HIV Prevention Update

John J Faragon, PharmD, BCPS, AAHIV-P
Regional Pharmacy Director,
NY/NJ AIDS Education and Training Center
Pharmacist, Albany Medical Center
Objectives

1. Describe the NYS plan to end the AIDS epidemic.
2. Discuss the role of tenofovir/emtricitabine in the role of HIV prevention.
3. Review the CDC and NYSDOH guidelines for HIV pre-exposure prophylaxis.
4. List 5 interventions the pharmacist can do to ensure safe and effective use of tenofovir/emtricitabine for PrEP.
New York/New Jersey AIDS Education and Training Center

We provide education, training and consultation services to health care professionals in New York and New Jersey to improve access to and quality of HIV/AIDS care.
NY/NJ AETC partners with 14 sites to bring HIV clinical expertise to health care providers:

Funded by the USDHHS and Health Resources and Services Administration (HRSA)
Audience

We build and expand capacity for HIV care by training:

- Physicians
- Advanced Practice Nurses
- Nurses
- Oral Health Providers
- Pharmacists
- Physician Assistants
- Other Healthcare Professionals
Training Programs

We develop and deliver high quality educational and training initiatives, including:

- Didactic Presentations
- Skills Building Workshops
- Hands On Clinical Training
- Individual and Group Clinical Guidance
- Technical Assistance
Addressing the needs of the New York and New Jersey healthcare community

For more information contact:

NY/NJ AETC Central Office
Columbia University
College of Physicians & Surgeons
212-304-5530

Visit our website www.nynjaetc.org
Watch presentations, and download clinical support tools!
### DHHS Guidelines Update 2015: Recommended Regimens in ARV Naives

<table>
<thead>
<tr>
<th>PI – Based Regimens:</th>
<th>Brand Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Darunavir/ritonavir + tenofovir/emtricitabine (AI)</td>
<td>Prezista/Norvir Truvada</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>INSTI – Based Regimens:</th>
<th>Brand Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dolutegravir plus abacavir/lamivudine – ONLY if patient HLA-B*5701 negative (AI)</td>
<td>Triumeq</td>
</tr>
<tr>
<td>Dolutegravir plus tenofovir/emtricitabine (AI)</td>
<td>Tivicay Truvada</td>
</tr>
<tr>
<td>Elvitegravir/cobicistat/tenofovir/emtricitabine – ONLY if pre-ART CrCl &gt;70ml/min (AI)</td>
<td>Stribild</td>
</tr>
<tr>
<td>Raltegravir plus tenofovir/emtricitabine (AI)</td>
<td>Isentress Truvada</td>
</tr>
</tbody>
</table>

= Single Tablet Regimen
DHHS Guidelines Initial Recommended Regimens - 2015

- **Darunavir/ritonavir + TDF/FTC**
  - 3/day

- **Raltegravir (BID) + TDF/FTC**
  - 3/day

DHHS Guidelines Initial Recommended Regimens - 2015

Dolutegravir + TDF/FTC OR
Dolutegravir + ABC/3TC

Elvitegravir/cobicistat/TDF/FTC

1-2/day

1/day

### DHHS Guidelines Update 2015: Alternative Regimens

#### PI – Based Regimens:

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>PI – Based Regimens:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evotaz + Truvada</td>
<td>Atazanavir/cobicistat + tenofovir/emtricitabine ONLY if pre-ART CrCl &gt;70ml/min (BI)</td>
</tr>
<tr>
<td>Reyataz/Norvir + Truvada</td>
<td>Atazanavir + ritonavir + teneofovir/emtricitabine (BI)</td>
</tr>
<tr>
<td>Prezcobix + Truvada</td>
<td>Darunavir/cobicistat + tenofovir/emtricitabine ONLY if pre-ART CrCL &gt;70ml/min (BII)</td>
</tr>
<tr>
<td>Prezcobix or Prezista/Norvir + Epzicom</td>
<td>Darunavir/cobicistat OR Darunavir + ritonavir + abacavir/lamivudine ONLY if HLA-B*5701 negative (BII, BIII)</td>
</tr>
</tbody>
</table>

#### NNRTI – Based Regimens:

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>NNRTI – Based Regimens:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atripla</td>
<td>Efavirenz/tenofovir/emtricitabine (BI)</td>
</tr>
<tr>
<td>Complera</td>
<td>Rilpivirine/tenofovir/emtricitabine ONLY if pretreatment VL&lt;100,000 copies/ml and CD4 &gt;200 cells/mm³ (BI)</td>
</tr>
</tbody>
</table>

= Single Tablet Regimen

Atazanavir/Cobicistat, Darunavir/Cobicistat

- Cobicistat now co-formulated with each preferred protease inhibitor, **alternatives** on DHHS Guidelines, April 2015

Atazanavir/ritonavir  
Darunavir/ritonavir  

Atazanavir/cobi  
Darunavir/cobi

Pre-exposure Prophylaxis - PrEP
HIV Risk Reduction

- **Sexual risk reduction strategies**
  - Abstinence
  - Partner reduction/monogamy
  - Selecting partners that have lower risk
  - Engage in lower-risk sexual practices

- **Condom use**
  - Reported consistent use (100%) offers 80-85% protection against HIV, due to rates of improper usage
  - New data in men who have anal sex showed that 100% use offers 70% protection, but intermittent use provides no benefits at all when compared to those who don’t use condoms\(^1\)
  - Use of condoms also protects against other STIs that can affect HIV acquisition and transmission

\(^1\)Smith D et al. 20\(^{th}\) CROI 2013; Atlanta, Georgia, Abstract 32
HIV Risk Reduction

• **Reduction in IV drug needle sharing**
  – Encourage patients to take advantage of available needle-exchange programs
  – Seek treatment for the drug addiction (i.e. methadone clinic)

• **Counseling and regular testing for HIV and other STIs**
Sexual Harm Reduction

• The concept of “serosorting”
  – Choosing to have sex with a partner of the same HIV status
  – Requires disclosure and accurate knowledge of HIV status

• Restricting unprotected sex to acts less likely to transmit HIV
  – For MSM, the HIV-negative partner is insertive and HIV-positive partner is receptive (strategic or seropositioning)
  – Ejaculating outside the body
Sexual Harm Reduction

• Using an HIV-positive partner’s viral load to decide whether to have unprotected sex
  – Thinking that undetectable = noninfectious
  – Misinterpretation of one’s own viral load and therefore infectiousness

• These strategies may be beneficial in people who do not use condoms, however there is a lot of guesswork in using these strategies and so they may backfire

• These strategies do not protect against other STIs, including Hepatitis B & C
Why PrEP?

- The number of new HIV infections in the USA has remained at about 50,000 per year, an incidence that has not changed for the past 20 years.
  - 27% of new infections were in heterosexual men and women, 64% in MSM, including 3% in MSM who inject drugs.
  - 75% of new infections are in men.
  - MSM have a 19.3-fold higher odds of HIV infection on all continents.
  - HIV incidence in black men is 8 times higher than in whites.
  - HIV incidence in Hispanic men is 3 times higher than in whites.
- Unprotected anal sex in MSM (2% of the population over age 13) accounts for 56-61% of new HIV infections annually.
- New HIV infections in MSM 13-29 years of age increased 38% from 2006 to 2009, largely due to a 48% increase among young black MSM.
Estimated that only 19% of HIV-infected individuals in the US have undetectable HIV viral load.
End of AIDS – NYS

- On June 29, 2014, Governor Andrew M. Cuomo detailed a three-point plan.
- Goal is to reduce the number of new HIV infections to just 750 (from an estimated 3,000) by 2020 and achieve the first ever decrease in HIV prevalence in New York State.
- 3-point plan:
  - Identifies persons with HIV who remain undiagnosed and link them to health care.
  - Links and retains persons diagnosed with HIV in health care to maximize virus suppression so they remain healthy and prevent further transmission.
  - Facilitates access to Pre-Exposure Prophylaxis (PrEP) for high-risk persons to keep them HIV negative.
New York State’s Blueprint to End the AIDS Epidemic

- **Ending the Epidemic Blueprint Summary** (PDF)
- The four committees of the Task Force (Care, Prevention, Housing & Supportive Services and Data) reviewed nearly 300 recommendations submitted online and received during regional Listening Forums held across New York State. Committees used this information to develop 44 committee recommendations (CRs) - including recommendations that move beyond the goal of 750 to zero infections.
  - ETE Task Force Committee Recommendations (CRs)
- A form in SurveyMonkey was developed to collect recommendations. The recommendations form was shared through various avenues and remained live until November 26, 2014. Below is a listing of the recommendations received and shared with Task Force members for review and consideration.
  - Recommendations submitted for consideration by the Task Force (PDF)
    - Recommendations Reviewed by the Care Committee
    - Recommendations Reviewed by the Data Committee
    - Recommendations Reviewed by the Housing & Supportive Services Committee
    - Recommendations Reviewed by the Prevention Committee
Use of TDF/FTC for PrEP
FDA Approval of Truvada for PrEP, July 2012

- Extended indication for TDF/FTC to include use as PrEP in combination with safer sex practices to reduce the risk of sexually acquired HIV infection in adults at high risk
- Strengthened TDF/FTC boxed warning
  - TDF/FTC for PrEP must be used *only* by individuals who are confirmed to be HIV negative prior to prescribing the drug and at least every 3 mos during use
- Approval accompanied by REMS
  - Goal is to minimize risk of acquiring HIV infection and to reduce the risk of development of resistant HIV-1 variants in those receiving PrEP
  - Central component is training and education program to assist prescribers in counseling individuals who are taking or considering TDF/FTC for PrEP
Overall Results of PrEP Trials, CDC

Results from randomized, placebo-controlled, clinical trials of the efficacy of daily oral antiretroviral preexposure prophylaxis (PrEP) for preventing human immunodeficiency virus (HIV) infection

<table>
<thead>
<tr>
<th>Clinical trial</th>
<th>Participants</th>
<th>Type of medication</th>
<th>mITT efficacy*</th>
<th>Adherence-adjusted efficacy based on TDF detection in blood</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bangkok Tenofovir Study</td>
<td>Injecting drug users</td>
<td>TDF</td>
<td>49 (10–72)</td>
<td>70 (2–91)</td>
</tr>
<tr>
<td>Partners PrEP</td>
<td>HIV discordant couples</td>
<td>TDF</td>
<td>67 (44–81)</td>
<td>86 (67–94)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TDF/FTC</td>
<td>75 (55–87)</td>
<td>90 (58–98)</td>
</tr>
<tr>
<td>TDF2</td>
<td>Heterosexually active men and women</td>
<td>TDF/FTC</td>
<td>62 (22–83)</td>
<td>84 NS</td>
</tr>
<tr>
<td>iPrEx</td>
<td>Men who have sex with men</td>
<td>TDF/FTC</td>
<td>42 (18–60)</td>
<td>92 (40–99)</td>
</tr>
<tr>
<td>Fem-PrEP</td>
<td>Heterosexually active women</td>
<td>TDF/FTC</td>
<td>NS</td>
<td>NA</td>
</tr>
<tr>
<td>VOICE</td>
<td>Heterosexually active women</td>
<td>TDF/FTC</td>
<td>NS</td>
<td>NA</td>
</tr>
</tbody>
</table>

iPrEx: Efficacy

- **Efficacy through study end (mITT): 42% (95% CI: 18% to 60%)**

\[
P = .002
\]

TDF2: PrEP Reduces HIV Acquisition

- 9 vs 24 patients seroconverted in TDF/FTC vs placebo arms, respectively
- Overall protective efficacy of TDF/FTC: 62.2% (95% CI: 21.5-83.4; P = 0.03)
- Reduction in HIV acquisition with TDF/FTC observed in both men and women but study underpowered to demonstrate sex-based differences in outcomes

On Demand PrEP
IPERGAY Study

- 2 Truvada 2-24 hours prior to sex, then once daily for 2 doses, given 24 hours after sexual activity, 86% protection
IPERGAY
On Demand PrEP

- French Canadian Study
- 40 HIV negative men
  - Reported condomless sex with at least 2 partners in past 6 months
- Randomized to as needed PrEP or to placebo
- 199 taking on demand PrEP, 201 taking placebo
IPERGAY

- Median age 35
- Over 90% in each arm white
- Well educated, 85% employed
- 25% reported recent sexually transmitted infection
- Median sexual acts in past 4 weeks – 10
- Median sexual partners in past 2 months – 8
IPERGAY - DSMB

- Stopped study in October 2014
- Average 13 months follow up
  - 2 infections in the TDF/FTC group
  - 14 infections in placebo group
- HIV incidence
  - 0.94 per 100 person-years with TDF/FTC
  - 6.6 per 100-person-years with placebo
- Overall 86% relative reduction in HIV incidence
- Number needed to treat to prevent one HIV infection in 1 year was 18!
On Demand PrEP

PROUD Study

- Truvada in MSM in England
- Gay or bisexual men reporting condom free anal intercourse in past 90 days
- Randomized to immediate open label TDF/FTC or to defer for 12 months
- Follow up every 3 months
- 24 month trial

PROUD

- 545 men enrolled, 276 to immediate PrEP, 269 to deferred PrEP
- Median age 35
- 80% white
- 40% not born in UK
- 60% university education
- About 75% in both arms reported recreational drug use in past 90 days

PROUD

- DSMB stopped study in October 2014
- 3 HIV infections in immediate arm compared to 19 in the deferred arm
- HIV incidence
  - 1.3 per 100-person years in immediate arm
  - 8.9 per 100-person years in deferred arm
- Number needed to treat to prevent one infection in 1 year was 13!

**PROUD**

**Sexually Transmitted Infections**

- 60% of men in the immediate arm and almost 50% in the deferred arm had any STI ($P = 0.08$).
- Confirmed STI indicating anal sex without condoms
  - Rates of rectal chlamydia or gonorrhea were 30% in both arms
  - STI screening more common immediate immediate group
- Median total number of male sexual partners in the last 90 days was 10
- Number of condomless receptive and insertive anal partners were lower but also similar in the two arms: about 3.

PrEP Safety
iPrEx: Adverse Events

- No significant differences in adverse events between arms

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>TDF/FTC (n = 1251)</th>
<th>Placebo (n = 1248)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>Events</td>
<td>%</td>
</tr>
<tr>
<td>Any grade 3/4 event</td>
<td>12</td>
<td>248</td>
<td>13</td>
</tr>
<tr>
<td>Death</td>
<td>&lt; 1</td>
<td>1</td>
<td>&lt; 1</td>
</tr>
<tr>
<td>Serious adverse event</td>
<td>5</td>
<td>76</td>
<td>5</td>
</tr>
<tr>
<td>Elevated creatinine</td>
<td>2</td>
<td>28</td>
<td>1</td>
</tr>
<tr>
<td>Creatinine elevation confirmed on next visit</td>
<td>0.4</td>
<td>7.0</td>
<td>0</td>
</tr>
</tbody>
</table>

iPrEx: BMD Changes, Fractures

- BMD changes were small (~1%); no evidence of negative effect on health\(^1\)
- No differences in fracture rates between groups\(^1,2\)
- All fractures were trauma related
- Need longer follow-up to evaluate effects on bone density and fracture risk over time

iPrEx: Nausea on History


![Graph showing patients reporting nausea (%)](image-url)
PrEP and Resistance

- Resistance was rare in clinical trials of PrEP, except for those with acute infection at baseline
- Resistance mutations seen: K65R (TDF) or M184V/I (FTC)

<table>
<thead>
<tr>
<th>Trial</th>
<th>HIV Infected After Enrollment, n/N</th>
<th>Seronegative Acute HIV Infection at Enrollment, n/N</th>
<th>HIV Infections Averted, n</th>
</tr>
</thead>
<tbody>
<tr>
<td>iPrEx[^1,2]</td>
<td>0/36</td>
<td>2/2</td>
<td>28</td>
</tr>
<tr>
<td>Partners PrEP[^3]</td>
<td>0/30</td>
<td>2/8</td>
<td>74</td>
</tr>
<tr>
<td>TDF2[^4]</td>
<td>0/10</td>
<td>1/1</td>
<td>16</td>
</tr>
</tbody>
</table>

PrEP Adherence

NY\NJ AETC
AIDS EDUCATION & TRAINING CENTER
## PrEP

### It Works When Taken

<table>
<thead>
<tr>
<th></th>
<th>Blood Samples With Tenofovir Detected, %</th>
<th>HIV Protection Efficacy in Randomized Comparison, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partners PrEP*[1]</td>
<td>81</td>
<td>75</td>
</tr>
<tr>
<td>TDF2[2]</td>
<td>79</td>
<td>62</td>
</tr>
<tr>
<td>iPrEx[3]</td>
<td>51</td>
<td>44</td>
</tr>
</tbody>
</table>

* TDF/FTC arm

---

There is a clear dose-response between evidence of PrEP use and efficacy

iPrEX OLE

- TFV-DP: tenofovir diphosphate (measurable tenofovir in dried blood spots)

**HIV Incidence and Drug Concentrations**

<table>
<thead>
<tr>
<th>TFV-DP in fmol/punch</th>
<th>HIV Incidence per 100 Person-Yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>0LLOQ</td>
<td>&lt; 2 Tablets/Wk</td>
</tr>
<tr>
<td>350</td>
<td>2-3 Tablets/Wk</td>
</tr>
<tr>
<td>500</td>
<td>4-6 Tablets/Wk</td>
</tr>
<tr>
<td>700</td>
<td>7 Tablets/Wk</td>
</tr>
<tr>
<td>1500</td>
<td>Off PrEP</td>
</tr>
<tr>
<td>1250</td>
<td>On PrEP</td>
</tr>
</tbody>
</table>

- **Follow-up, %:** 26, 12, 21, 12
- **Risk Reduction, %:** 44, 84, 100, 100
- **95% CI, %:** -31 to 77, 21 to 99, 86 to 100 (combined)

PrEP should not be offered as a sole intervention for HIV prevention. PrEP should only be prescribed as part of a comprehensive prevention plan.

PrEP may help protect the HIV seronegative partner in a serodiscordant relationship during attempts to conceive.

PrEP is indicated for individuals who have a documented negative HIV test result and are at ongoing high risk for HIV infection.

- A negative HIV test result needs to be confirmed as close to initiation of PrEP as possible, ideally on the same day the prescription is given.
- Clinicians should wait to prescribe PrEP until confirmation of a negative test result is available.
NYS DOH PrEP Guidance

- **Efficacy of PrEP is dependent on adherence.** PrEP should only be prescribed to those who are able to adhere to the regimen and express a willingness to do so.
- Although consistent condom use is a critical part of a prevention plan, **lack of use of barrier protection is not a contraindication to PrEP.**
- PrEP is contraindicated in individuals with documented HIV infection or creatinine clearance <60 mL/min, and in those who are not ready to adhere to daily PrEP.
- **The first prescription of PrEP** (Truvada 1 tablet PO daily) should only be for 30 days to allow for a follow-up visit to assess adherence, tolerance, and commitment.
  - At the 30-day visit, a prescription for 60 days may be given; the **patient should then return for 3-month HIV testing** and other assessments.
  - After that visit, **prescriptions can be given for 90 days, provided that the patient is adherent.**
NYS DOH PrEP Guidance

- Patients receiving PrEP require regular visits, at least every 3 months, to monitor HIV status, adherence, and side effects. Follow-up and monitoring of patients receiving PrEP also includes prevention services that are part of a comprehensive prevention plan, such as risk-reduction counseling, access to condoms, STI screening, and mental health and substance use screening, when indicated.

- Whenever patients present with symptoms of acute HIV infection, an HIV serologic screening test should be used in conjunction with a plasma HIV RNA assay.

- Discontinue PrEP immediately for patients who receive a positive HIV test result. Obtain a genotypic assay, and refer and link to HIV care.

www.hivguidelines.org
Clinicians should discuss PrEP with the following non-HIV-infected individuals who have substantial and ongoing risk:

- Men who have sex with men (MSM) who engage in unprotected anal intercourse
- Individuals who are in a serodiscordant sexual relationship with a known HIV-infected partner
- Male-to-female and female-to male transgender individuals engaging in high-risk sexual behaviors
- Individuals engaging in transactional sex, such as sex for money, drugs, or housing
- Injection drug users who report any of the following behaviors: sharing injection equipment (including to inject hormones among transgender individuals), injecting one or more times per day, injecting cocaine or methamphetamine, engaging in high-risk sexual behaviors
- Individuals who use stimulant drugs associated with high-risk behaviors, such as methamphetamine
- Individuals diagnosed with more than one anogenital sexually transmitted infection in the last year
- Individuals who have been prescribed non-occupational post-exposure prophylaxis (nPEP) who demonstrate continued high-risk behavior or have used multiple courses of nPEP
NYSDOH – PrEP Prescribing

Table 3. Important Considerations when Prescribing PrEP

Does the patient have chronic active hepatitis B virus (HBV) infection? TDF/FTC is active against HBV infection.
- Although not FDA-approved for the treatment of HBV, TDF/FTC may be used simultaneously as treatment for HBV infection and as PrEP.
- Discontinuation of TDF/FTC requires close monitoring in patients with chronic hepatitis B infection because of the concern for rebound viremia.

Is the patient pregnant or attempting to conceive? PrEP may be one of several options to help protect the HIV seronegative partner from acquiring HIV infection in serodiscordant couples during attempts to conceive.
- If a woman is pregnant when starting PrEP or becomes pregnant while on PrEP, discuss the known risks and benefits of taking TDF/FTC during pregnancy (see bottom of Table 5)
- After discussing the potential risks of TDF/FTC, recommend continuation of PrEP during pregnancy or breastfeeding for those with ongoing risk for HIV.
- Providers should report information regarding use of PrEP during pregnancy to the Antiretroviral Pregnancy Registry

Is the patient an adolescent?
- PrEP has not been studied in individuals younger than 18 years of age.

Is the patient taking concomitant nephrotoxic drugs or drugs that have interactions with TDF/FTC?
- Obtain a thorough medication history

Does the patient have osteopenia/osteomalacia/osteoporosis? There may be a risk of bone loss associated with tenofovir.
- Discuss risk of bone loss with individuals with pre-existing risk factors or demonstrated osteoporosis/osteomalacia/osteopenia.
NYSDOH – Pre Prescription Resources

- Pre-Prescription Assessment Checklist
- Pre-Prescription Patient Education Checklist
- Pre-Prescription Lab Checklist
CDC PrEP Guidelines
2014 CDC PrEP Guidelines

- PrEP Guidelines released in May 2014
- Addresses the role of tenofovir/emtricitabine in the following adult populations
  - Men who have sex with men
  - Heterosexual men and woman
  - Injection Drug Users
  - Sero-discordant couples

2014 CDC PrEP Guidelines – Indications for PrEP Use in MSM

- Adult man AND
  - Without acute or established HIV infection
  - Any male sex partners in past 6 months
  - 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

2014 CDC PrEP Guidelines – Indications for PrEP, Heterosexual Men and Women

• Adult person AND
  • 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)
• 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

2014 CDC PrEP Guidelines – Indications for PrEP Use IVDUs

- 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

2014 CDC PrEP Guidelines –

Monitoring

All patients receiving PrEP should be seen as follows:
At least every 3 months to
• Repeat HIV testing and assess for signs or symptoms of acute infection to document that patients are still HIV negative
• Repeat pregnancy testing for women who may become pregnant
• Provide a prescription or refill authorization of daily TDF/FTC for no more than 90 days (until the next HIV test)
• Assess side effects, adherence, and HIV acquisition risk behaviors
• Provide support for medication adherence and risk-reduction behaviors
• Respond to new questions and provide any new information about PrEP use

2014 CDC PrEP Guidelines – Monitoring

At least every 6 months to
- Monitor eCrCl
- If other threats to renal safety are present renal function may require more frequent monitoring or may need to include additional tests
- A rise in serum creatinine is not a reason to withhold treatment if eCrCl remains ≥60 ml/min.
- If eCrCl is declining steadily (but still ≥60 ml/min), consultation with a nephrologist may be indicated.
- Conduct STI testing recommended for sexually active adolescents and adults (i.e., syphilis, gonorrhea, chlamydia)

At least every 12 months to
- Evaluate the need to continue PrEP as a component of HIV prevention
2014 CDC PrEP Guidelines – Risk Reduction Counseling

Establish trust and 2-way communication and provide feedback on HIV risk factors identified during 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 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

PrEP Reimbursement

- Patient assistance available through manufacturer
  - 866.290.4767
- Government pricing available for community clinics
- Most private insurances are providing coverage
- NYS program to pay for labs, visits associated with PrEP
Summary: PrEP and the Pharmacist – Counselling Points

- Truvada, once daily established, max of 90 day supply (30 with 2 refills)
- HIV testing required quarterly
- Prevention package with other risk reduction strategies included
- Nausea; Renal and bone adverse events long term a possible issue
Summary: PrEP and the Pharmacist – Counselling Points

- Repeat pregnancy testing for women who may become pregnant every 3 months
- Assess adherence and HIV acquisition risk behaviors
- Provide support for medication adherence and risk-reduction behaviors
- Respond to new questions and provide any new information about PrEP use
Resources for You

Huldrych F. Günthard, MD*; Judith A. Aberg, MD*; Joseph J. Eron, MD*; Jennifer F. Hoy, MBBS, FRACP*; Arnaldo Telenti, MD, PhD*; Constance A. Benson, MD*; David M. Burger, PharmD, PhD*; Pedro Cafín, MD, PhD*; Joel E. Gallant, MD, MPH*; Marshall J. Glesby, MD, PhD*; Peter Reiss, MD, PhD*; Michael S. Saag, MD*; David L. Thomas, MD, MPH*; Donna M. Jacobsen, BS*; Paul A. Volberding, MD*  

http://aidsinfo.nih.gov/guidelines/
As part of a national network of 11 regional and 3 nat centers (and more than 100 associated sites) the NYNJ AETC conducts targeted, multi-disciplinary education training programs for healthcare providers treating people living with HIV/AIDS.

The NY/NJ AETC's mission is to assist health care professionals, through education and training, to provide optimum quality services and sensitive care to HIV- positive persons, and to provide access to current research and treatment of HIV/AIDS. We serve the New York and New Jersey healthcare community by providing AIDS and HIV education and training to treat, manage, diagnose, or counsel individuals with HIV infection or to help prevent HIV infection-related health and HIV transmission.
PSYCHIATRIC MEDICATIONS AND HIV ANTIRETROVIRALS
ADULT MANAGEMENT
Winter 2013
www.hiv-druginteractions.org

LATEST ARTICLES

Review - Pharmacology of integrase inhibitors

Drug Interactions - Lopinavir and etrionbopag


Meeting Report - 14th Workshop on HIV Comorbidities and ADRs, Washington

Drug Interactions - Lopinavir/r and Pitavastatin

Case Report - Fluticasone, fluconazole and ritonavir interactions.

Click here for previous news items

SITE UPDATES

ARVs for patients with swallowing difficulties.
We have produced a list of ARV formulations that can be used for patients who have difficulty swallowing...

Expanded General Anaesthetics Section The General Anaesthetics section has been expanded to include muscle relaxants and additional genera...

FOLLOW US ON TWITTER

For the latest additions and updates to the site, click the button to follow hivinteractions on Twitter.
CEI
Clinical Education Initiative
NYS Department of Health - AIDS Institute
WWW.CEITRAINING.ORG

CLINICAL INQUIRY FOR: HIV • HCV • STD • PEP • PrEP

CEI LINE
1-866-637-2342

ASK AN EXPERT
Call for a clinical inquiry regarding your patient with an STD, HIV, HCV, or those in need of PEP or PrEP

866-637-2342 WWW.CEITRAINING.ORG
Questions?