

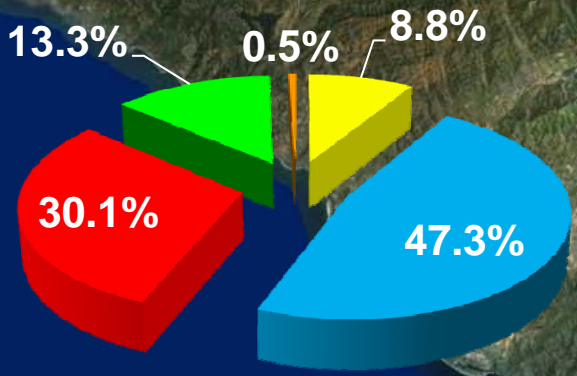
An HIV Post-Exposure Prophylaxis Pilot Program Implemented in Public Health Settings in Los Angeles

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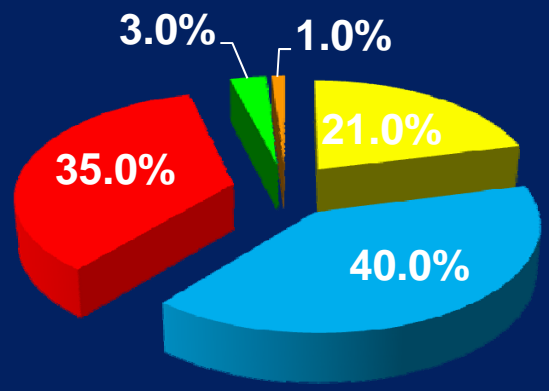


Population	Estimated HIV/AIDS Cases
9,848,011	61,700

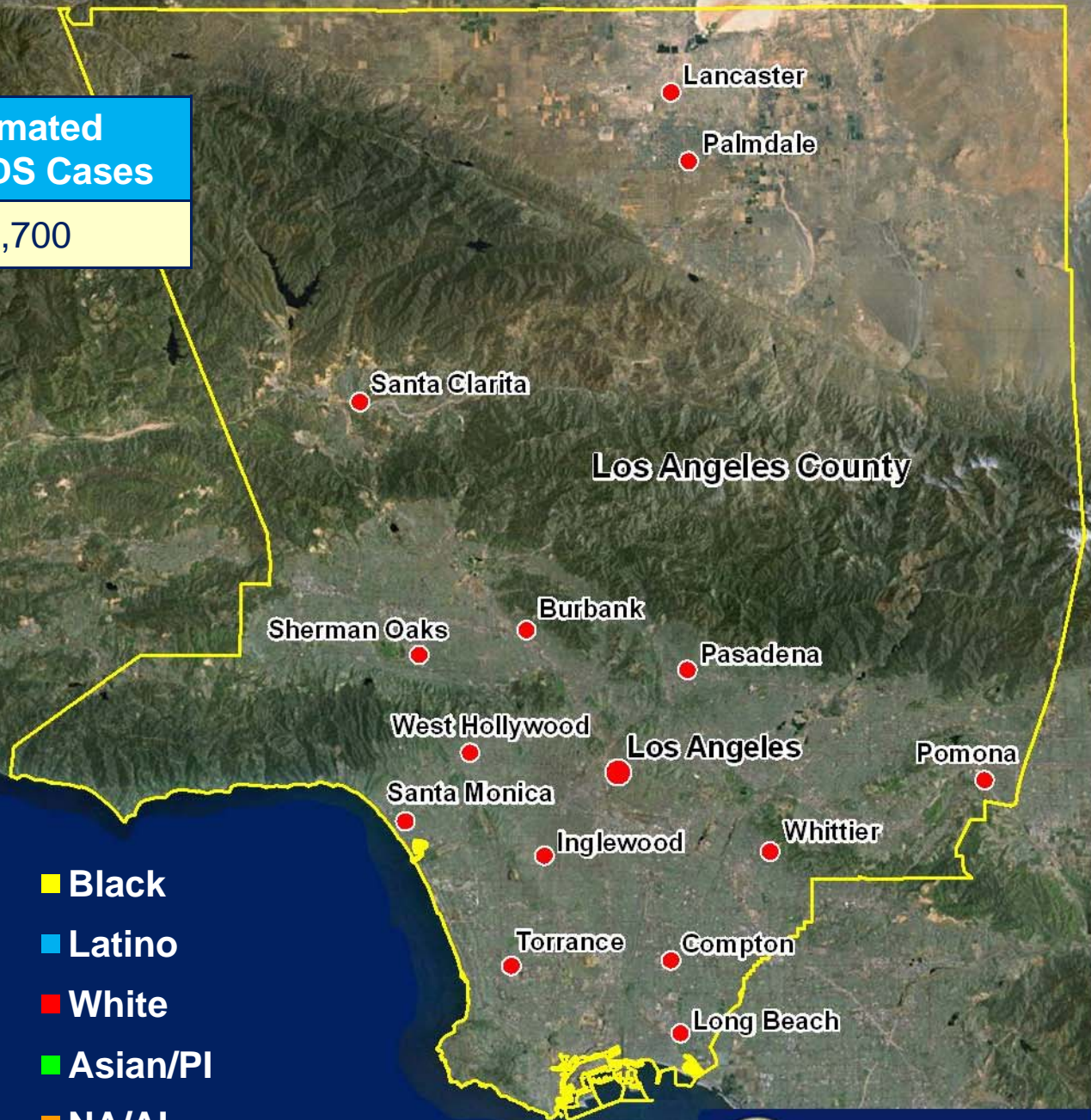
Overall, Race/Ethnicity



HIV/AIDS Cases



- Black
- Latino
- White
- Asian/PI
- NA/AI



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

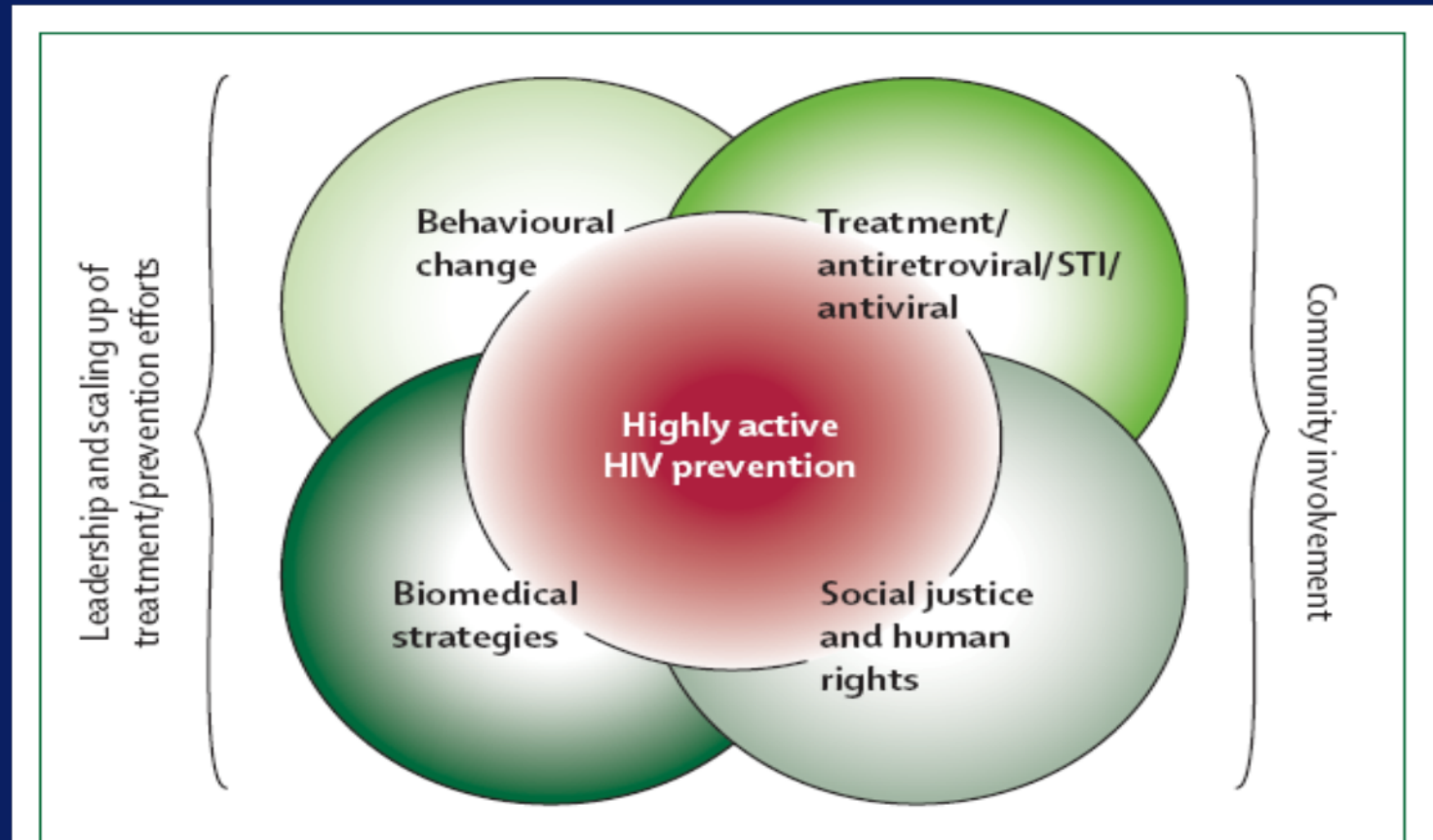
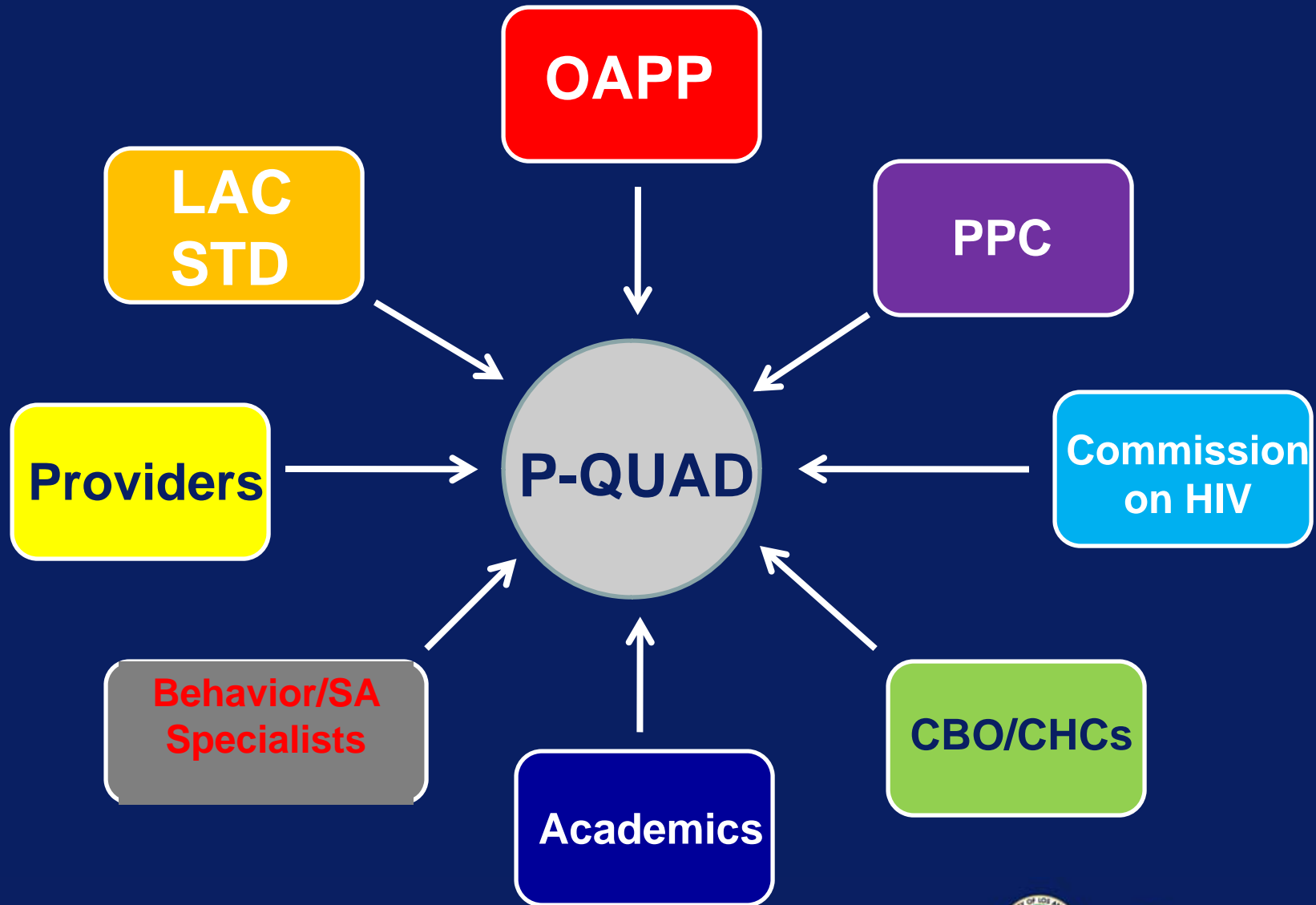
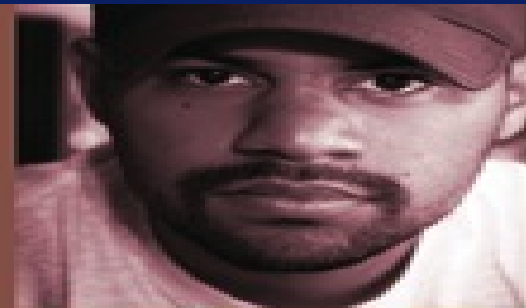


Figure 1: Highly active HIV prevention

This term was coined by Prof K Holmes, University of Washington School of Medicine, Seattle, WA, USA.⁵ STI=sexually transmitted infections.

LA County nPEP Genesis





EXPOSED to HIV?



Post Exposure Prophylaxis (PEP)
FACT SHEET

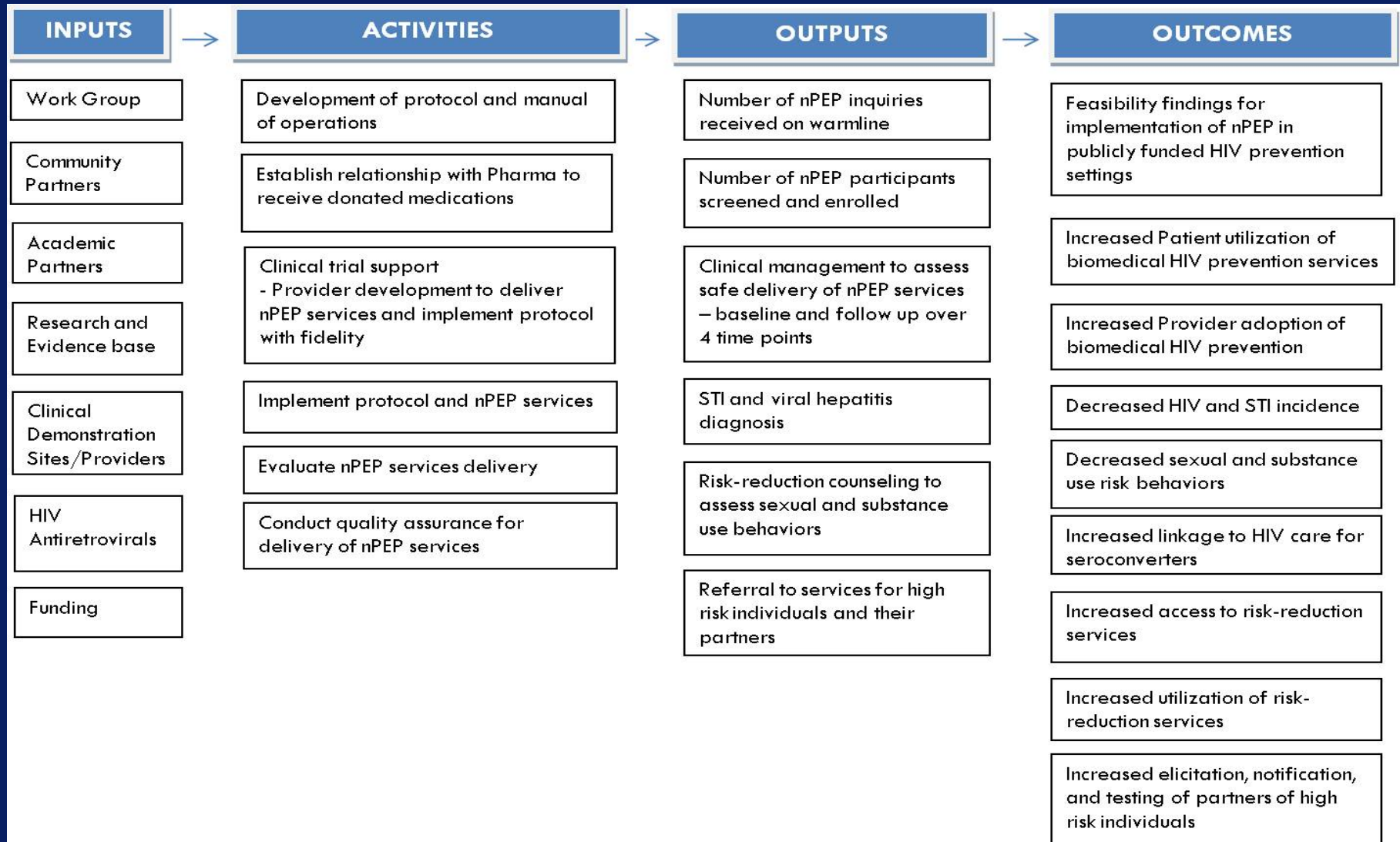


The nPEP Pilot: Comprehensive Biomedical HIV Prevention for LAC

- 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



nPEP Pilot Components

	Baseline (Day 0)	Week 2 Visit (Day 10-14)	Week 4-6 Visit	Week 12 Visit	Week 24 Visit
ART Dispensed	X	X			
HIV ELISA ^c	X		X	X	X
Urine GC/CT	X	X ^b	X ^b	X ^b	X ^b
Rectal GC/CT					
Pharynx GC					
Serum RPR	X			X	
Urine HCG ^a	X	X ^b	X ^b	X ^b	X ^b
HBsAg	X				
CB, Cr, LFTs,	X	X ^b			
HIV Viral Load					
HIV Genotype					
Stored Plasma ^d	X		X	X	X
Adherence Cnsl	X	X			
Drug and Alc Assess	X				
Risk Assess	X		X	X	X
Risk Red (Standard)	X	X	X ^b	X ^b	X ^b
Referral to Behavioral Programming (Expanded)	X				

^aFemales of childbearing potential only

^bIf clinical signs and symptoms direct, not routine

^cPositive or indeterminate rapid HIV ELISA testing will be confirmed with a serum Western Blot

^dPlasma 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

1.3%

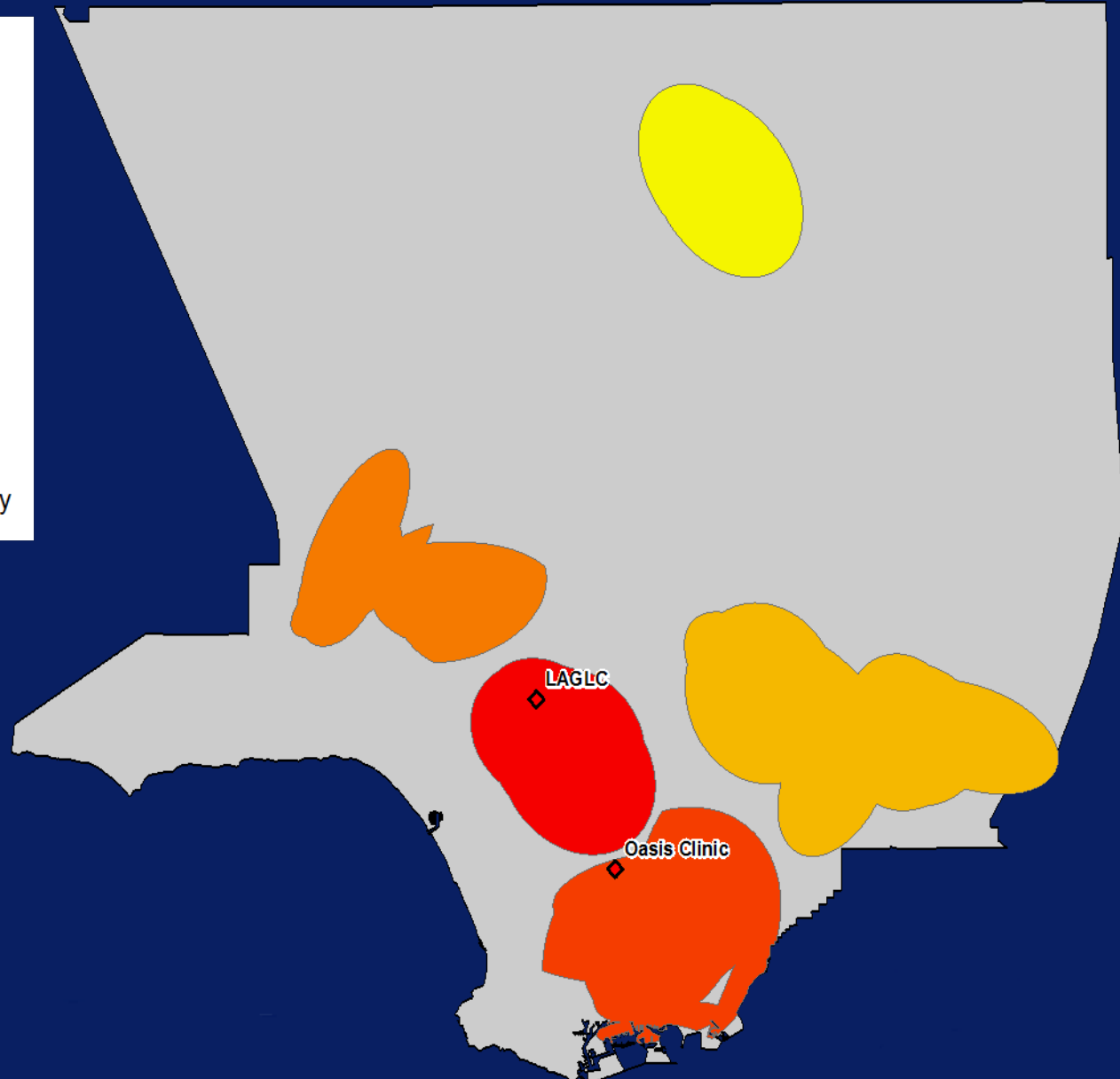
6.6%

9.2%

18.4%

46.3%

Los Angeles County Boundary

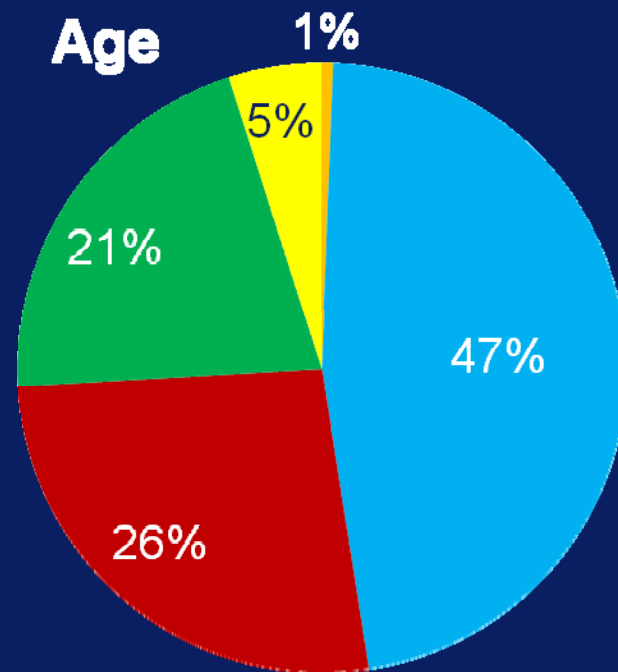
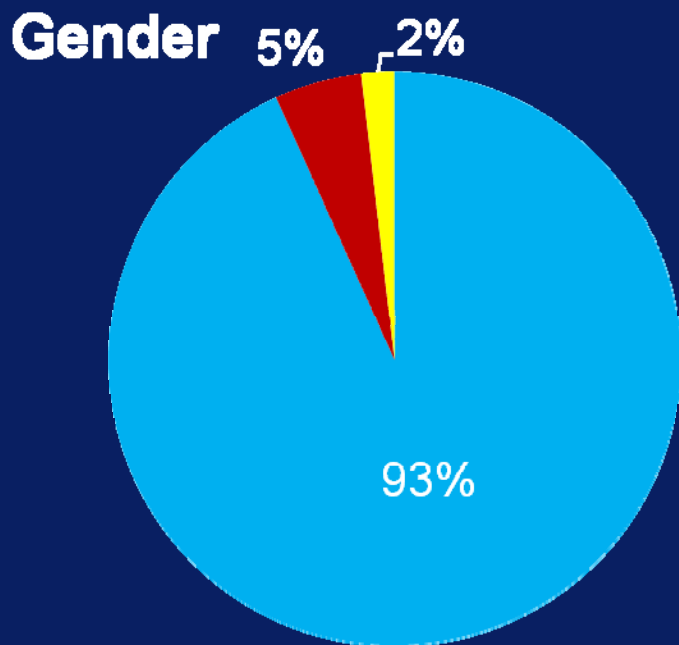


Data Source: HIV Testing Services Data, CY2009; Zip Codes with <100 tests not included in analysis



COUNTY OF LOS ANGELES
Public Health

Demographics: Gender and Age (N = 163)



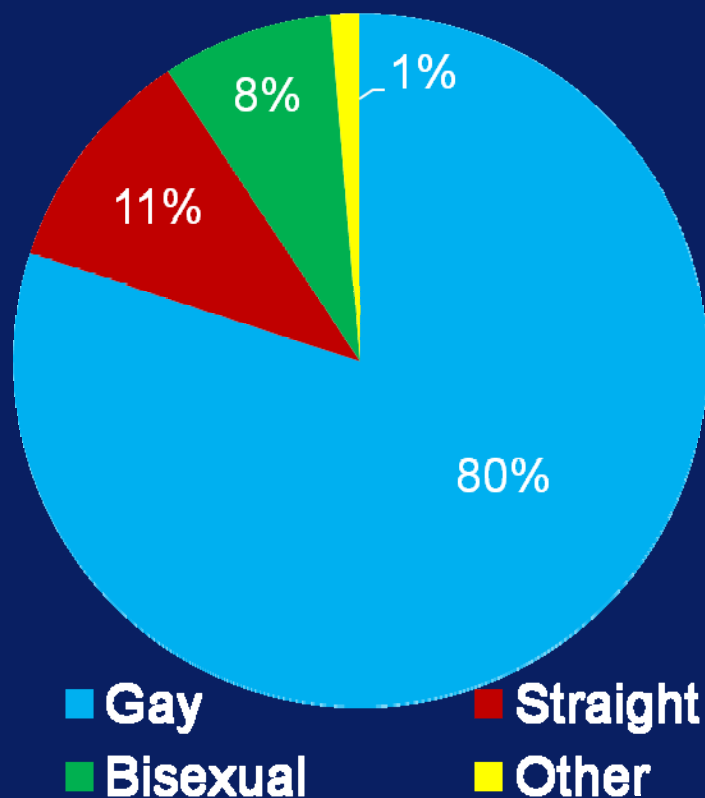
■ Male ■ Female ■ MTF Transgender

■ <20 ■ 20-30
■ 31-40 ■ 41-50

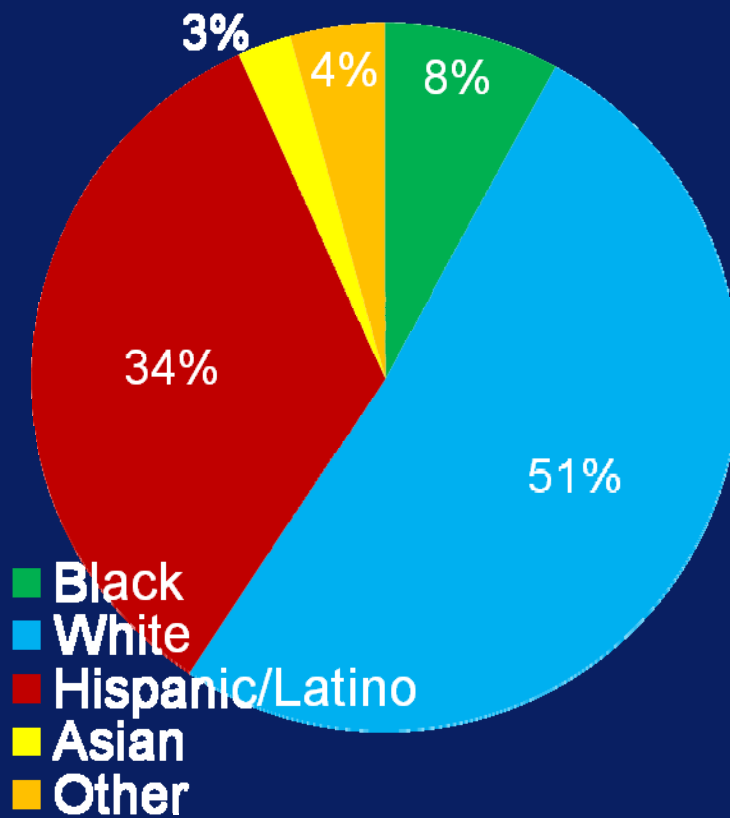


Demographics : Sexual Orientation and Race/Ethnicity (N=163)

Sexual Orientation

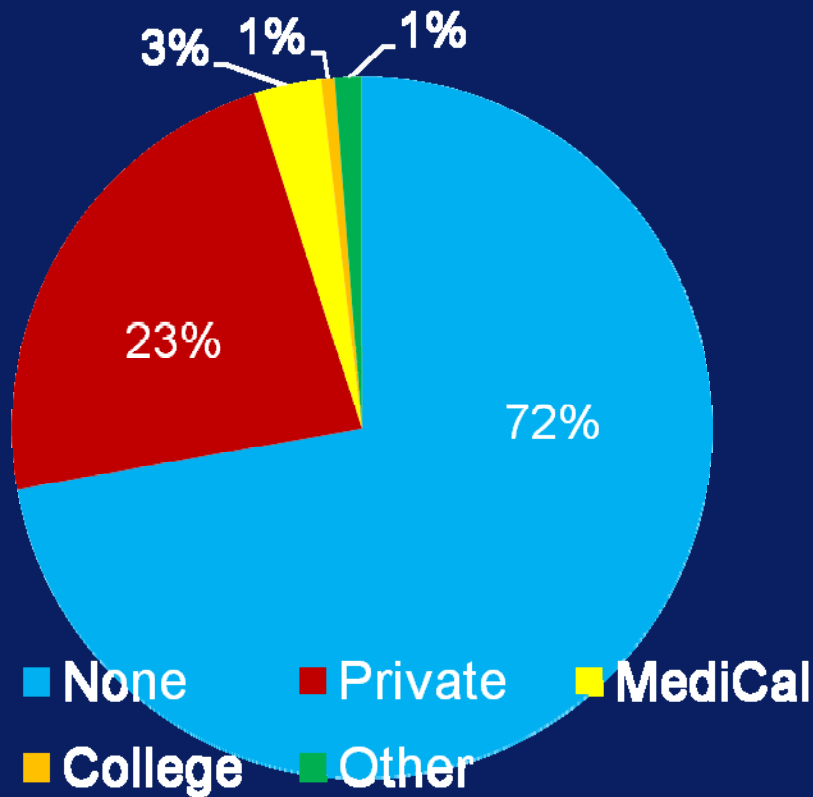


Race/Ethnicity

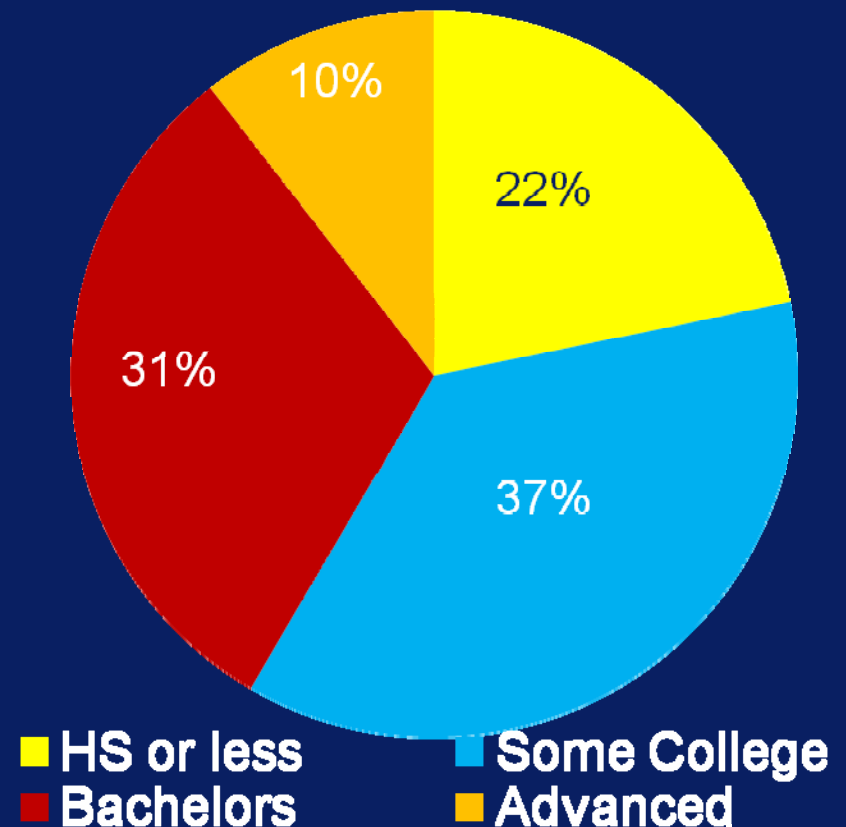


Demographics: Health Insurance and Education (N=163)

Health Insurance Type

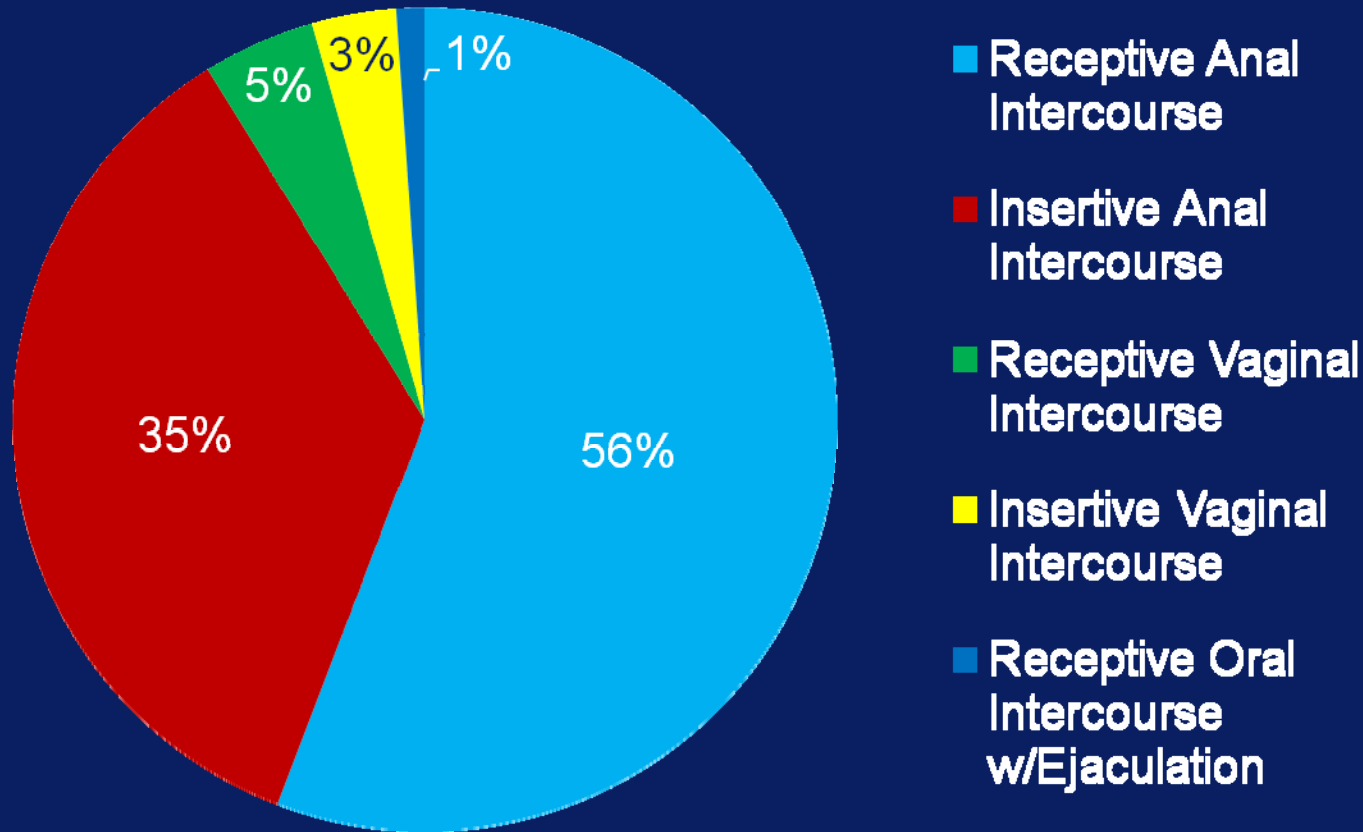


Education



Enrollment Risk Exposure (N=163)

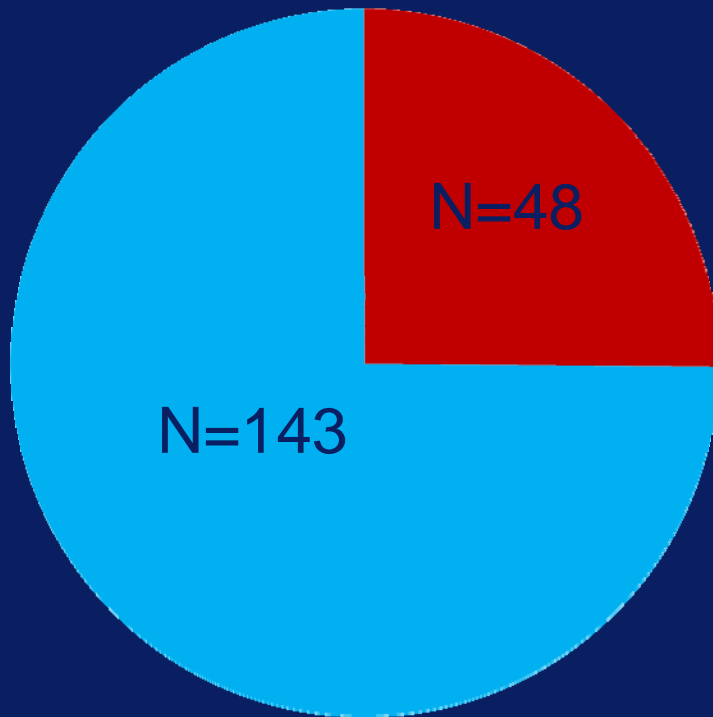
(multiple category reply)



Baseline Sexual Risk Behavior

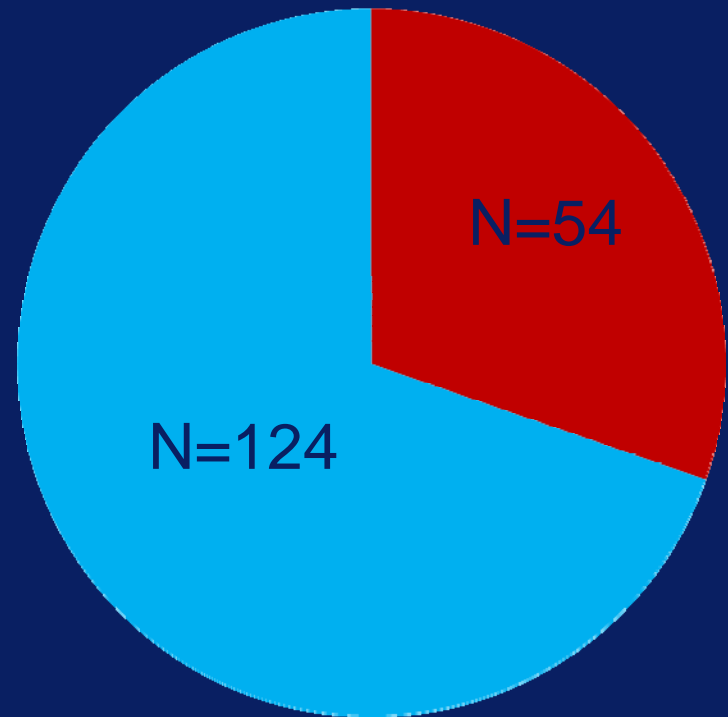
URAI / UIAI Acts by Status of Partner

URAI last 30 Days



■ HIV+ ■ HIV Unk

UIAI last 30 days



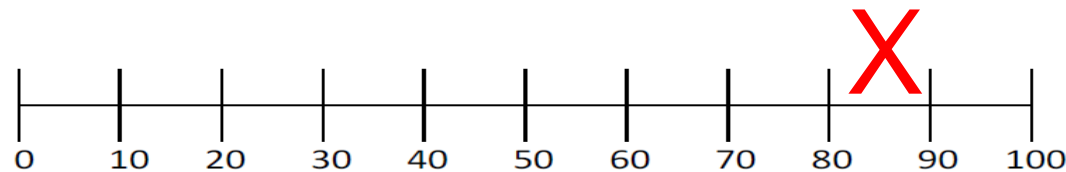
■ HIV+ ■ HIV Unk



Medication Adherence by Visual Analog Scale

Put a mark on the line below at the point that shows your best guess about how much of your prescribed HIV medication you have taken in your first 2 weeks of treatment.

Example: 0% means you have taken no medication, 50% means you have taken half your medication, 100% means you have taken every single dose of your medication.



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

Baseline	Day 14	Week 4-6	Week 12	Week 24
163/163 (100%)	146/163 (90%)	131/163 (80%)	98/161 (61%)	62/161 (39%)

***As of July 1, 2011:**

2 Significant Adverse Events: both continued treatment

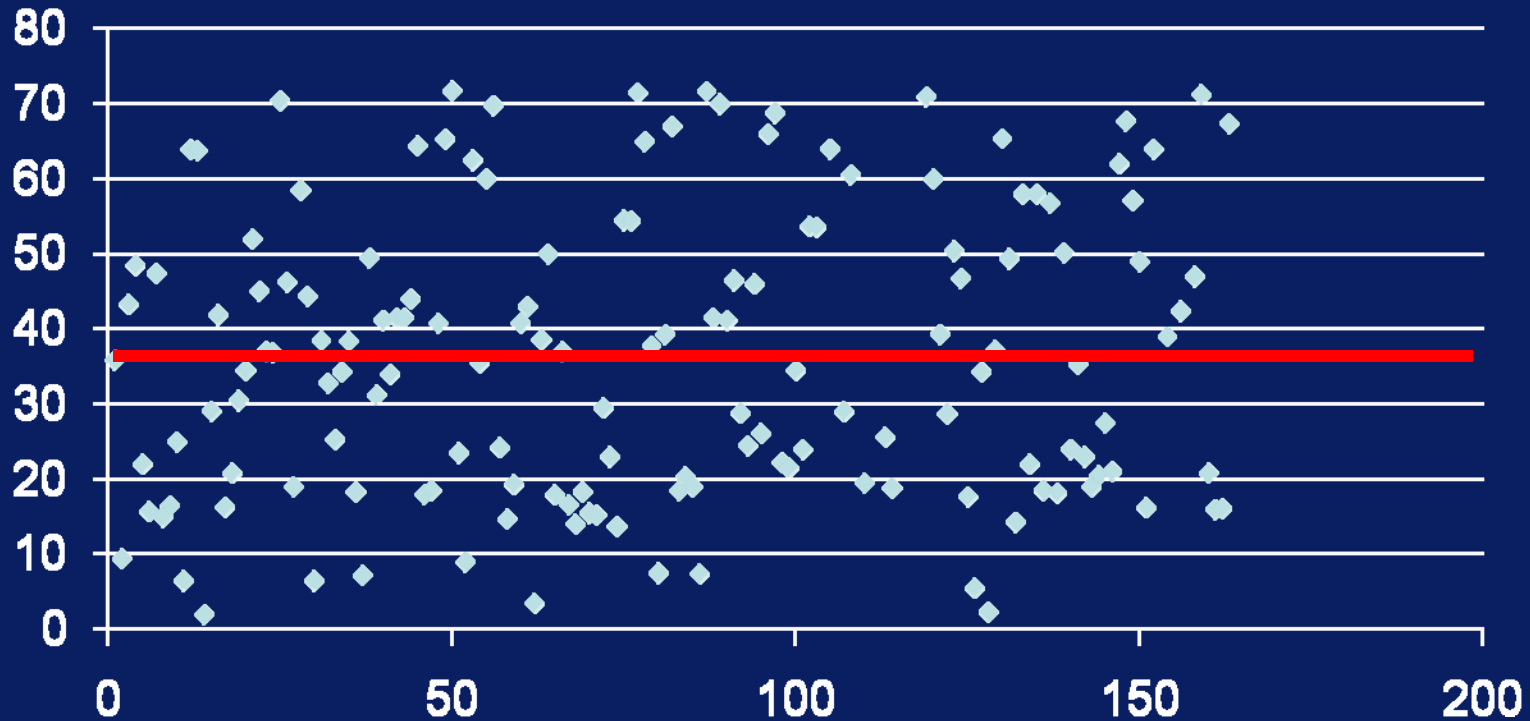


Time Interval: Exposure to First Dose

*N=151

Mean: 36.33 hrs (SD 19.17)

Range: 2 – 71.7 hrs



* N=12 missing

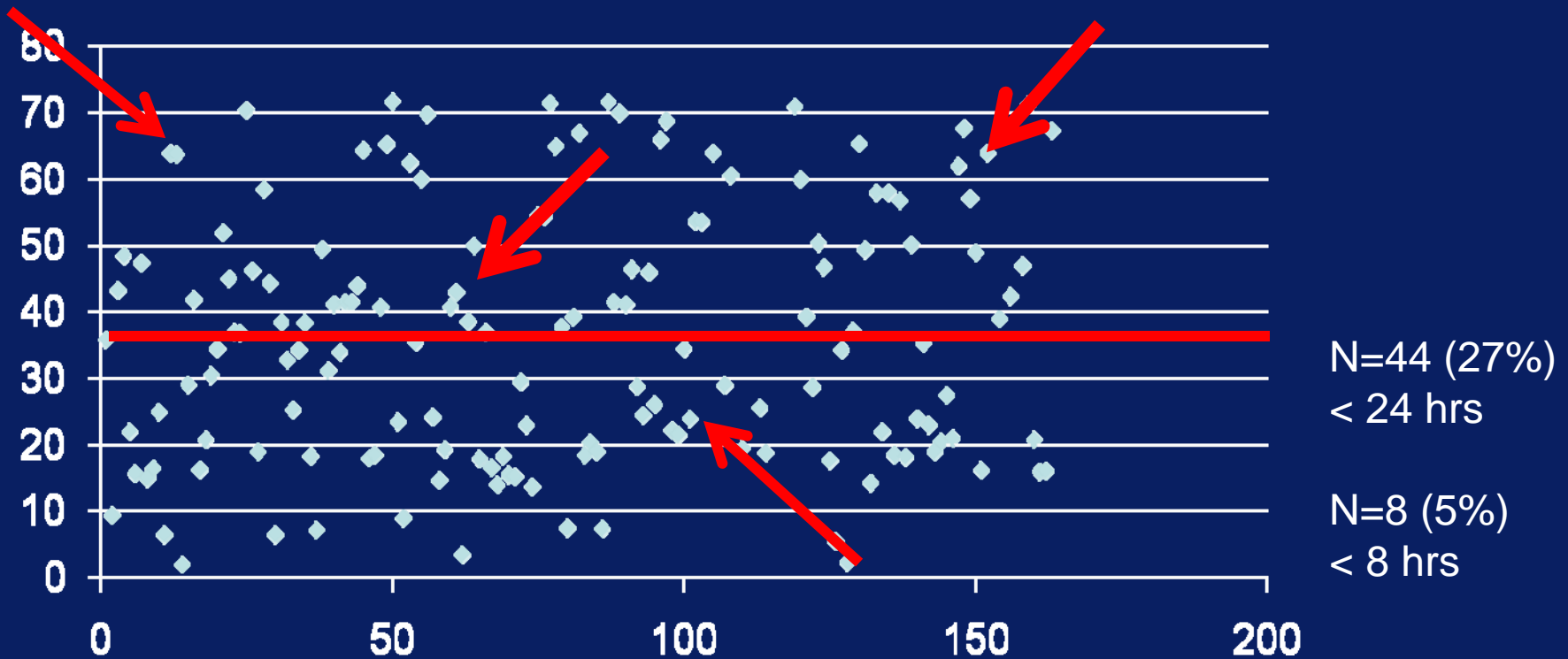


Time Interval: Exposure to First Dose

*N=151

Mean: 36.33 hrs (SD 19.17)

Range: 2 – 71.7 hrs



* N=12 missing



Seroconversions N=4

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



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



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- **OASIS Clinic Site Staff**



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