

# Be PrEPared to Prevent HIV

Danny Thomason, DO, AAHIVS

# Learning Objectives

- Identify which patients should be offered PrEP.
- Become familiar with medications used to prevent HIV.
- Learn how to implement PrEP in your practice.

# HIV in the United States, 2018

- HIV Prevalence Estimate  
1.2 million

**OF THE 37,968 NEW HIV DIAGNOSES IN THE UNITED STATES (US) AND DEPENDENT AREAS IN 2018:**

**69% WERE  
AMONG GAY,  
BISEXUAL, AND OTHER  
MEN WHO HAVE  
SEX WITH MEN**



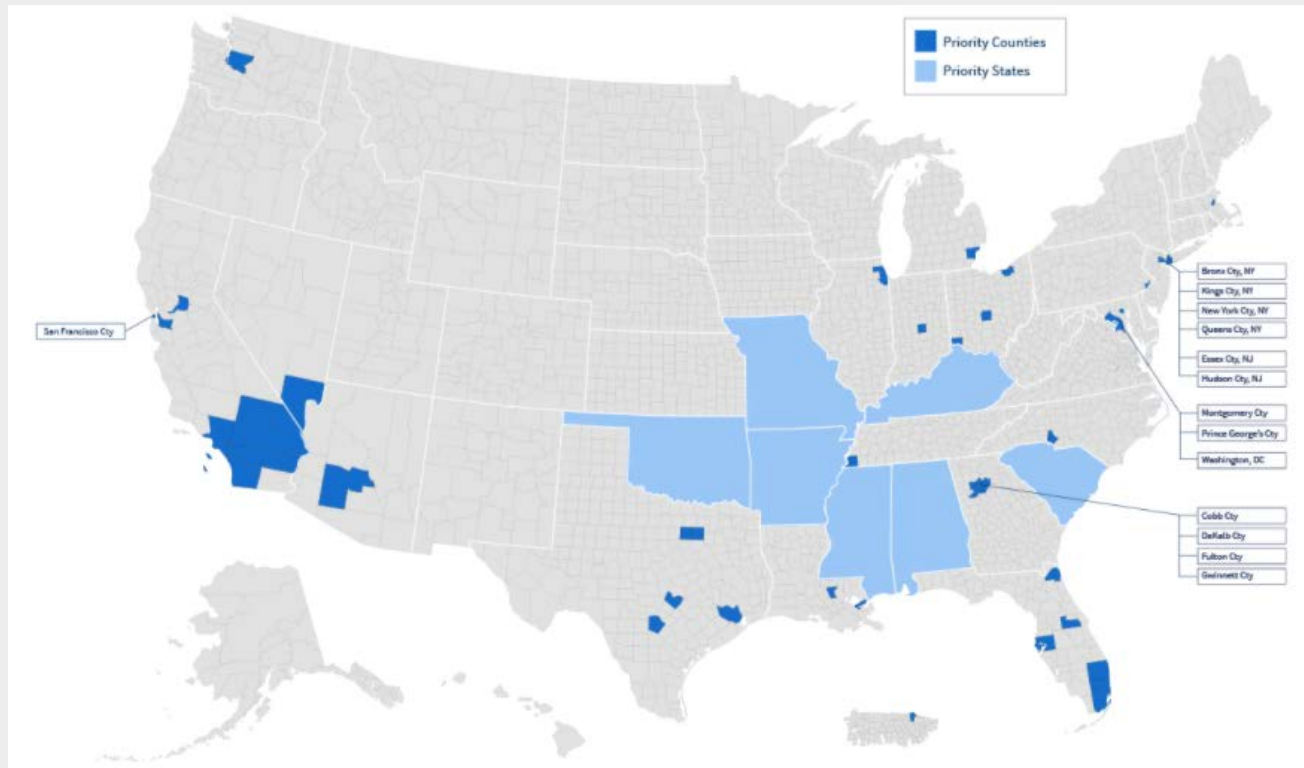
**24% WERE AMONG  
HETEROSEXUALS**



**7% WERE AMONG  
PEOPLE WHO  
INJECT DRUGS**



# HIV in Oklahoma 2013 - 2017



- Oklahoma, one of the 7 states with a disproportionate HIV occurrence in rural areas
- Lawton had a 117% increase in new cases
- 12% overall decrease in newly diagnosed HIV cases
- Increase in cases among:
  - Hispanic
  - African Americans
  - Native Americans
  - MSM
  - IV Drug Users
- Most new cases ages 20 to 29

# Ending the HIV Epidemic

## GOAL:

reaching  
**75%**  
reduction  
in new HIV  
infections  
by 2025  
and at least  
**90%**  
reduction  
by 2030.



**HHS will work with each community to establish local teams on the ground to tailor and implement strategies to:**



**Diagnose** all people with HIV as early as possible after infection.

**Treat** the infection rapidly and effectively to achieve sustained viral suppression.



**Prevent** new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs).

**Respond** quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.



# What is Pre-Exposure Prophylaxis?

- PrEP: the use of antiviral medication by individuals who do not have HIV to reduce the risk of acquiring HIV
- FDA approved antiviral drugs for PrEP
  - Truvada (tenofivir disoproxil fumarate/emtricitabine, TDF/FTC)
  - Descovy (tenofivir alafenamide/emtricitabine, TAF/FTC)



# Who is at the highest risk of acquiring HIV?

- Men who have sex with men (MSM)
- Transgender women who have sex with men
- Persons who inject drugs
- STI in the last 12 months
- Inconsistent or no condom use
- Persons with multiple sex partners
- Persons with HIV-positive partner
- Persons who exchange sex for money, drugs, food or housing
- Persons who request PrEP or self-identify as high risk

# PrEP is Effective

- 92-99% reduction in risk of contracting HIV when taken daily
- It only works if you take it:
  - 7 pills per week, 99% effective
  - 4 pills per week, 96% effective
  - 2 pills per week, 76% effective



# PrEP Risks

- Common side effects
  - nausea
  - diarrhea
  - gas
  - headache
  - weight loss
  - Dizziness
- Symptoms typically resolve by the end of the 1<sup>st</sup> month

# PrEP Risks

- Potentially serious
  - Acute/chronic kidney injury
    - Small non-progressive, reversible decline in CrCl
    - Avoid TDF/FTC (Truvada) if CrCl <60 mL/min
    - Avoid TAF/FTC (Descovy) if CrCl <30mL/min
  - Bone loss
    - Reversible after discontinuation
  - HIV Drug Resistance
    - Greatest risk among patients with undiagnosed early HIV infection who start PrEP
  - Hepatitis-B flare (rebound HBV viremia) following discontinuation of PrEP
    - Consider continuation of Truvada or Descovy for HBV when PrEP no longer indicated
    - Consider co-management of HBV+ pts on PrEP with ID/GI

# Does PrEP lead to higher risk behaviors?

- No, it doesn't appear to
  - iPrEx/Partners PrEP Trials
    - Percentage of participants who reported unprotected intercourse decreased during the study period

# What about “On-Demand” PrEP?

- Not FDA-approved
- Not recommended by the CDC
- “2-1-1” schedule
  - 2 pills 2 to 24hrs before sex
  - 1 pill 24hrs after sex
  - 1 pill 24hrs after 2<sup>nd</sup> dose
- There is evidence it’s effective for MSM
- May pan out, but don’t recommend anything except daily dosing yet

# Patient Education

- Benefits, risks and potential side effects of PrEP
- PrEP isn't 100% effective
- PrEP reduces risk for HIV, but not other STIs or pregnancy
- Safer sex and condom use
- Adherence to PrEP daily dosing schedule
- Importance of scheduled HIV and STI testing, routine monitoring
- How to obtain refills from your office
- Accessing PrEP meds through insurance, drug manufacturer, etc

# Before prescribing PrEP – History/Exam

- Are there signs/symptoms of acute HIV infection in the previous 6 weeks?  
Fever, flu-like symptoms?
  - Rule out acute HIV – check HIV viral load
- Was there a high-risk sexual exposure in the last 4 weeks? 72 hours?
  - Exposure in last 4 weeks – check HIV viral load
  - Exposure in last 72 hours – test and start PEP (Post Exposure Prophylaxis)
- Is sex partner(s) HIV positive? Is their viral load known?
- Planning to get pregnant?
- Is there a history of kidney disease?
- Is there a history of hepatitis B disease? Hepatitis B vaccination?
- Physical exam for signs of HIV or other STI

# Before prescribing PrEP – Labs

- HIV test (4<sup>th</sup> generation antibody/antigen test preferred)
- HIV viral load (only if recent exposure or s/s of acute HIV infection)
- CMP (GFR and liver enzymes)
- Urinalysis
- Pregnancy test
- Viral hepatitis panel
- Gonorrhea, chlamydia, and syphilis screening

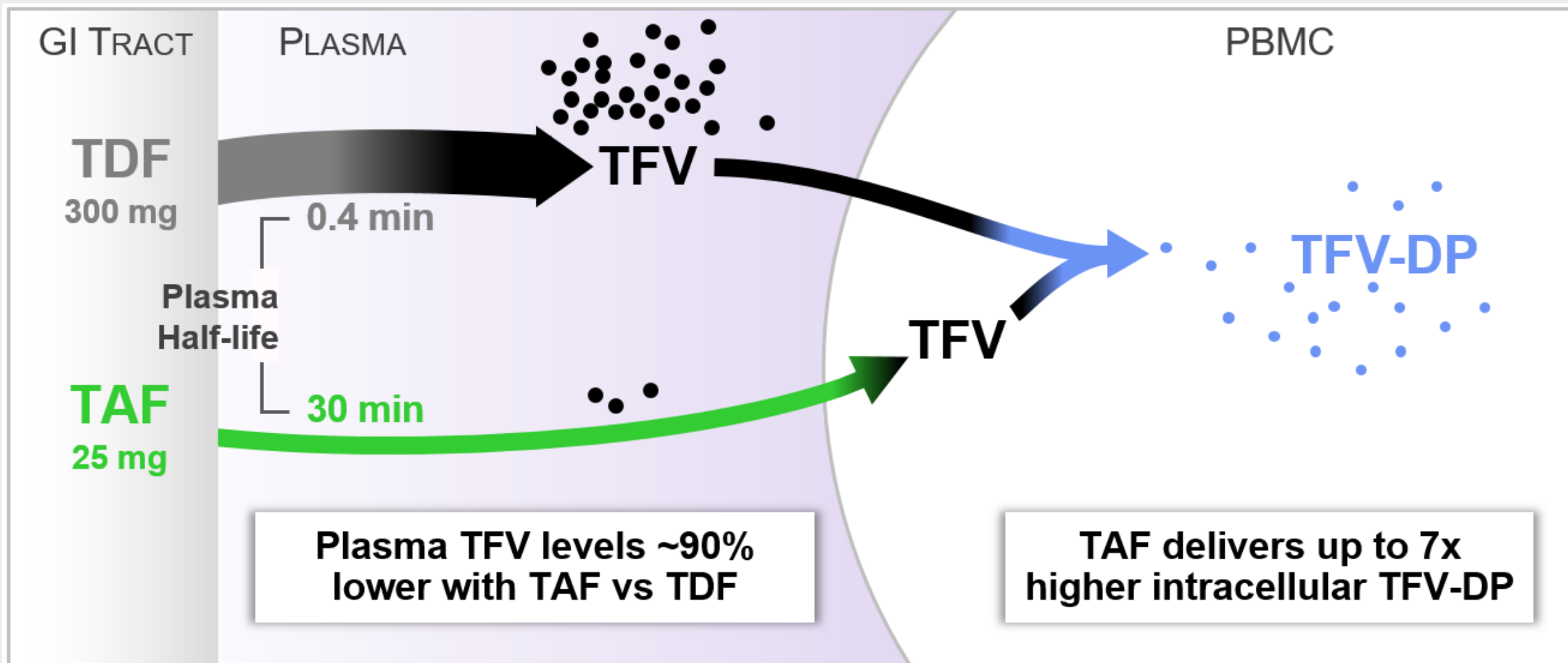
# Truvada (TDF/FTC)

- Tenofovir disoproxil fumarate 300mg – emtricitabine 200mg
- Once daily with or without food
- FDA indicated for preventing HIV across all populations
- CrCL must be above 60mL/min
- Cost: generic available; still expensive ~\$1400/mo



# Descovy (TAF/FTC)

- Tenofovir alafenamide 25mg – emtricitabine 200mg
- Once daily with or without food
- FDA approved for MSM and transgender women; not a recommended option for exposure through receptive vaginal sex
- Preferred option for:
  - MSM and transgender women with pre-existing renal disease or osteoporosis
  - Multiple risk factors for developing renal disease or osteoporosis
- CrCL must be above 30mL/min
- Cost: ~\$1900/mo



# Which medication should I prescribe for daily PrEP?

## TDF/FTC (Truvada)

FDA approval: 2012



19 mm



### EFFECTIVENESS

- ✓ for multiple populations

### SAFETY

- Small ↓ in eGFR and BMD

### COST

- \$1,845/month in 2019
- Generic in 2020



100

0

### EFFECTIVENESS\*

MSM & TRANS WOMEN  
HETEROSEXUALS  
PWID

### SAFETY / 48 WKS

eGFR (mL/min)  
HIP BMD  
LDL (mg/dL)  
BODY WEIGHT (kg)



12.5 mm

## TAF/FTC (Descovy)

FDA approval: 2019



### EFFECTIVENESS

- ✓ for MSM and transwomen
- ? for other populations

### SAFETY

- Small ↑ in LDL and weight

### COST

- \$1,845/month in 2019



0

100

# Time to Protection

- 7 days; 20 days is optimal
- Taking 2 pills the first day will decrease the time to achieve protective drug levels

# Ongoing Monitoring

- PrEP can be taken as long as the patient is at risk
- First follow-up visit at 3 months
  - HIV test
  - BMP (creatinine and eGFR)
  - Discuss med adherence and safer sex practices
- Ongoing office visits every 6 months (and as indicated)
- 90-day supply of meds given initially
- HIV test every 90 days; no refill without an HIV test
- BMP every 6 months
- UA annually
- STI screening every 6 months (and more frequently as indicated)
- Pregnancy test every lab visit (childbearing age women not on birth control)

# When to discontinue PrEP?

- If risk for acquiring HIV goes down
- Confirmed positive HIV test
  - Recommend immediate antiviral treatment regimen for HIV
  - Consult with HIV treatment provider
- CrCl <50mL/min for Truvada (TDF/FTC)
  - Consider switch to Descovy
- CrCl <30mL/min for Descovy (TAF/FTC)
- Lack of adherence to HIV testing
  - Don't stop PrEP immediately; work with the patient to stay on PrEP when possible

# Note on Discontinuing PrEP

- When risk for acquiring HIV goes down
  - PrEP should be continued for at least 28 days after last potential exposure

# READY, SET, PrEP



**Manufacturer Patient  
Assistance Program**

[www.gileadadvancingaccess.com](http://www.gileadadvancingaccess.com)



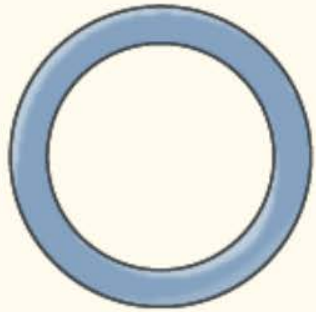
**Ready, Set, PrEP – HHS.gov**

[www.getyourprep.com](http://www.getyourprep.com)



## NIAID is funding research on 4 types of long-acting HIV prevention.

### INTRAVAGINAL RING (IVR)



Polymer ring inserted into the vagina releases antiretroviral drug over time.

### IMPLANT



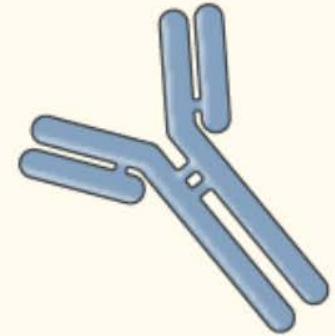
Device implanted in the body releases antiretroviral drug over time.

### INJECTABLE



Long-acting antiretroviral drug is injected into the body.

### ANTIBODY



Antibody is infused or injected into the body.

# Future of PrEP? – Long Acting Injectable Cabotegravir

- [HPTN 084 Study Demonstrates Superiority of CAB LA to Oral FTC/TDF for the Prevention of HIV](#) - November 2020
  - *Both cabotegravir and oral FTC/TDF have high efficacy for PrEP among women in sub-Saharan Africa*
- [HPTN 083 Study Demonstrates Superiority of Cabotegravir for the Prevention of HIV](#) - July 2020
  - *Both cabotegravir and oral tenofovir/emtricitabine (TDF/FTC) have high efficacy for pre-exposure prophylaxis (PrEP)*
- [Long-acting injectable cabotegravir is highly effective for the prevention of HIV infection in cisgender men and transgender women who have sex with men](#) - May 2020
  - *Independent Data and Safety Monitoring Board Recommends Unblinding Study Participants*



PrEP: PRE-EXPOSURE PROPHYLAXIS  
855-448-7737 | 855-448-PrEP

[www.nccc.ucsf.edu](http://www.nccc.ucsf.edu)



## Pre-exposure management advice for clinicians, by clinicians:

- Medication management
- Laboratory evaluation and follow-up testing
- Transitioning from PEP to PrEP
- Managing PrEP as a safer conception tool



CLINICIAN  
CONSULTATION  
CENTER

National rapid response for HIV management  
and bloodborne pathogen exposures.

# References

- Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2017 Update - <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>
- Clinical Providers' Supplement: Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2017 Update - <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2017.pdf>
- New York State Guidance for the Use of PrEP to Prevent HIV Transmission – 2014 - <https://www.hivguidelines.org/prep-for-prevention>
- Ending the HIV Epidemic: A Plan for Oklahoma - <https://www.ok.gov/health2/documents/DRAFT-Oklahoma%20Ending%20the%20HIV%20Epidemic%20Plan.pdf>
- HPTN.org
- CDC. HIV Surveillance Supplemental Report 2020;25(1).