PEP & PrEP
From Guidelines to Practice

A.E. Radix, MD, MPH
Callen-Lorde Community Health Center
Disclosure

No financial conflicts to disclose
Learning objectives

Upon completion of this presentation, learners should be better able to:

• Analyze the rationale for FDA approval of PrEP

• Identify individuals who are eligible for PrEP/PEP

• Review guidelines for the use of PrEP/PEP

• State the evaluation and monitoring required for prescribing PrEP/PEP
Have you prescribed post-exposure prophylaxis (PEP) in the last year?

1. No
2. 1-5 patients
3. 5-10 patients
4. More than 10 patients
Have you prescribed pre-exposure prophylaxis (PrEP) in the last year?

1. No
2. 1-5 patients
3. 5-10 patients
4. More than 10 patients
Greg

- 34 year old gay male presents **28 hours** after engaging in condomless anal receptive sex with male partner he met on Scruff
- He doesn’t know the status of his sex partner
- No significant PMH
- He is uninsured
What are you going to do?

1. Rapid HIV test, if negative start zidovudine, lamivudine, tenofovir
2. Rapid HIV test, if negative start emtricitabine, tenofovir, raltegravir
3. Rule out acute seroconversion & obtain HIV RNA. Wait before starting emtricitabine, tenofovir, raltegravir
4. It is too late to initiate PEP
HIV Post-Exposure Prophylaxis (PEP)

The use of ARVs to prevent infection following exposure to HIV

• Occupational (oPEP)
  – percutaneous (needlestick, sharp objects), splashes

• Non-occupational (nPEP)
  – Sexual, needle sharing
Questions

• What is the risk of HIV transmission?
• Is PEP effective? When to start?
• What is the preferred regimen?
• How do you get ARVs for an uninsured patient?
• What is needed for monitoring?
## What is the Risk of HIV transmission?

<table>
<thead>
<tr>
<th>Type of Exposure</th>
<th>Risk of a Single Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receptive anal intercourse</td>
<td>0.5% - 3%</td>
</tr>
<tr>
<td>Insertive anal intercourse</td>
<td>0.06 –0.62%</td>
</tr>
<tr>
<td>Receptive penile-vaginal intercourse</td>
<td>0.1%</td>
</tr>
<tr>
<td>Insertive penile-vaginal intercourse</td>
<td>0.05%</td>
</tr>
<tr>
<td>Receptive oral intercourse</td>
<td>0.005-0.01%</td>
</tr>
<tr>
<td>Insertive oral intercourse</td>
<td></td>
</tr>
</tbody>
</table>

Other factors that increase risk

- High viral load of source
- Other sexually transmitted infections
Is PEP effective?

• Animal studies – reduction in SIV in Macaques
  – No seroconversions if treated within 36 hours
  – Infections occurred with treatment delays, shorter course (10 days)

• Brazil study 202 MSM receiving PEP, 81% fewer seroconversions on those who took nPEP

• CDC case-control study – AZT reduced transmission 81%

HIV Prophylaxis Following Non-Occupational Exposure

**STEP 1:** Evaluation of exposure: Is nPEP indicated?

**LOWER-RISK EXPOSURES:**
- Oral-vaginal contact (receptive and insertive)
- Oral-anal contact (receptive and insertive)
- Receptive penile-oral contact with or without ejaculation
- Insertive penile-oral contact with or without ejaculation

**HIGHER-RISK EXPOSURES:**
- Rectal and insertive vaginal or anal intercourse with HIV+ or unknown source
- Needle sharing with HIV+ or unknown source
- Injuries with exposure to blood or other potentially infected fluids from HIV+ or unknown source (including needlesticks with a hollow-bore needle, human bites, accidents)

**EXPOSURES THAT DO NOT WARRANT nPEP:**
- Oral-to-oral contact without mucosal damage (kissing or mouth-to-mouth resuscitation)
- Human bites not involving blood
- Exposure to solid-bore needles or sharps not in recent contact with blood
- Mutual masturbation without skin breakdown or blood exposure

Provide risk-reduction counseling and offer HIV test.

**STEP 2:** Is patient presenting within 36 hours?

**YES**

**STEP 3:** Initiate first dose of nPEP regimen

28-DAY REGIMEN — Recommended PEP Regimen
- Tenofovir 300 mg PO qd + Emtricitabine* 200 mg PO qd
- Plus
- Raltegravir* 400 mg PO bid or Dolutegravir* 50 mg PO qd

See Tables 4 and 5 for alternative regimens.

**STEP 4:** Baseline testing

**BASELINE TESTING OF EXPOSED PERSON:**
- HIV test
- Pregnancy test for women
- GC/CT NAAT (based on site of exposure)
- RPR for syphilis

*nPEP should not be continued in those who decline baseline HIV testing

See Section IX for hepatitis B and C post-exposure management.

**SOURCE TESTING, if source is available:**
- Obtain HIV test with turnaround time <1 hour
- If the test results are not immediately available, continue exposed person’s nPEP while awaiting results
- If the source person’s HIV screening test result is negative but there may have been exposure to HIV in the previous 6 weeks, obtain plasma HIV RNA assay
- Continue exposed person’s nPEP until results of the plasma HIV RNA assay are available

**STEP 5:** Provide risk-reduction counseling

- Provide risk-reduction and primary prevention counseling
- Refer for mental health and/or substance use programs when indicated; consider need for intensive risk-reduction counseling services
- Discuss future use of PrEP with persons with ongoing risk behavior (see Appendix C for AI-funded referral sources)

NYSDOH 2014

Consideration of nPEP

**PEP Recommended**
- Receptive and insertive vaginal or anal intercourse
- Needle sharing
- Injuries with exposure to blood or other potentially infected fluids from a source known to be HIV-infected or HIV status is unknown

**Lower-Risk Exposures** (Case-by-Case Evaluation for nPEP)
- Oral-vaginal contact (receptive and insertive)
- Oral-anal contact (receptive and insertive)
- Receptive penile-oral contact with or without ejaculation
- Insertive penile-oral contact with or without ejaculation

**PEP not Recommended**
- Kissing
- Oral-to-oral contact without mucosal damage (mouth-to-mouth resuscitation)
- Human bites not involving blood

NYSDOH 2014
Testing (Exposed)

Baseline Labs
• HIV Testing
• STI Testing (not assault)
  – CT/GC NAAT, RPR
• CBC, Serum liver enzymes, BUN, creatinine
• Pregnancy test
• Assess Hep B/C

Follow-up Labs
• HIV Testing @ 4 weeks, 12 weeks – lab based
• Serum liver enzymes, BUN, creatinine @ 2 weeks, 4 weeks
• Consider STI screen @ 2 weeks

Evaluate weekly while receiving PEP to assess treatment adherence, side effects of treatment, interval physical complaints, and emotional status
Which of these antiretroviral regimens should be avoided as PEP?

1. Tenofovir, atazanavir, ritonavir
2. Raltegravir, emtricitabine, tenofovir
3. Abacavir, lamivudine, nevirapine
4. Lamivudine, zidovudine, raltegravir
## ART to Avoid

<table>
<thead>
<tr>
<th>Drug</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Efavirenz</strong></td>
<td>Poor adherence&lt;br&gt;CNS side effects&lt;br&gt;Avoid in first 6 weeks of pregnancy and in women of childbearing potential&lt;br&gt;Substantial EFV resistance in community HIV isolates</td>
</tr>
<tr>
<td><strong>Nevirapine</strong></td>
<td>Contraindicated for use in PEP due to potential for severe hepatotoxicity</td>
</tr>
<tr>
<td><strong>Abacavir</strong></td>
<td>Potential for hypersensitivity reactions</td>
</tr>
<tr>
<td><strong>Stavudine, didanosine</strong></td>
<td>Possibility of toxicities</td>
</tr>
<tr>
<td><strong>Nelfinavir, indinavir</strong></td>
<td>Poorly tolerated</td>
</tr>
<tr>
<td><strong>CCR5 co-receptor antagonists</strong></td>
<td>Lack of activity against potential CXCR4 tropic virus</td>
</tr>
</tbody>
</table>
Preferred PEP Regimens

Tenofovir 300 mg PO daily + Emtricitabine 200 mg PO daily

Plus

Raltegravir 400 mg PO twice daily or Dolutegravir 50 mg PO daily

The preferred alternative PEP regimen is tenofovir + emtricitabine* plus ritonavir-boosted darunavir, atazanavir, or fosamprenavir

NYSDOH 2014
PEP: When to Start

When?

- Ideally as soon as possible (2-4 hours)
- Not >72 hours (CDC), 36 hours (NYSDOH)
- Do not delay while awaiting results

WHAT?

- 3 active drugs

HOW LONG?

- 4 weeks
- Stop if source tests HIV-
Challenges of PEP: Cost

• Cost and insurance coverage remains #1 issue
  – Providers confused about payment options
    • Who gets funded PEP, co-pay cards, medication assistance programs (MAP)
  – MAP letters must be written, faxed
  – Prior authorizations
  – Exceptions to the mail order rule—takes time!
  – Frustrated patients
  – Meanwhile the clock is ticking ...
## Challenges of PEP: Cost

<table>
<thead>
<tr>
<th>Insurance</th>
<th>PEP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicaid</td>
<td>PEP is covered</td>
</tr>
<tr>
<td>Private Insurance</td>
<td>PEP coverage based on plans. Co-pay cards from manufacturers. May have mail order requirements</td>
</tr>
<tr>
<td>Insured, PEP not covered</td>
<td>Medication Assistance Programs (24-48 hours for raltegravir)</td>
</tr>
<tr>
<td>Medication Assistance Programs</td>
<td>Common patient assistance application</td>
</tr>
</tbody>
</table>
Sample letter for medication assistance program

May 02, 2014

Patient Name: John Doe
Patient DOB: 11/14/1977

To whom it may concern,

JOHN DOE is a patient at Callen-Lorde Community Health Center. JOHN DOE had an exposure to HIV on (date of exposure) and is a candidate for post-exposure prophylaxis (PEP). JOHN DOE is uninsured and unable to pay the cost of PEP.

PEP is medically necessary for this patient.

Sincerely,
PEP Summary

• Tenofovir + emtricitabine* plus raltegravir as the preferred initial PEP regimen
• HIV RNA for source person if risk behavior in the last weeks or suspected acute seroconversion
• Baseline STI testing is recommended
• Repeat HIV testing at 4 weeks and 12 weeks
• Consideration PrEP after completion of nPEP regimen in select patients
• Develop systems, e.g., starter packs, create form letters
Help!

PEPline at
http://www.nccc.ucsf.edu/about_nccc/pepline/
  – telephone: 888-448-4911

CEI PEP Line at 1-866-637-2342
Jamal
26 yo AA gay male was seen 5 months ago when he presented for PEP. He comes in today again requesting PEP. He engaged in condomless anal receptive sex 10 days ago with a partner of unknown HIV status. His rapid HIV test is negative. What do you do?

1. Prescribe PEP now
2. Prescribe PEP now and advise future consideration of PrEP
3. Not a candidate for PEP, offer PrEP after acute HIV infection ruled out
Need for Additional HIV Prevention Measures

• ~50,000 new HIV infections annually

• 63% of new HIV infections are in MSM
  – 12% increase among MSM
  – 22% increase among MSM age 13-24
  – Young AA MSM disproportionately represented

• 25% of new infections in heterosexual men and women
  – 66% African American

Pre-exposure Prophylaxis

Why do we need PrEP if we have TasP?

- 20% of HIV+ individuals in the US don’t know their status
- Majority of transmission in USA linked to sources undiagnosed/not in care
- There are still significant disparities in access to care
- Not all PLHIV want to start meds at high CD4 counts
- Modeling suggests synergy rather than competition
FDA Approval

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
Questions about PrEP

• Does PrEP work?
• What about real world effectiveness?
• What are the adverse effects?
  – Resistance
  – Risk compensation?
• Who pays for PrEP?
Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men

iPREX Trial

• Phase 3, double-blind, randomized, placebo-controlled, 11 sites in 6 countries, n=2499

• Adult HIV Neg MSM or transgender women in the US, Peru, Ecuador, Brazil, Thailand, South Africa

• Two study arms:
  – TDF/FTC (300mg/200mg) orally once daily
  – Placebo

• Primary Outcome: Prevention of HIV

IPREX Results: Safety

- TDF/FTC was well tolerated
  - GI-Nausea (2% vs <1%) and weight loss >5% (2% vs 1%)
  - No differences in severe (grade 3) or life-threatening (grade 4) laboratory abnormalities
  - Renal safety
    - no cases of RTA.
    - 10 subjects (7 tdf/ftc, 3 placebo) discontinued for creatinine elevation,
      - all resolved, 9 reinitiated treatment

IPREX results: Resistance

No drug resistant virus was found in the 100 participants infected after enrollment

11 subjects infected at entry (unrecognized acute HIV)
3/11 developed resistance mutations
   3 M184V, NO K65R

Rule out acute HIV infection in patients initiating PrEP!!

Risk Compensation

Condom use with high risk sex
# PrEP: Results from Clinical Trials

<table>
<thead>
<tr>
<th>Clinical trial</th>
<th>Participants</th>
<th>Number</th>
<th>Drug</th>
<th>mITT a efficacy of % reduction in acquisition of HIV infection b</th>
<th>Adherence adjusted efficacy based on TDF detection in blood c</th>
</tr>
</thead>
<tbody>
<tr>
<td>iPrEx</td>
<td>Men who have sex with men (MSM)</td>
<td>2499</td>
<td>TVD</td>
<td>42 (15-63)</td>
<td>92 (40-99)</td>
</tr>
<tr>
<td>Partners PrEP</td>
<td>HIV discordant couples</td>
<td>4747</td>
<td>TDF</td>
<td>67 (44-81)</td>
<td>86 (67-94)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>TVD</td>
<td>75 (55-87)</td>
<td>90 (58-98)</td>
</tr>
<tr>
<td>TDF 2</td>
<td>Heterosexually active men and women</td>
<td>1200</td>
<td>TVD</td>
<td>63 (22-81)</td>
<td>85d NS</td>
</tr>
<tr>
<td>Bangkok Tenofovir Study</td>
<td>IDU</td>
<td>2413</td>
<td>TDF</td>
<td>49 (10-72)</td>
<td>74 (17-94)</td>
</tr>
<tr>
<td>Fem-PrEP</td>
<td>Heterosexually active women</td>
<td>1951</td>
<td>TVD</td>
<td>NR -----</td>
<td>NR -----</td>
</tr>
<tr>
<td>VOICE</td>
<td>Heterosexually active women</td>
<td>5029</td>
<td>TVD</td>
<td>NR -----</td>
<td>NR -----</td>
</tr>
</tbody>
</table>

- **a.** Modified Intent to Treat
- **b.** Excluded only those enrolled patients later found to be infected at randomization and those with no follow-up visit or HIV test
- **c.** The percentage of reduction in HIV incidence among those with TFV detected in blood, compared with those without detectable TFV
- **d.** Finding not statistically significant

HIV Incidence and Drug Concentrations

Participants in randomized placebo-controlled iPrEx, ATN 089, or US PrEP Safety trials were enrolled in the 72-week open label extension (iPrEx OLE).

No infections in those with drug levels equal to ≥4 tabs/wk

<table>
<thead>
<tr>
<th>Drug Concentration</th>
<th>none</th>
<th>&lt;2 pills/week</th>
<th>2-3 pills/week</th>
<th>≥ 4 pills/week</th>
<th>7 pills/week</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Incidence per 100 PY (95%CI)</td>
<td>4.7 (2.99-7.76)</td>
<td>2.25 (1.19-4.79)</td>
<td>0.56 (0.00-2.50)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Risk Reduction (95%CI)</td>
<td>44% (-31-77)</td>
<td>84% (21-99)</td>
<td></td>
<td>100% (86-100)</td>
<td></td>
</tr>
</tbody>
</table>

Note: Recommended dose of TVD for PrEP in HIV-1 uninfected adults: One tablet once daily taken orally with or without food.
New Options for Dosing “On Demand”

• Taking PrEP “on demand” could improve adherence, cost effectiveness and safety (less drug exposure)

• Studies in macaques – double dose of oral TDF/FTC effective against rectal SHIV exposures

Garcia-Lerma. Sci Transl Med. 2010 Jan 13;2(14)
**IPERGAY**

Effectiveness of “on demand” PrEP
Randomized placebo-controlled trial

- High risk MSM
- Condomless anal sex with ≥ 2 partners within 6 m
- eGFR > 60 mL/mn

- Full prevention services* TDF/FTC before and after sex (n=950)
- Full prevention services* placebo before and after sex (n=950)

- Counseling, testing for STI, condoms, vaccination, PEP, self-support groups
- Follow-up visits month 1, 2, every 2 months
Ipergay: Event-Driven iPrEP

2 tablets (Truvada® / placebo) 2-24 hours before sex
1 tablet (Truvada® / placebo) 24 hours later
1 tablet (Truvada® / placebo) 48 hours later
Retention rate = around 85 %
Study Endpoints

• Primary Efficacy Endpoint: HIV-1 infection

• Secondary end points
  – Safety and tolerability
  – Adherence
  – Sexual behavior
  – STIs

October 2014: DSMB recommends discontinuation of study arm and PrEP offered to everyone
Mean follow-up of 13 months: 16 subjects infected 14 in placebo arm (incidence: 6.6 per 100 PY), 2 in TDF/FTC arm (incidence: 0.94 per 100 PY)

86% relative reduction in the incidence of HIV-1 (95% CI: 40-99, p=0.002) 
NNT for one year to prevent one infection: 18
Outcomes

• 276 STIs in 141 participants
  – similar rates of STIs (GC, CT, RPR, HCV) in both arms

• Adherence = 45% used PrEP correctly
  – 16 pills taken per month

• Mild GI adverse effects and grade 1 creatinine elevation using iPrEP
Pragmatic Open-Label Randomised Trial of Pre-Exposure Prophylaxis: the PROUD study

• If PrEP effective in real life settings??
  – Adherence may be worse outside of a clinical trial

• Demonstration project conducted in 220 sexual health clinics across England

http://www.proud.mrc.ac.uk/
**PROUD Pilot**

GMSM reporting UAI last/next 90 days; 18+; and willing to take a pill every day

Randomize HIV negative MSM (exclude if treatment for HBV/Truvada contra-indicated)

Risk reduction includes Truvada **NOW**  
Risk reduction includes Truvada **AFTER 12M**

Follow **3 monthly** for up to 24 months

Main endpoints in Pilot: recruitment and retention  
From April 2014: HIV infection in first 12 months
PROUD Pilot

Participant randomization

545 enrolled

276 assigned to IMMEDIATE

269 assigned to DEFERRED

- Used routine clinic data, 4th generation HIV screen (P24Ag/Ab)
- Serum creatinine at start, annually. UA for protein
- STI screen quarterly
- Offered behavior interventions, adherence support
• High rates of adherence to clinic follow-up in both groups
• 3/6 seroconverted at baseline developed 184V/I

**HIV incidence**

1.3/100 P-Y immediate
8.9/100 P-Y deferred

**Efficacy = 86% (95% CI: 58-96%)**
• No evidence of risk compensation
  – STIs & reported condomless anal sex did not differ
CDC recommends initiation of PrEP for the following individuals

• Is in an ongoing relationship with an HIV-infected partner

• Is not in a mutually monogamous relationship with a partner who recently tested HIV-negative, and who is:

  – A gay or bisexual man who has had sex without a condom or been diagnosed with a sexually transmitted infection within the past six months.

  – A heterosexual man or woman who does not regularly use condoms when having sex with partners known to be at risk for HIV (for example, injecting drug users or bisexual male partners of unknown HIV status) or whose partners are from communities with high rates of HIV infection.

  – Has injected illicit drugs within the past six months and has shared equipment or been in drug treatment within the past six months.

## PrEP Guidelines 2014 – Recommendations

<table>
<thead>
<tr>
<th>Detecting Substantial 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>• HIV-positive sexual partner</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>• Recent bacterial STI</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>• High number of sex partners</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• History of inconsistent or no condom use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Commercial sex work</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• In high-prevalence area or network</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Detecting Substantial risk of acquiring HIV infection</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Clinically eligible</td>
<td>Documented negative HIV test result before prescribing PrEP</td>
<td>No signs/symptoms of acute HIV infection</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Normal renal function; no contraindicated medications</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Documented hepatitis B virus infection and vaccination status</td>
<td></td>
</tr>
<tr>
<td>Prescription</td>
<td>Daily, continuing, oral doses of Truvada, ≤90-day supply</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prescription</td>
<td></td>
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<tr>
<td>Other services</td>
<td>Follow-up visits at least every 3 months to provide the following:</td>
<td>HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STI symptom assessment</td>
<td></td>
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<tr>
<td></td>
<td>At 3 months and every 6 months thereafter, assess renal function</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Every 6 months, test for bacterial STIs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do oral/rectal STI testing</td>
<td>Assess pregnancy intent</td>
<td>Access to clean needles/syringes and drug treatment services</td>
<td></td>
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<tr>
<td></td>
<td>Pregnancy test every 3 months</td>
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# PrEP Related ICD-9 Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>V01</td>
<td>Contact with or exposure to communicable diseases</td>
</tr>
<tr>
<td>E920.5</td>
<td>Needlestick</td>
</tr>
<tr>
<td>V15.85</td>
<td>Exposure to potentially hazardous body fluid</td>
</tr>
<tr>
<td>V01.8</td>
<td>Exposure to other communicable diseases</td>
</tr>
<tr>
<td>V01.7</td>
<td>Exposure to other viral diseases</td>
</tr>
<tr>
<td>V07.8</td>
<td>Other specified prophylactic measure</td>
</tr>
<tr>
<td>V07.9</td>
<td>Unspecified prophylactic measure</td>
</tr>
</tbody>
</table>
## Resources: Accessing TDF/FTC

<table>
<thead>
<tr>
<th></th>
<th>Gilead PrEP Medication Assistance Program</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Eligibility Criteria</strong></td>
<td>US resident, uninsured or no drug coverage, HIV-negative, low income</td>
</tr>
<tr>
<td><strong>Drug Fulfillment</strong></td>
<td>Covance Specialty Pharmacy, labeled for individual patient use and shipped to Prescriber</td>
</tr>
<tr>
<td><strong>Recertification</strong></td>
<td>6 months, with 90 day status check</td>
</tr>
</tbody>
</table>

http://www.truvada.com/starting-truvada
**INSURED**

**Patient Access Network Foundation**

PAN, a non-profit organization provides assistance through The HIV Treatment and Prevention Fund for PrEP and PEP for uninsured populations.

**Eligibility**

- HIV Negative
- 18+
- US Resident
- Less than $58,000
- Insured and insurance will cover medication.

**Gilead Co-Pay Card**

Gilead, the maker of Truvada (the drug used for PrEP) has a co-pay program that will help you with your insurance co-pays.

**Eligibility**

- HIV Negative
- 18+
- US Resident

- Can not be enrolled in any government prescription assistance program
- Must be insured

**Truvada Medication Assistance Program**

MAP assists eligible HIV-negative adults in the United States who do not have insurance obtain access to Truvada for PrEP.

**Eligibility**

- HIV Negative
- 18+
- New York Resident
- Income less than $51,000
PrEP Assistance Program (PrEP-AP)
PrEP-AP pays for the HIV testing, counseling, STI/STD testing and other primary care services that are related to PrEP-AP.

Eligibility
- HIV Negative
- 18+
- US Resident
- Less than $58,000
- Uninsured or insurance will not cover medication.

Patient Access Network Foundation (PAN)
PAN, a non-profit organization provides assistance through The HIV Treatment and Prevention Fund for PrEP and PEP for underinsured populations.

Eligibility
- HIV Negative
- 18+
- US Resident
- Less than $58,000
- Insured and insurance will cover medication.

Truvada Medication Assistance Program (MAP)
MAP assists eligible HIV-negative adults in the United States who do not have insurance obtain access to Truvada for PrEP.

Eligibility
- HIV Negative
- 18+
- New York Resident
- Income less than $51,000

Out-of-Pocket $1300-1500/ month
The Future of PrEP

• Intermittent PrEP
• Additional agents for PrEP
• Long acting agents under investigation
  – Injectable rilpivirine, GSK 744
• Topical antivirals- vaginal rings, anal preparations
Conclusion

- Daily oral Truvada for PrEP shown to be safe and effective in reducing the risk of sexual HIV acquisition in adults if medication adherence is high.

- HIV status, renal labs, and HBV status must be assessed prior to PrEP initiation. HIV negative status and renal function should be monitored regularly.

- Resistance is more prevalent with undiagnosed HIV-1 infection, prior to initiating PrEP.
Resources

• HIVguidelines.org

• CDC.gov/hiv/pdf/PrEPProviderSupplement2014.pdf
  Pre-exposure Prophylaxis for the Prevention of HIV infection in the United States: Clinical Provider’s Supplement
  Initiation checklist, patient contract, FAQ’s for patients, medication information sheet, Acute HIV, PrEP during Conception, Pregnancy and Breastfeeding,
Thank you!

Special thanks to Dr Anthony Urbina for sharing his PrEP webinar slides, Dr Rona Vail, Sarit Golub & Dr. GM from whom I borrowed liberally for this presentation.
HCV Exposure

- If the source is known to be positive for HCV antibody and/or HCV RNA, the follow-up schedule for the exposed person should be as follows:
  - Week 4: HCV RNA and liver panel
  - Week 12: HCV RNA and liver panel
  - Week 24: Liver panel and HCV antibody
Results

**HIV Incidence**

<table>
<thead>
<tr>
<th>Group</th>
<th>Infections, n</th>
<th>Follow-up (PY)</th>
<th>Incidence/100 person-years (90% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>22</td>
<td>453</td>
<td>4.9 (3.4-6.8)</td>
</tr>
<tr>
<td>Immediate</td>
<td>3</td>
<td>239</td>
<td>1.3 (0.4-3.0)</td>
</tr>
<tr>
<td>Deferred</td>
<td>19</td>
<td>214</td>
<td>8.9 (6.0-12.7)</td>
</tr>
</tbody>
</table>

- Use of post-exposure prophylaxis by arm:
  - IMM: 13 subjects (5%); 15 prescriptions
  - DEF: 83 subjects (31%); 174 prescriptions

86% (90% CI: 58%-96%) Risk Reduction; \( P=0.0002 \)
Number needed to treat=13 (90% CI: 9-25)

McCormack S, et al. CROI 2015; Seattle, WA. #22LB
IPERGAY: On-Demand PrEP

Adherence to PrEP Surrounding Recent Sexual Intercourse

<table>
<thead>
<tr>
<th>PrEP use, % (min-max)</th>
<th>TVD n=649 sex events</th>
<th>Placebo n=563 sex events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correct use*</td>
<td>45 (36-57)</td>
<td>40 (22-49)</td>
</tr>
<tr>
<td>Suboptimal use</td>
<td>27 (14-35)</td>
<td>31 (18-44)</td>
</tr>
<tr>
<td>No PrEP</td>
<td>27 (15-37)</td>
<td>29 (24-44)</td>
</tr>
</tbody>
</table>

*According to the protocol or at least one pill before and one pill after sex

“On demand PrEP” was not used as indicated by the protocol for almost 60% of the 1,212 sexual events reported by the 319 participants

Molina J, et al. CROI 2015; Seattle, WA. #23LB