Creating a HIV Pre-exposure Prophylaxis (PrEP) Clinic at a College Health Service

NYSCHA Annual Meeting
Session TH-5, October 20, 2016

Michael J. Huey, MD
Assistant Vice President and Executive Director
Emory University Student Health Services
Associate Professor, Family and Preventive Medicine
President-elect, American College Health Association
GREETINGS FROM EMORY UNIVERSITY and ACHA
Special thanks!

Colleen Kelley, MD, MPH  
Division of Infectious Diseases, Emory School of Medicine

Betsy Rothschild, PA-C  
Emory University Student Health Services

Raphael Coleman, MPH  
Emory University Office of Health Promotion

Lamar Green and Sterling Laboo  
Interns, Emory University Office of Health Promotion
Faculty Disclosure

• Neither I nor my spouse have a financial interest, arrangement or affiliation with any organization or business entity (including self-employment or sole proprietorship) that could be perceived as a conflict of interest or source of bias in the context of this presentation.
Learning Objectives

• Describe the literature supporting the use of anti-retroviral medication for pre-exposure HIV prophylaxis (PrEP) and discuss controversies surrounding the use of PrEP as a public health strategy.

• Identify the indications for PrEP.
  • Use of PrEP in MSM.
  • Use of PrEP in heterosexuals.
  • Use of PrEP in HIV discordant couples.
  • Use of PrEP in IV drug users.

• Describe steps to take to create a HIV PrEP clinic in a college health setting.
Global Burden of HIV Disease

Adults and children estimated to be living with HIV | 2012

- **North America**: 1.3 million
  - [880,000 – 1.9 million]
- **Caribbean**: 250,000
  - [220,000 – 280,000]
- **Latin America**: 1.5 million
  - [1.2 million – 1.9 million]
- **Sub-Saharan Africa**: 25.0 million
  - [23.5 million – 26.6 million]
- **Middle East & North Africa**: 260,000
  - [200,000 – 380,000]
- **Western & Central Europe**: 860,000
  - [800,000 – 930,000]
- **Eastern Europe & Central Asia**: 1.3 million
  - [1.0 million – 1.7 million]
- **East Asia**: 880,000
  - [650,000 – 1.2 million]
- **South & South-East Asia**: 3.9 million
  - [2.9 million – 5.2 million]
- **Oceania**: 51,000
  - [43,000 – 59,000]

**Total**: 35.3 million
- [32.2 million – 38.8 million]

[Images of World Health Organization and UNAIDS logos]
# US Incidence of HIV Disease

## Estimated Incidence of HIV Infection, Overall, and by Sex, 2007-2010 — United States

<table>
<thead>
<tr>
<th></th>
<th>2007 (95% CI)</th>
<th>2008 (95% CI)</th>
<th>2009 (95% CI)</th>
<th>2010 (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>39,600 (34,900–44,300)</td>
<td>35,500 (31,300–39,700)</td>
<td>34,400 (30,300–38,400)</td>
<td>38,000 (33,400–42,600)</td>
</tr>
<tr>
<td>Female</td>
<td>13,600 (11,500–15,600)</td>
<td>12,000 (10,100–13,900)</td>
<td>10,600 (9,000–12,300)</td>
<td>9,500* (8,100–10,900)</td>
</tr>
<tr>
<td>Total</td>
<td>53,200 (47,000–59,400)</td>
<td>47,500 (42,000–53,000)</td>
<td>45,000 (39,900–50,100)</td>
<td>47,500 (42,000–53,000)</td>
</tr>
</tbody>
</table>

Note: Because column totals for estimated numbers were calculated independently of the values for the subpopulations, the values in each column may not sum to the column total.

*CI = Confidence Interval. Confidence intervals reflect random variability affecting model uncertainty but may not reflect model-assumption uncertainty; thus, they should be interpreted with caution.

* Indicates significantly different (p < 0.05) from the 2008 estimate for the same group.
Rates of Persons Aged 18–64 Years Living with a Diagnosis of HIV Infection, Year-End 2008, United States

Rates are highest in the South

Estimated New HIV Infections in the United States (2010) for the Most Affected Subpopulations

Subpopulations representing 2% or less are not reflected in this chart. Abbreviations: MSM = men who have sex with men; IDU = injection drug user.

http://www.cdc.gov/hiv/statistics/basics/ataglance.html
HIV in MSM

- **Men who have sex with men (MSM)** of all races and ethnicities remain the population most profoundly affected by HIV.
- In 2010, the estimated number of new HIV infections among MSM was 29,800, a significant 12% increase from 2008.
- Blacks/African Americans represent approximately 12% of the U.S. population, but accounted for an estimated 44% of new HIV infections in 2010.
- In 2010, the greatest number of new HIV infections (4,800) among MSM occurred in young black/African American MSM aged 13–24.
- Young black MSM accounted for 45% of new HIV infections among black MSM and 55% of new HIV infections among young MSM overall.

http://www.cdc.gov/hiv/statistics/basics/ataglance.html
Black MSM in Atlanta

• Prevalence of HIV among black men who have sex with men (MSM) in Atlanta > 40% compared to ~15% in white MSM
• Incidence of HIV infection/year of young black MSM (< 25 years) in Atlanta = 12%
• Individual levels of risk behavior do not explain this disparity
Transmission risk per 10,000 HIV exposures

- Blood transfusion: 9250 (92.5%)
- Maternal-to-fetal transmission: 2260 (22.6%)
- Receptive anal intercourse: 138 (1.38%)
- Injection drug user: 63 (0.63%)
- Needle stick: 23 (0.23%)
- Insertive anal intercourse: 11 (0.11%)
- Receptive vaginal intercourse: 8 (0.08%)
- Insertive vaginal intercourse: 4 (0.04%)
The Mucosal Barrier

Balzarini J, and Van Damme L CMAJ 2005; 172: 461-464
HIV at Emory

• A college is not an island.
• After many years of no positive HIV tests (and the discontinuation of anonymous testing), in 2012 Emory SHCS began seeing + HIV tests in MSM-identified students and young male students still in a questioning phase.
• The majority of the new cases were in young African American MSM.
• Students began asking about PrEP (HIV Pre-exposure Prophylaxis)
PrEP

Daily **Truvada** [Tenofovir (TDF)/Emtricitabine (FTC)] approved by FDA in 2010 for prevention of HIV infection in high risk individuals

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES - 2014

A CLINICAL PRACTICE GUIDELINE
Human PrEP Efficacy Studies

- 39 Randomized controlled trials 1987-2009
- Enrolled 160,000 participants, mostly in Africa
- Standard measures of HIV prevention (education, condoms, STI screening/treatment) are not highly effective at reducing HIV transmission
- However, PrEP + prevention interventions (provided to both PrEP and control arms) was effective
- **Adherence**: If you **take** the medication, it is more likely to work
# Human PrEP Efficacy Studies 1987-2009 (2)

<table>
<thead>
<tr>
<th>Study</th>
<th>Drug(s)</th>
<th>Population</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>iPrEX</td>
<td>Oral TDF/FTC</td>
<td>MSM, 4 countries</td>
<td>44% efficacy (92% in those with detectable drug levels)</td>
</tr>
<tr>
<td>TDF2</td>
<td>Oral TDF/FTC</td>
<td>Men and women in Botswana</td>
<td>62% efficacy (85% in those with detectable drug levels)</td>
</tr>
</tbody>
</table>

## Human PrEP Efficacy Studies 1987-2009 (3)

<table>
<thead>
<tr>
<th>Study</th>
<th>Drug(s)</th>
<th>Population</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partners PrEP</td>
<td>Oral TDF/FTC; oral TDF</td>
<td>Discordant couples in Kenya and Uganda</td>
<td>75%; 67% efficacy (86-90% in those with detectable drug levels)</td>
</tr>
<tr>
<td>BTS</td>
<td>Oral TDF, topical TDF gel, oral TDF/FTC</td>
<td>Injection drug users</td>
<td>49% efficacy (74% in those with detectable drug levels)</td>
</tr>
</tbody>
</table>

The results are compelling...

• Data has shown an up to 92% reduction in HIV incidence in MSM adhering to a daily Truvada regimen.

• While the CDC strongly recommends the prescribing of PrEP in primary care, and MSM college students are clearly interested, very few college health services are taking the steps to begin prescribing PrEP.

• If your students have not already asked you for a PrEP program at your SHS, they likely will soon.

• With a thoughtful and careful approach, appropriate infectious diseases consultant back-up, and adequate primary care and health promotion capabilities, HIV PrEP medication can be managed in many college health settings.
Steps to Create a PrEP Clinic at a College Health Service
Goal of a College Health PrEP Clinic

• **Goal**: Reduce the acquisition of HIV infection in our college/university students
  - Prescribe medication regimen that are proven safe and effective for uninfected persons who meet recommended criteria
  - Educate patients about the medications and regimen to maximize safe use
  - Provide support for medication adherence
  - Monitor patients to detect HIV infection, medication toxicities, and assess levels of risk behavior
1. Gauge interest and enlist campus allies

- There is considerable work to do to create a PrEP clinic in your health service. There is no point in doing that work if no students are interested in PrEP.
- Office of LGBT Life can help to informally or formally ascertain student interest. Student interest groups may also be helpful.
- Hold open forums or focus groups or create an online survey.
- Work with your School of Public Health (including student interns or fellows) to design promotional campaigns.
- Not everyone is going to agree that PrEP is a good idea, both inside and outside your SHS. Make a compelling case, then make sure you have support up the chain of command.
Not everyone agrees with PrEP

Op-Ed: The Danger in Calling PrEP a "Party Drug"
Michael Lucas calls on the president of the AHF to be removed from his job for remarks about Truvada.

NEWSWEEK: The Pill Truvada Can Prevent HIV/AIDS, and for Some, That's a Problem
By Tim Fitzsimons / October 7, 2014

by Ian Lekus on September 25, 2014
2. Work with your ID experts

- At EUSHCS, we do not believe that PrEP/Truvada is a primary care medication . . . yet.
- Create an initial Memorandum of Understanding with your ID consultants to cover:
  - Participation in the initial evaluation of students for suitability for PrEP
  - Interpretation of initial lab results
  - Initial prescribing of Truvada
  - At least one follow-up visit to assess compliance and side effects
  - Coordinated transfer of care to SHS/Primary Care
  - Ease of access to consultation if problems arise
3. Create a partnership between Primary Care and Health Promotion

- The PrEP efficacy studies involved an aggressive health education component to reduce high-risk sexual behavior.
- The CDC guidelines clearly address the need for health education as part of follow-up.
- In college health, we are usually fortunate enough to have health promotion experts on our staff.
- We have made a health promotion visit a required part of our PrEP clinic follow-ups.
- Most specialists don’t . . .
4. Establish a PrEP patient flow chart

- Emory student is interested in PrEP
- Student schedules an INTEREST appointment with a SHS Clinical Provider
- Student is referred to ID at Emory Midtown
- Student decides not to pursue PrEP or isn't eligible for PrEP
PrEP Clinic at EUSHCS (2)

Student is referred to ID at Emory Midtown

Student initiates treatment at ID and continues through at least one successful 3 month follow-up visit

Student schedules a MAINTENANCE visit at SHS

Student meets with Health Educator then with Clinical Provider and has labs each visit

Student returns every 3 months

Student decides not to pursue PrEP or isn't eligible for PrEP
5. Create templates and handouts for the PrEP Clinic

- We have *Point and Click* templates for the Patient Portal questionnaire, PrEP Interest Screening Visit, PrEP Health Educator Visit, and PrEP Clinical Provider Follow-up Visit

- CDC has excellent patient information handouts about PrEP

---

**PrEP (HIV Pre-Exposure Prophylaxis) Visit**

**Instructions:**

*Please complete this form prior to being seen for your appointment.*

For your Student Health Services PrEP Visit, you will meet with the Health Educator, have a medication management visit with your Clinical Provider, and have laboratory testing done. It is likely that the entire visit process will take 90 minutes, so please plan accordingly.

**PLEASE NOTE: THIS QUESTIONNAIRE WILL NOT BE READ BY A CLINICIAN UNTIL THE TIME OF YOUR VISIT.**

- If you are experiencing chest pain, severe difficulty breathing, confusion, severe dizziness or other symptoms of acute distress, you should not schedule an appointment and instead call 911 or go to the nearest hospital emergency room. If you are unsure if you can wait to be seen at an appointment, please call 404-727-7551 and ask to speak to the nurse or the on call physician.

**Are you currently taking anti-retroviral medication (Truvada) to prevent HIV infection?**

- Yes
- No

**If “yes,” who prescribed it for you?**

- An Emory Student Health Services provider
- Emory Infectious Diseases HIV Clinic at Midtown
- Other (please elaborate below)

**When was your most recent PrEP visit?**

**Have you experienced any side effects of taking Truvada?**

- Yes
- No
- Unsure

If “Yes” or “Unsure,” please elaborate:
PrEP Handouts (2)

PrEP Patient Handout

It has been explained to me that:

- Taking a dose of PrEP medication every day may lower my risk of getting HIV infection.
- This medicine does not completely eliminate my risk of getting HIV infection, so I need to use condoms during sex.
- This medicine may cause side effects so I should contact my provider for advice by sending a secure message through the Student Health portal or by calling 404-727-7551 if I have any health problems.
- It is important for my health to find out quickly if I get HIV infection while I’m taking this medication, so I will contact my provider right away if I have symptoms of possible HIV infection (fever with sore throat, rash, headache, or swollen glands).
- My provider will test for HIV infection at least once every 3 months.

Therefore, I will:

- Try my best to take the medication my provider has prescribed every day.
- Talk to my provider about any problems I have in taking the medication every day.
- Not share the medication with any other person.
- Not request refills early before my next appointment.
- Attend all my scheduled appointments.
- Call 404-727-7551 to reschedule any appointments I cannot attend.

________________________________________  ____________
(Patient Signature) (Date)

Give one copy to patient.

6. Initial Visit: Screen for Eligibility

**Box B1: Recommended Indications for PrEP Use by MSM**

- Adult man
- Without acute or established HIV infection
- Any male sex partners in past 6 months (if also has sex with women, see Box B2)
- 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

Initial Visit: Screen for Eligibility (2)

**Box B2: Recommended Indications for PrEP Use by Heterosexually 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 Box B1 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

7. Summary: From the 2014 USPHS/CDC Clinical Practice Guidelines

### Summary of Guidance for PrEP Use

<table>
<thead>
<tr>
<th>Detection of Risk of Acquiring HIV Infection</th>
<th>Men Who Have Sex With Men</th>
<th>Heterosexual Women and Men</th>
<th>Injection Drug Users</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Sexual partner with HIV</td>
<td>• Sexual partner with HIV</td>
<td>• HIV-positive injecting</td>
<td></td>
</tr>
<tr>
<td>• Recent bacterial STD</td>
<td>• Recent bacterial STD</td>
<td>partner</td>
<td></td>
</tr>
<tr>
<td>• High number of sex partners</td>
<td>• High number of sex</td>
<td>• Sharing injection</td>
<td></td>
</tr>
<tr>
<td>• History of inconsistent or no condom use</td>
<td>partners</td>
<td>equipment</td>
<td></td>
</tr>
<tr>
<td>• Commercial sex work</td>
<td>• History of inconsistent or no condom use</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Commercial sex work</td>
<td>• Recent drug treatment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Lives in high-prevalence area or network</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Clinically Eligible                         |                                                               |
|---------------------------------------------|                                                               |
| • Documented negative HIV test before      |                                                               |
|   prescribing PrEP                          |                                                               |
| • No signs/symptoms of acute HIV infection |                                                               |
| • Normal renal function, no contraindicated|                                                               |
|   medications                               |                                                               |
| • Documented hepatitis B virus infection    |                                                               |
|   and vaccination status                    |                                                               |

<table>
<thead>
<tr>
<th>Prescription</th>
<th>Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90 day supply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other services:</td>
<td>Follow-up visits at least every 3 months to provide:</td>
</tr>
<tr>
<td></td>
<td>HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STD symptom assessment</td>
</tr>
<tr>
<td></td>
<td>At 3 months and every 6 months after, assess renal function</td>
</tr>
<tr>
<td></td>
<td>Every 6 months test for bacterial STDs</td>
</tr>
<tr>
<td></td>
<td>Do oral/rectal STD testing</td>
</tr>
<tr>
<td></td>
<td>Assess pregnancy intent</td>
</tr>
<tr>
<td></td>
<td>Pregnancy test every 3 months</td>
</tr>
<tr>
<td></td>
<td>Access to clean needles/syringes and drug treatment services</td>
</tr>
</tbody>
</table>

8. Truvada

- 2-drug combination: Tenofovir (TDF) and Emtricitabine (FTC)
- Mechanism of Action: Block important pathways that the virus uses to set up infection and therefore slows spread of HIV
  - Emtricitabine: Nucleoside analogue of cytidine; inhibits activity of HIV-1 reverse transcriptase (RT) by competing with natural substrate deoxycytidine 5'-triphosphate and by being incorporated into nascent viral DNA, which results in chain termination.
  - Tenofovir: Acyclic nucleoside phosphonate diester analogue of adenosine monophosphate; inhibits activity of HIV-1 RT by competing with the natural substrate deoxyadenosine 5'-triphosphate and, after incorporation into DNA, by DNA chain termination.
- One tablet daily
- Must use caution if kidney or liver disease = ID consultant
- If you contract HIV and continue Truvada, drug resistance can occur
### Truvada: Drug Interactions

**Table 10: PrEP Medication Drug Interactions**

<table>
<thead>
<tr>
<th>Drug Description</th>
<th>TDF</th>
<th>FTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine</td>
<td>No significant effect. No dosage adjustment necessary.</td>
<td>No data</td>
</tr>
<tr>
<td>Methadone</td>
<td>No significant effect. No dosage adjustment necessary.</td>
<td>No data</td>
</tr>
<tr>
<td>Oral contraceptives</td>
<td>No significant effect. No dosage adjustment necessary.</td>
<td>No data</td>
</tr>
<tr>
<td>Acyclovir, valacyclovir, cidofovir, ganciclovir, valganciclovir, aminoglycosides, high-dose or multiple NSAIDS or other drugs that reduce renal function or compete for active renal tubular secretion</td>
<td>Serum concentrations of these drugs and/or TDF may be increased. Monitor for dose-related renal toxicities.</td>
<td>No data</td>
</tr>
</tbody>
</table>
Truvada: Side effects

• Common: usually fade in one month
  • Upset stomach
  • Flatulence
  • Headache
  • Vomiting
  • Loss of appetite

• “Contact your provider right away for”
  • Fever or chills
  • Especially with sore throat, cough, rash, myalgias, joint pains, diarrhea, malaise
Truvada: Missed dose

- Take missed pill right away
- However, if almost time for next dose, then skip missed pill and take regular dose
- Do NOT take a double dose to make up for missed pill
- Missing doses impacts efficacy – this is not a “prn medication”
- PrEP is not PEP
9. 90-day Follow up Visits

- Patient informed when scheduling that the total visit (Health Promotion, Clinical Provider, Lab) will take 90-minutes

- **Health Promotion:**
  - Assessment of medication adherence + counseling support
  - Assessment of HIV risk behavior + counseling support (including condom use)

- **Clinical Provider**
  - Assessment of HIV status, including signs/symptoms of acute HIV infection (Remember: symptoms usually last for 14 days after HIV exposure)
  - Assessment of STI symptoms
  - Assessment of medication side effects
Labs

- HIV testing every 3 months or sooner if symptoms of acute HIV
- Other STI testing (oral, anal, urethral) every 6 months or sooner if symptoms
- Renal function every 3 months initially, then every 6 months (eCrCl of ≥60 ml/min)
Medication Refill

• 90-day supply Truvada
• Follow up required in 3 months
• **No** refills given early, even if lost/misplaced (or shared)
• Medication handout given
• Signature of patient
10. Does a PrEP Clinic work at a College Health Service?

Yes, it does . . .
References


Questions?

Michael J. Huey, MD
Emory University Student Health Services
mhuey@emory.edu