# PRESCRIBING Pre-EXPOSURE PROPHYLAXIS (PrEP) FOR HIV PREVENTION: A GUIDE FOR CLINICIANS IN THE CARIBBEAN

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# Planning Committee And Speaker

**Speaker: The following speaker has nothing to disclose in relation to this activity: John McNeil, MD, FACP**

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*Goulda A. Downer, PHD, RD, LN, CNS – Principal Investigator/Project Director*

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**AETC-Capitol Region Telehealth Project**
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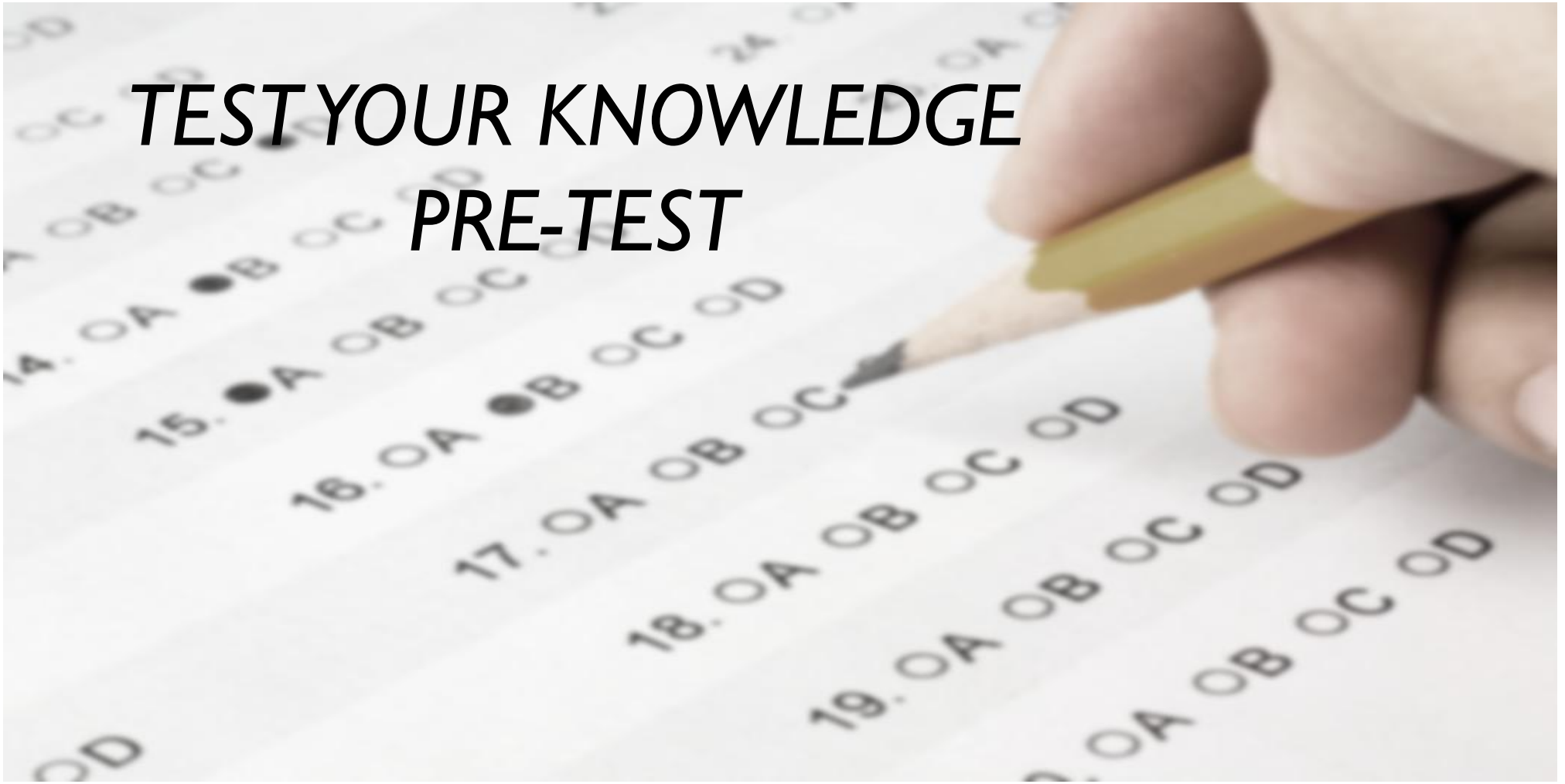
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# *TEST YOUR KNOWLEDGE*
# *PRE-TEST*



# Test Your Knowledge
# Question #1

**All but which of the following is recommended before prescribing PrEP?**

A. Metabolic panel

B. Urinalysis

C. Renal function

D. STI (e.g., syphilis, gonorrhea, chlamydia, HCV)

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# Test Your Knowledge
# Question #2

**All but which of the following is correct about fixed-dose PrEP regimen?**

A. It is indicated for uninfected individuals at high risk who are confirmed to be HIV-1 negative

B. It is dosed as a single pill to be taken once daily, with or without food

C. It should be provided a prescription or refill authorization for no more than 90 days

D. Efficacy is reached within 21 days for men and 7 days for women

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# Test Your Knowledge
# Question #3

**All except which is a recommendation to address with your patient before prescribing PrEP?**

A. Men or women who do not have HIV but who are at high risk of becoming infected with HIV through sex or injection drug use

B. Men or women who are HIV Negative

C. Men or women who are HIV Positive

D. Men or women who are gay or bisexual and are not in a monogamous relationship with a recently tested partner who is HIV negative

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# Test Your Knowledge
# Question #4

PrEP is a combination of which of the following:

A. Emtricitibine (FTC) 100 mg + Tenofovir disoproxil (TDF) 200 mg
B. Emtricitibine (FTC) 200 mg + Tenofovir disoproxil (TDF) 200 mg
C. Emtricitibine (FTC) 200 mg + Tenofovir disoproxil (TDF) 300 mg
D. Emtricitibine (FTC) 400 mg + Tenofovir disoproxil (TDF) 600 mg

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# Learning Objectives

**On completion of the program, participants should be better able to:**

- Describe the epidemiology of HIV in the Caribbean
- Discuss the biomedical advances and clinical considerations for PrEP
- Discuss the importance of risk reduction counselling for prevention of HIV
- Describe the process for initiating and prescribing PrEP
- Discuss the priorities for moving forward towards an AIDS Free Generation

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# Epidemiology of HIV in the Caribbean

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# Overview of HIV/AIDS in the Caribbean



**Caribbean (2017)**

**310,000** people living with HIV

**1.2%** adult HIV prevalence (ages 15-49)

**15,000** new HIV infections

**10,000** AIDS-related deaths

**58%** adults on antiretroviral treatment*

**52%** children on antiretroviral treatment*

https://www.avert.org/professionals/hiv-around-world/latin-america/overview

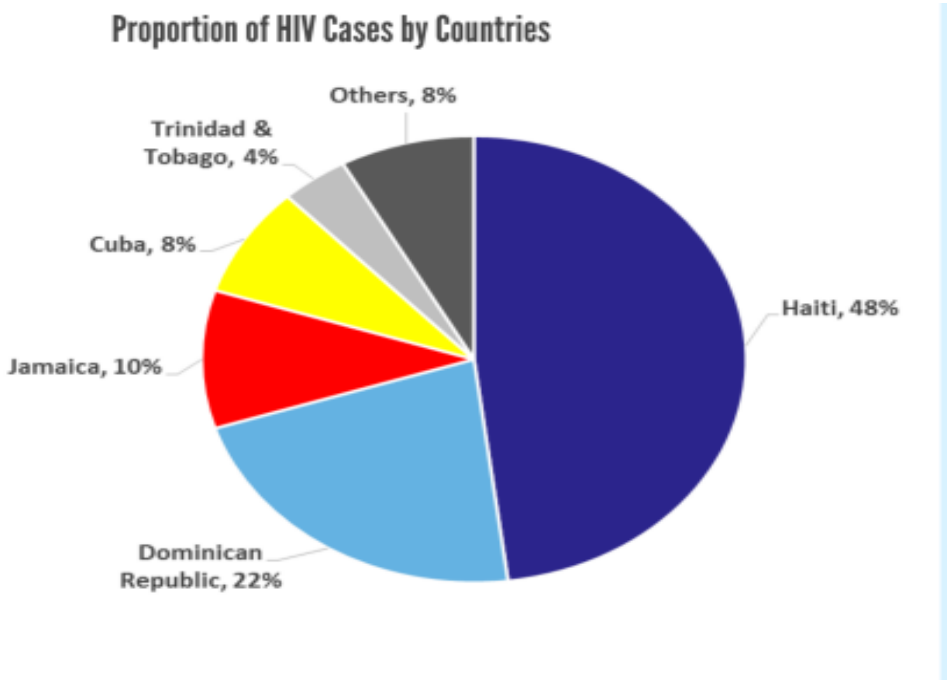
# HIV Prevalence in the CARIBBEAN - 2017

## HIV Prevalence

The HIV epidemic in the Caribbean has been stable over the last decade with a reported HIV prevalence of 1.3% and an estimated 310,000 people living with the disease at the end of 2016.

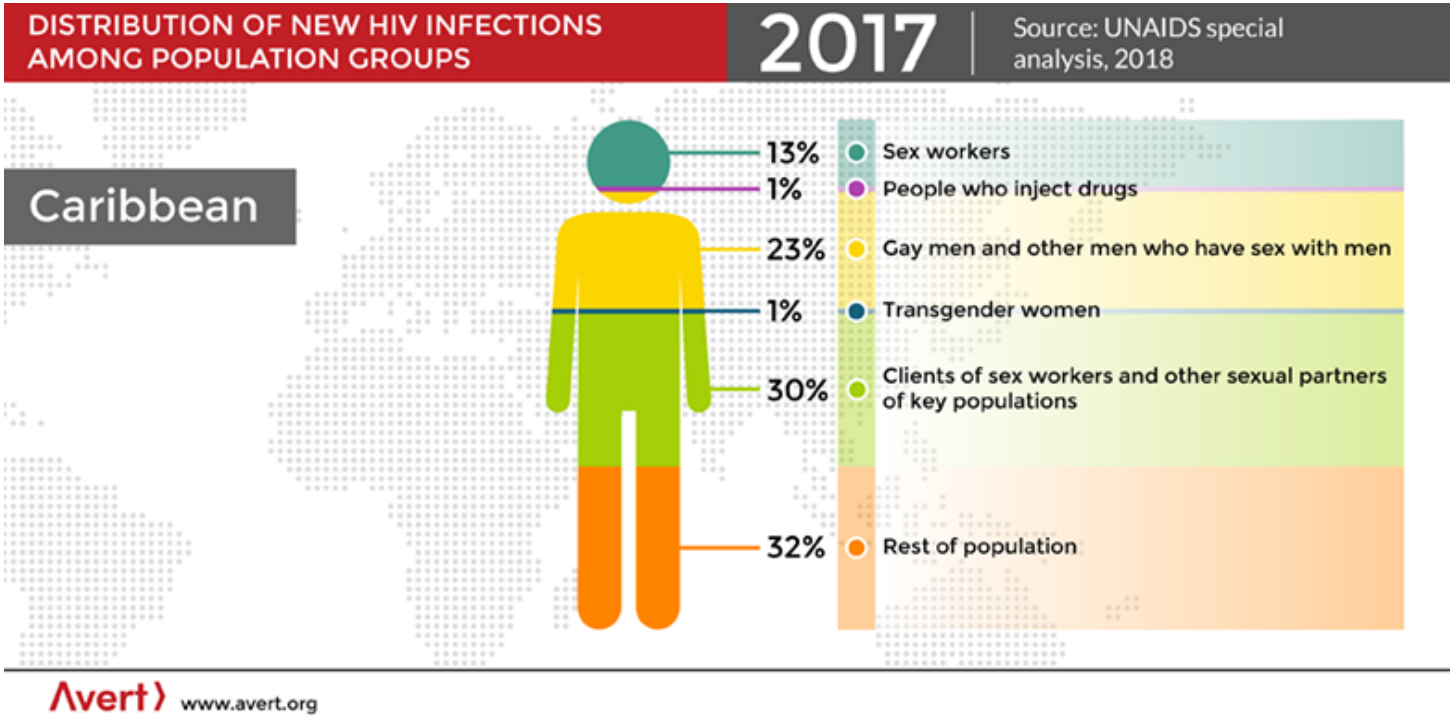
Five countries in the Caribbean accounted for the majority (92%) of infections:

- Haiti (48%)
- Dominican Republic (22%)
- Jamaica (10%)
- Cuba (8%)
- Trinidad and Tobago (4%)

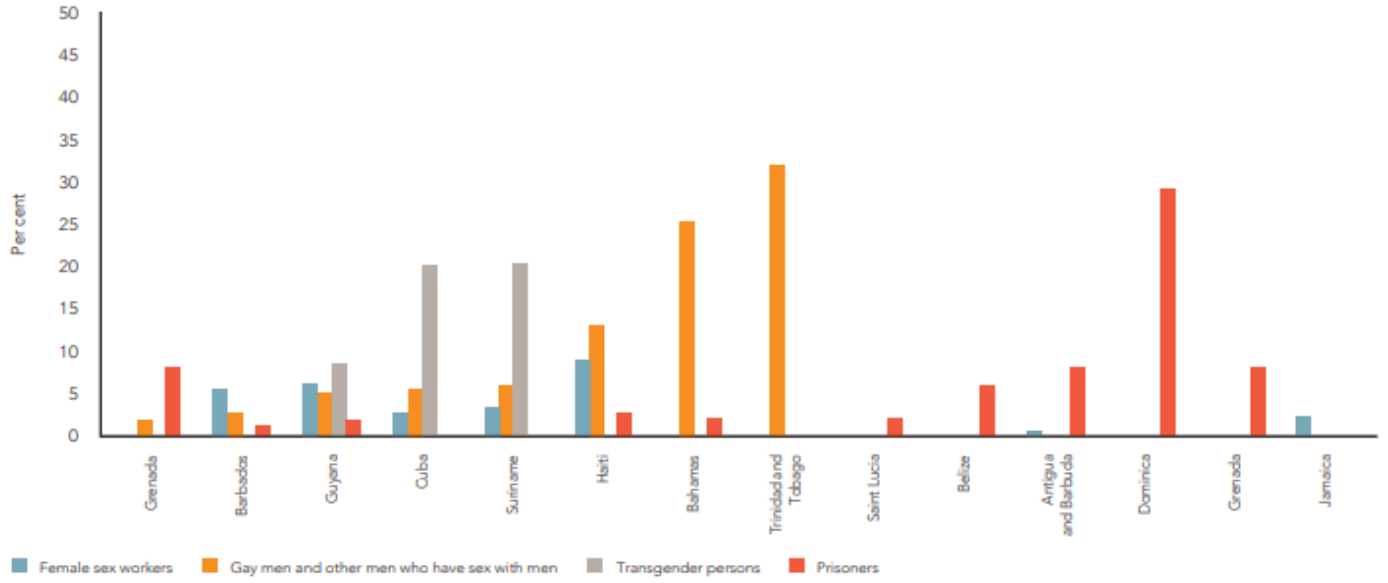



Source: www.pancap.org

# Overview of the Incidence of HIV Infections in the Caribbean

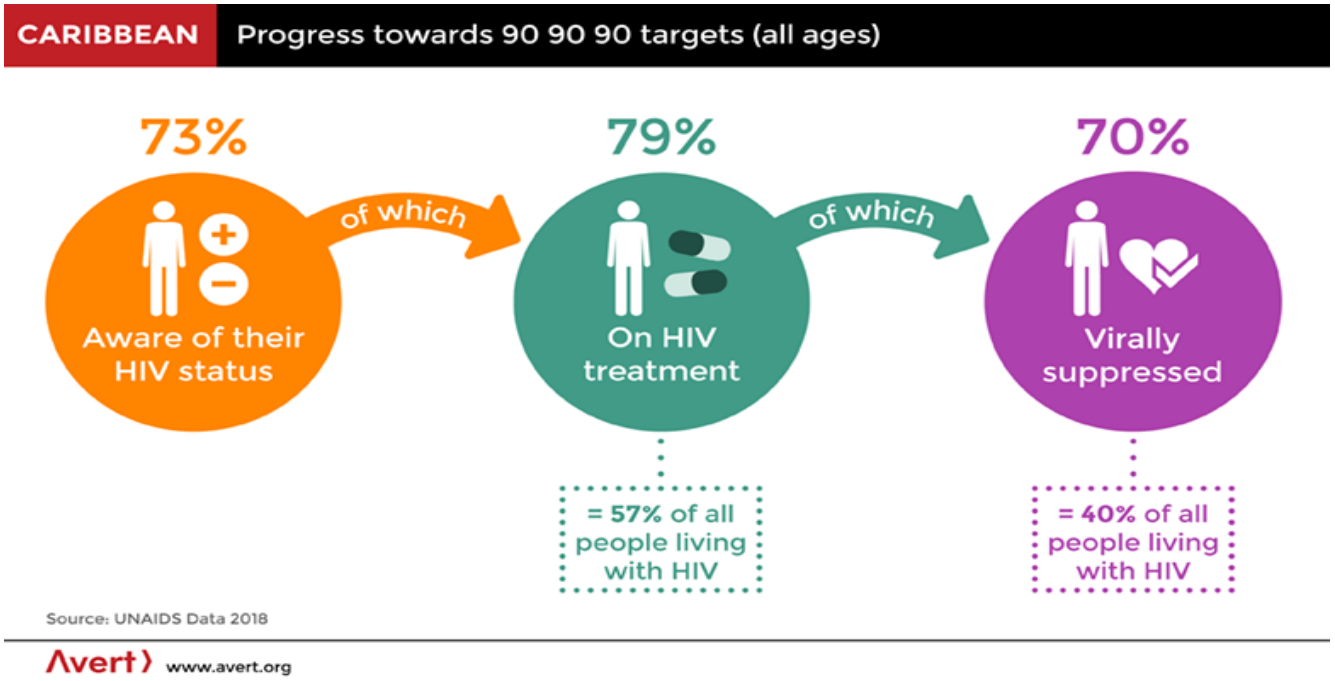


# HIV Infections in Key Populations by Country



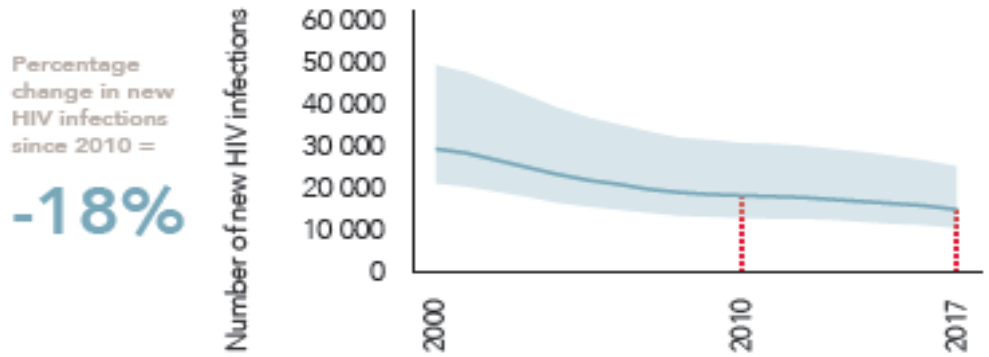

Source: 2018 Global AIDS Monitoring.

# Progress in HIV Treatment In the Caribbean



# Progress In HIV Treatment in the Caribbean

*Number of new HIV infections, Caribbean, 2000–2017*




Source: UNAIDS 2018 estimates.

# What is Pre-Exposure Prophylaxis

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# What is Pre-exposure Prophylaxis (PrEP)?

- **Pre**
  - → Before (and after)
- **Exposure**
  - → When a fluid containing HIV comes into contact with mucous membranes or non-intact skin
- **Prophylaxis**
  - → An action taken to prevent infection or disease

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# BIOMEDICAL ADVANCES:
# PrEP Historical Context

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# Historical Context of Treatment As Prevention and Biomedical Advances

- In the early 1990s, medications were given to expecting mothers who were HIV positive to prevent HIV from being transmitted to their unborn child.
  - This innovative approached led to a 90% decrease to maternal-to-child transmission of HIV in the United States
  - As a result, today, infected moms have a less than 1% chance of infecting their baby
- In the mid-1990s, the introduction of highly active antiretroviral therapies (HAART) expanded the life expectancy in people living with HIV
- In the 1990s, post-exposure prophylaxis was used for the prevention of HIV in persons who were occupationally exposed to HIV

Grant et al., 2010; UCSF, 2015

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# Historical Context of Treatment As Prevention and Biomedical Advances

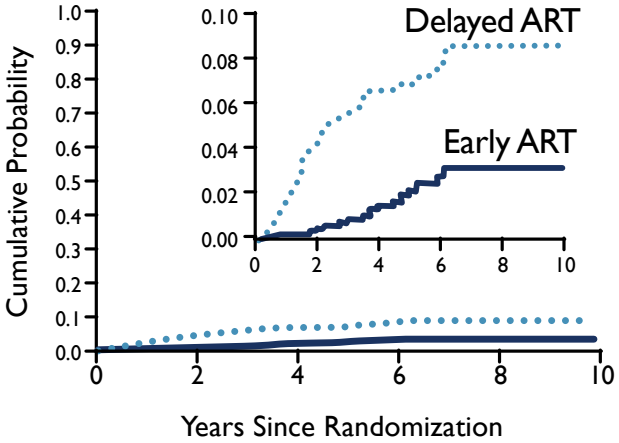
- In the early parts of 2000s, research evidence emerged that showed that treatment of people who were HIV-positive could keep their partners who were HIV-negative uninfected
  - This supported the rationale for treatment as prevention
  - HIV Prevention Trials Network (HPTN) 052 study (2011) found a 96% reduction in HIV acquisition in sero-discordant relationships

Grant et al., 2010; UCSF, 2015

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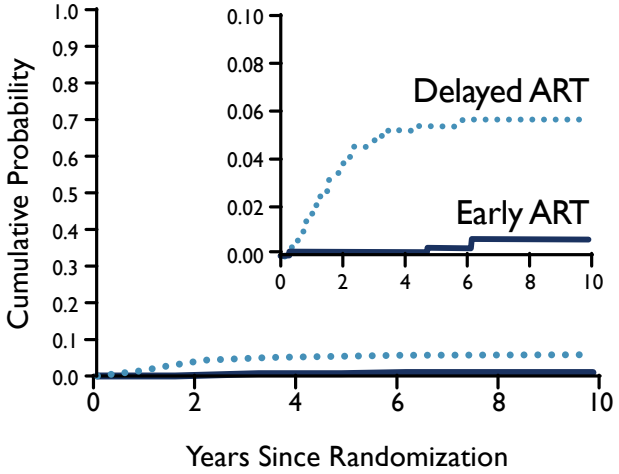
# HPTN 052: HIV Treatment as Prevention Works

## All Partner Infections




| No. at Risk | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Early ART | 903 | 808 | 746 | 697 | 645 | 569 | 263 | 95 | 28 | 26 | 1 |
| Delayed ART | 890 | 792 | 715 | 663 | 611 | 536 | 269 | 99 | 21 | 19 | 2 |

## Linked Partner Infections




| No. at Risk | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Early ART | 903 | 808 | 746 | 697 | 645 | 569 | 263 | 95 | 28 | 26 | 1 |
| Delayed ART | 890 | 792 | 715 | 663 | 611 | 536 | 269 | 99 | 21 | 19 | 2 |

…with no linked infections after 6 months of viral suppression.

ART, antiretroviral therapy.

Cohen MS, et al. N Engl J Med. 2016;375:830-839.

# Partner Study: HIV Transmission Risk Through Condomless Sex in Serodiscordant Couples

- Observational study (interim analysis)
  - Serodiscordant couples (n=767) in international multi-centered settings
    - HIV positive: on ART (HIV RNA <200)
    - HIV negative: not on PEP or PrEP
  - **Condomless sex**
- Phylogenetically linked transmissions
- MSM
  - Receptive anal: 70%
  - Receptive anal with ejaculation: 40%
  - Only insertive anal sex: 30%
- Heterosexual
  - Vaginal sex with ejaculation: 73%
- RESULT: **0 transmissions**

[Confid Intervals: MSM 0-4%, het 0-2%]

Rodger A, et al. 21st CROI. Boston, 2014. Abstract 153LB.

| Characteristics (Couples With Eligible Follow-Up) | | Heterosexual (n=445) | |
|---|---|---|---|
| | MSM (n=282) | Male (n=245) | Female (n=240) |
| **Study entry** | | | |
| **HIV(-): condomless sex (years)** | 1.5 | 2.7 | 3.5 |
| **HIV(+): on ART (years)** | 5 | 7 | 10 |
| **During follow-up** | | | |
| **HIV(-): years in study** | 1.1 | 1.5 | 1.5 |
| **Diagnosed with STI (%)** | | | |
| **HIV(-)** | 16 | 5 | 6 |
| **HIV(+)** | 16 | 4 | 5 |
| **HIV(-): condomless sex** | | | |
| **Number of acts/year** | 43 | 37 | 38 |
| **Total number** | 16,400 | 14,000 | 14,000 |

# Historical Context of Treatment As Prevention and Biomedical Advances

- Several studies were conducted to evaluate the efficacy of providing antiviral medication to uninfected persons for HIV prevention

- 2010 iPREX study confirmed that when used before rather than after exposure, antiviral medication reduced the risk of infection up to 92%.
  - The medications used were tenofovir disoproxil fumarate (brand name Viread) and emtricitabine (brand name Emtriva)
    - ✓ When used as a combination drug )



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# Research Supporting the Evidence on Biomedical Advances for HIV Prevention

- The research supporting PrEP was strongest in the **iPREX study**- Which was a randomized controlled trial (RCT; gold standard)
  - Participants in the PrEP group had a 44% protection against HIV
  - However, participants with detectable levels of the medication in their blood had as much as a 92% reduction in their risk of getting HIV
  - You must take the medication as prescribed to have the desired protective effect

Grant et al., 2010; UCSF, 2015

# DETERMINING HIV RISK

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# Determining HIV Risk in Heterosexual Adults

**Proposed questions: -** In the past 6 months:

- Have you had sex with men, women, or both?
- *(if opposite sex or both sexes)* How many men/women have you had sex with?
- How many times did you have vaginal or anal sex when neither you nor your partner wore a condom?
- How many of your sex partners were HIV-positive?
- *(if any positive)* With these HIV-positive partners, how many times did you have vaginal or anal sex without a condom?

https://www.cdc.gov/hiv/guidelines/index.html.

# Identifying HIV Risk in Non-Heterosexual Populations

- MSM
  - Male sex partner within 6 months
  - Not in monogamous partnership with a man recently tested and negative

    &
  - Anal sex without condoms within 6 months
  - Bacterial STI within 6 months

- PWID
  - Injection of drugs not prescribed by clinician in past 6 months
  - Sharing of injection or drug preparation equipment within 6 months
  - Risk of sexual acquisition

CDC PrEP Guidelines Update. 2017.

# Who Should Consider Taking PrEP?

- Individuals who are in a relationship with a partner known to have HIV
- Men who have sex with men (MSM) who engage in unprotected anal intercourse
- Individuals who have been prescribed non-occupational post-exposure prophylaxes (nPEP) who continue to engage in high-risk behavior or have used multiple courses of nPEP
- Individuals who trade sex for money, drugs, or shelter
- Individuals diagnosed with more than one sexually transmitted infection in the last year
- Injection drug users who share needles and other equipment

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# *CASE STUDY*



# Case Study #1

Bobby, a 26-year-old policeman lives on one island but works on another for three weeks out of every month. He was referred to your STI clinic.

Bobby reports having 2-3 male sexual partners per month. He engages in oral as well as anal sex and is inconsistent where condom use is concerned.

Physical examination is unremarkable, and he has had no chronic medical problems. He reports  no prior sexually-transmitted infections and as a matter of fact, three weeks ago, his STI testing, including HIV was negative.

***Is Bobby a candidate for PrEP?  What is the rationale for your answer?***

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# Case Study #1 Continued

***Which tests must be obtained before starting Bobby on PrEP?***

A. HIV antibody, hepatitis B surface antigen, serum creatinine

B. HIV antibody, hepatitis B surface antibody, urinalysis

C. HIV RNA, hepatitis B surface antibody, urinalysis

D. HIV RNA, hepatitis B surface antigen, serum creatinine

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# Considerations for PrEP

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# Considerations for PrEP Use

- PrEP should be discontinued immediately for patients who tested positive for HIV
- Heterosexual individuals who are on PrEP and in an on-going relationship with a person living with HIV should be instructed on the importance of HIV treatment for the HIV-infected partner
  - Infected partners who are in care and on treatment reduce the likelihood of passing the virus on their uninfected partner
- **Not wanting to use condoms consistently as part of the comprehensive prevention strategy should not be used as a reason to deny someone PrEP**

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# Considerations for PrEP Use

- **Persons interested in starting PrEP should be reminded that:**
  - It is not intended to be a life-long program
  - For some people, their life circumstances (i.e., intimate partner violence, inability to negotiate condom use, etc.) may change and the risk for HIV may be reduced or eliminated

NYS Taskforce to End AIDS, 2015; UCSF, 2015

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# Considerations for PrEP Use

- **To prevent HIV infections in all patient populations**
  - Efforts must be made to provide HIV testing among those greatest at risk
  - Linkage to and retention in care for those who are infected
  - Provide access to a **comprehensive prevention plan** for those who are negative
  - PrEP, condoms, behavioral counseling, etc.

CDC, 2013; NYS Taskforce to End AIDS, 2015; UCSF, 2015

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# When to have the PrEP Conversation

- Before initiating a conversations with your patients make sure you
  - Address your own educational needs around the subject
    - Prescribing information
    - Practice guidelines
    - Sex, drugs, HIV, adherence, and other STIs
- Address your patient's knowledge gaps

NYS Taskforce to End AIDS, 2015; UCSF, 2015

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# Cultural Sensitivity: Discussing PrEP

- Assess concerns related to initiating PrEP
- Discuss the potential impact of HIV on their respective communities (racial, ethnic,, gender, etc.)
- Address issues related to stigma directed towards marginalized groups (i.e., women, transgender people, or bisexual persons)
- Discuss issues related to substance use
- If negative experiences with health care are verbalized, validate them! Still discuss the advantages of PrEP in all communities and individuals.

NYS Taskforce to End AIDS, 2015; UCSF, 2015

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# Cultural Sensitivity Discussing PrEP

- Be sensitive to all cultural characteristics of your at-risk patients
- Breaking down barriers to PrEP may also facilitate access to and use of treatment for partners who are HIV+
- Remember that starting PrEP is a choice
  - Not every patient will ultimately decide on taking advantage of this prevention option

NYS Taskforce to End AIDS, 2015; UCSF, 2015

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# Taking a Sexual History

- Taking a sexual history is recommended for all adult and adolescent patients as part of ongoing primary care[1]
- Overcoming discomfort takes practice!
- Have a two-way conversation
  - Be nonjudgmental
  - Be sensitive and matter-of-fact
  - Avoid assumptions!
- Taking a sexual history before discussing options like PrEP increases the chance that young people of color understand the role of PrEP[2]

a OR, adjusted odds ratio; CI, confidence interval.

1. CDC. USPHS Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2017. https://stacks.cdc.gov/view/cdc/23447. Accessed March 12, 2019;
2. NYC.gov website. Taking a Sexual History. Adapted from CDC. A Guide to Taking a Sexual History. https://www.cdc.gov/std/treatment/sexualhistory.pdf. Accessed March 12, 2019. 3. Golub SA, et al. AIDS Behav. 2017 May;21(5):1315-1324.

# Helping To Prevent HIV Starts With a Candid Discussion

- Have you had sex with men, women, or both?[1]
  - How many men and/or women have you had sex with?
- Have you had sex under the influence of alcohol and/or recreational drugs?[1,2]
- Have you been screened for HIV, STIs, and/or hepatitis B and C? If so, what were the results?[2]
- Are you up to date on your hepatitis A and B and/or HPV vaccinations?[2]

**For MSM**[1]

- Do you have insertive sex (you are the top), receptive sex (you are the bottom), or both?
- How many times did you have anal sex without a condom?
- Have you used methamphetamine (such as crystal or speed)?
- How many of your sex partners did not know their status or were HIV positive?
  - With these HIV-positive male partners, how many times did you have anal sex without a condom?

**For heterosexual men and women**[1]

- How many times did you have vaginal or anal sex when you (if a male patient) or your partner (if a female patient) did not use a condom?
- How many of your sex partners did not know their status or were HIV positive?
  - With these HIV-positive partners, how many times did you have vaginal or anal sex without a condom?

# Before Prescribing Pre-Exposure Prophylaxis

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# Before Prescribing PrEP: Important Evaluations

- Required screenings
  - Renal function
    - Avoid PrEP with TDF/FTC in anyone with CrCl of < 60 mL/min
  - Hepatitis B infection
    - Document HBV negative and vaccinate patients who are HBV susceptible
- Recommended screenings
  - Metabolic panel
  - Urinalysis
  - STI (eg, syphilis, gonorrhea, chlamydia, HCV)
  - Pregnancy (for women)

CDC. PrEP for the Prevention of HIV Infection in the US -- 2014: A Clinical Practice Guideline. May 2014. www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf. Accessed 4/9/15.

# Prescribing PrEP

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# Prescribing Oral PrEP

***Fixed-dose TDF/FTC is the recommended PrEP regimen****

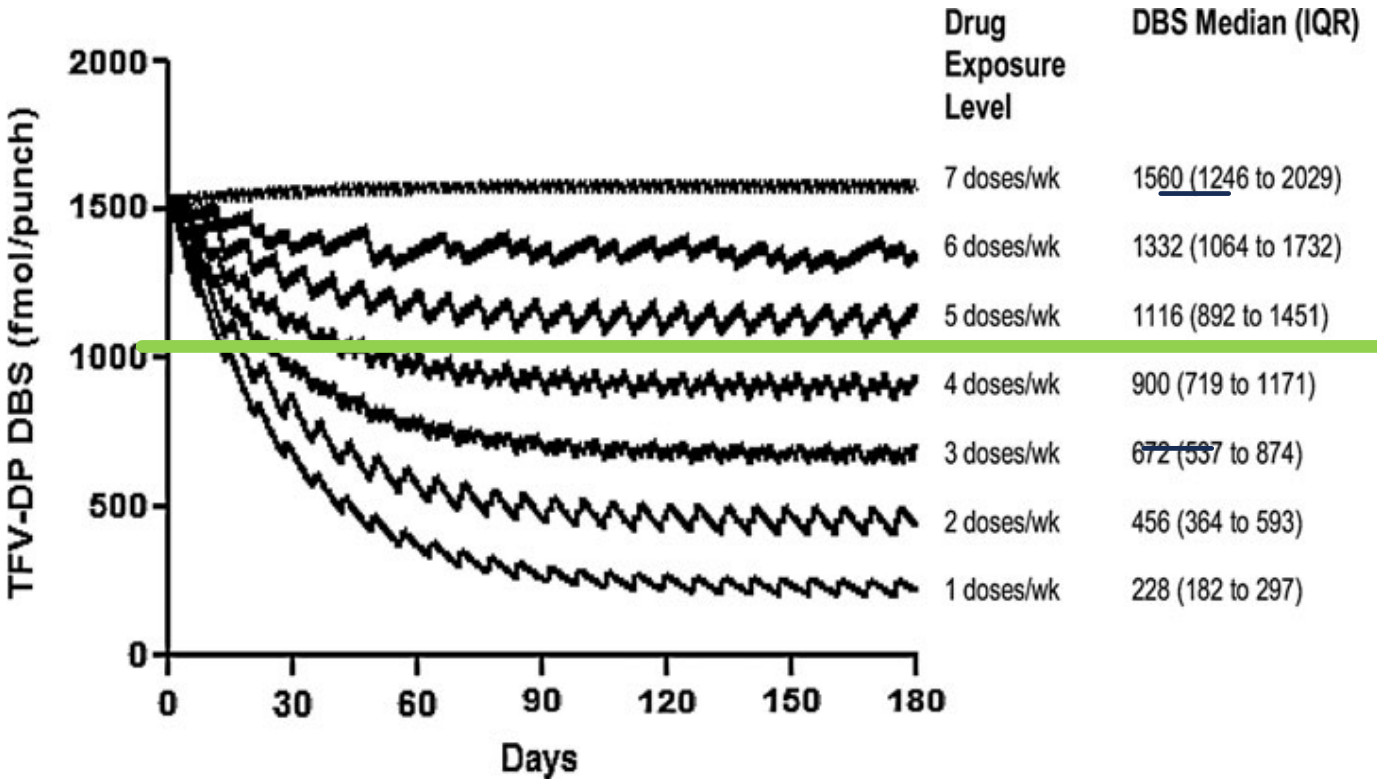
- Indicated for uninfected individuals at high risk who are confirmed to be HIV-1 negative
- Dosed as a single pill (300 mg TDF/200 mg FTC) once daily, with or without food
- Provide a prescription or refill authorization for no more than 90 days (until next HIV test and follow-up)
- Inform **MEN**: 7 days Rx before effective
- Inform **WOMEN**: 21 days Rx before effective



*MSM, heterosexually active men and women, and IDU who meet PrEP prescribing criteria.

CDC. PrEP for the Prevention of HIV Infection in the US -- 2014: A Clinical Practice Guideline. May 2014. www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf. Accessed 4/9/15.

# Need ≥4 of 7 Daily Pills per Week




| TFV-DP (fmol/punch) | Adherence Interpretation |
|---|---|
| >1250 | daily dosing |
| >700 to 1250 | 4-6 doses/wk |
| 350 to 700 | 2-3 doses/wk |
| <350 | < 2 doses/wk |

Castillo-Mancilla. 2012 AIDS Res Hum Retroviruses (PMID 22935078)

# PrEP RECOMMENDATIONS: DAILY USE VS "ON-DEMAND" USE

| United States | European Union[3] | IAS-USA[4] |
|---|---|---|
| **CDC**[1]<br>•Recommended for **daily use only**<br>•**Not recommended as coitally timed or other noncontinuous use** | • Recommended for **daily use**<br>• **Optional recommendation for on-demand use** for high-risk MSM | • Recommended for **daily use**<br>• **Optional recommendation for on-demand use** for MSM with infrequent sex |
| **FDA**[2]<br>•TDF/FTC indicated for PrEP **once daily** | • On-demand use: 2-1-1 dosing<br>  • Double dose before sex,<br>  1 dose 24 hrs after first dose,<br>  1 dose 48 hrs after first dose | |

1. CDC. PrEP Guidelines. 2017. 2. Tenofovir DR/emtricitabine PI. 3. EACS Guidelines. October 2017. 4. Saag. JAMA. 2018;320:379.

# PrEP Guidance: Follow-Up and Monitoring

| Follow-up | At Least Every 3 Months | At Least Every 6 Months | At Least Every 12 Months |
|---|---|---|---|
| **All patients** | • HIV testing<br>• Adherence assessment<br>• Side-effect assessment<br>• Medication adherence counseling<br>• Behavioral risk reduction support<br>• Answer any new questions | • Assess renal function (CrCl)<br>• Test for bacterial STIs | • Evaluate need to continue PrEP |

**Many experts recommend more frequent follow-up (i.e., monthly) of patients on PrEP, especially after initiation of TDF/FTC, to assess adherence and monitor for STI including HIV**

# PrEP Guidance: Follow-Up and Monitoring

- Three Month Follow-up
  - HIV testing and STI screening are conducted
  - Discuss issues around adherence, side effects (they should be minimal at this point), and their interest in continuing
  - Remember to continue to monitor CrCl levels and other important laboratory (i.e., pregnancy, BMD, etc.) assessment
  - If the patient continued to be HIV negative, adhere to the medication, have no serious medical complications a prescription for a 90 - day supply may be given at this point

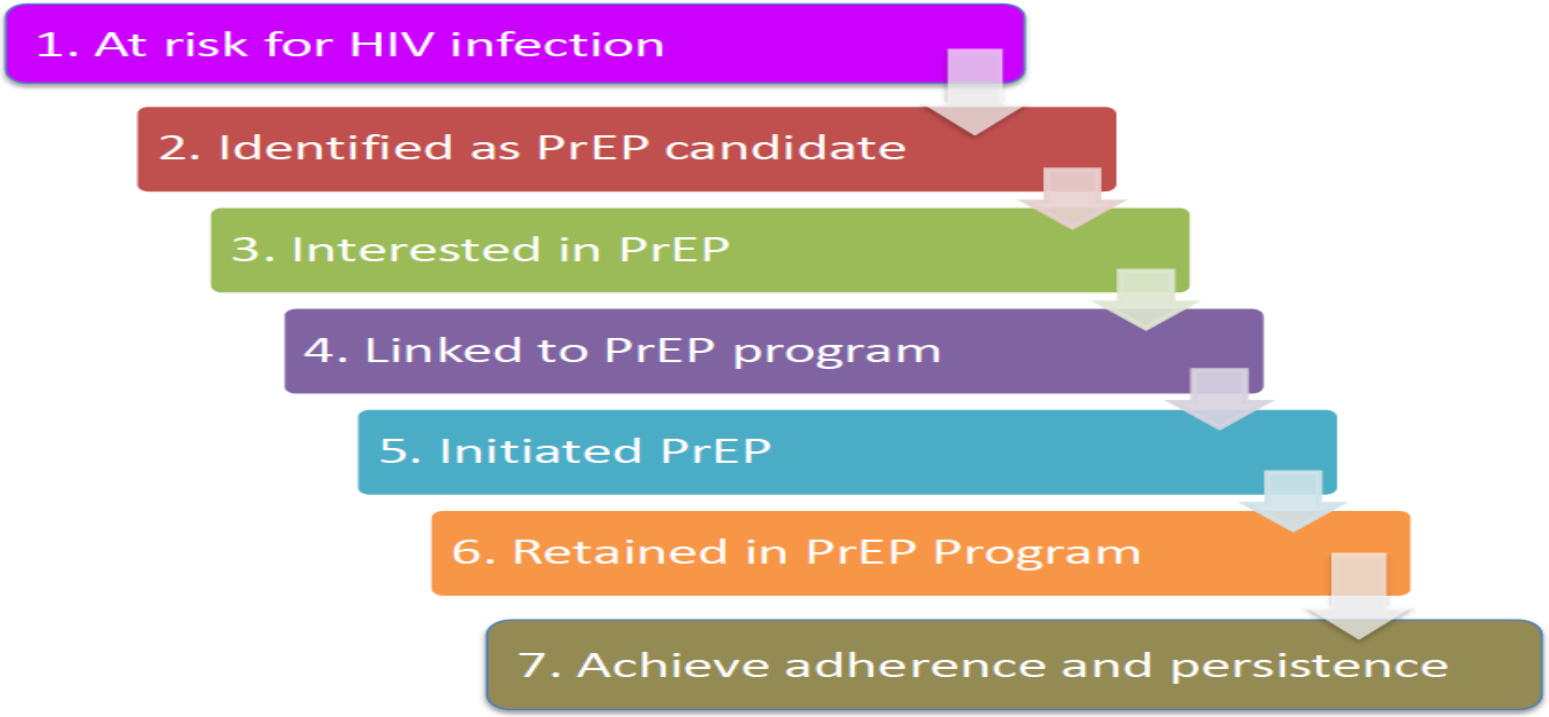
NYS Taskforce to End AIDS, 2015; UCSF, 2015

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# PrEP CASCADE: PRESCRIBING Pre-EXPOSURE PROPHYLAXIS (PrEP) FOR HIV PREVENTION



# The Proposed PrEP Cascade




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# Individuals at risk for HIV infection

| Metrics | Important considerations | Potential Interventions |
|---|---|---|
| • # HIV-uninfected, at risk for HIV (e.g. sexually active MSM or other populations at risk) | • Can choose level/scope of target population (e.g. clinic, city, region, national)<br>• Data sources may include clinic data, local or national surveillance data<br>• HIV testing is an entry point (HIV-negative status required for PrEP) | • Initiatives to increase HIV testing<br>• Strategies to improve clinic, surveillance data |

Lui et. al., The Spectrum of Engagement in HIV Prevention

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# Identifying PrEP Candidates

| Metrics | Important considerations | Potential interventions |
|---|---|---|
| • # identified as PrEP candidate (based on local criteria) | • Geographic setting and social/sexual networks should be considered in addition to individual risk behaviors<br>• PrEP candidates could be identified at a range of sites: HIV testing sites, STD clinics, HIV primary care settings<br>• Optimal prioritization strategies for PrEP still need evaluation | • Screening tools/ algorithms to identify individuals at highest risk (e.g. online, computer-based) |

Lui et. al., The Spectrum of Engagement in HIV Prevention

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# Individuals Interested in PrEP

| Metrics | Important considerations | Potential interventions |
|---|---|---|
| • # who express interest in pursuing PrEP<br>• Reasons for refusal | • PrEP knowledge limited among MSM and providers<br>• May be influenced by perception of risk, stigma<br>• How information is framed may affect uptake of PrEP | • Community campaigns to raise PrEP awareness and interest<br>• Informational videos/ testimonials of PrEP users |

Lui et. al., The Spectrum of Engagement in HIV Prevention

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# PrEP Initiation

| Metrics | Important considerations | Potential interventions |
|---|---|---|
| • PrEP initiation rates<br>• Reasons for ineligibility, refusal, or inability to access PrEP | • Eligibility criteria include clinical history, laboratory results (Cr, Hepatitis B status, negative HIV test)<br>• Individuals' decision to adopt PrEP | • Guidelines to assist providers in assessing eligibility<br>• Tools to help participants to decide whether PrEP is a good fit<br>• Reduced cost / patient assistance programs |

Lui et. al., The Spectrum of Engagement in HIV Prevention

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# Retention/Engagement in PrEP Care

| Metrics | Important considerations | Potential interventions |
|---|---|---|
| • Missed visits<br>• Appointment adherence<br>• Visit constancy<br>• Gaps in care | • Need to consider appointment scheduling and data collection systems in clinic | • Appointment reminders<br>• Consistent contact with clinic through staff / peers<br>• Interactive messaging (SMS / email) |

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# Maintaining Adherence and Persistence to PrEP

| Metrics | Important considerations | Potential interventions |
|---|---|---|
| • Self-report<br>• Pharmacy refill<br>• Drug level testing<br><br><u>*Less practical:*</u><br>• Pill counts<br>• Electronic drug monitoring | • Require measures that are easy to collect / minimal burden for staff and pt<br>• Low cost<br>• Accuracy – less influenced by white coat effects or social desirability | • PrEP Education<br>• Adherence counseling<br>• Interactive messaging (SMS /phone support)<br>• Drug level monitoring/ feedback<br>• Substance use, mental health interventions |

Lui et. al., The Spectrum of Engagement in HIV Prevention

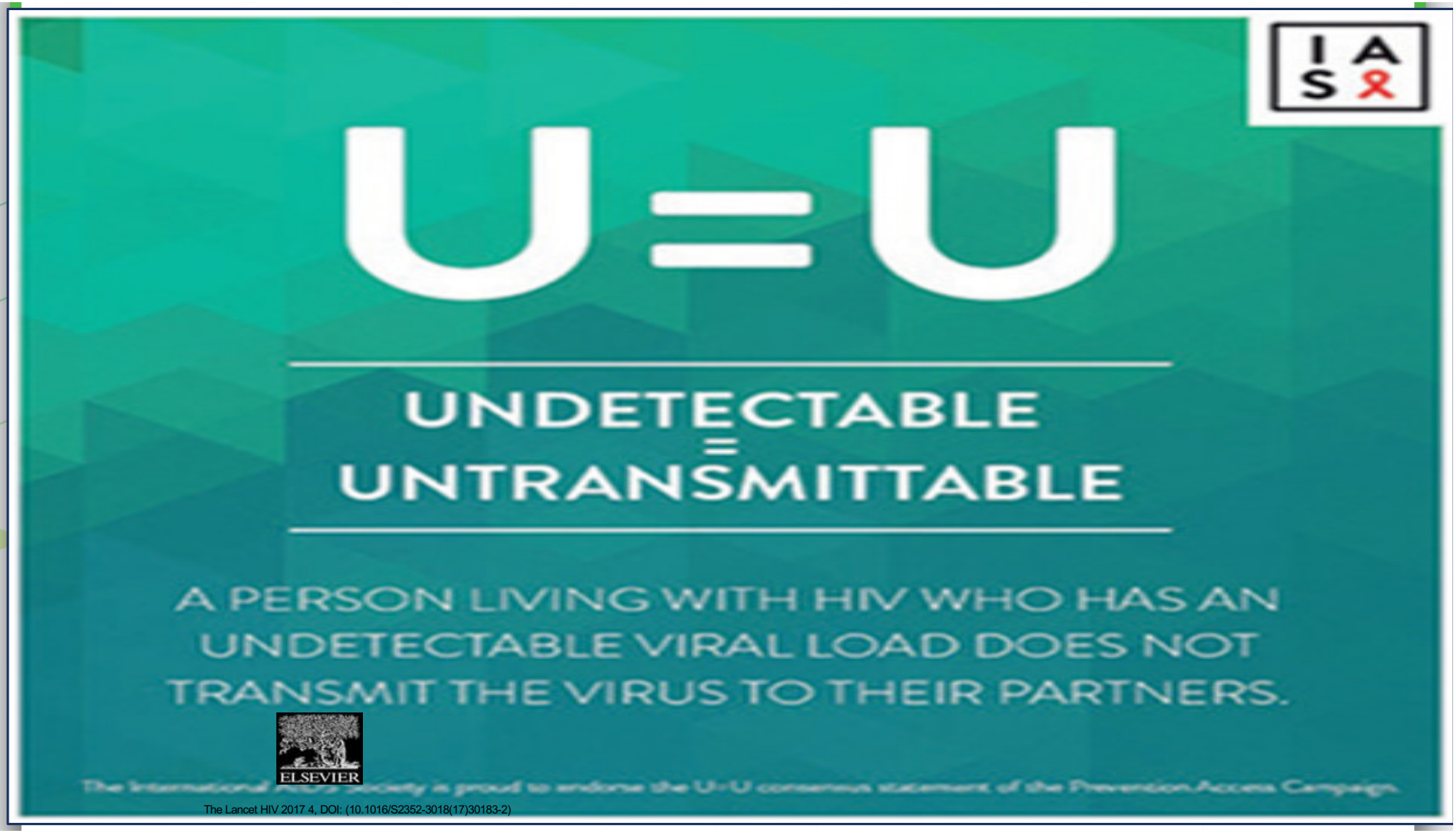
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# Referral and Linkage to PrEP Program

| Metrics | Important considerations | Potential interventions |
|---|---|---|
| • # successful PrEP referrals<br>• Total referred from community sources | • Novel mechanisms may be needed to collect data on referrals from CBOs, community providers/clinics | • Co-location of PrEP services in HIV testing sites/STD clinics or in community locations<br>• Active phone follow-up/linkage using staff or peer navigators |

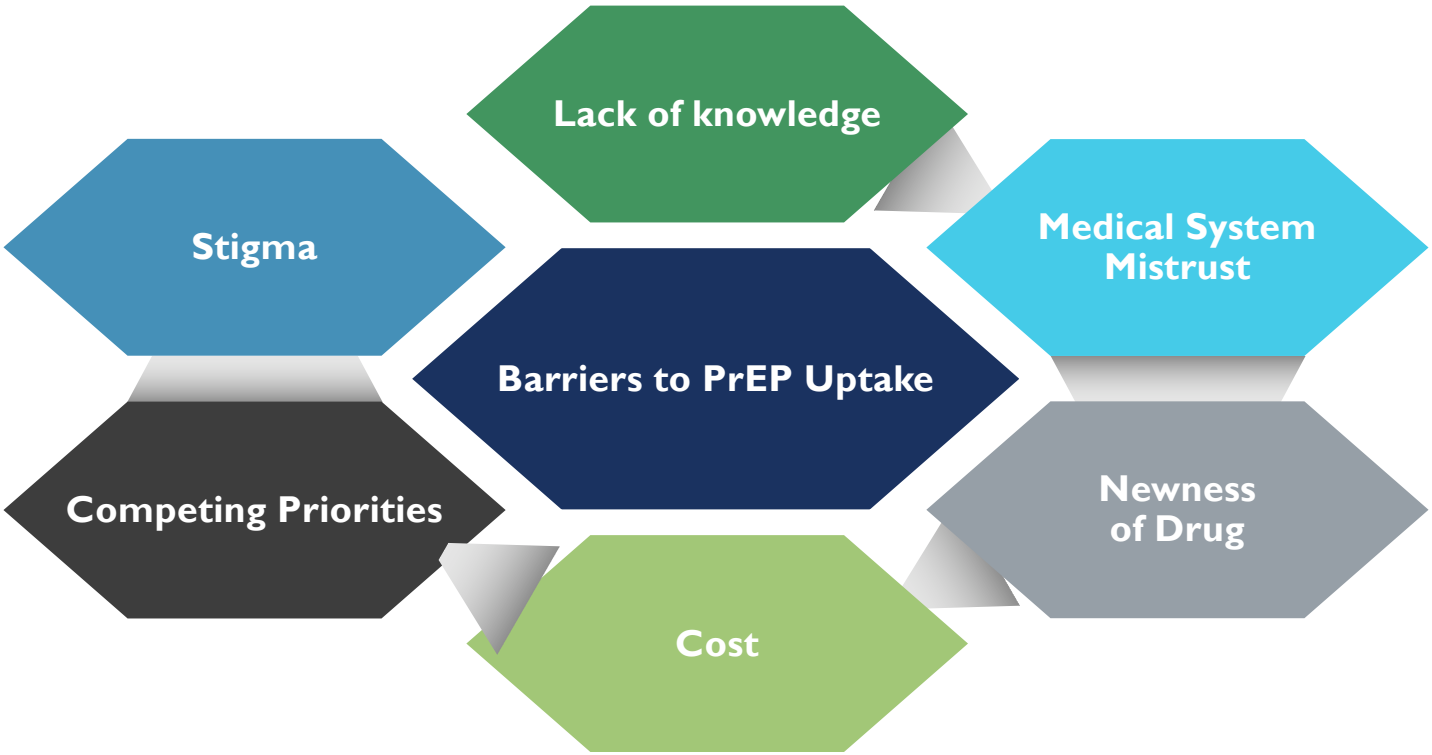
Lui et. al., The Spectrum of Engagement in HIV Prevention

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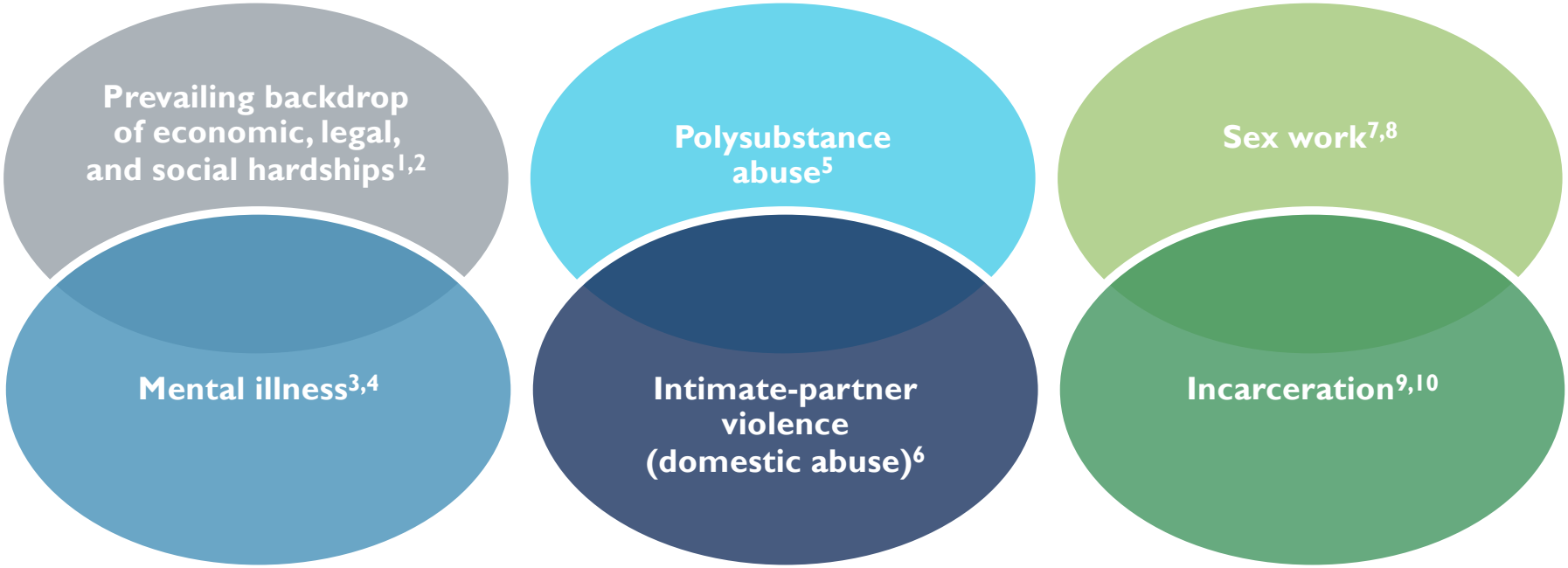



The Lancet HIV 2017 4, DOI: (10.1016/S2352-3018(17)30183-2)

# Barriers to PrEP Uptake



# **PrEP:** Monitor for Multiple Compounding Circumstances and Risks




1. ;
2. El-Bassel N, et al. Int J STD AIDS. 2017;28(2):160-169.

# Risk Compensation - While on PrEP

## Views on Risk Compensation

- Risk compensation is the idea that as a person feels greater protection from potentially contracting HIV - they may compensate by taking greater risk
  - They may engage in more unprotected sex with more people
- None of the studies mentioned above supported the argument of sexual risk compensation by people taking PrEP
- Risk reduction counseling should be consistently offered as a component of a **comprehensive HIV prevention strategy**

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# Summary: Priorities for Moving Forward

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# PrEP - Moving Forward in the Caribbean

- PrEP should be provided with adequate client-centered support
- The evidence to date supports the application of PrEP as an effective prevention strategy
- Work together with other members of the health care team to provide behavioral counseling, condoms, screening for STIs, and testing for clients interested in PrEP
- More research is needed to look at long-term side effects, potential soeroconversion while on PrEP, and address barriers to PrEP

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# PrEP: Comprehensive Prevention Plan

- PrEP should be a component of a comprehensive strategy for the prevention of and should include counseling about the following:
  - Consistent and correct use of condoms to avoid STIs
  - Safer sex practices and risk-reduction options
  - Mutual monogamy
  - Knowledge of their HIV status and that of their partner(s)
  - Routine screenings for other sexually transmitted diseases
  - Mental health and substance use screening, when indicated
- It is important to educate clients that having a STI can increase her/his chance of becoming infected with HIV if exposed to it. Patients should also be educated on the signs and symptoms of STIs and the importance of treatment

CDC, 2013; NYS Task Force to End AIDS, 2015

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# Objectives of the "PrEP and Treat all" Policy

1. **Expanded prevention options:** Offer and promote PrEP as an additional option in the context of combination prevention

2. **Increase access to treatment:** Provide treatment to those who test positive for HIV

3. **Integration:** Integrate PrEP and Treat All into other HIV prevention programmes, policies, and services

4. **Quality of care:** Provide PrEP and Treat All within the broader framework of quality health service provision

5. **Communication and community-based strategies:** Implement evidence-informed communication and advocacy strategies

# Conclusions

- Because PrEP is associated with high-risk sexual activity, it risks multiple stigmas that can differ according to specific cultural conditions
  - Cultural competence is a key component for maximizing uptake of PrEP as a valuable prevention method
- Biomedical HIV prevention is not here to replace condoms, but it can add to our HIV prevention arsenal, particularly for those sexually active individuals who may not use condoms every time they have sex
- Biomedical HIV prevention is one approach to get sexually active individuals (especially those at high risk) linked to the care, services, and the medical monitoring that goes along with PrEP
- Once in care, care providers can monitor for STIs; but without the link to healthcare, it is difficult for students to stay connected to care
- Like TasP and nPEP, PrEP implementation is a tool to help build pathways to end the epidemic

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# *CASE STUDY #2*



# Case #2: The Sero-Discordant Couple

- Marcus, a 20-year-old male, comes to your primary clinic today for a follow-up visit and HIV testing. Cherry, his female partner of two months disclosed her status to Marcus by revealing that she was seen three months ago in the emergency department, for fever, chills and a throbbing headache. She thought she had the flu but was diagnosed with acute HIV infection instead. Your medical records for Marcus noted that his last HIV test was two months ago. The result was negative.
- Marcus confides that he is in love with Cherry and plans to continue the relationship. Although they are not currently sexually active, Marcus revealed to you that he does not use condoms consistently as he finds them to be uncomfortable. The purpose for Marcus's visit with you today is to discuss how to safeguard his health and not acquire HIV.
- ***What do you recommend?***

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# Case #2: the Sero-Discordant Couple

- You are able to access Cherry's medical records. Her Plasma Viral Load (pVL) is undetectable.

- ***What do you recommend?***

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# To Summarize…….

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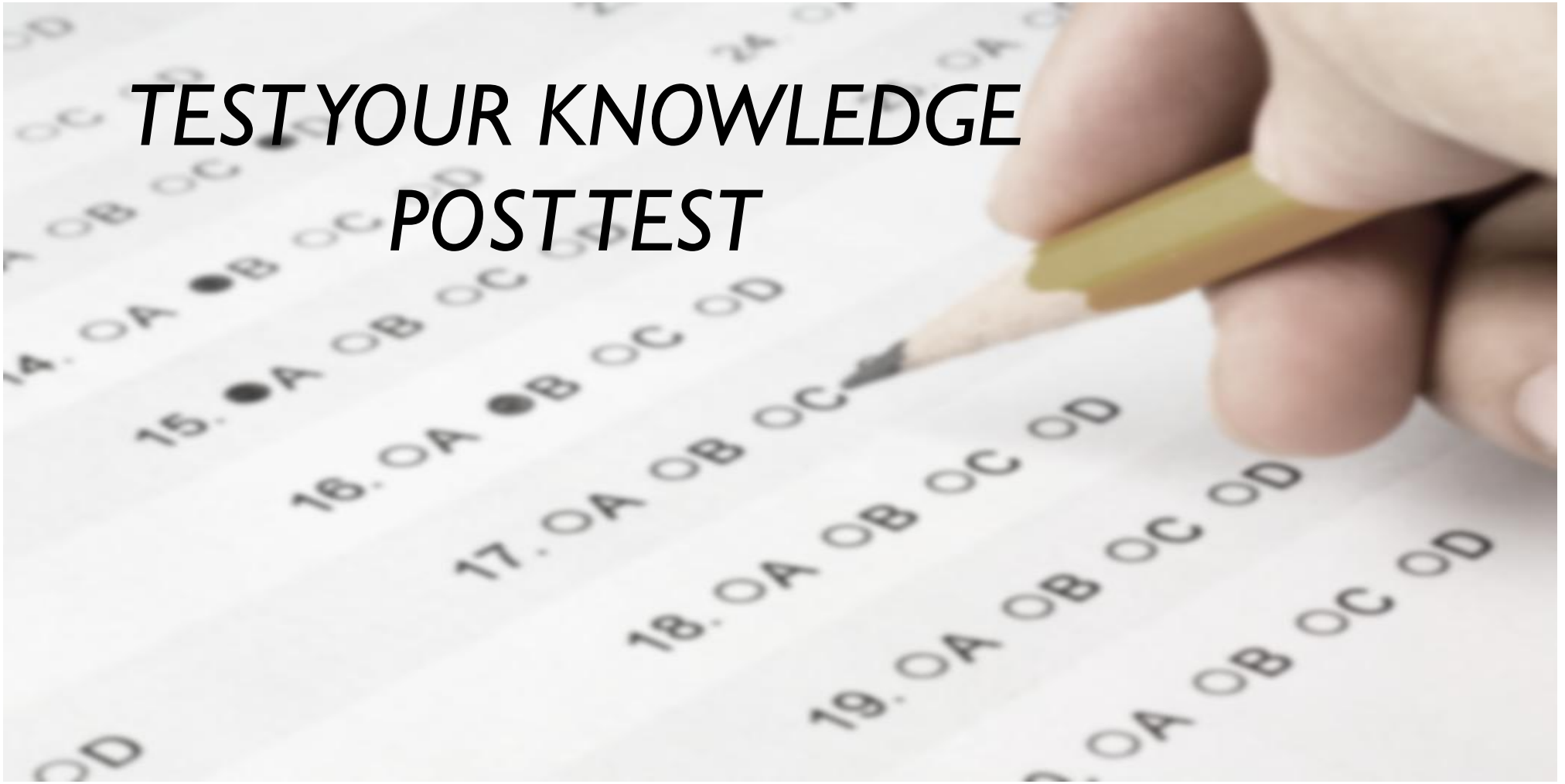
## Summary of Guidance for PrEP Use

| | Men Who Have Sex With Men | Heterosexual Women and Men | Injection Drug Users |
|---|---|---|---|
| **Detecting substantial risk of acquiring HIV infection:** | • Sexual partner with HIV<br>• Recent bacterial STD<br>• High number of sex partners<br>• History of inconsistent or no condom use<br>• Commercial sex work | • Sexual partner with HIV<br>• Recent bacterial STD<br>• High number of sex partners<br>• History of inconsistent or no condom use<br>• Commercial sex work<br>• Lives in high-prevalence area or network | • HIV-positive injecting partner<br>• Sharing injection equipment<br>• Recent drug treatment (but currently injecting) |
| **Clinically eligible:** | • Documented negative HIV test before prescribing PrEP<br>• No signs/symptoms of acute HIV infection<br>• Normal renal function, no contraindicated medications<br>• Documented hepatitis B virus infection and vaccination status | | |
| **Prescription** | Daily, continuing, oral doeses of TDF/FTC (Truvada), ≤90 day supply | | |
| **Other services:** | • Follow-up visits at least every 3 months to provide:<br>• HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STD symptom assessment<br>• At 3 months and every 6 months after, assess renal function<br>• Every 6 months test for bacterial STDs | | |
| | • Do oral/rectal STD testing | • Assess pregnancy intent<br>• Pregnancy test every 3 months | • Access to clean needles/ syringes and drug treatment services |

Source: US Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States —2014: a clinical practice guideline.

# *Thank You*

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TEST YOUR KNOWLEDGE
POST TEST

# Test Your Knowledge
# Question #5

**All but which of the following is recommended before prescribing PrEP?**

A. Recommended screenings

B. Metabolic panel

C. Urinalysis

D. Renal function

E. STI (e.g., syphilis, gonorrhea, chlamydia, HCV)

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# Test Your Knowledge
# Question #6

**All but which of the following is correct about fixed-dose PrEP regimen?**

A. It is indicated for uninfected individuals at high risk who are confirmed to be HIV-1 negative

B. It is dosed as a single pill to be taken once daily, with or without food

C. It should be provided a prescription or refill authorization for no more than 90 days

D. Efficacy is reached within 21 days for men and 7 days for women

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# Test Your Knowledge
# Question #7

**All except which is a recommendation to address with your patient before prescribing PrEP?**

A. Men or women who do not have HIV but who are at high risk of becoming infected with HIV through sex or injection drug use

B. Men or women who are HIV Negative

C. Men or women who are HIV Positive

D. Men or women who are gay or bisexual and are not in a monogamous relationship with a recently tested partner who is HIV negative

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# Test Your Knowledge
# Question #8

PrEP is a combination of which of the following:

A. Emtricitibine (FTC) 100 mg + Tenofovir disoproxil (TDF) 200 mg
B. Emtricitibine (FTC) 200 mg + Tenofovir disoproxil (TDF) 200 mg
C. Emtricitibine (FTC) 200 mg + Tenofovir disoproxil (TDF) 300 mg
D. Emtricitibine (FTC) 400 mg + Tenofovir disoproxil (TDF) 600 mg

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