PrEP: The Time is Now!

Katie Imborek, MD
Objectives

• Analyze evidence for PrEP
• Assess MSM for PrEP indications
• Perform initial labs
• Monitor for side effects
Disclosure

- No relevant financial relationships
- Will not discuss any off-label products
UI LGBTQ Clinic

Nationally recognized comprehensive healthcare in a welcoming and affirming environment

Request An Appointment

Welcome to UI LGBTQ Clinic

The University of Iowa LGBTQ Clinic serves the lesbian, gay, bisexual, transgender, queer and questioning communities. Our clinic provides full-
Patient Case

- 25 yo self-identified bisexual man
- Married to a woman
- 2 other non-monogamous male partners
- Penile-vaginal sex with his wife
  - Condom use 0% of the time
- Receptive and insertive anal sex
  - Condom use 90% of the time for each
- Receptive and insertive oral sex
  - Condom use 0% of the time
Diagnoses of HIV Infection among Adult and Adolescent Males, by Transmission Category, 2009–2013, United States and 6 Dependent Areas

- Male-to-male sexual contact
- Heterosexual contact
- Injection drug use
- Male-to-male sexual contact and injection drug use
- Other

Year of diagnosis

Diagnoses, No.
Diagnoses of HIV Infection among Men Who Have Sex with Men, by Age Group, 2009–2013—United States and 6 Dependent Areas

Note: Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays and missing transmission category, but not for incomplete reporting. Data on men who have sex with men do not include men with HIV infection attributed to male-to-male sexual contact and injection drug use.
HIV Diagnoses in US

- Adolescent and young adult MSM (13–24 years) saw a 22% increase in new diagnoses from 2008–2010.

- MSM represent 7% of the male population in the US but accounted for 81% of the new HIV infections among males in 2013.

http://www.cdc.gov/hiv/resources
HIV Diagnoses in US

- Adolescent and young adult MSM (13–24 years) saw a **22% increase** in new diagnoses from 2008–2010.

- MSM represent 7% of the male population in the US but accounted for 81% of the new HIV infections among males in 2013.

http://www.cdc.gov/hiv/group/msm/
Undiagnosed HIV Infection

Has your health care provider ever recommended that you be tested for HIV?

Keep calm and get tested.
Has your health care provider ever recommended that you be tested for HIV?

Kaiser Family Foundation Survey on Gay and Bisexual Men on HIV (July-August 2014)
KEEP CALM AND GET TESTED
Increased Risk Exposure
Rates of Diagnoses of HIV Infection among Adults and Adolescents, 2013—United States and 6 Dependent Areas

N = 47,958  Total Rate = 18.0

Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.
More Sex Partners
Low Perception of Risk

One-Third Know New HIV Infections Are On The Rise Among Gay And Bisexual Men

As the graphic indicates, the number of new HIV infections among gay and bisexual men is increasing, despite public awareness.
One-Third Know New HIV Infections Are On The Rise Among Gay And Bisexual Men

As far as you know, is the number of new HIV infections each year among gay and bisexual men increasing, decreasing, or staying about the same?

- Decreasing: 22%
- Increasing (correct answer): 32%
- Staying about the same: 26%
- Don't know: 20%

SOURCE: Kaiser Family Foundation Survey of Gay and Bisexual Men on HIV (July 17 - August 3, 2014)
Homophobia, stigma, discrimination
Diagnoses of HIV Infection and Population by Race/Ethnicity, 2013—United States

Diagnoses of HIV infection
N = 47,352

- American Indian/Alaska Native: 21%
- Asian: 2%
- Black/African American: 46%
- Hispanic/Latino*: 2%
- Multiple races: <1%
- Native Hawaiian/other Pacific Islander: 1%
- White: 28%

Population, United States
N = 316,128,839

- American Indian/Alaska Native: 5%
- Asian: 12%
- Black/African American: 63%
- Hispanic/Latino*: 1%
- Multiple races: <1%
- Native Hawaiian/other Pacific Islander: 1%
- White: 17%

Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.

* Hispanics/Latinos can be of any race.
PrEP vs nPEP

- Pre-exposure prophylaxis
- Non-occupational post exposure prophylaxis
Daily
Tenofovir/emtricitabine (TDF/FTC)
Truvada®

The time for debate on the effectiveness of PrEP is over.
iPrEx Trial

- Preexposure Prophylaxis Initiative
  - Peru, Ecuador, Brazil, Thailand, South Africa, US
- 2500 HIV negative MSM and transwomen sexually active with male bodied persons
- Daily fixed dose Truvada vs placebo
  - Overall 44% reduction in HIV acquisition
iPrEx Trial

- 51% of patients had Truvada detected in their system
  - 92% efficacy
- 99% protection based on modeling drug levels if taken daily
- 100% of iPrEx open label participants did NOT get infected if drug levels with consistent with taking 4 times/week or more
Does PrEP Increase High Risk Sexual Behaviors?
Box E: Key Components of Behavioral Risk-Reduction Counseling

Establish trust and 2-way communication
Provide feedback on HIV risk factors identified during sexual and substance use history taking
  ▪ Elicit barriers to, and facilitators of, consistent condom use
  ▪ Elicit barriers to, and facilitators of, reducing substance abuse

Support risk-reduction efforts
  ▪ Assist patient to identify 1 or 2 feasible, acceptable, incremental steps toward risk reduction
  ▪ Identify and address anticipated barriers to accomplishing planned actions to reduce risk

Monitor behavioral adherence in a non-judgmental manner
  ▪ Acknowledge the effort required for behavior change
  ▪ Reinforce success
  ▪ If not fully successful, assess factors interfering with completion of planned actions and assist patient to identify next steps

Adverse Effects

- "Start-Up Effect"
  - Most common side effects were nausea, headache, weight loss
  - Most dissipate by 1 month
  - Risk for decrease in renal function
    - Usually mild
  - Exacerbation of undiagnosed hepatitis B when discontinued
Provider Awareness

- 99% of ID providers
- 83% of primary care providers

- 40% felt that PrEP should be readily available to all at-risk persons
Gay and Bisexual Men

How much have you heard about PrEP?

- Nothing at all: 55%
- Only a little: 25%
- A fair amount: 11%
- A lot: 9%

Kaiser Family Foundation Survey on Gay and Bisexual Men on HIV (July–August 2014)
PrEP for High Risk Patient Groups

- MSM
- Adult heterosexually active men and women
- Adult injection drug users

PrEP Indications for MSM
- Adult heterosexual or established HIV infection
- Multiple sexual partners in the past 3 months
- Substantially increased risk of acquiring HIV within 3 months (e.g., with an HIV-negative partner, new and multiple sex partners in the past 3 months, diagnosed with an STI in the past 3 months, in an ongoing sexual relationship with an HIV-positive male partner)
PrEP Indications for MSM

- Adult man
- Without acute or established HIV infection
- Male sexual partner(s) in the past 6 months
- Not in a monogamous sexual relationship with an HIV negative partner
  - Any anal sex without condoms (receptive or insertive) in past 6 months
  - Diagnosed with an STD in the past 6 months
  - In an ongoing sexual relationship with an HIV-positive male partner

<table>
<thead>
<tr>
<th>Question</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>How old are you today?</td>
<td>5</td>
</tr>
</tbody>
</table>
| If <18 years, score 0
| If 18-28 years, score 8
| If 29-40 years, score 5
| If 41-48 years, score 2
| If 49 years or more, score 0                                             |       |
| In the last 6 months, how many men have you had sex with?                | 0     |
| If >10 male partners, score 7
| If 6-10 male partners, score 4
| If 0-5 male partners, score 0                                            |       |
| In the last 6 months, how many times did you have receptive anal sex (you were the bottom) with a man without a condom? | 10    |
| If 1 or more times, score 10
| If 0 times, score 0                                                       |       |
| In the last 6 months, how many of your male sex partners were HIV- If >1 positive partner, score 8 positive? | 0     |
| If >1 positive partner, score 8
| If 1 positive partner, score 4
| If <1 positive partner, score 0                                           |       |
| 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? | 0     |
| If 5 or more times, score 6
| If 0 times, score 0                                                       |       |
| In the last 6 months, have you used methamphetamines such as crystal If yes, score 6 or speed? | 0     |
| If yes, score 6
| If no, score 0                                                            |       |
| Add down entries in right column to calculate total score                | 15    |

**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.
Prescribing PrEP

**Starting PrEP**
- Thorough sexual history
- Current drug therapy
- Pregnancy considerations
- Discussing adherence
- Baseline testing
- Baseline viral load
- Consideration of PrEP initiation
- Start PrEP for 3 days

**Continuing PrEP Therapy**
- Every 3 months
- Review adherence
- Monitor for side effects
- Consider adding additional medications
- Continue discussion on PrEP effectiveness
- Monitor for changes in lifestyle

**Discontinuing PrEP**
- Risk behaviors
- Acute HIV infection
- Chronic non-adherence
- Patient choice

**Lab Tests and Procedures Required Before Initiating PrEP**
- HIV antibody test
- Syphilis serology
- Hepatitis B surface antigen
- Hepatitis C antibody
- Baseline viral load
Lab Tests and Procedures Required before Initiating PrEP

- HIV Antigen/Antibody test
- Screening for signs/symptoms of acute HIV infection
- Renal function (CrCl must be >60)
- Hepatitis B serologies – (vaccinate if non immune)
- Hepatitis C serology
<table>
<thead>
<tr>
<th>Symptom</th>
<th>Frequency %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever</td>
<td>75</td>
</tr>
<tr>
<td>Fatigue</td>
<td>68</td>
</tr>
<tr>
<td>Myalgia</td>
<td>49</td>
</tr>
<tr>
<td>Skin rash</td>
<td>48</td>
</tr>
<tr>
<td>Headache</td>
<td>45</td>
</tr>
<tr>
<td>Pharyngitis</td>
<td>40</td>
</tr>
<tr>
<td>Cervical adenopathy</td>
<td>39</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>30</td>
</tr>
<tr>
<td>Night sweats</td>
<td>28</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>27</td>
</tr>
</tbody>
</table>
Starting PrEP

- Truvada once daily
- 3 month supply
- Insurance coverage
  - Dx: High Risk Sexual Behavior
  - Drug Manufacturer Co-Pay Card
- Takes 7–21 days to take effect
## Cost

**Cash Price ~$1500**

<table>
<thead>
<tr>
<th>Age</th>
<th>Insurance Type</th>
<th>Cost/month</th>
</tr>
</thead>
<tbody>
<tr>
<td>23</td>
<td>No Insurance, Copay Assistance Program</td>
<td>$0</td>
</tr>
<tr>
<td>25</td>
<td>IA Medicaid (NO PA required)</td>
<td>$1</td>
</tr>
<tr>
<td>57</td>
<td>Medicare part D</td>
<td>$6.35</td>
</tr>
<tr>
<td>29</td>
<td>BC/BS</td>
<td>$30</td>
</tr>
<tr>
<td>42</td>
<td>BC/BS Federal</td>
<td>$45</td>
</tr>
<tr>
<td>25</td>
<td>BC/BS Classic Blue + copay coupon card</td>
<td>~$100</td>
</tr>
<tr>
<td>51</td>
<td>BC/BS UIChoice + copay coupon card</td>
<td>~$200</td>
</tr>
</tbody>
</table>
Continuing PrEP Therapy

- Every 3 months
  - HIV testing and symptoms screening
  - Assess for side effects, adherence, and HIV acquisition behaviors
  - Provide support to increase adherence and decrease high risk behavior
  - Provide refill for no more than 90 days
- Every 6 months
  - Renal function (CrCl)
  - STI testing
Discontinuing PrEP

- Acquisition of HIV
- Change in sexual risk behavior
- Chronic non-adherence
- Patient choice
Resources

- PrEPLine: 1-855-HIV-PREP
- CDC Guidelines
- UI LGBTQ Clinic website
  - uilgbtqcclinic.com
Acknowledgments

Michelle Miller, PharmD
PrEP: The Time is Now!

Katie Imborek, MD