# Prescribing HIV Prevention: Preexposure Prophylaxis (PrEP)

**Jonathan Baker, PA-C, MPAS, DFAAPA *(He/Him)***

Anorectal & Sexual Health PA | Laser Surgery Care | NYC
Immediate Past President | NYSSPA
Past President | LBGTPA
Delegate | AAPA HOD

**@RectalRockstar**
JonathanBaker.PA@gmail.com

# Disclosure

**Jonathan Baker** has relevant relationships with ineligible companies to disclose within the past 24 months. (Note: Ineligible companies are defined as those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.) Company name and type of financial relationship: Salary support from Franz Therapeutics, Inovio Pharmaceuticals, and Merck & Co.

*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 patients
- Become familiar with HIV prevention methods, including PrEP, PEP, and treatment as prevention
- Reference current guidelines for the use of ARVs as prevention
- Discuss how medical HIV prevention can be tailored as part of patient-centered care

# CDC Recommendations for PrEP

> “All sexually active adult & adolescent patients should receive information about PrEP”

CDC 2021, Smith 2015

# Preexposure Prophylaxis (PrEP)

HIV-negative people at risk of acquiring HIV
employing antiretroviral medication
to reduce risk of becoming infected with HIV
as part of comprehensive HIV prevention services

Oral tenofovir/emtricitabine (daily)
IM cabotegravir-LA (Q 2 months)

# CDC Recommendations for PrEP

Anal or vaginal sex in past 6 months AND any of the following:

- Sexual partner LWH
- Bacterial STI in past 6 months
- History of inconsistent/no condom use

>600,000 heterosexual individuals &
~500,000 MSM in the US meet this criteria

115,000 PWID with an injecting partner LWH
or who share injection equipment

CDC 2021, Smith 2015

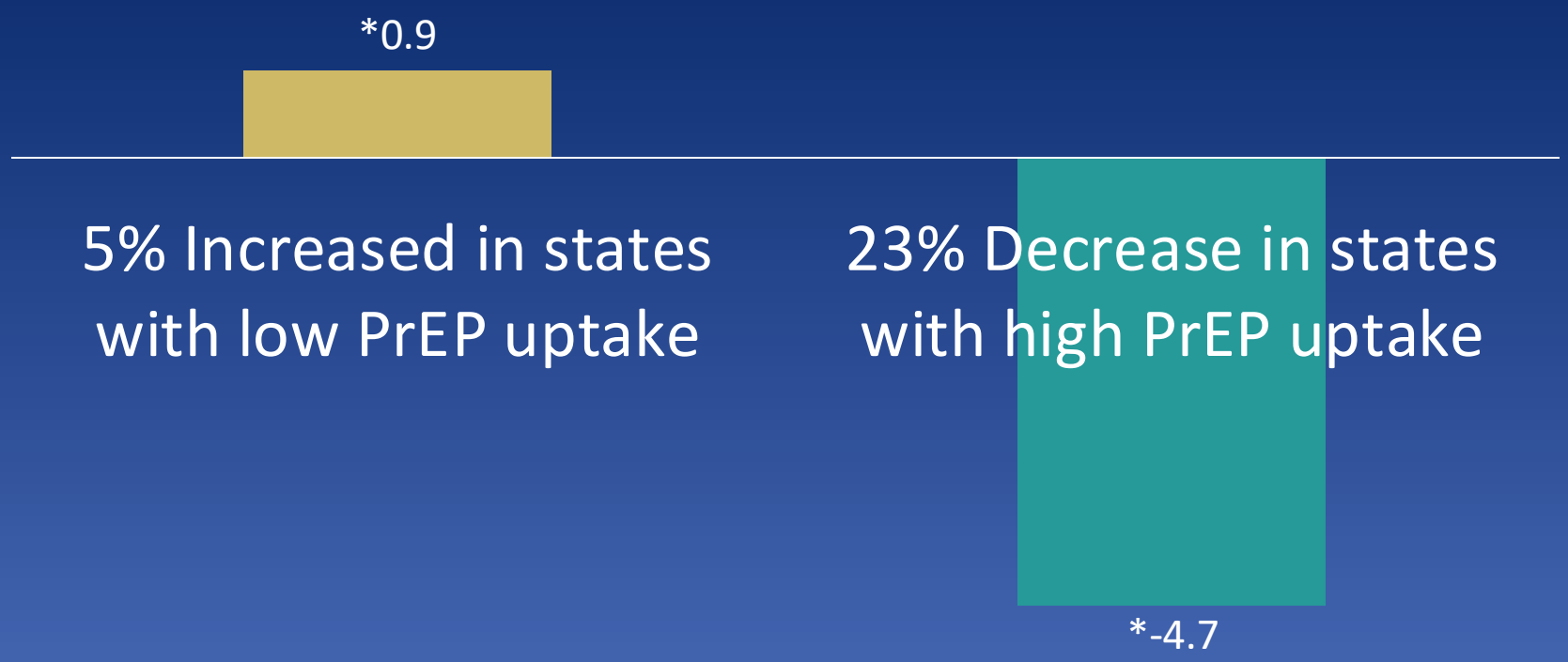
*Adolescents weighing at least 35 kilograms/77 pounds
**Syphilis or gonorrhea; or chlamydia among MSM, transgender women who have sex with men

# PrEP Randomized Controlled Clinical Trials

| Study | Location | Population | Drug | Prevention |
|---|---|---|---|---|
| iPrEX | International & Domestic | 2,499 MSM | F/TDF | 44% |
| Partners PrEP | Africa (Kenya, Uganda) | 4,758 heterosexual Serodiscordant couples | TDF<br>F/TDF | 62%<br>73% |
| TDF2 | Botswana | 1,219 heterosexuals (♂&♀) | F/TDF | 63% |
| Bangkok Tenofovir | Bangkok | 2413 IVDU (♂&♀) | TDF | 48.9% |
| iPergay | France & Canada | 414 MSM (2-1-1 dosing) | F/TDF | 86% |
| Discover | International & Domestic | | F/TAF | TAF noninferior* |
| FEM-PrEP | Africa | 1,951 heterosexual women | F/TDF | Unable to Evaluate |
| VOICE | Africa | 5,029 heterosexual women | F/TDF | |

Grant 2010, Baeten 2012, Thigpen 2011, Van Damme 2012, Molina 2015, Hare 2019, Marrazzo 2015 *compared to F/TDF

# Reduction in HIV Diagnosis




*EAPC of states in the top quintile and lowest quintile of PrEP uptake 2012-2016

Sullivan 2018

| F/TDF | F/TAF | <Daily |
|---|---|---|
| Approved 2012<br>Brand or **generic** | Approved 2016 (HIV)<br>Approved 2019 (PrEP) | **Not FDA approved**<br>Limited evidence |
| May ↓GFR (↑Cr)<br>Recovers in 4wks | No effect on BMD/Cr<br>Approved CrCL >30 | **2-1-1**<br>2 doses before & after each encounter |
| ~1%<br>May ↓BMD (No DEXA)<br>Recovers in 6mos | Possible ↑ in lipids, triglycerides, & weight (check annually) | **S&T**<br>Sat, Sun, Tues, Thurs |
| 2<br>Reported cases of Fanconi syndrome | **Not approved for vaginal exposure** | Less drug =<br>less cost, less S/E |
| 2-5%<br>Weight loss in some patients | | Still monitor every 3 months (esp HIV) |

Liu 2011, Grant 2016, Mugwanya 2016, Hare 2019, Mayer 2020

# PrEP: Injectable Cabotegravir

| CAB- LA | |
|---|---|
| ☑ | Approved 12/2021<br>Brand only |
| 2 mo | IM injection in office<br>Q2 months |
| 💉 | Injection site reaction<br>common (<3% d/c) |
| ▶ | Initiate w/ 1 mo oral or<br>2 doses, 1 month apart |
| 🛡 | Similar efficacy<br>to daily PrEP |


Landovitz 2021

# F/TDF vs Aspirin

Number of patients treated per year

to possibly result in a harmful outcome:

| | | |
|---|---|---|
| **F/TDF** | 114 | Nausea |
| | 90 | Weight loss |
| | 116 | Decreased creatinine clearance |
| **Aspirin** | 20 | Easy Bruising |
| | 94 | Melena |
| | 54 | Epistaxis |

CAB-LA & F/TAF AE severity & frequency not significantly different from F/TDF

Kojima 2015, Landovitz 2021

# PrEP Cost

| | |
|---|---|
| F/TDF | >$36/month |
| F/TAF | $2,000/month |
| CAB-LA | $3,700/dose (Q2 mo) |

**USPSTF Grade A Recommendation**

- $0 copay required by law
- Costs associated with q3mo visits & laboratory tests should have no out-of-pocket costs (modifier “33”)

# Baseline Labs

- **HIV Ag/Ab, HIV RNA, or HIV POC***
- Bacterial STI Screening
- HCG (if childbearing potential)

- For tenofovir based regimens:
  - Hep B surface ab/ag
  - Creatinine

CDC 2021

*Point-of-care HIV Ag/Ab should be confirmed by lab whenever possible; oral testing discouraged

# Follow Up Labs

- **Q 2-3mo:** HIV Ag/Ab **& HIV RNA**
- Routine STI Screening
- HCG (if childbearing potential)

- Creatinine (F/TDF or F/TAF only)
  - (within 3 months of initiation)
  - Q1yr for ≤50 yo
  - Q6mo for >50 yo or eCrCl <90

- For F/TAF
  - Annual weight & lipid panel

CDC 2018, CDC 2021

# Bacterial STI Screening on PrEP

- Syphilis Q6 mos
- MSM, TGWSM: syphilis, gc/Ct 3 sites Q3-4 mo
- Heterosexual men and women: genital gc Q6 mo; genital Ct Q12 mo
- Women who engage in RAI: rectal gc/Ct Q6 mo
- **All patients engaging in anal sex: Hep A ab, Hep C ab

CDC 2021

# 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**

Kojima 2016, Rekart 2017

# STI Risk in PrEP Users

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

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

Torres 2019, Chapin-Bardales 2019

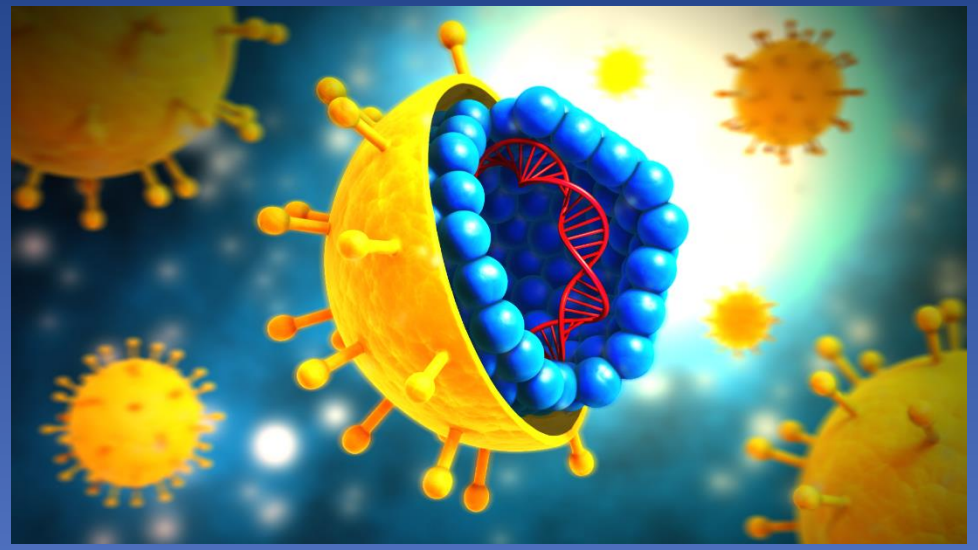
*(SF, DC, NY, MIA, Houston)

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

-World Health Organization

# Hepatitis C Transmission Among PrEP Users

- Sexual transmission of HCV among MSM living with HIV is well documented; few cases among HIV-negative MSM
- 2 cases of sexual HCV acquisitions among 485 MSM in Kaiser San Francisco



Volk 2015, CDC 2018

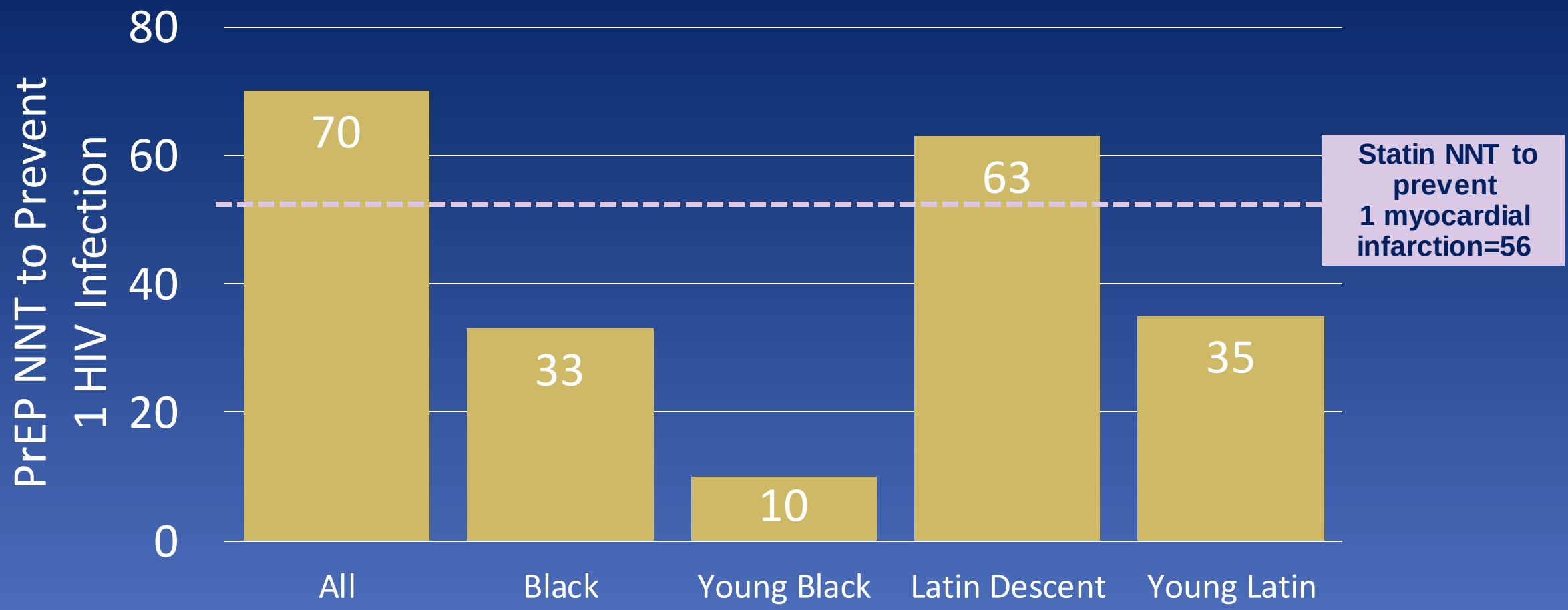
# PrEP and HIV Viral Resistance

Inadequate ARV therapy is known to result in resistance;

individuals who become infected with HIV should discontinue PrEP immediately to prevent development of resistance.

Grant 2010, Baeten 2012, Thigpen 2011, Van Damme 2012

# PrEP NNT MSM to Prevent 1 HIV Infection

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# Post Exposure Prophylaxis (PEP)

- Expert consultation is recommended in all cases, but do not delay PEP initiation
- Begin PEP within 72 hours of exposure; preferably within 2 hours
- Baseline Labs: HIV, CBC, CMP
- Repeat HIV Ab at 6 wks, 2 mos, 6 mos

- Occupational PEP – HCW exposure to HIV+ or unknown status source
- Non-occupational (nPEP) – Sexual or IVDU exposure

NYS DOH 2017, Harrison 2001, Smith 2005

F/TDF (200/300mg QD) & raltegravir (400mg BID) -OR- dolutegravir (50mg QD)*

**PEP Consultation for Healthcare Providers 888-448-4911**

NYS DOH 2017, Harrison 2001, Smith 2005

*Avoid dolutegravir and efavirenz in patients who are or may be pregnant

# PEP to PrEP Transition

> “Patients who seek one or more courses of nPEP and who are at risk for ongoing HIV exposures should be evaluated for possible PrEP use after confirming they have not acquired HIV”

CDC 2021

# Treatment as Prevention

## Undetectable = Untransmittable

## U=U

Rodger 2016, Donnell 2010, Cohen 2011

# Patient Awareness of PrEP

- Disparities by race
  - Non-Hispanic black MSM significantly less likely to be aware of PrEP compared to Non-Hispanic white MSM
- Education level
  - College educated MSM were significantly more aware of PrEP than MSM with education levels up to the 8$^{th}$ grade
- Having an HIV test or a +STI test **did not** increase awareness of PrEP
- Increased awareness if patients were out to their PCP

Raifman 2017

# Women Want to Know About PrEP

| **500 women seeking care at 4 FP clinics in ATL:** | |
|---|---|
| **18%** | Knew about PrEP before the study |
| **28%** | had ≥1 risk consistent with PrEP eligibility |
| **59%** | Expressed interest in learning more about PrEP |

## Women Suggested

**Advertising:** brochures, posters, phone calls, etc.

**Conversations:** with staff and providers

**Awareness:** broadly in the community

**Access:** to PrEP information & services

# F/TDF 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

Anderson 2012

*****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/emtricibine is NOT approved or recommended for intermittent use

Molina 2015

# “On Demand” or 2-1-1 Dosing

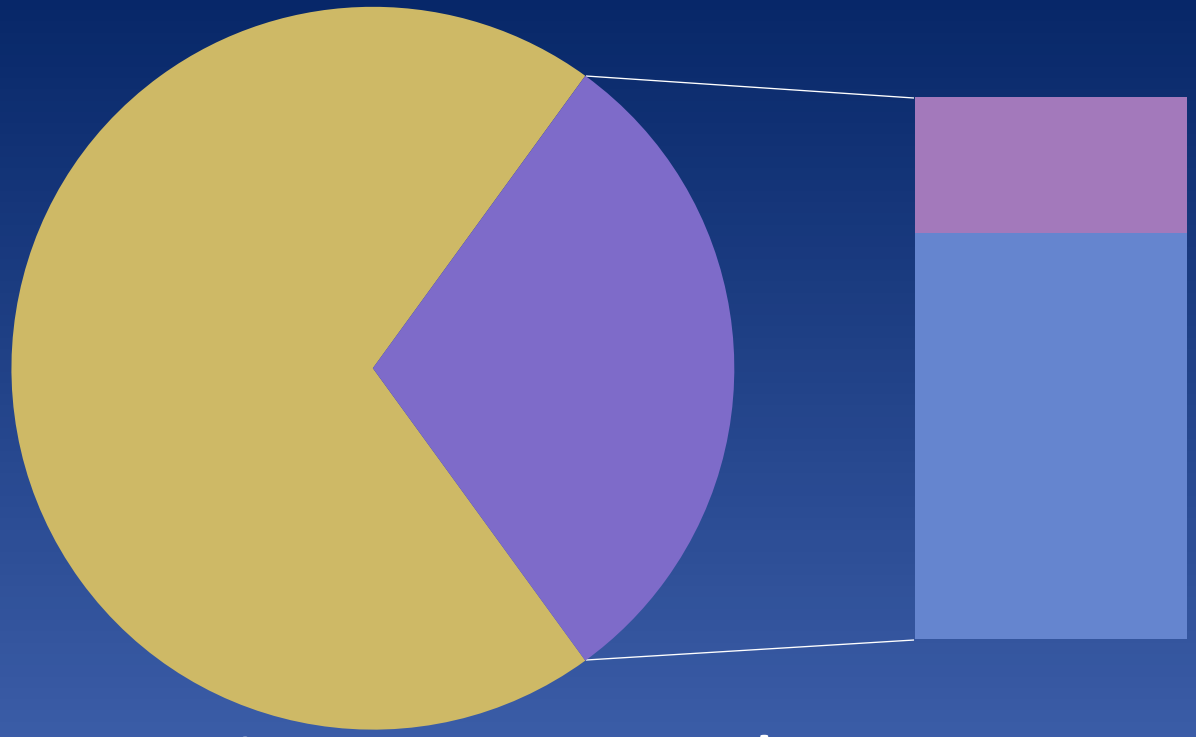
- **PrEP is NOT approved or recommended for intermittent use**
- Relies on anticipation of sex
- Less drug = less potential for side effects and adverse events

- Glidden *et al* suggest:

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

Glidden 2016

# Domestic Heterosexual AI



- 70% Deny Heterosexual AI
- 30% Report Heterosexual AI
- 20-30% Report Condom Use During AI
- 70-80% Deny Condom Use During AI

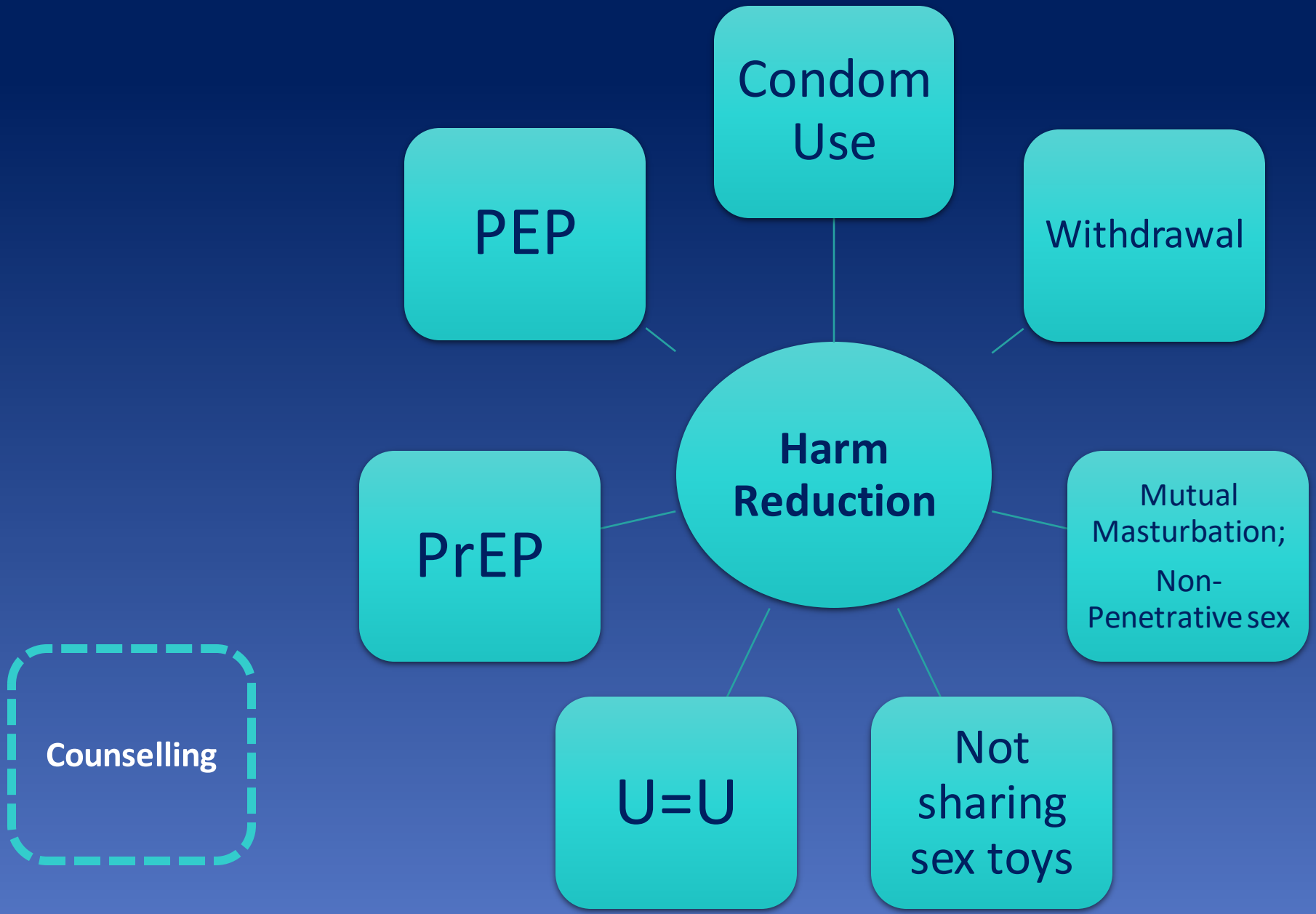
Habel 2018

# AI and HIV Risk

Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act

| Type of Sexual Exposure | Risk per 10,000 Exposures |
|---|---|
| Receptive anal intercourse | 138 |
| Receptive penile-vaginal intercourse | 8 |
| Insertive anal intercourse | 11 |
| Insertive penile-vaginal intercourse | 4 |
| Oral intercourse | low |

CDC 2013




Grant 2010, Metsch 2013, Vallabhaneni 2012, Smith 2015, Cohen 2011, Smith 2005

# Take Home Points

- HIV prevention IS the responsibility of health care providers
- Medical HIV prevention options vary and meet the needs of a diverse patient population
- Pre-exposure prophylaxis for HIV is highly effective, safe, and easy to manage in any care setting

# Resources

| | |
|---|---|
| Finding a PrEP Provider | www.preplocator.org<br>www.greaterthan.org/get-prep/<br>www.glma.org/referrals |
| CME | LBGT PA Caucus<br>GLMA annual conference |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# Questions?

JonathanBaker.PA@gmail.com

@RectalRockstar