Disclosure

- Speaker’s Bureau: Gilead, VIIV, BMS, Merck, Serono
LEARNING OBJECTIVES:

1. Review the timeline for major PrEP Studies

2. Define the role of the primary care provider in screening patients for PrEP

3. Describe the follow up visits required for PrEP
FDA Approval

In July 16, 2012, FDA approved the use of tenofovir (300mg) + emtricitabine (200 mg) (TDF/FTC or Truvada®) for HIV PrEP in adults **who are at high risk for becoming HIV-infected**

- **Dosage:** One tablet once daily taken orally with or without food

- Four trials found PrEP to be effective for preventing HIV infection **when taken as prescribed**\(^1,2,3,6\)

- FEM-PrEP and VOICE trials in **females** did not show a benefit, likely because of poor adherence\(^4,5\)

- All trials found PrEP to be **safe**

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## PrEP Efficacy Trials

<table>
<thead>
<tr>
<th>Study Name</th>
<th>Population</th>
<th>N</th>
<th>Results</th>
<th>Efficacy By Detection of Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partners PrEP</td>
<td>Heterosexual couples</td>
<td>4,758</td>
<td>TDF: <strong>67%</strong> efficacy FTC/TDF: <strong>75%</strong> efficacy</td>
<td>86% 90%</td>
</tr>
<tr>
<td>TDF2 Study</td>
<td>Heterosexual Men and Women</td>
<td>1,219</td>
<td>FTC/TDF: <strong>62%</strong> efficacy</td>
<td>85%</td>
</tr>
<tr>
<td>iPrEx</td>
<td>MSM/trans women</td>
<td>2,499</td>
<td>FTC/TDF: <strong>44%</strong> efficacy</td>
<td>92%</td>
</tr>
<tr>
<td>FEM-PrEP</td>
<td>Women</td>
<td>1,951</td>
<td>FTC/TDF: <strong>futility</strong></td>
<td>NR</td>
</tr>
<tr>
<td>VOICE</td>
<td>Women</td>
<td>5,029</td>
<td>TDF, TDF/FTC, Vaginal TFV gel: <strong>futility</strong></td>
<td>NR</td>
</tr>
<tr>
<td>Thai IVDU</td>
<td>IVDU</td>
<td>2,413</td>
<td>TDF: <strong>49%</strong> efficacy</td>
<td>74%</td>
</tr>
</tbody>
</table>
US Public Health Service PrEP Guidelines

Background

- On May 14th, 2014, CDC released clinical, practice guidelines for PrEP:
  - Provide clear criteria for determining a person’s HIV risk and indications for PrEP use
  - Require that patients receive HIV testing to confirm negative status before starting PrEP
  - Underscore importance of counseling about adherence and HIV risk reduction, including encouraging condom use for additional protection

http://www.cdc.gov/hiv/prevention/research/prep/
CDC Defines Substantial Risk

- For **sexual transmission**, this includes anyone who is in an ongoing relationship with an HIV-positive partner.
- It also includes anyone who (1) is not in a mutually, monogamous relationship with a partner who recently tested HIV-negative, and (2) is a:
  - Gay or bisexual man who has had anal sex without a condom or been diagnosed with an STD in the past 6 months or
  - Heterosexual man or woman who does not regularly use condoms during sex with partners of unknown HIV status who are at substantial risk of HIV infection
    - For example, people who inject drugs or have bisexual male partners

http://www.cdc.gov/hiv/prevention/research/prep/
CDC Defines Substantial Risk

- For **people who inject drugs**, this includes those who have injected illicit drugs in the past 6 months and who have shared injection equipment or been in drug treatment for injection drug use in the past 6 months.
- Providers should also discuss PrEP with HIV discordant couples during conception and pregnancy
  - *As one of several options to protect the HIV-negative partner*
- PrEP is only for people who are at ongoing, substantial risk of HIV infection.
  - Post exposure prophylaxis (PEP) should be offered to people who present after a single high-risk event of potential HIV exposure

http://www.cdc.gov/hiv/prevention/research/prep/
On Jan 14th, 2014 NYS DOH published Guidance for the Use of PreP to Prevent HIV transmission

www.hivguidelines.org

NYS DOH Guidance

Candidates for PrEP:

- PrEP is indicated for individuals who have a **documented negative HIV test** and are at **ongoing, high risk** for HIV infection
  - Negative, HIV test result needs to be confirmed as close to initiation of PrEP as possible
- PrEP is not meant to be used as a lifelong intervention, but rather as a method of increasing prevention during “high risk” periods

NYS DOH Guidance
Candidates for PrEP

- Providers need to obtain a thorough sexual and drug use history and regularly discuss risk-taking behaviors
  - For example, How many episodes of “condomless” intercourse or unsafe injecting practices have occurred?
  - Encourage safer-sex practices and safer injection techniques
- Individuals who do not have continued risk, should be educated about non-occupational post exposure prophylaxis

# NYS DOH Guidance Candidates for PrEP

<table>
<thead>
<tr>
<th>MSM who engage in unprotected anal intercourse $^1,^2$</th>
<th>Stimulant drug use, especially methamphetamine $^4$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals in a sero-discordant sexual relationship, especially during attempts to conceive</td>
<td>Individuals with $\geq 1$ ano-genital STI per year$^5$</td>
</tr>
<tr>
<td>Transgender individuals</td>
<td>Individuals who have been prescribed nPEP with continued high-risk behavior or multiple courses $^6$</td>
</tr>
<tr>
<td>IDUs, including injecting hormones $^3$</td>
<td>Individuals engaging in transactional sex</td>
</tr>
</tbody>
</table>

Psycho-Social
- Lack of readiness and/or ability to adhere
- Efficacy of PrEP is dependent on adherence to ensure that plasma drug levels reach a protective level

Medical
- Documented HIV Infection
  - Drug resistant HIV has been identified in patients with undetected HIV who subsequently received TDF/FTC for PrEP
- Kidney Dysfunction
  - CrCl <60 mL/min

Although consistent condom use is a critical part of a prevention plan for all persons prescribed PrEP

Lack of use of barrier protection is not a contraindication to PrEP

Symptoms of Acute HIV Infection
- Febrile, “flu”, or “mono”-like illness in last 6 weeks

Medication List

Substance Use and Mental Health Screening

Knowledge about PrEP
- Patient understanding and misconceptions
- Health Literacy

Readiness and Willingness to adhere to PrEP

Primary Care
- Does the patient have a PCP?

Partner Information
- Determine status of partners

Domestic Violence Screening

Housing Status

Means to Pay for PrEP
- Is patient insured?

Reproductive Plans (for Women)

NYS DOH Guidance
Pre-prescription: Lab Tests

- **HIV Test**
  - Obtain 3rd or 4th generation HIV test
  - Perform viral load test for HIV for:
    - Patient with sxs of AHI or whose HIV AB is negative but reports unprotected sex in last month
- **Basic Metabolic Panel**
  - Do not start PrEP if CrCl <60 mL/min
- **Urinalysis**
  - Identify pre-existing proteinuria
- **Serology for Hep A, B and C** (Immunize for A and B if not immune)
  - Screen for sexually transmitted infections, GC and chlamydia (genital, rectal, pharyngeal)
    - RPR for syphilis
    - Consider vaccinations for HPV and meningococcus, if indicated
- **Pregnancy Test**

NYS DOH Guidance
Prescribing PrEP

• The first prescription of TDF/FTC should only be for 30 days

• At the 30 day visit (after assessing adherence, tolerance and commitment), a prescription for 60 days may be given

  • Creatinine and CrCl for patients with borderline renal function or at increased risk for kidney disease (>65 years of age, black race, HTN or DM)

• After 3 month visit, prescriptions can be given for 90 days provided that patient is adherent

• Patient should then return for 3-month visits for HIV testing and other assessments:

## Table 8. PrEP: Follow-Up Visits

At each visit:
- Assess adherence
- Provide risk-reduction counseling
- Offer condoms
- Manage side effects, follow up 2 weeks after initiation to assess side effects (in person or by phone)

### Laboratory Testing: Follow-Up and Monitoring

<table>
<thead>
<tr>
<th>Laboratory Test</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HIV Testing</strong></td>
<td></td>
</tr>
</tbody>
</table>
| 3rd generation or higher rapid antibody test | ○ Every 3 months, and  
List of 3rd and 4th generation tests is available [here.](#)  
○ Whenever there are symptoms of acute infection (serologic screening test + HIV RNA test) |
| **STI screening**     |                                                                           |
| Ask about symptoms    | ○ Every visit                                                             |
| NAAT to screen for gonorrhea and chlamydia, based on exposure sites  | ○ At least every 6 months, even if asymptomatic (Note: Monogamous discordant couples may not need STI screening as frequently), and  
○ Whenever symptoms are reported |
| Rapid plasma reagin (RPR) for syphilis                              |                                                                           |
| Inspection for anogenital lesions                                 |                                                                           |
| **Hepatitis C screening** | ○ At least annually for injection drug users, MSM, and those with multiple sexual partners |
| Hepatitis C IgG        |                                                                           |
| **Renal function**    |                                                                           |
| Serum creatinine and calculated creatinine clearance              | ○ 3 months after initiation, then every 6 months                           |
| Urinalysis             | ○ Annually                                                                |
| **Pregnancy testing** | ○ Every 3 months                                                          |
NYSDOH Guidance
Discontinuation of PrEP

- **Immediately**, if patient receives a positive HIV test result
  - **Big risk of resistance** if patient is maintained on TDF/FTC only
  - Obtain a genotypic assay and refer and link to HIV care
  - Discontinuation of TDF/FTC in patients with chronic active hepatitis B can cause exacerbations of hepatitis B

- Develops renal disease
- Non-adherent to medication or appointments after attempts to improve
- Using medication for purposes other than intended
- Reduce risk behaviors to the extent that PrEP is no longer needed

PrEP is now part of a menu of evidence-based interventions to prevent HIV transmission.

Although the overall number of new HIV infections is decreasing in NYS, subpopulations such as young MSM continue to increase--especially in young, black men.

PrEP may be an effective option to augment behavior change in these high-risk populations.
Questions?

Antonio E. Urbina, MD
aurbina@chpnet.org

To set up training on HIV, Hepatitis C, PEP or PrEP please contact Terri Wilder at twilder@chpnet.org
http://www.ceittraining.org/
PROMOTION AND IMPLEMENTATION OF PrEP: UTILIZING SOCIAL WORKERS IN PRACTICE

Rachel Legatt, LMSW
Social Worker
Institute for Advanced Medicine
DISCLOSURE

There are no disclosures
1. Discuss the social work role as an addition to the provider role in the PrEP protocol

2. Define a social work role in PrEP promotion

3. Cite social work opportunities in PrEP implementation
Social worker role vs. provider role

• Additional time to spend with patients
  – Ability to weigh pros and cons of PrEP with patient
  – Discuss patient feelings/perceptions of PrEP
  – Counsel on use and process

• Counseling training and experience
  – Can provide sexual health counseling, adherence counseling
  – Can counsel patients who are unsure about PrEP, assist patients in making their right decision
Promotion of PrEP

• Introduce concept of PrEP
• Inform about PrEP, process and requirements
• Recognize benefits and concerns of PrEP
• Decide if PrEP is relevant to individual
• Connect patient with PrEP if interested/able
• If not interested, maintain availability PrEP
Introducing PrEP

• HIV testing/PEP/in context of sexual health counseling
• Has patient ever heard of PrEP?
  – If so, what does patient know about PrEP?

• Differentiate PrEP vs. PEP
  – PEP (Post):
    • “I think I may have been exposed to HIV, so I will take 1 month of medications to try to prevent becoming infected
  – PrEP (Pre):
    • “I haven’t yet been exposed, but I’m worried I might be at risk, so I will take a medication daily to try to prevent infection”
Describing PrEP

- 1 pill once a day - Truvada
- Adherence is essential
  - Discuss efficacy with adherence
- Monitoring is part of PrEP
  - Frequency of visits
  - Benefits of having a PCP
- Ensuring negative status
- Evaluating timeline for being on PrEP
PrEP access

• If patient uninsured, can they obtain Medicaid/an exchange plan?
• No access program for uninsured to pay for full protocol (meds, labs, medical visits)

• Covered by NYS Medicaid
• Covered by some commercial/ACA plans
  – Explore medication/provider visit co-pays
• Gilead PrEP Patient Assistance Program
  – Covers Truvada only (cannot access medical visits/labs)
  – For patients without insurance/significant insurance barriers
PrEP pros and cons

• Ask what patient sees as the benefits and risks of PrEP:
  – Do you feel this could be a relevant tool for you?
  – Why or why not?

• Pros: lowered risk HIV, health promoting for patient and partners, maintaining negative status, strategy removed from encounter (differs from condoms)

• Cons: medication side effects, needing to take medication daily, stigma (concept of promiscuity)
PrEP stigma

- Pervasive in practice
- Belief of PrEP as promiscuity-inducing medication
  - “Truvada whore”
- Fear of being “found out” as on PrEP
- Fear of side effects or fear of taking medications

- Discuss the literature
- Discuss personal choice
  - Does this work for your health and your life?
- Discuss NOT going on PrEP
  - What would it mean for you to test positive for HIV?
- Address self-stigmatizing beliefs
  - Do you feel you would pursue risky behaviors if you went on PrEP? And if so, would this be a concern for you?
Connecting patient to PrEP

• If patient has expressed willingness to pursue PrEP, ensure connection to services

• Can patient schedule an appointment at the clinic, be referred, or discuss with outside PCP?
  – Assist patient in scheduling/referral if needed
  – Inform of clinic process to become a new patient

• Review process
  – Ensure patient understands what must be established before they can begin first dose

• For patients disinterested in PrEP, ensure patients are aware of how to access PrEP services if interest arises
Implementation of PrEP

• Ensure that first visit is scheduled in clinic or advise patient to discuss w/outside PCP
  – Assist patient with barriers, e.g. what can patient do if outside PCP refuses
• Ask patient, if willing, to meet again with SW to follow up after PCP appointment when PrEP is prescribed
• Ensure SW availability to patient for insurance issues, other issues related to accessing PrEP, or sexual health counseling
Meeting with patients on PrEP

• Ask patient how their experience on PrEP has been
  – Any barriers to accessing medication or provider?

• Assess adherence
  – When was your last missed dose?
  – Reiterate why adherence is important

• Discuss patient sexual encounters
  – Have encounters changed in any way once patient started PrEP?
  – Counsel patient on any goals related to sexual health

• For patients continuing on PrEP
  – Continue visits if adherence/other issues, or as needed
  – Counsel patients weighing PrEP timeline: how do you see your PrEP use moving forward?
Please remember to fill out your evaluations! Thank you!