ACTHIV 2016: A State-of-the-Science Conference for Frontline Health Professionals
The Door is Open – PrEP in Practice

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Learning Objectives

• As a result of participating in this activity, participants will be better able to:

  • Discuss the latest data demonstrating how PrEP works across different patient populations

  • Describe the basic infrastructure elements needed to assure a successful PrEP program, and

  • Provide practical solutions to address common barriers to PrEP
ARQ #1

- PrEP is **NOT** contraindicated in which of the following:

  A. Individuals with documented HIV infection
  B. A creatinine clearance <60 ml/minute
  C. Individuals who are not ready to adhere to daily tenofovir/emtricitabine
  D. Individuals who do not consistently use condoms
• View results in your browser: https://api.cvent.com/polling/v1/api/polls/spjlu7o2
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

# 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: 67% efficacy FTC/TDF: 75% 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: 62% efficacy</td>
<td>85%</td>
</tr>
<tr>
<td>iPrEx</td>
<td>MSM/transwomen</td>
<td>2,499</td>
<td>FTC/TDF: 44% efficacy</td>
<td>92%</td>
</tr>
<tr>
<td>FEM-PrEP</td>
<td>Women</td>
<td>1,951</td>
<td>FTC/TDF: futility</td>
<td>NR</td>
</tr>
<tr>
<td>VOICE</td>
<td>Women</td>
<td>5,029</td>
<td>TDF, TDF/FTC, Vaginal TFV gel: futility</td>
<td>NR</td>
</tr>
<tr>
<td>Thai IVDU</td>
<td>IVDU</td>
<td>2,413</td>
<td>TDF: 49% efficacy</td>
<td>74%</td>
</tr>
</tbody>
</table>

Kahle E, et al. 19th IAC; Washington, DC; July 22-27, 2012; Abst. TUAC0102.
PrEP: PROUD and iPERGAY Studies

**PROUD: 545 MSM in England**

- Immediate treatment: 300 not infected, 50 HIV infected
- Deferred treatment: 300 not infected, 50 HIV infected

86% reduction in incidence

**iPERGAY: On demand Truvada vs. placebo--445 MSM in France and Canada**

- Treatment: 250 not infected, 250 HIV infected
- Placebo: 250 not infected, 250 HIV infected

86% reduction in incidence


Kaiser Open Label Study

• 32 months of observation
• 1045 individuals referred for PrEP, 657 (64%) started Emtricitabine/Tenofovir Disproxil Fumurate (TDF/FTC)
• Over 2.5 years of observation, no new HIV infections among PrEP users
• 30% developed STI infection by 6 months, 50% by 12 months. (Chlamydia 33%, gonorrhea 28%, syphilis 5.5%)
• 56% reported no change in condom use; 41% reported decreased condom use

# 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 ≥ 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>

NYS DOH Guidance
Contraindications to PrEP

• 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

NYS DOH Guidance

Contraindications to PrEP

- 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

PrEP

- Describe the basic infrastructure elements needed to assure a successful PrEP program
ARQ # 2

• Which of the following items is NOT part of the pre-prescription checklist for providers prescribing PrEP:

A. Perform screening for hepatitis B
B. Confirm negative HIV-1 status of individual
C. Confirm creatinine clearance > 60ml/minute
D. Perform testing for TB
E. For women of childbearing potential, obtain a pregnancy test
• View results in your browser: https://api.cvent.com/polling/v1/api/polls/spkelzo8
## NYS DOH Guidance
### Important Considerations for PrEP

<table>
<thead>
<tr>
<th>Question</th>
<th>Consideration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the patient have chronic active hepatitis B?</td>
<td>Although not FDA-approved for treatment of HBV, TDF/FTC may be used to treat hepatitis B. Discontinuation may cause flare.</td>
</tr>
<tr>
<td>Is the patient pregnant or attempting to conceive?</td>
<td>Discuss the known risks and <strong>benefits</strong>. Providers need to report to the Antiretroviral Pregnancy Registry.</td>
</tr>
<tr>
<td>Is the patient an adolescent?</td>
<td>No data in &lt; 18 years of age.</td>
</tr>
<tr>
<td>Is the patient taking other nephrotoxic drug or drugs that interact with TDF/FTC?</td>
<td>Obtain a thorough medication history. Especially chronic use of NSAIDs.</td>
</tr>
<tr>
<td>Does patient have osteopenia/osteomalacia/osteoporosis?</td>
<td>Discuss risk of bone loss, especially those with risk factors.</td>
</tr>
</tbody>
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NYS DOH Guidance
Pre-Prescription: Assessment Checklist

- 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 3\textsuperscript{rd} or 4\textsuperscript{th} generation HIV test
  - Perform viral load test for HIV for:
    - Patient with sx 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**

### 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)

<table>
<thead>
<tr>
<th>Laboratory Testing: Follow-Up and Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Laboratory Test</strong></td>
</tr>
<tr>
<td>HIV Testing</td>
</tr>
</tbody>
</table>
| 3<sup>rd</sup> generation or higher rapid antibody test | o Every 3 months, and  
Whenever there are symptoms of **acute infection** (serologic screening test + HIV RNA test) |
| List of 3<sup>rd</sup> and 4<sup>th</sup> generation tests is available [here](http://www.hivguidelines.org/clinical-guidelines/pre-exposure-prophylaxis/guidance-for-the-use-of-pre-exposure-prophylaxis-prep-to-prevent-hiv-transmission/) | |
| STI screening | |
| Ask about symptoms | o Every visit |
| NAAT to screen for gonorrhea and chlamydia, based on exposure sites | o 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 | |
| Hepatitis C IgG | o At least annually for injection drug users, MSM, and those with multiple sexual partners |
| Renal function | |
| Serum creatinine and calculated creatinine clearance | o 3 months after initiation, then every 6 months |
| Urinalysis | o Annually |
| Pregnancy testing | o Every 3 months |
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:

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

• Provide practical solutions to address common barriers to PrEP
ARQ # 3

- A patient on PrEP has not been seen in the clinic for over 3 months. He calls the clinic requesting a refill. Patient states he has been adherent to daily FTC/TDF but will run out of meds in 3 days. As per your last note, he last presented with rectal chlamydia. Which of the following would you do?
  - A. Prescribe a month with 2 refills and have patient make an appointment in 3 months.
  - B. Refuse the refill and ask patient to come in for HIV and monitoring labs prior to issuing refill
  - C. Refill FTC/TDF for 1 month only and ask patient to make appointment for HIV and monitoring labs
• View results in your browser: https://api.cvent.com/polling/v1/api/polls/sp-cj45ia
Creating PrEP process in clinic

• Ensure established plan
• Discussions agency-wide, between and within disciplines
• **Ensure buy-in; address discontent and disagreement**
• Refer to mission, public health focus to remember shared goals
• Clearly develop **protocol**, expectations and roles
  – EMR Template, HIV testing diagnostics (POC versus labs based)
• Flexibility: test and change plan as needed
• If feasible, appoint a point person for PrEP
  – Troubleshoot implementation issues, manage crises: “go-to” person
  – Institute change process when needed and provide feedback

Interdisciplinary PrEP Services

• Additional time to spend on-boarding patients
  – Weigh pros and cons PrEP, discuss ambivalence
  – Inform on insurance, guide through process

• Where available
  – Social Worker / Case Manager / HIV Counselor / Peer
  – Mental health and Substance use referrals

• Internal or external agency collaboration as alternative

Insurance categories

- Medicaid
- Commercial/employer plan
- Marketplace plan (Obamacare)
- Medicare
- Uninsured
Prohibitive Medication Co-Pays

- FTC/TDF co-pay assistance
  - Pharmaceutical company covers up to $300 per fill; max $3,600 per year

- If still high after co-pay assistance:
  - Refer to Patient Assistance Network (PAN)
    - Up to $4,000 per year
    - Must meet income & insurance eligibility criteria
    - Medical-necessity/code dependent

- If co-pay still prohibitive:
  - Consider and counsel on alternative insurance options
    - Patient may need to wait until next open enrollment
    - Cost-benefit analysis of wait
  - Assess eligibility for Medication Assistance Program through pharmaceutical company
PrEP Medication Assistance Program

- Uninsured
- Medication caps
- No prescription coverage

Challenges
- Eligibility criteria
- Mail-order requirement – Covance Pharmacy
- Communication challenges
HIV Education

• Should be integrated into PrEP process and training across all staffs

• Gain familiarity of how HIV is transmitted
  – Understand role of acute HIV infection
  – PEP versus PrEP

• Enhancing understanding of safer sex with positive partners/partners of unknown status

• Improving understanding of risk

• Reduction HIV stigma

Daskalakis D et al. *Accelerating the implementation* of antiretroviral *medications to prevent HIV infection in New York City.* National HIV Prevention Conference, abstract 1419, 2015
Protocol Barriers

• Manage patient expectations *immediately*
  – Timeline for access
  – Review procedure and why each step necessary
  – Availability of providers
    • For new patients
    • For employed patients

• Medication refills
  – Process for accessing refills
  – Education about “pharmacokinetic tail”

Daskalakis D et al. *Accelerating the implementation of antiretroviral medications to prevent HIV infection in New York City.* National HIV Prevention Conference, abstract 1419, 2015
PrEP Stigmatization

• Fear of side effects
  – Short and long-term, specifically acute kidney injury and bone loss
• Fear/dislike of taking medications
  – Opportunity for a cost-benefit analysis
• Fear of peer judgment
  – Labeling individual’s behaviors
  – Being grouped with a specific population/action
• Address self-stigmatizing beliefs
  – Do you feel you would pursue risky behaviors if you went on PrEP? If so, would this be a concern for you?

Bringing Community into Conversation

• **Relationship status:** if in a relationship:
  – Open or closed?
    • For individual/partner?
    • Partner testing?
  – Positive partner?
    • On ARVs?
    • Discuss and educate about labs, undetectable status
  – Negative partners
    • Is PrEP being considered?

• **Patient & partner’s beliefs/fears** raised and discussed

• **Potential for changed dynamics in relationship**
  – Reduction in anxiety possible in serodiscordant couples and/or couples in open relationships

• Special thanks:
  – NYS DOH, Clinical Education Initiative
  – Rachel Legatt, MSW
    • Mount Sinai Institute for Advanced Medicine
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