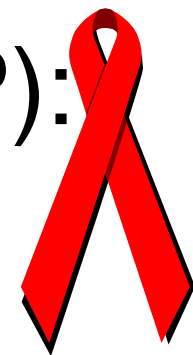


# Pre-Exposure Prophylaxis (PrEP): Best Practices for Pharmacists



Tina J Kanmaz, PharmD, AAHIVE  
Associate Clinical Professor  
Assistant Dean, Experiential Pharmacy Education  
St. John's University  
College of Pharmacy & Health Sciences



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# Learning Objectives

1. Discuss guidelines on the use of PrEP to prevent HIV infection
2. Describe the pharmacist's and pharmacy staff's role in HIV PrEP
3. Counsel patients on the appropriate use of Truvada for HIV prevention



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# Disclosures

Dr. Kanmaz has no conflicts of interest  
to disclose



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# Poll Question

I have been directly involved in either prescribing, dispensing or counseling patients on PrEP?

1. Yes
2. No



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# Poll Question

How would you rate your knowledge of PrEP?

1. I do not know anything about PrEP
2. I know what PrEP is but that is all
3. I have some baseline knowledge of PrEP
4. I know a lot about PrEP
5. I am an expert on PrEP



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# HIV TRANSMISSION



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# Infectious Body Fluids

Blood contains the highest concentration of the virus, followed closely by semen and then vaginal fluids

**Blood**

Breast Milk

HIV can be transmitted from an infected person to another through...

**Semen**

**Vaginal Secretions**

Other fluids where HIV is present



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# Routes of HIV Transmission

## Needles

- Injection Drug Use
- Tattooing
- Body Piercing

## Sexual

- Anal
- Vaginal
- Oral

## Razors & Toothbrushes

- When blood is present

## Perinatal

- Mother to baby



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# Exposure Type & Estimated Risk

## Needle-Sharing

- 0.63% (1/150)

## Receptive Anal Intercourse

- 0.5% (1/200) – 3% (6/200)

## Receptive Vaginal Intercourse

- 0.1% (1/1000)

## Insertive Anal Intercourse

- 0.065 (1/1500)

## Insertive Vaginal Intercourse

- 0.05% (1/2000)

## Oral Sex with Ejaculation

- Conflicting data, but felt to be low-risk. PEP recommended for receiver.



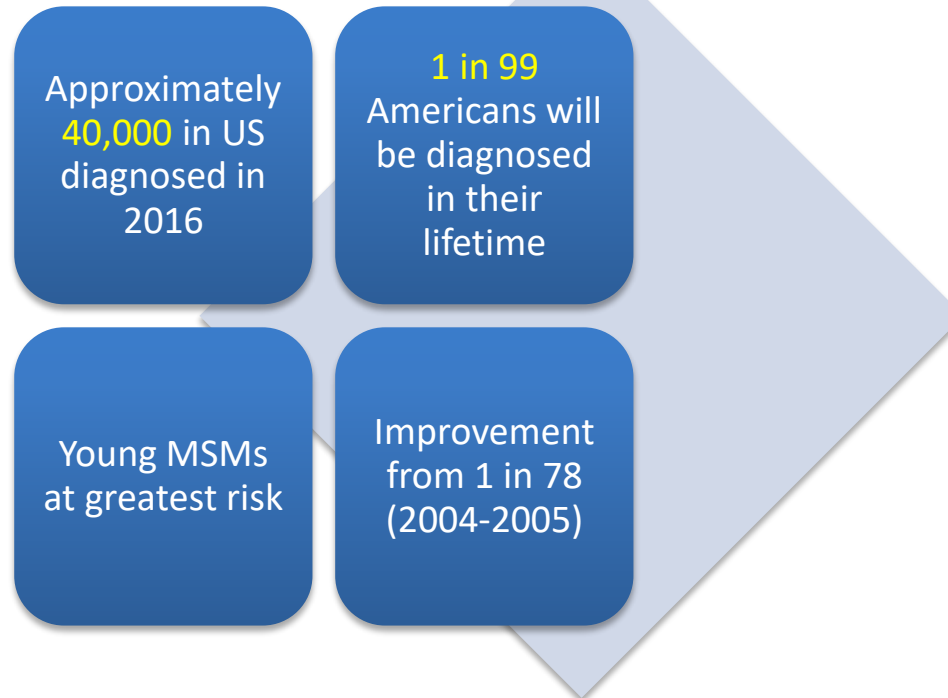
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# HIV DIAGNOSES IN THE US



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# HIV Transmission Statistics in the US

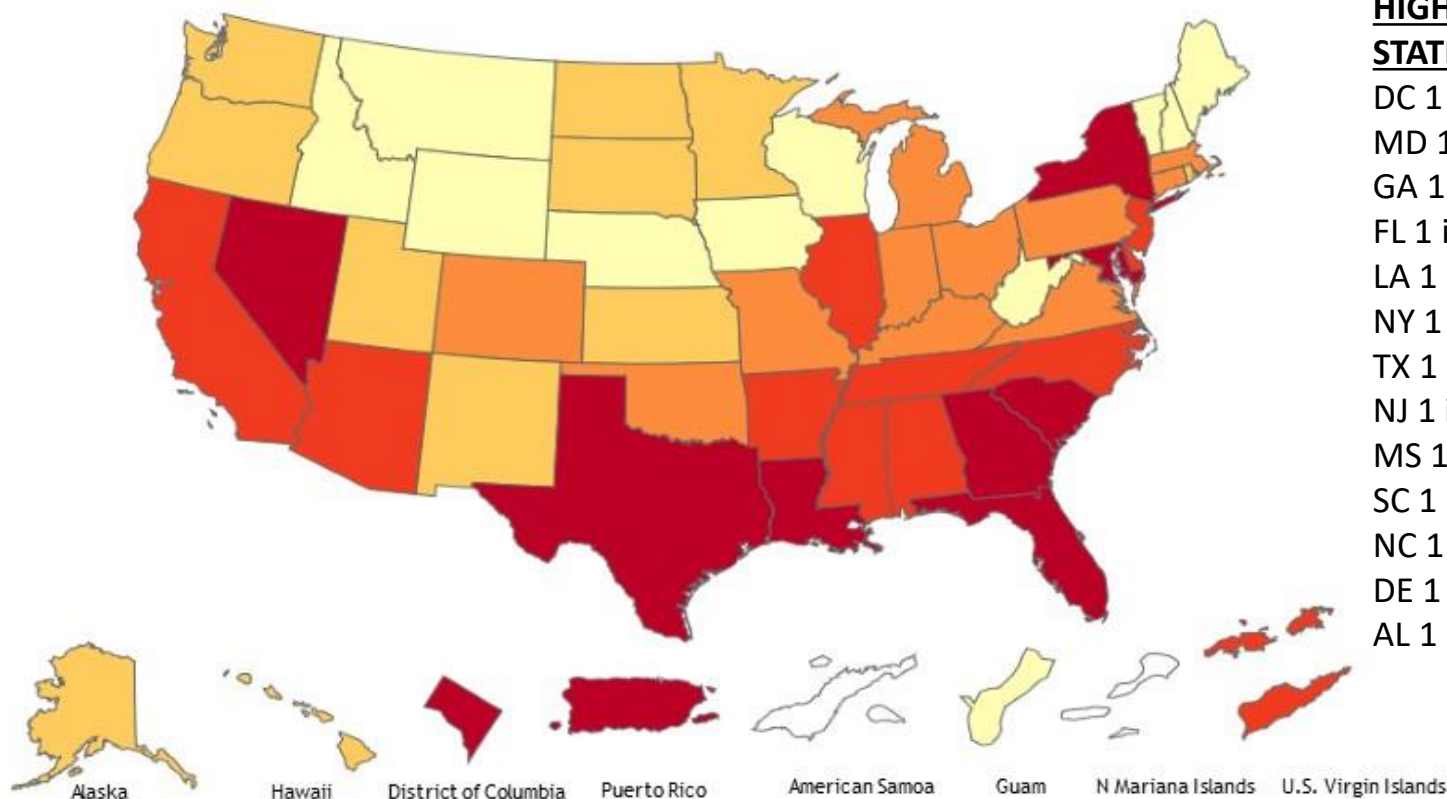


CDC. Lifetime risk of HIV diagnosis. <https://www.cdc.gov/nchhstp/newsroom/2016/croi-press-release-risk.html>.

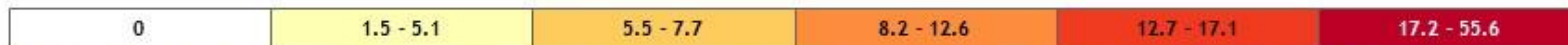


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HIV diagnoses | 2016 | All races/ethnicities | Both sexes | Ages 13 years and older | All transmission categories | US Map-State Level



Rate per 100,000 among selected population



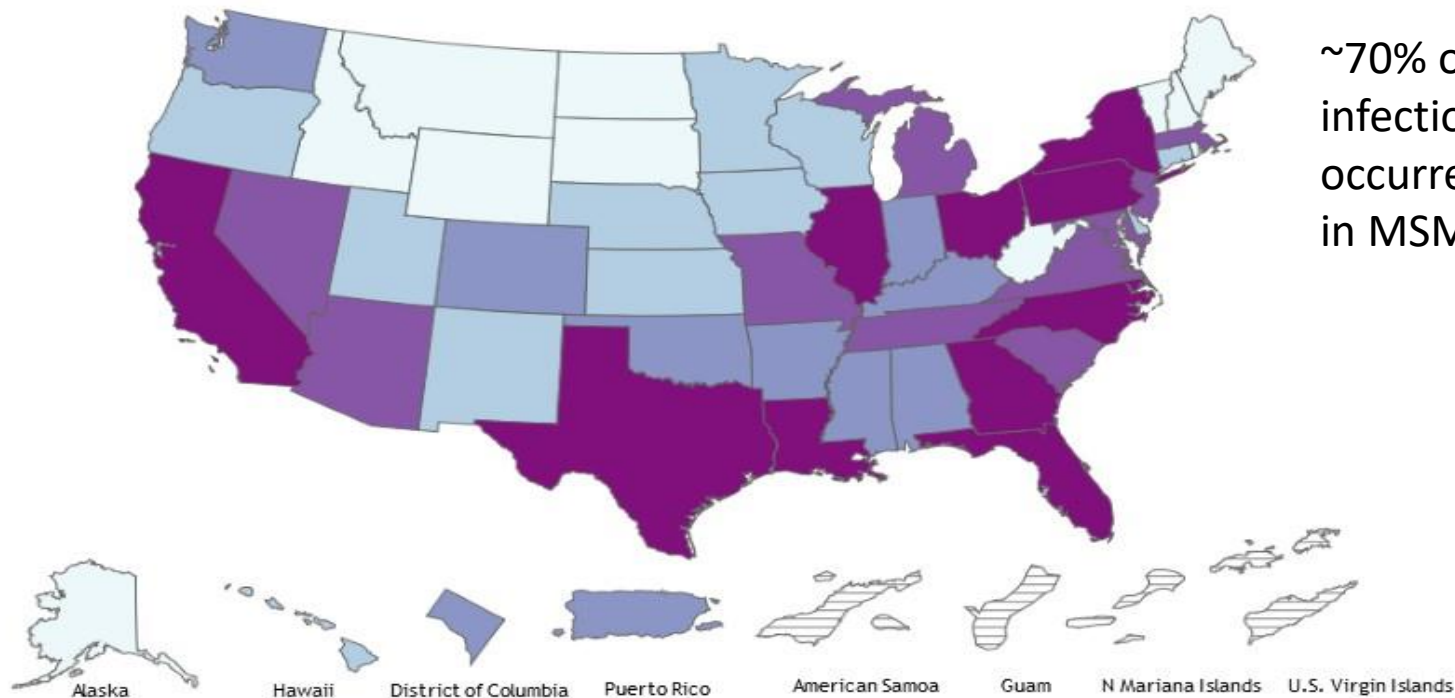
**Note:** HIV data for the year 2016 are preliminary and based on 6 months reporting delay. Therefore, trend data should be based on data through the year 2015 to allow sufficient time (at least 12 months) for reporting of case information to accurately assess trends.

### **HIGHEST STATE RISK\***

DC 1 in 13  
MD 1 in 49  
GA 1 in 51  
FL 1 in 54  
LA 1 in 56  
NY 1 in 69  
TX 1 in 81  
NJ 1 in 84  
MS 1 in 85  
SC 1 in 86  
NC 1 in 93  
DE 1 in 96  
AL 1 in 97

HIV diagnoses | 2016 | All races/ethnicities | Both sexes | Ages 13 years and older | Male-to-male sexual contact | US Map-State Level

~70% of new infections occurred in MSM



Cases

Data suppressed	6 - 40	49 - 173	184 - 343	364 - 645	649 - 3,874
-----------------	--------	----------	-----------	-----------	-------------

Note: HIV data for the year 2016 are preliminary and based on 6 months reporting delay. Therefore, trend data should be based on data through the year 2015 to allow sufficient time (at least 12 months) for reporting of case information to accurately assess trends.



Centers for Disease Control and Prevention  
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention



**CBA**  
CENTER

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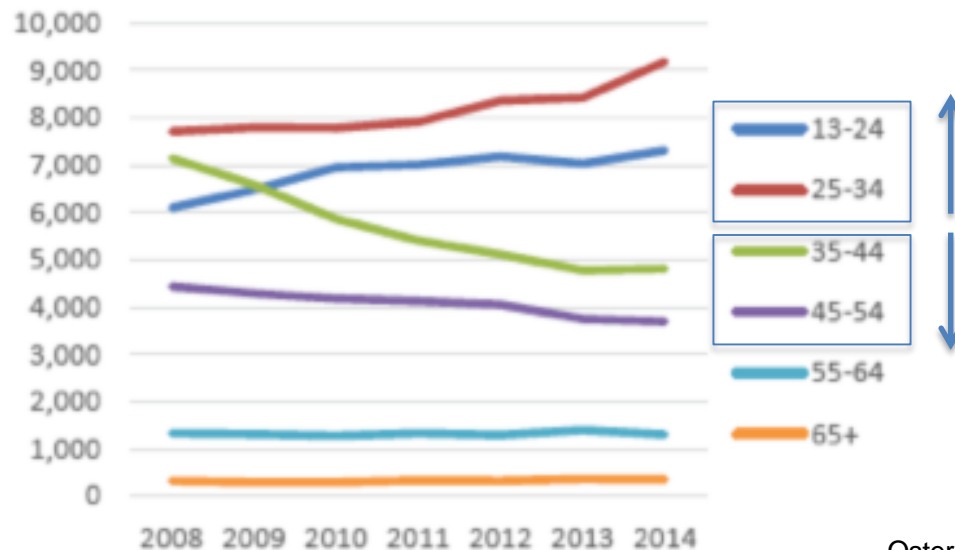


# New HIV Infections in MSM

## 2008-2014

- CDC - National HIV Surveillance System
- 27,026 (2008) decreased to 26,637 (2014)

Figure 2. Trends in HIV diagnoses among MSM, by age group.



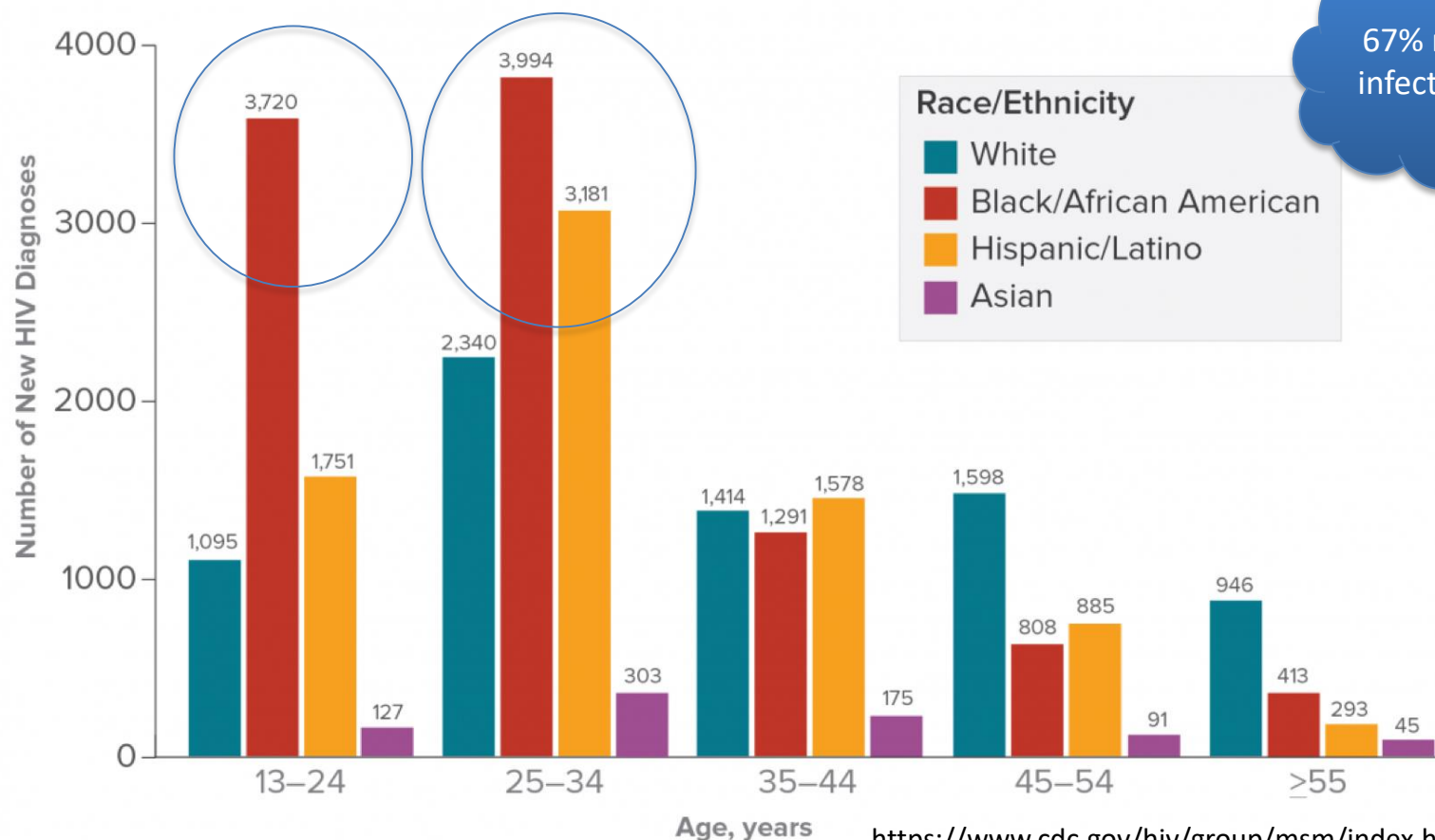
Oster, et al. IAS 2017. Abstract TUPEC0790.



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# HIV Diagnoses In Gay & Bisexual Men

By Age and Race/Ethnicity in the US and 6 Dependent Areas 2016



<https://www.cdc.gov/hiv/group/msm/index.html>

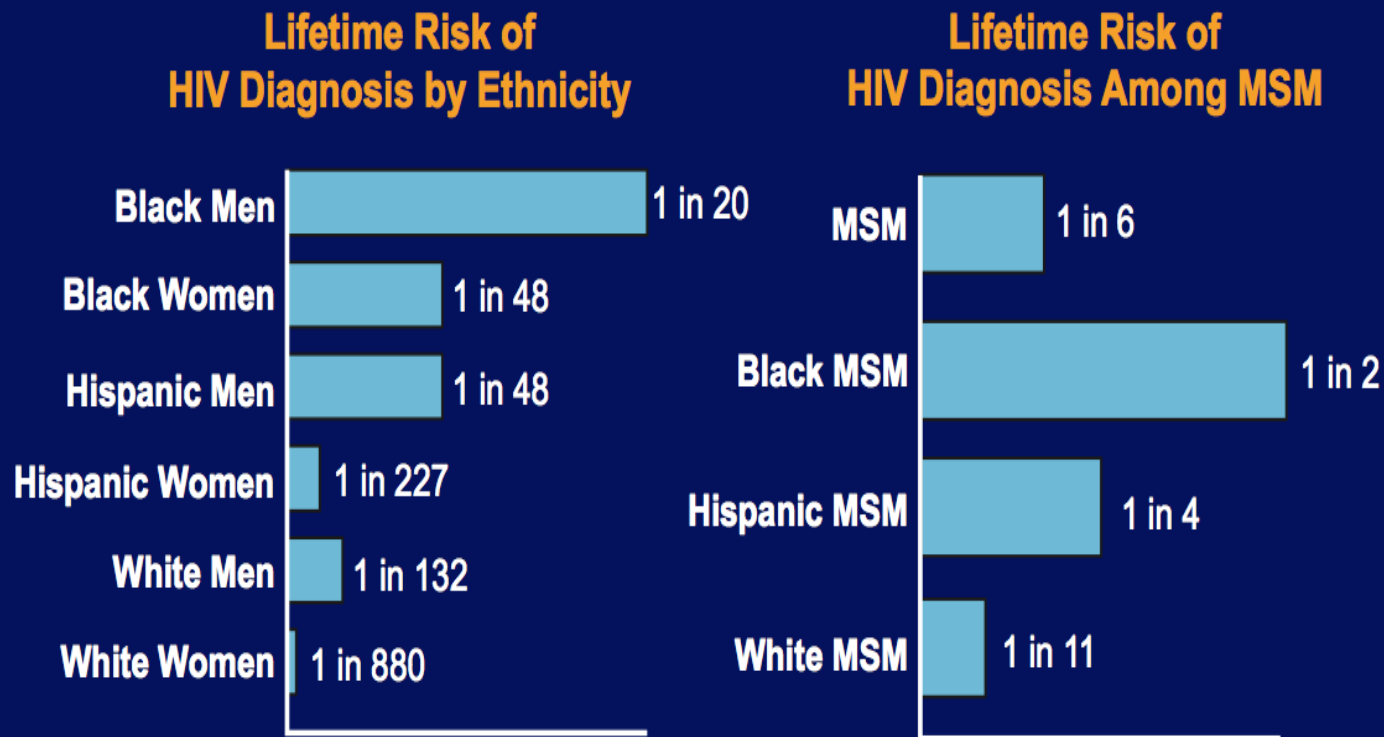
Subpopulations representing 2% or less of HIV diagnoses among gay and bisexual men are not reflected in this chart.

Source: [Diagnoses of HIV infection in the United States and dependent areas, 2016](#) . HIV Surveillance Report 2017;28.





# CDC: Lifetime HIV Infection Risk by Subgroup

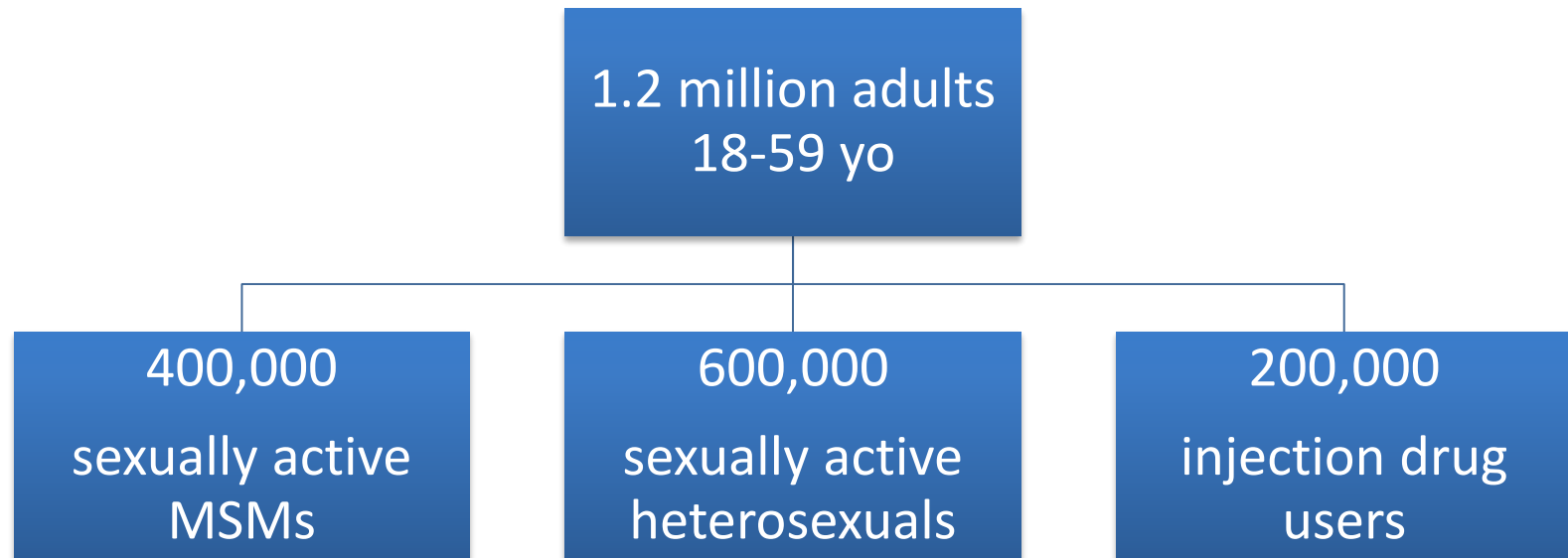


- People living in the South and Northeast US more likely to be diagnosed with HIV vs other Americans
  - Highest risk in Washington, DC (1 in 13) and the lowest risk in North Dakota (1 in 670)



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# How Many Can Benefit from PrEP in the US?



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# How Many Are Actually Using PrEP?

- National electronic database evaluated >80% of pharmacies
- 98,732 individuals started PrEP since 2012
- 36,732 individuals started PrEP in 2016 alone



- Highest rates in those >25y
- Proportion of use in women continues to decline



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Mera Giler, et al. IAS 2017. Abstract WEPEC0919.

# Eliminating HIV Transmission

- HIV Testing
- Pre-Exposure Prophylaxis (PrEP)
- Post-Exposure Prophylaxis (PEP)
- Treatment as Prevention (TasP)
- Consistent Condom Use
- Access to sterile needles and syringes

UNDETECTABLE = UNTRANSMITTABLE



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# NYS AIDS Institute

## Undetectable = Untransmittable Campaign



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Governor

Department  
of Health

HOWARD A. ZUCKER, M.D., J.D.  
Commissioner

SALLY DRESLIN, M.S., R.N.  
Executive Deputy Commissioner

September 2017

Dear Colleagues:

Though I usually cover two topics each month, I have chosen to focus on just one for my September letter. The reason for this decision is to ensure that all practitioners are aware of recent significant scientific developments and publications which have a direct impact on one of our most important initiatives: ending the AIDS epidemic in New York State. These developments address the concept of Treatment as Prevention (TasP), which the broader HIV-affected community refers to as Undetectable=Untransmittable, or U=U. There is now evidence-based confirmation that the risk of HIV transmission from a person living with HIV who is on Antiretroviral Therapy (ART), and has achieved an undetectable viral load in their blood for at least 6 months, is negligible. (Negligible is defined as: *so small or unimportant as to be not worth considering; insignificant.*)<sup>1</sup>

As many of you know, for more than a decade clinical trials and cohort studies have indicated that adherence to effective ART reduces the risk of HIV transmission. Today, with immediate ART treatment recommended for all individuals living with HIV, TasP has become the accepted strategy for reducing new infections. Cumulative, evidence-based scientific data supporting the concept of U=U has confirmed the previous epidemiological conclusion posited in 2008: effective antiretroviral therapy blocks HIV sexual transmission.<sup>2</sup>



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# HIV PREP GUIDELINES





# US PrEP Guidelines

- CDC US Public Health Service PrEP guidelines updated in 2017<sup>[1]</sup>
  - Reviews clinical trials on PrEP in specific populations
  - Designed to help providers make decisions about PrEP use
  - PrEP indicated in adults at substantial risk of acquiring HIV
  - Includes clinical eligibility, prescribing information, and other services to support PrEP care
- FDA approved Tenofovir Disoproxil Fumarate/Emtricitabine (Truvada) PrEP for **adolescents  $\geq 35$  kg** in 2018
  - Indications and follow-up are the same as for adults
  - Adolescent use will be incorporated into next update



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1. CDC. PrEP Guidelines. 2017.

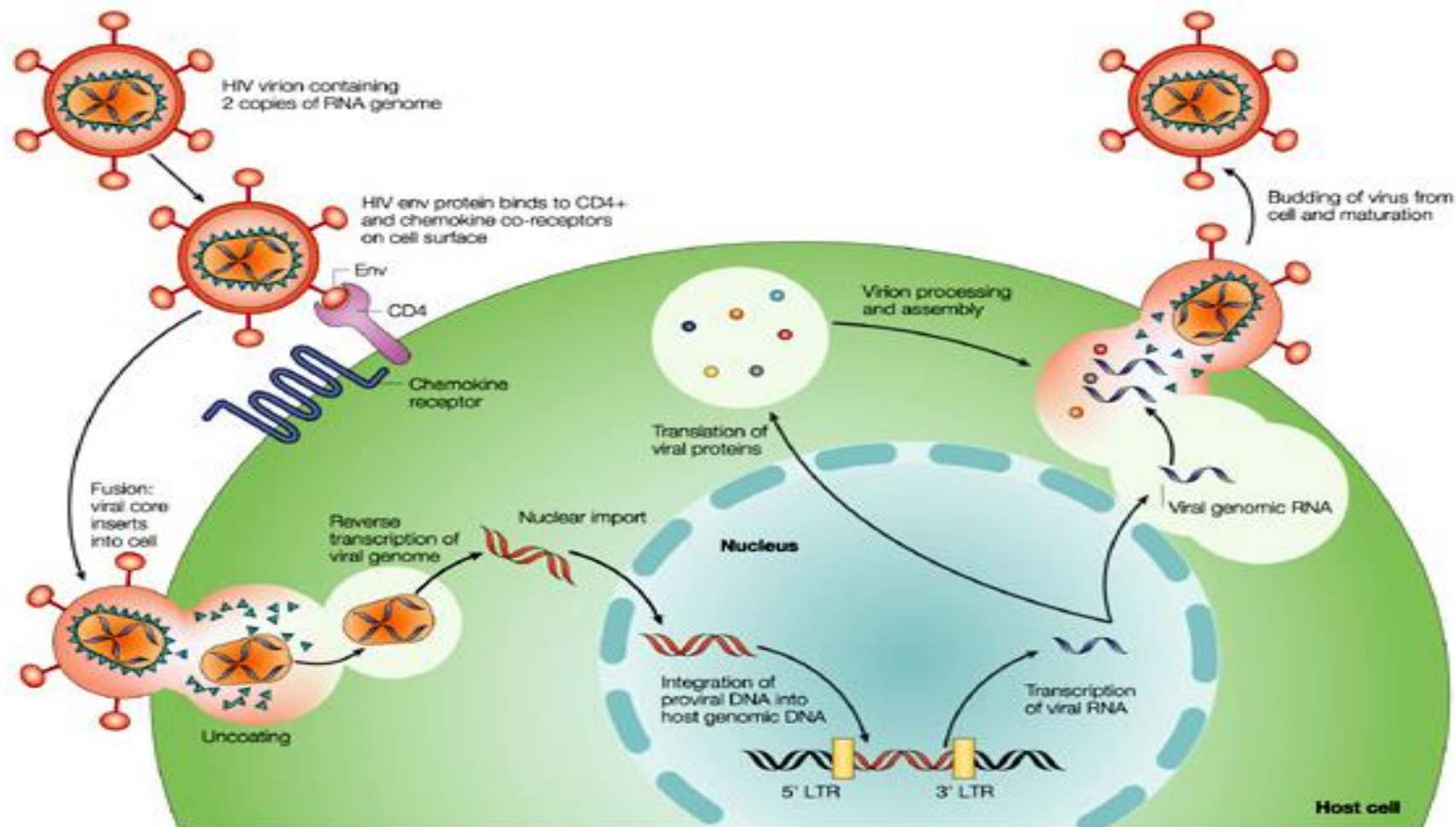
# Pre-Exposure Prophylaxis

- What is PrEP?
  - When people at very high risk for HIV take HIV medicines daily to lower their chances of getting infected
- Truvada
  - Tenofovir Disoproxil Fumarate (TDF) 300 mg  
Emtricitabine (FTC) 200 mg
  - One tablet taken by mouth daily
  - Only FDA-approved antiretroviral for PrEP
- Tenofovir Disoproxil Fumarate (TDF) 300 mg alone can be used in PWID and heterosexual men and women as an alternative



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CDC. PrEP Guidelines. 2017.



Nature Reviews | Genetics



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# Candidates for PrEP

MSM	Heterosexual Women & Men	Injection Drug Users
<ul style="list-style-type: none"><li>▪ HIV+ sexual partner</li><li>▪ Recent bacterial STD</li><li>▪ High # of sex partners</li><li>▪ History of inconsistent or no condom use</li><li>▪ Commercial sex work</li></ul>	<ul style="list-style-type: none"><li>▪ HIV+ sexual partner</li><li>▪ Recent bacterial STD</li><li>▪ High # of sex partners</li><li>▪ History of inconsistent or no condom use</li><li>▪ Commercial sex work</li><li>▪ In high-prevalence area</li></ul>	<ul style="list-style-type: none"><li>▪ HIV+ injecting partner</li><li>▪ Share injection equipment</li></ul>

- People who use stimulant drugs associated with high-risk behaviors (methamphetamine)
- People prescribed multiple courses of non-occupational post-exposure prophylaxis (nPEP)



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CDC. PrEP Guidelines. 2017.



# How Long Does it Take to Achieve Protection?

Rectal Tissue – 7 days

Cervicovaginal Tissue – 20 days

Blood – 20 days



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CDC. PrEP Guidelines. 2017.

# Eligibility Criteria

- ✓ Documented negative HIV test
- ✓ No signs/symptoms of acute HIV infection
- ✓ Creatinine clearance  $\geq 60$  mL/min
- ✓ Weight  $\geq 35$  kg
- ✓ No contraindicated medications
- ✓ Documented hepatitis B virus infection and vaccination status



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CDC. PrEP Guidelines. 2017.

# Prescription and Follow-Up

## All Patients

- **Truvada: Tenofovir 300mg/Emtricitabine 200 mg once daily by mouth; No more than 90-day supply**
- Follow-up visits at least every 3 months
- HIV test, adherence counseling, behavioral risk reduction support, side effect assessment, STI assessment
- At 3 months and every 6 months thereafter assess renal function
- Every 3 months, test for bacterial STI

MSM	Heterosexual Women & Men	Injection Drug Users
Oral/Rectal STI Testing	<ul style="list-style-type: none"><li>▪ Pregnancy test every 3 months</li></ul>	Access to clean needles/syringes and drug treatment services



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CDC. PrEP Guidelines. 2017.



# HOW WELL DOES PREP WORK?



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# Overall Results of PrEP Trials

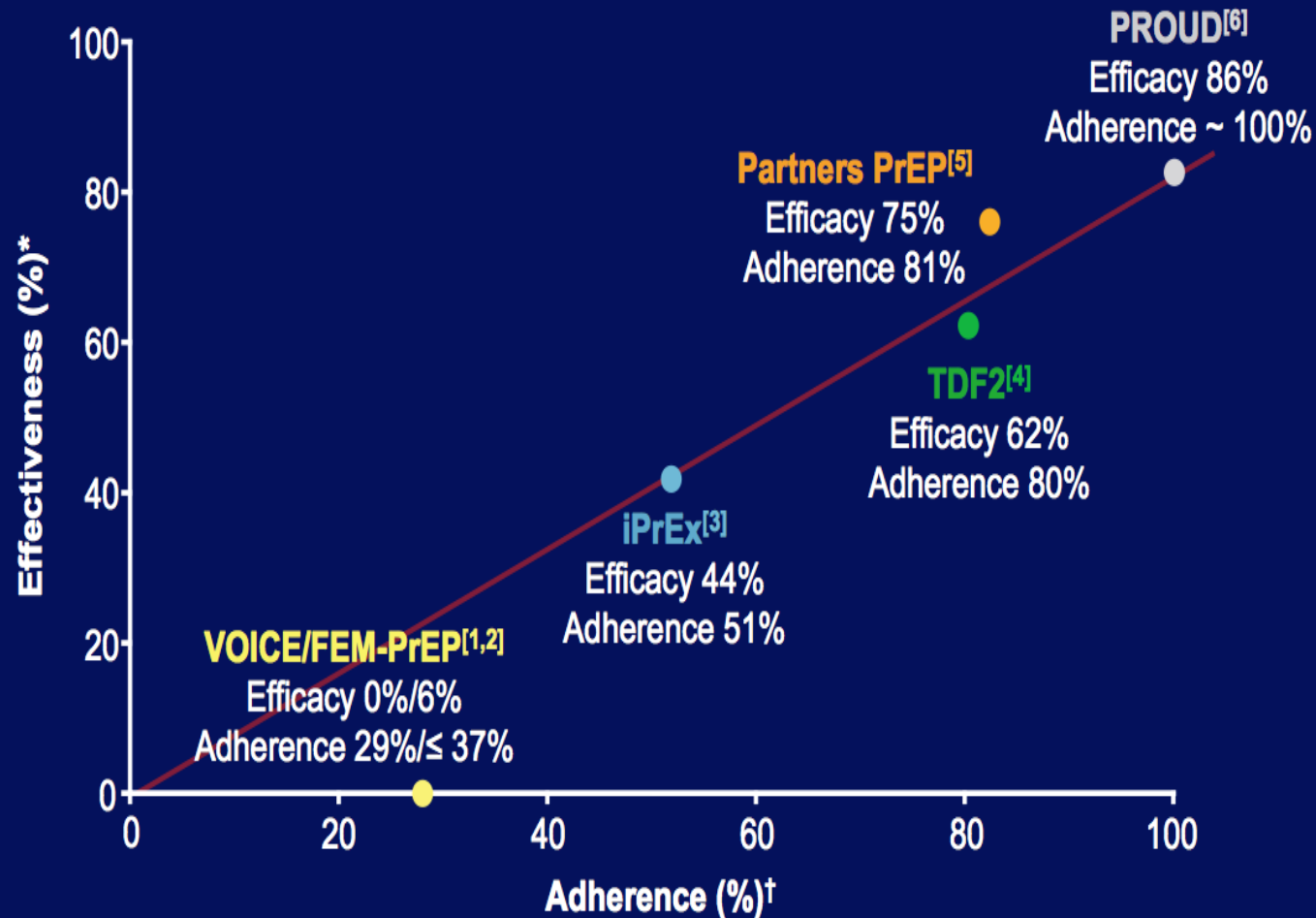
Clinical Trial	Participants	Medication	mITT efficacy*		Adherence-adjusted efficacy based on TDF detection in blood	
			%	(95% CI)	%	(95% CI)
Bangkok Tenofovir Study	Injecting drug users	TDF	49	(10–72)	70	(2–91)
Partners PrEP	HIV discordant couples	TDF	67	(44–81)	86	(67–94)
		TDF/FTC	75	(55–87)	90	(58–98)
TDF2	Heterosexually active men & women	TDF/FTC	62	(22–83)	84	NS
iPrEx	Men who have sex with men	TDF/FTC	42	(18–60)	92	(40–99)
Fem-PrEP	Heterosexually active women	TDF/FTC	NS	—	NA	—
VOICE	Heterosexually active women	TDF	NS	—	NA	—
		TDF/FTC	NS	—	NA	—



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CDC. PrEP Guidelines. 2017.

# Effectiveness of TDF/FTC PrEP Improves With Adherence



\*Reduction in HIV incidence vs control. †Based on pill counts or the detection of study drug in plasma.

References in slidenotes.

Slide credit: [clinicaloptions.com](http://clinicaloptions.com)

# Case Reports of PrEP Failure: HIV Infection Despite High Adherence

Patient	PrEP Adherence	Seroconversion	Likely Cause of PrEP Failure
43-yr-old MSM <sup>[1]</sup>	24 mos, supported by pharmacy records, blood concentration analyses, clinical history	Acquired MDR HIV	Exposure to PrEP-resistant, multiclass-resistant HIV strain
MSM in his 20s <sup>[2]</sup>	Excellent by self-report, supported by blood and hair concentration analyses	Acquired MDR HIV after 2 x condomless insertive anal sex with 2 different partners within 11 wks before diagnosis	Exposure to PrEP-resistant, multiclass-resistant HIV strain
50-yr-old MSM <sup>[3]</sup>	Excellent by self report, supported by blood analyses	Acquired wild-type HIV after 2-5 median condomless anal sex partners per day in each mo following PrEP initiation	Chronic rectal inflammation ± trauma
34-yr-old MSM <sup>[4]</sup>	Hair sample indicative of high adherence in preceding months	Acquired MDR HIV	Exposure to PrEP-resistant, multiclass-resistant HIV strain
21 year-old MSM <sup>[5]</sup>	Excellent by self-report, supported by blood and hair concentration analyses	Acquired MDR HIV	Exposure to FTC-resistant, but TDF-susceptible HIV strain

PrEP is not 100% effective, but it is highly protective; condom use with PrEP optimizes HIV prevention and protects against STIs



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1. Knox DC, et al. N Engl J Med 2017;376:501-502. 2. Markowitz M, et al. J Acquir Immune Defic Syndr. 2017;76:e104-e106. 3. Hoornenborg E, et al. CROI 2017. Abstract 953. 4. Thaden JT, et al. AIDS. 2018;32:F1-F4. 5. Cohen SE, et al. IDWeek 2018. Abstract 1298.

# Sharp Increase in STIs

2.3 million cases in 2017 surpasses record set in 2016 by more than 200,000 cases  
4<sup>th</sup> consecutive year

## Gonorrhea

- **Increased 67%** (from 333,004 to 555,608 cases)
- Nearly doubled among men (from 169,130 to 322,169)
- Cases in women, up for 3<sup>rd</sup> year in a row from 197,499 to 232,587

## Primary & Secondary Syphilis

- **Increased 76%** (from 17,375 to 30,644 cases)
- MSM made up almost 70% of primary and secondary syphilis cases

## Chlamydia

- Remained most common condition reported to CDC
- 1.7 million+ cases in 2017, 45% among 15- to 24-year-old females



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<https://www.cdc.gov/media/releases/2018/p0828-increases-in-stds.html>



# SAFETY



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# Side Effects of Truvada

- Common side effects: headache, stomach-pain and decreased weight
- Black Box Warning: worsening of hepatitis B infection upon discontinuation
- BMD decreases: calcium & vitamin D
- GFR decreases, not clinically significant



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# Is TDF/FTC PrEP Safe?

- Meta-analysis of randomized, placebo-controlled PrEP studies demonstrated that the **risk of any AE or grade 3/4 AEs is not increased** for TDF-based PrEP vs placebo<sup>[1]</sup>
- Bone safety: iPrEx bone mineral density substudy<sup>[2,3]</sup>
  - High-risk MSM/TGW who received TDF/FTC PO QD PrEP and had dual-energy x-ray absorptiometry assessment (N = 498)
  - **Small net decrease in spine and total hip BMD with TDF/FTC vs PBO at Wk 24** (-0.91% and -0.61%, respectively;  $P = .001$  for both)
  - **No difference in fracture rate** between groups ( $P = .62$ )
  - **BMD lost from hip and spine during TDF/FTC use recovered following discontinuation**

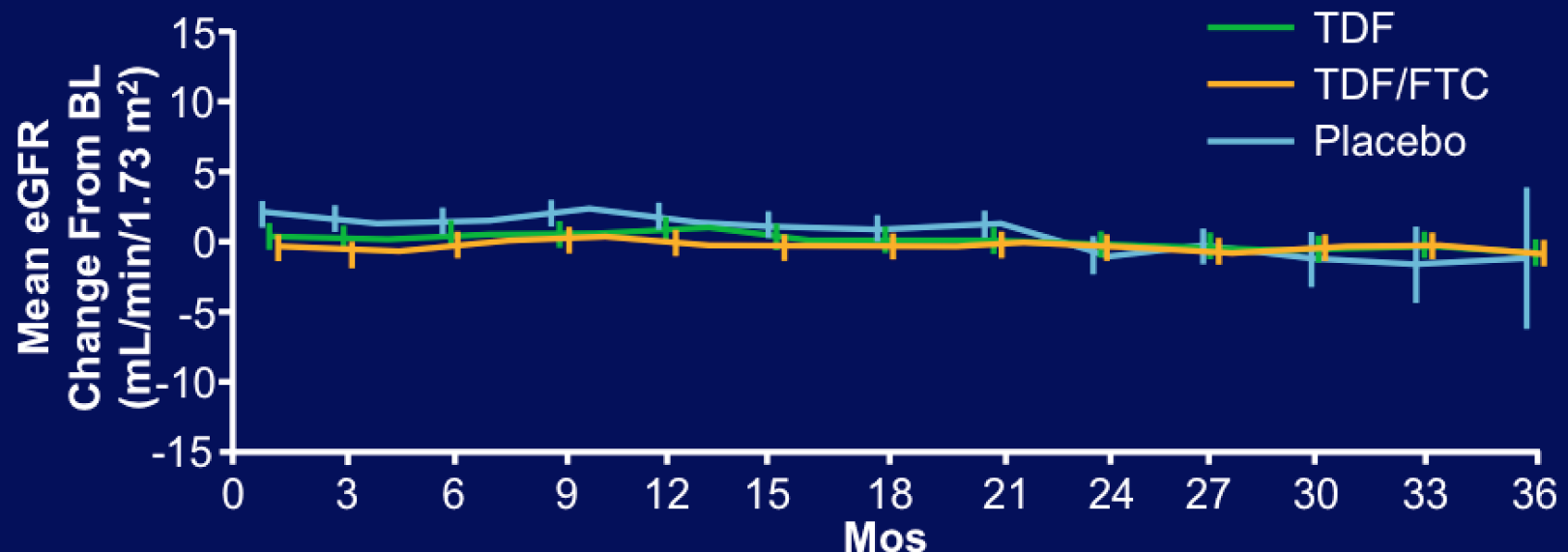
1. Fonner VA, et al. AIDS. 2016;30:1973-1983.

2. Mulligan K, et al. Clin Infect Dis. 2015;61:572-580.

3. Grant R, et al. CROI 2016. Abstract 48LB.

# PrEP and Renal Safety

- Analysis of eGFR changes with TDF ± FTC PrEP in Partners PrEP (N = 4640)<sup>[1]</sup>
  - Over 36 mos of continuous use, PrEP use did not result in a progressive change in renal function



- Analysis of renal function in iPrEx OLE (N = 220): eGFR decrease to < 70 mL/min more frequent at higher levels of TFV exposure among those with **BL eGFR < 90 mL/min** or who were **older than 40 yrs**<sup>[2]</sup>

1. Mugwanya KK, et al. JAMA Intern Med. 2015;175:246-254.

2. Gandhi M, et al. CROI 2016. Abstract 866.

# THE ROLE OF THE PHARMACIST & PHARMACY STAFF IN PREP



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# The Pharmacist's and Pharmacy Staff's Role in PrEP

- Patient Education
- HIV Testing
- Medication Access
  - <https://www.truvada.com/how-to-get-truvada-for-prep/truvada-cost>
- Gilead Advancing Access Program
  - <https://www.gileadadvancingaccess.com/>
- Adherence Counseling



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# PrEP Drug Interactions

Medication	Tenofovir
Acyclovir, valacyclovir, cidofovir, ganciclovir, valganciclovir, aminoglycosides, high-dose or multiple NSAIDs or other drugs that reduce renal function or compete for active renal tubular secretion.	<ul style="list-style-type: none"><li>• Serum concentrations of these drugs and/or tenofovir may be increased.</li><li>• Monitor for dose-related renal toxicities</li></ul>



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# Truvada Patient Counseling

- You must have a **negative HIV test** before taking this drug and at least every 3 months while you take it. Tell your doctor if you think you have been exposed to HIV.
- **Call your doctor** right away if you have fever, headache, feel tired, joint or muscle aches, throwing up, loose stools (diarrhea), sore throat, rash, night sweats, or swollen glands.
- Call your doctor right away if you had any of these signs within 1 month before you start taking this drug.



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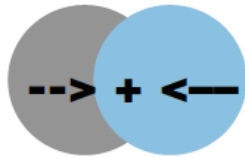
# Take charge of your health and prevent HIV with PrEP

(tenofovir disoproxil fumarate and emtricitabine)



**PrEP stands for Pre-Exposure Prophylaxis.**

The definition of “*prophylaxis*” is an action to prevent disease. The goal of PrEP is to prevent HIV infection from taking hold by taking medicine before you are exposed to the virus.



tenofovir  
disoproxil  
fumarate

emtricitabine

- PrEP is a medicine prescribed to people who do not have HIV infection but are at high risk for getting it.
- PrEP is a combination of two medicines to prevent HIV. It is made up tenofovir disoproxil fumarate and emtricitabine in one pill, which ensures you are getting the right combined daily dose for the medicine to work.

<https://www.cdc.gov/actagainstaids/pdf/campaigns/prescribe-hiv-prevention/aaa-php-patient-prep-guide.pdf>



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## How should this medicine be used?

- You must take one tablet by mouth every day. **With or without food**
- Do not stop taking PrEP without talking to your doctor. When your supply of medicine starts to run low, contact your doctor or pharmacy to get more.
- You will be at higher risk of becoming infected with HIV if you miss multiple doses or stop taking PrEP than if you take it every day.



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## What should I do if I forget a dose?



- Take the missed dose as soon as you remember it.

*However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule.*

- **Do not take a double dose** to make up for a missed one.
- An occasional missed dose will not greatly impact overall effectiveness, but it is important to take the medicine every day. If you miss doses frequently, talk to your doctor.



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## What side effects can this medication cause?

- Most people do not have side effects while taking PrEP. However, you might experience some of the following when you begin taking the medication:
  - *upset stomach*
  - *headache*
  - *vomiting*
  - *loss of appetite*
- These side effects usually fade during the first month of taking PrEP. Tell your doctor if any of these symptoms are severe or do not go away.

## What other information should I know?

Call your doctor immediately if you have any unusual problems while taking this medication or if you have any of the following:

- *fever or chills especially with sore throat, cough, rash or other signs of infection*



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## Take your PrEP medication daily to ensure you are protected

The goal of PrEP is to prevent HIV infection from taking hold if you are exposed to the virus. Taking your PrEP medicine regularly is critical to keep from getting HIV. For PrEP to work, you need to have enough medicine in your body at all times. When you miss doses, you make it harder for the medicine to protect you.



***Taking PrEP every day gives you the most protection.***



***Not taking PrEP regularly greatly lowers your protection against HIV.***



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## Is PrEP all you need?

Even though PrEP is one important tool for protecting yourself from HIV, no method offers 100% protection. While taking your PrEP medicine, you can further reduce your chance of getting HIV by:

- Using condoms during sex
- Cleaning injection equipment if you inject drugs

Plus, while PrEP greatly reduces your risk for contracting HIV, it won't protect you from other sexually transmitted infections. ***Together, these methods offer more complete protection.***

**Do not share toothbrushes or razors**



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## Tips to help you take your PrEP

- Match your medicine schedule to your life: add taking your medicines to things you already do each day, like brushing your teeth or eating a meal.
- Try a pill tray with compartments for each day of the week so you can see whether or not you took your pills that day.
- Set the alarm on your clock, watch, or cell phone for the time you take your medicines.
- Use a calendar to check off the days you have taken your medicines, and circle the date of your next medical appointment.
- Download a free app for your phone that can help remind you of your medical appointments and when it's time to take your medicines. CDC's "**Every Dose, Every Day**" app is available for free in the iTunes app store and Google Play.
- Keep a reminder note on a mirror, on your refrigerator, or anywhere else you will see it each day. Put your next appointment card there, too.





## PrEP medications are very safe

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



### ***You can get support for taking your medicine***

- Talk to another PrEP user about what works for them.
- Find a PrEP user support group or online forum.
- Ask friends or family members to remind and support you.
- Find a community program that can assist you.
- Use other services provided by pharmacists or social workers if you have access to them.



# Truvada Patient Counseling

- **Hepatitis B** has gotten worse when this drug was stopped in some people with hepatitis B. Close follow-up for a few months is needed when therapy is stopped in people who have hepatitis B. Do not stop taking this drug without calling your doctor. Talk with your doctor.



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# Truvada Patient Counseling

- **Bone problems** like bone pain, soft bones, and thin bones have happened with this drug. This may lead to broken bones. You may need to have a test to check your bones.
- Take calcium and vitamin D as instructed by your doctor.
- Have your urine checked as instructed by your doctor to monitor your **kidney** function.



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# Truvada Patient Counseling

- Many HIV-1 tests can miss HIV-1 infection in a person who has recently become infected
- You must continue to use safer sex practices. Just taking TRUVADA for PrEP may not keep you from getting HIV
- If you do become HIV-1 positive, you need more medicine than TRUVADA alone to treat HIV-1



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# Truvada Patient Counseling

- This drug **does not always prevent HIV**. It needs to be used as part of a program that has **other measures** to help prevent HIV. This includes safer sex habits, testing for diseases passed by having sex, and talking with sex partners who have HIV about their HIV treatment. Talk with the doctor for more information.



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## Box D: Key Components of Medication Adherence Counseling

### Establish trust and bidirectional communication

### Provide simple explanations and education

- Medication dosage and schedule
- Management of common side effects
- Relationship of adherence to the efficacy of PrEP
- Signs and symptoms of acute HIV infection and recommended actions

### Support adherence

- Tailor daily dose to patient's daily routine
- Identify reminders and devices to minimize forgetting doses
- Identify and address barriers to adherence

### Monitor medication adherence in a non-judgmental manner

- Normalize occasional missed doses, while ensuring patient understands importance of daily dosing for optimal protection
- Reinforce success
- Identify factors interfering with adherence and plan with patient to address them
- Assess side effects and plan how to manage them



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# When to Stop PrEP

- Patient chooses to stop PrEP
- Evidence of HIV infection
- Adverse events
- Chronic non-adherence



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# Select Ongoing PREP Studies

- Truvada versus Descovy
  - Started September 2016
  - Expected completion 2020
- Cabotegravir injectable
  - HPTN-083 – 4 sites in NYC
  - Expected completion 2021
  - Other studies reported, phase 2 HPTN 077
- Dapivarine vaginal ring



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# HELPFUL RESOURCES



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# Resources

- Preexposure prophylaxis for the prevention of HIV Infection in the United States– 2017 Update: A Clinical Practice Guideline <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>
- Riddell J, Amico K, Mayer K. HIV Preexposure Prophylaxis: A Review. JAMA. 2018;319(12):1261-1268
- CDC Act Against AIDS  
<https://www.cdc.gov/actagainstaids/campaigns/prescribe-hiv-prevention/index.html>



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# National HIV Curriculum – hiv.uw.edu



The screenshot shows the homepage of the National HIV Curriculum website. At the top is a navigation bar with icons and links for Antiretroviral Medications, Course Modules, Question Bank, Clinical Challenges, Tools & Calculators, Master Bibliography, and HIV Resources. Below the navigation bar is a large banner with the title "National HIV Curriculum" and a description: "A free educational web site from the AETC National Coordinating Resource Center and the University of Washington." There is a "Contributors" link and a note about funding from the Health Resources and Services Administration. The main content area is titled "Course Modules" and features three columns of information: "Screening and Diagnosis" (describing the module's purpose), "Overview / Quick Reference" (linking to rapid access info), "Question Bank" (highlighted with a yellow CNE/CME tag, describing interactive board-review style questions), "Self-Study" (highlighted with a yellow CNE/CME tag, describing progress tracking), and "Clinical Challenges" (describing expert opinions on challenging cases).

**National HIV Curriculum**

A free educational web site from the AETC National Coordinating Resource Center and the University of Washington.

[Contributors](#)

Funded by a grant from the Health Resources and Services Administration

## Course Modules

### Screening and Diagnosis

This module is for any health care provider who would like to establish core competence in testing for HIV, recognizing acute HIV infection, and linking persons diagnosed with HIV to medical care.

### Overview / Quick Reference >

Rapidly access info about Screening and Diagnosis

### Self-Study **CNE/CME**

Track your progress and receive CE credit

### Question Bank **CNE/CME**

Interactive board-review style questions with CE credit

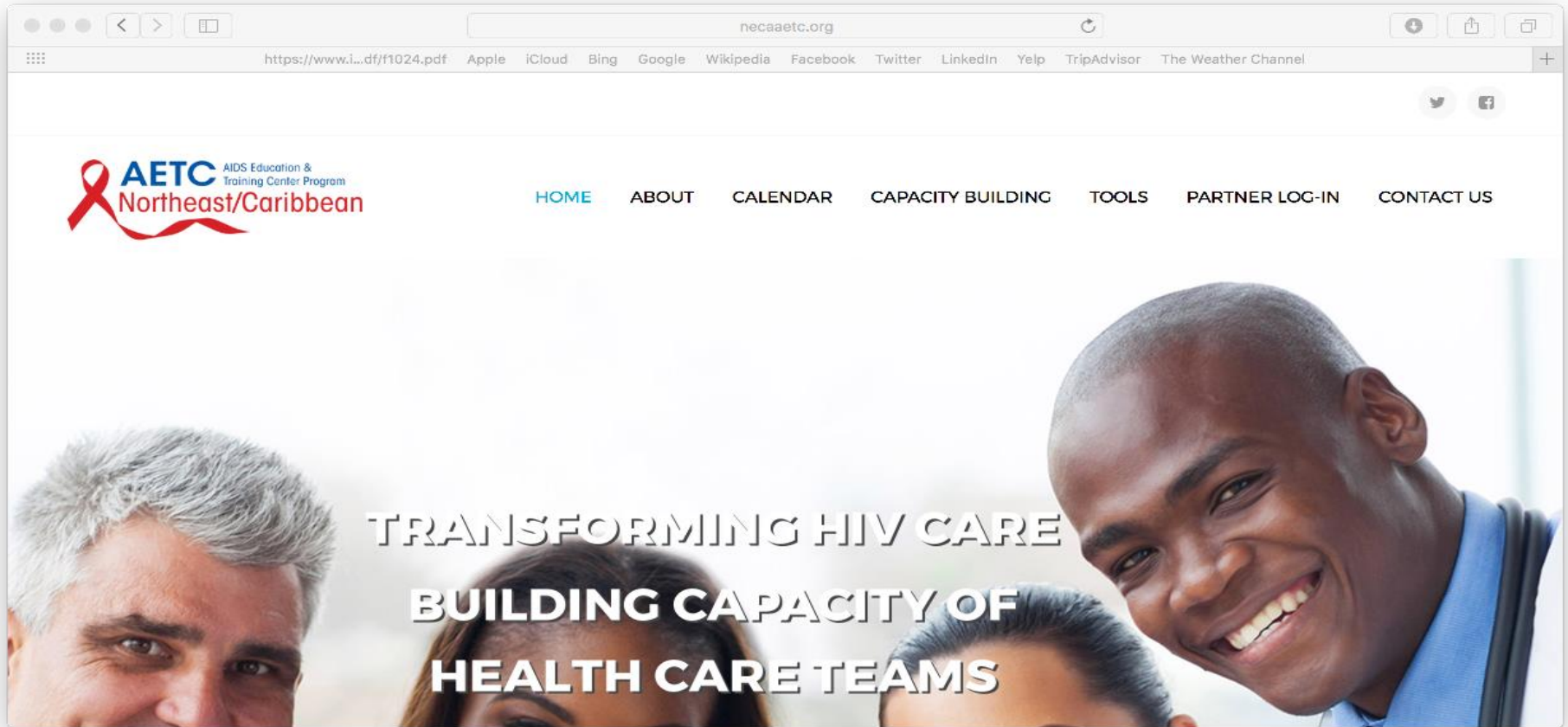
### Clinical Challenges

Expert opinions for challenging and controversial cases



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# www.necaaetc.org



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# Learning Objectives

1. Discuss guidelines on the use of PrEP to prevent HIV infection
2. Describe the pharmacist's role in HIV PrEP
3. Counsel patients on the appropriate use of Truvada for HIV prevention



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# Questions

Tina J Kanmaz, PharmD, AAHIVE  
[kanmazt@stjohns.edu](mailto:kanmazt@stjohns.edu)



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# Learning Collaborative Discussion:

1. Is there a patient demographic that your PrEP program is having a harder time reaching?
2. What barriers are you experiencing with starting patients on PrEP?
3. How well are your patients adhering to PrEP and associated monitoring/follow-up?
4. What resources are needed to increase awareness and use of PrEP?



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# Back-Up Slides



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# Same-Day PrEP Initiation at Drop-in STD Clinic

- Prospective study of same-day PrEP initiation for adults meeting CDC guidelines for HIV PrEP and receiving care at Denver Metro Health Clinic, a drop-in STD clinic offering integrated low-/no-cost services
  - STD clinic provider prescribed 30-day FTC/TDF PrEP (no refills), provided counseling, ordered baseline labs
  - PrEP navigator/study coordinator scheduled 1-mo f/u at participating clinic, provided counseling, addressed financial assistance/coverage
  - On-site pharmacy dispensed free FTC/TDF PrEP, provided counseling
- Same-day PrEP initiated in 100 patients during current analysis time period
  - Of those 100, 78 attended  $\geq 1$  PrEP f/u appt and 57 attended  $\geq 2$  PrEP f/u appts
  - No AEs or abnormal labs

Kamis KF, et al. IDWeek 2018. Abstract 859.

Slide credit [clinicaloptions.com](http://clinicaloptions.com)



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# Same-Day PrEP Initiation: Baseline Characteristics and Predictors for Attending $\geq 1$ F/U Appointment

Characteristic	Patients (N = 100)	Logistic Regression of Predictors for Attending $\geq 1$ Follow-up Appointment	
		Parameter	Adjusted OR (95% CI)
Median age, yrs (IQR)	28 (25-33)		
Male sex, %	98		
Race/ethnicity, %			
▪ Non-Hispanic white	53	Nonwhite vs white	1.11 (0.36-3.37)
▪ Hispanic (any race)	34	race	
▪ Non-Hispanic black	8		
Median annual income, \$ (IQR)	24,000 (14,400-38,000)	Age (units = 5 yrs)	1.48 (0.88-2.46)
Any type of health insurance, %	62	<b>Annual income (units = \$10,000)</b>	<b>1.68 (1.07-2.65)</b>
▪ Medicaid	24	Uninsured vs insured	0.38 (0.13-1.17)
Has PCP, %	26	<ul style="list-style-type: none"> <li>Each additional increase in annual income of \$10,000 associated with 1.68-fold increase in odds of attending <math>\geq 1</math> f/u appt after adjusting for age, health insurance, and race/ethnicity (<math>P = .02</math>)</li> </ul>	
GC/CT/syphilis in past 180 days, %	50		



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# Meta-analysis of Safety in Randomized Placebo-Controlled TDF-Based PrEP Trials

- 13 randomized placebo-controlled FTC/TDF or TDF PrEP trials (N = 15,678; 22,250 person-yrs of f/u)
  - 7 in MSM, 3 in women, 2 in serodiscordant couples, 1 in PWID; 3 of TDF alone, 1 of on-demand PrEP in MSM
  - Trials with >1 yr follow-up showed significantly lower serious AE risk with PrEP vs placebo (RD: -0.01%;  $P = 0.02$ )

Safety Outcome, %	PrEP	Control	Pooled Risk Difference, %	P Value
Grade 3/4 AEs	17.4	16.8	0	.53
Serious AEs	9.4	10.1	0	.80
Bone fractures	3.7	3.3	0	.50
Grade 3+ SCr elevations	0.1	0.1	0	.68
Grade 1-4 SCr elevations	4.3	2.3	2	.04



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Pilkington V, et al. Glasgow 2018. Abstract O143.



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Slide credit: [clinicaloptions.com](http://clinicaloptions.com)



# On Demand PrEP

## Previnir Study

- 1435 at-risk, HIV-negative individuals, nearly all MSM, in Paris region
- **At enrollment, 44% of participants used PrEP daily and 53% used it on demand**
- 1628 people have enrolled, almost all of whom (98.8%) are men who have sex with men
  - 12 heterosexual men and women as well as 8 transgender people have enrolled
- **Double dose of PrEP (two pills) from 2-24 hours before anticipated sex, and then, if sex happens, additional pills 24 hours and 48 hours after the double dose**
- In the event of sex on several days in a row, one pill should be taken each day until 48 hours after the last sexual intercourse
- **Zero Infections in both arms**
- Condoms have been used during 22% and 19% of sexual acts, in those using on-demand and daily PrEP, respectively



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Molina J-M, et al. IAC 2018, Amsterdam. Abstract WEAE0406LB.



# OnDemand PrEP, AKA 2-1-1

- 2-1-1 regimen achieved target exposures of tenofovir diphosphate and emtricitabine triphosphate in colorectal tissue at the time of coitus in 81% and 98% of the population when administered 2 and 24 hours before coitus,
- If intercourse is planned, the first (double) dose of PrEP should be taken closer to the 24-hour precoital time
- 2 doses with food 2 to 24 hours before sex, 1 dose 24 hours after the first (double) dose, and 1 dose 24 hours later (“2-1-1” dosing). For consecutive sexual contacts, men were instructed to take 1 pill per day until 2 days after the last sexual encounter.
- **ONLY DATA IN MSM!**

Saag M, et al. JAMA. 2018;320(4):379-396



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# PEP Guidelines, April 2016, Regimens Adults with Normal Renal Function

Age	Preferred/Alternative	Regimen
Adults and adolescents aged $\geq 13$ years, including pregnant women, with normal renal function (creatinine clearance $\geq 60$ mL/min)	Preferred	Tenofovir DF 300 mg <b>and</b> emtricitabine 200 mg (Truvada) once daily <b>with</b> raltegravir 400 mg twice daily <b>or</b> dolutegravir 50 mg once daily
	Alternative	Tenofovir DF 300 mg <b>and</b> emtricitabine 200 mg (Truvada) once daily <b>with</b> darunavir 800 mg once daily <b>and</b> ritonavir 100 mg once daily

US DHHS. Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016. Located at <https://aidsinfo.nih.gov/hiv-aids-health-topics/108/post-exposure-prophylaxis>



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# Recommended Indications for PrEP by MSM

## Males Meeting All of These Criteria

- Adult male or adolescent weighing > 35 kg
- No acute or established HIV infection
- Any male sex partner in previous 6 months\*
- Not in monogamous relationship with a recently tested, HIV-negative man

\*Assess males who also have sex with women for heterosexual risk.

## And $\geq 1$ of These Criteria

- Any anal sex without a condom in previous 6 months
- Bacterial STI (syphilis, gonorrhea, or chlamydia) in previous 6 months

- CDC summary table also includes a high number of sex partners or commercial sex worker



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CDC. PrEP Guidelines. 2017.

# Recommended Indications for PrEP by Heterosexual Women/Men

## Males & Females Meeting All of These Criteria

- Adult or adolescent weighing > 35 kg
- No acute or established HIV infection
- Any sex with opposite sex partner in previous 6 months
- Not in monogamous relationship with a recently tested, HIV-negative partner

## And ≥ 1 of These Criteria

- Is a male who has sex with both men and women (bisexual)\*
- Infrequent condom use with ≥ 1 partner(s) with unknown HIV status at substantial risk of HIV infection (PWID or bisexual male)
- Is in ongoing relationship with HIV+ partner
- Bacterial STI (syphilis, gonorrhea in females or males) in previous 6 months

\*Assess males who also have sex with men for MSM risk.

- CDC summary table also includes a high number of sex partners or commercial sex worker



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CDC. PrEP Guidelines. 2017.

# Recommended Indications for PrEP by People Who Inject Drugs (PWID)

## PWID Meeting All of These Criteria

- Adult or adolescent weighing > 35 kg
- No acute or established HIV infection
- Any injection of drugs not prescribed by a clinician in the previous 6 months

## And ≥ 1 of These Criteria

- Any sharing of injection or drug preparation equipment in the past 6 months
- Risk of sexual acquisition\*



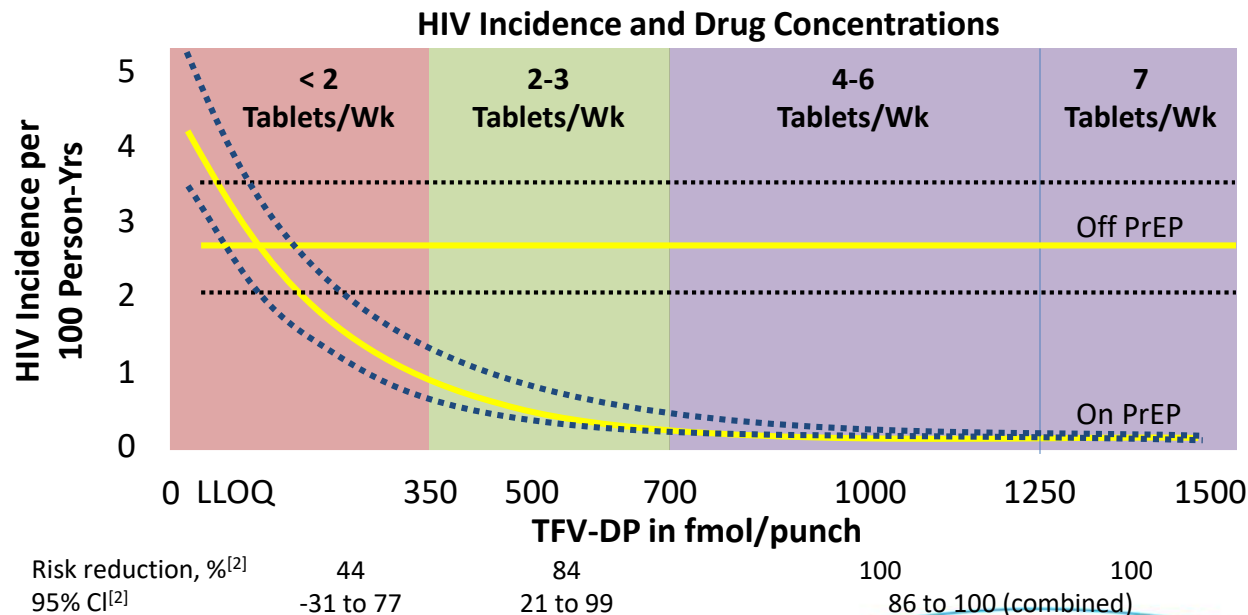
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CDC. PrEP Guidelines. 2017.



# OLE: PrEP Reduces Incidence of HIV in MSM Even With Incomplete Adherence

- Open-label extension of ATN 082, iPrEx, and US Safety Study PrEP trials in HIV-negative MSM and transgender women (N = 1603; 76% receiving daily oral TDF/FTC)<sup>[1]</sup>



1. Grant RM, et al. Lancet Infect Dis. 2014;14:820-829. 2. Grant RM, et al. IAC 2014. Abstract TUAC0105LB.



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Slide credit: [clinicaloptions.com](http://clinicaloptions.com)