


# Prescribing HIV Prevention: Preexposure Prophylaxis (PrEP)

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# Disclosures

- No relevant commercial relationships to disclose
- Generic and brand names will be used as appropriate

\*Off label content identified on slides

# Objectives

At the end of this session, participants should be able to:

- Identify risk factors for HIV among their patients
- Become familiar with prescribed HIV prevention methods including all available PrEP options
- Reference current guidelines for the use of ARVs as prevention
- Discuss how medical HIV prevention can be tailored as part of patient-centered care

# Case 1

**A 52 year old black patient presents for annual exam**

- **PMHx:** hyperlipidemia, HTN
- **Medications:** atorvastatin, lisinopril
- **NKDA,** no significant family Hx, no surgical Hx
- **Social Hx:** has been separated from his wife for 9 months

Intake Forms  
Demographics

Laser Surgery Care

Assigned Sex at Birth: Male / Female / \_\_\_\_\_

Gender: Male / Female / \_\_\_\_\_

Pronouns: He / Him / His  
She / Her / Hers  
They / Them / Theirs  
other: \_\_\_\_\_

- **On sexual history** the patient reports 6 female partners in the last 6 months. He reports using condoms most of the time, but some exceptions: 1 partner he trusts, 2 partners in the context of etoh.

He engages in oral-penile intercourse, oral-vaginal intercourse, penile-vaginal intercourse. He denies anal intercourse or anolingus.

- Recommend screenings: HIV, urine gc/Ct, oral gc/Ct, syphilis
- He declines HIV testing stating that he is not at risk...
- What patient education is appropriate?

Daily  
tenofovir/emtricitabine  
reduces risk of HIV  
acquisition by up to 99%

# Baseline Labs

- **HIV Ag/Ab**
- **Hep B surface ab/ag**
- **Creatinine**
- **Urine HCG** (*if childbearing potential*)
- *TPPA/RPR*
- *Hep A ab (if AI)*
- *Hep C ab*
- *Gc/Ct (genital, pharyngeal, rectal)*



# Q3 Month Follow Up Labs

- **HIV Ag/Ab**
- **Creatinine**
- **Urine HCG** (*if childbearing potential*)
- *STI Screening depending on patient's risk (q3-6months):*
  - *RPR, three site gc/Ct*





# PrEP Side Effects

Number of patients treated per year

to possibly result in a harmful outcome:

<b>F/TDF</b>	{	114	Nausea
		90	Weight loss
		116	Decreased creatinine clearance
<b>Aspirin</b>	{	20	Easy Bruising
		94	Melena
		54	Epistaxis

# PrEP Side Effects

<b>Common</b>	<b>Uncommon</b>	<b>Serious</b>
<b>Diarrhea (2%)</b>	Vomiting	<b>↓ Bone mineral density</b>
<b>Dizziness (2%)</b>	Abdominal pain	<b>Kidney failure</b>
Gas	Decreased appetite	Lactic acidosis
Nausea	Weight loss	Liver disease
Headache	Malaise	Muscle weakness
Rash	Muscle pain/cramp	Pancreatic disease
Skin discoloration	Dysphagia	
	Shallow breathing	
	Sleepiness	

## Case 2

**Talia is a 16-year-old patient presents for a school physical with their caregiver (aunt)**

- **No PMHx, significant Family Hx**
- **No Medications, NKDA**
- **Social Hx:** senior in high school,  
On softball team, lives with aunt  
Alcohol: 2-3 beers per setting at parties  
Marijuana weekly  
Tried cocaine this past summer

23<sup>rd</sup> St Medical

**Intake Forms**  
Demographics

Assigned Sex at Birth: M (F) \_\_\_\_\_

Gender: M / F / \_\_\_\_\_

Pronouns: He/She/They/ \_\_\_\_\_  
(Select all that apply)

## **When you get to sexual practices, auntie leaves the room:**

- Non-binary, AFAB, reports oral sex, receptive vaginal sex, receptive anal sex
- Using condoms 50% of the time
- No prior HIV testing or STI testing
- No history of HPV vaccine

**Talia had consensual, unprotected receptive vaginal and anal sex two days ago.**

**HIV status of partner unknown.**

What's next?

Exposure to HIV is  
considered a medical  
emergency

# Which PEP Regimen Would You Recommend?

- A. F/TDF daily x 30 days
- B. F/TAF daily x 28 days
- C. F/TDF + Dolutegravir x 28 days
- D. F/TDF + Efavirenz x 28 days

# Post-Exposure Prophylaxis (PEP)

- Administered after high-risk exposure to HIV
- F/TDF + dolutegravir daily OR raltegravir twice daily X 28 days
- Administer first dose ASAP (72 hours)
- Laboratory tests
  - HIV negative → buy Ab tests for the office!!!
  - Hepatitis B surface antigen, renal function, HIV viral load
  - +/- urine HCG
- Follow up
  - Repeat testing at 4-6 weeks for HIV and 3 months
  - Consider PrEP, if applicable



**PE:** W: 60 kg, H: 66 inches, No significant findings

**Labs:**

- HIV antibody test negative in office (pew)
- Urine HCG test negative
- 3-point STI testing collected in office
- Lab requisition for additional diagnostic testing

**Assessment and Plan:**

- PEP x 28 days
- Administer Plan B
- +/- Prophylactic GC/CT and trichomonas treatment
- Administer HPV vaccine 1 of 3
- Follow up in 4 weeks for repeat testing and PrEP consultation

# Talia returns in 4 weeks

- Two days left of PEP treatment
- Interested in transitioning to PrEP immediately
- Discuss birth control options

# Transmission Rate

- MSM, MSMW, and transgender women make up 81% of new HIV diagnoses
  - Anal sex
- 19% cisgender/endosex women
  - Receptive vaginal sex
- HIV disproportionately affects transgender women
  - 1 in 2 are Black
  - 1 in 4 are Latinx
- 58% of transgender men diagnosed with HIV are Black

# PEP to PrEP

## **Labs:**

- HIV antibody and HIV viral load testing
- Urine pregnancy test
- STI testing: GCCT, RPR
- Renal function

## **Assessment:**

- F/TDF vs F/TAF
- Discuss Hepatitis A/B vaccination
- Birth control discussion

TDF VS TAF?

# Descovy (F/TAF)

- FDA approved for PrEP October 2019
- Indications:
  - Adolescents and adults  $\geq 35\text{kg}$ , high risk for HIV-1 transmission
  - \***EXCLUDES**: individuals having receptive vaginal sex
- Dose: FTC 200mg / TAF 25mg daily
  - TAF absorbed quicker,
  - Plasma exposure to TAF, intracellularly converted to TDF at higher levels
  - Lower drug levels

# Limitations of DISCOVER Trial

- Double blind, randomize HIV seronegative
- Median age: 34
- Majority white
- Criteria:
  - $\geq 2$  condomless unique sexual partners in previous 12 weeks OR
  - Diagnoses of GC, CT, syphilis within 24 weeks
- Cisgender MSM and TGW
  - \*Does not include cisgender/endo women or transmen or any vaginal receptive sex
- Subjects were seen in follow-up visits at Weeks 4, 12, and every 12 weeks thereafter; 50% followed up at 96 weeks

# Plan for Talia

- Complete PEP regimen
- Continue F/TDF daily for PEP to PrEP transition
- Start ethinyl estradiol/norgestimate daily
- Referral to GYN for progestin-releasing implant
- Repeat labs and follow-up appointment in 3 months.



# Case 3

## 55 year old presents for treatment of rectal gc

- Medications: Lisinopril, Humalog, Alendronate, Vit D, Calcium
- No relevant family history of surgical history
- Sexual history: Partner is UVL, exploring CNM

Intake Form  
Demographics

Assigned Sex at Birth  M /  F / \_\_\_\_\_

Gender: Male

Pronouns:  He /  She /  They / \_\_\_\_\_

(Circle all that apply)

- Primary partner is UVL (Undetectable Viral Load)
- Rectal gc likely from an outside partner when they "played"
- Engages in
  - Receptive penile-anal
  - Receptive/insertive oral-anal intercourse
  - Receptive/insertive oral-genital intercourse

# HIV Incidence is Increasing Among Which Population?

- A. All men who have sex with men
- B. Young MSM (age 13-24)
- C. Black heterosexual women
- D. All of the above

## F/TAF



Approved 2016 (HIV)  
Approved 2019 (PrEP)



No effect on BMD/Cr  
Approved CrCL >30



Possible weight gain

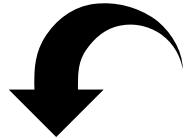


Not approved for  
vaginal exposure

## F/TDF



Approved 2012  
Brand or **generic**



May ↓GFR (↑Cr)  
Recovers in 4wks

~1%

May ↓BMD (No DEXA)  
Recovers in 6mos

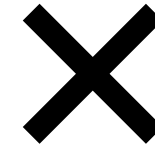
2

Reported cases  
of Fanconi syndrome

2-5%

Weight loss in some  
patients

## <Daily



**Not FDA approved**  
Limited evidence

**2-1-1**

2 doses before &  
after each encounter

**S&T**

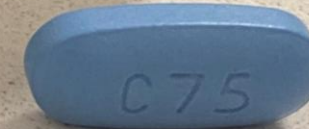
Sat, Sun, Tues, Thurs

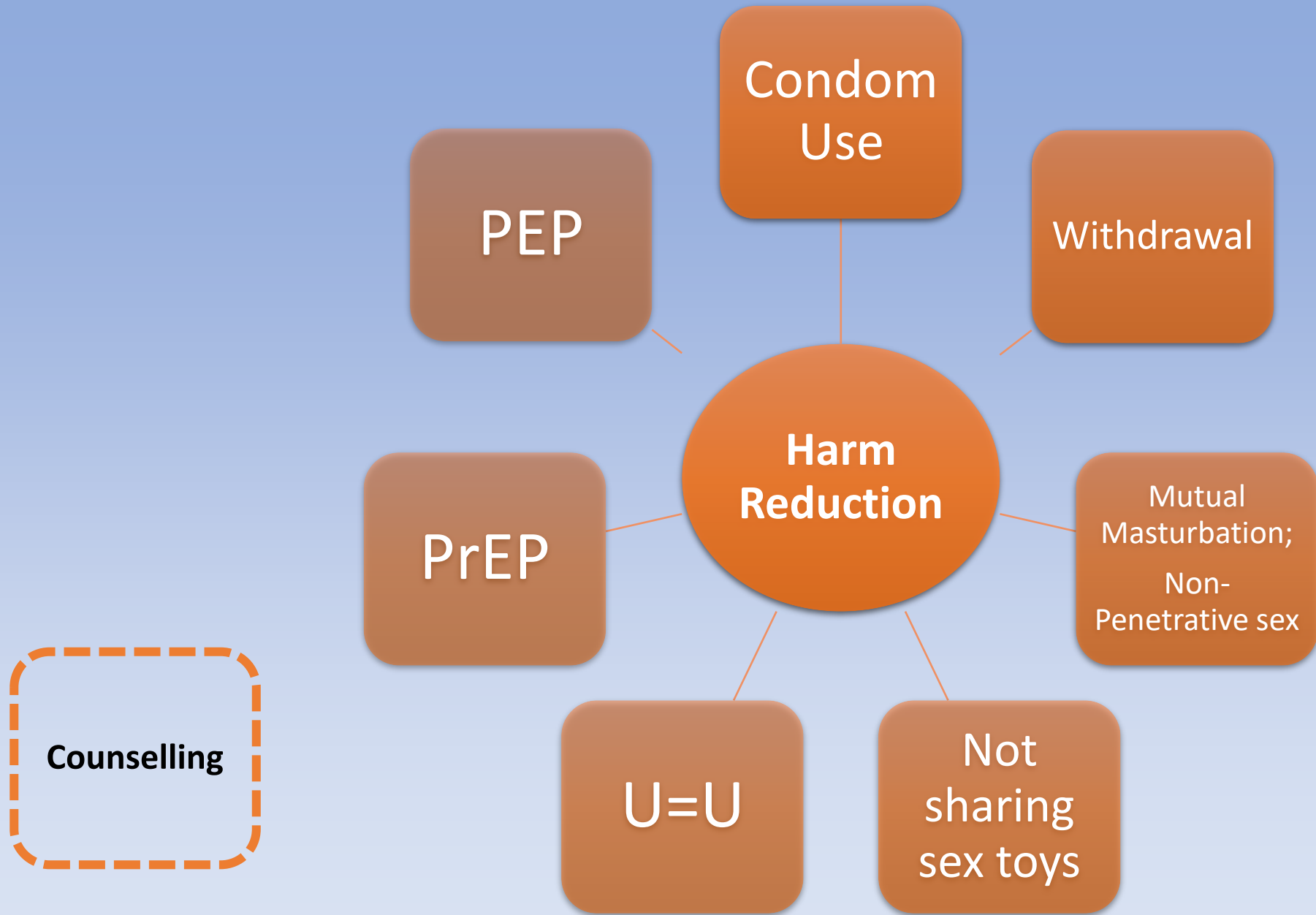


Less drug =  
less cost, less S/E



Still monitor every 3  
months (esp HIV)





# Treatment as Prevention

Undetectable = Untransmittable

# Case 4

## A 35 yo presents as new patient for PrEP intake

- Patient has been on the DISCOVER Trial for 3 years at UCLA
- Found out he was on F/TAF and has been released from trial
  - No adverse effects
- Recently got PPO insurance and is in office to continue F/TAF
- Prior to being on study, he was on F/TDF for 5 years
  - Experienced GI discomfort

23<sup>rd</sup> St. Medical

Patient Information

Assigned Sex at Birth: Male

Gender: Male

Pronouns: He/They

- **PMHx:** Rectal GC, negative repeat testing on multiple occasions; history of secondary syphilis 6 months ago
- **Medications:** Descovy (F/TAF), finasteride 1 mg daily
- **NKDA,** no significant family Hx
- **Social Hx:** Alcohol: 5 drinks on weekends, Drugs: marijuana weekly, MDMA 3-4 times per year, GHB 3-4 times per year, lives with main partner, works at home for marketing firm



# Insurance Concerns

- PrEP history
  - Time on medication
- PMH
  - Age
  - Renal
  - BMD
- Adverse effects
- Laboratory discrepancies
- Documentation, documentation, documentation

# Insurance Concerns

- Internal review
- External review
- Denial discussion

# Case 5

## 36 year old male presents to establish care

- No known drug allergies, medical history, or medications
- Social: Denies drug, alcohol, or tobacco use
- Occupation: masseuse
- Hesitant to start any medication but wants to talk about PrEP

Lasersurgery Care

**Patient Information**

Assigned Sex at Birth:   M  

Gender:   M  

Pronouns:   He Series

# Sexual History

- Regularly engages in scheduled sexual encounters with clients
  - Condomless with HIV-negative and UVL clients
- Engages in
  - Receptive/insertive penile-anal
  - Receptive/insertive oral-anal intercourse
  - Receptive/insertive oral-genital intercourse

# PrEP PK/PD

## Daily F/TDF

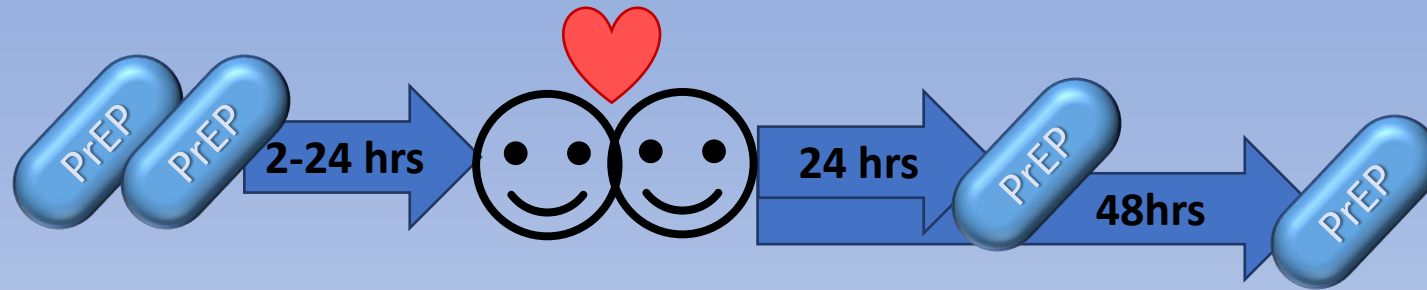
- 2 doses/week – 76% efficacy
- **4 doses/week – 96% efficacy**
- 7 doses/week – 99% efficacy

## Potential for alternative dosing strategies

1. S's & T's (Sat, Sun, Tues, Thurs)
2. Pericoital/on-demand/2-1-1

**\*\*\*Tenofovir/emtricitabine is NOT approved or recommended for less than daily use**

# “On Demand” or 2-1-1 Dosing



- Ipergay (France) 414 HIV-negative, high risk MSM
- 86% reduction (39.4-98.5%) P=0.002
- (14 seroconversions in Placebo arm; 2 in PrEP arm)
  
- Median of 14 pills/mo
- (4/wk is ~90%+ effective)

**\*\*\*Tenofovir/emtricitabine is NOT approved or recommended for intermittent use**

# “On Demand” or 2-1-1 Dosing

**Tenofovir/emtricitabine is NOT approved or recommended for intermittent use**

- Relies on anticipation of sex
- Less drug = less potential for side effects and adverse events

*“[Intermittent dosing] is clearly preferable to no PrEP at all”*

# Review: What Labs are Drawn to Initiate PrEP (at a minimum)

1. HIV, Hepatitis B, Cr, Urine HCG\*
2. HIV, Hepatitis Panel (A/B/C), CMP, Urine HCG\*
3. HIV, Hepatitis B/C, Cr, LFTs, Urine HCG\*
4. HIV, LFTs, BUN/Cr, Urine HCG\*

*\*(if childbearing potential)*



# 3 Month Lab Results

## 3 month Lab Results:

- HIV Ag/Ab NR
- Syphilis NR
- Genital gc/Ct NR
- Oral gc/Ct **Gc+/Ct-**
- Rectal gc/Ct NR
- HBsAb/HBsAg **Reactive/NR**
- HAV Ab, HCV Ab NR
- Creatinine 1.15

# Will PrEP Increase Risky Behaviors?

Risk homeostasis\risk compensation posits an individual will maintain an average level of risk they find acceptable.

# Increased STI Risk Among PrEP Users

**MSM on PrEP are**

**25.3X**

more likely to acquire  
**gonorrhea**

**11.2X**

more likely to acquire  
**Chlamydia**

**44.6X**

more likely to acquire  
**Syphilis**

**Than MSM not on PrEP**

**However, they are screened more frequently  
and may represent a higher risk population**

# STI Risk in PrEP Users

<b>275 MSM at risk of HIV exposure in DC:</b>
<b>41%</b> who were using PrEP were:
<b>3X</b> more likely to self report an STI in the past year
<b>=</b> Just as likely to have a current STI

<b>1922 MSM in 5 cities*</b>
<b>29%</b> who were using PrEP were:
<b>2X</b> as likely to be tested in the past year
<b>↑/=</b> Slightly more likely to have gc/Ct detected at any site (15% vs 12%)
<b>↑/=</b> ↑ risk of rectal Ct otherwise similar

\*(SF, DC, NY, MIA, Houston)

*“Sexual health is a state of  
physical, mental, and social well-being  
in relation to sexuality.”*

•  
-World Health Organization

# PrEP: Injectable Cabotegrevir

**( Q2 month IM cabotegravir  
At least as effective as F/TDF )**

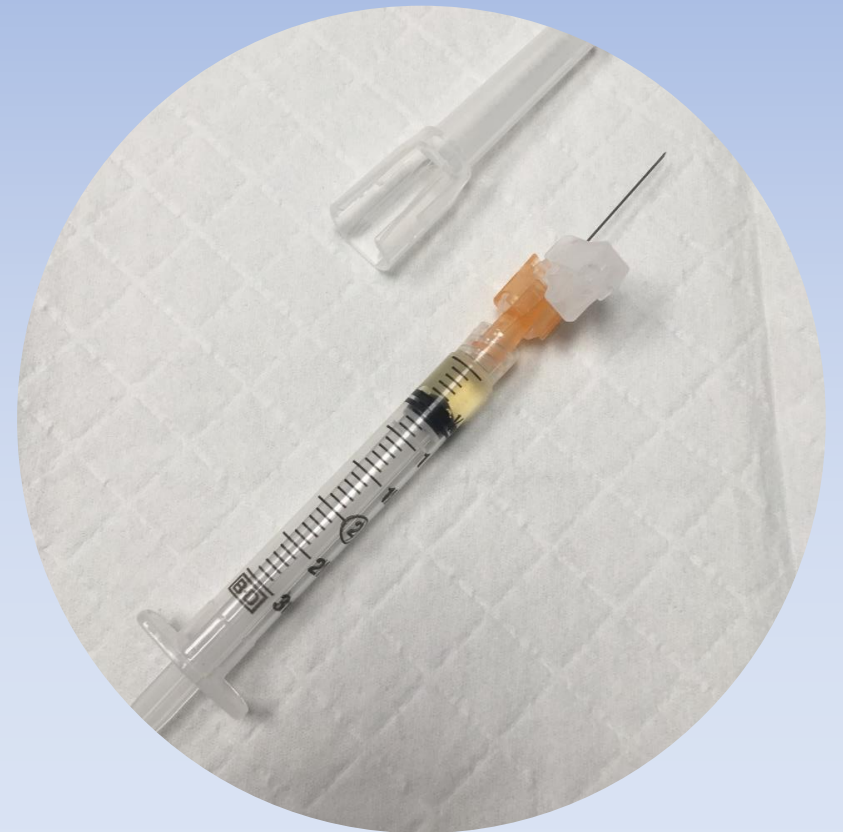
- S/E: injection site reaction
- Oral lead-in
- Q2 month IM vs Q3 month labs



# PrEP Pipeline

- **Injectable** PrEP every 3 months?
- PrEP **vaginal ring** (27% effective women in Sub-Saharan Africa)
- **Implantable** PrEP (\$140 million grant)
- **Topical** PrEP for RAI (Rectal Microbicides)

**None of these are approved  
or recommended for PrEP**



*“No more excuses,*

*We have the tools to end the epidemic:*

*It is up to us to do it.”*



*-Dr. Anthony Fauci  
Director of the NIAID at NIH*





# Resources

Finding a PrEP Provider

[www.prelocator.org](http://www.prelocator.org)

[www.greaterthan.org/get-prep/](http://www.greaterthan.org/get-prep/)

Uninsured/underinsured/  
Copay Assistance

[www.panfoundation.org](http://www.panfoundation.org)

[www.copays.org](http://www.copays.org)

[www.health.ny.gov/](http://www.health.ny.gov/) (PrEP-AP)

Manufacturer rebate programs

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# Take Home Points

- HIV prevention **IS** the responsibility of health care providers
- HIV prevention options vary and meet the needs of a diverse patient population
- Tenofovir/emtricitabine as daily pre-exposure prophylaxis for HIV is highly effective, safe, and easy to manage in a primary care setting
- Additional options for PrEP coming soon

# AAPA CME

Toward Health Equity: Social Determinants of Health and PA Practice

Update on Sexual Transmitted Infections: Advanced and Interesting Cases

Basic Principles of Culturally Sensitive Care for Sexual and Gender Diverse Patients  
(Including LGBT+)

Caring for Gender Diverse Patients in Your Practice


HPV: Here, There, and Everywhere

Getting to the Bottom of Anorectal Pathology

Dermatologic Care for Sexual and Gender Minorities

Caring for Lesbian, Bisexual, and Queer (LBQ) Womxn

# Prescribing HIV Prevention: Preexposure Prophylaxis (PrEP)

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