

PrEP is for women, too!

Oni J. Blackstock, MD, MHS

Assistant Professor of Medicine

Montefiore Medical Center/Albert Einstein College of Medicine, Bronx, NY

Ending the Epidemic:

Achieving and Sustaining Viral Suppression among Women

November 18, 2015

2015 Blueprint

For achieving the goal set forth by Governor Cuomo to end the epidemic in New York State by the end of 2020.

The plan's stated goals are:

- Identify persons with HIV who remain undiagnosed and link them to health care;
- Link and retain persons diagnosed with HIV to health care and get them on anti-HIV therapy to maximize HIV virus suppression so they remain healthy and prevent further transmission; and
- Facilitate access to Pre-Exposure Prophylaxis (PrEP) and non-occupational post-exposure prophylaxis (nPEP) for high-risk persons to keep them HIV-negative.

End AIDS.



Department
of Health

health.ny.gov/ete

What is PrEP?

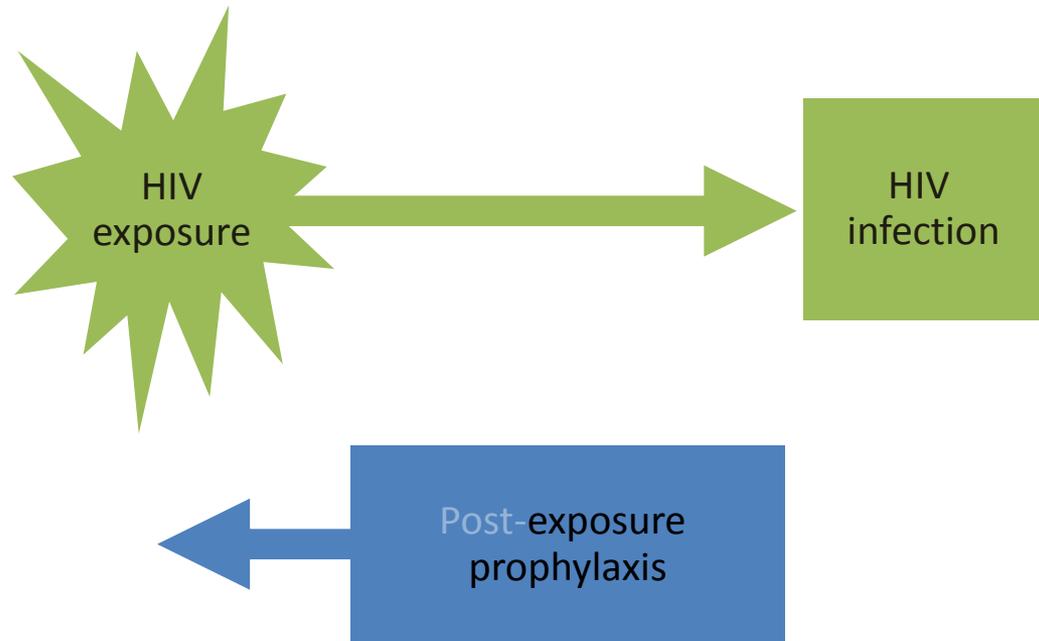
- Pre-Exposure Prophylaxis is a new HIV prevention method in which an HIV-uninfected individual takes antiretroviral medication before a potential HIV exposure to prevent infection.
- A new application of an old idea

Women take birth control pills prior to sexual intercourse to prevent pregnancy



Pre- vs Post-exposure Prophylaxis

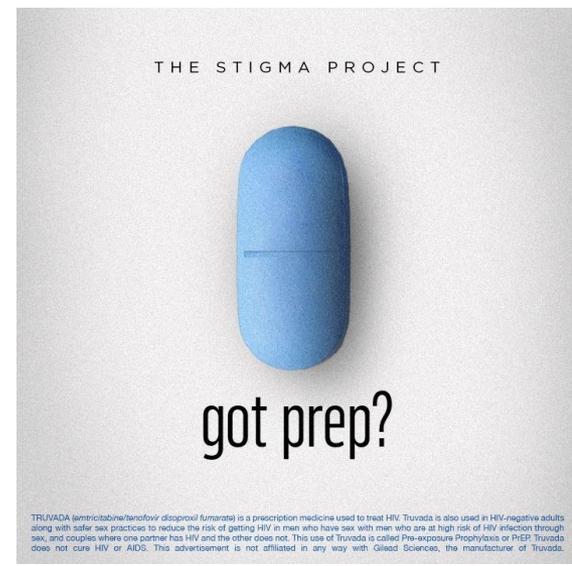
- After exposure to HIV, infection may become established
- Postexposure prophylaxis involves initiation of treatment soon after exposure
- Pre-exposure prophylaxis involves starting treatment before the exposure



0 hr 36 hrs 72 hrs **///** 1 mos 3 mos 5 mos

What is PrEP?

- Tenofovir/emtricitabine (Truvada[®]) is only the medication currently approved for PrEP in the U.S.
- Why was this medication chosen for PrEP?
 - Multiple clinical studies have shown it works for PrEP
 - One pill, once a day
 - Favorable safety and tolerability profiles



PrEP Timeline

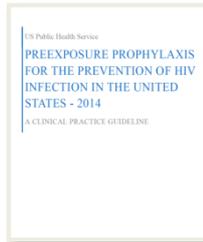
July 2012:

FDA approves Tenofovir/emtricitabine (Truvada) for PrEP



May 2014:

DHHS releases the first federal PrEP guidelines



May-June 2015:

New York state announces a comprehensive plan to end AIDS epidemic including facilitating access to PrEP



2012

2013

2014

2015



HIV CLINICAL RESOURCE

OFFICE OF THE MEDICAL DIRECTOR, NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE
IN COLLABORATION WITH JOHNS HOPKINS UNIVERSITY DIVISION OF INFECTIOUS DISEASES

June 2014:

NYS DOH releases guidance for the use of PrEP

July 2015:

The Updated National HIV/AIDS Strategy was released—PrEP was described as a much needed HIV/AIDS prevention tool

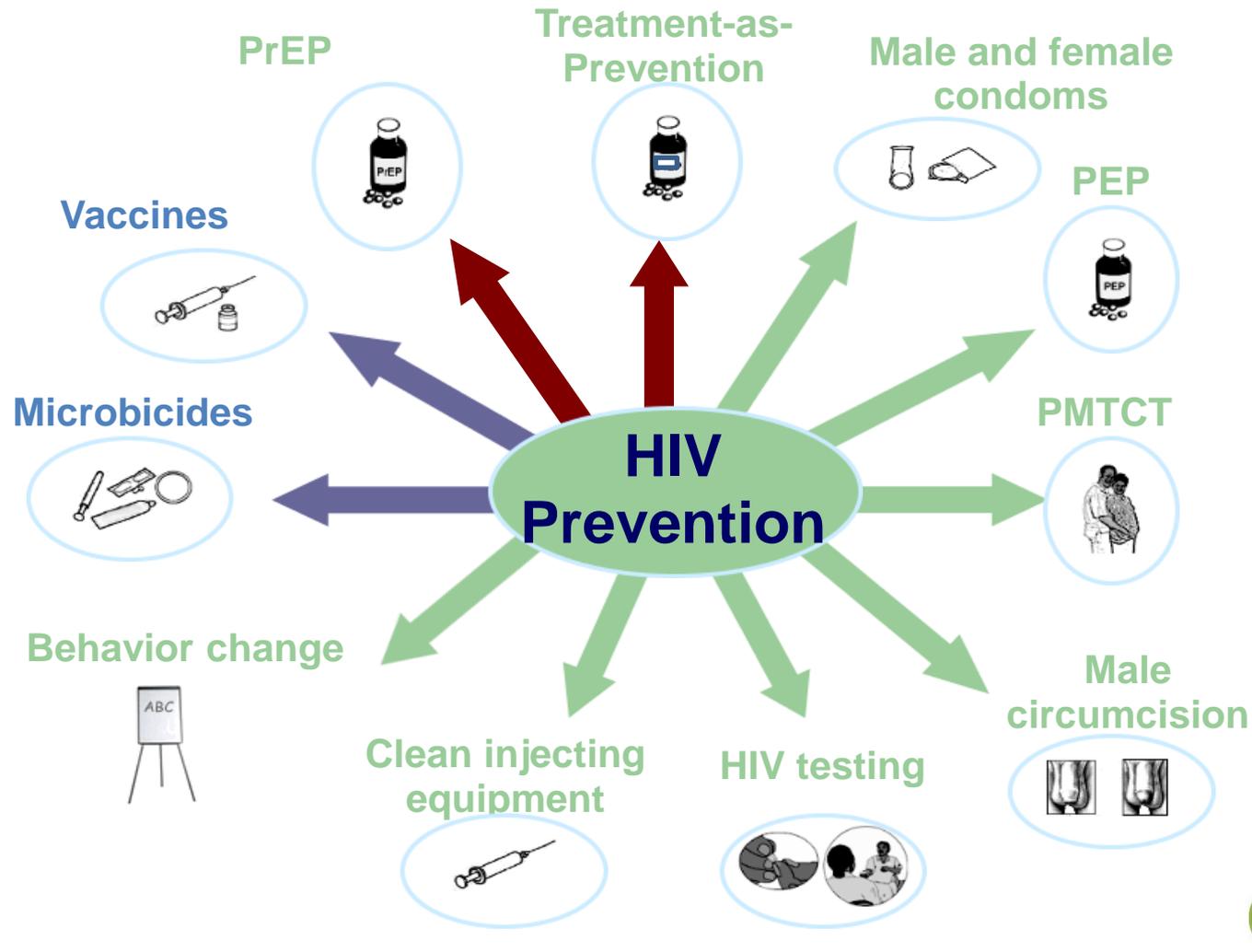


PrEP is one of many HIV prevention strategies

PrEP



PrEP is one of many HIV prevention strategies



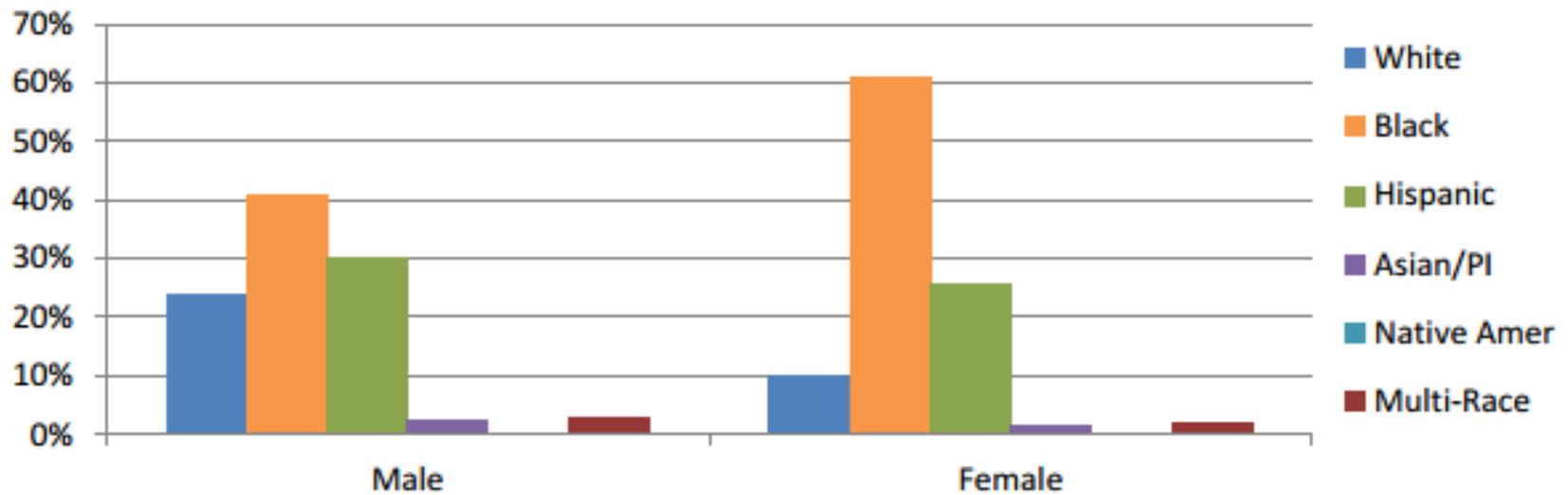
Other important points about PrEP

- Reduces the risk of acquiring HIV, but does not eliminate the risk
- Does not:
 - protect against other sexually transmitted infections
 - prevent pregnancy
 - cure HIV or function as HIV treatment alone for someone living with HIV

Why is PrEP important for women?

- Significant racial/ethnic disparities in HIV infections among women

Newly diagnosed HIV cases, by gender and race, NYS, 2010

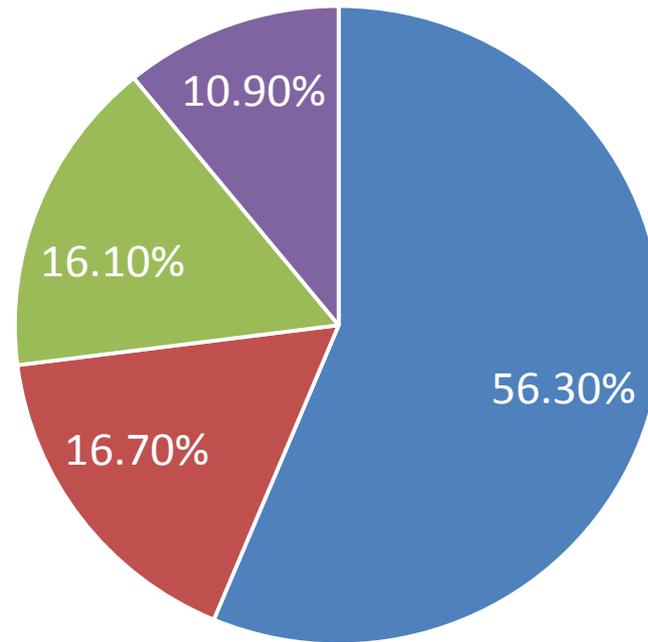


PI = Pacific Islander, Native Amer = Native American

Why is PrEP important for women?

- Significant racial/ethnic disparities in HIV infections among women
- Certain populations of women continue to have high levels of infection

Transwomen of color are disproportionately represented among newly diagnosed transwomen



■ Black ■ Latina ■ White ■ Other

Why is PrEP important for women?

- Significant racial/ethnic disparities in HIV infections exist among women
- Certain populations of women continue to have high levels of infection
- **Primary mode of HIV acquisition among women is sexual contact with a male partner**

Why is PrEP important for women?

- Significant racial/ethnic disparities in HIV infections exist among women
- Certain populations of women continue to have high levels of infection
- Primary mode of HIV acquisition among women is sexual contact with a male partner
- **Limited options that can be controlled by women themselves**

Why is PrEP important for women?

- Significant racial/ethnic disparities in HIV infections exist among women
- Certain populations of women continue to have high levels of infection
- Primary mode of HIV acquisition among women is sexual contact with a male partner
- Limited options that can be controlled by women themselves
- PrEP can empower women to achieve their sexual health goals and have pleasurable sex lives

Why is PrEP important for women?

- Significant racial/ethnic disparities in HIV infections exist among women
- Certain populations of women continue to have high levels of infection
- Primary mode of HIV acquisition among women is sexual contact with a male partner
- Limited options that can be controlled by women themselves
- PrEP can empower women to achieve their sexual health goals and have pleasurable sex lives

How do we know PrEP works for women?

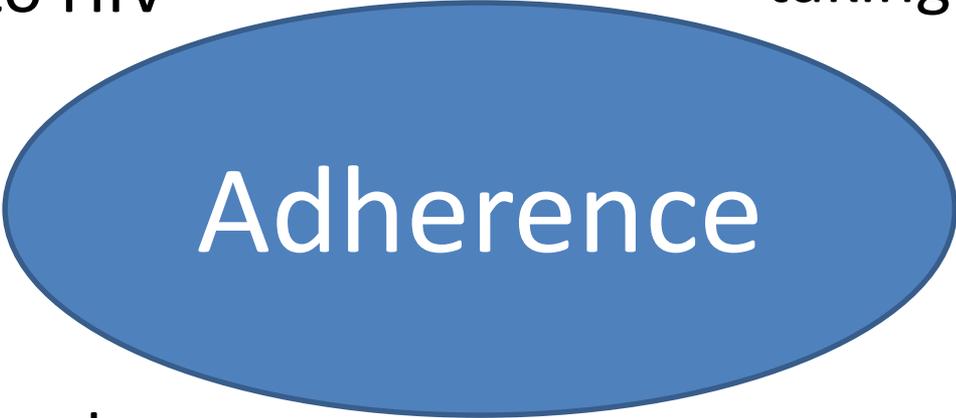
Study	Location	Population	Overall HIV risk reduction
iPrEX	6 countries including the US	MSM & transgender women	↓44%
Partners PrEP	Kenya, Uganda	Cisgender men*	↓84%
		Cisgender women*	↓66%
TDF2	Botswana	Cis men and women	↓62%
Fem-PrEP	Kenya, South Africa, Tanzania	Cisgender women	No reduction
VOICE	Uganda, South African, Zimbabwe	Cisgender women	No reduction

*serodifferent or serodiscordant heterosexual couples

Why was there poor adherence in studies of PrEP in women?

Stigma of taking a pill related to HIV

Challenges of taking a pill daily



Adherence

Lack of support from partners & family

Concerns about side effects

Why was there poor adherence in studies of PrEP in women?

Stigma of taking a pill related to HIV

Challenges of taking a pill daily

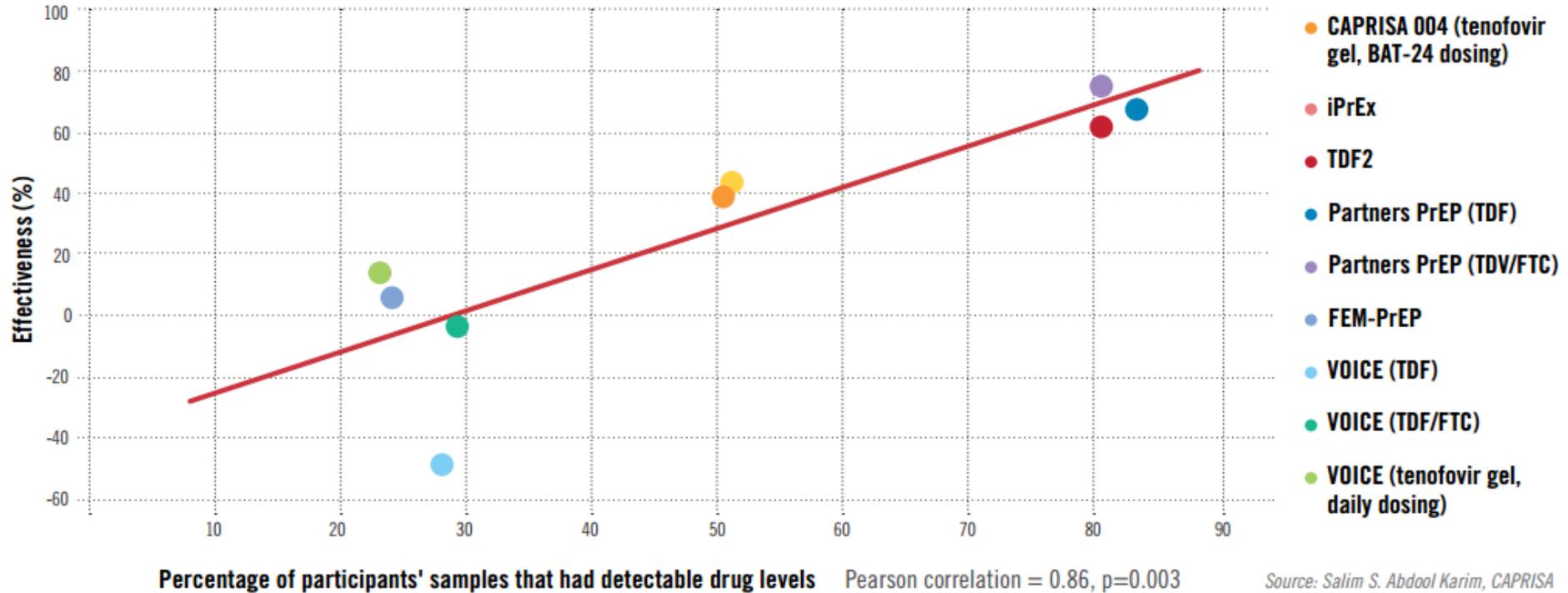


Adherence

Lack of support from partners & family

Concerns about side effects

PrEP only works if you take it



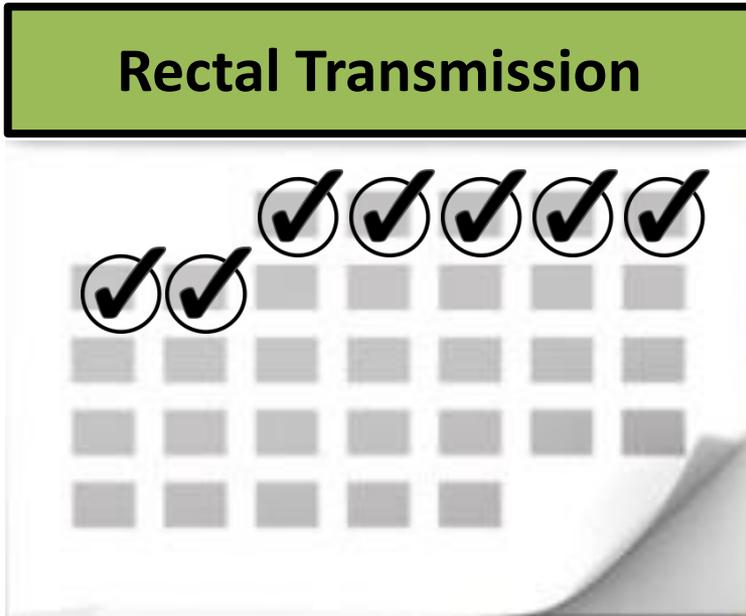
The importance of PrEP adherence for vaginal intercourse

- Tenofovir reaches lower concentrations in vaginal tissues as compared with rectal tissues
- Therefore, adherence to PrEP (i.e., taking PrEP as prescribed) may be more important for vaginal vs. anal intercourse



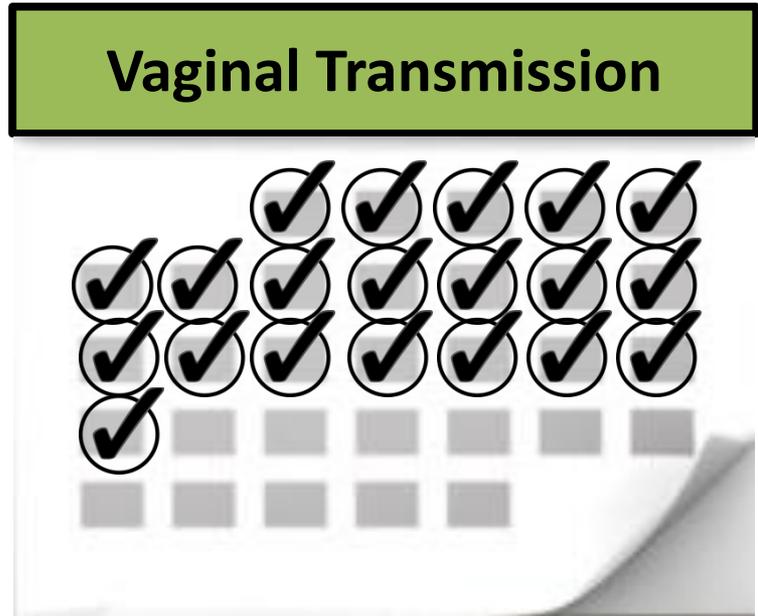
Time to protection

Rectal Transmission



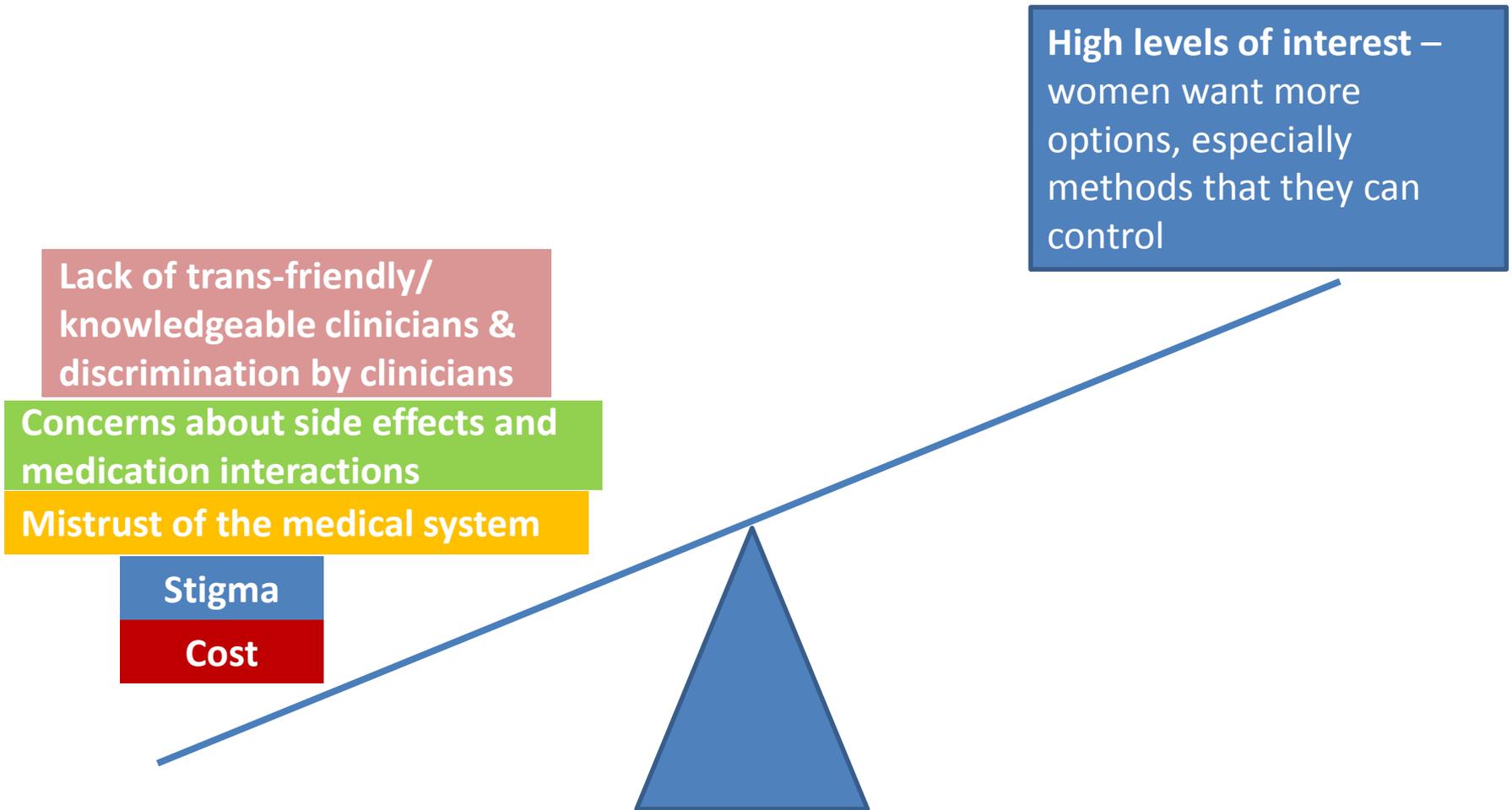
7 days

Vaginal Transmission



20 days

Women's perceptions of PrEP



1. Auerbach JD, et al. Knowledge, attitudes, and likelihood of pre-exposure prophylaxis (PrEP) use among US women at risk of acquiring HIV. *AIDS Patient Care STDS* 2015;29:102-10. 2. Flash CA, et al. Perspectives on HIV prevention among urban black women: a potential role for HIV pre-exposure prophylaxis. *AIDS Patient Care STDS* 2014;28:635-42. 3. Sevelius J, Keatley J., Arnold E. "I Am Not a Man": Trans-Specific Barriers and Facilitators to PrEP Acceptability among Transgender Women. IAPAC Treatment and Prevention Adherence Conference. Miami, Florida 2015.

For whom might PrEP be beneficial?

- Any HIV-negative woman who:
 - Is in a sexual relationship with a known HIV-positive male partner
 - Is transgender & engages in high-risk sexual behaviors
 - Injects drugs & reports sharing equipment, engaging in high-risk sexual behaviors, etc.
 - Engages in transactional sex
 - Reports at least one other sexually transmitted infection in the last year
 - In high prevalence area or sexual network

Cases in which starting PrEP is *not* appropriate

- Documented HIV infection
- Abnormal kidney function
- *Lack of readiness to adhere*



What about PrEP & pregnancy?

- Is your patient or client pregnant or trying to get pregnant?
 - If pregnant or becomes pregnant, discuss known risks & benefits
 - Continuation of PrEP during pregnancy & breastfeeding is recommended
 - Providers should report PrEP use in pregnancy to Antiretroviral Pregnancy Registry



Initial assessment

- Knowledge about PrEP
- Readiness and willingness to adhere
- Substance use & mental health screening
- Symptoms of acute HIV infection
- Partner information
- Reproductive plans

Initial assessment

- Knowledge about PrEP
- Readiness and willingness to adhere
- Substance use & mental health screening
- Symptoms of acute HIV infection
- Partner information
- Reproductive plans



- How PrEP works & limitations of PrEP
- PrEP use
- Common side effects, long term safety
- Baseline tests and schedule for monitoring
- When to discontinue
- Discussion of benefits, potential toxicity of PrEP in pregnancy

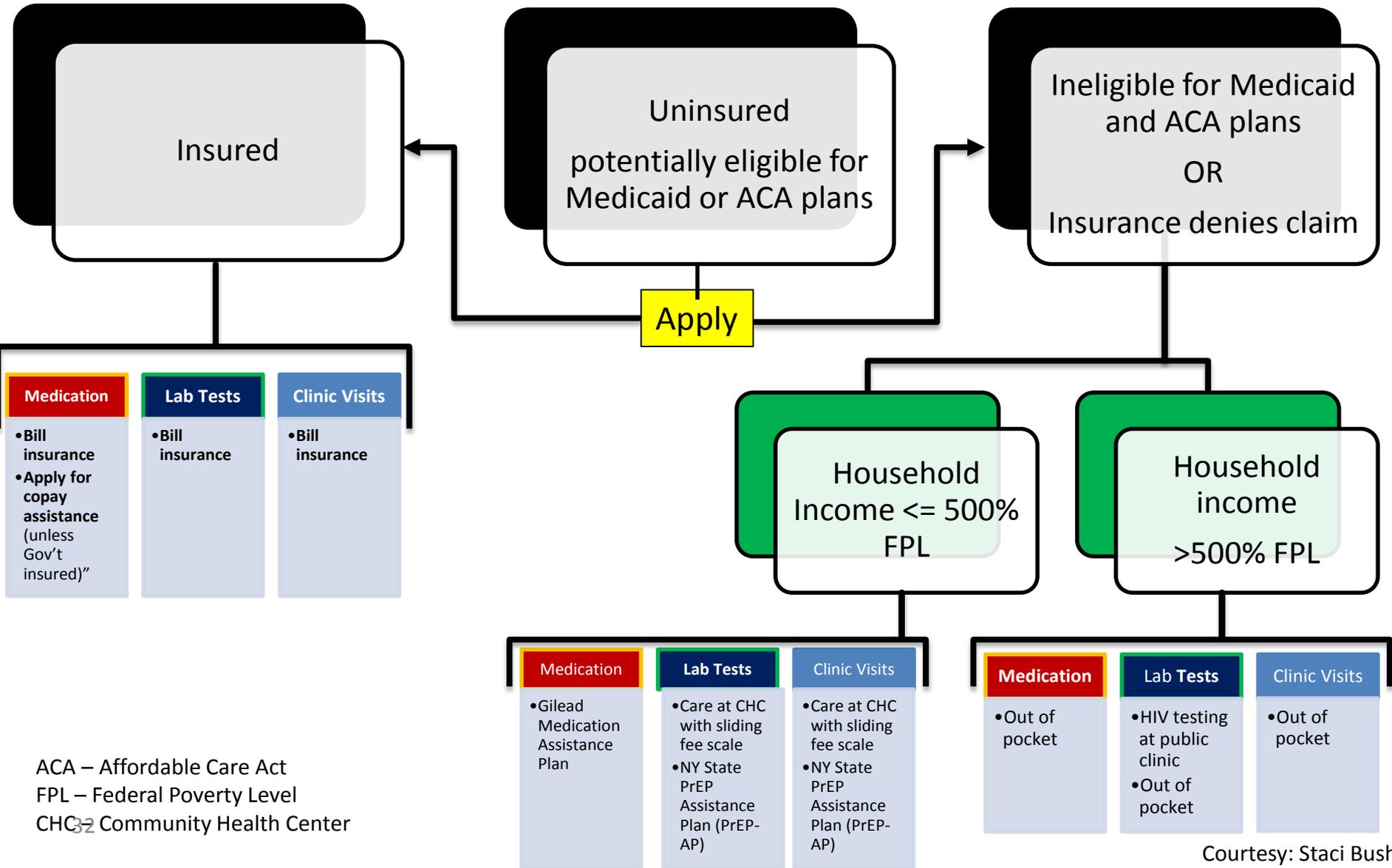
Before PrEP is prescribed:

- Negative baseline HIV test
- Normal kidney function
- Urinalysis
- Pregnancy test
- Screen for sexually transmitted infections
- Screen for hepatitis A, B, and C
 - Immunize as needed

PrEP take-home messages

- PrEP is a choice
 - Depending on situation, PrEP may be a life-long commitment or only used during “seasons of risk”
- PrEP is one of many HIV prevention strategies
 - The more approaches used, the better the protection against HIV
- Individuals must test HIV negative to start and continue PrEP
- Adherence is essential for PrEP to work, especially for protection during vaginal intercourse

Covering the Cost of PrEP Care



Medication	Lab Tests	Clinic Visits
<ul style="list-style-type: none"> • Bill insurance • Apply for copay assistance (unless Gov't insured)" 	<ul style="list-style-type: none"> • Bill insurance 	<ul style="list-style-type: none"> • Bill insurance

Medication	Lab Tests	Clinic Visits
<ul style="list-style-type: none"> • Gilead Medication Assistance Plan 	<ul style="list-style-type: none"> • Care at CHC with sliding fee scale • NY State PrEP Assistance Plan (PrEP-AP) 	<ul style="list-style-type: none"> • Care at CHC with sliding fee scale • NY State PrEP Assistance Plan (PrEP-AP)

Medication	Lab Tests	Clinic Visits
<ul style="list-style-type: none"> • Out of pocket 	<ul style="list-style-type: none"> • HIV testing at public clinic • Out of pocket 	<ul style="list-style-type: none"> • Out of pocket

ACA – Affordable Care Act
 FPL – Federal Poverty Level
 CHC – Community Health Center

The future of PrEP

Other oral medications



Long-acting injectables



Vaginal ring



Implants





What's needed

- Increase awareness about PrEP among women (e.g., outreach, peer educators, health care providers speaking with their patients)
- Refer or link women who are potential PrEP candidates to health care settings that provide PrEP services
- Assist with obtaining coverage for PrEP
- Support adherence to PrEP
- Address unique needs of different subpopulations of women



A blue scroll graphic with a white text box. The scroll is unrolled on the left side and has a small tab on the right side. The text is centered within the white box.

PrEP may not be for EVERY woman,
but it's an option for ALL women

-Kimberleigh Smith, Harlem United

Thank you!

Please feel free to contact me at oblackst@montefiore.org if you have additional questions about PrEP for women after this webinar.

Follow-up and Monitoring

Follow-up	At Least Every 3 Mos	After 3 Mos and at Least Every 6 Mos Thereafter	At Least Every 6 Mos	At Least Every 12 Mos
All patients	<ul style="list-style-type: none"> ▪ HIV test ▪ Adherence counseling ▪ Risk reduction counseling ▪ Side effect assessment ▪ STI symptom assessment 	<ul style="list-style-type: none"> ▪ Assess kidney function 	<ul style="list-style-type: none"> ▪ Test for STIs 	<ul style="list-style-type: none"> ▪ Evaluate need to continue PrEP ▪ HCV serologies in MSM, people who inject drugs, and those with multiple sex partners ▪ Urinalysis
Women	<ul style="list-style-type: none"> ▪ Pregnancy test (where appropriate) 			

Prescription and follow-up visits

- 1st prescription: 30-day supply and return in 1 month to assess adherence, side effects
- 2nd prescription given at 30-day visit: 60-day supply
- Subsequent prescriptions: No more than 90-day supply, confirmed HIV test result required for refill

