "FINANCIAL SUPPORT" and "INSURANCE SUPPORT". A large red banner features the text "INSURANCE SUPPORT" and three links: "Help with Coverage & Benefits", "Help When Insurance & Coverage Changes", and "Understanding Insurance". Below the banner, three promotional cards are visible: "The Advancing Access CO-PAY COUPON PROGRAM", "The Advancing Access PATIENT SUPPORT PROGRAM", and "Advancing Access OVERVIEW". A red arrow points from the top-left text to the "INSURANCE SUPPORT" banner, and another red arrow points from the "PATIENT SUPPORT PROGRAM" card to the "INSURANCE SUPPORT" banner.

ADVANCING ACCESS

FINANCIAL SUPPORT INSURANCE SUPPORT

INSURANCE SUPPORT

- Help with Coverage & Benefits >
- Help When Insurance & Coverage Changes >
- Understanding Insurance >

The Advancing Access CO-PAY COUPON PROGRAM
Helping you save on your Gilead prescription co-pay. [Get Started](#)

The Advancing Access PATIENT SUPPORT PROGRAM
Financial and coverage support for your Gilead medication. Call **1-800-226-2000**, [download the Enrollment Form](#), or [enroll online](#) to get started.

Advancing Access OVERVIEW

GILEAD Terms of Use | Privacy Policy | Contact Us | Site Map

ADVANCING ACCESS, GILEAD, and the GILEAD Logo are trademarks of Gilead Sciences, Inc.

Medication Assistance Program

ADVANCING ACCESS [®]		ENROLLMENT FORM		PAGE 1 OF 3	
		PHONE: 1-800-226-2056		FAX: 1-800-216-6857	
1. REQUESTED PATIENT SUPPORT (REQUIRED)			CHECK ALL BOXES THAT APPLY		
<input type="checkbox"/>	Benefits Investigation		<input type="checkbox"/>	Prior Authorization and Appeals Information	
<input type="checkbox"/>	Patient Assistance Program (PAP) or Medication Assistance Program (MAP) Eligibility Screening		<input type="checkbox"/>	Co-pay Coupon Program Enrollment	
2. GILEAD MEDICATION PRESCRIBED (REQUIRED)					
Product Name:		img			
If requesting TRUVADA [®] , please indicate for: <input type="checkbox"/> Treatment <input type="checkbox"/> PrEP/Prevention					
3. PATIENT INFORMATION (REQUIRED)					
First Name:		Last Name:		M.I.:	Preferred Language:
Address:		Apt./Unit #	City:		
State:		Zip Code:	Phone #:	SSNF (Last 4 digits):	
Email:		DOB:			
Alternate Contact Name:		Phone #:	Relationship:		
CONTACT AUTHORIZATION					
I authorize Advancing Access to leave a detailed message, including the name of my prescription, if I am unavailable when they call. <input type="checkbox"/> Yes <input type="checkbox"/> No					
4. INSURANCE INFORMATION (REQUIRED)			PLEASE INCLUDE A COPY OF THE FRONT AND BACK OF INSURANCE CARDS		
<input type="checkbox"/> Patient is insured (Please fill out all of the applicable insurance information below. Attach copy—front and back—of patient card).			<input type="checkbox"/> Patient is uninsured (ie, no health insurance through any public or private payer) SEE OPTIONAL "PATIENT FINANCIAL INFORMATION" SECTION 9 BELOW		
Primary Insurance:			Is this a Medicare Part D plan? <input type="checkbox"/> Yes <input type="checkbox"/> No		
Plan name:			Insurance Phone Number:		
Subscriber Name:		Policy Holder Name:	Policy Holder Relationship to Patient:		
Policy #:	Group #:	Rx Bin #:	Rx PCN #:		
<input type="checkbox"/> Check box if patient has secondary insurance coverage and fax a copy of insurance cards, if available.					
5. PRESCRIBER INFORMATION (REQUIRED)					
Prescriber Name:			Facility Name:		
Address:			City:		
State:		Zip Code:	Office Contact:		
Phone #:		Fax #:	NPI #:		
Tax ID #:		State License #:			
6. DIAGNOSIS/MEDICAL INFORMATION					
MUST BE COMPLETED BY HEALTHCARE PROVIDER					
Diagnosis (Please include ICD code): _____					
7. PRESCRIBER CERTIFICATION AND STATEMENT OF MEDICAL NECESSITY					
<p>By signing this form, I certify that I am prescribing Gilead medication for the patient identified in Section 5. I certify that this prescription medication is medically necessary for the patient and that it will be used as directed. I certify that I will be supervising the patient's treatments and verify that the information provided is complete and accurate to the best of my knowledge. I agree that I shall not seek reimbursement for any Gilead medication dispensed to the patient through the Patient Assistance Program/Medication Assistance Program ("PAP/MAP") from any government program or third-party insurer.</p> <p>If prescribing TRUVADA for PrEP[®], I certify that the applicant has been tested for HIV infection and found to be HIV negative, and regular HIV testing will be conducted as part of the applicant's care plan. As part of my applicant's eligibility, I agree to periodically verify continued use of Gilead medication and resident's current prescriptions.</p> <p>I certify that I have received the appropriate written authorization from the patient, in accordance with the Health Insurance Portability and Accountability Act of 1996, applicable state health information privacy laws, and any other applicable requirements, in order to release the patient's personal and medical information to Gilead and its agents and contractors for the purposes of: 1) verifying the patient's insurance coverage and eligibility for benefits; 2) seeking prior authorization if needed on the patient's behalf; 3) providing financial assistance, support, and referral support as needed; 4) facilitating the provision of the patient's prescription medication to the patient; 5) contacting the patient with educational materials about the patient's prescription medication or to evaluate the effectiveness of the Advancing Access Program and/or the PAP/MAP; and 6) for Gilead's internal business purposes.</p>					
PRESCRIBER SIGNATURE (REQUIRED):				DATE	

Medication Assistance Program

ADVANCING ACCESS [®]		ENROLLMENT FORM PAGE 1 OF 3 PHONE: 1-800-226-2056 FAX: 1-800-216-6857	
1. REQUESTED PATIENT SUPPORT (REQUIRED) <input type="checkbox"/> Benefits Investigation <input type="checkbox"/> Prior Authorization and <input type="checkbox"/> Patient Assistance Program (PAP) or Medication Assistance Program (MAP) E		ADVANCING ACCESS ENROLLMENT FORM PHONE: 1-800-226-2056 FAX: 1-800-216-6857 PAGE 2 OF 3 PATIENT NAME: _____ DATE OF BIRTH: _____	
2. GILEAD MEDICATION PRESCRIBED (REQUIRED) Product Name: _____ If requesting TRUVADA [®] , please indicate for: <input type="checkbox"/> Treatment <input type="checkbox"/> PrEP/P		8. PATIENT AUTHORIZATION FOR USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION (REQUIRED) <p>I understand that I must complete this enrollment form before I can receive assistance through Gilead Sciences, Inc.'s Advancing Access ("Program") and the Patient Assistance Program/Medication Assistance Program ("PAP/MAP"). As part of this process, Gilead and its agents and contractors (collectively, "Gilead") will need to obtain, review, use and disclose my personal and medical information as described below. I hereby authorize my healthcare providers and health plans to disclose my personal and medical information as described below to Gilead in connection with the Program and/or the PAP/MAP, all in accordance with this authorization, and I authorize Gilead to use and disclose the information in accordance with the authorization.</p> <p>Information to Be Disclosed: Personal health information ("PHI"), including information about me (for example, my name, mailing address, financial information, and insurance information), my past, current and future medical condition (including information about my HIV-related status or treatment with this prescription medication and related medical condition), and all information provided on this enrollment form.</p> <p>Persons Authorized to Disclose My Information: My healthcare providers, including any pharmacy that fills my prescription medication, and any health plans or programs that provide me healthcare benefits. I understand that my pharmacy providers may receive remuneration for disclosing my PHI pursuant to this authorization.</p> <p>Persons to Which My Information May Be Disclosed: Gilead, including the third party administrator responsible for the administration of the Program and the PAP/MAP.</p> <p>Purposes for Which the Disclosures Are to Be Made: Disclosures of PHI may be made to Gilead so that Gilead may use and disclose the PHI for purposes of: 1) completing the enrollment process and verifying my enrollment form; 2) establishing my eligibility for benefits from my health plan or other programs; 3) providing financial assistance, support, and referral support, and communicating with my healthcare providers, including, but not limited to, facilitating the provision of my prescription medication to me; 4) contacting me to evaluate the effectiveness of the Program and/or the PAP/MAP; 5) for Gilead's internal business purposes, including quality control and support enhancing surveys; and 6) to send me marketing information, offers, and educational materials related to my treatment and/or my prescription medication, including the customer relationship marketing program (this use of my personal information is optional and by checking the box under the signatures below, I may opt in).</p> <p>I understand that once my PHI has been disclosed hereunder, federal privacy law may no longer restrict its use or disclosure. I understand further that I may refuse to sign this authorization and that if I refuse, my eligibility for health plan benefits or ability to obtain treatment from my healthcare providers will not change, but I will not have access to the support offered by Program and/or the PAP/MAP. I also understand that I may cancel this authorization at any time by notifying Gilead in writing at Advancing Access, PO Box 13185, La Jolla, CA 92039-3185. If I cancel, Gilead will stop using this authorization to obtain, use or disclose my PHI after the cancellation date, but the cancellation will not affect uses or disclosures of any PHI that have already been made pursuant to this authorization before the cancellation date. I am entitled to a copy of this signed authorization, which expires the earlier of two (2) years from the date it is signed by me or other time period required under the laws of the state in which I reside.</p>	
3. PATIENT INFORMATION (REQUIRED) First Name: _____ Last Name: _____ Address: _____ Apt./Unit # _____ State: _____ Zip Code: _____ Email: _____ Alternate Contact Name: _____ CONTACT AUTHORIZATION <input type="checkbox"/> I authorize Advancing Access to leave a detailed message, including the name of m			
4. INSURANCE INFORMATION (REQUIRED) PL EA <input type="checkbox"/> Patient is insured (Please fill out all of the applicable insurance information below. Attach copy - front and back - of patient card). Primary Insurance: _____ Is _____ Plan name: _____ In _____ Subscriber Name: _____ Policy Holder Name: _____ Policy #: _____ Group #: _____ Re _____ <input type="checkbox"/> Check box if patient has secondary insurance coverage and fax a copy of ins		<input type="checkbox"/> By checking this box, I agree to receive marketing information, offers and educational materials related to my medical condition, treatment, and/or my prescription medication, including the customer relationship marketing program.	
5. PRESCRIBER INFORMATION (REQUIRED) Prescriber Name: _____ Fa _____ Address: _____ Ci _____ State: _____ Zip Code: _____ Of _____ Phone #: _____ Fa _____ Tax ID #: _____ St _____		SIGNATURE OF PATIENT OR PATIENT'S REPRESENTATIVE (REQUIRED): _____ DATE: _____ Patient Representative's Name (if signing for the patient): _____ Patient Representative's Relationship to Patient: _____	
6. DIAGNOSIS/MEDICAL INFORMATION Diagnosis (Please include ICD code): _____		FAX COMPLETED FORM TO ADVANCING ACCESS AT 1-800-216-6857	
7. PRESCRIBER CERTIFICATION AND STATEMENT OF MEDICAL NECESSITY <small>By signing this form, I certify that I am prescribing Gilead medication for the patient identified in patient and that it will be used as directed. I certify that I will be supervising the patient's treatment of my knowledge. I agree that I shall not seek reimbursement for any Gilead medication dispensed Program ("PAP/MAP") from any government program or third-party insurer. If prescribing TRUVADA for PrEP[®], I certify that the applicant has been tested for HIV infection and applicant's care plan. As part of my applicant's eligibility, I agree to periodically verify continued I certify that I have received the appropriate written authorization from the patient, in accordance health information privacy laws), and any other applicable requirements, in order to release the p the purposes of: 1) verifying the patient's insurance coverage and eligibility for benefits; 2) seeking support, and referral support as needed; 4) facilitating the provision of the patient's prescription in patient's prescription medication or to evaluate the effectiveness of the Advancing Access Program.</small> PRESCRIBER SIGNATURE (REQUIRED): _____		<small>© 2017 Gilead Sciences, Inc. All rights reserved. ADMC0300 12/17</small>	
<small>© 2017 Gilead Sciences, Inc. All rights reserved. ADMC0300 12/17</small>		<small>© 2017 Gilead Sciences, Inc. All rights reserved. ADMC0300 12/17</small>	

Medication Assistance Program

ADVANCING ACCESS

1. REQUESTED PATIENT SUPPORT (REQUIRED)

Benefits Investigation Prior Authorization and Patient Assistance Program (PAP) or Medication Assistance Program (MAP) E

2. GILEAD MEDICATION PRESCRIBED (REQUIRED)

Product Name: _____

If requesting TRUVADA, please indicate for: Treatment PrEP

3. PATIENT INFORMATION (REQUIRED)

First Name: _____ Last Name: _____

Address: _____ Apt./Unit #: _____

State: _____ Zip Code: _____

Email: _____

Alternate Contact Name: _____

CONTACT AUTHORIZATION

I authorize Advancing Access to leave a detailed message, including the name of my

4. INSURANCE INFORMATION (REQUIRED)

Patient is insured (Please fill out all of the applicable insurance information below. Attach copy - front and back - of patient card)

Primary Insurance: _____

Plan name: _____

Subscriber Name: _____ Policy Holder Name: _____

Policy #: _____ Group #: _____

Check box if patient has secondary insurance coverage and fax a copy of ins

5. PRESCRIBER INFORMATION (REQUIRED)

Prescriber Name: _____

Address: _____

State: _____ Zip Code: _____

Phone #: _____

Tax ID #: _____

6. DIAGNOSIS/MEDICAL INFORMATION

Diagnosis (Please include ICD code): _____

7. PRESCRIBER CERTIFICATION AND STATEMENT OF MEDICAL NECESSITY

By signing this form, I certify that I am prescribing Gilead medication for the patient identified in patient and that it will be used as directed. I certify that I will be supervising the patient's treatment of my knowledge. I agree that I shall not seek reimbursement for any Gilead medication dispensed Program ("PAP/MAP") from any government program or third party insurer.

If prescribing TRUVADA for PrEP, I certify that the applicant has been tested for HIV infection and applicant's care plan. As part of my applicant's eligibility, I agree to periodically verify continued I certify that I have received the appropriate written authorization from the patient, in accordance with health information privacy laws, and any other applicable requirements, in order to release the patient's insurance coverage and eligibility for benefits; 2) seeking support, and referral support as needed; 4) facilitating the provision of the patient's prescription in patient's prescription medication or to evaluate the effectiveness of the Advancing Access Program

PRESCRIBER SIGNATURE (REQUIRED):

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ENROLLMENT FORM PAGE 1 OF 3
 PHONE: 1-800-226-2056 FAX: 1-800-216-6857

ADVANCING ACCESS ENROLLMENT FORM PHONE: 1-800-226-2056 FAX: 1-800-216-6857

PATIENT NAME: _____ DATE OF BIRTH: _____

8. PATIENT AUTHORIZATION FOR USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION (REQUIRED)

I understand that I must complete this enrollment form before I can receive assistance through Advancing Access ("Program") and the Patient Assistance Program/Medication Assistance Program ("PAP/MAP") and its agents and contractors (collectively, "Gilead") will need my personal and medical information as described below. I hereby authorize my personal and medical information as described below to Gilead in connection with the PAP/MAP, all in accordance with this authorization, and I authorize Gilead to use and disclose my personal and medical information as described below to Gilead in connection with the PAP/MAP.

Information to Be Disclosed: Personal health information ("PHI"), including information, name, mailing address, financial information, and insurance information), my past (including information about my HIV-related status or treatment with this prescription medication), and all information provided on this enrollment form.

Persons Authorized to Disclose My Information: My healthcare providers, including my primary care physician, and any health plans or programs that provide me healthcare benefits. My healthcare providers may receive remuneration for disclosing my PHI pursuant to this authorization.

Persons to Which My Information May Be Disclosed: Gilead, including the third party administrator of the Program and the PAP/MAP.

Purposes for Which the Disclosures Are to Be Made: Disclosures of PHI may be made for the following purposes: 1) completing the enrollment process and verifying my eligibility for benefits from my health plan or other programs; 2) providing financial support, and communicating with my healthcare providers, including, but not limited to, my prescriber, to ensure that I am receiving the most appropriate prescription medication to me; 3) contacting me to evaluate the effectiveness of the Gilead's internal business purposes, including quality control and support enhancement, information, offers, and educational materials related to my treatment and/or my patient relationship marketing program (this use of my personal information is not for the purposes of the Program or the PAP/MAP); 4) contacting me to evaluate the effectiveness of the signatures below, I may opt in).

I understand that once my PHI has been disclosed hereunder, federal privacy laws may apply. I understand further that I may refuse to sign this authorization and that if I refuse, my ability to obtain treatment from my healthcare providers will not change, but I will not be eligible for the Program and/or the PAP/MAP. I also understand that I may cancel this authorization at any time by writing to Advancing Access, PO Box 13185, La Jolla, CA 92039-3185. If I cancel, Gilead will not use or disclose my PHI after the cancellation date, but the cancellation will not affect PHI that have already been made pursuant to this authorization before the cancellation date, which expires the earlier of two (2) years from the date it is signed or the laws of the state in which I reside.

By checking this box, I agree to receive marketing information, offers and educational materials related to prescription medication, including the customer relationship marketing program.

SIGNATURE of PATIENT or PATIENT'S REPRESENTATIVE (REQUIRED):

Patient Representative's Name (if signing for the patient):

Patient Representative's Relationship to Patient:

FAX COMPLETED FORM TO ADVANCING ACCESS AT 1-800-216-6857

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ADVANCING ACCESS ENROLLMENT FORM PHONE: 1-800-226-2056 FAX: 1-800-216-6857

PATIENT NAME: _____ DATE OF BIRTH: _____

9. PATIENT FINANCIAL INFORMATION REQUIRED ONLY IF APPLYING FOR THE PATIENT ASSISTANCE PROGRAM/MEDICATION ASSISTANCE PROGRAM (PAP/MAP)

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 returns, W2, last 2 pay stubs, etc.).
 If there is no household income, indicate how the patient/household is being supported: _____

ADDITIONAL INSURANCE INFORMATION

Social Security Number: _____

Has the patient applied for ADAP? Yes No If Yes, date of application: _____

Has the patient applied for Medicaid? Yes No If Yes, date of application: _____

Is the patient eligible for Medicaid? Yes No If No, state reason: _____

Is the patient eligible for VA benefits? Yes No If Yes, has the patient tried to obtain the medication through the VA? Yes No

Has the patient applied for an insurance plan offered through a state insurance marketplace (also known as an exchange)? Yes 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)? Yes No If No, state reason: _____

APPLICANT DECLARATIONS AND AUTHORIZATIONS (REQUIRED ONLY IF APPLYING FOR THE PAP/MAP)

I certify that all of the information provided in this application, including household income, is complete and accurate. I understand that program assistance will terminate if Advancing Access becomes aware of any false or inaccurate information or if this medication is no longer prescribed for me. I understand that completing this application does not ensure that I will qualify for patient assistance. If I receive free product through the PAP/MAP, I certify that I will not seek reimbursement or credit for this medication from any insurer, health plan, or government program. If I am a member of a Medicare Part D plan, I will not seek to have this medication or any cost for items associated with it counted as part of my out-of-pocket cost for prescription drugs. I understand that the PAP/MAP reserves the right to modify the application form, modify or discontinue this program, or terminate assistance at any time and without notice. I authorize the PAP/MAP and its administrator to forward my prescription to a dispensing pharmacy on my behalf. I authorize Gilead and its third party administrator to use the information provided on this form to obtain a personal credit report about me to verify the information on this form and determine my eligibility for the PAP/MAP.

SIGNATURE OF PATIENT/PATIENT REPRESENTATIVE (REQUIRED ONLY IF APPLYING FOR PAP/MAP)

DATE: _____

FAX COMPLETED FORM TO ADVANCING ACCESS AT 1-800-216-6857

State Plans

- Illinois - IDPH PrEP Assistance Program
 - PrEP Navigation, funding for cost assistance through IDPH
- Massachusetts - Massachusetts Pre-Exposure Prophylaxis Drug Assistance Program (PrEP-DAP)
 - Assistance for copays, co-insurance, full cost of Truvada ®
 - Limited to <500% FPL
- Washington - Pre-Exposure Prophylaxis Drug Assistance Program (PrEP-DAP)
 - PrEP Navigation, assistance for medication and cost of labs/visits
 - No income limitation
- New York - Pre-exposure Prophylaxis Assistance Program (PrEP-AP)
 - Assistance for cost of labs and provider visits
 - Enrollment criteria based on AIDS Drug Assistance Program (ADAP)
- California - PrEP Assistance Program (PrEP-AP)
 - Launched early 2018
 - Assistance for cost of labs and provider visits
 - Limited to <500% FPL

Advice to patients

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

PrEP eligibility

Summary of Guidance for PrEP Use			
	Men Who Have Sex With Men	Heterosexual Women and Men	Injection Drug Users
Detecting substantial risk of acquiring HIV infection:	<ul style="list-style-type: none"> Sexual partner with HIV Recent bacterial STD High number of sex partners History of inconsistent or no condom use Commercial sex work 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> HIV-positive injecting partner Sharing injection equipment Recent drug treatment (but currently injecting)
Clinically eligible:	<ul style="list-style-type: none"> 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 doses of TDF/FTC (Truvada), ≤90 day supply		
Other services:	<ul style="list-style-type: none"> Follow-up visits at least every 3 months to provide: <ul style="list-style-type: none"> HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STD symptom assessment At 3 months and every 6 months after, assess renal function Every 6 months test for bacterial STDs 		
	<ul style="list-style-type: none"> Do oral/rectal STD testing 	<ul style="list-style-type: none"> Assess pregnancy intent Pregnancy test every 3 months 	<ul style="list-style-type: none"> 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.

PrEP eligibility

Summary of Guidance for PrEP Use

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

Source: US Public Health Service. Preexposure proph

PrEP eligibility

Summary of Guidance for PrEP Use

	Men Who Have Sex With Men	Heterosexual Women and Men	Injection Drug Users
Detecting substantial risk of acquiring HIV infection:	<ul style="list-style-type: none"> - Sexual p - Recent b - High nu - partners - History o - no cond - Commer 		
Clinically eligible:	<ul style="list-style-type: none"> - Do - No - No - Do 		
Prescription			
Other services:	<ul style="list-style-type: none"> - Fol - HIV - sid - At 3 - Eve 		
	<ul style="list-style-type: none"> - Do oral/re 		

HIRI-MSM Risk Index*			
1	How old are you today	<18 years	score 0
2	How many you have had sex with in the last 12 months		
3	In the last 12 months, how many times did you have sex with a partner who has HIV or is at high risk of HIV?		
4	How many partners have you had sex with in the last 12 months (yours and theirs)?		
5	In the last 12 months, how many times have you had sex with a partner who has HIV or is at high risk of HIV?		
6	In the last 12 months, how many times have you had sex with a partner who has HIV or is at high risk of HIV?		
7	In the last 12 months, how many times have you had sex with a partner who has HIV or is at high risk of HIV?		

Medication Guide	
TRUVADA® (tru-VAH-dah) (emtricitabine and tenofovir disoproxil fumarate) tablets	
Read this Medication Guide before you start taking TRUVADA and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.	
This Medication Guide provides information about two different ways that TRUVADA may be used (see the Medication Guide section "What is TRUVADA?" for important information about how TRUVADA may be used):	
<ul style="list-style-type: none"> • to treat Human Immunodeficiency Virus-1 (HIV-1) infection, and • to reduce the risk of getting HIV-1 infection in adults who are HIV-negative 	
HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).	
What is the most important information I should know about TRUVADA?	
If you also have hepatitis B virus (HBV) infection and take TRUVADA, your hepatitis B may become worse if you stop taking TRUVADA.	
<ul style="list-style-type: none"> • Do not stop taking TRUVADA without first talking to your healthcare provider. • Do not run out of TRUVADA. Refill your prescription or talk to your healthcare provider before your TRUVADA is all gone. • If your healthcare provider stops TRUVADA, your healthcare provider will need to watch you closely for several months to check your hepatitis B infection, or give you a medication to treat hepatitis B. 	
Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking TRUVADA.	
For more information about side effects, see the section "What are the possible side effects of TRUVADA?" in this Medication Guide.	
Other important information for people who take TRUVADA to help reduce their risk of getting HIV-1 infection:	
Before taking TRUVADA to reduce your risk of getting HIV-1 infection:	
<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 	

*To identify their male partners, women, or injection drug users.

†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.

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

PrEP eligibility

Summary of Guidance for PrEP Use

	Men Who Have Sex With Men	Heterosexual Women and Men	Injection Drug Users
Detecting substantial risk of acquiring HIV infection:	<ul style="list-style-type: none"> Sexual p Recent b High nu partners History o no cond Commer 	HIRI-MSM Risk Index*	
Clinically eligible:	<ul style="list-style-type: none"> Do No No Do 	1 How old are you today <18 years score 0	
Prescription		2 How many you have had in the last 12 months	
Other services:	<ul style="list-style-type: none"> Fol HIV sid At 3 Eve Do oral/re 	3 In the last 12 months, how many times did you have anal sex with a partner who is HIV positive	
		4 How many sex partners have you had in the last 12 months	
		5 In the last 12 months, how many times did you have sex with a partner whose HIV status is unknown	
		6 In the last 12 months, how many times did you use injection drugs	
		7 In the last 12 months, how many times did you have sex with a partner who injects drugs	

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

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

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

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

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

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

The USPSTF recommends the following persons be considered for PrEP:

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

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

PrEP eligibility

Summary of Guidance for PrEP Use

	Men Who Have Sex With Men	Heterosexual Women and Men	Injection Drug Users
Detecting substantial risk of acquiring HIV infection:	<ul style="list-style-type: none"> - Sexual p - Recent b - High nu - partners - History o - no cond - Commer 	HIRI-MSM Risk Index*	
		1 How old are you today	<18 years
		2 How many you have in the	

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

Read this Medication Guide before you start taking TRUVADA and each time you get a refill. There may be new

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

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

- A recent STI with syphilis or gonorrhea
- 3. Persons who inject drugs and have one of the following characteristics:
 - Share drug injection equipment
 - Are at risk of sexual acquisition of HIV (see above)

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%)

What about $U=U$?



U=U

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

U=U

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

HIV risk is
behavioral, individual, transitional

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

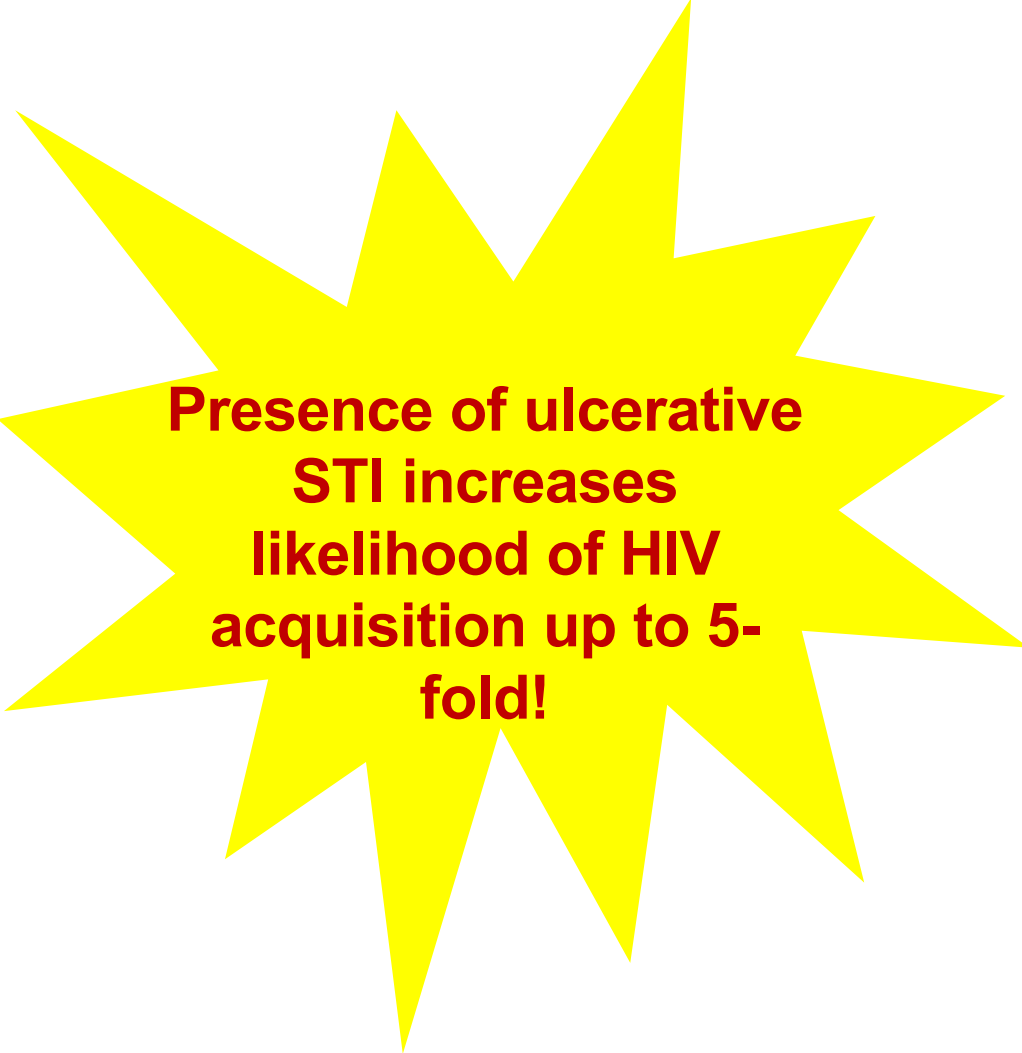
PrEP is a PROGRAM

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



STIs Facilitate HIV Transmission

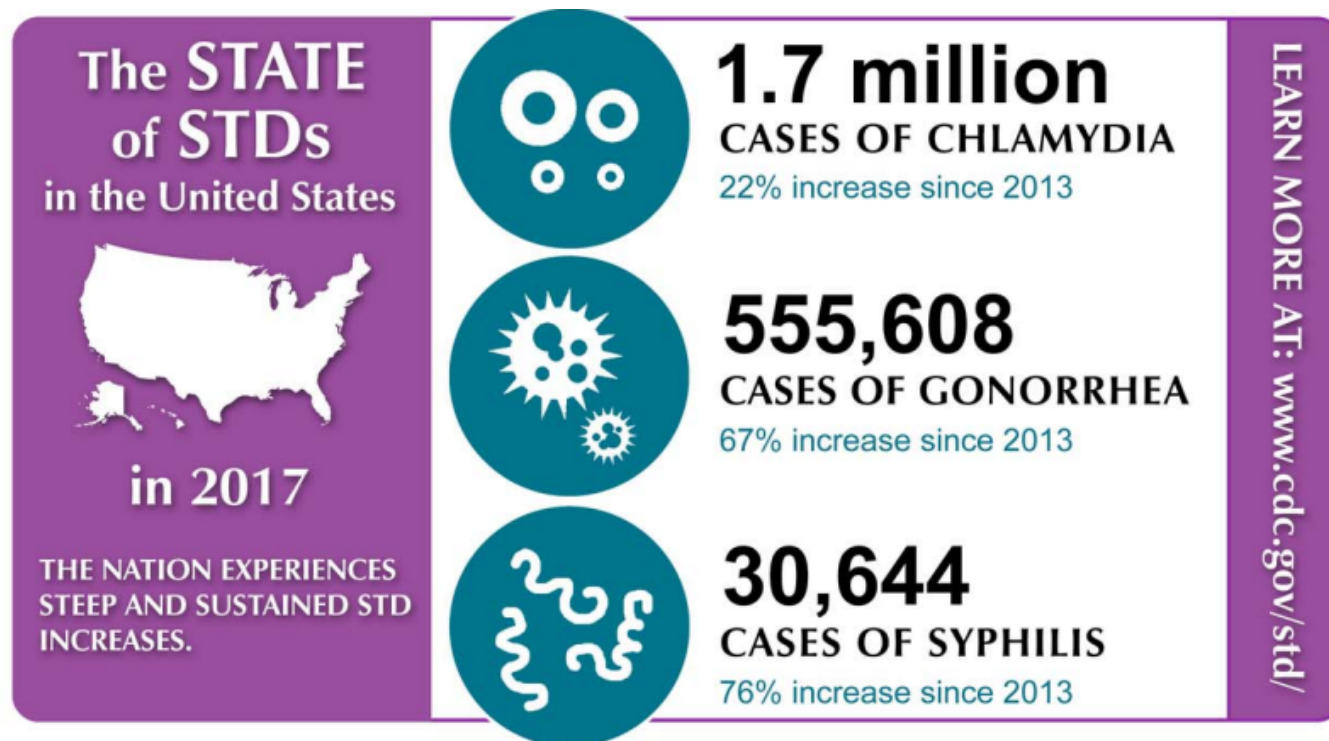
- Disruption of mucosal integrity
- Increase HIV target cells in genital tract due to immune reaction to infection
- STIs promote HIV shedding in the genital tract



**Presence of ulcerative
STI increases
likelihood of HIV
acquisition up to 5-
fold!**

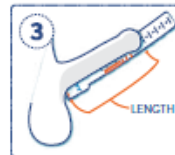
Condom use

- Truvada® does NOT protect against bacterial and other STIs
- These are at record highs!



How many sizes of condoms are there?

Introducing myONE®, the world's first perfect-fit condom with 60 different sizes for maximum pleasure & comfort.



FitKit™ Instructions

STEP 1: Print your fit kit. It's important that the Fit Kit print correctly so you are sized properly. To verify, place a bank card onto the illustration below. If it fits, so will you. Troubleshooting printer issues: Printer scaling is the most common reason the FitKit does not print correctly. Be sure to turn printer scaling off and verify that you're printing the document at 100% size.

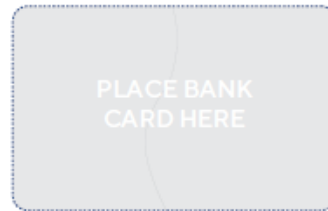
STEP 2: Cut out the measuring tool. Letters are for length and numbers are for width.

STEP 3: Find your length. Place the measuring tool under your erection with the wide end toward your body. Be sure that the edge of the Fit Kit is at the base of your penis, ensuring that the entire shaft will be covered. Your length is the letter that you see above the tip of your penis.

STEP 4: Find your width. Wrap the measuring tool gently around the middle of your erection. Your width is shown where the arrows meet the numbers. If your size is in between two numbers, select the number that is closest.

STEP 5: Determine your size. Combine your Length Letter with your Width Number to determine your myONE condom size. Visit myonecondoms.com to purchase or locate a retailer near you.

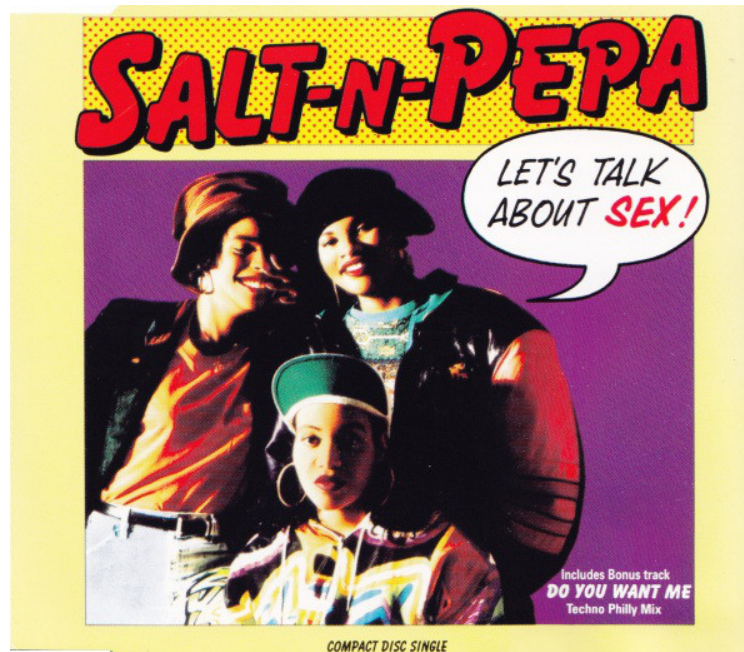
Please note: your myONE size is a suggested size based on your measurements. You may want to choose a slightly different size based on your personal preference. If your combination is not shown, to make the best choice choose a nearby size. It's better that a condom has more length or less width rather than be too wide or short. A proper fit is both comfortable and held snugly in position. Don't be afraid to try more than one code combination!



© 2017, ONE® Condoms. All Rights Reserved. FitKit™ & myONE® distribution strictly by authorized representative only.
 Warning: myONE® may actually improve your sex life! myONE® FitKit™ Version USA, 2017 03. ALWAYS USE THE MOST UP TO DATE FitKit™ TO MAXIMIZE FITTING ACCURACY AND FITTED COMFORT. CHECK MYONECONDOMS.COM FOR DETAILS.

The Sexual History

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



The Sexual History

- 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.

- Recognize that this is our duty as physicians
- It's a learnable skill (like all things in medicine)
- With experience comes comfort

Barriers to the Sexual History

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

Sexual History Misconceptions

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

Principles of a comprehensive sexual history

- Ensure privacy and confidentiality.
- Be professional.
- Be open minded and non-judgmental.
- Recognize non-verbal cues.
- Explain procedures and treatments thoroughly.

Effective Communication Skills

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

The Sexual History

- Preface

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

The Sexual History

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

The Sexual History

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

The Sexual History

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

The Sexual History

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



Ready, set, PrEP!



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
Depression	43 (3)	46	62 (5)	63	0.07
Nausea	20 (2)	22	9 (<1)	10	0.04
Unintentional weight loss (≥5%)	27 (2)	34	14 (1)	19	0.04
Diarrhea	46 (4)	49	56 (4)	61	0.36
Bone fracture	15 (1)	16	11 (<1)	12	0.41
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.

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Adverse Events

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

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

* ALT denotes alanine aminotransferase, and AST aspartate aminotransferase.

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

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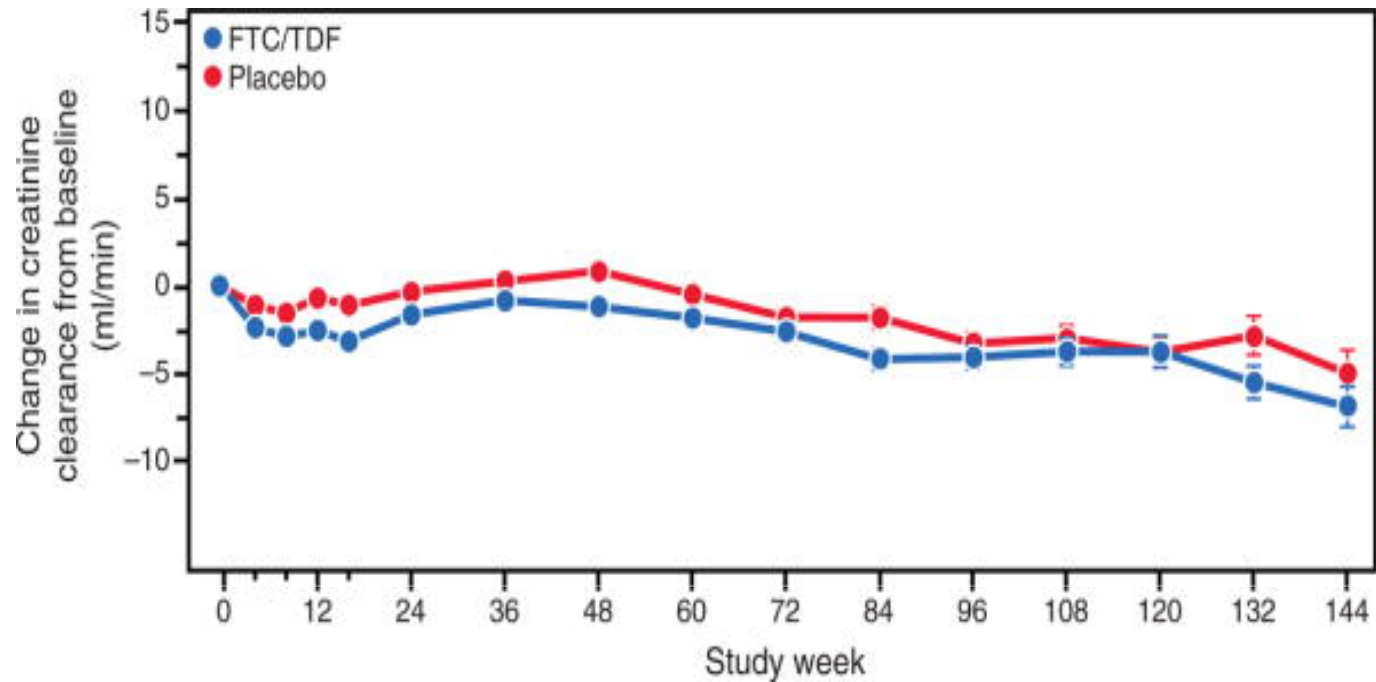
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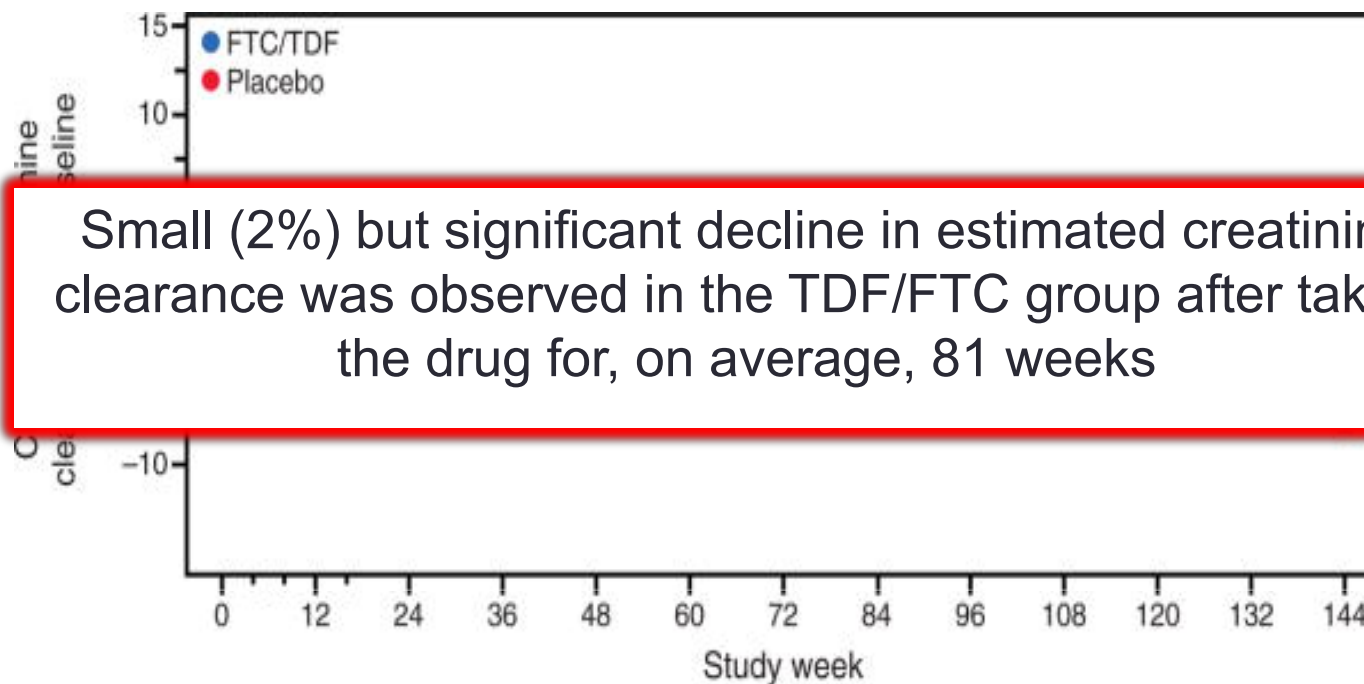
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Adverse Events



Adverse Events



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

Adverse Events

Table 3. Bone Mineral Density Scores.*

Assessment	Forearm			Hip			Lumbar Spine		
	TDF-FTC (N=109)	Placebo (N=112)	P Value	TDF-FTC (N=109)	Placebo (N=112)	P Value	TDF-FTC (N=109)	Placebo (N=112)	P Value
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	

* 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.

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	-0.87	-0.13		0.20	0.76		-1.09	-0.28	

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

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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
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The First Visit

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

The Second Visit

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

Every 3 months

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

Every 6 months

- Screen for other STIs
- Repeat serum creatinine

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+

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”
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 - Z79.2 “Long-term (current) use of antibiotics”
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Special considerations

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

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



Future of PrEP



Descovy®

- Similar to Truvada®
 - Truvada® = tenofovir **disoproxil fumarate** (TDF) + emtricitabine
 - Descovy® = tenofovir **alafenamide** (TAF) + emtricitabine
 - Currently approved for HIV treatment, but not PrEP
- 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 (eGFR >30 mL/min)

Does the lower plasma/tissue concentration affect efficacy as PrEP?

DISCOVER trial - Update

- 5400 MSM and transgender women
- Randomized to Truvada® vs Descovy®
- Descovy® is non-inferior to Truvada® at 48 weeks
- Adverse events similar



Long-acting PrEP

- Cabotegravir (integrase inhibitor)
 - Formulated as a long-acting, depot-controlled nanosuspension
 - Half life ~50 days
 - Injection every 8 weeks
 - Injection site reactions common, though still favored over daily pill
 - Phase III trial (cabotegravir vs TDF/FTC) underway



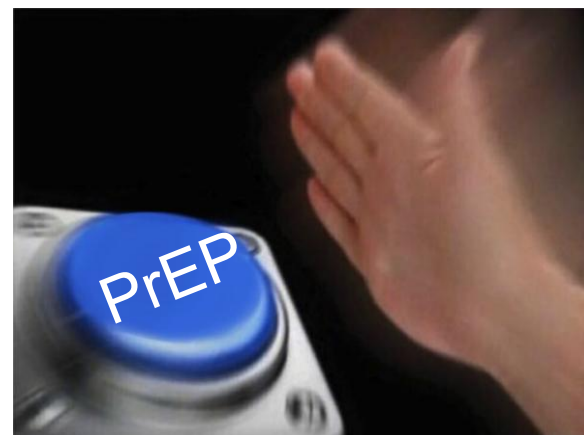
PrEP + contraception

- Dapivirine (NNRTI) 25mg ring
 - Two phase III trials (ASPIRE and The Ring Study) demonstrated about 30% HIV risk reduction
 - Low efficacy likely due to low adherence
 - Two open label extension studies pending
- Dapivirine 200mg + levonorgestrel 320mg
 - Phase I trial demonstrated safety



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 patient-doctor relationship
- Sexual history is essential to comprehensive health care
- Ask for help! sean.g.kelly@vumc.org



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

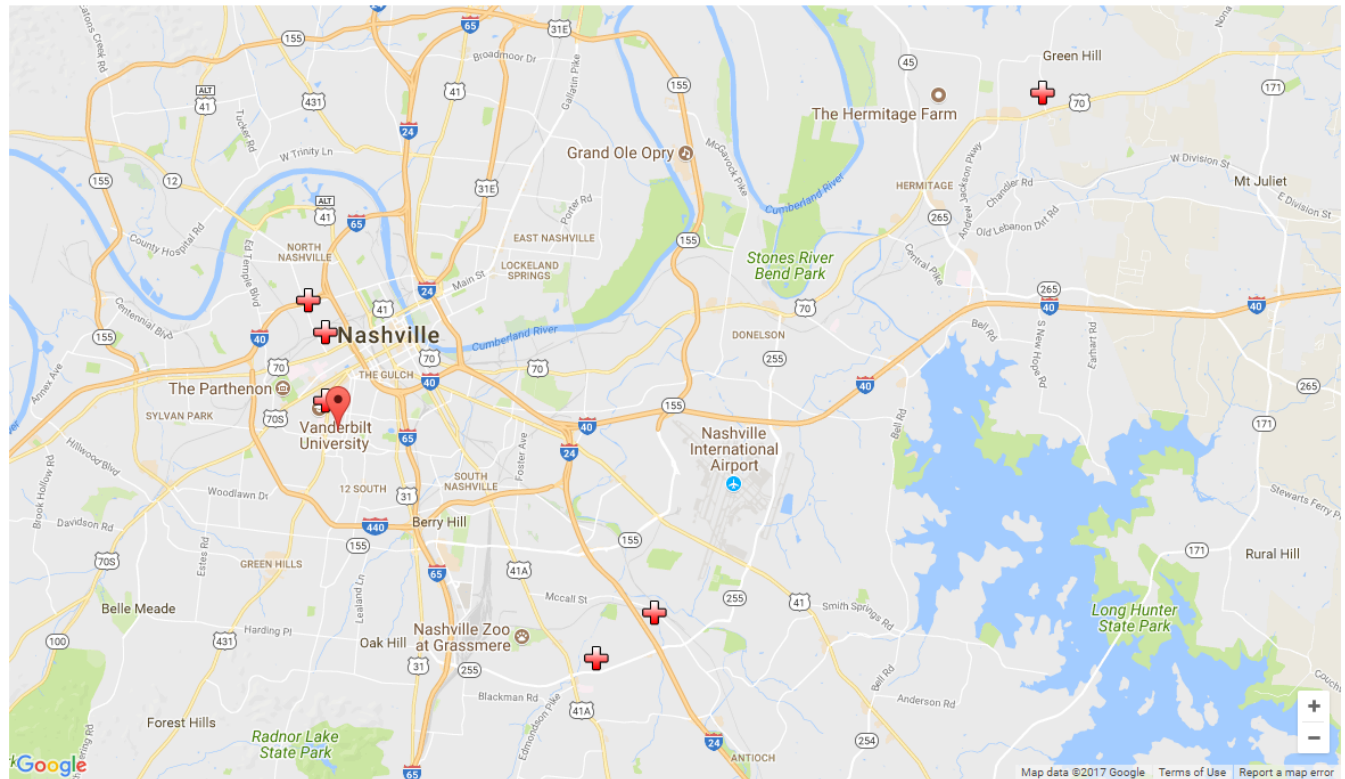
Distance from your location: 6 miles

Neighborhood Health @ MyHouse

42 Metrolplex Drive
Building 4
Nashville, TN 37211

[Add PrEP Locator to Your Site](#)

[Suggest a provider for the directory](#)



<https://preplocator.org>

Help us increase PrEP provision in TN!

- Anonymous 40-question survey to identify barrier providers have in prescribing PrEP.
- You can find the link on the event page along with the slides from today.
- <https://redcap.vanderbilt.edu/surveys/?s=YKE8YHNNHT>

Questions?

