PREVENTION OF HIV IN THE TIMES OF PREP

Daniela Chiriboga, MD
Florida Department of Health in Polk County
MAKING THE CASE FOR PREVENTION
The Epidemic in Florida

Population in 2014: 19.6 million →
(3rd in the nation)

Newly diagnosed** HIV infections in 2014: 5,897
(1st in the nation in 2013)

Newly diagnosed** AIDS cases in 2014: 2,349
(1st in the nation in 2013)

Cumulative pediatric AIDS cases diagnosed ** through 2014: 1,548
(2nd in the nation in 2013)

Persons diagnosed and living*** with HIV disease through 2014: 110,000 →
(3rd in the nation in 2013)

HIV prevalence estimate through 2014: 128,000
(accounts for 14% national estimated unaware of their status)

HIV Incidence Estimates in 2013: 4,120
(There was a 18% decrease from 2007-2013)

HIV-related deaths in 2014: 878
(Down 6% from 2013)

57% White
15% Black
24% Hispanic
4% Other*

30% White
47% Black
21% Hispanic
2% Other*

* Other = Asian/Pacific Islanders; American Indians/Alaskan Natives; multi-racial.
** Data by year of diagnosis for 2014, data as of 06/30/2015
*** Living (prevalence) data as of 06/30/2015
Polk HIV Infection Cases from 2007-2016

Female | Male | Overall
--- | --- | ---
2007 | 36 | 125
2008 | 59 | 172
2009 | 68 | 101
2010 | 70 | 100
2011 | 72 | 118
2012 | 66 | 86
2013 | 71 | 97
2014 | 61 | 84
2015 | 74 | 92
2016 | 89 | 122

2007-2016
HIV infection Cases (N = 122), from January – December, 2016
By Gender and Race/Ethnicity

**Male - HIV infection Cases, N = 89**
- Black: 51%
- White: 28%
- Hispanic: 19%
- Other: 2%

**Female - HIV Infection Cases, N = 33**
- Black: 67%
- White: 18%
- Hispanic: 11%
- Other: 1%
HIV Infection Cases By Gender and Age Group, 2016

Male HIV Infection Cases, N = 89
- Age 13-19: 7%
- Age 20-29: 42%
- Age 30-39: 25%
- Age 40-49: 25%
- Age 50+: 18%

Female HIV Infection Cases, N = 33
- Age 13-19: 3%
- Age 20-29: 10%
- Age 30-39: 14%
- Age 40-49: 25%
- Age 50+: 24%

Legend:
- Blue: Age 13-19
- Red: Age 20-29
- Green: Age 30-39
- White: Age 40-49
- Pink: Age 50+
### By Age Group

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Female N</th>
<th>Female %</th>
<th>Male N</th>
<th>Male %</th>
<th>Total N</th>
<th>Total %</th>
</tr>
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<tbody>
<tr>
<td>Age 0-12</td>
<td>1</td>
<td>&lt;1</td>
<td>3</td>
<td>&lt;1</td>
<td>4</td>
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<tr>
<td>Age 13-19</td>
<td>13</td>
<td>1</td>
<td>10</td>
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<td>Age 20-24</td>
<td>19</td>
<td>2</td>
<td>58</td>
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<td>77</td>
<td>3</td>
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<td>Age 25-29</td>
<td>50</td>
<td>6</td>
<td>113</td>
<td>7</td>
<td>163</td>
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<td>Age 30-39</td>
<td>131</td>
<td>16</td>
<td>233</td>
<td>15</td>
<td>364</td>
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<td>Age 40-49</td>
<td>233</td>
<td>29</td>
<td>331</td>
<td>22</td>
<td>564</td>
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<tr>
<td>Age 50-59</td>
<td>242</td>
<td>30</td>
<td>483</td>
<td>32</td>
<td>725</td>
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<td>Age 60+</td>
<td>117</td>
<td>14</td>
<td>294</td>
<td>19</td>
<td>411</td>
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<td>Total</td>
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<td>100</td>
<td>1525</td>
<td>100</td>
<td>2331</td>
<td>100</td>
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</table>

### By Race/Ethnicity

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Female N</th>
<th>Female %</th>
<th>Male N</th>
<th>Male %</th>
<th>Total N</th>
<th>Total %</th>
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<td>55</td>
<td>606</td>
<td>40</td>
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<tr>
<td>White</td>
<td>192</td>
<td>24</td>
<td>580</td>
<td>38</td>
<td>772</td>
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<td>Hispanic</td>
<td>148</td>
<td>18</td>
<td>313</td>
<td>20</td>
<td>461</td>
<td>20</td>
</tr>
<tr>
<td>Other</td>
<td>21</td>
<td>3</td>
<td>26</td>
<td>2</td>
<td>47</td>
<td>2</td>
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<tr>
<td>Total</td>
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<td>100</td>
<td>1525</td>
<td>100</td>
<td>2331</td>
<td>100</td>
</tr>
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### By Risk Factor

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Female</th>
<th>Female %</th>
<th>Male</th>
<th>Male %</th>
<th>Total</th>
<th>Total %</th>
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<tr>
<td>MSM</td>
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<td></td>
<td>N/A</td>
<td></td>
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<td>54</td>
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<td>MSM/IDU</td>
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<td></td>
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<tr>
<td>IDU</td>
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<td>13</td>
<td>104</td>
<td>7</td>
<td>212</td>
<td>9</td>
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<tr>
<td>Heterosexual Contact</td>
<td>602</td>
<td>75</td>
<td>368</td>
<td>24</td>
<td>970</td>
<td>42</td>
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<td>Perinatal Transmission</td>
<td>27</td>
<td>3</td>
<td>19</td>
<td>1</td>
<td>46</td>
<td>2</td>
</tr>
<tr>
<td>Other+NIR</td>
<td>69</td>
<td>9</td>
<td>125</td>
<td>8</td>
<td>194</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>806</td>
<td>100</td>
<td>1525</td>
<td>100</td>
<td>2331</td>
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</tr>
</tbody>
</table>
• 185,000 HIV infections in U.S. in next 5 years could be prevented by expanding testing, treatment, PrEP

According to Ben Young, chief medical officer of the International Association of Providers of AIDS Care (IAPAC), the world has everything it needs to end the HIV/AIDS epidemic and related deaths.
A FOUR-PRONGED STRATEGY TO PREVENT HIV
50,000 new infections per year

Number of Individuals

1,200,000
1,000,000
800,000
600,000
400,000
200,000
0

HIV-Infected 100%
HIV-Diagnosed 86%
Linked to HIV Care 80%
Retained in HIV Care 40%
Prescribed ART 37%
Undetectable Viral Load 30%
TREATMENT AS PREVENTION

• Those individuals who are HIV positive and have not yet been diagnosed or are not linked to care are responsible for 90% of new infections.

• Once virologically suppressed, an individual is 96% less likely to transmit HIV.

• Diagnosing HIV and linking to care is crucial in preventing transmission.
Florida’s Plan to Eliminate HIV Transmission and Reduce HIV-related Deaths

Four Key Components

1. Test and treat

2. Antiretroviral pre-exposure prophylaxis (PrEP), occupational post-exposure prophylaxis (oPEP) and non-occupational post-exposure prophylaxis (nPEP)

3. Routine HIV and STI screening in healthcare settings/targeted testing in non-healthcare settings

4. Community outreach and messaging
ROUTINE HIV TESTING IN THE HEALTHCARE SETTING
CDC HIV TESTING GUIDELINES

• All individuals aged 13-64 should be tested at least once

• Annual testing for those with risk factors:
  • MSM
  • HIV positive partner
  • More than 1 sex partner since last test
  • Injection drug users
  • Sex for money or drugs
  • Diagnosed or treated for another STD
  • Diagnosed or treated for hepatitis or TB
  • Had sex with someone with the above risk factors.

• Testing every 3-6 months for sexually active gay or bisexual men.

• Testing in pregnancy- 1\textsuperscript{st} and 3\textsuperscript{rd} trimester.
NO WRITTEN CONSENT IS NEEDED

• November 2016, Florida Statute 381.004
• No need for written informed consent
• Must inform verbally
• Opt-out testing.
TEST AND TREAT
Four Scenarios of the Potential Impact of Expanded HIV Testing, Treatment and PrEP in the United States, 2015-2020

- **New infections**
- **HIV infections prevented due to expanded testing and treatment**
- **HIV infections prevented due to PrEP (assumes PrEP use among high-risk populations = 40% MSM; 10% PWID; 10% HET)**

**Scenario 1:**
Projected new infections by 2020 at current testing and treatment rates

- Total number of new HIV infections, 2015-2020: 265,330

**Scenario 2:**
If PrEP use increases among high-risk populations at current testing and treatment rates

- 48,221 infections prevented through PrEP
- Total number of new HIV infections, 2015-2020: 217,109

**Scenario 3:**
If 85% of people diagnosed are linked to care, 60% achieve viral suppression, plus PrEP use

- 88,908 infections prevented through testing and treatment
- Total number of new HIV infections, 2015-2020: 144,434

**Scenario 4:**
Achieving NHAS goals — if 85% of people diagnosed are linked to care, 80% achieve viral suppression, plus PrEP use

- 16,928 infections prevented through PrEP
- Total number of new HIV infections, 2015-2020: 168,132

Source: Centers for Disease Control and Prevention

http://www.cdc.gov/nchhstp/newsroom/images/2016/croi_four_scenarios_graph.jpg
TEST AND TREAT MODEL

- Early initiation of therapy would:
  - Decrease morbidity and mortality
  - Decrease infectivity
  - In acute disease, limit reservoirs and hyperinfectivity

Study in San Francisco General. 2013-2014
HIV PRE-EXPOSURE PROPHYLAXIS (PREP)
PREP (PRE-EXPOSURE PROPHYLAXIS)

- TRUVADA (Tenofovir Disopropyl-Fumarate) and Emtricitabine
- If used daily, can prevent infection with HIV.
TARGET POPULATION

• Individuals in sero-discordant couples
• Gay or bisexual men who have unprotected anal sex and have had an STI in the past 6 months.
• Individuals having unprotected sex with people of unknown serostatus who are high risk for HIV.
• Individuals who use injection drugs or are in rehab.
DOES PREP WORK?

- Efficacy highly dependent on adherence.
- In 100% adherent patients, efficacy is very close to 100%.
- Less condom use = increase in STIs.
- Very few side effects
- Monitor for renal toxicity
Not enough health care providers know about PrEP.

Pre-exposure prophylaxis (PrEP) is a medicine taken daily that can be used to prevent HIV infection. PrEP is for people without HIV who are at very high risk for acquiring it from sex or injection drug use.

90% Daily PrEP can reduce the risk of sexually acquired HIV by more than 90%.

70% Daily PrEP can reduce the risk of HIV infection among people who inject drugs by more than 70%.

1 in 3 1 in 3 primary care doctors and nurses haven’t heard about PrEP.

SOURCE: CDC Vital Signs, Dec. 2015
CLINICAL ELIGIBILITY

• Documented negative HIV test
• No signs/symptoms of acute HIV infection
• Normal renal function (eCrCL >60)
• No contraindicated medications
• Documented hepatitis B infection and vaccination status.
INTIAL LABS

• HIV test
• Testing for gonorrhea, chlamydia, RPR.
• Testing for hepatitis B
• Renal function testing.
TRUVADA

• Tenofovir 300 mg and Emtricitabine 300 mg
• 90 day supply
• Side effects: Nausea, flatulence, rash, headache
• Tenofovir can cause Fanconi syndrome
• Long term effects: decrease in bone density
MONITORING- EVERY 3 MONTHS

Follow-up visits at least every 3 months to provide the following:
- HIV test
- Sexual history
- Medication adherence counseling
- Behavioral risk reduction support
- Side effect assessment
- STI symptom assessment
- Test for bacterial STIs every 3 months (Rectal/urethral/pharyngeal gonorrhea and chlamydia)
- At 3 months, and every 6 months thereafter, assess renal function
- HCV testing (at initial visit, then yearly)

<table>
<thead>
<tr>
<th>Oral/rectal STI testing if clinically indicated in addition to urine NAAT</th>
<th>MSM</th>
<th>FEMALES</th>
<th>IV DRUG USERS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Access to clean needles/syringes and drug treatment services
- Assess pregnancy intent
- Pregnancy test every 3 months
ARE YOU INSURED TO COVER YOUR COSTS FOR PrEP?

**YES**

1. Gilead Advancing Access Co-pay Card
   - gileadcopay.com
   - 877-505-6986
   - $3,600 max/calendar year
   - No income restrictions
   - Covers co-pays, deductibles and co-insurance
   - Reapply if needed
   - Proof of US residence (utility bill, etc.)
   - Not used with state/federal plans, such as Medicare (apply to PAF or PAN Foundation).

2. Patient Advocate Foundation (PAF)
   - https://www.copays.org/diseases/hiv-aids-and-prevention
   - $7,500 max/year for those enrolling after Feb 2016
   - $5,000 max/year (until Jan 2017) for those who enrolled before Feb 2016
   - Family income < 400% FPL, though takes cost of living into consideration for some people
   - Based on taxable income (1040 line 7, 1040 EZ line 1)
   - Must be insured
   - Covers co-pays only
   - Proof of US residence (utility bill, etc.)
   - Case managers available to help resolve medical costs issues (800-552-5274)

3. Patient Access Network (PAN) Foundation
   - panfoundation.org/hiv-treatment-and-prevention
   - 866-316-7263
   - As of March 2016, PAN stopped enrolling new applicants and re-enrolling continuing applicants due to a lack of funds. We will update this chart should PAN re-open this program.

**NO**

U.S. RESIDENT?

- [ ] Enroll in Medicaid if eligible
  - www.medicaid.gov
- [ ] Enroll in an insurance marketplace plan
  - www.healthcare.gov

If you have no health insurance and you generally have higher costs. Silver plans will offer lower costs for people earning up to 250% FPL ($29,425). Gold & Platinum plans offer better coverage if you can afford them. Carefully select the right plan for you.

IF NO

NON-RESIDENT/UNDOCUMENTED?

- [ ] Check if you’re eligible for your state Medicaid plan.
- [ ] Check if you can get an insurance plan through marketplace/employer.

**WHAT’S THE DATE?**

- **NOV 1 – JAN 31**
  - Enroll in Medicaid if eligible
    - www.medicaid.gov

- **FEB 1 – OCT 31**
  - below 138% FPL/yr
    - (≤ 138% FPL)
  - above 138% FPL/yr
    - (> 138% FPL)

**WHO HAS 500% FPL?**

- [ ] Enroll in the Gilead MAP
  - www.truvada.com/truvada-patient-assistance
  - only drug costs

**IF YOU’RE A RESIDENT, THESE STATE PLANS MAY ALSO HELP:**


**UPDATED AS OF MAY 17, 2016**
BILLING FOR PREP

<table>
<thead>
<tr>
<th>ICD-9</th>
<th>DESCRIPTION</th>
<th>ICD-10</th>
<th>DESCRIPTION</th>
<th>CPT</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>V69.2</td>
<td>High-risk sexual behavior</td>
<td>Z72.5</td>
<td>High-risk sexual behavior</td>
<td>99401</td>
<td>Preventive counseling (15 minutes)</td>
</tr>
<tr>
<td>V01.79</td>
<td>Exposure to other viral diseases (including HIV)</td>
<td>Z20.82</td>
<td>Contact with and (suspected) exposure to other viral communicable diseases</td>
<td>99402</td>
<td>Preventive counseling (30 minutes)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>99403</td>
<td>Preventive counseling (45 minutes)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>99404</td>
<td>Preventive counseling (60 minutes)</td>
</tr>
</tbody>
</table>
DISCONTINUING PREP

• Re-asses need for PREP annually
• Beware of Hepatitis B infection
INDIVIDUALS WHO TEST POSITIVE FOR HIV ON PREP

• Rapid linkage to care
• Risk for NRTI resistance- 2 reported cases.

"The fact that this is the first case report among the tens of thousands of people now taking PrEP shows that it is very rare."
# RECOGNIZING ACUTE HIV

## Table 7: Clinical Signs and Symptoms of Acute (Primary) HIV Infection

<table>
<thead>
<tr>
<th>Features (%)</th>
<th>Overall (n = 375)</th>
<th>Male (n = 355)</th>
<th>Female (n = 23)</th>
<th>Route of transmission</th>
<th>Injection Drug Use (n = 34)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever</td>
<td>75</td>
<td>74</td>
<td>83</td>
<td>77</td>
<td>50</td>
</tr>
<tr>
<td>Fatigue</td>
<td>68</td>
<td>67</td>
<td>78</td>
<td>71</td>
<td>50</td>
</tr>
<tr>
<td>Myalgia</td>
<td>49</td>
<td>50</td>
<td>26</td>
<td>52</td>
<td>29</td>
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<tr>
<td>Skin rash</td>
<td>48</td>
<td>48</td>
<td>48</td>
<td>51</td>
<td>21</td>
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<tr>
<td>Headache</td>
<td>45</td>
<td>45</td>
<td>44</td>
<td>47</td>
<td>30</td>
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<tr>
<td>Pharyngitis</td>
<td>40</td>
<td>40</td>
<td>48</td>
<td>43</td>
<td>18</td>
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<tr>
<td>Cervical adenopathy</td>
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<td>39</td>
<td>39</td>
<td>41</td>
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<tr>
<td>Arthralgia</td>
<td>30</td>
<td>30</td>
<td>26</td>
<td>28</td>
<td>26</td>
</tr>
<tr>
<td>Night sweats</td>
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<td>22</td>
<td>30</td>
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<tr>
<td>Diarrhea</td>
<td>27</td>
<td>27</td>
<td>21</td>
<td>28</td>
<td>23</td>
</tr>
</tbody>
</table>

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65. Further details on the table can be found in the original source.
PERICONCEPTIONAL USE OF PREP

• Data of PREP during pregnancy limited, but lots of data on Truvada use in HIV-positive pregnant women.
• Consider risk of HIV infection late in pregnancy - high risk of vertical transmission.
• Small amounts of drugs appear in breastmilk - 20% transmission if mother becomes infected while breastfeeding.
• If PREP is discontinued after conception - wait at least 1 month after last known exposure.
• More frequent HIV testing may be recommended in the pregnant female.
HIV NON-OCCUPATIONAL POST-EXPOSURE PROPHYLAXIS
N-PEP
N-PEP (NON-OCCUPATIONAL POST-EXPOSURE PROPHYLAXIS)

• Medication taken after an HIV exposure has occurred to prevent infection.
• Similar to occupational PEP
• Exposure must have occurred in the past 72 hours
### EVALUATING THE EXPOSURE

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

<table>
<thead>
<tr>
<th>LOWER-RISK EXPOSURES:</th>
<th>HIGHER-RISK EXPOSURES:</th>
<th>EXPOSURES THAT DO NOT WARRANT nPEP:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral-vaginal contact (receptive and insertive)</td>
<td>Receptive and insertive vaginal or anal intercourse with HIV+ or unknown source</td>
<td>Oral-to-oral contact without mucosal damage (kissing or mouth-to-mouth resuscitation)</td>
</tr>
<tr>
<td>Oral-anal contact (receptive and insertive)</td>
<td>Needle sharing with HIV+ or unknown source</td>
<td>Human bites not involving blood</td>
</tr>
<tr>
<td>Receptive penile-oral contact with or without ejaculation</td>
<td>Injuries with exposure to blood or other potentially infected fluids from HIV+ or unknown source (including needle sticks with a hollow-bore needle, human bites, accidents)</td>
<td>Exposure to solid-bore needles or sharps not in recent contact with blood</td>
</tr>
<tr>
<td>Insertive penile-oral contact with or without ejaculation</td>
<td></td>
<td>Mutual masturbation without skin breakdown or blood exposure</td>
</tr>
</tbody>
</table>

**STOP**

nPEP not indicated. Provide risk-reduction counseling and offer HIV test.

If nPEP is indicated, go to Step 2.

**STOP**

nPEP not indicated. Provide risk-reduction counseling and offer HIV test.
CLINICAL ELIGIBILITY

• Do not delay initiation of PEP to wait for tests
• Obtain baseline labs:
  • HIV test (4th generation)
  • CMP, CBC
  • STD testing
  • Hepatitis B and C testing
  • Pregnancy test
• Consider preventive treatment for STI and emergency contraception.
PREFERRED OPTIONS

PREFERRED HIV 3-DRUG nPEP REGIMEN

Tenofovir/Emtricitabine 300/200 mg (Truvada®) po daily
PLUS
[Raltegravir (Isentress®) 400 mg po twice a day OR dolutegravir (Tivicay®) 50 mg po daily]
SIDE EFFECTS

• TRUVADA- Nausea, headache, rash, flatulence.
• Dolutegravir- Insomnia, depression.
• Isentress- fatigue
TESTING

• Baseline
• 6 weeks, 12 weeks, 6 months
• Test regardless of n-PEP use.
• Check CMP at baseline, 2 weeks and 4 weeks.
• Consider re-testing for STDs.
PAYING FOR N-PEP

• Covered by Medicaid
• May have high co-pays for private insurance
  • Use resources such as manufacturer assistance programs.
• Patient assistance programs.
• Rape crisis victims-special funding may be available.
DISCONTINUING N-PEP

- Completed 28 days of therapy
- Source confirmed to be HIV negative.
- Missed 3 consecutive days of therapy.
- Decided not to take it / side effects.
GETTING HELP

nPEP Quick Help Card - FLORIDA

For timely answers for urgent HIV exposure management call:

- The Clinician Consultation Center PEPLINE -
  Phone Consultation
  (888) 448-4911
  9:00 a.m. – 2:00 a.m. (EST), seven (7) days a week
  http://nccc.ucsf.edu/clinical-resources/pep-resources/pep-quick-guide/