Pre-exposure Prophylaxis and Primary Care

National Latino HIV and Hepatitis C Conference
June 7\textsuperscript{th}, 2016

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Denver Prevention Training Center
Who’s in the audience?
Disclosures

• Allison Finkenbinder has no financial relationships or interests to disclose.
Objectives

• Describe pre-exposure prophylaxis (PrEP) and the guidelines for prescribing PrEP

• Understand who are appropriate candidates for PrEP
Polling Question #1: Where is your organization at in the implementation of PrEP?

• A. Don’t plan on implementing PrEP
• B. Thinking about it
• C. We’ve begun the planning process
• D. Have protocols or currently prescribing PrEP
PrEP and HIV Prevention

What is PrEP?

What Clinicians Need to Know

Data Supporting PrEP
PrEP: Prevention before exposure

What are we talking about?

• Daily combination pill
PEP: Isolated HIV Exposure

HIV Exposure → HIV Infection

0 hr 72 hr 1 mo 5 mo
PEP: Prevents Infection After Isolated Exposure

HIV Exposure → X → PEP
(taken for 28 days after initiation)

0 hr 72 hr 1 mo 5 mo
PrEP: Prevents Infection Before Exposure
PrEP

Treatment before exposure to HIV
Evolution of HIV Therapies Related to PrEP
Evolution of HIV Therapies Related to PrEP

Antiretroviral Therapy (ART)
Evolution of HIV Therapies Related to PrEP

Antiretroviral Therapy (ART)

Prevention of mother-to-child transmission (PMTCT)
Evolution of HIV Therapies Related to PrEP

- Antiretroviral Therapy (ART)
- Prevention of mother-to-child transmission (PMTCT)
- Post-exposure prophylaxis (PEP)
Evolution of HIV Therapies Related to PrEP

- Antiretroviral Therapy (ART)
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- Post-exposure prophylaxis (PEP)
- Treatment as prevention (TasP)
Evolution of HIV Therapies Related to PrEP

- Antiretroviral Therapy (ART)
- Prevention of mother-to-child transmission (PMTCT)
- Post-exposure prophylaxis (PEP)
- Treatment as prevention (TasP)
- Pre-exposure prophylaxis (PrEP)
Data Supporting PrEP
Polling Question #2

• How effective are condoms as a biomedical intervention in the prevention of HIV?
  • A. 20%
  • B. 40%
  • C. 60%
  • D. 80%
Prevention Science Overview: Biomedical Intervention Efficacy

Modified from Abdool Karim, Lancet, 2011; Smith et al (JAIDS 1999)
Prevention Science Overview: Biomedical Intervention Efficacy

Modified from Abdool Karim, Lancet, 2011; Smith et al, JAIDS 1999
iPrEx Study: PrEP in MSM

Among the men with detectable levels of medicine in their blood (meaning they had taken the pill consistently), PrEP reduced the risk of infection by 92%.

Participants who became infected had far less drug in their blood, compared with matched participants who remained uninfected.
Partners PrEP Study: Heterosexual Serodiscordant Couples

Among those with detectable levels of medicine in their blood, PrEP reduced the risk of HIV infection by 90%.

Efficacy: 62 – 73%

Increased Adherence Associated With Increased Efficacy

Abdool Karim, CAPRISA, 2013
Increased Adherence Associated With Increased Efficacy

Efficacy
84%  100%

Grant, Lancet, 2014
On Demand PrEP: IperGay Trial, France

- 400 high risk HIV-negative MSM enrolled
- RR reduction of 86% in intervention arm

Molina et al. CROI 2015 Abstract 23LB
Prevention Science Overview: Biomedical Intervention Efficacy

Modified from Abdool Karim, Lancet, 2011; Smith et al (JAIDS 1999)
Raise of Hands

Do you have patients that come to your clinic frequently, or repeatedly, and are diagnosed with an STI?
Case in Study

- Joe – 38 yo male, MSM
  - Went out this past weekend, had sex with someone didn’t know that well
  - Received text Monday from friend that the guy he had sex with has HIV
  - Here today requesting PEP
PrEP Implementation: Potential Candidates

High risk sexual behavior
PrEP Implementation:

Potential Candidates

- Men who have sex with men at substantial risk for HIV
- High risk heterosexuals
- Men or women with partners living with HIV
- People who inject drugs (PWID)
Indications for PrEP in MSM

• Adult man:
  • Without acute or established HIV infection
  • Any male sex partners in past 6 months
  • Not in a monogamous partnership with a recently tested, HIV-negative man

• AND at least one of the following:
  • Any anal sex without condoms (receptive or insertive) in past 6 months
  • Any STI diagnosed or reported in past 6 months
  • Is in an ongoing sexual relationship with an HIV-positive male partner
Back to Joe...

He came in to talk about PEP.
Should I also have a conversation with him about PrEP?
Polling Question #3: Is Joe eligible for PrEP?

• A. Yes
• B. No
• C. I need more information from Joe
Joe’s Sexual History

• **Partners:** Men only

• **Practices**
  – Oral sex: gives and receives
  – Anal sex: top and bottom; uses condoms only when on bottom

• **Past STDs:** had rectal GC dx in August 2014. Treated.

• **Protection:** uses condoms most of the time, especially with anonymous partners. When drunk, tends not to use.
Joe’s Sexual History

• Most recent sexual activity
  – 2 days ago
  – Condom-less anal sex with partner possibly positive for HIV

• Labs today:
  – HIV results (4th generation): **Non-reactive**
  – RPR: **Pending**
  – GC/CT: **Pending** (rectal, oral, and urine samples)
Is Joe eligible for PrEP?

Indications for PrEP in MSM

- Adult man: +
  - Without acute or established HIV infection ?
  - Any male sex partners in past 6 months +
  - Not in a monogamous partnership with a recently tested, HIV-negative man +

- AND at least one of the following:
  - Any anal sex without condoms (receptive or insertive) in past 6 months +
  - Any STI diagnosed or reported in past 6 months +
  - Is in an ongoing sexual relationship with an HIV-positive male partner -
Indications for PrEP in Heterosexual Men and Women

• Adult person:
  • Without acute or established HIV infection
  • Any sex with opposite sex partners in past 6 months
  • Not in a monogamous partnership with a recently tested, HIV-negative partner

• AND at least one of the following:
  • Is a man who has sex with both women and men (behaviorally bisexual) [also evaluate indications for PrEP use by MSM criteria]
  • Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be at substantial risk of HIV infection (IDU or bisexual male partner)
  • Is in an ongoing sexual relationship with an HIV-positive partner
Indications for PrEP in People Who Inject Drugs

• Adult person:
  • Without acute or established HIV infection
  • Any injection of drugs not prescribed by a clinician in past 6 months

• AND at least one of the following:
  • Any sharing of injection or drug preparation equipment in past 6 months
  • Been in a methadone, buprenorphine, or suboxone treatment program in past 6 months
  • Risk of sexual acquisition (also evaluate by MSM and Heterosexual criteria)
PrEP in Adolescents

• The data on efficacy and safety in adolescents are insufficient.

• The risks and benefits of PrEP for adolescents should be weighed carefully in the context of local laws and regulations about autonomy in health care decision-making by minors. (IIIB)
## Summary of Guidance for PrEP Use

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### Prescription

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<td>HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STD symptom assessment</td>
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<td>Every 6 months test for bacterial STDs</td>
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### Other services:

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<th>Do oral/rectal STD testing</th>
<th>Assess pregnancy intent</th>
<th>Access to clean needles/syringes and drug treatment services</th>
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<td>•</td>
<td>• Pregnancy test every 3 months</td>
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Federal PrEP Guidelines
Consider Using an Objective Tool to Assess Risk

MSM Risk Index from the US Public Health Service Clinical Provider’s Supplement to the PrEP

<table>
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<th>MSM Risk Index*25</th>
<th>1. How old are you today?</th>
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<tbody>
<tr>
<td></td>
<td>If &lt;18 years, score 0</td>
</tr>
<tr>
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<td>If 18-28 years, score 8</td>
</tr>
<tr>
<td></td>
<td>If 29-40 years, score 5</td>
</tr>
<tr>
<td></td>
<td>If 41-48 years, score 2</td>
</tr>
<tr>
<td></td>
<td>If 49 years or more, score 0</td>
</tr>
<tr>
<td>2. In the last 6 months, how many men have you had sex with?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If &gt;10 male partners, score 7</td>
</tr>
<tr>
<td></td>
<td>If 6-10 male partners, score 4</td>
</tr>
<tr>
<td></td>
<td>If 0-5 male partners, score 0</td>
</tr>
<tr>
<td>3. In the last 6 months, how many times did you have receptive anal sex (you were the bottom) with a man without a condom?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If 1 or more times, score 10</td>
</tr>
<tr>
<td></td>
<td>If 0 times, score 0</td>
</tr>
<tr>
<td>4. In the last 6 months, how many of your male sex partners were HIV-positive?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If &gt;1 positive partner, score 8</td>
</tr>
<tr>
<td></td>
<td>If 1 positive partner, score 4</td>
</tr>
<tr>
<td></td>
<td>If &lt;1 positive partner, score 0</td>
</tr>
<tr>
<td>5. In the last 6 months, how many times did you have insertive anal sex (you were the top) without a condom with a man who was HIV-positive?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If 5 or more times, score 6</td>
</tr>
<tr>
<td></td>
<td>If 0 times, score 0</td>
</tr>
<tr>
<td>6. In the last 6 months, have you used methamphetamine such as crystal or speed?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If yes, score 6</td>
</tr>
<tr>
<td></td>
<td>If no, score 0</td>
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</table>

Add down entries in right column to calculate total score

TOTAL SCORE*

* If score is 10 or greater, evaluate for intensive HIV prevention services including PrEP.
If score is below 10, provide indicated standard HIV prevention services.
Online Risk Calculator

• A decision-analytic model of PrEP for MSM.
• Tool available online at: https://ictrweb.johnshopkins.edu/ictr/utility/prep.cfm.
• Population Cost-Effectiveness Calculator also developed and available at same web address.

# HIV Pre-Exposure Prophylaxis (PrEP) Risk Assessment Tool: Individual Risk Calculator

1. What percent of the time do you use condoms when having anal sex, including both receptive (bottom) and insertive (top)?
   - 50%

2. What percent of the time are you the insertive partner (top) when having anal sex?
   - 50%

3. On average, how many times per month do you have anal sex?
   - 6 times

4. Are you in a monogamous relationship with an HIV positive partner?
   - Yes

4b. What is the HIV prevalence in your community?
   - 16%
   (Click here for CDC estimates of HIV prevalence among MSM by metropolitan area, age, and race/ethnicity. If left blank, the national average of 19% will be used)

## Risk of acquiring HIV this year:

<table>
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<tr>
<th>Without PrEP</th>
<th>1 in 44 (2.3%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PrEP, expected adherence</td>
<td>1 in 77 (1.3%)</td>
</tr>
<tr>
<td>PrEP, expected adherence + increase in risky behavior</td>
<td>1 in 59 (1.7%)</td>
</tr>
<tr>
<td>PrEP, high adherence</td>
<td>1 in 538 (0.2%)</td>
</tr>
<tr>
<td>PrEP, high adherence and 100% condom use</td>
<td>1 in 1614 (0.1%)</td>
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STAND UP AND STRETCH BREAK
Prescribing PrEP

Clinical Eligibility
## Summary of Guidance for PrEP Use

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</tr>
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<td></td>
<td>Recent bacterial STD</td>
<td>Sharing injection equipment</td>
</tr>
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<td>High number of sex partners</td>
<td></td>
<td>High number of sex partners</td>
<td>Recent drug treatment (but currently injecting)</td>
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<td>Commercial sex work</td>
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<td>Lives in high-prevalence area or network</td>
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### Prescription

Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90 day supply

### Other services:

- Follow-up visits at least every 3 months to provide:
- HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STD symptom assessment
- At 3 months and every 6 months after, assess renal function
- Every 6 months test for bacterial STDs
- Do oral/rectal STD testing
- Assess pregnancy intent
- Pregnancy test every 3 months
- Access to clean needles/syringes and drug treatment services

Prescribing PrEP

Rule out chronic and acute HIV infection

• Query patient about recent exposure
• Ask about symptoms of acute or primary HIV infection
• Perform HIV screening test
• If acute infection is possible:
  o Screen using a highly sensitive test: 4th generation or viral load test
  o Or postpone PrEP until repeat HIV screening completed in one month
Prescribing PrEP

- **Renal function**
  - Renal function: PrEP should not be prescribed to persons with a creatinine clearance of < 60 ml/min

- **Hepatitis B and C**
  - As PrEP may have partial efficacy against hepatitis, it is important to document infection
  - Vaccination for hepatitis A and B is recommended for MSM

- **STI screening in all appropriate anatomic sites:** gonorrhea, chlamydia, syphilis
Joe’s Sexual History

• Most recent sexual activity
  – 2 days ago
  – Condomless anal sex with partner possibly positive for HIV

• Labs today:
  – HIV results (4th generation): Non-reactive
  – RPR: Pending
  – GC/CT: Pending (rectal, oral, and urine samples)
Polling Question #4

Given Joe’s recent sexual history, and the clinical eligibility criteria for PrEP, would you prescribe PrEP today?

A. Yes
B. No
Joe’s plan...

• **Start PEP immediately**

• **Additional labs**
  – Renal function/creatinine
  – Hepatitis B and C serology

• **RTC in 1 month**
  – Repeat HIV test
  – Review labs with patient
  – Answer patient’s questions
  – Adherence and commitment counseling
Next month. . .

• Lab results
  – Renal function: WNL
  – Hepatitis
    • Has had Hep A and B vaccinations
    • Hep C: Non-reactive
  – HIV test today: Non-reactive
• Condoms used this past month
• Discuss adherence (daily pill!) and possible adherence challenges
Prescribing PrEP

- **Prescribe up to 3 months worth of PrEP**
  - The only regimen approved by the FDA and recommended for PrEP with all populations specified in the guideline is the co-formulated tenofovir 300 mg/emtricitabine 200 mg (Truvada). (IA)
  - Tenofovir alone has shown efficacy and safety in heterosexuals and IDU (but not MSM) and can be considered for these populations. (IC)
  - The use of other medications in place or in addition to TDF/FTC or TDF alone is not recommended. (IIIA)
  - Prescribing PrEP for coitally-timed or other noncontinuous daily use is not recommended. (IIIA)
# PrEP Follow-up Visits

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<tr>
<th>Clinical follow-up</th>
<th>Adherence counseling</th>
<th>Reinforcing safe behaviors</th>
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**Clinical follow-up**

**Adherence counseling**

**Reinforcing safe behaviors**

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**Notes:**
- PrEP Follow-up Visits
- Clinical follow-up
- Adherence counseling
- Reinforcing safe behaviors

---
Clinical Follow-up: 3 months

- Repeat HIV testing and assess for signs/symptoms of acute infection to document that patients are still HIV-negative. (IA)
- Repeat pregnancy testing for women who may become pregnant.
- Provide a prescription or refill authorization of daily TDF/FTC for no more than 90 days (until the next HIV test).
Clinical Follow-up: 6 months

- Monitor creatinine clearance. (IIIA)
- Conduct STI testing recommended for sexually active adolescents and adults (i.e. syphilis, gonorrhea, chlamydia).
Adherence counseling: Every visit

• Establish trust and bidirectional communication
• Provide simple explanations and education
  • Dosing
  • Side effects
• Adherence affects effectiveness
• Acute HIV signs and symptoms
Adherence counseling: Every visit

- Support adherence
  - Dosing schedule tailored to daily routine
  - Reminders
  - Identify barriers to adherence
- Monitor medication adherence in a nonjudgmental manner
  - Reinforce success
  - Identify and manage side effects
Polling Question #5

People with chronic conditions only take about _____ of their prescribed medicine.

A. $\frac{1}{4}$
B. $\frac{1}{2}$
C. $\frac{3}{4}$
Reinforcing Safe Behaviors: Every visit

• Establish trust and bidirectional communication
• Provide feedback on HIV risk factors identified during sexual and substance use history taking
  o Barriers to and facilitators of consistent condom use
  o Barriers to and facilitators of reducing substance use
Reinforcing Safe Behaviors: Every visit

• Support risk reduction efforts
  o Identify acceptable incremental steps to risk reduction
  o Identify and address barriers to risk reduction plans
• Monitor behavioral adherence in a nonjudgmental manner
  o Reinforce success
  o If not successful, assist in modifying risk reduction plans
Discontinuing PrEP

• Document HIV status
• Understand reason for discontinuing PrEP
• Counsel based on recent adherence and risk behaviors
Implementation Concerns

- Adherence and PrEP efficacy
- Drug resistance
- Side effects
- Behavioral risk discussions
Drug Resistance

It was on a short-cut through the hospital kitchens that Albert was first approached by a member of the Antibiotic Resistance.
Side Effects

Similar to those seen following years of antiretroviral use in persons living with HIV:

• Diarrhea
• Headache
• Nausea
• Renal dysfunction
• Antiretroviral resistance
• Decreased bone mineral density
PrEP

Behavioral Disinhibition
iPrEX Study
iPrEX Study
Implementation Challenges

- Identifying those who might benefit
- Paying for medications
- Follow up visits
- Getting the word out
Chat box: what are some challenges you anticipate in implementing PrEP?
Summary

• PrEP is a biomedical AND a behavioral intervention
• Adherence is closely associated with efficacy
• Behavioral disinhibition – though not seen in the studies – could potentially negate PrEP benefits in real world use settings
• Ongoing risk discussions and risk reduction planning should be an integral component to PrEP
• PrEP can be very effective at preventing the acquisition of HIV
# Clinical Resources

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# Marketing and Multimedia Resources

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<td>San Francisco AIDS Foundation (posters, postcards, brochure, rackcard)</td>
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<td>Howard Brown Health Center (brochure)</td>
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- Do oral/rectal STD testing

Special Thanks To:

**NACCHO:** Slides adapted from NACCHO’s Webcast Series on PrEP and Local Health Departments

**Denver PTC Staff:**

- Mark Thrun, MD
- Katie Amaya
- Teri Anderson
- John Fitch