Practical Strategies for Implementing PrEP in Primary Care Setting
Presenter: Jeffrey Klausner
September 30, 2015
Pre-Exposure Prophylaxis (PrEP) for HIV Infection

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Disclosures

- Dr. Klausner is a faculty member of the University of California Los Angeles
- Dr. Klausner is a guest researcher with the US CDC Mycotics Diseases Branch
- Dr. Klausner is a member of the WHO STD Guidelines group
- Dr. Klausner is a board member of YTH, Inc, non-profit
- Dr. Klausner is unpaid medical advisor for Healthvana.com

- In the past 12 months, Dr. Klausner and UCLA Regents have received:
  - Research funding, supplies or unrestricted gifts from the NIH, CDC, DOD, Hologic, Gilead Sciences, Cepheid, Standard Diagnostics, MedMira, AIDS Healthcare Foundation, and Sentient Research

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Learning Objectives

- Increase participant’s knowledge of the effectiveness and safety of Truvada for PrEP
- Enhance participant’s capacity to identify those who would benefit from Truvada for PrEP
- Understand when to prescribe Truvada for PrEP and manage drug and behavioral side effects
Outline

• What is PrEP?
• How well does is work?
• Is it safe?
• Offering PrEP
• Cases
• Resources
What is PrEP?

- Truvada (emtricitabine/tenofovir) (FTC-3TC)
- One pill, once a day
- FDA-approved, July 2012
Effectiveness of Truvada

- **iPrEx (TDF/FTC)**: 42% CI: 15-63
- **FEM-PrEP (TDF/FTC)**: 6% CI: -52-41
- **TDF2 (TDF/FTC)**: 49% CI: -22-81, 80% CI: 25-97
- **VOICE (TDF/FTC)**: -49% CI: +3 to -129, -4.4% CI: +27 to -149
- **Partners PrEP (TDF)**: 63% CI: 20-83
- **Partners PrEP (TDF/FTC)**: 71% CI: 37-87
- **PROUD (TDF/FTC)**: 66% CI: 28-84, 84% CI: 54-94
- **iPERGAY (TDF/FTC)**: 86% CI: 58-96, 86% CI: 40-99

Slide courtesy of Raphael Landovitz, MD, UCLA, March 2015
Effectiveness in iPERGAY study

Mean follow-up of 13 months: 16 subjects infected
14 in placebo arm (incidence: 6.6 per 100 PY), 2 in TDF/FTC arm (incidence: 0.94 per 100 PY)

86% relative reduction in the incidence of HIV-1 (95% CI: 40-99, p=0.002)
NNT for one year to prevent one infection : 18

Molina JM, CROI 2015, Abstract 23LB
Safety of Truvada

• Clinical
  – Mild short-term nausea +/- diarrhea (10%)
  – Decreased appetite + weight loss (5-10%)
  – Reversible small decrease in bone density (1%)
  – Reversible small decrease in kidney function (0.5%)

• Sexual health
  – Decrease in condom use
  – Increase in syphilis and rectal gonorrhea and chlamydia
Key Steps in a PrEP Program

- Identify the population at risk – young men who have sex with men, men who have sex with men of color, men who have sex with men attending STD clinics, sex workers, sex partners of injection drug users
- Identify the clinical setting for care
- Assemble a multi-disciplinary team—medical provider (MD, NP, PA), social worker, phlebotomist, other health workers
- Create protocols for inclusion, exclusion, quarterly follow-up and testing (clinical and STD)
- Educate and outreach to target community
- Enrollment—informed consent
- Adherence support—OregonReminders.org
- Monitoring and evaluation

Adapted by JD Klausner from GW Daughtridge, et al., ID Special Edition, 2015
Routine HIV Testing 101

- HIV testing should be routine
- CDC recommends all persons age 13-64 years undergo at least 1 HIV test
- MSM and those with > 1 partner at least annual testing, often 2-4x/ year
- Clinic policy should be all patients undergo HIV testing, unless patient declines (“opt out”)

Case 1

• 22 year old man, recent syphilis treatment, reports sex with other men
• Tested HIV-negative 2 months ago
• What additional history is needed?
• What tests are needed?
• Should Truvada for PrEP be prescribed?
Identify those at HIV risk

• **Men who have sex with men**
  – Ask every man if they have had sex with men, women or both in past 12 months
  – If sexually active with men, ask about types of partnerships, relationships and HIV status of partners:
    • Steady, main partner
      – If has main partner, ask about monogamy or sexual agreement
    • Regular, occasional partners
    • Casual, anonymous partners
      – Ask about where he meets partners—clubs, online, etc.
  – Any exchange of money/drugs for sex
CDC Recommended Indications for PrEP Use by Men who have Sex with Men

• Adult man
• Without acute or established HIV infection
• Any male sex partners in past 6 months (if also has sex with women, see heterosexual criteria)
• 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

Case 2

- 42 year old woman with HIV-infected partner
- Partner’s viral load is unknown
- Has condomless sex when he’s in town
- Is Truvada for PrEP indicated?
- Risks vs. benefits?
- Baseline history and testing?
Identify those at HIV risk

- **Women**
  - Ask every woman if they have had sex with men, women or both in past 12 months
  - If sexually active with men, ask about types of partnerships, relationships and HIV status of partners:
    - Steady, main partner
      - If has main partner, ask about HIV status
      - Ask if main partner has other partners or other male partners
    - Regular, occasional partners
    - Casual, anonymous partners
  - Any exchange of money/drugs for sex
  - Injection drug use
Identify those at HIV risk (cont.)

- **Men who have sex with women**
  - If sexually active with women, ask about types of partnerships, relationships and HIV status of partners:
    - Steady, main partner
      - If has main partner, ask about HIV status/ injection drug use
    - Regular, occasional partners
    - Casual, anonymous partners
  - Any exchange of money/drugs for sex
  - Injection drug use
CDC Recommended Indications for PrEP Use by heterosexual active 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

Identify those at HIV risk

• **Transgender Adults**
  – Ask every person their gender identity.
  – Ask every person if they have had sex with men, women or both in past 12 months.
  – If sexually active with men, ask about types of partnerships, relationships and HIV status of partners:
    • Steady, main partner
      – If has main partner, ask about HIV status
      – Ask if main partner has other partners or other male partners
    • Regular, occasional partners
    • Casual, anonymous partners
  – Additionally ask about:
    • Any exchange of money/drugs for sex
    • Injection drug use
    • Intimate partner violence
    • Experiences with healthcare
CDC Recommended Indications for PrEP Use by Injection Drug Users

- 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)

Case 3

- 36 year old man with fever, chills, mild rash
- Reports condomless receptive anal sex 3 weeks ago at a sex club
- Interested in PrEP
Signs and symptoms of acute HIV

• Fever
• Rash
• Sore throat
• Headache
• Swollen glands
• Diarrhea

Source: www.etsu.edu
# Truvada for PrEP and Resistance

<table>
<thead>
<tr>
<th>Trial</th>
<th>Resistance Among Those Infected at Enrollment</th>
<th>Resistance Among Those Infected Later In The Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>iPrex</td>
<td>1 of 8 in the placebo arm</td>
<td>0 of 64 in the placebo arm</td>
</tr>
<tr>
<td></td>
<td>2 of 2 in the PrEP arm</td>
<td>0 of 36 in the PrEP arm</td>
</tr>
<tr>
<td>Partners PrEP</td>
<td>1 of 6 in the placebo arm</td>
<td>0 of 52 in the placebo arm</td>
</tr>
<tr>
<td></td>
<td>2 of 8 in the PrEP arm</td>
<td>0 of 30 in the PrEP arm</td>
</tr>
<tr>
<td>TDF2</td>
<td>1 of 2 in the placebo arm</td>
<td>1 of 24 in the placebo arm</td>
</tr>
<tr>
<td></td>
<td>1 of 1 in the PrEP arm</td>
<td>0 of 9 in the PrEP arm</td>
</tr>
<tr>
<td>TOTAL</td>
<td>1 of 16 in the placebo arm</td>
<td>1 of 140 in the placebo arm</td>
</tr>
<tr>
<td></td>
<td>5 of 11 in the PrEP arm</td>
<td>0 of 75 in the PrEP arm</td>
</tr>
</tbody>
</table>

7 with resistance: 5 of 7 with HIV before starting Truvada

Adapted from Ard. PrEP in the Real World
Clinical setting and team

• Routine primary care
  – Create PrEP friendly environment
  – Use CDC infographics

• PrEP champion

• Add tools into e-health system
  – Best practice advisories
  – Patient self-completed risk assessment

• Social worker or benefits expert

http://www.cdc.gov/hiv/library/infographics.html
http://www.cdc.gov/hiv/prevention/research/prep/
Typical Clinical Evaluation

• Baseline
  – 4th generation HIV Ab/Ag or HIV RNA testing
  – STI screening for syphilis, rectal chlamydia, gonorrhea and pharyngeal gonorrhea
  – Hepatitis B & C screening
    • HBV vaccine if negative
  – Kidney function testing

• Every 3 month follow-up
  – HIV testing
  – Pregnancy test for women who may become pregnant
  – STI screening for syphilis, rectal chlamydia, gonorrhea and pharyngeal gonorrhea
  – Kidney function testing (at 3 months then 6-mos.)
  – Bone scan not recommended
Prescribe Truvada

- Truvada 1 tab daily by mouth, #30, refills x 2
- Follow-up visit at 1 month to review dosing, adherence, side-effects
- Manage other interventions, vaccinations, etc.
- Risk-reduction counseling
  - How do you keep yourself at low risk from STIs?
  - Any substance use issues?
    - How does substance use impact sexual behavior?
  - Identify at least one concrete step to reduce risk
Medication Assistance

- Gilead will provide Truvada for PrEP at no cost for individuals who qualify for the assistance program (< 500% poverty level)
- Gilead will provide Co-Pay assistance for insured patients

<table>
<thead>
<tr>
<th>Program Element</th>
<th>Truvada PrEP Medication Assistance Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligibility Criteria</td>
<td>US resident, uninsured or no drug coverage, HIV-negative, low income</td>
</tr>
<tr>
<td>Drug Fulfillment</td>
<td>Product dispensed by Covance Specialty Pharmacy, labeled for individual patient use and shipped to prescriber (30 day supply); no card or voucher option</td>
</tr>
<tr>
<td>Recertification Period</td>
<td>6 months, with 90 day status check</td>
</tr>
</tbody>
</table>
Programmatic Support

CDC

http://www.cdc.gov/hiv/prevention/research/prep/

Gilead

http://www.truvadapreprems.com/
Online Resources

http://www.cdc.gov/hiv/guidelines/preventing.html

http://www.projectinform.org/orderprepbooklets/

http://www.thebody.com/index/treat/tenofovir_prevention.html

http://prepfacts.org/
“PrEP is a party drug”  Michael Weinstein, AHF

PrEP users fight back
Clinical Resources

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