PrEP for HIV Prevention

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HealthHIV
HealthHIV Core Capabilities

- Diverse staff of professionals with HIV, HCV, and LGBT clinical, global, cultural competency, prevention, and other experience – particularly within LGBT and other underserved communities

- Numerous strategic partnerships with national and local organizations (non-profit, clinical, behavioral, political, and technological)
HealthHIV CBA Programs

- ASO/CBO Capacity Building
- Health Department Capacity Building
- Workforce Capacity Building
- Patient-Centered HIV Care Model
- HIV Prevention Technical Assistance
- Health Center Capacity Building
- Retention in Care Institute
- Municipal Leadership Capacity Building
Mentoring Program

- Mentoring Program
Available for Download

Following the webinar today:

- Slide Deck
- Webinar Recording
- Q&A
- Other Materials

www.HealthHIV.org
Male and female condoms

Post-Exposure Prophylaxis

Prevention of mother-to-child transmission

Voluntary counseling and testing

Clean injecting equipment

Behavior change

Microbicides

Vaccines

PrEP

Treatment-as-Prevention

HIV Prevention


www.healthhiv.org
What Is PrEP?

• Medication used to treat HIV can also be used to prevent individuals at high risk of HIV from becoming infected or to prevent mother-to-child transmission
What Is PrEP?

- Medication used to treat HIV can also be used to prevent individuals at high risk of HIV from becoming infected or to prevent mother-to-child transmission
- New application of an old idea:
  - Women take birth control pills before becoming pregnant to prevent pregnancy
  - People take anti-malaria medication before traveling to places where the risk of contracting malaria is high
  - People take HIV medication before they are exposed to the virus to prevent infection

What Is PrEP? (cont.)

• Only 1 medication is available for PrEP in the US
  – Emtricitabine and tenofovir disoproxil fumarate (Truvada)
  – Approved for PrEP by the FDA in 2012
  – Recommended by the CDC for people at substantial risk in 2014
  – Pill taken once a day

• Additional options may be available in the future
  – Other oral medications
  – Long-acting injections
  – Long-acting implants
  – Vaginal rings
# HIV Medications for HIV Prevention: 3 Different Approaches

<table>
<thead>
<tr>
<th>Use</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre-exposure prophylaxis (PrEP)</strong></td>
<td>Before HIV exposure</td>
<td>• Potentially high cost, depending on insurance coverage</td>
</tr>
<tr>
<td></td>
<td>Highly effective at preventing HIV infection when drug is taken as prescribed</td>
<td>• Does not protect from other STIs (eg, chlamydia, gonorrhea, syphilis)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Only one medication is currently available</td>
</tr>
<tr>
<td><strong>Post-exposure prophylaxis (PEP)</strong></td>
<td>Within 3 days of a potential HIV exposure</td>
<td>• Potentially high cost, depending on insurance coverage</td>
</tr>
<tr>
<td></td>
<td>Reduces the chance that HIV will spread throughout the body</td>
<td>• Multiple medications required</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Must start within 72 hours of exposure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Must take daily for 28 days</td>
</tr>
<tr>
<td><strong>Treatment as Prevention (TasP)</strong></td>
<td>After HIV diagnosis</td>
<td>• Potentially high cost, depending on insurance coverage</td>
</tr>
<tr>
<td></td>
<td>Highly effective at controlling an individual’s viral load and preventing HIV transmission to others</td>
<td>• Multiple medications required</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Lifetime use</td>
</tr>
</tbody>
</table>

PrEP: Important Considerations

• Daily oral PrEP does not:
  – Guarantee 100% protection against HIV
  – Protect against STIs (e.g., chlamydia, gonorrhea, syphilis)
  – Prevent pregnancy
  – Cure HIV
  – Function as a stand-alone treatment for individuals living with HIV disease

• PrEP is only one component of an HIV prevention strategy
# HIV Risk Reduction From Clinical Trials of PrEP

<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 US)</td>
<td>MSM and trans women</td>
<td>44%</td>
</tr>
<tr>
<td>Partners PrEP</td>
<td>Kenya, Uganda</td>
<td>Men*</td>
<td>84%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Women*</td>
<td>66%</td>
</tr>
<tr>
<td>TDF2</td>
<td>Botswana</td>
<td>Men and women*</td>
<td>62%</td>
</tr>
<tr>
<td>Bangkok Tenofovir Study</td>
<td>Bangkok</td>
<td>People who inject drugs</td>
<td>49%</td>
</tr>
<tr>
<td>IPERGAY</td>
<td>France, Canada</td>
<td>MSM</td>
<td>86%</td>
</tr>
<tr>
<td>PROUD</td>
<td>England</td>
<td>MSM</td>
<td>86%</td>
</tr>
<tr>
<td>FEM-PrEP</td>
<td>3 African countries</td>
<td>Women</td>
<td>6%</td>
</tr>
<tr>
<td>VOICE</td>
<td>3 African countries</td>
<td>Women</td>
<td>-4%</td>
</tr>
</tbody>
</table>

* Serodiscordant, heterosexual couples

## PrEP vs. Other HIV Prevention Strategies

<table>
<thead>
<tr>
<th>Study</th>
<th>Reduction in HIV Transmission</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPTN 052 (Treatment as prevention)(^1)</td>
<td>96%</td>
</tr>
<tr>
<td>iPrEx (FTC/TDF) in MSM(^1)</td>
<td>44%</td>
</tr>
<tr>
<td>Subjects with detectable drug levels(^2)</td>
<td>94%</td>
</tr>
<tr>
<td>Partners PrEP (FTC/TDF) in discordant couples(^3)</td>
<td>75%</td>
</tr>
<tr>
<td>Subjects with detectable drug levels(^3)</td>
<td>90%</td>
</tr>
<tr>
<td>Condoms in heterosexuals(^4)</td>
<td>80%</td>
</tr>
<tr>
<td>Condoms in US MSM(^5)</td>
<td>70%</td>
</tr>
<tr>
<td>TDF2 (FTC/TDF) in men &amp; women(^1)</td>
<td>62%</td>
</tr>
<tr>
<td>Medical male circumcision(^1)</td>
<td>54%</td>
</tr>
<tr>
<td>STD treatment(^1)</td>
<td>42%</td>
</tr>
</tbody>
</table>

iPrExOLE: 100% Adherence to Oral PrEP Not Needed for Full Benefit

HIV Risk Reduction

- 44%
- 84%
- 100%
- 100%

**PrEP Effectiveness Is Associated With Drug Concentration: Risk Reduction Modeling**

<table>
<thead>
<tr>
<th>Route of HIV Exposure</th>
<th>Drug Concentration Commensurate With Doses</th>
<th>HIV Risk Reduction (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rectal tissues</td>
<td>2 per week</td>
<td>76% (56%-96%)</td>
</tr>
<tr>
<td></td>
<td>4 per week</td>
<td>96% (90%-99%)</td>
</tr>
<tr>
<td></td>
<td>7 per week</td>
<td>99% (96%-99%)</td>
</tr>
<tr>
<td>Vaginal/cervical tissues</td>
<td>6-7 per week</td>
<td>94% (-17%-100%)</td>
</tr>
</tbody>
</table>

What Makes Daily Oral PrEP So Effective?

What Makes Daily Oral PrEP So Effective:

- Higher drug levels in the body
- Drugs stay in the body for a long time

= High likelihood of preventing HIV infection

"Forgiveness" of missed doses

Why Such Variable Results With Women?

- Primary driver: suboptimal adherence
- However, tenofovir reaches lower concentrations in vaginal and cervical tissues than rectal tissues

Adherence may be even more important for PrEP efficacy among women engaged in vaginal sex

Update on Recent Research Studies
IPERGAY: Intermittent Dosing and HIV Reduction

- 400 MSM engaging in frequent sex in France and Canada

Relative HIV risk reduction: 86% (95% CI, 39.4%-98.5%)

However, it is unclear whether on-demand dosing would protect MSM who were having sex less frequently (and therefore taking PrEP less often)

ADAPT: Feasibility and Acceptability of Different Dosing Regimens

ADAPT: Key Take-Away Points

- Adherence was higher for daily regimens in all 3 locations
  - Habits formed around daily pill-taking
  - Missed doses most often were pills meant for after sex (twice-weekly and event-driven regimens)

- Non-daily PrEP may be a good option for men who have sex less often, but who know in advance when it may happen

Overall: PrEP regimens should be adaptable to fit the unique circumstances of individuals’ lives
PrEP Demo Project: High Overall Adherence Measured by Drug Levels

- 63% had protective DBS levels at all visits
- 3% always had DBS levels < 2 doses/week
- PrEP dispensation interrupted in 15%; most commonly due to side effect concerns or low perceived risk


- 550 MSM, 7 transgender women
  - 54% self referred
  - 46% clinic referred

- Overall adherence varied across cities and racial/ethnic groups

- Having more condomless sex was associated with better adherence

<table>
<thead>
<tr>
<th>City</th>
<th>Adherence (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>San Francisco</td>
<td>90%</td>
</tr>
<tr>
<td>Washington, DC</td>
<td>88%</td>
</tr>
<tr>
<td>Miami</td>
<td>65%</td>
</tr>
<tr>
<td>Whites</td>
<td>91%</td>
</tr>
<tr>
<td>Latinos</td>
<td>77%</td>
</tr>
<tr>
<td>Blacks</td>
<td>57%</td>
</tr>
</tbody>
</table>
No Evidence of Risk Compensation in PrEP Clinical Trials

What Facilitates Safe Behavior During PrEP Use?

• Less denial of HIV
  – Paralyzing fear replaced by action
  – Pills serve as a daily reminder of imminent threat of HIV
  – Risk mitigation strategies thought through in calm moments over many days
  – Acceptable solutions to the threat of HIV

• Social support
  – Regular, consistent contact with testing, counseling, and peers focused on HIV
  – Acceptance of social and sexual goals
Other Key Research Findings With PrEP

• Being on PrEP does not appear to lead to people engaging in riskier sexual behaviors (i.e., sexual risk compensation)

• Side effects are mild and usually temporary
  
  – Most common: nausea, cramping, unintended weight loss
    • Occur in the first few weeks of treatment
    • Quickly subside
  
  – Other observed side effects
    • 1% average decrease in bone mineral density
      • Levels off over time and does not progress
      • Does not usually warrant treatment
    • 1 in 200 experience kidney problems
      • Resolves after stopping medication
      • Can be safe to re-start

Considerations for PrEP Use
Candidates for PrEP

- Men or women, regardless of sexual orientation, in an ongoing sexual relationship with a partner who has HIV (particularly if trying to conceive)

- MSM, heterosexual men, or heterosexual women who engage in condomless sex with individuals with unknown HIV status who are at high risk of HIV infection

- People who inject illicit drugs and who share injection equipment

PrEP Cascade

**Patients**

1. At risk of HIV infection
2. Identified as PrEP candidate
3. Interested in PrEP

**Providers**

1. Provide healthcare to high-risk populations
2. Educated about PrEP
3. Willing to provide PrEP

4. Linked to PrEP program
5. Initiated PrEP
6. Retained in PrEP program
7. Achieve and maintain medication adherence
No new cases of HIV among individuals on PrEP despite high rates of STIs and self-reported decreases in condom use among 41% of PrEP users.
Integrating PrEP into Clinical Practice

- Identify Patients
- Prescribing PrEP and adherence support
- On-going monitoring of PrEP
- Discontinuation of PrEP
- Patient support
Before Initiating PrEP: Take a History

- Determine eligibility
- Take a sexual history
- Discuss last exposure (if within 72 hours offer PEP)
- Assess for signs and symptoms of acute HIV infection
Prescribing PrEP in Practice: Integrating Sexual History

• Helps assess STI/HIV risk and offer opportunities to discuss PrEP
• Important to:
  – Acknowledge your beliefs and background and how they affect your views on sex and sexuality
  – Put the patient at ease
  – Be open so that patients feel comfortable
Have you been sexually active in the past year?

If No: Have you ever been sexually active?

If Yes: Are you having sex with women, men, or both?

How many sex partners have you had in your lifetime? (If have sex with both men and women, ask this question for each)

If more than one partner, do a risk assessment

If one partner, ask about length of relationship and if their partner has other partners

If relationship is not monogamous, do a risk assessment

If one partner, ask about length of relationship and if their partner has other partners

How many people have you had sex with in the last six months? (If have sex with both men and women, ask this question for each)

If more than one partner, do a risk assessment

If one partner, ask about length of relationship and if their partner has other partners

If relationship is not monogamous, do a risk assessment

Prescribing PrEP in Practice: Testing

- Document negative HIV antibody test within a week before starting PrEP
  - Do not use oral rapid antibody test
- Check for creatinine clearance (do not prescribe if under 60)
- Screen for Hep B (offer vaccination if susceptible) and HCV
- Screen and test for STIs
- Pregnancy test if applicable
Prescribing PrEP in Practice: Rx

- Tenofovir DF/Emtricitabine (300/200 mg) 1 tablet daily
- Prescribe no more than a 90-day supply
- Refill only after confirming patient remains HIV uninfected
Helping Patients Develop a PrEP Adherence Plan

- Tailor dosing time to correspond with regularly scheduled activities to integrate medication taking into existing habits
- Use reminders/technical devices to reduce forgetfulness
- Make contingency plans to address changes in routines and schedules
- Identify friends/family who may be able to help support individuals’ adherence

Follow Up on PrEP

- Follow-up while on PrEP
- Evaluate adherence at each visit
- Pregnancy testing at each visit (if applicable)
- HIV antibody test at least every 3 months
- Assess risk behaviors; provide counseling & condoms
- Test for STIs every 6 months regardless of symptoms
- Check BUN/Cr 3 months after initiation, then every 6 months

Discontinuing PrEP

Potential reasons patients may discontinue PrEP:

- Personal choice
- Chronic nonadherence
- Lowered risk of HIV acquisition (changed life situations)
- Intolerable toxicities

Discontinuing PrEP

• PrEP is there when you need it and patients can stop at any time.
  – Periods of sexuality and relationships are fluid and changing, PrEP is a tool that can be used when needed”

• At time of D/c patients should
  – Preferably continue PrEP for 30 days after last activity that could place individual at increased risk of HIV (treat like PEP)
  – Have a HIV test and their HIV status documented
  – Check kidney function and STI’s
  – Have a discussion about other prevention tools
    • Plan can include restarting PrEP if desired
Paying for PrEP

- Covered by Medicaid and most private insurance companies

- Gilead (https://start.truvada.com/individual/truvadaprep-copay)
  - PrEP Medication Assistance Program (MAP)
    - Income below 500% of the FPL and **no other sources for health insurance or prescription coverage**
  - Co-pay for Truvada (www.gileadcopay.com)
    - Deductible and co-insurance coverage is limited to $300 per month
    - **Must have private insurance**
    - Does not cover individuals with Medicaid or Medicare
    - No income requirement
The Future of PrEP

- Tools to help PrEP use in the real world
  - Decision-support resources for individuals
  - Directories of PrEP-friendly providers
  - Studies in older adolescents

- Intermittent dosing

- New medications

- New formulations

- New delivery systems
Using PrEP is a choice
- Not a life-long commitment
- Good tool for people moving in and out of “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 initiate and continue PrEP

Adherence is essential for effectiveness

Time to protection is longer for women (~20 days) than men (~7 days), regardless of whether PrEP is being initiated for the first time or restarted
Conclusions

- Daily oral PrEP protects individuals from HIV when taken consistently
  - Patients and providers must work together to develop strategies to maximize adherence
  - Demonstration projects illustrate this is a feasible addition to HIV prevention efforts
Integrating PrEP into Practice

PrEP

Medical
Pharmacy
Research
HIV Testing Counseling
Public Benefits
Behavioral Health
PEP
Substance Abuse Programs
STI Treatment
Dental

Integrating PrEP into Practice
Thank you for your time and attention.

Any questions?