PrEP is for women, too!

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Ending the Epidemic:
Achieving and Sustaining Viral Suppression among Women
November 18, 2015
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.
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

Courtesy: Carlos Malvestutto, Nationwide Children’s Hospital, Ohio State University Medical Center
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
2012

July 2012:
FDA approves Tenofovir/emtricitabine (Truvada) for PrEP

2013

2014

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

June 2014:
NYS DOH releases guidance for the use of PrEP

2015

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 is one of many HIV prevention strategies.

- PrEP
- Treatment-as-Prevention
- Male and female condoms
- PEP
- PMTCT
- Male circumcision
- HIV testing
- Clean injecting equipment
- Microbicides
- Vaccines
- Behavior change

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

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.

http://www.cdc.gov/hiv/group/gender/transgender/
Why is PrEP important for women?

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- Primary mode of HIV acquisition among women is sexual contact with a male partner.
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How do we know PrEP works for women?

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

*serodifferent or serodiscordant heterosexual couples
Why was there poor adherence in studies of PrEP in women?

Adherence

Stigma of taking a pill related to HIV

Challenges of taking a pill daily

Lack of support from partners & family

Concerns about side effects

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

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Challenges of taking a pill daily

Concerns about side effects

PrEP only works if you take it

Percentage of participants' samples that had detectable drug levels

Pearson correlation = 0.86, p=0.003

Source: Salim S. Abdool Karim, CAPRISA

http://www.avac.org/sites/default/files/resource-files/By_The_Numbers_PrEP.pdf
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

Courtesy: Med-IQ
Women’s perceptions of PrEP

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

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- 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

**Insured**
- Medication: Bill insurance
- Lab Tests: Bill insurance
- Clinic Visits: Bill insurance

**Uninsured potentially eligible for Medicaid or ACA plans**
- Apply

**Household Income <= 500% FPL**
- Medication: Gilead Medication Assistance Plan
- Lab Tests: Care at CHC with sliding fee scale, NY State PrEP Assistance Plan (PrEP-AP)
- Clinic Visits: Care at CHC with sliding fee scale, NY State PrEP Assistance Plan (PrEP-AP)

**Household income >500% FPL**
- Medication: Out of pocket
- Lab Tests: HIV testing at public clinic, Out of pocket
- Clinic Visits: Out of pocket

**Ineligible for Medicaid and ACA plans OR Insurance denies claim**

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

Courtesy: Staci Bush
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
PrEP may not for EVERY woman, but it’s an option for ALL women

– Kimberleigh Smith, Harlem United
Thank you!

Please feel free to contact me at obblackst@montefiore.org if you have additional questions about PrEP for women after this webinar.
## Follow-up and Monitoring

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>At Least Every 3 Mos</th>
<th>After 3 Mos and at Least Every 6 Mos Thereafter</th>
<th>At Least Every 6 Mos</th>
<th>At Least Every 12 Mos</th>
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<tbody>
<tr>
<td><strong>All patients</strong></td>
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<tr>
<td>▪ HIV test</td>
<td></td>
<td>▪ Assess kidney function</td>
<td>▪ Test for STIs</td>
<td>▪ Evaluate need to continue PrEP</td>
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<tr>
<td>▪ Adherence counseling</td>
<td></td>
<td></td>
<td></td>
<td>▪ HCV serologies in MSM, people who inject drugs, and those with multiple sex partners</td>
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<tr>
<td>▪ Risk reduction counseling</td>
<td></td>
<td></td>
<td></td>
<td>▪ Urinalysis</td>
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<tr>
<td>▪ Side effect assessment</td>
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<tr>
<td>▪ STI symptom assessment</td>
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| **Women** |  |  |  |  |
| ▪ Pregnancy test (where appropriate) | | | | |


Courtesy: Carlos Malvestutto, Nationwide Children’s Hospital, Ohio State University Medical Center
Prescription and follow-up visits

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