



# PreExposure Prophylaxis

**Overcoming the barriers: What they didn't teach you in school**

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October 10, 2019**

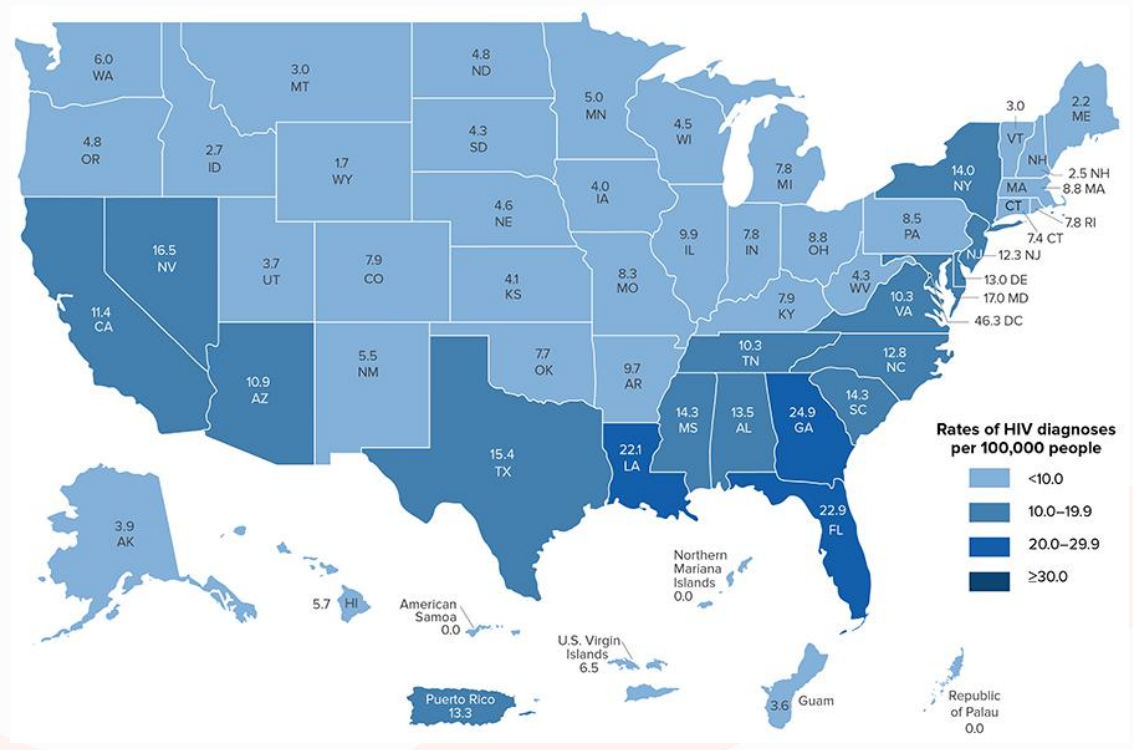
# Layout

- Introduction to PrEP
- Where is the Evidence
- Indications for usage
- Selecting patients
- Confidentiality and payment
- Behavioral change
- Making it work in a busy general pediatrics clinic
- Q&A

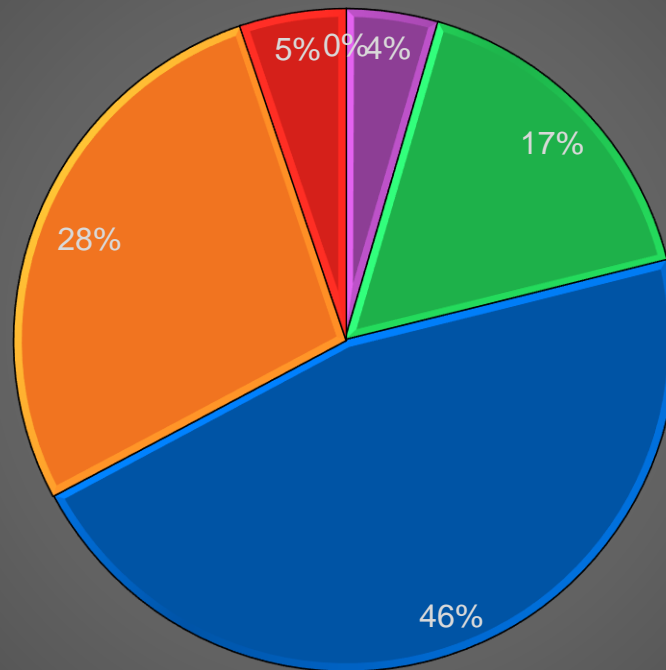
# Conflicts of Interest



# New Infection Rate in 2017



## New cases By AGE



CDC 2017 HIV US and

■ 13-14 ■ 15-19 ■ 20-24 ■ 25-39 ■ 40-59 ■ 60+

<https://www.cdc.gov/hiv/statistics/overview/index.html>

<https://www.cdc.gov/nchstp/newsroom/2017/HIV-testing-and-time-from-infection-to-diagnosis-press-release.html>

# HIV PreExposure Prophylaxis (PrEP)

- Preventative *medication* delivered to an **HIV negative** individual at **high risk** of acquiring the infection, prior to potential exposure.

# Types of PrEP

- Condoms -> 80% reduced risk of transmission
- HPTN 052 = treatment as prevention -> 93% reduction (n=1171 c)
- CAPRISA 004: 1% tenofovir gel -> 28-54% reduced transmission (n=889 W)
- Vaccine HVTN 100+ -> underway
- iPrex: TDF/FTC daily -> 42-92% risk reduction (n=2499 MSM)
- Partners PrEP: TDF/FTC daily -> 66F & 84M – 90% risk reduction (n = 4747 c)

# Tenofovir-emtricitabine (TDF-FTC)



[https://www.bing.com/images/search?view=detailV2&ccid=%2f4C71Lsr&id=55D504EE0F2E2E2C2FC354FCA31FE5A1CAE46671&thid=OIP.\\_4C71LsrYypr3UqMUeWTRwHaD8&mediaurl=https%3a%2f%2fthegavoice.com%2fwp-content%2fuploads%2f2014%2f06%2fScreen-Shot-2014-06-05-at-7.37.26-PM-750x400.png&exph=400&expw=750&q=truvada+blue+pill&simid=608034980196057923&selectedIndex=77&ajaxhist=0](https://www.bing.com/images/search?view=detailV2&ccid=%2f4C71Lsr&id=55D504EE0F2E2E2C2FC354FCA31FE5A1CAE46671&thid=OIP._4C71LsrYypr3UqMUeWTRwHaD8&mediaurl=https%3a%2f%2fthegavoice.com%2fwp-content%2fuploads%2f2014%2f06%2fScreen-Shot-2014-06-05-at-7.37.26-PM-750x400.png&exph=400&expw=750&q=truvada+blue+pill&simid=608034980196057923&selectedIndex=77&ajaxhist=0)



# Safety and Efficacy in Adolescents

## Study Design

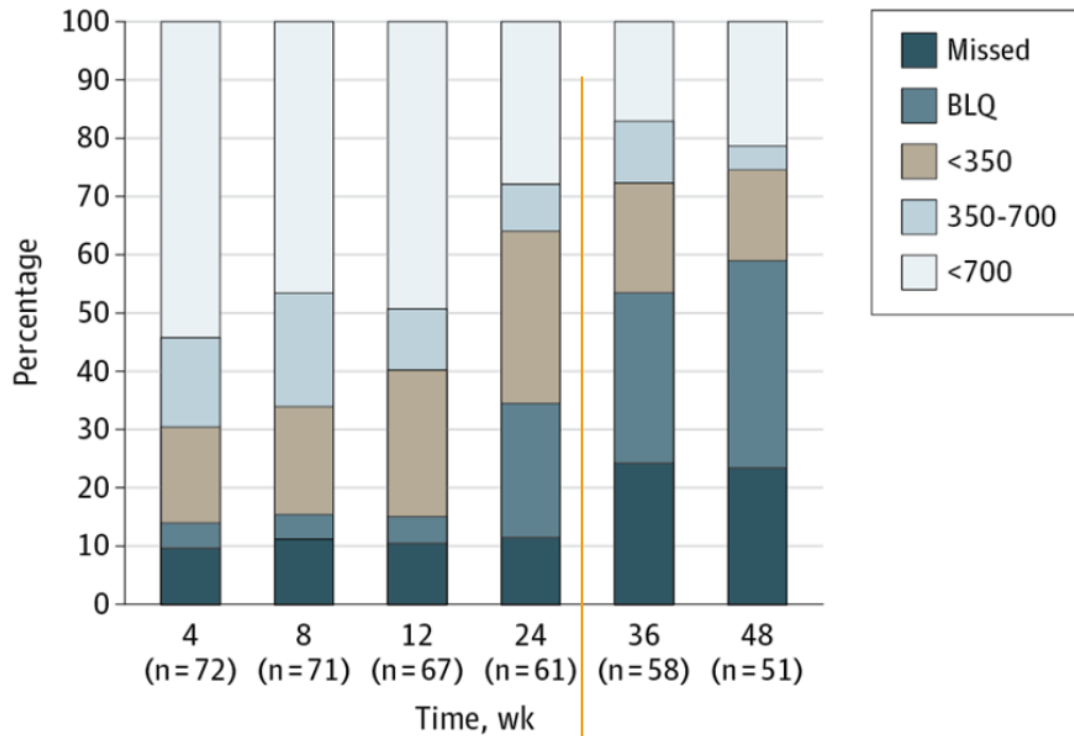
- Open label in 6 cities
- n = 72
- MSM between the ages of 15 and 17
- 48 week follow up
- TDF/FTC + behavioral intervention
- Monthly visits x 3 then q3mo

*\*\*excluded eGFR <75, bone fracture, proteinuria, liver or blood abnormalities*

Hosek et. Al. Safety and Feasibility of Antiretroviral Preexposure Prophylaxis for Adolescent Men Who Have Sex With Men Aged 15 to 17 Years in the United States. JAMA Pediatr. 2017;171(11):1063-1071.

## Results

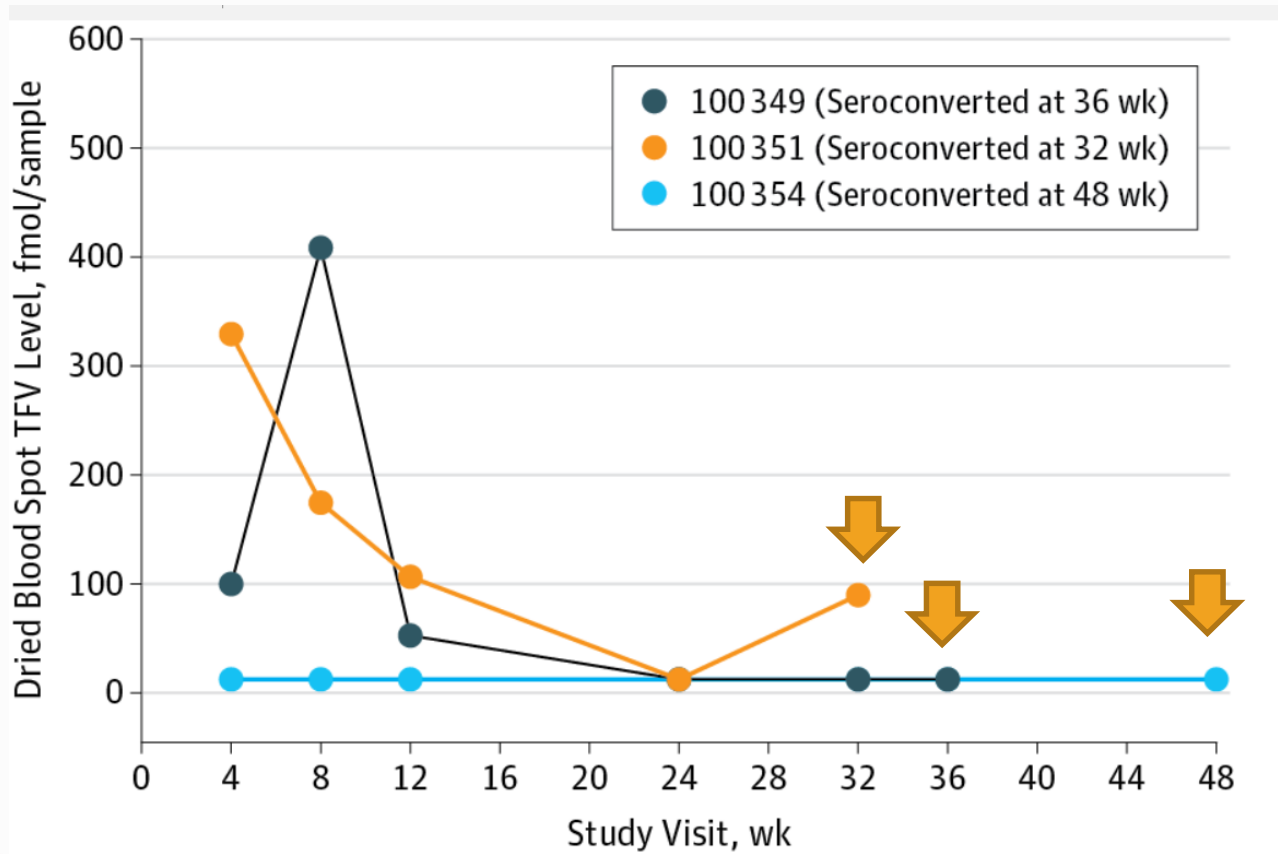
- **Effective when taken** (3 positives)
- Safe: mild side effects. 1 discontinued secondary to severe weight loss
- **Adherence was poor!!**
- Condom use and number of partners was stable



**Adherence via Tenofovir Diphosphate in Dried Blood Spots**  
 BLQ indicates below the lower limit of quantitation.

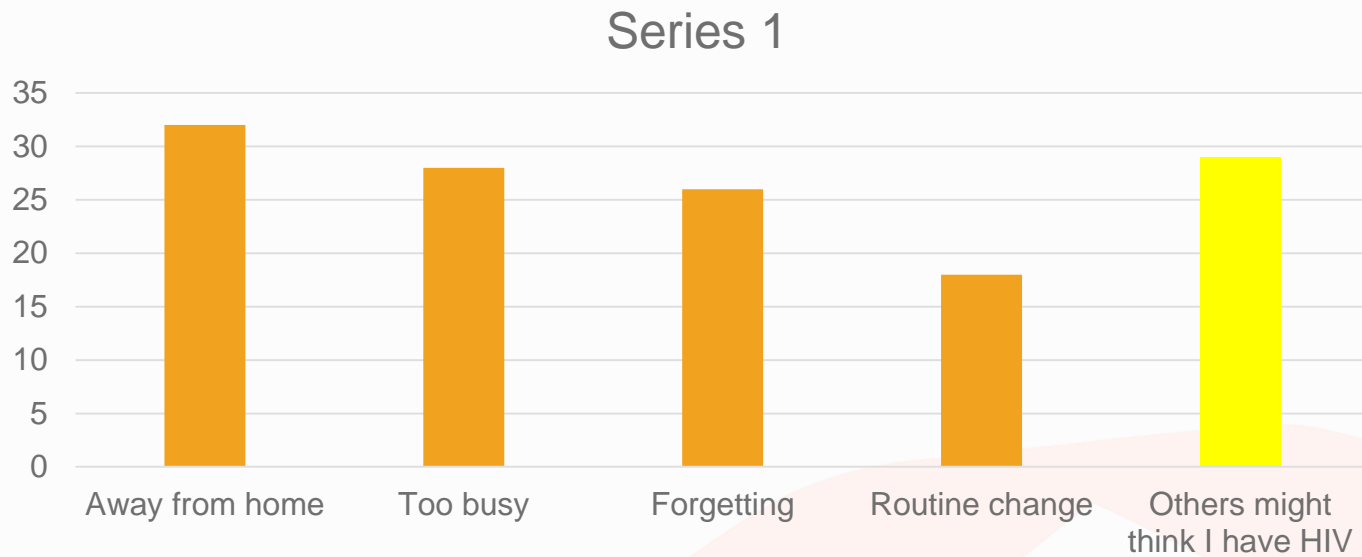
0-2 tb ~ <350  
 2-3 tb ~ 350-700  
 4+ ~ >700

Hosek et. Al. Safety and Feasibility of Antiretroviral Preexposure Prophylaxis for Adolescent Men Who Have Sex With Men Aged 15 to 17 Years in the United States. JAMA Pediatr. 2017;171(11):1063-1071.



Hosek et. Al. Safety and Feasibility of Antiretroviral Preexposure Prophylaxis for Adolescent Men Who Have Sex With Men Aged 15 to 17 Years in the United States. *JAMA Pediatr.* 2017;171(11):1063-1071.

# Adherence



Hosek et. Al. Safety and Feasibility of Antiretroviral Preexposure Prophylaxis for Adolescent Men Who Have Sex With Men Aged 15 to 17 Years in the United States. JAMA Pediatr. 2017;171(11):1063-1071.

12,100,000 Results

Any time ▾

**May 15, 2018** U.S. Food and Drug Administration Approves Expanded Indication for **Truvada**® (Emtricitabine and Tenofovir Disoproxil Fumarate) for Reducing the Risk of Acquiring HIV-1 in Adolescents

[U.S. Food and Drug Administration Approves Expanded ...](#)

[www.gilead.com/news-and-press/press-room/press-releases/2018/5/us-food-and-drug-administ...](http://www.gilead.com/news-and-press/press-room/press-releases/2018/5/us-food-and-drug-administ...)

# USPSTF: Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis

Release Date: June 2019

The USPSTF recommends that clinicians offer preexposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition.

**A**

- **MSM**
  - Serodiscordant
  - Inconsistent condom usage with anal sex
  - Syphilis, gonorrhea, or chlamydia in the past 6 months
- **Heterosexuals**
  - Serodiscordant
  - Inconsistent condom usage with high risk partner (e.g. MSM or IJU)
  - Syphilis or gonorrhea in the past 6 months
- **Injection drug users**
  - Shared needles
  - Risk of sexual acquisition

# Indications for Usage

- HIV negative\*
- 12 + yo
- >35 kg
- eCrCL >60 ml/min
- High risk or patient concern
- Hepatitis B negative\*
- Pregnancy?

# Consent and Confidentiality

- In South Carolina, Minors may consent to HIV testing and treatment at the age of 16 (SC code of laws section 63-5-340 Minor's Consent to Health Services)\* ■
  - Separate charts
  - Scanned documents
  - Family Planning Medicaid
  - STI clinics and health departments
  - **Whenever possible, get a parent involved!!**



# Paying for it all

- \$1,772.10 per month (GoodRx 2019)
- Covered 100% by many insurance plans
- GileadAdvancingAccess.com -> up to \$7,200 in copays/year covered
- Medication Assistance Program for uninsured
- \$200-1200 for labs (insured, negotiated rates, online options)
- Cost savings options from negotiated contracts (labs)
  
- **DOCUMENT IT CORRECTLY!!**

# Making it Work

- Identify patients who may be at risk
- Discuss it with them
- Obtain screening labs
- Rx a 3mo prescription
- See them back in a month
- Work on behavioral change!!
- Adherence, buy in, change
- Discontinue after a substantial reduction in risk has been sustained

# Behavioral change

- Screen for depression, anxiety, and substance usage
- Demonstrate how to use a condom and give them feedback
- Personalized cognitive counseling
- Integrated Next Step Counseling
- Text messaging program
- Become their ally

Dilley JW, Woods WJ, Sabatino J, Lihathsh T, Adler B, Casey S, et al. (2002). Changing Sexual Behavior Among Gay Male Repeat Testers for HIV: A Randomized, Controlled Trial of a Single-Session Intervention, *Journal of Acquired Immune Deficiency Syndromes*, 30(2), 177-86

Amico, K.R., Miller, J., Balthazar, C. et al. *AIDS Behav* (2019) 23: 1812. <https://doi.org/10.1007/s10461-018-2291-2>

CROI 2017 (Abstract 964)- Khosropour et al

# Identifying Patients



**Joe 1:** 17yo early college student presents for nurse visit, STI screening. You recall he was bisexual though not sexually experienced. The clinic is incredibly busy. What do you do?

- No STI only visits in my clinic
- Set aside appropriate time
- Explore his motivations for sex
- Obtain baseline labs today
- Give him condoms
- Give him a call
- See him back in a month

**Joe 2:** 16yo gender dysphoric youth presents to his PCP in another town for a painless ulcer. He is diagnosed with syphilis and referred to your clinic for consideration of PrEP.

- Go slow
- Assess parent involvement
- Judgement free zone

**Joe 3:** At his 16yo WCC, your HM reveals that he is gay. His family is catholic and they hate homosexuals. He has had several UAI and doesn't even know where to begin with navigating intimacy.

- Safety assessment
- Find an ally in his community
- Take your time, handouts work great. Separate appointment?
- Call a friend?
- This kids going to need a lot of work.
- Frequent, frequent visits.

# Q&A







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