HIV Prevention with Pre-Exposure Prophylaxis

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Disclosures

There is no commercial support for this enduring material

Dr. Leo Moore reports receiving financial remuneration from Gilead Sciences within the past year: he served on a Medical Affairs Community Advisory Board and provided unbranded presentations about HIV prevention. This presentation has been reviewed; there is no commercial bias, the best available evidence is used, and there is no mention of any specific brand-name agents.

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Agenda

• Avoiding the "Faux Pas" of Sexual Health: Taking a Good Sexual History
• Making the case for PEP and PrEP: Epi and research review
• Guidelines Overview: Who should receive PrEP?
• Starting the conversation about PrEP: Addressing barriers and myths
• PrEP Patient Management: How to PrEP?
• Considerations for Special Populations
• Educating your patient: Tools to promote self-efficacy
Taking a Good Sexual History

Avoiding the “Faux Pas” of Sexual Health:

• Provider comfort level in asking sexual health questions influences patients’ willingness to disclose information about their sexual practices.

• Introduce the topic
  – Normalize the questions and state importance
  – Acknowledge it sensitive and confidential
  – Remember the “Five P’s” of sexual history:
    – Partners
    – Practices
    – Protection from STDs
    – Past History of STDs, and
    – Prevention of Pregnancy
Partners/Practices
– In the past year, have you had sex with men, women, or both?
– Tell me more about your sexual practices…
– In the past 12 months, have you had vaginal sex? Anal sex? How many partners?
– When you have anal sex, how much of the time are you the bottom, the top?

Prior STDs
– Have you ever been diagnosed with a sexually transmitted disease?

Protection from STDs/HIV
– How are you keeping yourself safe from STDs/HIV?
– Tell me more about your use of condoms? Ever used PEP or PrEP in the past?

Protection from pregnancy
– How are you keeping yourself or your partner from getting pregnant?

Helpful Hints: For sexual history taking (and other conversations!)
• Make no assumptions
• Recognize patient anxiety
• Talk less. And listen more
• Recognizing our own biases
– Something is pushing your buttons
• Avoid value laden language
– “You should…”
– “Why didn’t you…”
– “I think you…”
• FIX YOUR FACE!

Epidemiology Review
Making the case for PEP and PrEP:

Epidemiology Review
Making the case for PEP and PrEP:
Why New HIV Prevention Tools are Needed

• Despite testing, counseling, condoms, and ART, 40,000-50,000 new infections annually in the U.S.

• Incidence especially high in certain U.S. populations
  • Men who have sex with men (MSM)
  • Transwomen (MTF)
  • Women in the Southeast
  • Racial and ethnic minorities, especially youth
  • Injection drug users (IDU)
What is PrEP?

• The use of daily oral antiretroviral medication in HIV-negative persons to reduce the risk of acquiring HIV infection.
• The only medication currently approved for PrEP is a combination of two antiretroviral medications: Emtricitabine and Tenofovir.
• When taken daily as prescribed, can decrease risk of HIV infection by up to 99%.
Using ART Medications for HIV Prevention

**PrEP**
Pre-exposure Prophylaxis
Daily regimens to reduce HIV risk if taken daily

**PEP**
Post-exposure Prophylaxis
An 8 week course of 2 or 3 drug ART regimen

**TasP**
Treatment as Prevention
Individuals with suppressed viral load 96% less likely to infect partner with HIV

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### PrEP Landmark Studies

<table>
<thead>
<tr>
<th>Trial</th>
<th>Population</th>
<th>Location</th>
<th>Active arm(s)</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>iPrEx</td>
<td>2499 MSM and MTF TG</td>
<td>South America, USA, Thailand, South Africa</td>
<td>FTC/TDF</td>
<td>44% (95% CI 18-60)</td>
</tr>
</tbody>
</table>

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</thead>
<tbody>
<tr>
<td>TDF-2</td>
<td>1219 heterosexual men and women</td>
<td>Botswana</td>
<td>FTC/TDF</td>
<td>63% (95% CI 22-83)</td>
</tr>
</tbody>
</table>

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<th>Efficacy</th>
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</thead>
<tbody>
<tr>
<td>Partners PrEP</td>
<td>4758 serodiscordant heterosexual couples</td>
<td>Kenya and Uganda</td>
<td>FTC/TDF</td>
<td>75% (95% CI 55-87)</td>
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</tbody>
</table>

<table>
<thead>
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<th>Active arm(s)</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEM-PrEP</td>
<td>2120 heterosexual women</td>
<td>Kenya, Tanzania, Zimbabwe, South Africa</td>
<td>FTC/TDF</td>
<td>No difference</td>
</tr>
</tbody>
</table>

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<th>Location</th>
<th>Active arm(s)</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>VOICE</td>
<td>5000 heterosexual women</td>
<td>Uganda, Zimbabwe, South Africa</td>
<td>FTC/TDF</td>
<td>No difference</td>
</tr>
</tbody>
</table>

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<th>Active arm(s)</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROUD</td>
<td>545 MSM</td>
<td>Public GUD clinics in UK</td>
<td>FTC/TDF</td>
<td>86% (90%CI 58-96, P=0.0002)</td>
</tr>
</tbody>
</table>

\[NNT=13\]

*Courtesy of Dr. Stephanie Cohen, SF DPH*

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### Real World Data

- **Kaiser NorCal**
  - One of the first and largest evaluations of PrEP in a clinical practice setting
  - 575 people
  - Followed for 2.5 years
  - Average length of use during the study was 7.2 months
  - More likely to report multiple sex partners
  - Self-report of condom use was unchanged in 50%, decreased in 41%
  - At 6 months, 36% of PrEP users had been diagnosed with an STD
  - At 12 months, 50% of PrEP users had been diagnosed with an STD

No new HIV infections among the population
PrEP works extremely well IF taken

Does Adherence Have to Be Perfect?

- Study of MSM and transgender women on intermittent dosing regimen based on sexual activity
- Overall efficacy = 86%
- Great variability in use of PrEP

PrEP works extremely well IF taken

- No infections seen w/ ≥ 4 doses/week

Grant RM, Anderson PL et al. Lancet Inf Dis 2014

Does Adherence Have to Be Perfect?

- Dosing Estimated
- PrEP Efficacy
  - 2x/week 76%
  - 4x/week 96%
  - Daily 99%

Who should receive PrEP?

Los Angeles County PrEP Guidelines
Available at http://getprepla.com/for-providers.html

CDC recommendations for PrEP use

**Males**
- HIV positive sex partner
- History of a bacterial STD in the past 12 months
- History of multiple sex partners of unknown HIV status
- Engages in unprotected anal intercourse
- Other risk factors that increase HIV risk
- History of PEP use

**Transgender Persons**
- HIV positive sex partner
- History of a bacterial STD in the past 12 months
- History of multiple sex partners of unknown HIV status
- Other risk factors that increase HIV risk
- Sharing injection equipment
CDC recommendations for PrEP use (continued)

<table>
<thead>
<tr>
<th>Heterosexual Women</th>
<th>Drug Users</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-positive sex partner;</td>
<td>Injection drug users who share injection equipment, inject once or more times per day, inject cocaine or methamphetamine, or engage in high-risk sexual behaviors.</td>
</tr>
<tr>
<td>History of syphilis diagnosed in the past 12 months;</td>
<td>• Use of stimulant drugs associated with high-risk behaviors</td>
</tr>
<tr>
<td>A male partner who may be having sex with men;</td>
<td>• Injection drug users who share injection equipment, inject once or more times per day, inject cocaine or methamphetamine, or engage in high-risk sexual behaviors.</td>
</tr>
<tr>
<td>Other risk factors that increase HIV risk</td>
<td>• Injection drug users who share injection equipment, inject once or more times per day, inject cocaine or methamphetamine, or engage in high-risk sexual behaviors.</td>
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</table>

How to PrEP?

Screening/Enrollment

Follow-up:
• Symptom review: Sx of acute HIV?
• Assessment, counseling:
• Behavior
• Adherence
• HIV testing
• STI testing
• Renal function testing
• Dispense 30 tabs

Sample PrEP Visit Schedule

First Visit: Assessment
• Sexual Risk Assessment
• Basic Medical History, exam
• Sx of acute HIV?
• PrEP Basics: how it works, adherence, side effects
• Labs: HIV, STI, Safety (renal function, HBV)
• Navigation services: Provider/Clinic referrals as needed; Financial Case Management
• Dispense 30 tabs

Second Visit:
• Follow-up: Symptom review: Sx of acute HIV?
• Assessment, counseling:
• Behavior
• Adherence
• HIV testing
• STI testing
• Renal function testing
• Dispense 90 tabs
### PrEP Clinical Tools

Available at http://getprepla.com/for-providers.html

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### Obtain Baseline Testing

- HIV Antibody test (rapid if available).
- Strongly suggest obtaining a viral load to test for acute HIV when PrEP initiated.
- Creatinine (CrCl should be ≥ 60 ml/min)
- HBsAg
- STDs
- Pregnancy test, if applicable
- Offer Hep B immunization if not immune
- Offer HPV immunization if <26

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### Ongoing Monitoring and Support

<table>
<thead>
<tr>
<th>Timeframe</th>
<th>Action</th>
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<tbody>
<tr>
<td>30 days after initiation</td>
<td>- Assess side effects and the patient's interest in continuing&lt;br&gt; - Adherence counseling; reinforce importance of daily use and address any challenges patient has faced.</td>
</tr>
<tr>
<td>Every 3 months</td>
<td>- HIV test: 4th generation preferred&lt;br&gt; - If the patient has been off PrEP form more than a week, consider screening for acute HIV at time of PrEP re-initiation&lt;br&gt; - Creatinine: stop if CrCl &lt; 60 ml/min&lt;br&gt; - STD screening&lt;br&gt; - Pregnancy test for women; if pregnant, ensure that the patient has been informed about use during pregnancy and that she discusses PrEP use with her prenatal provider&lt;br&gt; - Renew prescription for 90 days only if HIV test negative&lt;br&gt; - At each adherence and risk reduction counseling</td>
</tr>
</tbody>
</table>
Counseling: Medication issues

• Adherence
  – Ask about pill taking several ways:
    • What makes it easier to take your pills daily?
    • What makes it more difficult?
  – Tools: alarms, pillboxes, combining PrEP with other daily meds or activities
• Discussion of most common side effects, mitigation strategies
  – With/without food, bedtime dosing, waiting it out
  – Anticipatory guidance re. start-up syndrome

Approximate Sensitivity of HIV Tests for Acute/Recent Infection

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Sensitivity (% of Positive Tests)</th>
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<tbody>
<tr>
<td>Lab RNA</td>
<td>28-35</td>
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<tr>
<td>Lab-based p24 antigen/antibody</td>
<td>22-35</td>
</tr>
<tr>
<td>Lab-based Antibody</td>
<td>11-16</td>
</tr>
<tr>
<td>RAPID Ag/Ab (4th gen)</td>
<td>0-1</td>
</tr>
<tr>
<td>RAPID Antibody</td>
<td>0-1</td>
</tr>
</tbody>
</table>

Screening for Acute HIV Infection

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Overall</th>
<th>Male</th>
<th>Female</th>
<th>Black</th>
<th>White</th>
<th>Hispanic</th>
<th>Asian</th>
<th>Other</th>
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<tbody>
<tr>
<td>0-24</td>
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<td>25-44</td>
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<td>65+</td>
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IF YOU SUSPECT AHI, REFER FOR IMMEDIATE EVALUATION, RNA TESTING!!!!
What if my patient has a positive HIV test?

- Discontinue PrEP to avoid development of resistance
- Order and document results of an HIV genotype
- Ensure patient is linked to an HIV primary care provider for care and possible early initiation of ART
- Inform Division of HIV and STD Programs (213) 351-8146 and please let us know the patient was on PrEP

Billing for PrEP

- Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure)
  - 90441: approx. 15 minutes
  - 90442: approx. 30 minutes
  - 90443: approx. 60 minutes

- Annual screening for hepatitis B or C, or 1st trimester screening for pregnant women; care setting and pregnancy are additional considerations for documentation and billing as services (493, 494)

billing-codes

- PrEP Code
  - 99281: Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure)
  - 99282: Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure)
Considerations for Special Populations

Patients with Chronic Active Hepatitis B Virus Infection (HBV)

- TDF/FTC active against both HIV and HBV infection
- All persons with + HBsAg should be further evaluated, including obtaining HBV DNA
- Co-management with Infectious Disease or Hepatology based on comfort level of primary provider
- There has been concern that discontinuation of TDF/FTC may lead to a rapid flare Hepatitis B infection.

- Analysis of data from study participants with Active Hepatitis B from the iPrEX study
  - 6 patients with active Hepatitis B were randomized to FTC/TDF arm
  - No patients experienced Hepatitis B flare following discontinuation of PrEP
  - Risk of flares seems to be limited to people with advanced liver disease (i.e. cirrhosis)


Patients with Chronic Renal Failure

- Patients with eGFR < 60 ml/min should not take PrEP because safety below this level was not evaluated in clinical trials.

PrEP in Adolescent Minors

- PrEP is an important HIV prevention tool for adolescents.
- None of the completed PrEP trials have included persons under the age of 18.
  - Open label demonstration project currently underway for YMSM ages 15 - 22
- Tenofovir/Emtricitabine has been FDA-approved for HIV treatment in combo with other ARVs since 2004.
- NOTE: Minors ages 12 or older may request testing and consent to medical care related to the diagnosis and treatment of Sexually Transmitted Diseases/HIV (Cal. Family Code § 6926)

Adolescents can be referred to the following clinics for PrEP services:
- Children’s Hospital Los Angeles
  5000 Sunset Blvd. 4th Floor, LA 90027
  (323) 361-7522
  Client should ask for the “PrEP Navigator”
**PrEP in Transgender People**

- Analysis of Transgender data from two research studies shows effectiveness of PrEP in transgender women.
- “No evidence or clinical studies of potential drug interactions between different classes and combinations of antiretroviral medications (ARV) and cross-sex hormone therapy (csHT) used by transgender women for gender transition and feminization.”
- Supported by the World Health Organization.

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**Quick terms review/Tips to promote patient comfort**

**Terms**
- Transgender (adjective)
  - Trans male to female (MTF), or trans woman
  - Trans female to male (FTM), or trans man
- Cis-gender/ non-transgender
- Non-binary/Genderqueer/Gender fluid

**Tips**
- Ask patients their desired pronoun
  - Ex. “Do you prefer to be referred to as he, she, or they?”
- Refer to chest/breast area as “top” and genital area as “bottom”
  - Ex. “Please remove your shirt so that I can check your top for any lumps or masses.”
- http://www.transhealth.ucsf.edu/trans?page=guidelines-home

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**Educating Your Patient**

Tools to Promote Self-Efficacy
• Patient education sheet
• Available in both English and Spanish
• For this document and more, visit http://getprepla.com/for-providers.html

Los Angeles County PrEP Website:
• Information about PrEP and PEP
• How to find a doctor
• Resources for providers
• English/Spanish
• LA County Contact
• Insurance information
DHSP Social Marketing Materials Available

- Current Pamphlets available (below)
- Future Pamphlet with more detailed information coming soon!
  - "Get PrEP in Five Easy Steps", more details regarding access
  - Map and contact information for all DHSP-funded sites
- "The Protectors"—new characters will be unveiled soon, and will include new collateral material

PrEP Materials

DHSP: Targeted client education materials (wallet brochures)
Available via online order
Email prepinfo@ph.lacounty.gov

Questions?
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