Research to Practice: Building the Capacity of Health Department's to Conduct Research and Use the Findings to Implement Services in their Jurisdiction

HIV Prevention Leadership Summit
December 13, 2010

Mario J. Pérez, Director
County of Los Angeles
Department of Public Health
Office of AIDS Programs and Policy

County of Los Angeles Public Health

Or...

Research to Practice: Leveraging the Research Assets of a Local Jurisdiction to Improve HIV/AIDS Program Practice

County of Los Angeles Public Health

A workshop is an interactive session designed for sharing lessons learned and increasing knowledge around a particular aspect of HIV prevention – through audience participation

Workshop Overview

- Review research assets and capacity
- Review research drivers from a local health department perspective
- Review research challenges and opportunities
- Review four Los Angeles County case studies that involve translating research into practice
- Have a solution-oriented discussion

Research to Practice Summary

Problem

Research Question

Critical Partner(s)

Health Department Role

Translating to Practice

CDC Charge or Role

"Right now, we are experiencing a domestic epidemic that demands a renewed commitment, increased public attention, and leadership."

"I look forward to working with Congress, State, tribal and local governments, and other stakeholders to support the implementation of a Strategy that is innovative, grounded in the best science, focuses on the areas of greatest need, and that provides a clear direction for moving forward together.

-- President Obama

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Overview of the Los Angeles County Epidemic

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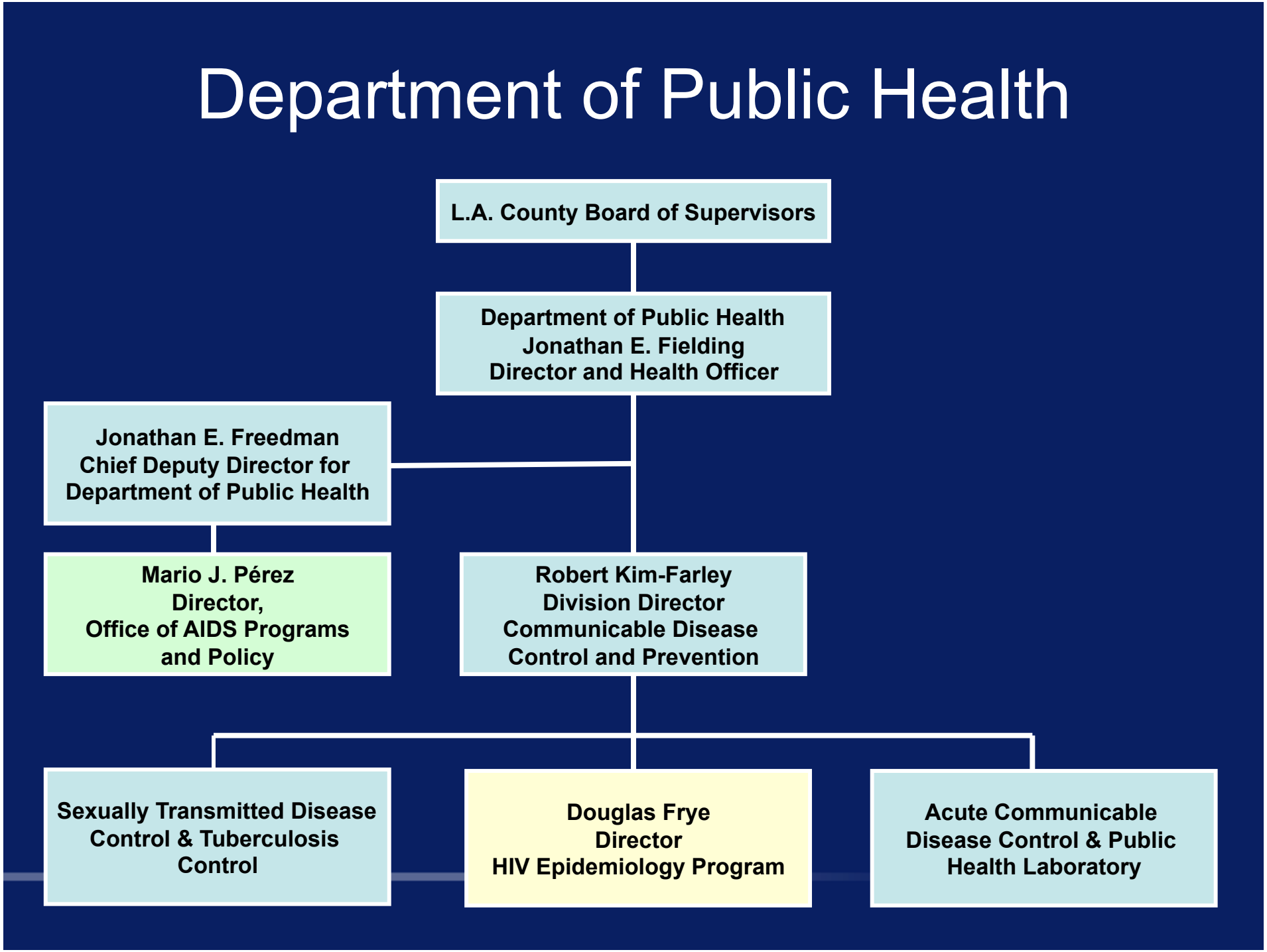
Department of Public Health



County of Los Angeles

Square Miles: 4,086
Population[1]: 10.3 Million

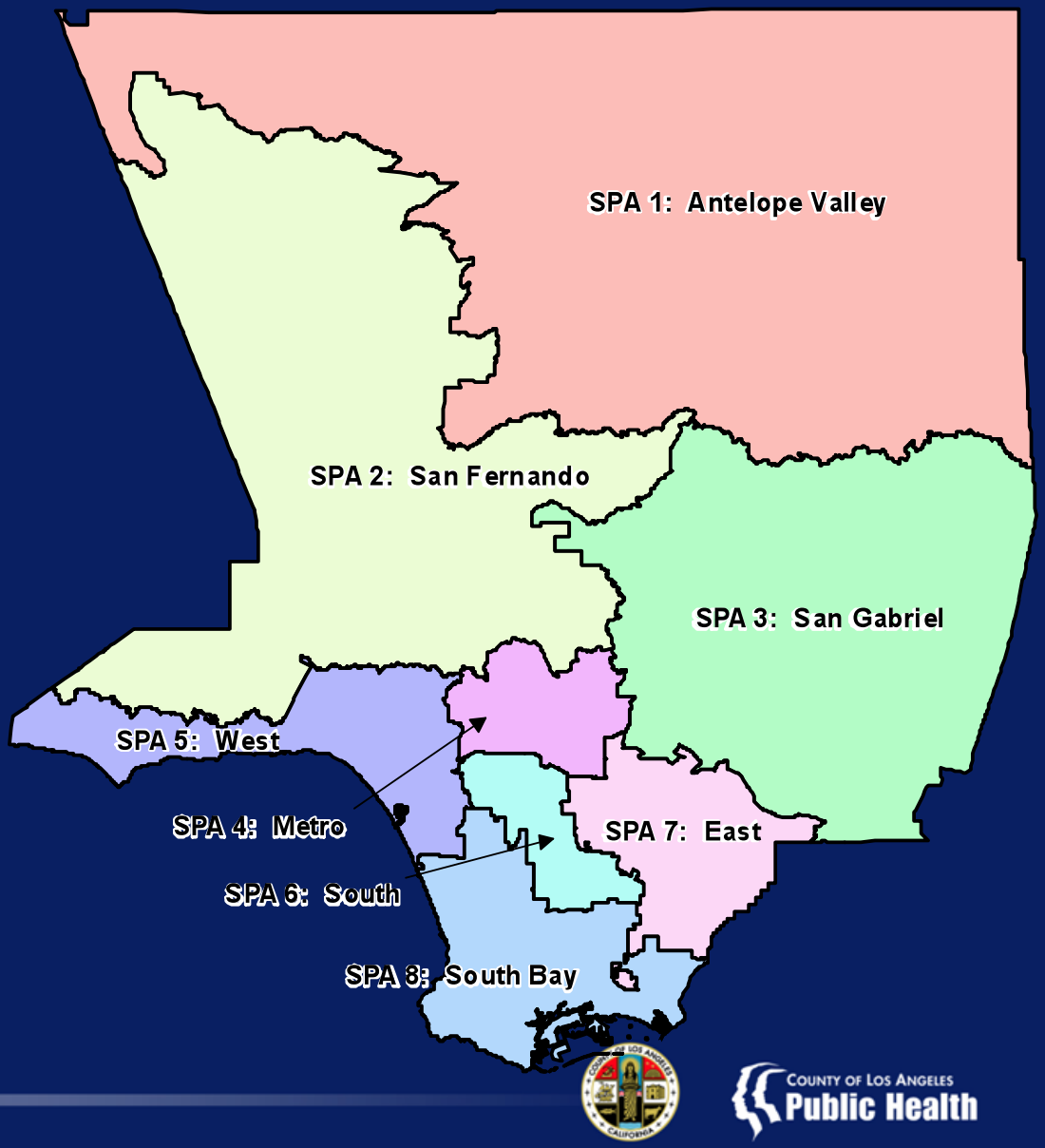
Latino/a	47.0%
White	28.9%
Asian/PI	12.6%
African-American	9.0%
Native American	0.3%

Proportion of California Population[2]: 29%

Proportion of California AIDS Cases[3]: 36%

Proportion of U.S. AIDS Cases[3]: 5%

Living with HIV/AIDS[3]: 61,700 (Estimated)



[1]United Way, Los Angeles (2008)
[2]U.S. Department of Commerce (2008)
[3]Los Angeles County HIV Epidemiology Program (2008)

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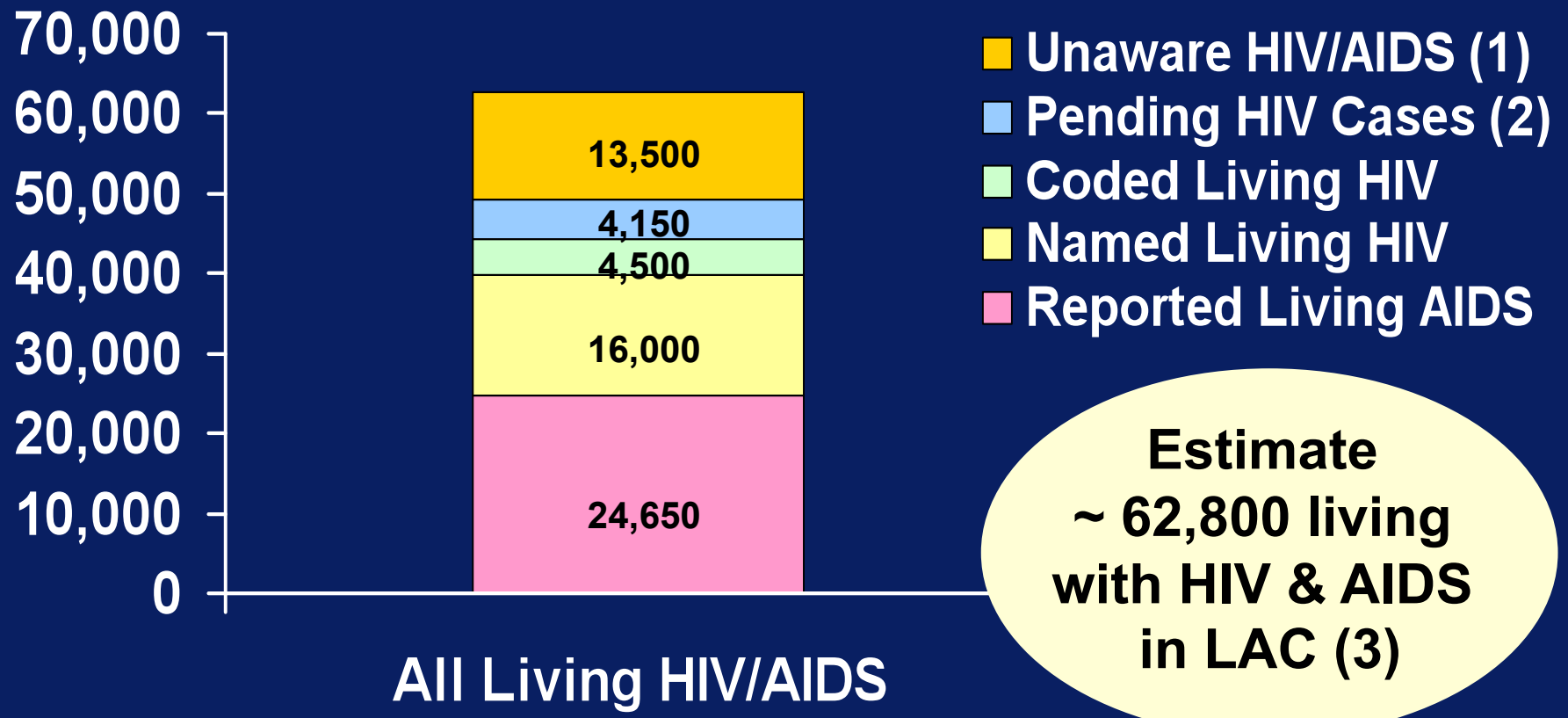
Estimated Number of PLWHA in LAC



Estimate ~ 62,800 living with HIV & AIDS in LAC (3)

Source: LAC HIV Epidemiology Program, reported as of 12/31/2009.

(1) Estimate that 21.5% of HIV+ in LA County are unaware of their infection; modified from CDC estimate.

(2) Of 6,700 notifications pending investigation, estimate >4,000 to be cases.

(3) Estimate based on a 1:1 ratio of HIV (non-AIDS) to living AIDS cases and includes reported, named, coded, pending and unaware HIV and AIDS cases.

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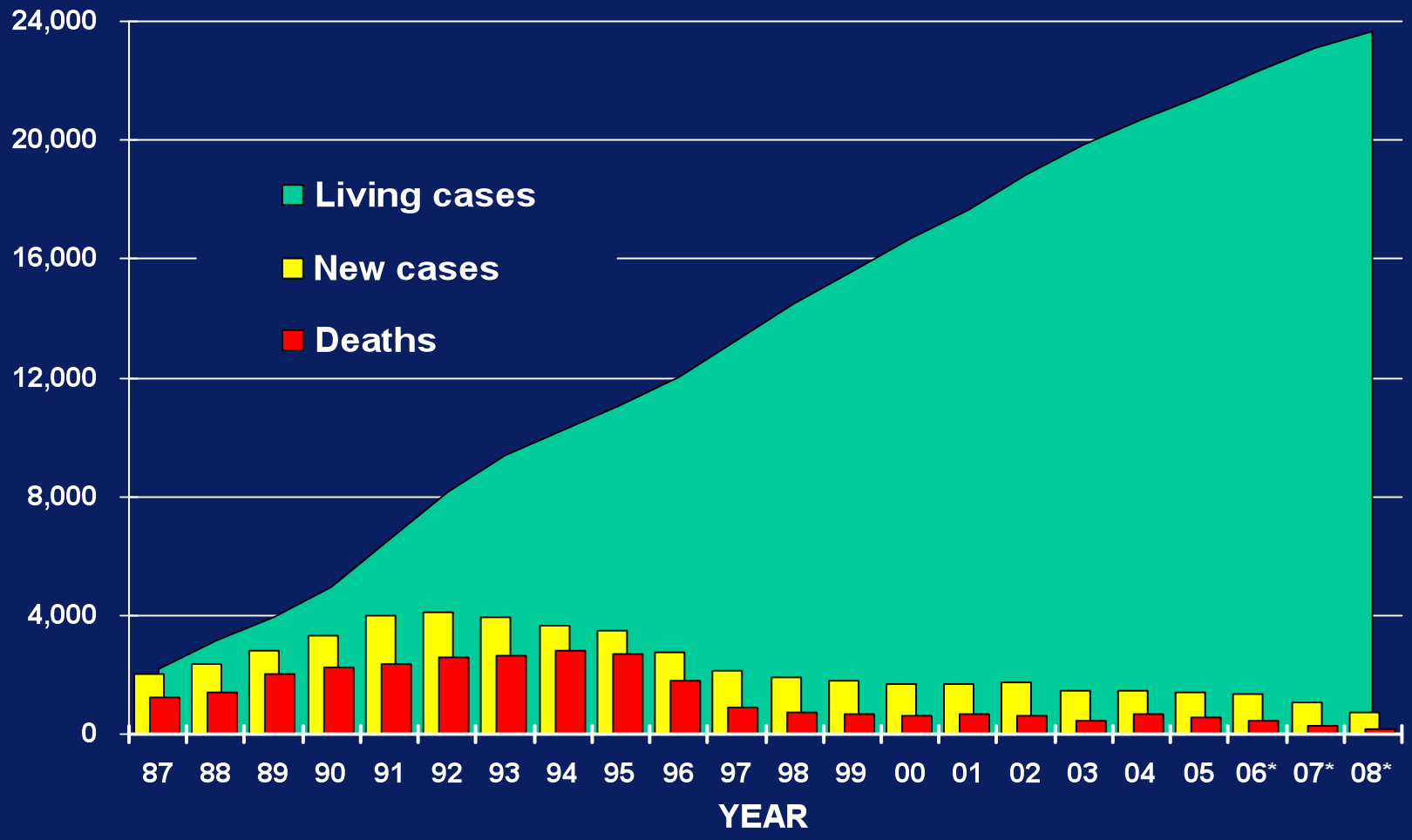
AIDS Cases, Deaths and PLWA,‘87-’08



1. Number of new cases diagnosed each year.
2. Number of deaths occurred each year among persons reported with AIDS.
3. Number of persons living with AIDS at the end of each calendar year.

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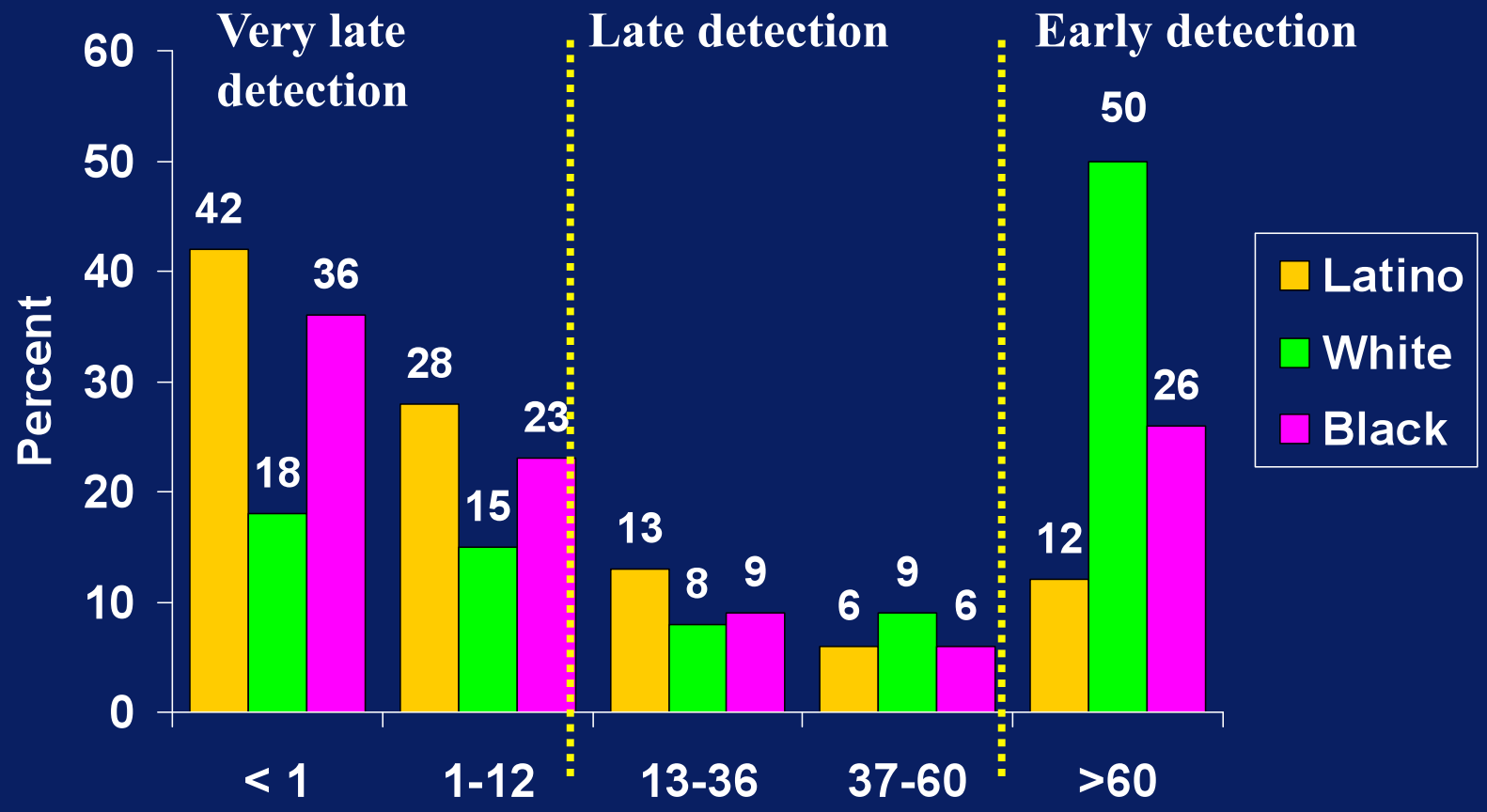
Months Between First Learned of HIV+ Status and AIDS Diagnosis



SHAS, HIV Epidemiology Program. LAC, 2000 - 2004 (N = 672)

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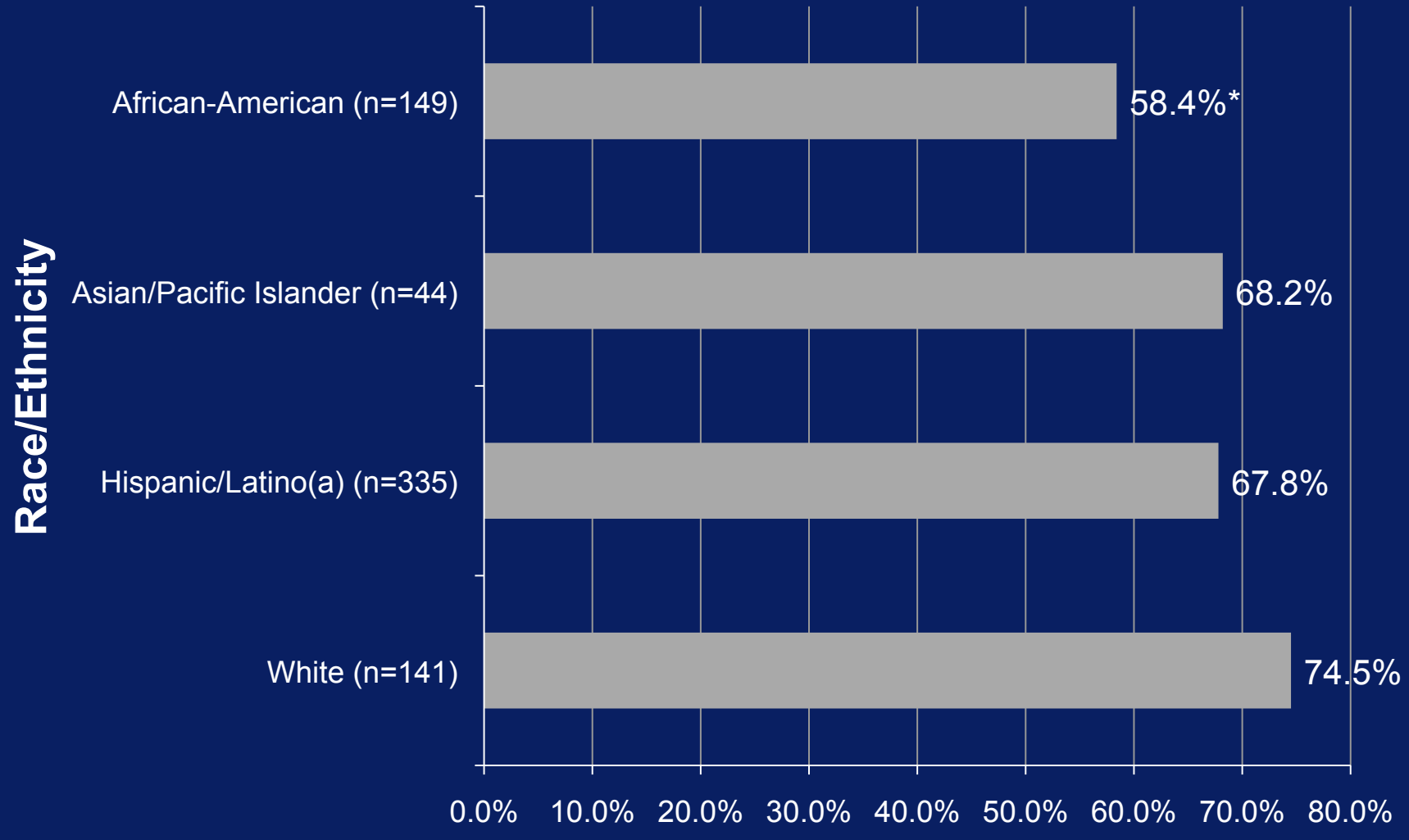
Linked to Care by Race/Ethnicity[1], 2006-08



*Statistically significant, p=.05, [1]Native American/Alaska Native not included due to small sample size

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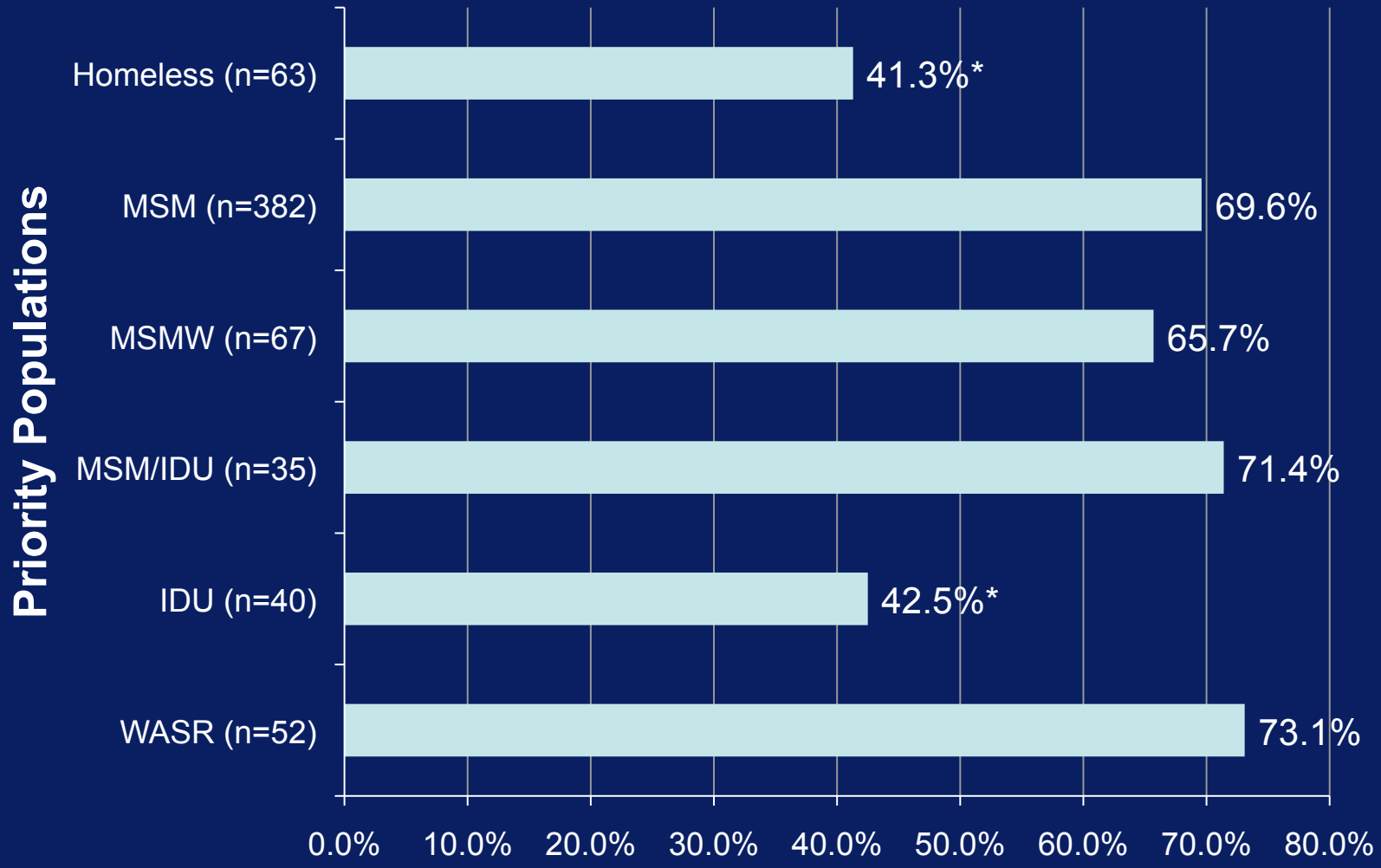
Linked to Care by Priority Populations, 2006-08



*Statistically significant, *p*=.05

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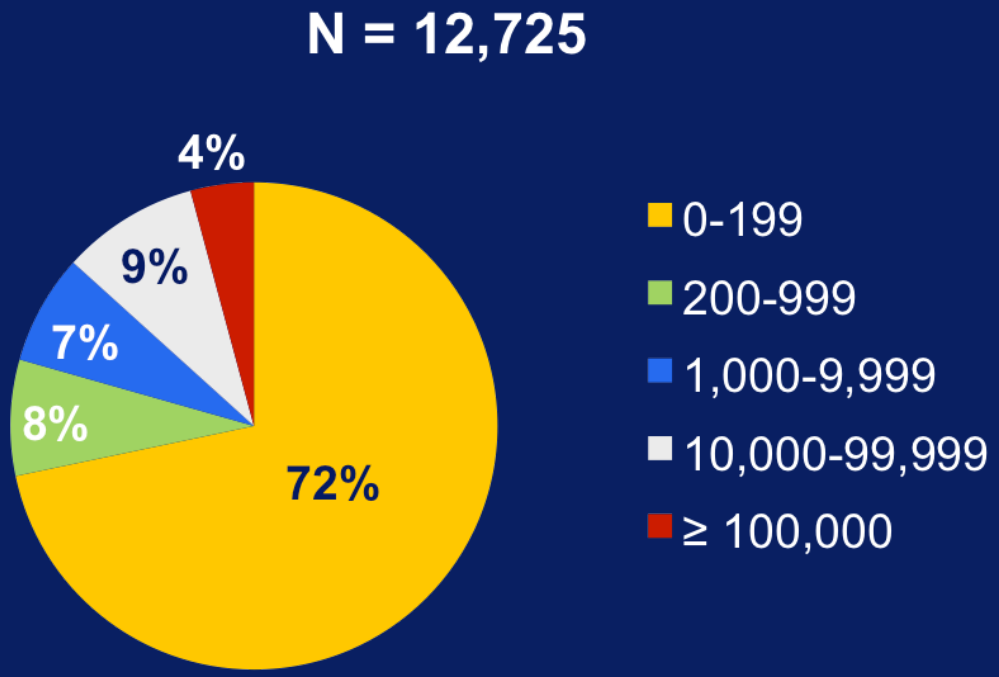
HIV-1 Viral loads among RW Clients

- 14,875 RW clients database had 1 or more medical outpatient (MOP) visit in YR 19.
  - Of that, 12,725 (~86%) had at least one viral load test during that year.



Source: *Casewatch YR 19 (Feb. '09 – Mar. '10):*
Data limited to RW Client w/ 1 or more MOP visit.

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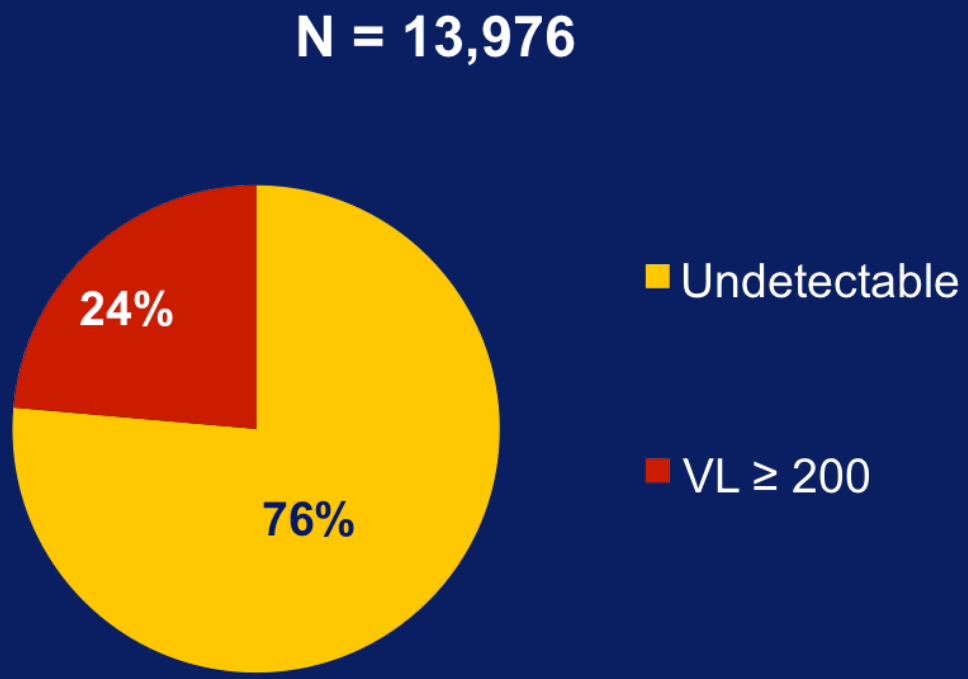
Viral Load of RW Clients on ART

- Among RW Clients w/ 1 or more MOP visit, 13,976 (~94%) are on antiretroviral therapy.



Source: *Casewatch YR 19 (Feb. '09 – Mar. '10):*
Data limited to RW Client w/ 1 or more MOP visit.

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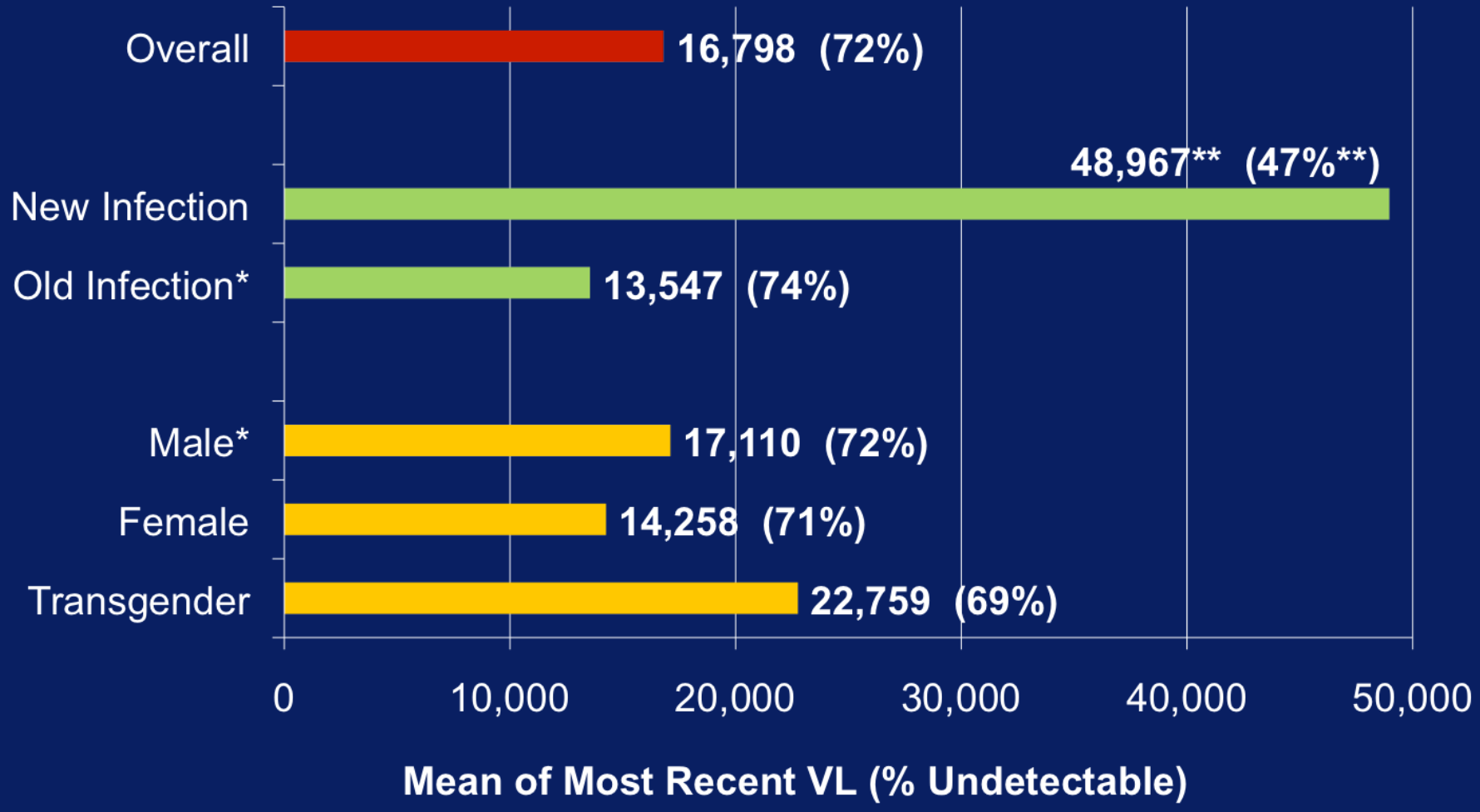
Mean Viral Load & Demographics



Source: *Casewatch YR 19 (Feb. '09 – Mar. '10):*
Data limited to RW Client w/ 1 or more MOP visit.
* Indicates reference/comparison group
** Significantly different from reference group (p-value < 0.05)

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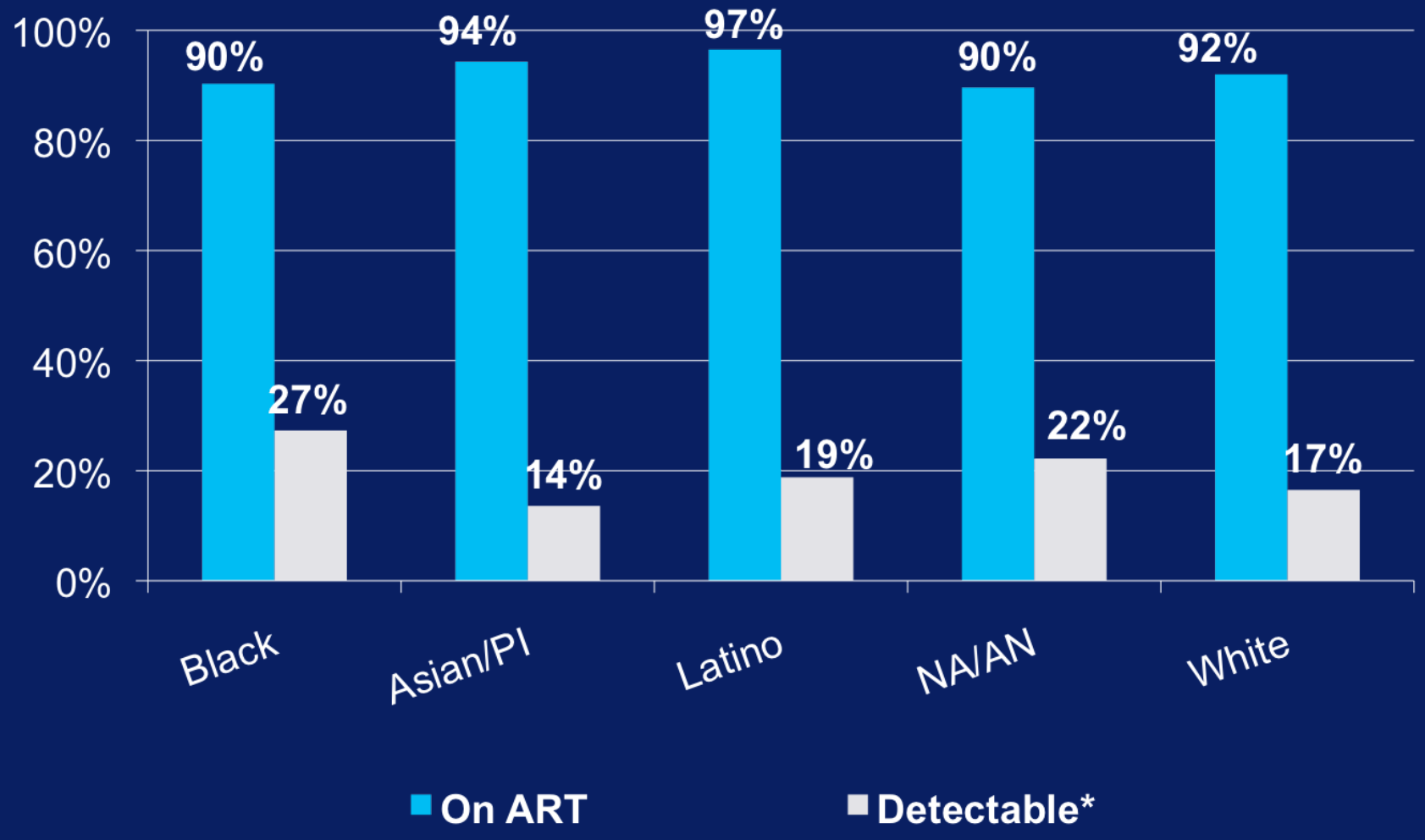
ART Use in RW System



Source: *Casewatch YR 19 (Feb. '09 – Mar. '10):*
Data limited to RW Client w/ 1 or more MOP visit.
* Detectable is a subset of those on antiretroviral therapy with > 200 copies VL.

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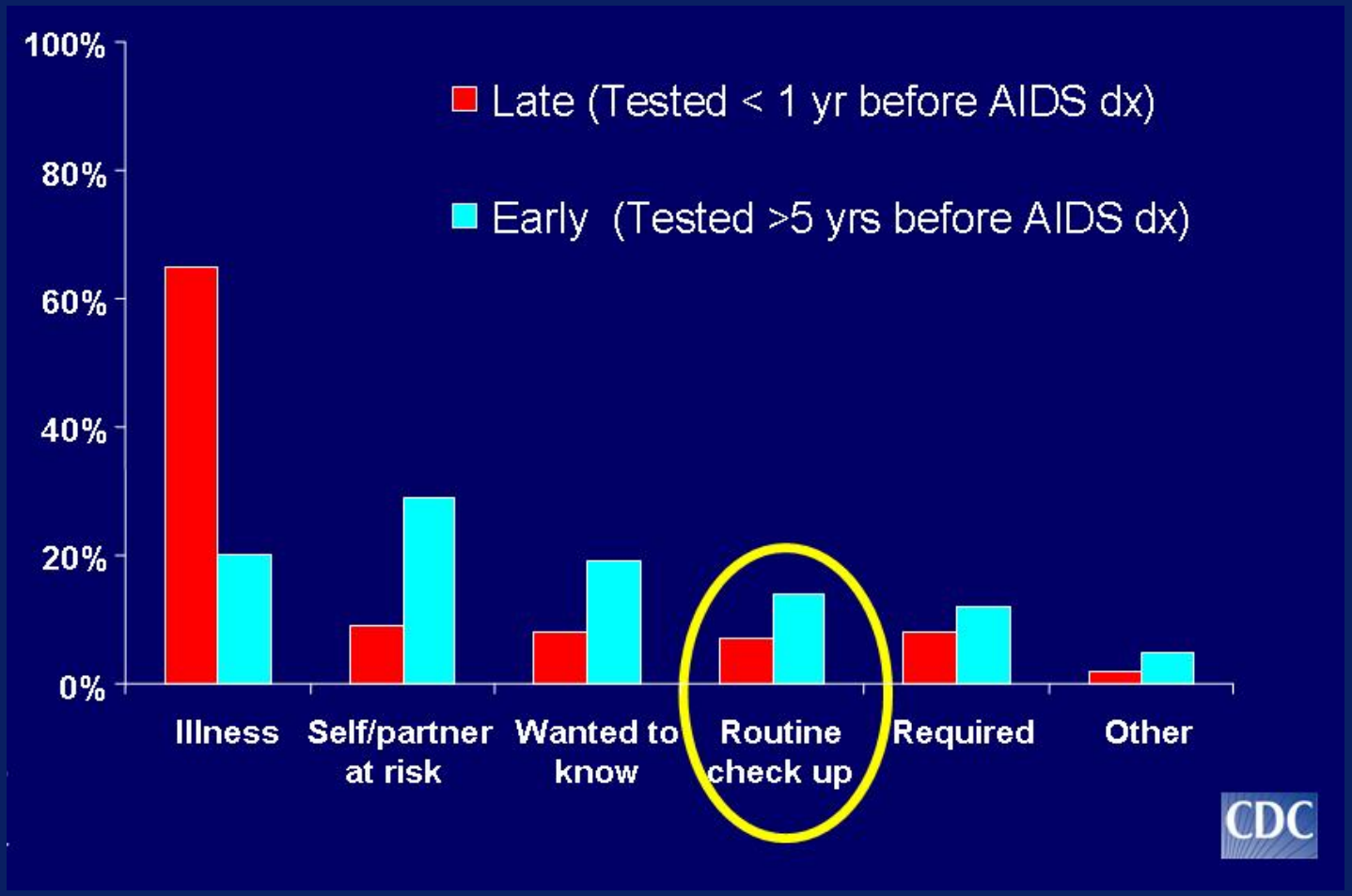
Testing Reason: Late vs. Early Testers



Supplement to HIV/AIDS Surveillance, 2000-2003

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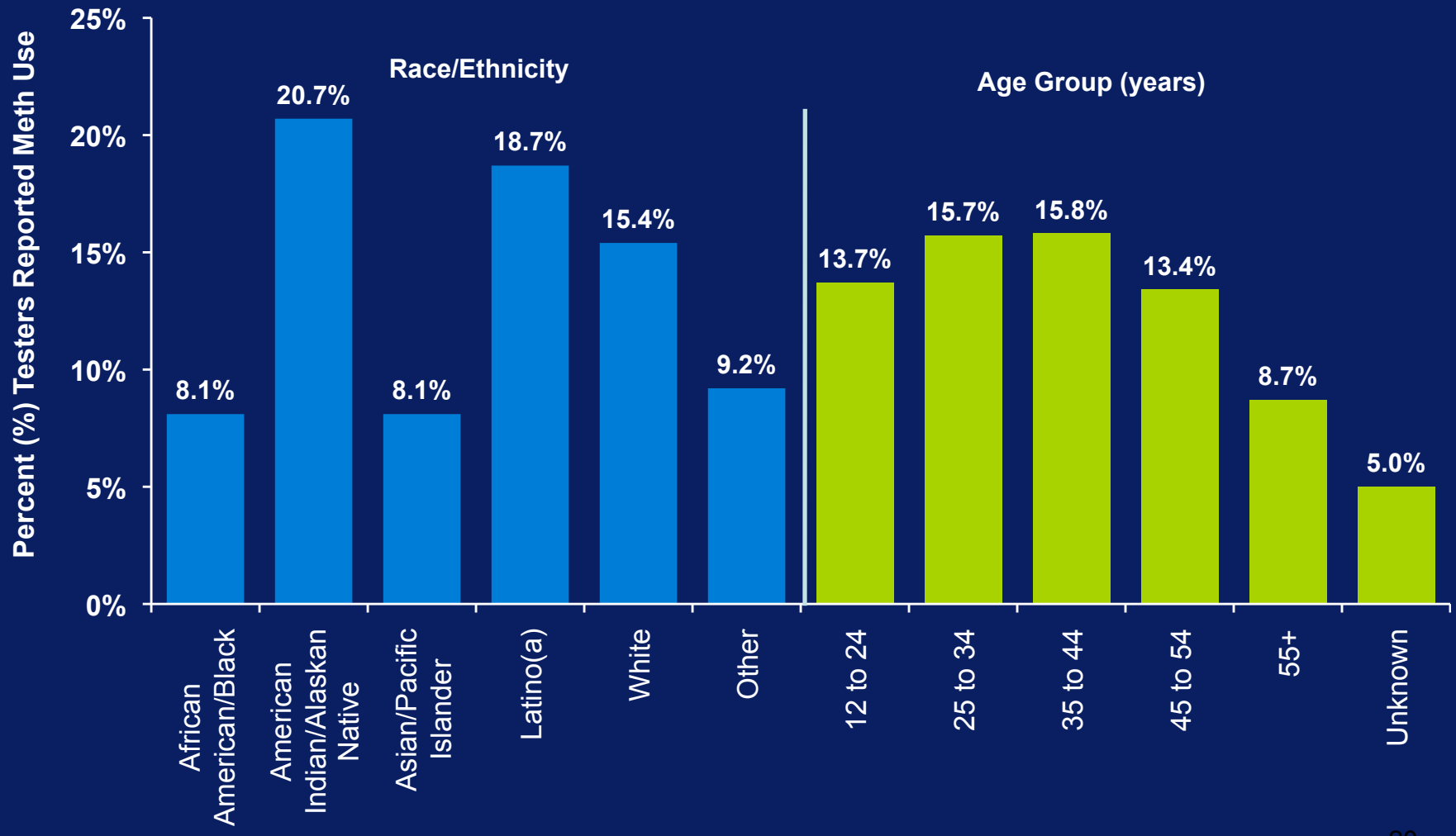
Meth Use by Race/Ethnicity and Age Group, 2008



Data Source: HIV Counseling and Testing Data, HIV Resources Information Systems (HIRS), January 1 - December 31, 2008. Data are provisional, numbers are based on tests, not necessarily individuals.

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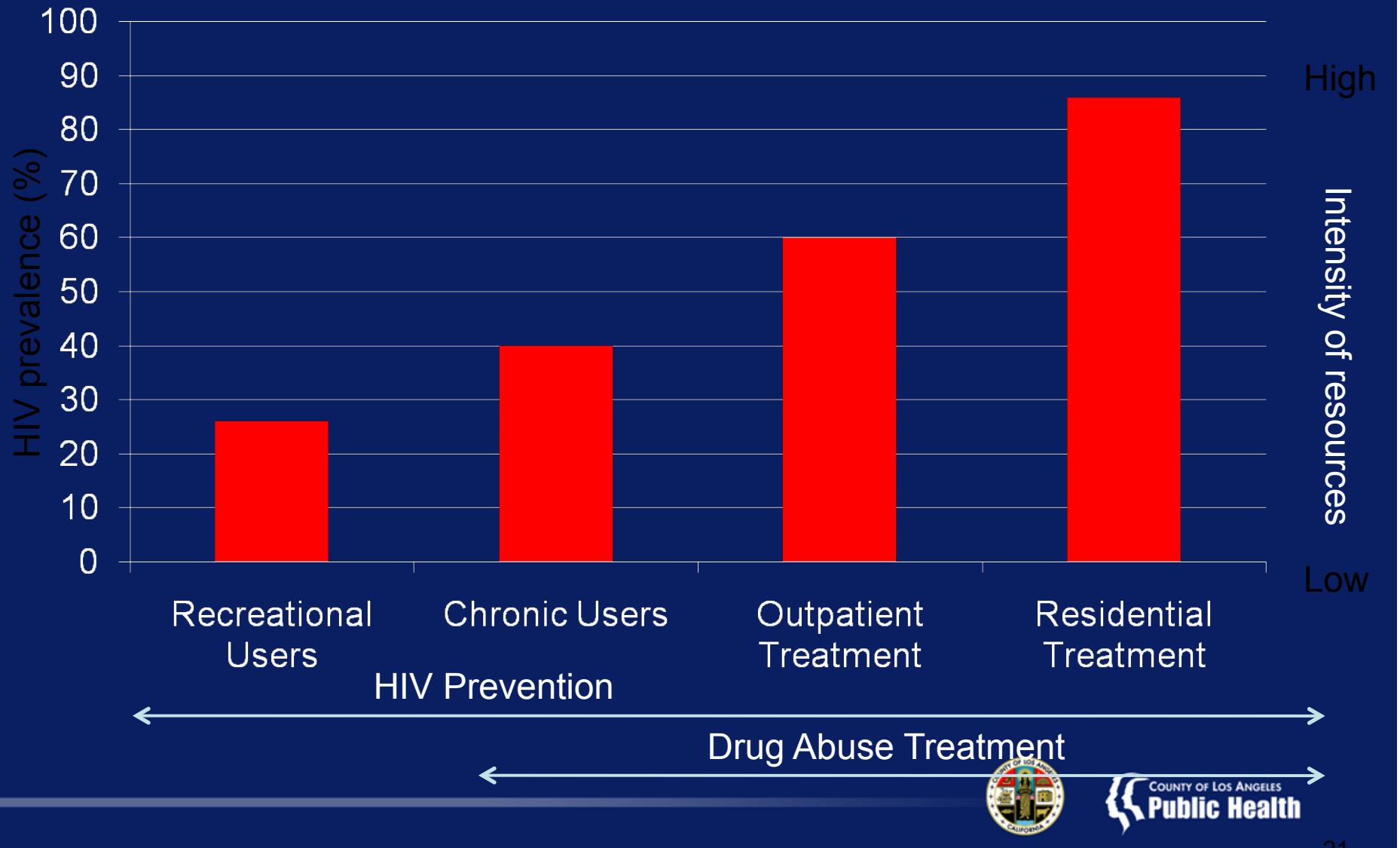
"Time-to-Response" Association



Source: Shoptaw, S. and Reback, C.J., (2006). *Journal of Urban Health, 83 (6):1151-1157*

Los Angeles Coordinated HIV Needs Assessment
HIV-Positive MSM Risk Profile, 2007

Risk Behaviors	AA MSM (n = 32)	Latino MSM (n = 84)	White MSM (n = 34)
Inconsistent Condom Use	38%	33%*	59%
Serodiscordant Partner	44%	46%	32%
Sex while Drunk	34%	21%	38%
Sex while High (meth)	6%*	16%	24%
Sharing Needles	3%	1%	0%
STD Diagnosis	19%	12%	12%
Sex Trade	9%	7%	15%
Any Risk**	**81%**	**79%**	**85%**

* Significantly different from White MSM - reference (p-value < 0.05).
** Any risk is defined as: at least 1 (out of 7) reported risk behaviors.

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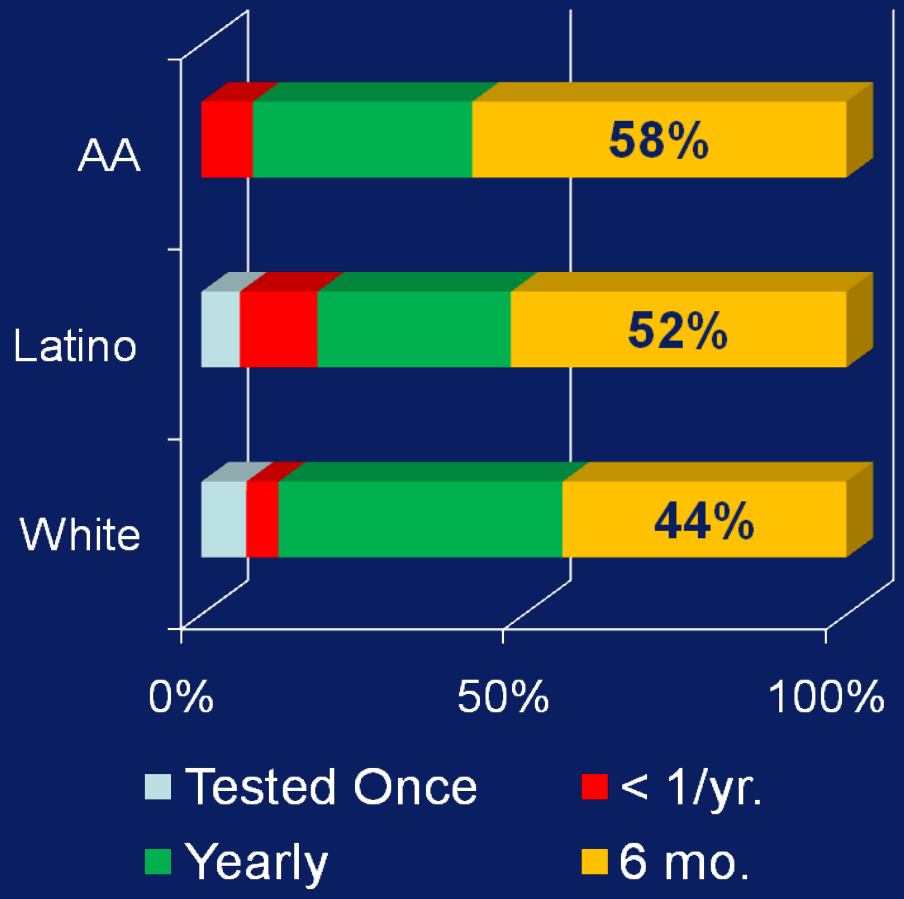
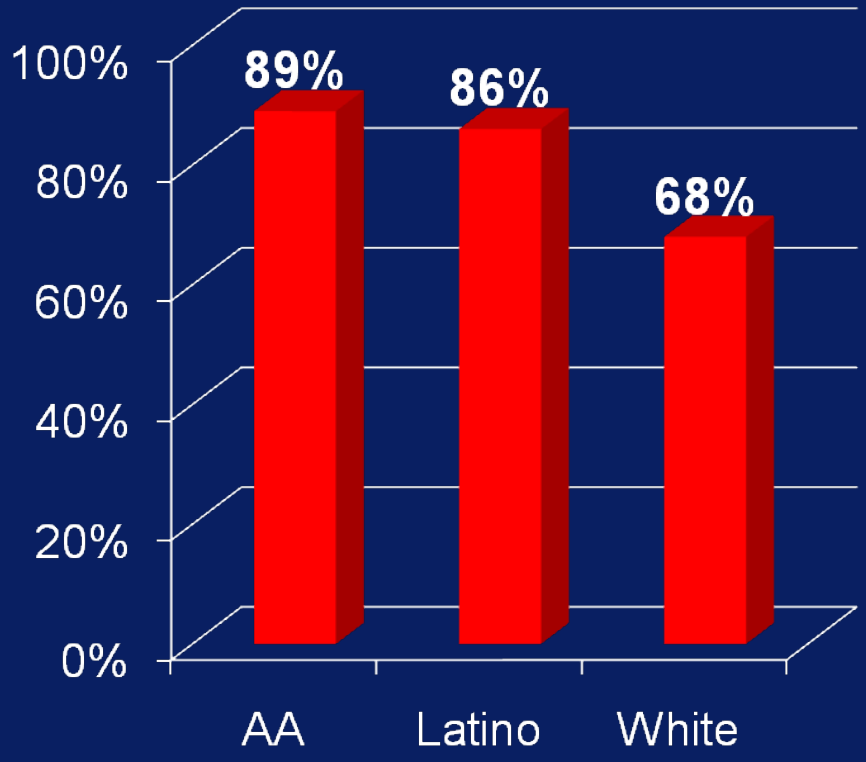
Los Angeles Coordinated HIV Needs Assessment
MSM Prevention* Service Utilization, 2007

Testing Frequency



Prevention Services** Utilized



* Only among HIV-negative or unknown status (n = 295).

** Includes ILI, GLI, HIV information, public HIV test, or needle exchange.

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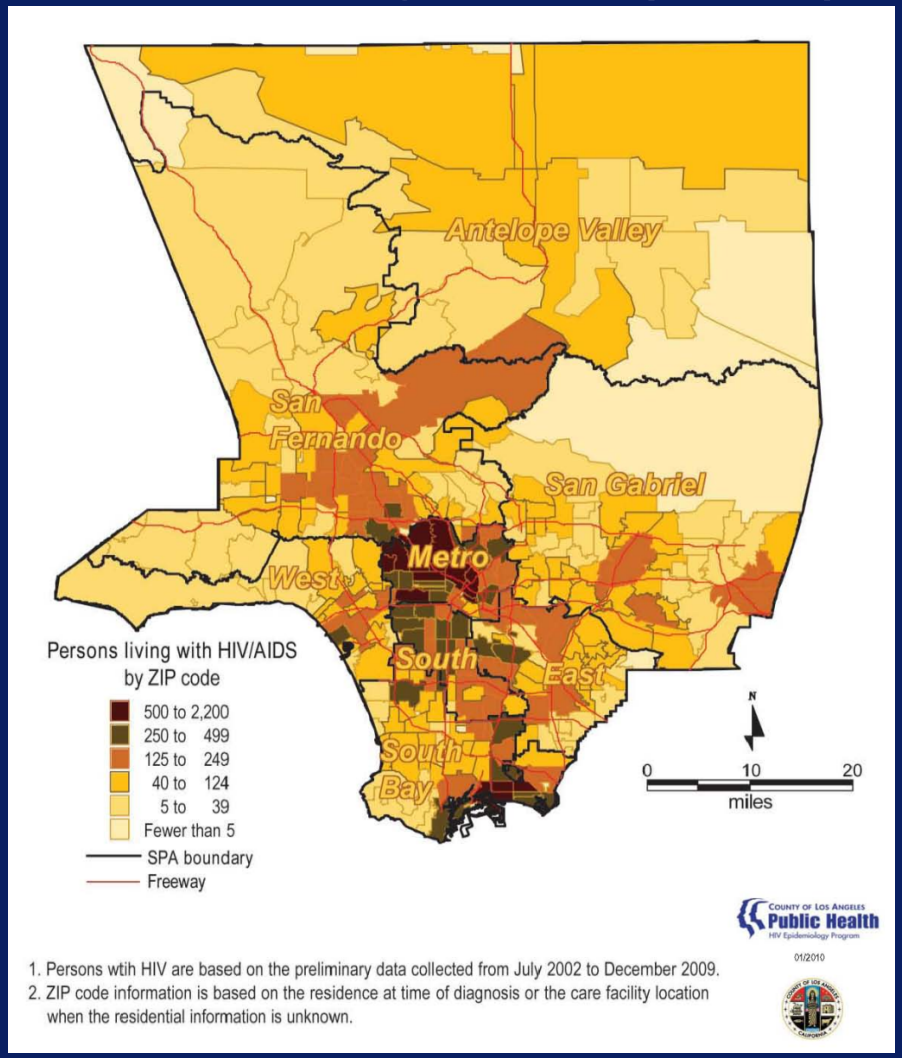
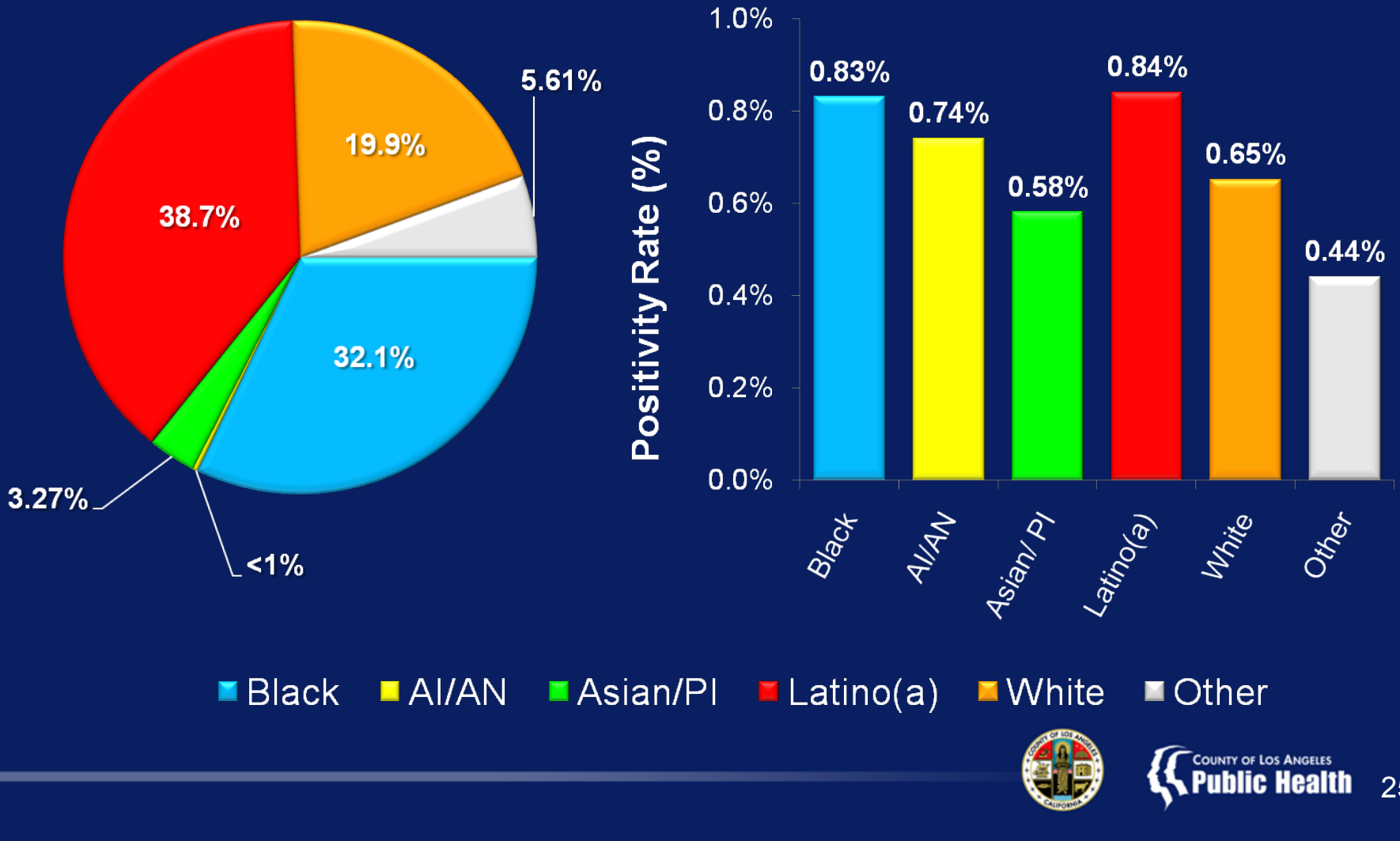
Persons Living with HIV/AIDS* within Los Angeles County Service Planning Areas (SPAs), 2009



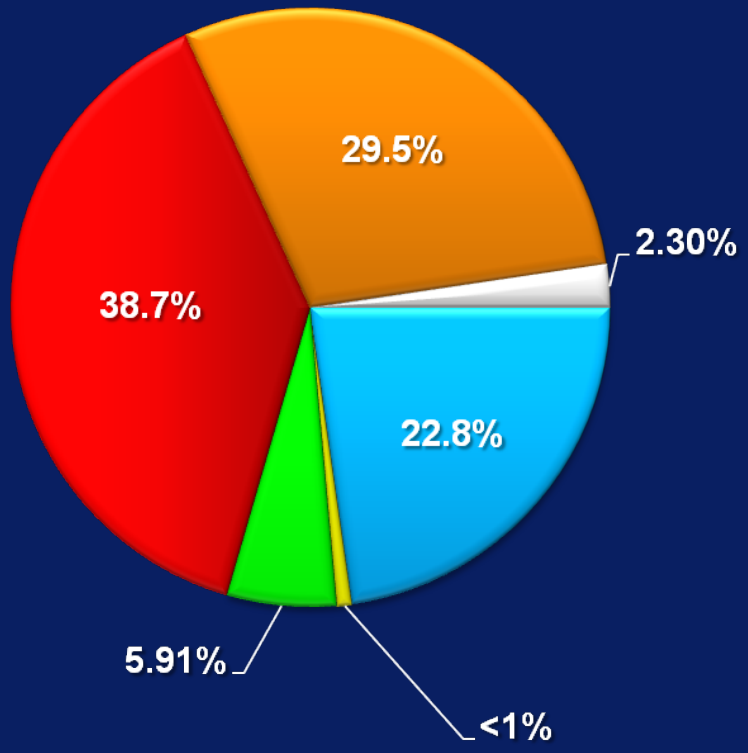
Overall Demographics

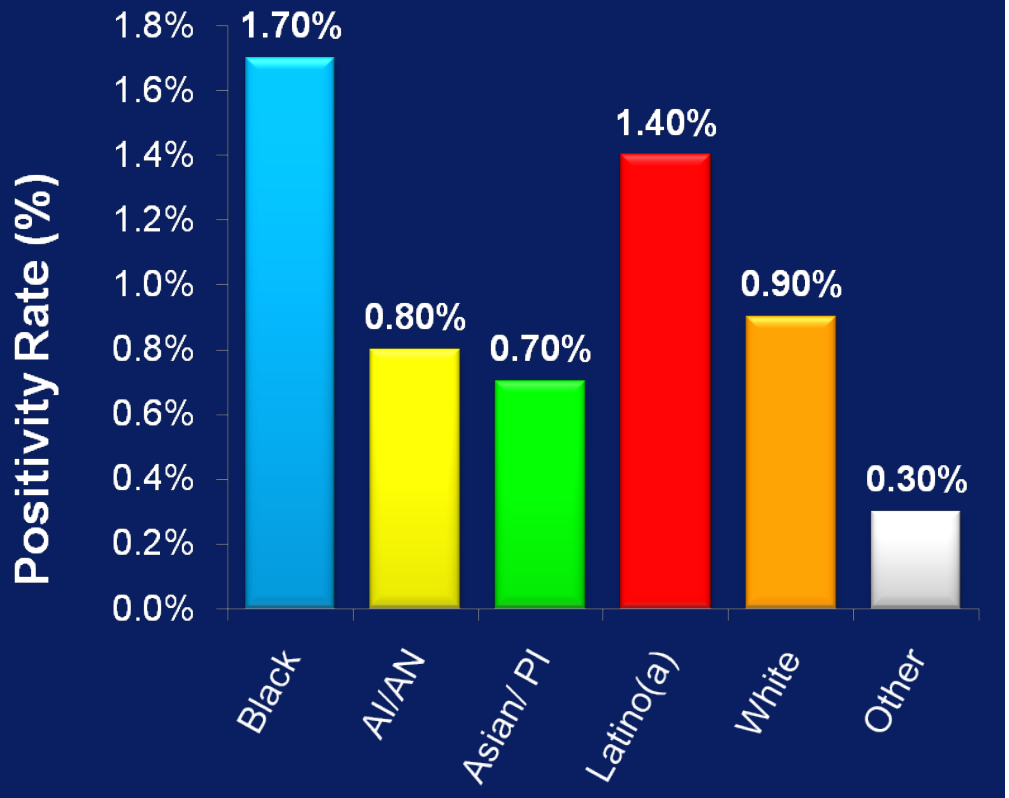
Race/Ethnicity (N = 69,006)



Targeted Testing Demographics

Race/Ethnicity (N = 28,920)

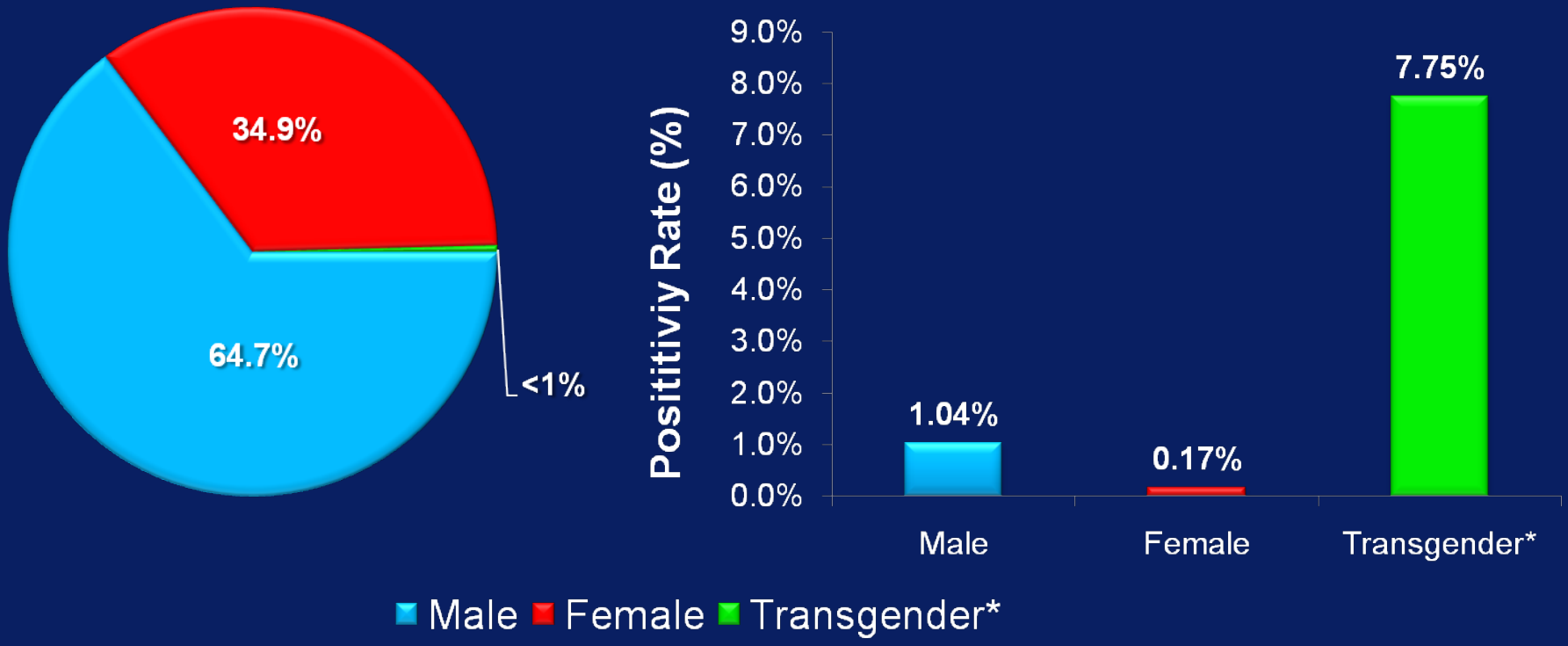




Black AI/AN Asian/PI Latino(a) White Other

Overall Demographics

Gender (N = 69,006)



* Transgender includes both male-to-female and female-to-male. <0.1% with unknown gender.

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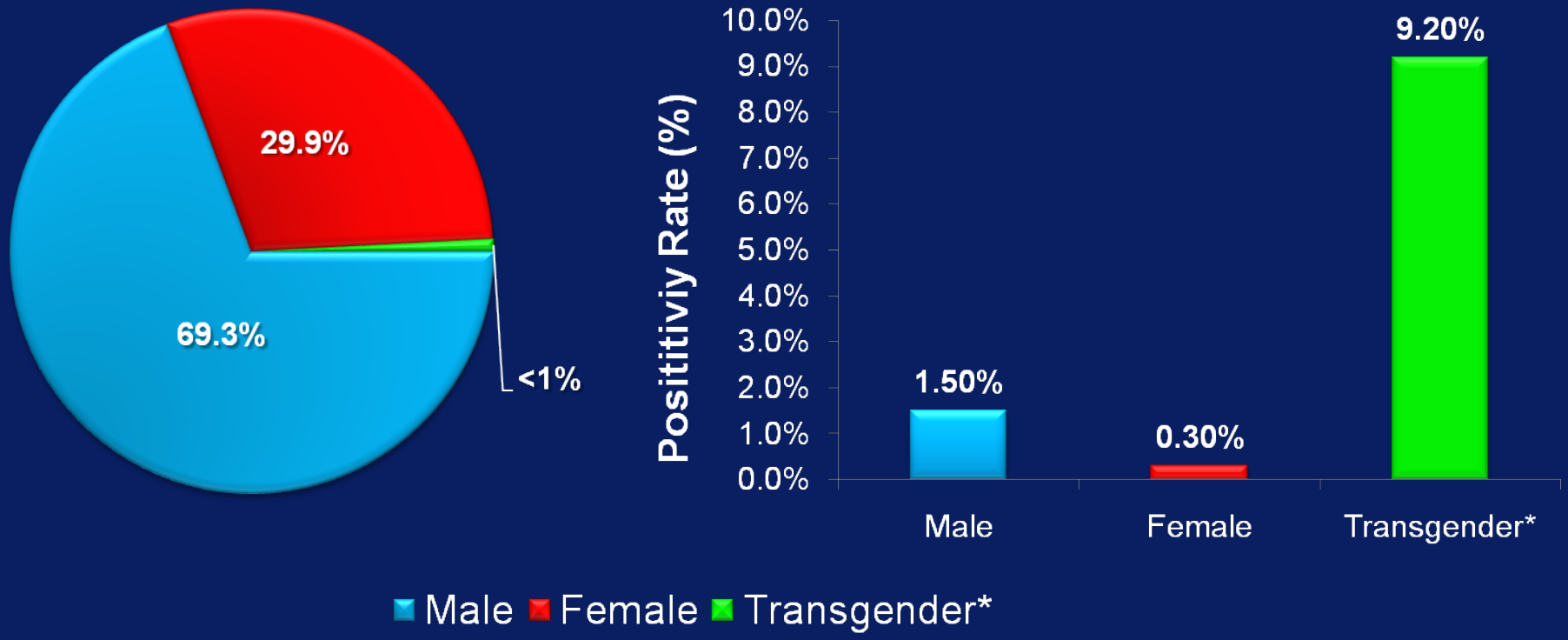
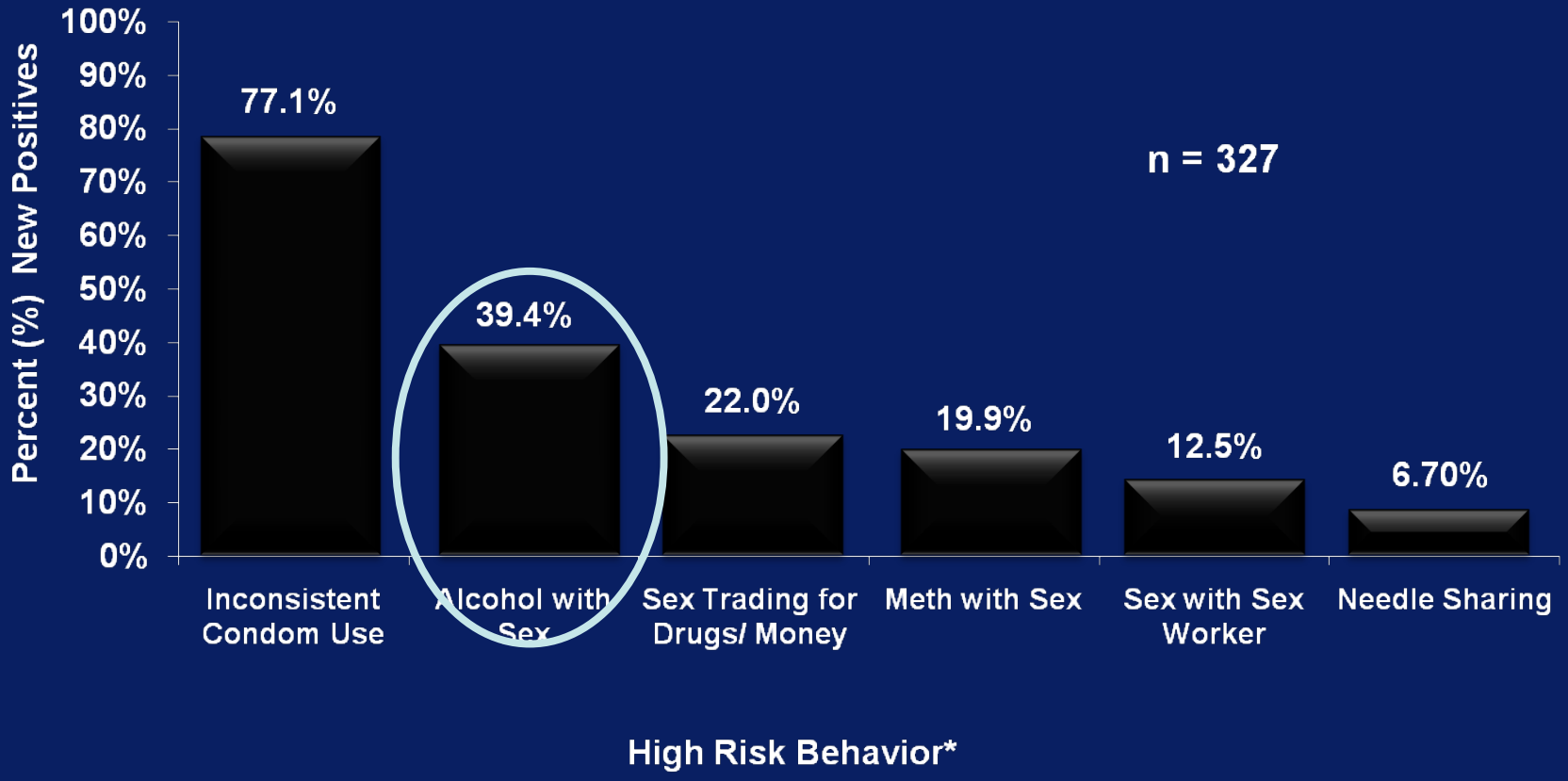
Targeted Testing Demographics

Gender (N = 28,920)



New Positives Identified at OAPP-funded HCT Sites by HIV Risk Behavior, 2009



* High risk behaviors are not mutually exclusive. Individuals may have engaged in more than one high risk behavior.

[1] New Positives refer to individuals who self-report never having a prior positive HIV test result.

[2] Inconsistent condom use includes never or sometimes using condoms.

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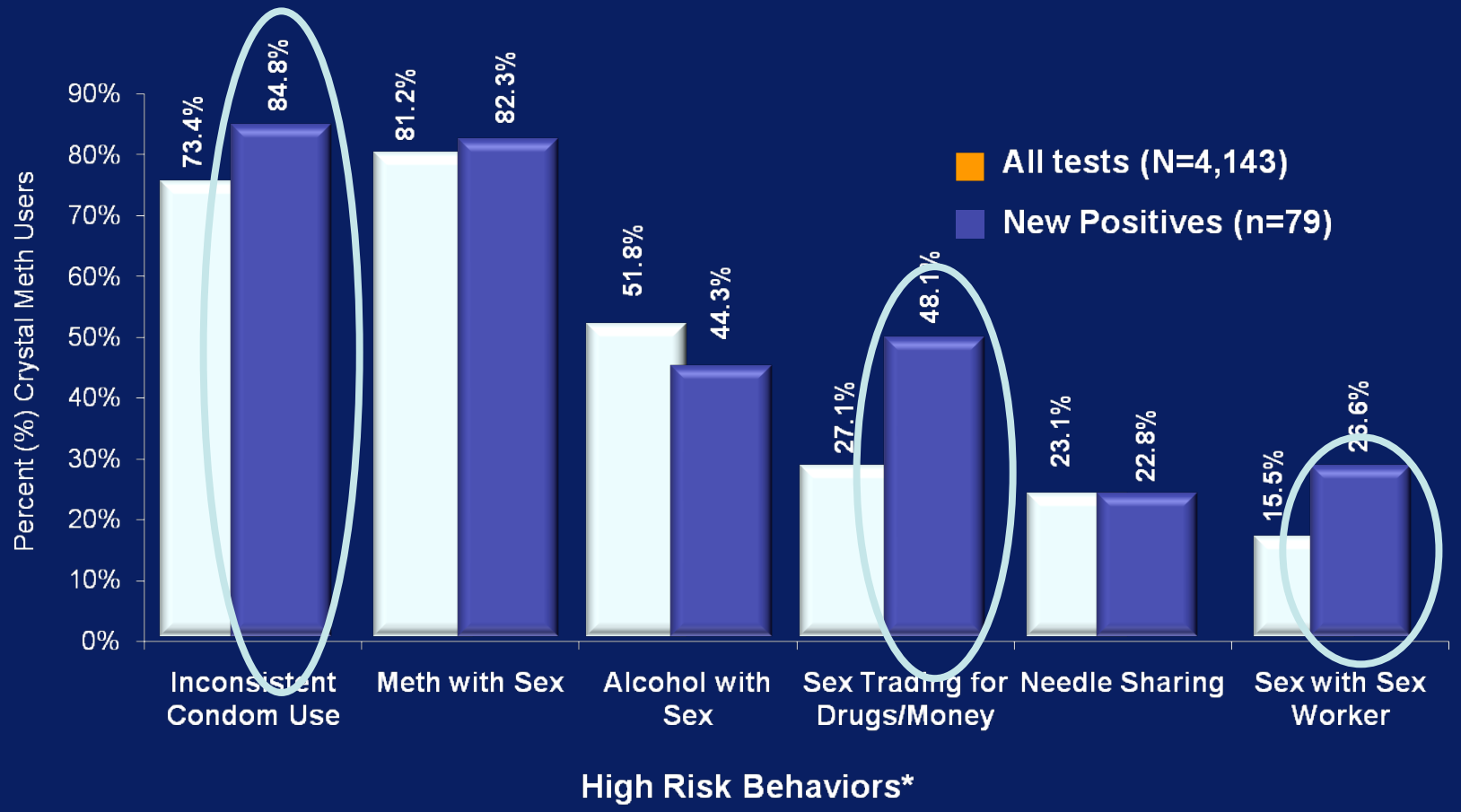
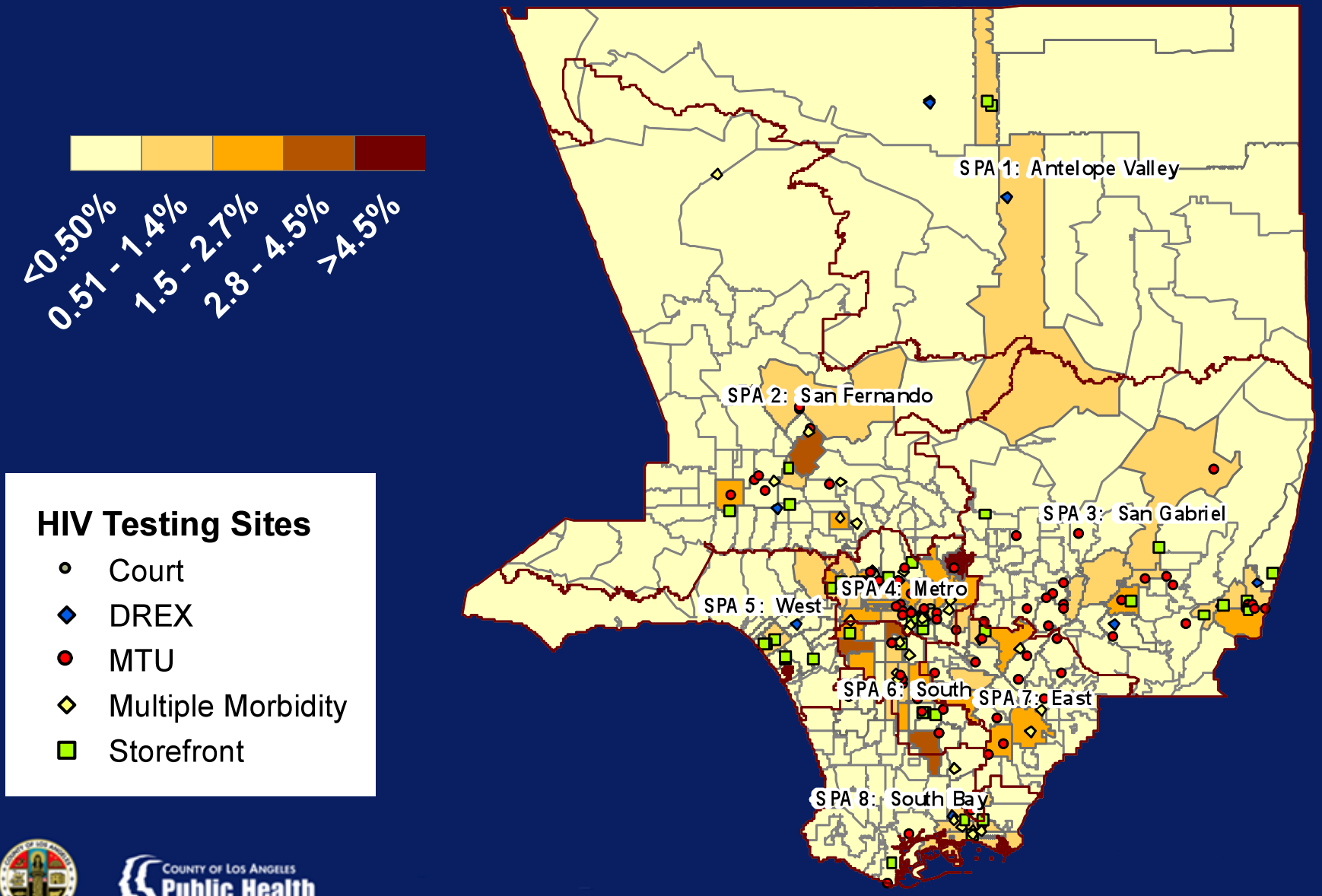
High Risk Behavior among Testers Reporting Meth Use



HIV New Positivity by Zip Code and Testing Sites, 2009



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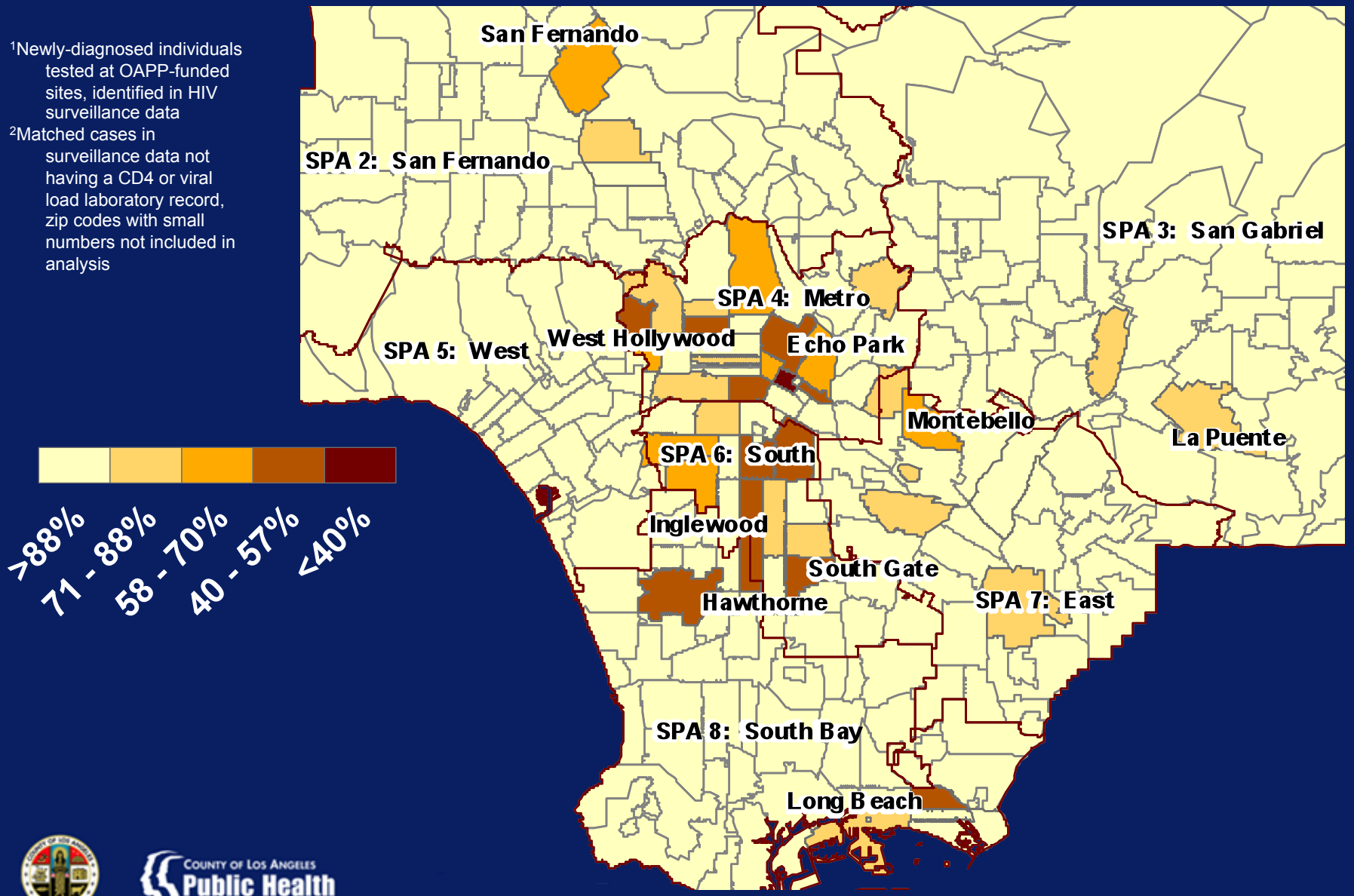
Data Source: Office of AIDS Programs and Policy, HIV Counseling and Testing Data [1]Newly-diagnosed individuals tested at OAPP-funded sites, (self-report)

HIV-positive Individuals[1] Linked to Care[2], 2006-08 by Zip Code

[1]Newly-diagnosed individuals tested at OAPP-funded sites, identified in HIV surveillance data

[2]Matched cases in surveillance data not having a CD4 or viral load laboratory record, zip codes with small numbers not included in analysis



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Data Source: HIV Epidemiology Program, 2010

1Newly-diagnosed individuals tested at OAPP-funded sites, identified in HIV surveillance data 2Matched cases in surveillance data not having a CD4 or viral load laboratory record

Questions Persist

- Which prevention interventions are having the greatest impact?
- How do we most efficiently reduce disparities?
- What are the right incentives to improve linkage to care?
- How do you best interrupt transmission in sexual and social networks?
- Where will condom saturation programs be most effective?

Local HD Responsibilities

- Invest federal, state and local HIV/AIDS resources prudently
- Map and understand the local epidemic
- Identify program gaps, trends and disparities
- Help guide and support a responsive and progressive research and evaluation agenda
- Translate research into sustained practice
- Be held and hold federal, state and local partners accountable

Understanding our Capacity and Leveraging our Assets

- Department of Public Health
  - OAPP
  - HIV Epidemiology Program
  - Sexually Transmitted Disease Program
- Health Research Associates
- Los Angeles BioMed
- Community-Based Organizations

Understanding our Capacity and Leveraging our Assets

- University of California at Los Angeles
  - CHIPTS
  - AIDS Institute
  - Center for Clinical AIDS Research & Education
- Charles Drew University of Medicine & Science
- University of Southern California
- RAND Corporation

Driving Research: Understanding our Investigation Environment

What drives activity locally?

- Publish or perish constructs
  - Peer Reviewed Publications
- Agency value
  - DPH Science Summit
  - PPC Science Summit and Colloquia
- Resource scarcity
- Capacity and interest

Driving Research: Understanding our Investigation Environment

What drives the agenda?

- Funder philosophy and focus areas
  - NIH, CDC, SPNS, CHRP,
- Whatever is exciting
- The unknown
- A known program or service failure

Four Research Case Studies

1. CM/PEP for HIV-negative Gay Male Methamphetamine Users
2. Rapid Testing Algorithm
3. Non-occupational PEP for High-risk Negative Individuals
4. Interruption Disease Transmission Among Sexual Networks

Research Study 1: Contingency Management/ Post-Exposure Prophylaxis

County of Los Angeles Public Health

A Combined Biobehavioral Intervention for HIV-negative Methamphetamine-using Men who have Sex with Men

Cathy J. Reback, Ph.D.*,**
Raphael J. Landovitz, M.D., M.Sc.***
Steven Shoptaw, Ph.D.****

*Friends Research Institute, Inc.
**UCLA Integrated Substance Abuse Programs
***UCLA Center for Clinical AIDS Research & Education
****UCLA Department of Family Medicine

This study is sponsored by the County of Los Angeles, Department of Public Health, Office of AIDS Programs and Policy, Contract #H-2702632.

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Post-exposure prophylaxis (PEP) for HIV

- Standard-of-care after occupational exposures to HIV-infected blood and bloody body fluids in healthcare settings (e.g., needle sticks or mucous membrane splashes)
- Also recommended to prevent HIV acquisition in non-occupational settings:
  - Anal or vaginal intercourse or injection drug needle-sharing
  - With a known HIV+ or unknown HIV-status or high-risk source
- Guidelines suggest administration within 72 hours of exposure, treatment for 28 days
- Has been estimated to reduce the risk of acquiring HIV after a high-risk exposure by more than 80%[1]

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[1]Cardom DM, *et al. N Engl J Med.* **1997**.

Contingency Management (CM)

- CM as a behavioral intervention
  - Demonstrated to be more effective than cognitive behavioral therapy for inducing and maintenance methamphetamine abstinence[2,3]

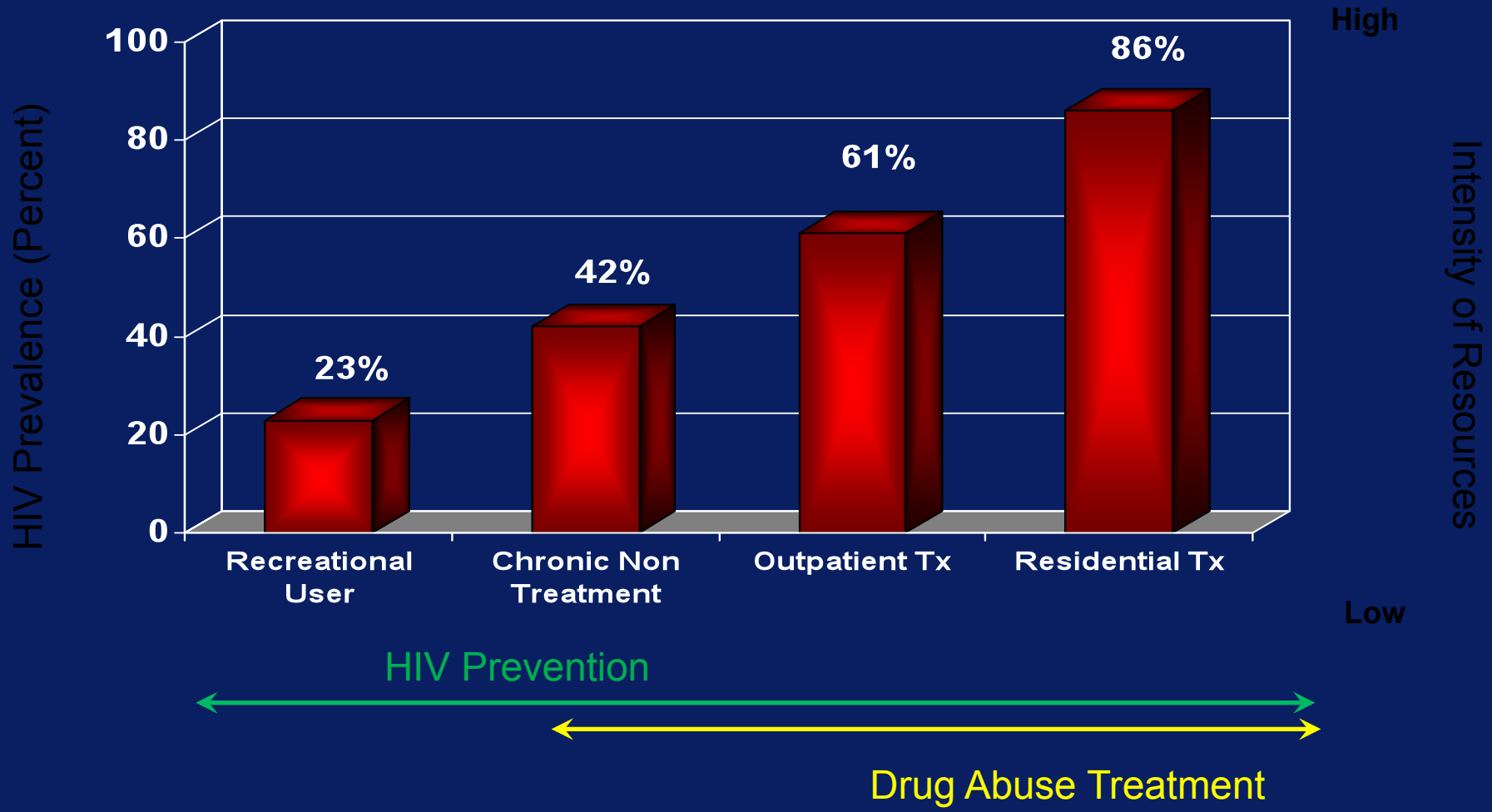
- Escalating voucher-based remuneration for thrice-weekly urine samples which test negative for methamphetamine metabolites

[2]Shoptaw S, Reback CJ, Peck JA, *et al*. *Drug Alcohol Depend.* 2005.
[3]Rawson RA, McCann MJ, Flammino F, *et al. Addiction.* 2006.

Program Aims

- Assess the feasibility of employing a combination PEP +CM intervention in methamphetamine-using MSM;
- Assess impact of intervention on methamphetamine use and sexual risk behaviors;
- Increase medication adherence rates as compared to historical controls in other PEP cohorts (non meth-using); and
- Assess prevalent and incident STI infections.

Methamphetamine and HIV in MSM: A Time-to-Response Association



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Source: Shoptaw & Reback, "Associations between Methamphetamine Use and HIV among Men Who Have Sex with Men: A Model for Guiding Public Policy," *Journal of Urban Health*, 83:1151-1157.

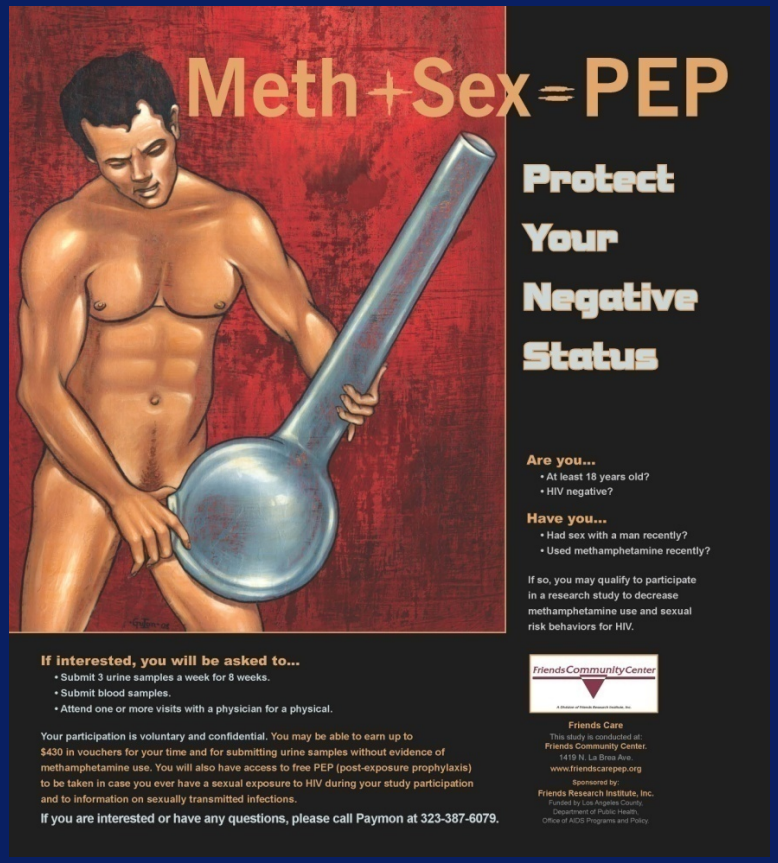
Program Design

- Prospective single arm, open-label, pilot safety and feasibility program
- Eligibility:
  - MSM
  - > 18 years
  - HIV negative (self report and rapid test)
  - Self-reported meth use in the previous 30 days
  - Self-reported unprotected anal intercourse with HIV-positive/unknown partner in the previous 90 days

Procedures

- Program approved by IRBs of FRI, Inc. and UCLA
- Planned enrollment: 55 participants, currently enrolling
- CM, three times a week for 8 weeks
  - Participants may “cash in” accumulated voucher points for goods or services at any time
- Participants enrolling in the absence of an eligible high-risk exposure to HIV are provided a 4-dose starter pack of Truvada
  - In the event of high-risk exposure to HIV, starter pack use is initiated
  - Attempt to reduce exposure-to-dose time
- Participants reporting at *baseline* a high-risk HIV exposure within the previous 72 hours will initiate PEP concomitantly with enrollment and CM

Recruitment Material



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Conclusions

- When integrated with CM, PEP use among meth-using MSM appears to be safe and feasible for HIV prevention. Time to PEP initiation and adherence rates appear comparable to non-methamphetamine using populations.
- Meth-using MSM demonstrate high rates of sexual risk behavior as evidenced by high prevalent STI rates.
- Although a small sample size, there was only one incident sero-conversion.

Research to Practice Summary

Problem: Rates of HIV among meth-using gay men

Research Q: Can CM-PEP help curb infections?

Critical Partner: Friends Research Institute

HD Role: Funder, risk-taker, advocate

Practice Outlook: Part of our local portfolio, new funds secured, financing meds critical

CDC/NIH/SAMHSA Role: Support more widely

Research Study 2:
Rapid Testing Algorithm

County of Los Angeles
Public Health

Use of a Three Rapid HIV Test Algorithm at Point-of-care Settings: County of Los Angeles, Department of Public Health Experience

Jacqueline Rurangirwa MPH[1], Mike Janson MPH[1], Peter Kerndt MD MPH[2], Jan King MD MPH[3]

1.County of Los Angeles Department of Public Health, Office of AIDS Programs and Policy
2.County of Los Angeles Department of Public Health, Sexually Transmitted Diseases Program
3.County of Los Angeles Department of Public Health, Area Health Officer

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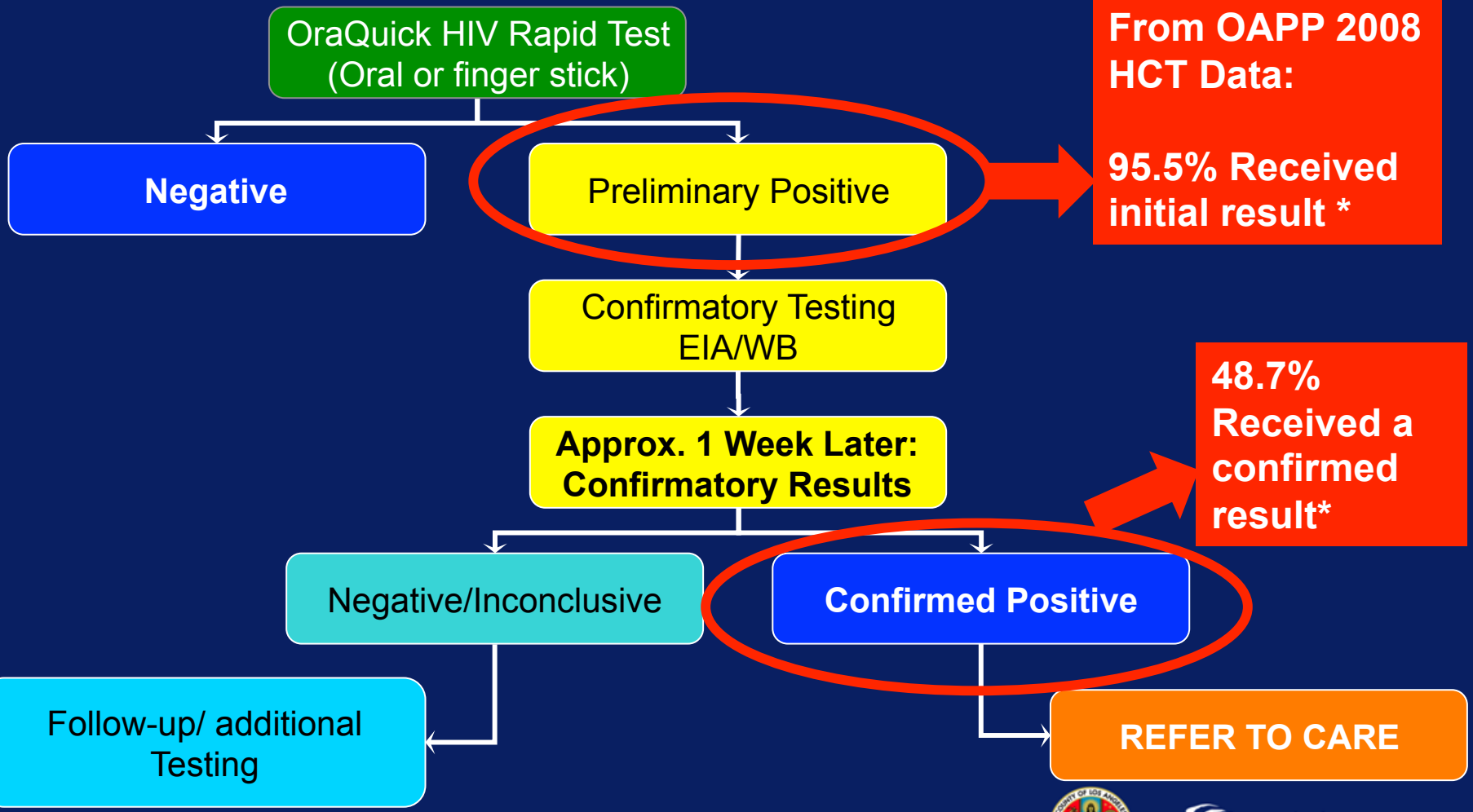
Evolution of Rapid HIV Testing

- 1989 – CDC and APHL two-test algorithm for HIV testing: EIA/WB
  - considered “gold standard”
- 1994 – UNAIDS and WHO
  - 3 types of rapid HIV testing algorithms
- 1994 – Present: RT technology development
  - FDA approved CLIA-waived tests
  - Sensitivity and specificity of tests exceed that of “gold standard”
  - Tests permit use in multi-test algorithms

Rapid HIV Testing in LAC



*Office of AIDS Programs and Policy, Los Angeles County Department of Public Health, HIV Counseling and Testing Annual Report, January through December 2008, June, 2009, 1- 35.

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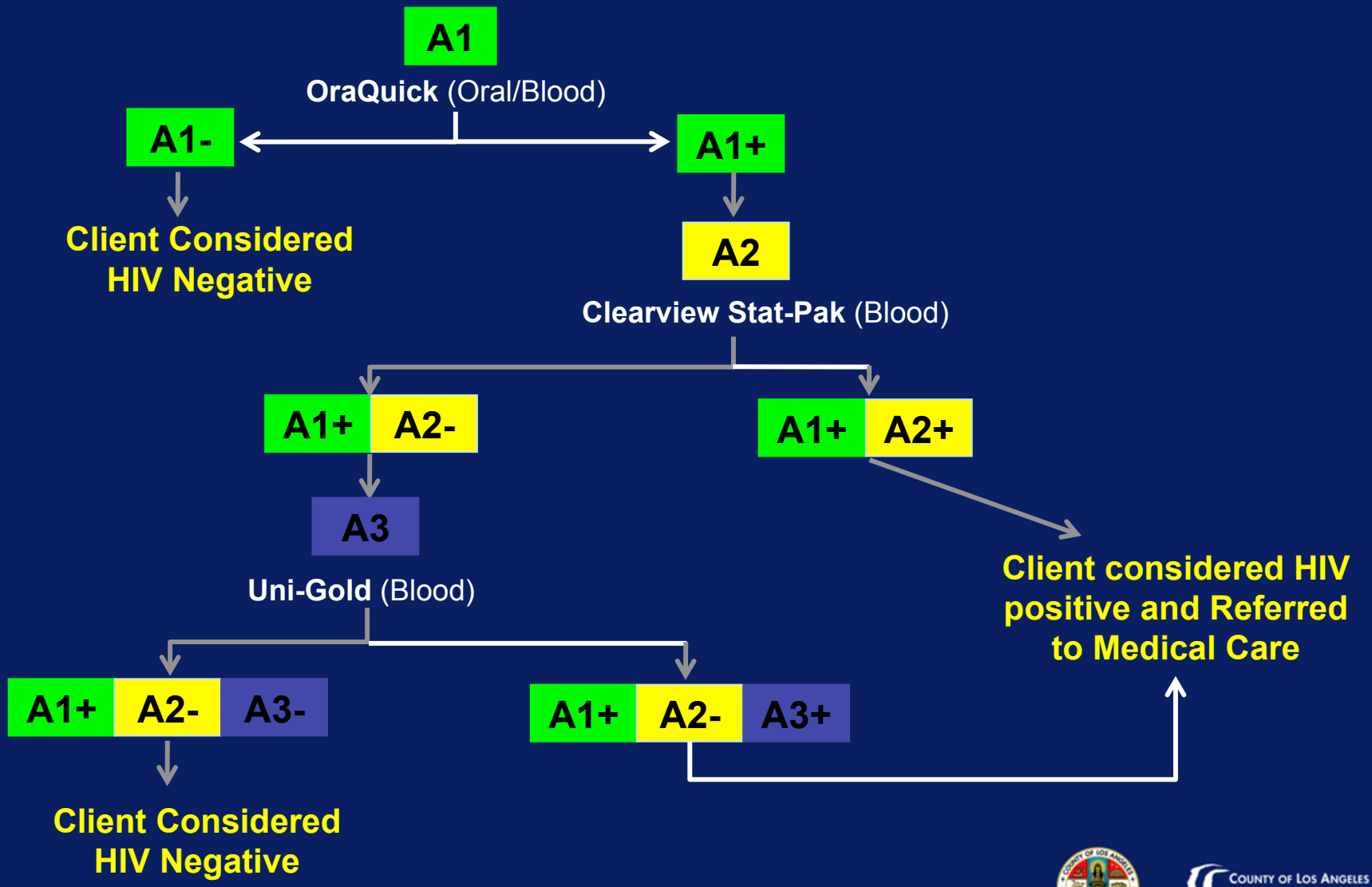
Rapid Testing Algorithm Study

- CDC-funded study
- Goal: Evaluate the impact and feasibility of using a sequence of up to 3 HIV rapid tests, to provide clients with information about their HIV status within 1 hour and link into care
- Los Angeles Sites: All OAPP-funded rapid HCT sites
  - RTA Intervention sites: 4 (MTUs, Storefronts, Community clinics)
  - Comparison sites: 12
- Project period: August 2007 – March 2009

RTA at Intervention Sites



HIV Testing Algorithms: A Status Report: POC Algorithm 4. Available at http://www.aphl.org/aphlprograms/infectious/hiv/Pages/HIVStatusReport.aspx

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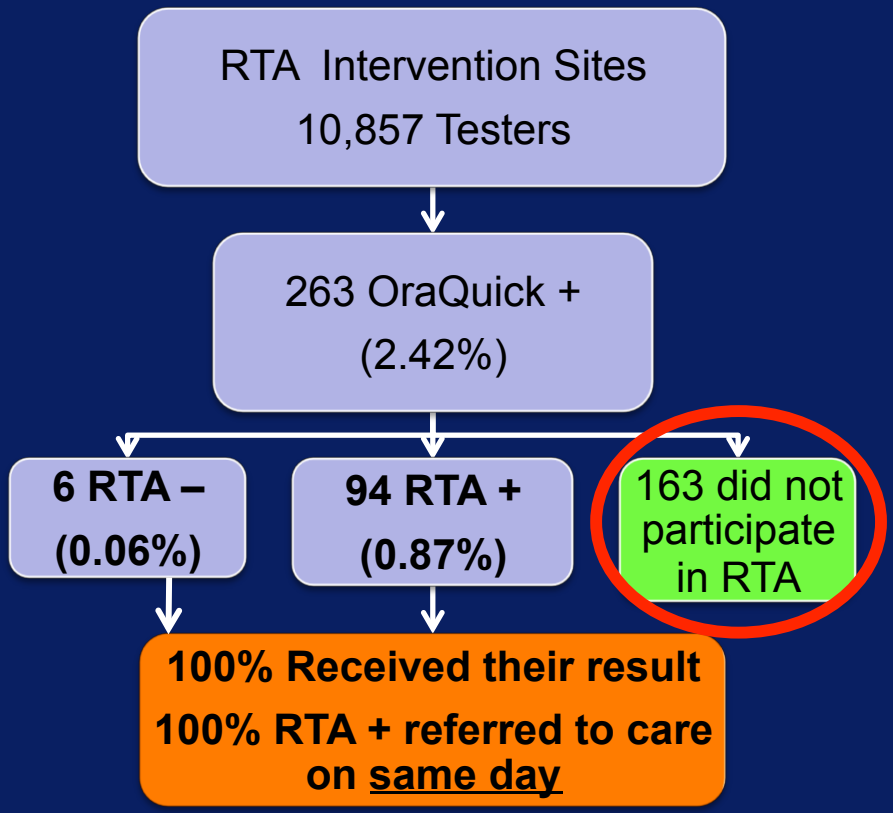
Results: Intervention vs. Comparison Sites

Study Period: August 1, 2007 – March 31, 2009

Intervention Sites

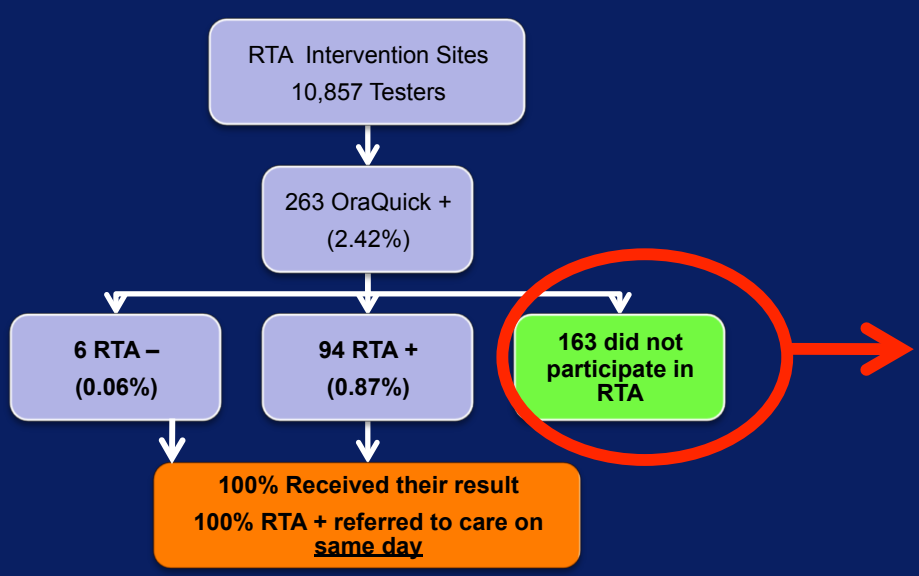


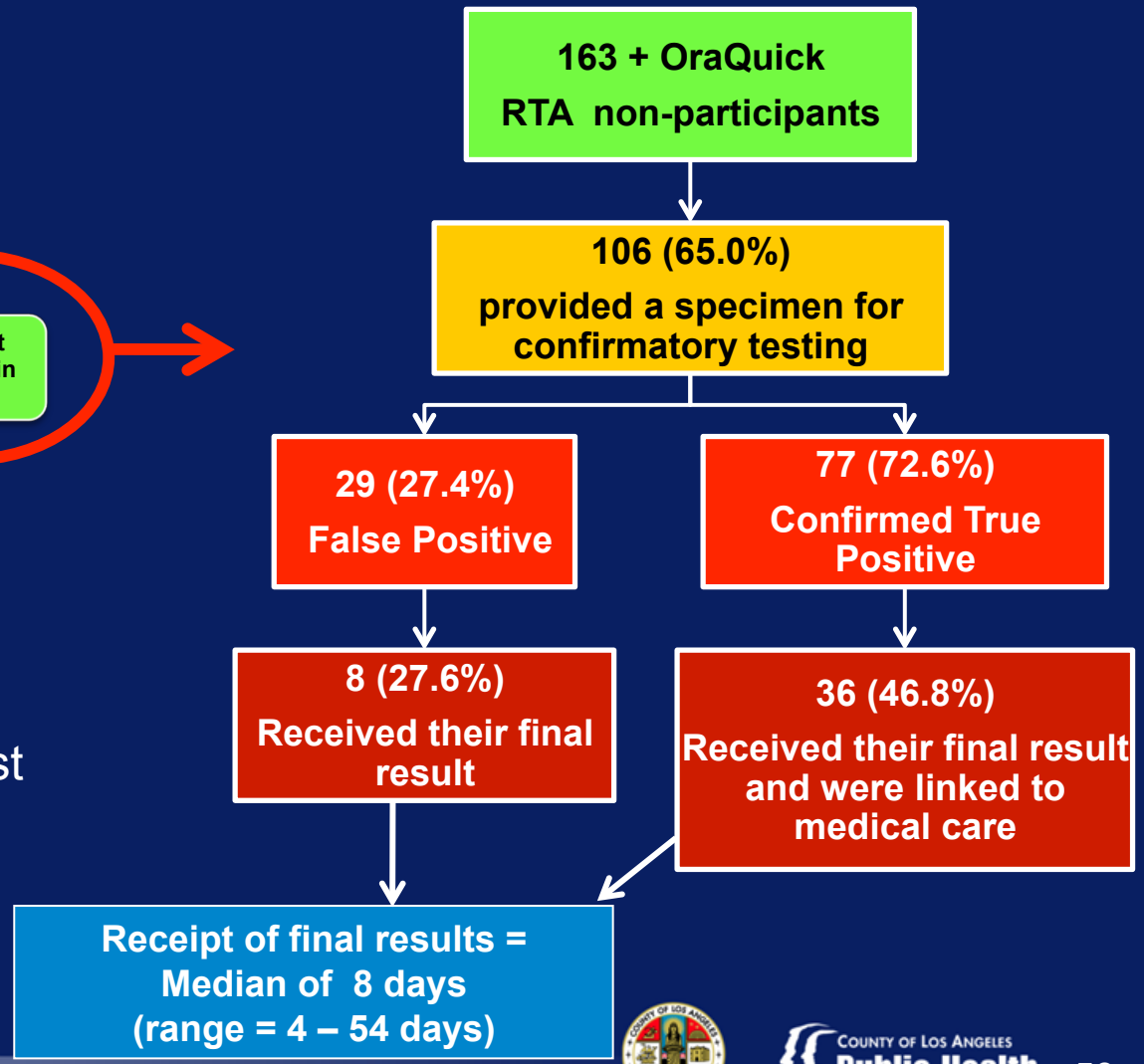
Comparison Sites

Characteristic	N (%)
# Tested	32,929
# Screened Reactive	487 (1.48%)
# False Positive	41 (0.12%)
# Received Confirmatory Test Results	206 (42.3%)
Median # Days Referred to Medical Care (range)	8 days (1 – 55 days)

Data Source: OAPP HIV Counseling and Testing Data , 2009

Results: Intervention Sites (Cont.)





Site Challenges:

- Client refused confirmatory test
- Phlebotomy capacity not consistently available

Results Summary

- At RTA Intervention Sites:
  - 100% of clients received their test results on the same day
  - All RTA reactive clients referred to care on the same day
  - 6 false positive results resolved on the same day
  - Receipt of confirmed results among non-RTA participants was similar to those at comparison sites (~42%)
- Comparison Sites:
  - 42% received confirmatory results
  - Median 8 days until referral to medical care
- Linkage to care? Analysis currently ongoing.

Lessons Learned

- Phlebotomy capacity was not consistently available in order to offer the RTA
  - Solution: Fingerstick law (AB 221) passed in California in September 2009
- Significant time investment at start up
  - Slow roll out of an RTA program is important
- Rarely used the third test in the RTA (n=6)
  - More cost effective to use a two-test algorithm

Next Steps

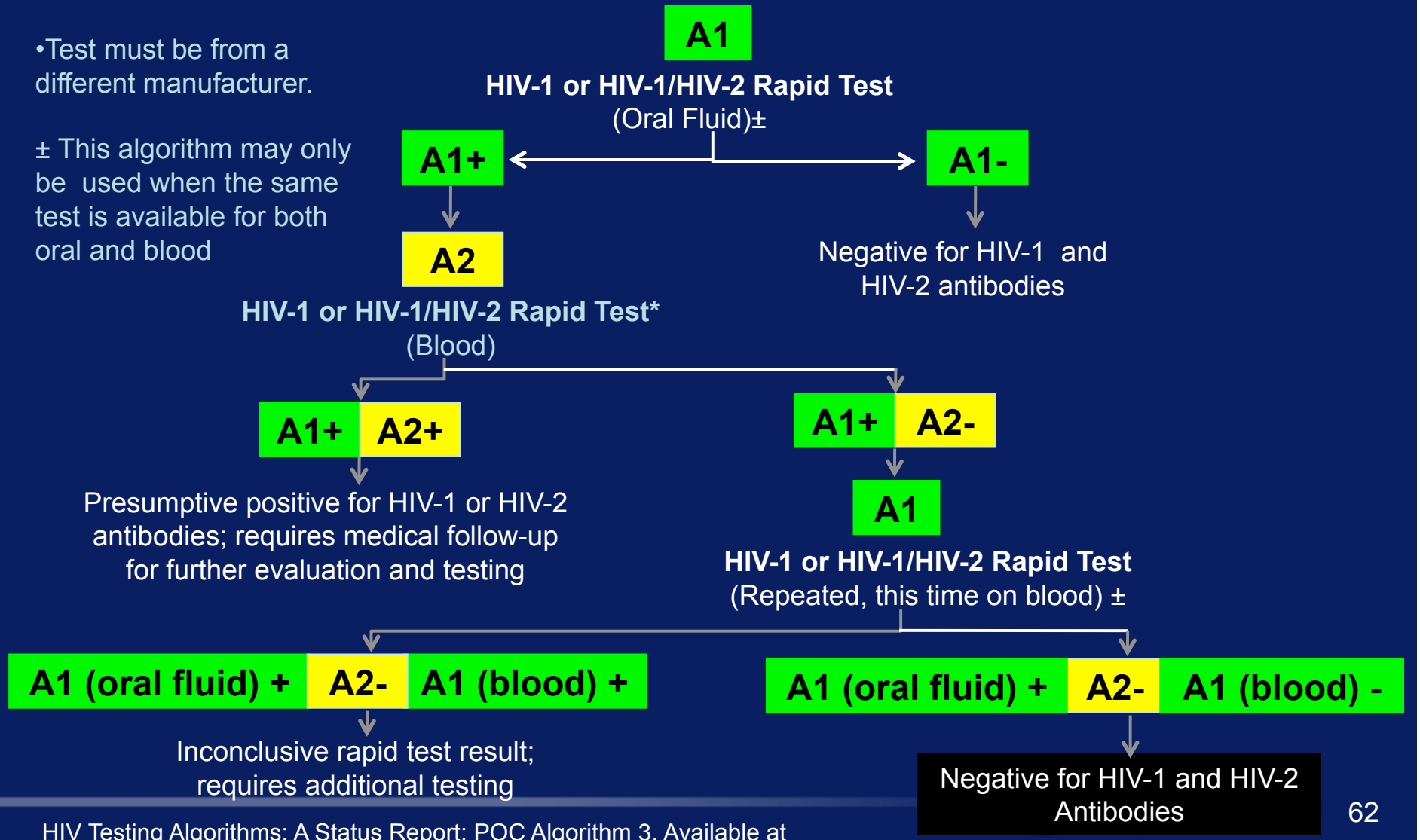
- Modified RTA Algorithm – POC Algorithms* 2 and 3 using 2 types of rapid HIV test kits
- RTA will be offered at select POC sites post-study
  - Mobile testing units
  - Commercial sex venues
  - Homeless shelters
  - Jail settings
  - High testing volume events (e.g. TestFest, HCT week)
- Offer RTA at routine testing clinics
  - Emergency Departments, STD clinics
  - RTA is currently part of routine testing training curriculum

* HIV Testing Algorithms: A Status Report. Available at http://www.aphl.org/aphlprograms/infectious/hiv/Pages/HIVStatusReport.aspx

Next Steps – 2 Test POC Algorithm

•Test must be from a different manufacturer.

± This algorithm may only be used when the same test is available for both oral and blood



HIV Testing Algorithms: A Status Report: POC Algorithm 3. Available at http://www.aphl.org/aphlprograms/infectious/hiv/Pages/HIVStatusReport.aspx

Implementation of an RTA Program

CDC Role

- Clear guidelines/recommendations regarding:
  - Use of an RTA at POC settings
  - Include case reporting with an RTA result at POC without confirmatory testing (EIA/WB or IFA) as an option

Implementation of an RTA Program

State Role

- Change language in the California Code of Regulations (CCR Title 17 § 1230. HIV Screening Testing by Laboratories.).
  - Currently states "Confirm all reactive or indeterminate HIV test results by following the HIV confirmation protocols recommended by the federal Centers for Disease Control and Prevention as published in the Mortality and Morbidity Weekly Report prior to reporting the result as positive"
- Inclusion of other CLIA-waived HIV rapid HIV tests as part of testing portfolio at publicly funded testing sites
- Standardized fingerstick training for rapid HIV testing

Implementation of an RTA Program

Local Role

- Implement RTA training as part of basic counselor training
- Establish criteria for sites offering an RTA
  - Rapid testing and quality assurance history
  - Sustainability for offering an RTA
  - Site testing volume

Research to Practice Summary

Problem: Disclosure rates of HIV test results

Research Q: Can a new RTA help improve confirmed positive disclosure rates?

Critical Partners: CDC, local HCT providers, biotech

HD Role: Research intermediary, efficiency and effectiveness advocate

Practice Outlook: Implementation on a limited basis, need federal partner support

CDC Role: See previous slide

County of Los Angeles Public Health

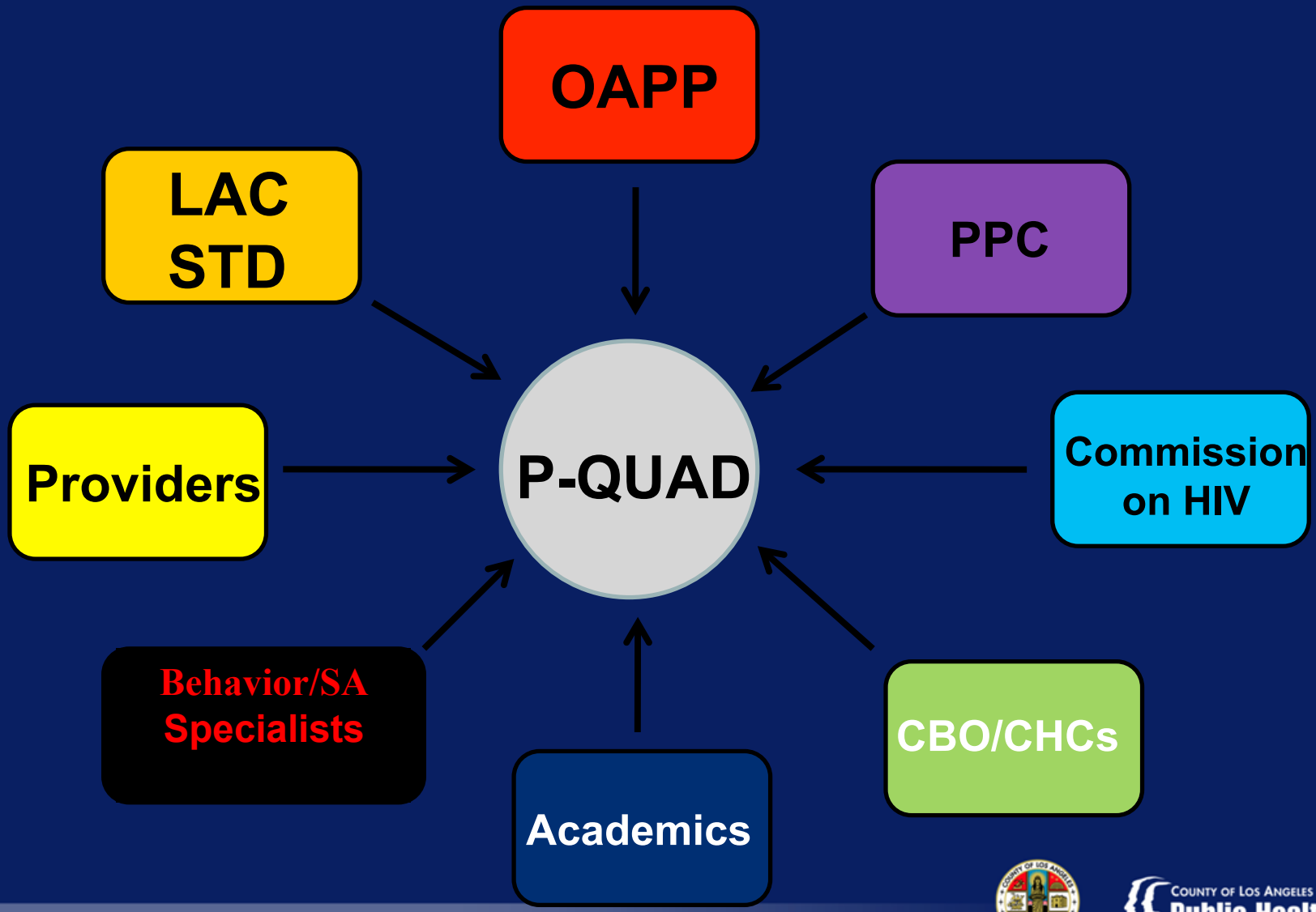
Research Study 3: Post-Exposure Prophylaxis

P-QUAD

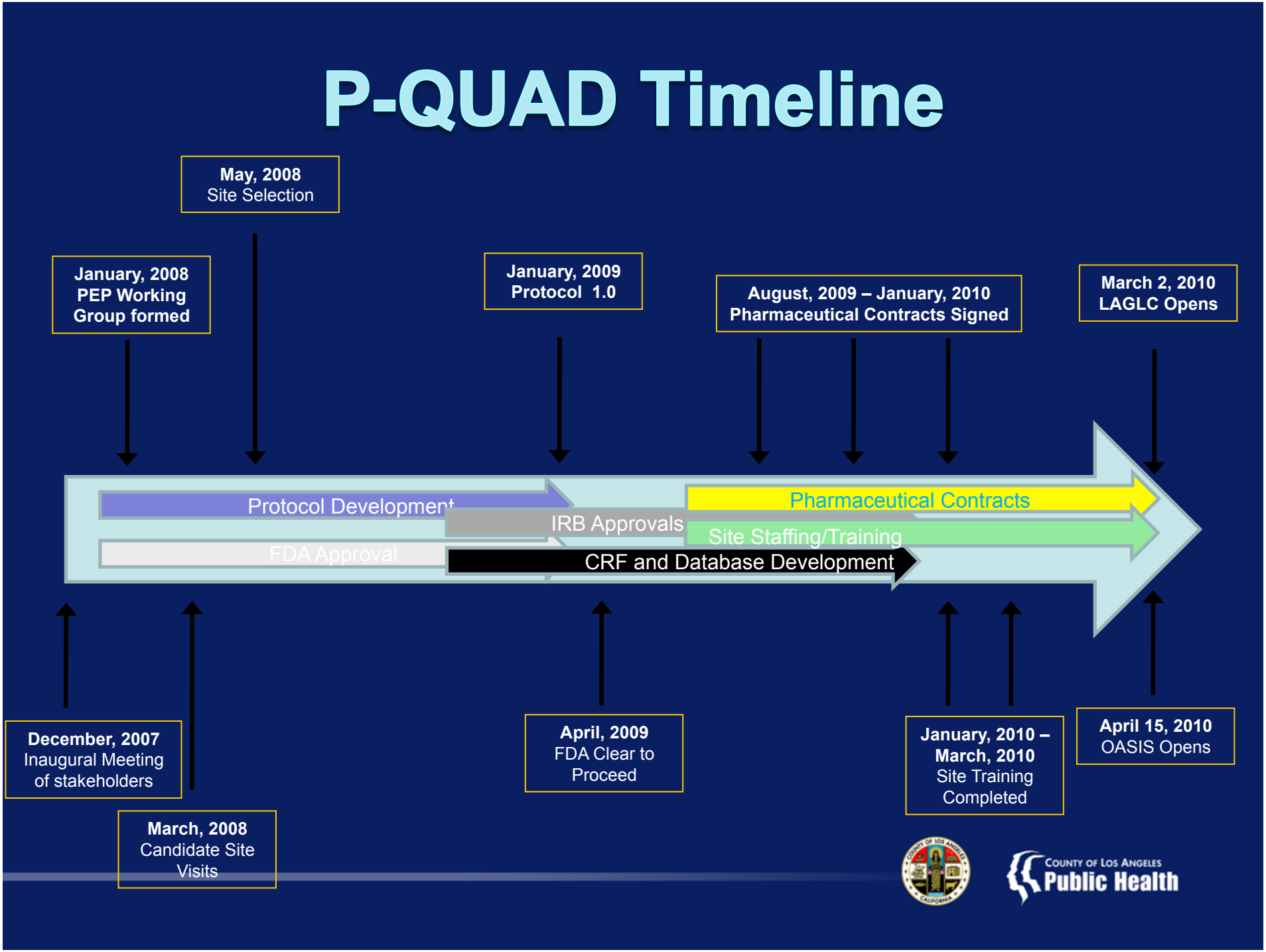
A Pilot Project to Operationalize Post-exposure Prophylaxis following Sexual Exposure to HIV in Los Angeles County

County of Los Angeles Public Health

P-QUAD Genesis



P-QUAD Timeline



County of Los Angeles Public Health

EXPOSED to HIV?

CALL: 213-351-7699

IF YOU THINK YOU MAY HAVE HAD AN EXPOSURE
WITHIN THE LAST 72 HOURS (3 DAYS)
YOU MAY BE ELIGIBLE FOR **PEP** (Post Exposure Prophylaxis)

PEP is available for people who have had a high risk exposure to HIV
(unprotected sex or needle sharing with a partner of unknown HIV status or known HIV+ status.)

PARTICIPATING SITES:

The L.A. Gay & Lesbian Center
1625 N. Schrader Blvd., L.A., CA 90028
(near Hollywood/West Hollywood)
CALL: 323-860-5880

OASIS Clinic
1807 E. 120th St., L.A., CA 90059
(near Downton/Compton)
CALL: 310-668-5131

with generous support from: Abbott Labs, Gilead Sciences, GlaxoSmithKline and Merck

P-QUAD
Post-exposure Prophylaxis (PEP) Pilot Program

P-QUAD is a Pilot Project to Operationalize the Prevention Strategy of Post-exposure Prophylaxis following Sexual Exposure to HIV in combination with Educational Programming and Behavioral Risk Reduction Strategies in Los Angeles County

WHAT IS POS PROPHYLAX

Post Exposure Prophylaxis (PEP) i
tions that can be taken after some
HIV infection. **PEP is NOT a "morn
not a cure for AIDS.** PEP is a comb
that **MAY** prevent HIV infection, if
time after possible HIV exposure.
your risk of becoming HIV+ by app
prevent exposure to HIV in the firs
using clean needles, reducing the
ner's HIV status before sex.

How does PEP work?

It takes several days for HIV infect
drugs stop HIV from multiplying ir
HIV-infected would then die natur
person who has been exposed to
hours after the exposure), this ma
the virus from establishing itself in

When do I take PEP?

We think PEP is only effective if t
to HIV. The sooner you take PEP, t
becoming infected with HIV. If you
for PEP. Research has shown that
infection could already occur. How

gram?

shared needles with someone whose HIV
is at risk for being HIV infected) **OR** if you
d needles with someone who is HIV+, you may
provider will ask you questions about your
need to take an HIV test to make sure that
IV. If you qualify, you will be prescribed 28

for 28 days and not miss any doses. If you miss
PEP treatment may not work. Remember: no
is 100% effective for preventing HIV infection.

EP?

ea, fatigue, vomiting, headaches and diarrhea.
take PEP experience side effects, however
t people don't have to change or stop taking
ects.

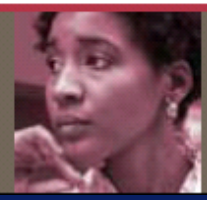
nt?

potential will be tested for pregnancy. If you
ast feeding immediately and transition to a
card program.

h the 28-day dose?

se of PEP treatment, test for HIV again at 4-6
er the risk exposure to make sure you are not
ative status, and try not to expose yourself to

Need PEP,
1-7699



Planned enrollment

- 300 participants; 28 days of treatment
  - TDF/FTC or AZT/3TC
  - TDF/FTC + r/LPV or AZT/3TC + r/LPV
  - Currently additional option for TDF/FTC + RAL or AZT/3TC + RAL
- Safety labs, serial HIV testing at 4-6 weeks, 3 months, and 6 months
- STI testing at baseline, repeat RPR at 3 months
- Substance use and behavioral assessments
- Planned transition to Public Health Service Delivery Model

P-QUAD nPEP Inclusion Criteria
(All must be satisfied)

1. 18 yrs of age and able 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

County of Los Angeles Public Health

P-QUAD Medication Regimens

- Standard Regimen:
  - Truvada – for high-risk exposures (100 doses)
  - Combivir – for intolerance to Truvada (50 doses)
- Expanded Regimen:
  - Kaletra or Raltegravir – for highest-risk exposures or suspected source drug resistance, add to the above medication administration (100 and 50 doses, respectively)

Clinical and Laboratory Evaluations

	Baseline (Day 0)	Week 2 Visit (Day 10-14)	Week 4-6 Visit	Week 12 Visit	Week 24 Visit
Meds Dispensed	X	X			
HIV ELISA[c]	X		X	X	X
Urine GC/CT Rectal GC/CT Pharynx GC	X				
Serum RPR	X			X	
Urine HCG[a]	X	X[b]	X[b]	X[b]	X[b]
HBsAg	X				
Cr, LFTs, CBC	X	X[b]			
HIV RNA					
HIV Genotype					
Stored Plasma/PBMCs[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			
Behavioral Program (Expanded)	X				

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

County of Los Angeles Public Health

As of Dec 1, 2010

- Totals
  - Screened 155, Enrolled 141
  - Data to follow N=112 (106 at LAGLC, 6 at OASIS)
  - 27 had already initiated PEP at another location (ED, Primary Care, AHF)
- LAGLC
  - Screened 142, enrolled 132
- OASIS
  - Screened 13, enrolled 9

Demographics (N*=112)

Variable	N (%)
Sex	
Male	103 (92)
Female	8 (7)
Transgender	1 (.8)
Age, years	
<20	1 (.9)
20-30	53 (47)
31-40	29 (26)
41-50	23 (21)
>50	6 (5)
Race/Ethnicity	
White/Caucasian	61 (54)
Black/African-American	9 (8)
Hispanic/Latino	33 (29)
Asian/Pacific Islander	4 (4)
Mixed Race/Other	5 (4)

*as of 12/1/10

Education and Income (N=112)

Education Level	N (%)
High School or less	24 (21)
Some College or Associates Degree	44 (39)
Bachelor's Degree	32 (28)
Advanced Degree	11 (10)
Missing	1 (.9)
Family Income	
<$10,000	35 (31)
$10 – 30,000	37 (33)
$30 – 50,000	22 (20)
$50 – 75,000	10 (9)
$75 – 100,000	4 (3.5)
Missing	4 (3.5)

Insurance Status (N=112)

Health Insurance Type	N (%)
None	78 (70)
Private	26 (23)
MediCal	5 (4)
University Provided	1 (.9)
COBRA	1 (.9)

Type of Exposure

(Totals Sum to > 100% as multiple routes of exposure possible)

Exposure	N (%)
Receptive anal intercourse	67 (60)
Insertive anal intercourse	51 (45)
Receptive vaginal intercourse	8 (7)
Insertive vaginal intercourse	3 (3)
Receptive oral intercourse with ejaculation	1 (.9)

Baseline STIs (N=112)

All linked to treatment

Infection	N (%)
Gonorrhea	
Urethra	2 (2)
Rectum	6 (5)
Pharynx	6 (5)
Chlamydia	
Urethra	3 (3)
Rectum	5 (4)
Syphilis (Incident)	3 (3)
Hepatitis B	1[1] (.9)

[1]Participant 4-days post-HBV vaccination – f/u HBsAg was negative, pt has not presented for HBV DNA testing due to cost

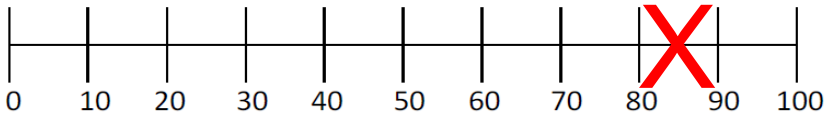
Follow up Rates: Clinical Evaluations, *N = 112

Baseline	Day 14	Week 4-6	Week 12	Week 24
112/112 (100%)	101/112 (90%)	88/112 (79%)	44/86 (51%)	17/49 (35%)

Adherence by VAS

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.

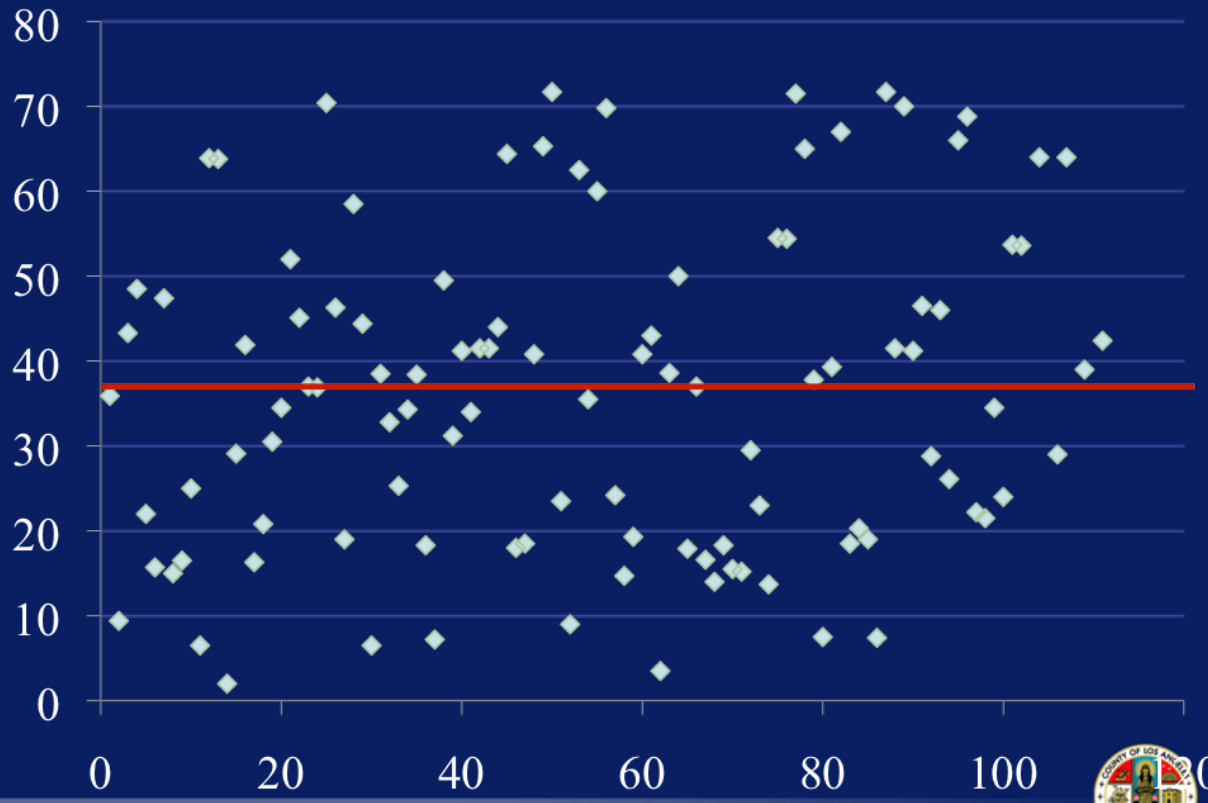
Example: 0% means you have taken no medication, 50% means you have taken half your medication, 100% means you have taken every single dose of your medication.



- 2 Week Visit
  - Mean self-reported adherence 97.70% (SD 10.92)
  - Range 10-100%
  - N=21 Missing
- 4 Week Visit
  - Mean self-reported adherence 96.43% (SD 12.79)
  - Range 0-100%
  - N=32 Missing

Time Interval: Exposure to First Dose (N*=112)

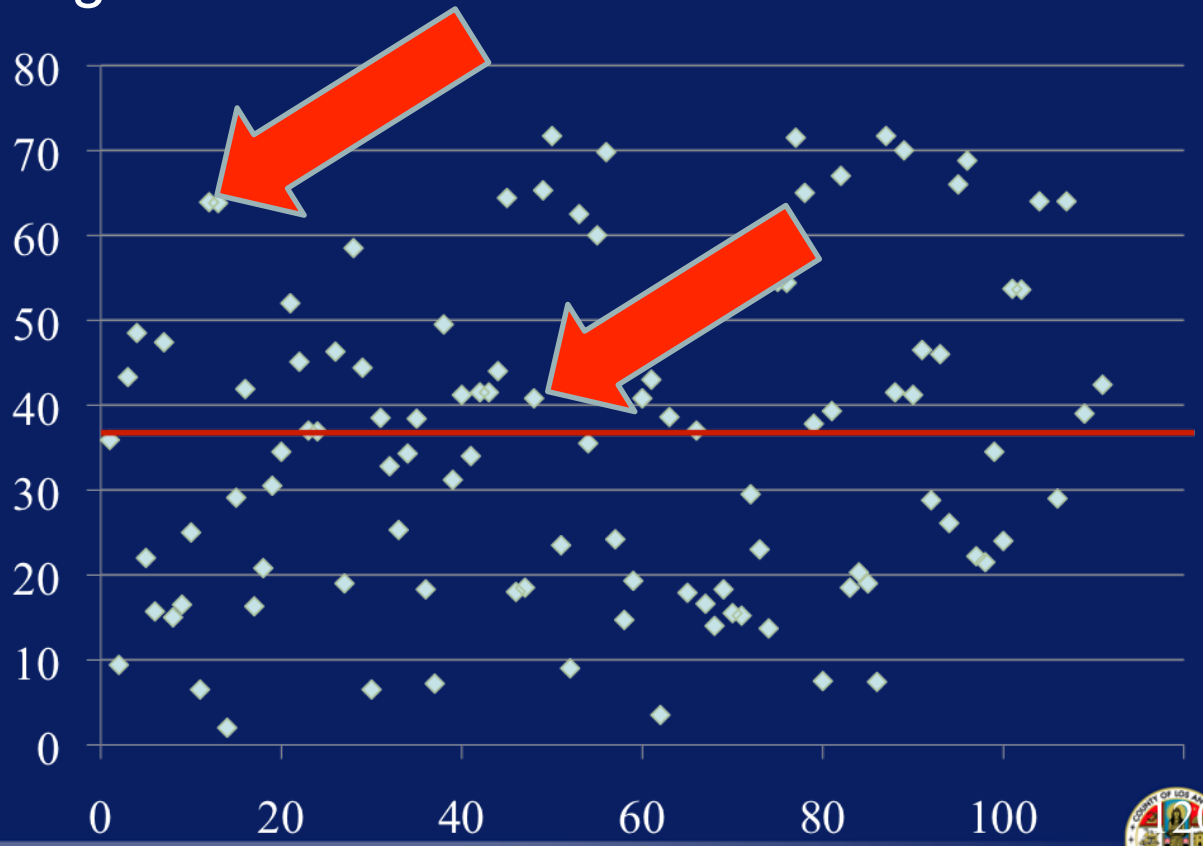
- Mean: 36.19 hrs (SD 18.93)
- Range: 2 – 71.7 hrs



* N=5 missing

Time Interval: Exposure to First Dose

- Mean: 36.19 hrs (SD 18.93)
- Range: 2 – 71.7 hrs



N=32 (29%) <24 hrs

N=6 (5%) < 8 hrs

Seroconversions (N=2)

- 1016 reported RAI with recently seroconverted HIV+ partner
- Interval of time from exposure to first dose = 64 hrs
- Baseline EIA negative*, week 4-6 EIA negative*, week 12 EIA positive with positive WB (p17/18, p24, gp41, p51, gp160)

- Baseline: 4/2/10 – Viral RNA not detected, <48
- Week 4: 4/30/10 – Viral RNA not detected, <48
- Week 12: 7/2/10 – 145,000 copies/mL

- Genotype with ONLY protease mutation L10I (wild type virus)
- No Baseline or 3-month STI's
- Denies repeat exposures
- 100% medication adherence reported
- Currently being linked to care

*Also NAAT negative

Seroconversions (cont'd)

- 1064 reported RAI with recently seroconverted HIV+ partner
- Interval of time from exposure to first dose = 41 hrs
- Baseline EIA negative*, week 4-6 EIA negative*, week 12 EIA positive with positive WB (p24, gp41, p55, gp120, gp160)

- Baseline: 7/13/10 – Viral RNA not detected, <48
- Week 4: 8/12/10 – Viral RNA not detected, <48
- Week 12: 10/1/10 – 32,500 copies/mL

- Genotype with A71V only (minor protease mutation)
- No Baseline or 3-month STI's
- Notes a series of exposures antecedent to sentinel exposure, outside of 72 hour window, and one IAI subsequent exposure
- 100% medication adherence reported
- Linked to subspecialty HIV care

Serious Adverse Events

- Two SAEs reported
  - Both involved overdoses of medication
  - No clinical sequellae
  - Did not discontinue nPEP regimens

Future Steps

- Design and implement a nPEP public health program premised on the findings from the demonstration project
- Streamline procedures
- Provider visit at baseline; nPEP coordinator visits at follow-up
- Integrate existing HIV risk reduction counseling and HIV testing programs into nPEP service delivery model

Collaborators

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David Pegues (UCLA)

PHL
Debbie Emlein
Ramiro Garate

UCLA CARE - Kat Rogers

County of Los Angeles Public Health

Research to Practice Summary

Problem: HIV transmission after high-risk non-occupational exposure

Research Q: Can nPEP help avert new HIV transmissions among high risk individuals?

Critical Partners: UCLA, OAPP Medical Director, FDA, GLC, Oasis Clinic, PEP Workgroup, Director of Public Health, Gilead

Research to Practice Summary

HD Role: Research ally, advocate, funder

Practice Outlook: Implementation on a non-study basis, need federal partner support, need sustainable drug supply

CDC/HRSA/SAMHSA/CMS/NCQA Role: Help leverage pharmaceutical support of biomedical interventions

Research Study 4: Interrupting Sexual Networks

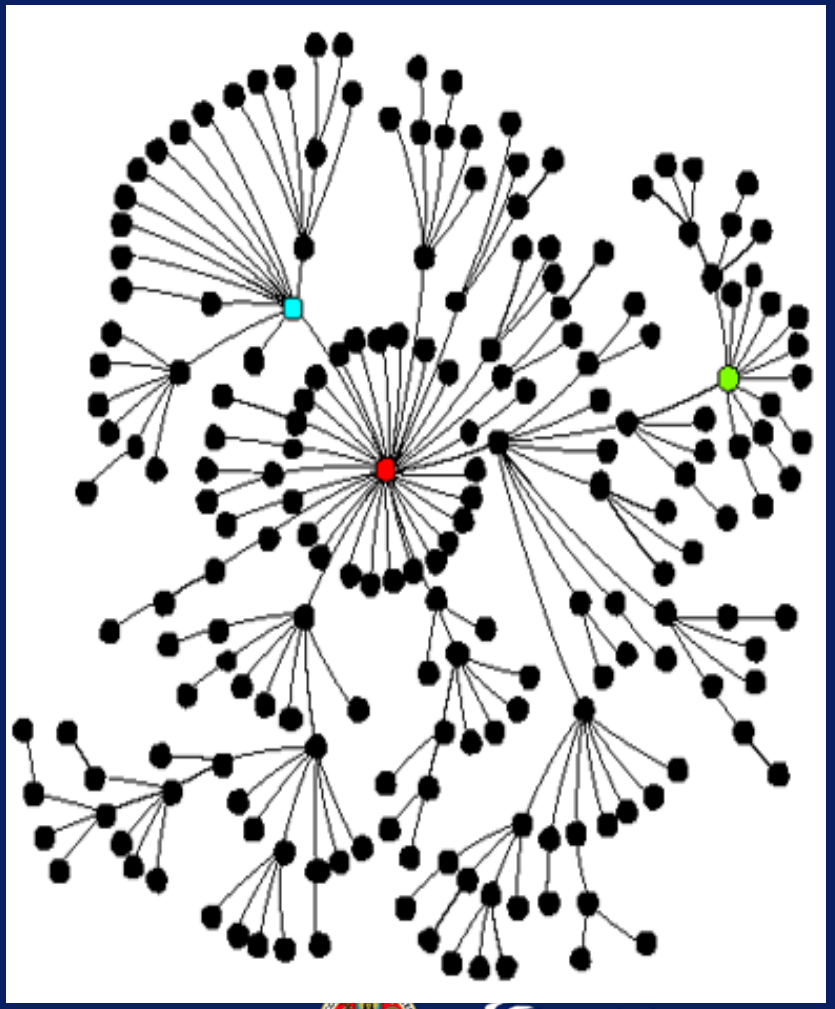
County of Los Angeles Public Health

Syphilis, HIV and Sexual Networks among MSM in Los Angeles County

Chris M. O'Leary, Ph.D., Jorge A. Montoya, Ph.D., & Peter R. Kerndt, MD, MPH
Los Angeles County Department of Public Health
Sexually Transmitted Disease Program

Sexual Networks & Disease Transmission

- Infections come from unambiguous relations
- Core transmitters are easily identified
- “Bridges” readily apparent
- Easier to determine best way to interrupt
- Use other data to determine specific STD exposure; Refine



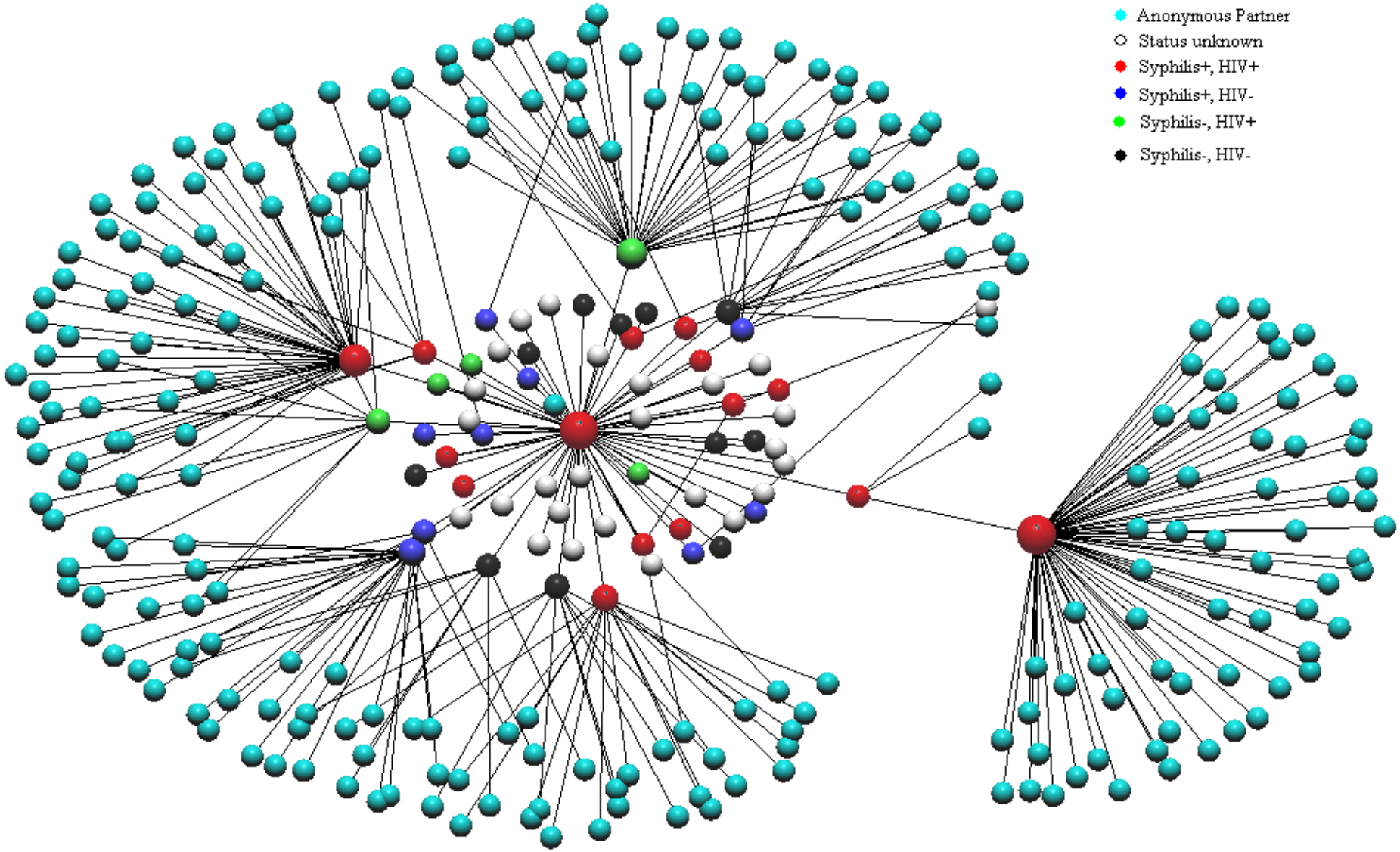
Methodology

- Elicit contacts
- Find contacts
- Repeat…until exhaustion
- *Additionally*
  - ✓ **Critical period for syphilis, defines likely exposure**
  - ✓ **Analyzed with UCINet → <u>Graphical result</u>**

Internet Sexual Network

- 1 person with syphilis with **66 partners b/w July and August 2007 (2 prior syphilis infections)**
- Field staff investigation led to 319 partners (280 anonymous)
  - **Met online**
  - **Limited data on demographics, drug use**
- Average age = 37.4 (n=29)
- Syphilis history (n=22)
  - Average 2.2 previous syphilis infections
- 17 “Bridges”

Internet Sexual Network



Morbidity & Exposure in Internet Network

Morbidity

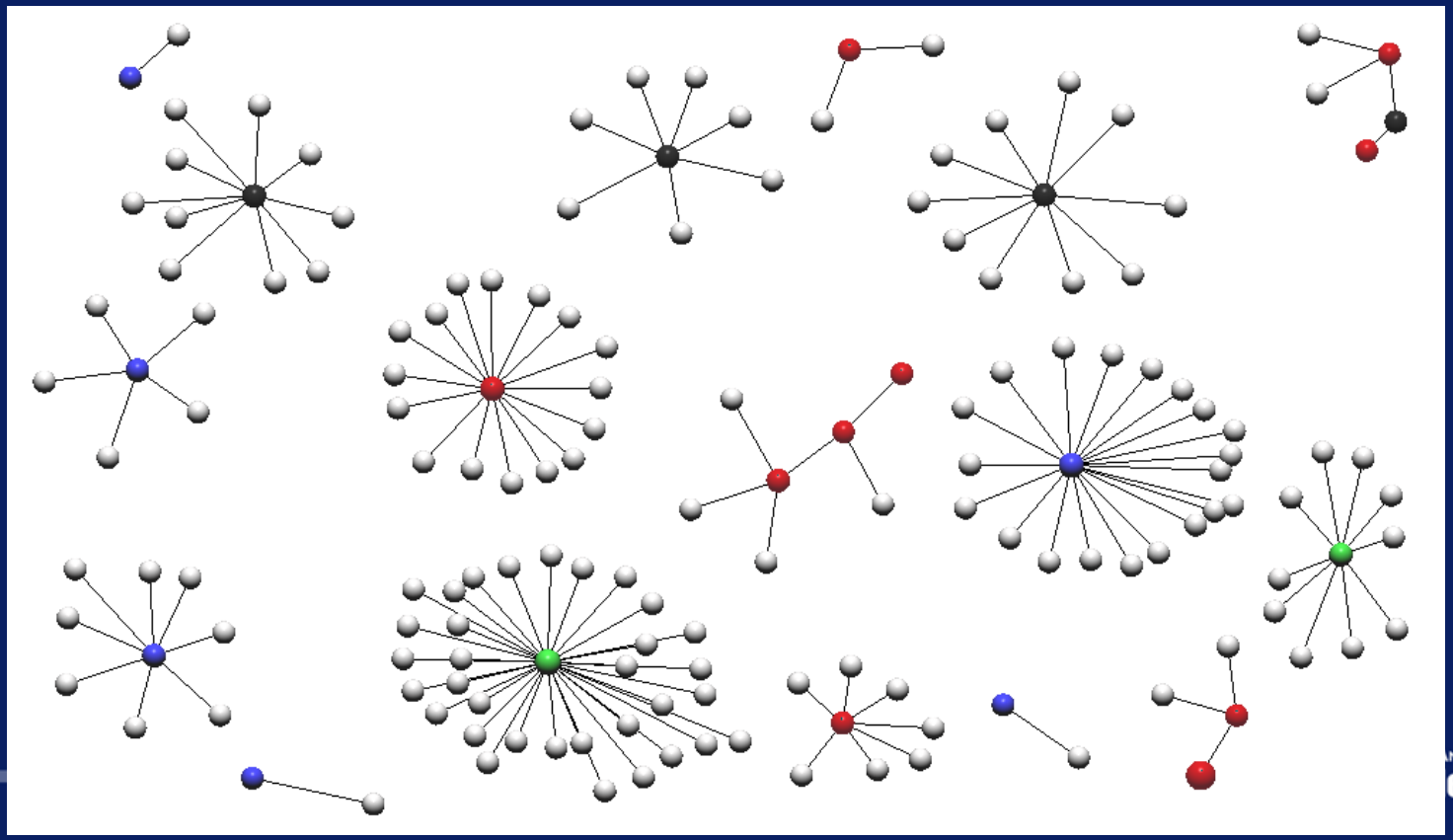
- **11 (3%) no disease, or out of time period**
- **9 (3%) syphilis (primary and secondary)**
- **5 (2%) HIV only**
- **15 (5%) syphilis/HIV**
- ***279 (87%) unknown***

Exposure

- 1 degree (sex with infected person)
  - **24 (8%) no known exposures**
  - **36 (11%) syphilis only**
  - **44 (14%) HIV only**
  - **217 (68%) to syphilis/HIV**
- 2 degrees (sex with somebody who had sex with somebody)
  - ***100% syphilis/HIV***

Maximize Disruption of Internet Network

- Remove ONLY 3 actors
  - Network = 159 members (50% drop) -17 unconnected clusters



Bar Sexual Network

- 1 person with syphilis with **19 partners (July-August 2007)**
- Field staff investigation led to 123 partners (**102 anonymous)**
  - **Mostly through bars, some online**
  - **Some drug use**
- Avg. age = 24.3 (n=19)
- Syphilis history (n=5)
  - Average 1.4 previous syphilis infections
- 5 “Bridges”

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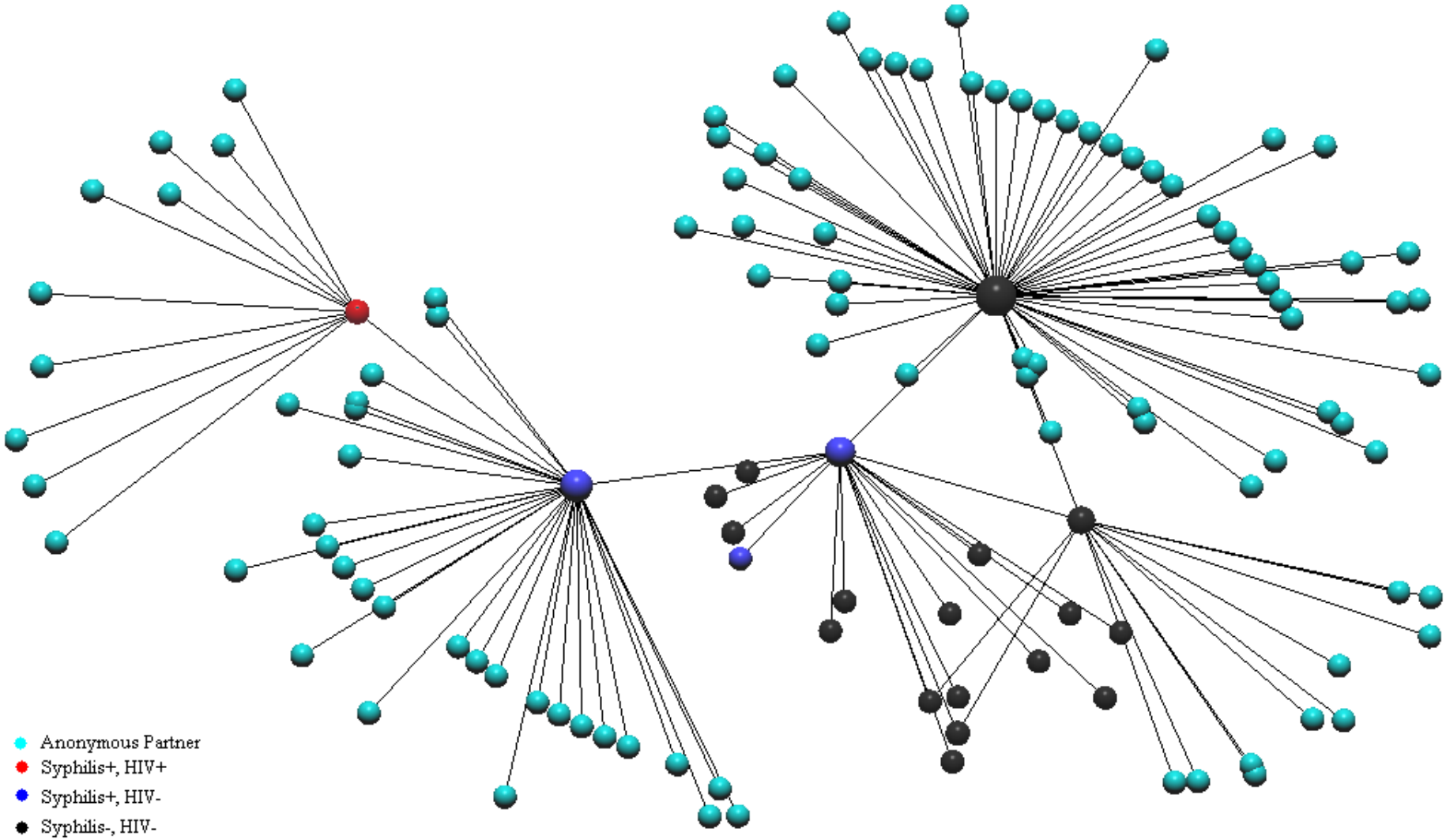
Bar Network Diagram



Morbidity and Exposure

Morbidity

- **17 (14%) no disease, no contact during critical period**
- **3 (2%) syphilis**
- **0 HIV only**
- **1 (1%) syphilis/HIV**
- ***102 (83%) unknown***

Exposure

- 1 degree (sex with infected person)
  - **69 (58%) no known exposures**
  - **50 (42%) syphilis only**
  - **11 (9%) to syphilis/HIV**
- 2 degrees (sex with somebody who had sex with somebody)
  - **42 (34%) syphilis/HIV**
  - *100% syphilis*

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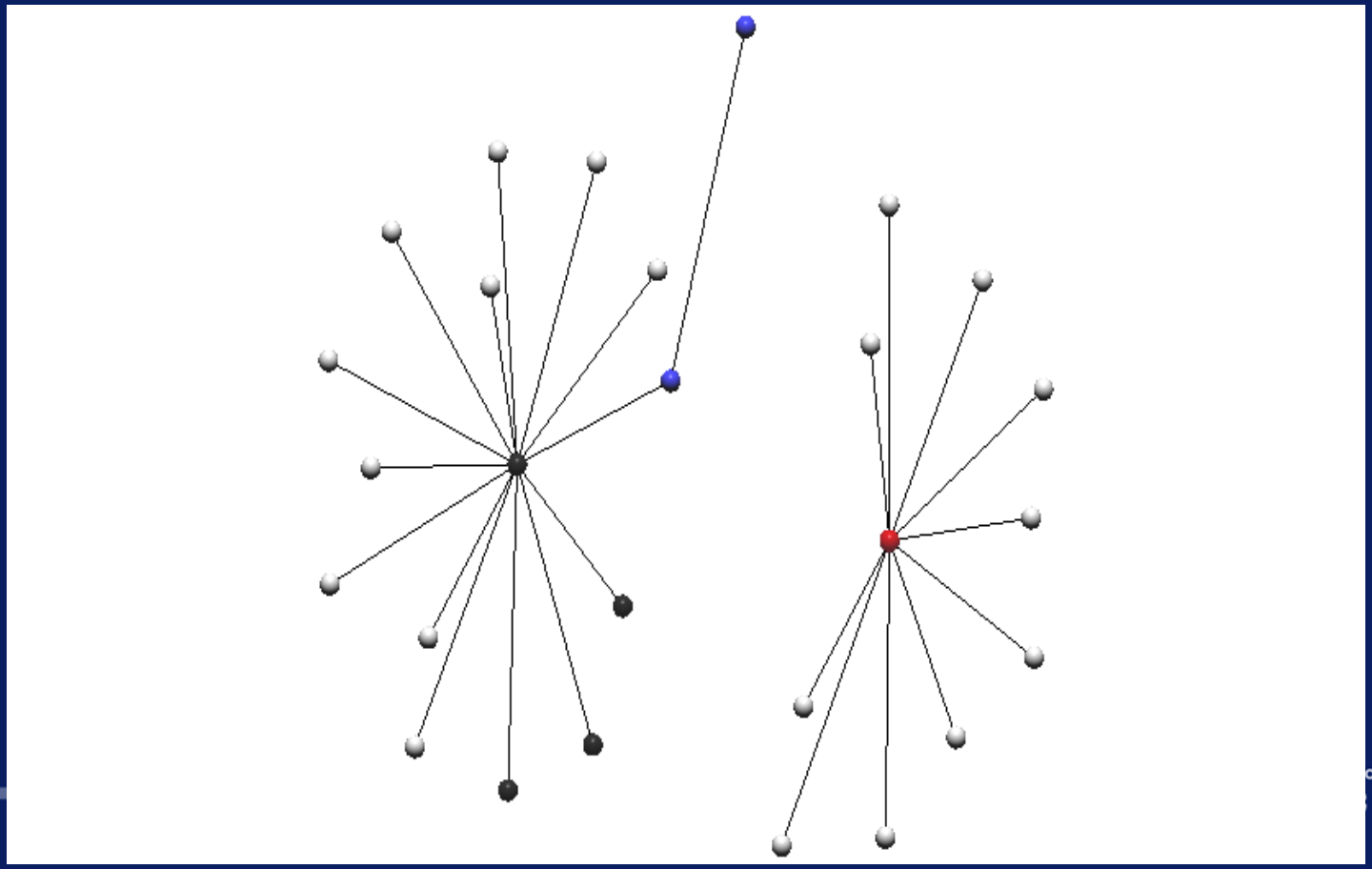
Maximize Disruption of Bar Network

- Remove 3 actors
  - Network = 26 members (79% drop) - 2 unconnected clusters



Program Practice Implications

- Prioritize cases based on venue
  - Internet case over bar/club
- Focus on removal of cores and bridges
  - How to identify before transmission occurs?
- Proxy to identify likely “core transmitters”
  - Re-infection (“Re-infectors”) a possibility
  - Preemptive field visits (some case management)
  - Client-centered interventions

Program Practice Implications

- Focus our efforts on interventions with previous syphilis cases (likely “core transmitters”)

Number of Early Syphilis Incidences, January 1, 2000 through October 31, 2007

Number of times infected	Frequency	Percent (%)	Cumulative Frequency	Cumulative Percent (%)
1	5968	89.9	5968	89.9
2	555	8.3	6523	98.3
3	101	1.5	6624	99.8
4	10	.1	6634	99.9
6	1	.02	6635	100

Conclusions

- Internet and Bar Networks both centralized
  - Core Transmission is apparent
- Key differences
  - The internet more centralized
  - Bar has a more linear structure with some overlap
  - Internet older, more disease, higher risk of HIV
- Further Social Network Research
  - Rapid fieldwork with good record keeping
    - Tracking more risk factors (e.g., drug use, venues, etc.)
    - Eliciting and interviewing partners
- **Social netowrks only work if people/cases are cooperative.**

County of Los Angeles Public Health

Research to Practice Summary

Problem: Sexual Networks propagation of disease

Research Q: How do you best interrupting network transmission patterns?

Critical Partners: STDP, DIS, O'Leary, Internet Hosters, Bar Owners

HD Role: Practitioner, Funder

Practice Outlook: Implementation on a limited basis, need to develop sustainable capacity

CDC Role: DIS, Field staff support

Chris M. O'Leary, PhD
1973 - 2008

COUNTY OF LOS ANGELES
Public Health
Sexually Transmitted Disease Program

COUNTY OF LOS ANGELES
Public Health

More Research Q's and Efforts

- Does providing incentives improve linkage to care rates for newly diagnosed persons?
- Can HIV-positive peers with histories of incarceration help us improve linkage to care rates?
- Where do you target condom saturation programs over 2500 square miles, resource-rich areas with high disease burden or resource-poor areas with low to medium burden?

More Research Q's and Efforts

- Are DEBI's have the intended effect?
- Which interventions are helping us reach our national HIV prevention goals most? [Attributable fraction]
- Will home test kits have the intended casefinding and awareness effects?
- Is an HIV only approach cost-effective or sustainable?
- Where are all the biostatisticians?

Important Health Department Research Attributes

- Understand as many angles of your epidemic as possible
- Understand and build IRB navigation capacity
- Develop and leverage local research assets
- Foster a collaborative and responsive research environment
- Identify creative research funding approaches
- Harness a team of research analysts, clinicians, preventionists, field staff
- Don’t be risk averse

County of Los Angeles Public Health

Vision for the NHAS

The United States will become a place where new HIV infections are rare and when they do occur, every person, regardless of age, gender, race/ethnicity, sexual orientation, gender identity or socio-economic circumstance, will have unfettered access to high quality, life-extending care, free from stigma and discrimination.

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Gracias!

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