An HIV Post-Exposure Prophylaxis Pilot Program Implemented in Public Health Settings in Los Angeles

Jennifer N Sayles, MD, MPH, Gary P García, MPH, Rosemary C Veniegas, PhD, Robert K Bolan, MD, Wilbert C Jordan, MD, and Raphael J Landovitz, MD, MsC
HIV/AIDS Cases

Overall, Race/Ethnicity

<table>
<thead>
<tr>
<th>Population</th>
<th>Estimated HIV/AIDS Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>9,848,011</td>
<td>61,700</td>
</tr>
</tbody>
</table>

Overall, Race/Ethnicity:
- Black: 35.0%
- Latino: 40.0%
- White: 3.0%
- Asian/PI: 1.0%
- NA/AI: 8.8%
- Other: 0.5%
- Unknown: 13.3%

Data Source: U.S. Department of Commerce, 2010; Los Angeles County Department of Public Health, HIV Surveillance, 2010
A Case for nPEP?

A 26 year old man presents to an outpatient clinic, reporting that the night before last (36 hours ago) he had receptive anal intercourse without the use of a condom with a new male partner, who he just learned from a mutual acquaintance is infected with the Human Immunodeficiency Virus (HIV). The patient is known to the clinic and has had several negative HIV tests (most recently 6 months ago), and he recently lost his job and health insurance. He wants to know if there is anything he can do to help prevent transmission of HIV from this recent exposure.
Approach to HIV Prevention

Figure 1: Highly active HIV prevention
This term was coined by Prof K Holmes, University of Washington School of Medicine, Seattle, WA, USA. STI = sexually transmitted infections.
EXPOSED to HIV?

Post Exposure Prophylaxis (PEP)
FACT SHEET
The nPEP Pilot: Comprehensive Biomedical HIV Prevention for LAC

- 2 demonstration sites; 28 days of ART
- IRB and FDA regulatory oversight
- Structured Protocol and Manual of Procedures
- Demonstration site preparation and training
- Safety labs and serial HIV and STI testing
- Sexual/substance use risk-reduction counseling
- Planned transition to Public Health Service Model
## nPEP Logic Model

<table>
<thead>
<tr>
<th>INPUTS</th>
<th>ACTIVITIES</th>
<th>OUTPUTS</th>
<th>OUTCOMES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work Group</td>
<td>Development of protocol and manual of operations</td>
<td>Number of nPEP inquiries received on warmline</td>
<td>Feasibility findings for implementation of nPEP in publicly funded HIV prevention settings</td>
</tr>
<tr>
<td>Community Partners</td>
<td>Establish relationship with Pharma to receive donated medications</td>
<td>Number of nPEP participants screened and enrolled</td>
<td>Increased Patient utilization of biomedical HIV prevention services</td>
</tr>
<tr>
<td>Academic Partners</td>
<td>Clinical trial support - Provider development to deliver nPEP services and implement protocol with fidelity</td>
<td>Clinical management to assess safe delivery of nPEP services - baseline and follow up over 4 time points</td>
<td>Increased Provider adoption of biomedical HIV prevention</td>
</tr>
<tr>
<td>Research and Evidence base</td>
<td>Implement protocol and nPEP services</td>
<td>STI and viral hepatitis diagnosis</td>
<td>Decreased HIV and STI incidence</td>
</tr>
<tr>
<td>Clinical Demonstration Sites/Providers</td>
<td>Evaluate nPEP services delivery</td>
<td>Risk-reduction counseling to assess sexual and substance use behaviors</td>
<td>Decreased sexual and substance use risk behaviors</td>
</tr>
<tr>
<td>HIV Antiretrovirals</td>
<td>Conduct quality assurance for delivery of nPEP services</td>
<td>Referral to services for high risk individuals and their partners</td>
<td>Increased linkage to HIV care for seroconverters</td>
</tr>
<tr>
<td>Funding</td>
<td></td>
<td></td>
<td>Increased access to risk-reduction services</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Increased utilization of risk-reduction services</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Increased elicitation, notification, and testing of partners of high risk individuals</td>
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</tbody>
</table>
## nPEP Pilot Components

<table>
<thead>
<tr>
<th>Component</th>
<th>Baseline (Day 0)</th>
<th>Week 2 Visit (Day 10-14)</th>
<th>Week 4-6 Visit</th>
<th>Week 12 Visit</th>
<th>Week 24 Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>ART Dispensed</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV ELISA&lt;sup&gt;c&lt;/sup&gt;</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Urine GC/CT</td>
<td>X</td>
<td>X&lt;sup&gt;b&lt;/sup&gt;</td>
<td>X&lt;sup&gt;b&lt;/sup&gt;</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Rectal GC/CT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Pharynx GC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serum RPR</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urine HCG&lt;sup&gt;a&lt;/sup&gt;</td>
<td>X</td>
<td>X&lt;sup&gt;b&lt;/sup&gt;</td>
<td>X&lt;sup&gt;b&lt;/sup&gt;</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>HBsAg</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CB, Cr, LFTs,</td>
<td>X</td>
<td>X&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
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<td></td>
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<tr>
<td>HIV Viral Load</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>HIV Genotype</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Stored Plasma&lt;sup&gt;d&lt;/sup&gt;</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Adherence CnsI</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Drug and Alc Assess</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk Assess</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Risk Red (Standard)</td>
<td>X</td>
<td>X</td>
<td>X&lt;sup&gt;b&lt;/sup&gt;</td>
<td>X&lt;sup&gt;b&lt;/sup&gt;</td>
<td>X&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Referral to Behavioral Programming (Expanded)</td>
<td>X</td>
<td></td>
<td></td>
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</tbody>
</table>

<sup>a</sup>Females of childbearing potential only
<sup>b</sup>If clinical signs and symptoms direct, not routine
<sup>c</sup>Positive or indeterminate rapid HIV ELISA testing will be confirmed with a serum Western Blot
<sup>d</sup>Plasma will be drawn and stored at indicated time points. If HIV seroconversion occurs, these samples will be run for HIV RNA (viral load) and genotyping
Inclusion Criteria

1. 18 yrs of age and ability to provide consent
2. High-risk exposure (unprotected or with failed condom):
   • Receptive/Insertive anal intercourse
   • Receptive/Insertive vaginal intercourse
   • Receptive oral intercourse w/ejaculation with HIV+ source
   • Sharing intravascular injection drug works
3. High-risk source (one or more):
   • Known HIV+, MSM, MSM/W, IDU, CSW, sexual perpetrator, history of incarceration, from an endemic country (prevalence >1%), partner of one of the above
4. Exposure within 72-hrs of presentation
5. Not known to be HIV+
6. No countermanding concomitant medications or allergies
Medication Regimens

Standard ART Regimen for high-risk exposures:

- Truvada
- Combivir – for intolerance to Truvada

Expanded ART Regimen:

- For highest-risk exposures or suspected source drug resistance; added to the above medication administration
  - Kaletra or Raltegravir
Preliminary Findings

Presentation data as of July 1, 2011

- Screened 303, Enrolled 283
- Data to follow N=163 (151 at Site 1, 12 at Site 2)
- N=38 had already initiated PEP at another location (ED, Primary Care, HIV clinic)

Site 1: LAGLC – Los Angeles Gay and Lesbian Ctr
- Screened 271, enrolled 260

Site 2: OASIS
- Screened 32, enrolled 23
nPEP Sites, HIV/STI Clusters, 2009

Legend
- nPEP sites

HIV/STI Disease Clusters
HIV Cases, 2009
- Yellow: 1.3%
- Orange: 6.6%
- Dark Orange: 9.2%
- Red: 18.4%
- Dark Red: 46.3%
- Gray: Los Angeles County Boundary

Data Source: HIV Testing Services Data, CY2009; Zip Codes with <100 tests not included in analysis
Demographics: Gender and Age (N = 163)

Gender:
- Male: 93%
- Female: 5%
- MTF Transgender: 2%

Age:
- <20: 5%
- 20-30: 47%
- 31-40: 26%
- 41-50: 1%
Demographics: Sexual Orientation and Race/Ethnicity (N=163)

Sexual Orientation:
- Gay: 80%
- Straight: 1%
- Bisexual: 11%
- Other: 8%

Race/Ethnicity:
- Hispanic/Latino: 34%
- White: 51%
- Black: 8%
- Asian: 4%
- Other: 3%
Enrollment Risk Exposure (N=163) (multiple category reply)

- Receptive Anal Intercourse: 5%
- Insertive Anal Intercourse: 3%
- Receptive Vaginal Intercourse: 1%
- Insertive Vaginal Intercourse: 35%
- Receptive Oral Intercourse w/Ejaculation: 56%
Baseline Sexual Risk Behavior
URAI / UIAI Acts by Status of Partner

URAI last 30 Days
- N=143
- N=48

UIAI last 30 days
- N=124
- N=54

HIV+  HIV Unk
Medication Adherence by Visual Analog Scale

2 Week Clinical Evaluation
• Mean self-reported adherence 96.90% (SD 12.81)
• Range 7-100%

4 Week Clinical Evaluation
• Mean self-reported adherence 96.57% (SD 11.32)
• Range 0-100%
Follow up Rates: Clinical Evaluations
*N=163

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Day 14</th>
<th>Week 4-6</th>
<th>Week 12</th>
<th>Week 24</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>163/163</td>
<td>146/163</td>
<td>131/163</td>
<td>98/161</td>
<td>62/161</td>
</tr>
<tr>
<td></td>
<td>(100%)</td>
<td>(90%)</td>
<td>(80%)</td>
<td>(61%)</td>
<td>(39%)</td>
</tr>
</tbody>
</table>

*As of July 1, 2011:
2 Significant Adverse Events: both continued treatment
Time Interval: Exposure to First Dose
*N=151

Mean: 36.33 hrs (SD 19.17)
Range: 2 – 71.7 hrs

* N=12 missing
Time Interval: Exposure to First Dose
*N=151

Mean: 36.33 hrs (SD 19.17)
Range: 2 – 71.7 hrs

*N=12 missing

N=44 (27%) < 24 hrs
N=8 (5%) < 8 hrs

N=44 (27%) < 24 hrs
N=8 (5%) < 8 hrs

* N=12 missing
## Seroconversions N=4

<table>
<thead>
<tr>
<th>PID</th>
<th>Date Seroconversion identified</th>
<th>Exposure</th>
<th>Time to PEP</th>
<th>Med Adherence Self-Report</th>
<th>STIs</th>
<th>Repeat Exposures Self-Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>1016</td>
<td>12-week</td>
<td>URAI and UIAI w/recently seroconverted Source</td>
<td>64hrs</td>
<td>100%</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>1064</td>
<td>12-week</td>
<td>URAI and UIAI w/recently seroconverted Source</td>
<td>41hrs</td>
<td>100%</td>
<td>+ GC at baseline</td>
<td>Yes</td>
</tr>
<tr>
<td>1101</td>
<td>12-week</td>
<td>UIAI with known HIV+ Source; Source reported to be undetectable on meds</td>
<td>26hrs</td>
<td>95%</td>
<td>None</td>
<td>Yes</td>
</tr>
<tr>
<td>1155</td>
<td>12-week</td>
<td>RAI with failed condom w/known HIV+ Source</td>
<td>62hrs</td>
<td>100%</td>
<td>Positive RPR 3 month</td>
<td>Yes</td>
</tr>
</tbody>
</table>
nPEP Pilot: Summary

- Demonstrated feasible implementation of nPEP in clinical care settings for high risk population
- Real life example of how to develop and implement comprehensive biomedical and behavioral HIV prevention interventions
- Cost of ART is significant and can be an obstacle to scaling up service delivery
- Education for primary care (non HIV specialty) needed to support providers to deliver nPEP more broadly
Next Steps: Sustained nPEP Program

Public health program premised on the findings from pilot with few modifications:

- 2 drug regimen (Truvada) except in cases of documented drug resistance from source patient (3rd drug Raltegravir/Kaletra)
- Integrated hepatitis screening and vaccination
- Streamlined data reporting
- PEP coordinator to do follow up visits
- Full 28 day ART dispensed at intake
- Integrated risk-reduction counseling via DHSP funded behavioral programs
Acknowledgements

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  – Jim Rooney
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  – Sarah Guerry
  – Peter Kerndt
• LAC Public Health Lab
  – Debbie Emlien
  – Ramiro Garate
• LAGLC Site Staff
• OASIS Clinic Site Staff
Contact Information

Jennifer N. Sayles, MD, MPH
Medical Director
Division of HIV and STD Programs
600 South Commonwealth Avenue, 10th Floor
Los Angeles, California 90005-4001
Phone: (213) 351-8264
E-mail: jsayles@ph.lacounty.gov