



HIV PREVENTION TRIALS NETWORK

Findings from HIV Prevention Trials Network 061 Study: Using Data to Set HIV Prevention Priorities in Los Angeles

**S. SHOPTAW, J. WILLIAMS, G. VICTORIANNE, C. HUCKS-ORTIZ,
K. MAYER, B. KOBLIN, & D. WHEELER FOR THE HPTN 061
PROTOCOL TEAM**



Acknowledgement

- HPTN 061 is sponsored by NIAID, NIDA, NIMH under the Cooperative Agreement #UM1 AI 068619
- The 284 Study Participants (UCLA site) and 1,553 study participants (all sites Atlanta, Boston, New York, San Francisco & Washington)
- HPTN 061 Protocol Team & Black Caucus Members
- HPTN 061 BROTHERS Vine Street Community Advisory Board Members : Darrin Aiken, Vincent Allen, Joseph Benson, Carl Gradford, Robby Mason, Marcus McCrae, Russell Robinson, Blaine Teamer , Greg Wilson

Overview

- Review HPTN 061 study design
- Initial findings from overall study
- Overview of Los Angeles specific findings, including incidence
- Review first cuts on incident cases
- Using data to set HIV prevention and care priorities in Los Angeles

HPTN 061 Study Design

Purpose of HPTN061

- To determine the feasibility and acceptability of a multi-component intervention for Black MSM, including peer health system navigation

HPTN 061 Methods

- Conducted in Atlanta, Boston, Los Angeles, New York City, San Francisco and Washington DC between 7/09-10/10
- Black MSM recruited from the community or referred by sexual partners
- Eligibility criteria:
 - At least 18 years old
 - Identified as a man, or male at birth
 - Identified as Black, African American, Caribbean, African or multi-ethnic Black
 - At least one episode of unprotected anal intercourse with a man in the past six months
- Participants were offered incentives to refer up to 5 Black sexual partners for participation in the study

HPTN 061 Study Methods

- Demographic information collected and behavioral assessment using ACASI
- Social and sexual network questionnaire completed with an interviewer
- Tested for HIV, Gonorrhea, Chlamydia, Syphilis
- Risk-reduction counseling
- Offer of services of a peer community navigator to link to clinical and social services
- Participants testing positive for any infection linked to treatment and medical care services

HPTN 061 Participant Categories

- HIV-uninfected at enrollment
- Newly detected HIV-infected at enrollment
- Prior HIV diagnosis, but not engaged in care, and/or having unprotected sex with partner(s) who were uninfected or of unknown HIV status
- Prior HIV diagnosis and in care or only having sex with positive partners limited to not more than 10 per site

Study population

- 1,553 men were enrolled
 - 174 reported a prior HIV diagnosis
- 1,379 without a prior HIV diagnosis
 - 46 refused testing and/or a baseline specimen was not available for confirmatory testing at the HPTN NL
 - 165 (12.4%) were newly diagnosed, including 3 with acute infection (identified by the HPTN NL)
 - 1,168 uninfected at baseline
 - 1,009 tested for HIV during study follow-up

Study population (n=1553)

- 34% were 30 yrs or younger
- 46% had some college education or more
- 31% worked full or part time
- 60% had annual income less than \$20,000
- 2% transgender
- 30% identified as gay/homosexual

HPTN 061 Study Findings



HIV PREVENTION TRIALS NETWORK

An Evolving Concentrated Epidemic: Comparison of Newly Diagnosed, Previously Diagnosed and HIV-Uninfected Black Men Who Have Sex with Men in 6 U.S. Cities

**K.H. MAYER , L. WANG, B. KOBLIN, C. MAO, S. MANNHEIMER,
M. MAGNUS, C. DEL RIO, S. BUCHBINDER, L. WILTON,
V. CUMMINGS, C. WATSON, S. GRIFFITH, D. WHEELER
FOR THE HPTN 061 PROTOCOL TEAM**



Comparison of Black MSM found to be Newly Infected and those who were HIV-Uninfected

Multivariate Logistic Regression

<u>Variable</u>	<u>O.R.</u>	<u>95% C.I.</u>
Unprotected receptive anal intercourse	1.90	(1.21, 2.91)
Age >30	3.73	(2.28, 6.10)
Unemployed	2.42	(1.48, 3.95)
Lack stable housing	0.41	(0.18, 0.98)
Household annual income		
< \$10,000	3.60	(1.49, 8.65)
\$10,000 to \$49,999	3.26	(1.41, 7.51)
City of Enrollment (compared to Boston)		
NYC, Harlem	4.22	(1.89, 9.42)
Washington D.C.	3.35	(1.43, 7.84)
Atlanta	2.32	(1.09, 4.94)
STI diagnosed at visit		
1	2.02	(1.21, 3.39)
>1	6.64	(2.71, 16.3)

Conclusions

- The rates of undiagnosed HIV and STIs among Black MSM in this 6 city U.S. study were very high, representing a major health disparity
- Structural, behavioral, and biological factors (i.e. poverty, unemployment, unprotected receptive anal sex, and STIs) were independently associated with undiagnosed HIV infections among Black MSM, suggesting the need for multi-component programs
- Given these findings, culturally tailored programs for Black MSM are urgently needed that encourage repeated HIV/STI testing, engagement in care, the use of antiretroviral medications for treatment or prevention, while addressing social and environmental factors



HIV PREVENTION TRIALS NETWORK

Nonadherence to HIV Testing Guidelines and Late HIV Testing Is Common Among US Black Men Who Have Sex with Men (MSM)

**S. Mannheimer, L. Wang, H.V. Tieu, C. del Rio,
S. Buchbinder, L. Wilton, S.N. Glick, V. Cummings,
and K.H. Mayer for the HPTN 061 Study group**



Definitions:

- **Nonadherence to HIV testing guidelines:** Participants reporting past HIV-uninfected or unknown status at enrollment and no HIV testing within the prior 12 months
- **Late HIV diagnosis:** Participants with newly diagnosed HIV at enrollment and CD4 count < 200 at the time of HIV diagnosis

Summary

- Nonadherence to HIV testing guidelines was reported by 23% of participants at enrollment; 14% reported never HIV testing prior to this study
- Nonadherence to testing guidelines was associated with age ≥ 35 , unemployment, and not having seen a medical provider
- 97.5% of HPTN 061 participants agreed to HIV testing through the study
- 19% of participants with newly diagnosed HIV had a late HIV diagnosis (CD4 < 200)
- Late diagnosis was associated with age ≥ 35



HIV PREVENTION TRIALS NETWORK

Correlates of HIV incidence among black men who have sex with men in 6 U.S. cities (HPTN 061)

**B. KOBLIN, K. MAYER, S. ESHLEMAN, L. WANG, S. SHOPTAW, C.
DEL RIO, S. BUCHBINDER, M. MAGNUS, S. MANNHEIMER, T-Y
LIU, V. CUMMINGS, E. PIWOWAR-MANNING, S. FIELDS, S.
GRIFFITH, V. ELHARRAR, D. WHEELER
FOR THE HPTN 061 TEAM**



Baseline behaviors in prior 6 months (n=1,009)

- Median no. of biological male partners: 3 (IQR: 2 - 5)
- Unprotected anal intercourse
 - 47% receptive
 - 76% insertive
- Transactional Sex
 - 23% received money/goods
 - 10% provided money/goods
- 38% used stimulants
- 4% had any STI

Summary and conclusions

- In the largest prospective cohort of Black MSM in the US, HIV incidence was high (2.8%; 95% CI: 1.8,4.1), and even higher among:
 - Young men (5.9%; 95% CI: 3.6, 9.1)
 - Gay/homosexual-identified men (5.0%; 95% CI: 2.6, 8.8)
 - Those reporting unprotected receptive anal intercourse (4.9%; 95% CI: 3.0, 7.4)
- Findings do not represent all black MSM in US
- Additional analyses will be conducted to assess changes in behaviors and uptake of peer health navigation during the study and relationship to HIV incidence
- Targeted, tailored and culturally appropriate combination HIV prevention strategies (behavioral, social, structural and biomedical) are urgently needed.



HIV PREVENTION TRIALS NETWORK

The High Prevalence of Incarceration among Black Men who have Sex with Men (BMSM): Associations and Implications

Brewer, R., Magnus, M., Wang, L., Liu, T., and Mayer, K. on behalf of the HPTN 061 Study Team



Purpose:

- Determine the prevalence of incarceration experience among BMSM and describe the correlates of incarceration history among BMSM enrolled in the HPTN 061 study

Definitions:

- **Incarceration History:** Participants reporting spending at least one or more days in jail or prison in their lifetime

Summary

- 60% of Black MSM reported a history of incarceration
- Variations in incarceration history by city - ranging from 30% in Washington, DC to 70% in Los Angeles, CA
- Transgender identity, straight or heterosexual identity, childhood violence, early childhood sexual experience, and increasing age were associated with a history of incarceration



HIV PREVENTION TRIALS NETWORK

Differences in Psychological, Social, Substance Use and HIV Sexual Risks between Urban Black Men who have Sex with Men Only (BMSMO) and Black Men who have Sex with Men and Women (BMSMW)

T . Penniman Dyer, L. Wilton, N. Harawa, L. Wang, S.S. Ou, V. Cummings, S. Shoptaw on behalf of The HIV Prevention Trials Network 061 Study Team



Aims and Hypotheses:

- Compare the characteristics of at-risk BMSMW to BMSMO. We hypothesized that, compared to BMSMO, BMSMW will report more internalized homophobia, less social support and more depression. In addition, BMSMW, compared to BMSMO will more often:
- H1: Report alcohol use with unprotected anal intercourse (UAI) with last male partner
- H2: Report drug use with UAI with last male partner
- H3: Report giving money for or drugs sex with last male partner
- H4: Report receiving money or drugs for sex with last male partner

Summary

- 47% of the men in the study were MSMW
- BMSMW were significantly more likely to report internalized homophobia, substance use (including alcohol), more depressive symptoms and less social support, compared to BMSMO
- BMSMW were also significantly more likely to report using drugs and alcohol within 2- hours of unprotected insertive anal intercourse with their most recent male partner, as well as to receive money or drugs for sex, compared to BMSMO



HIV PREVENTION TRIALS NETWORK

A Study of Perceived Discrimination in Black MSM and its Association with Healthcare Utilization and HIV Testing

R. IRVIN, L. WILTON, G. BEAUCHAMP, L. WANG, AND S. BUCHBINDER FOR THE HPTN 061 STUDY GROUP



What role does discrimination play in the disproportionate impact of HIV/AIDS on black MSM?

- **Definitions (Affirmative response to questions):**
 - **Healthcare discrimination**: “Have you, a family member, a friend, or someone you know been treated unfairly due to race or ethnic background when getting medical care?” (ACASI)
 - **Healthcare utilization** : “In the last 6 months, have you seen a healthcare provider?” (interviewer)
 - **HIV testing in past year**: “Have you been tested for HIV in the past year?” (ACASI)
- **Results:**
 - Overall Prevalence:
 - Healthcare Discrimination- 19%
 - Healthcare Utilization in the past 6 months- 60%
 - HIV Testing in the past year- 81%

What role does discrimination play in the disproportionate impact of HIV/AIDS on black MSM?

- **Results (cont'd):**
 - Healthcare Discrimination was positively associated with Healthcare Utilization and HIV Testing
 - Some possible reasons:
 - lack of trust caused individuals to seek care
 - differential sensitivity to, recognition of, and reporting of discrimination
 - individuals that had more experience with the healthcare system also had more opportunity to experience discrimination



HIV PREVENTION TRIALS NETWORK

Lessons Learned from Implementing a Black Caucus into HPTN 061: Demonstrated Community Engagement

S. FIELDS, C. WATSON, L. WILTON, J. LUCAS, D. WHEELER AND
THE HPTN 061 BLACK CAUCUS



Summary

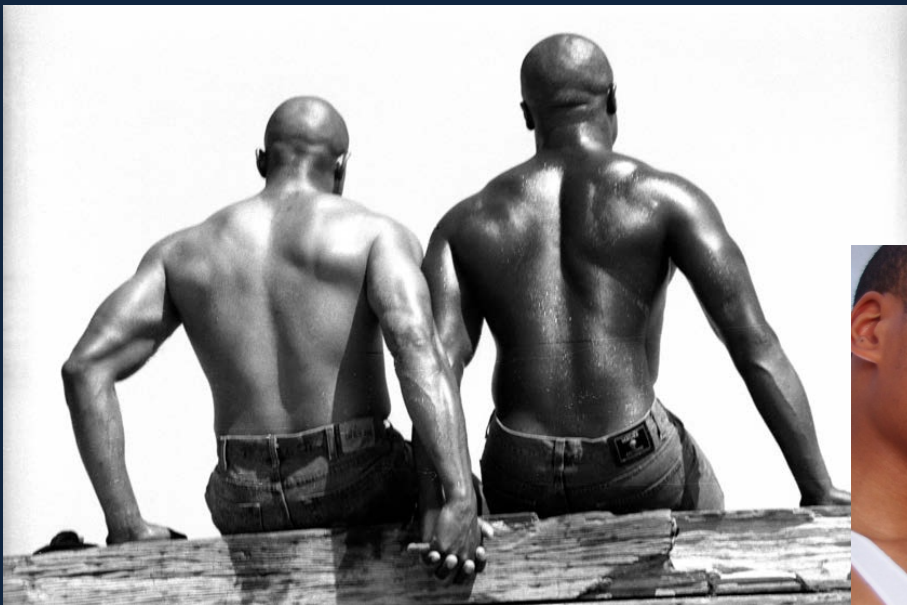
- The Black Caucus was formed based on CBPR concepts and functioned to provide a vehicle whereby the silent voices of BMSM could be heard, respected and understood.
- The Black Caucus ensured that the design, implementation, analysis and interpretation of study data was racially and culturally appropriate and that the study was responsive to the needs of BMSM.
- Recommendations from Black Caucus members to HPTN leadership culminated in diversified protocol leadership and BMSM employed in key positions at each clinical research site.
- The Black Caucus developed a retention analysis covering burden/benefit analysis, intervention delivery and community engagement to increase retention among all clinical research sites participating in HPTN 061.
- The Black Caucus model should be duplicated across all of the DAIDS funded study networks with BMSM and other hard to reach at risk populations.

Los Angeles Experience

The BROTHERS Project

Feasibility Study of a Community-level, Multi-component Intervention for Black MSM

Broadening the Reach Of Testing, Health, Education, Resources and Services

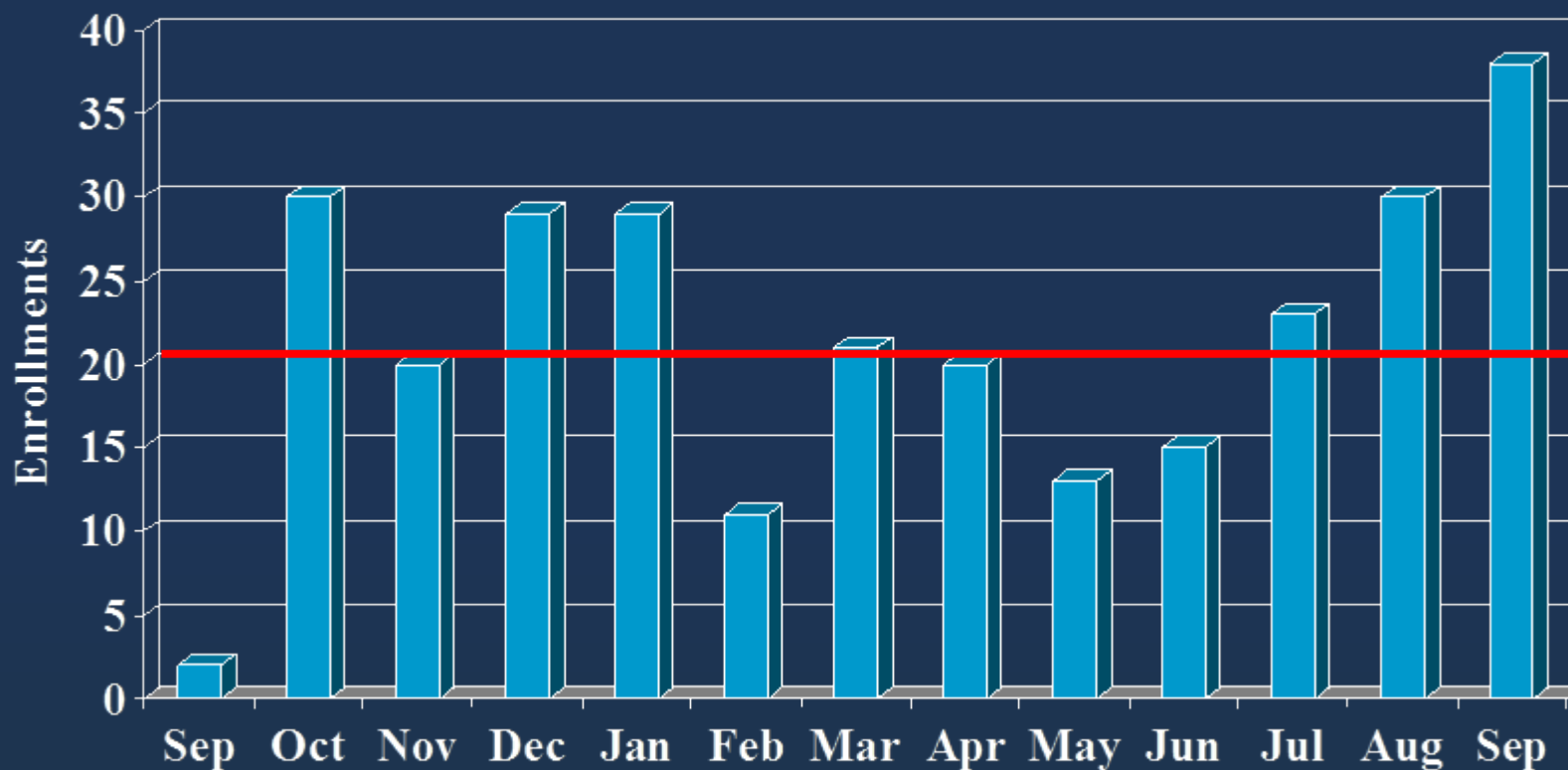


Recruitment Non Traditional Drop Off Spots

- Bars
- Night Clubs
- Adult Book Shops
- HIV Testing Sites
- Sex Clubs / Bath Houses
- LGBT Youth Centers
- Bus Stops



Enrollments: September 2009 to September 2010



Demographics (n=279)

	# or Mean	% or S.D.
Age (median = 40)		
18-30	97	35%
31-40	46	16%
41-50	99	35%
50+	37	14%
Partner/Spouse		
No partner	260	93%
Male	16	6%
Female	3	1%
Working		
Full-time/Part-time	66	24%
Unemployed	159	57%
Unable to work	59	20%

Demographics (n=279)

	# or Mean	% or S.D.
Education		
< H.S.	50	17%
H.S.	116	42%
Some College	90	32%
Bachelors +	23	9%
Household Status		
Alone	97	35%
Partner	22	8%
Roommate	72	26%
Relatives	44	16%
No home/other	44	16%
Current Healthcare?	102	37%

Demographics (n=279)

	# or Mean	% or S.D.
Annual Income		
<\$5,000	106	38%
\$5,000-\$9,999	45	16%
\$10,000-\$19,999	66	24%
\$20,000-\$29,999	34	12%
>\$30,000	28	10%
Frequency of Insufficient Income		
Never	137	49%
Once in awhile	96	34%
Fairly often	29	10%
Very often	17	6%

Demographics (n=279)

	# or Mean	% or S.D.
Sexual Identity		
Homosexual	81	29%
Gay	127	46%
Bisexual	90	32%
Heterosexual	7	3%
Same gender loving	47	17%
Sexual	35	13%
Queer	10	4%
Two spirited	12	4%
Questioning	7	3%
Polyamorous	1	<1%
Pansexual	2	1%
Straight	10	4%

36 participants were sent to prison/jail over the 1 year = 12.9% prevalence

HIV Characteristics (n=88)*

	# or Mean	% or S.D.
CD4 Count (median=507)	500	209
<350	10	24%
351 - 500	10	24%
501 - 1105	22	52%
PVL copies (median=136)		
<48 (UDL)	15	36%
49 - 676	9	21%
4339 – 20,000	6	14%
20,001 – 300,000	12	29%

* Provisional site data

Treatment Cascade

- 100% of participants testing HIV positive were facilitated to HIV-medical care
 - Process documented in the chart and in the notes
- We are evaluating whether those facilitated to care actually received HIV-medical care
 - This information is limited as we only have that information for those actively engaged in Navigation

Los Angeles Incidence

	No. Participants [†]	No. Events	PYs	Incidence (Exact CI)
Overall	1008	28	926.0	3.0 (2.0, 4.4)
Los Angeles, CA	167	10	144.1	6.9 (3.3, 12.8)

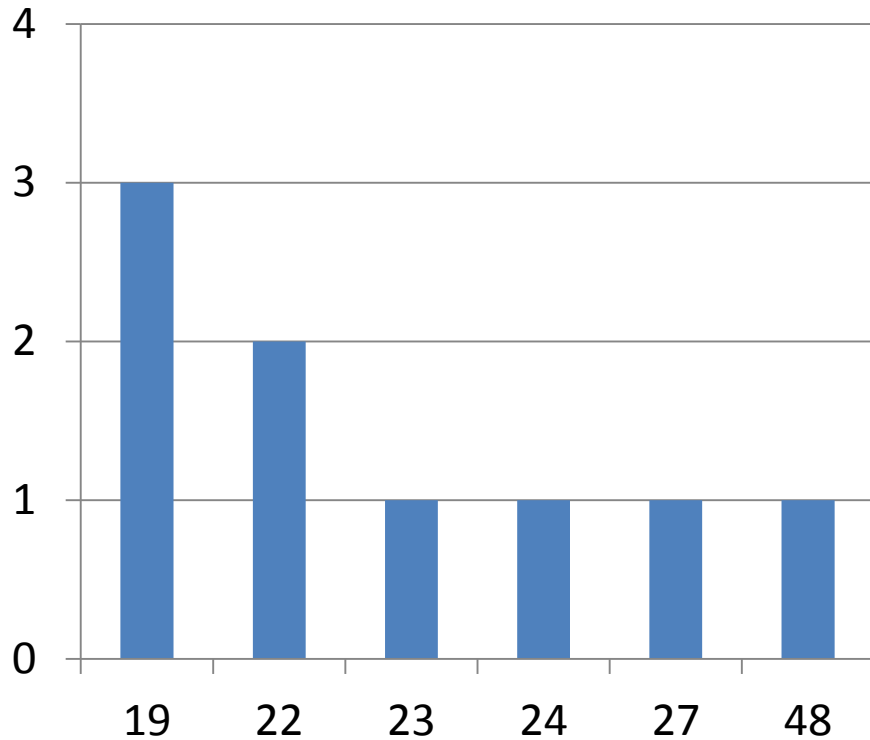
Preliminary Findings as of 1-9-13;

Who were the HIV Incident Cases?

- 7 tested HIV-positive at 6-months follow-up
- 2 tested HIV-positive at 12-months follow-up
- 1 tested HIV positive at baseline (acute case), who was not part of these analyses

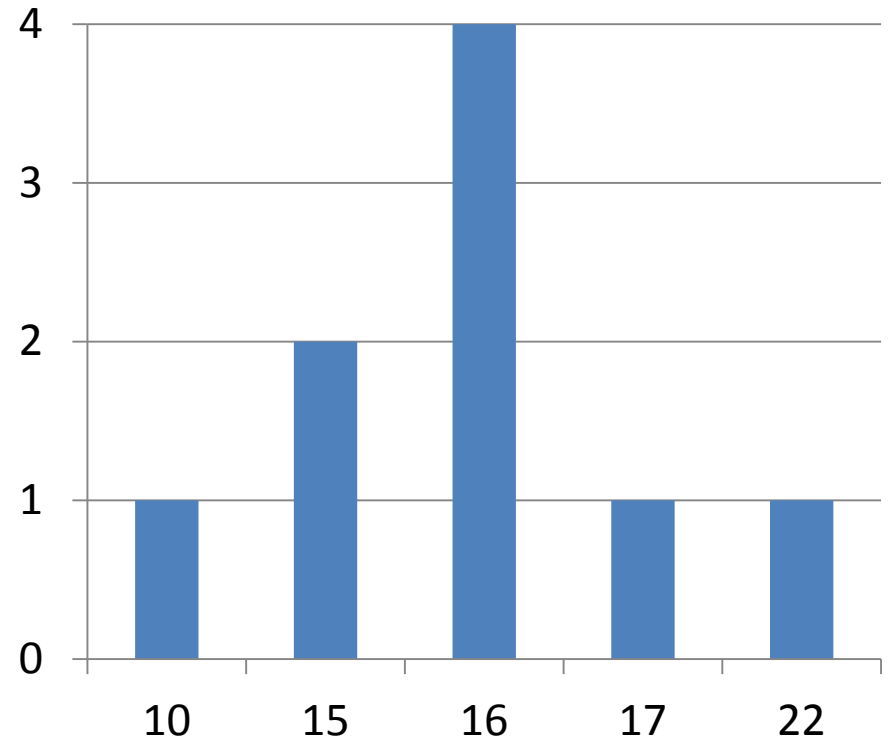
Preliminary Findings as of 9-11-12

Age Distribution for Incident HIV Cases in Los Angeles



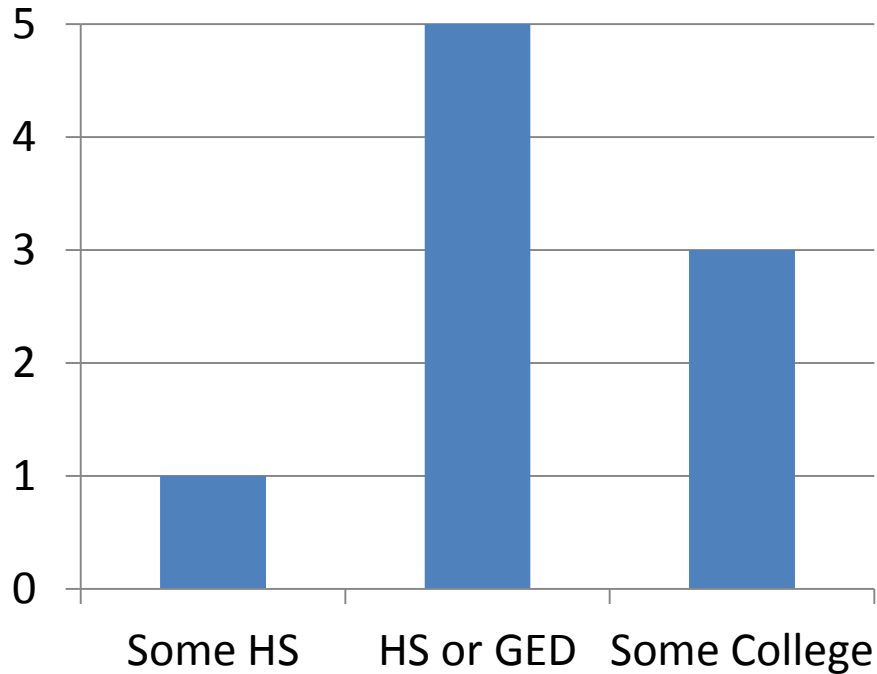
Acute case was 20 years old

Age Sexual Behavior Started: Incident HIV Cases in L.A.



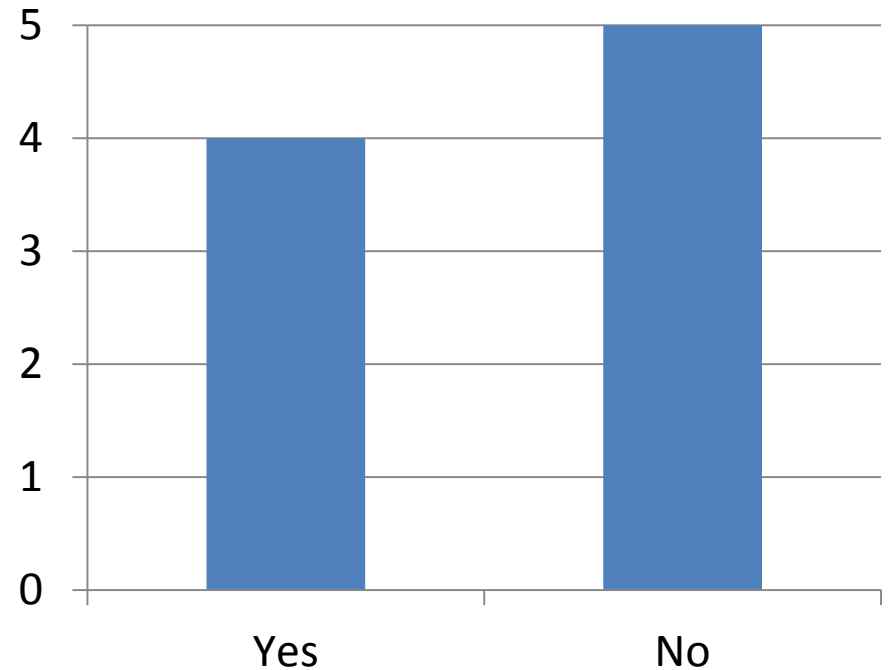
Acute case reported sex started at 18 years

Education Completion: Incident HIV Cases in Los Angeles



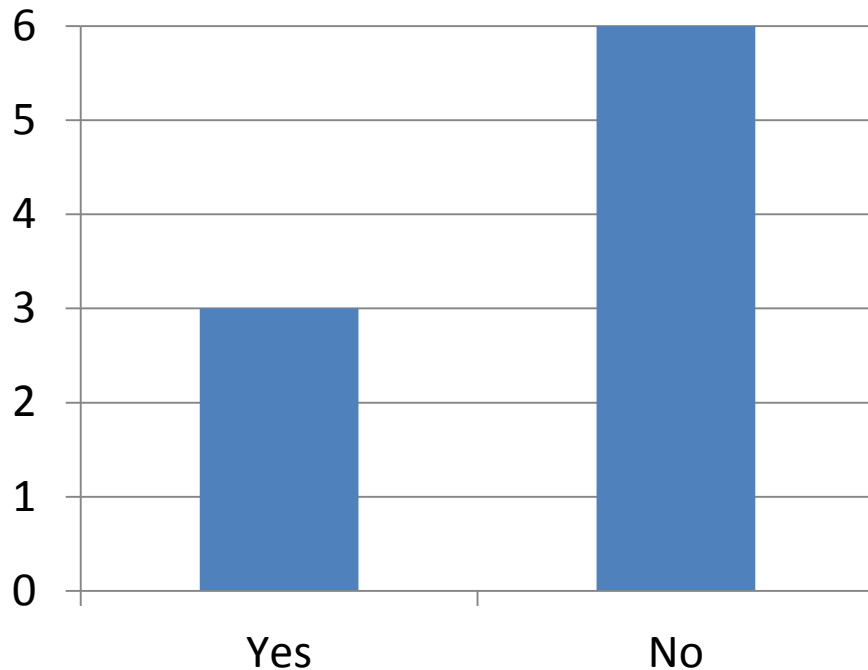
Acute case completed HS/GED

Health Care Coverage Among Incident HIV Cases in Los Angeles



Acute case reported having health care coverage

Needed Health Care and Did Not Get Among Incident HIV Cases in Los Angeles

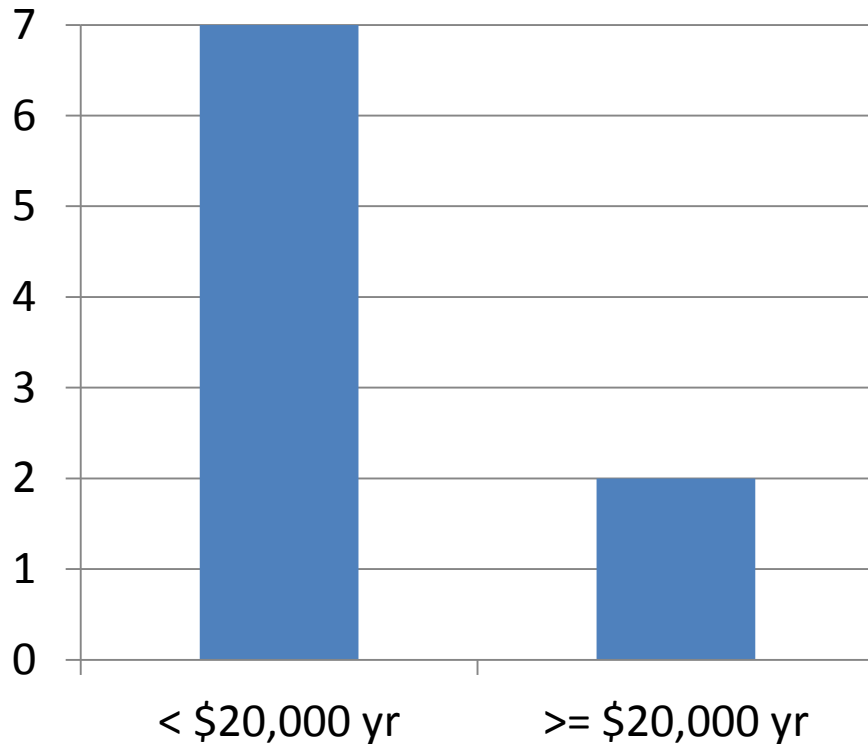


Among the 3 cases who reportedly needed health care and didn't get it, the reason cited for why was:

Health care was too expensive

Acute case did not need health care and not get it

Household Incomes: Incident HIV Cases in Los Angeles



Acute case reported < \$20,000 yr

Two incident HIV cases reported stimulant use in the 6 months prior to enrollment:

- One subject reported using crack cocaine only
- One subject reported using crack cocaine and methamphetamine

The acute case reported no stimulant drug use

Viral Loads at 1 Year (n=8)

# Subjects	Status
0	$X < 50$ copies
4	$200 < x < 2,000$ copies ng/mL <ul style="list-style-type: none"> • 3 decreased 1+ log from 6 to 12 months • 1 seroconverted; only one sample
3	$2,000 < x < 20,000$ copies ng/mL <ul style="list-style-type: none"> • 1 unchanged from 6 to 12 months • 2 seroconverted; only one sample
1	$360,000$ copies ng/mL <ul style="list-style-type: none"> • No change from 6 to 12 months
Acute Infection: 73 ng/mL; 2 log decrease from 6 to 12 months	

Summary

- Los Angeles site successfully recruited Black MSM at risk for HIV infection
- The majority of the men were older (over 30) and lived on less than \$10,000 per year
 - At study mid-point, we stopped recruitment and restarted with focus on younger MSM
- Very high prevalence of HIV at baseline
 - Highest HIV prevalence rate at baseline
 - Analyses will be conducted to assay ARVs
- High rates of depression symptoms

Summary

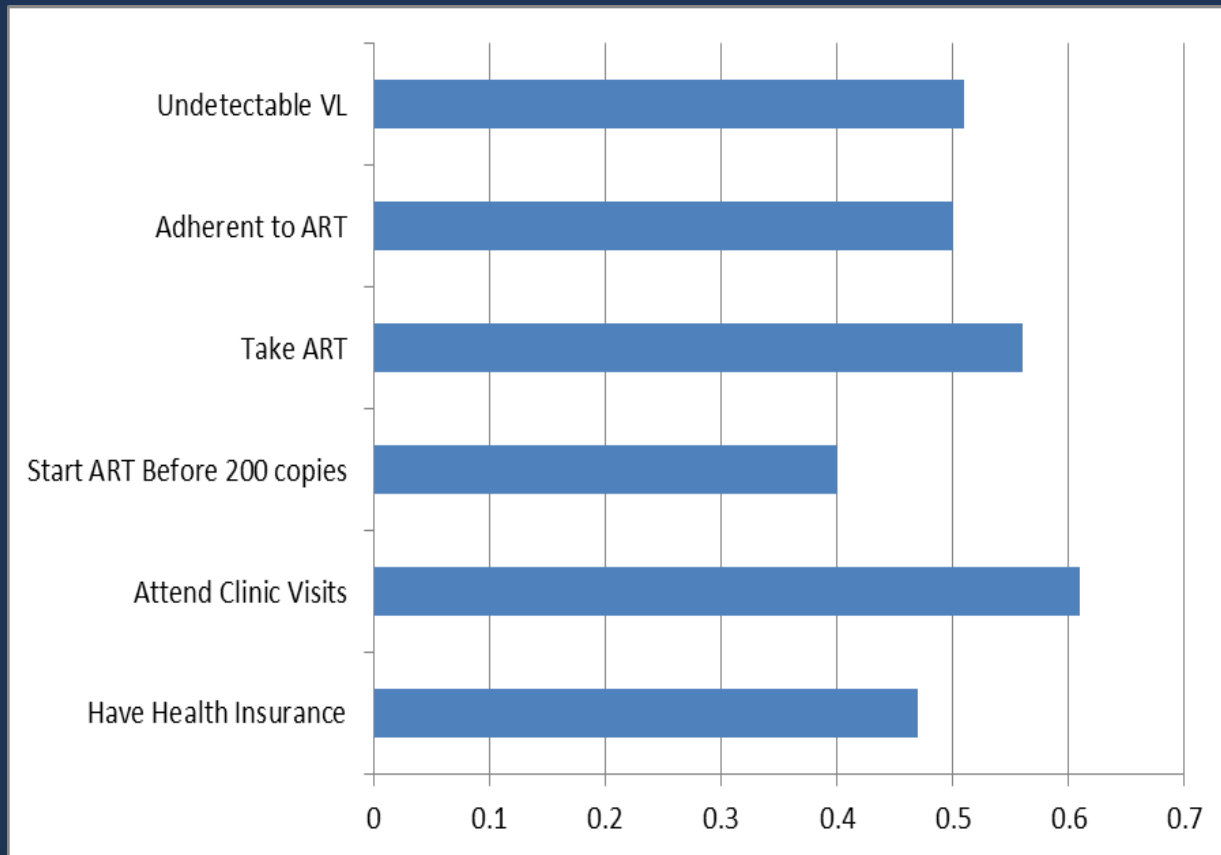
- Los Angeles has an important voice
 - Lived experiences of Black MSM are important to informing domestic HIV prevention approaches
- Los Angeles' contributions to network science are important
 - Leadership in Black Gay Research Group
 - Emerging leaders in behavioral science
- Preparing for follow-up study – HPTN 073

Challenges: Behavior

- Black MSM have risky sex at the same rates as other MSM
 - Given incidence of ~7% in this group in the context of the current outlay of HIV prevention dollars, what is the value of more behavioral HIV prevention?
 - Biobehavioral prevention interventions to consider range from Treatment as Prevention, PEP, PrEP.

Leaky Cascade -

- Meta-analysis of Black MSM compared to other MSM point to higher infectiousness, isolating prevalence as key factor



Millett, IAS 2012; Lancet 2012

Structural Factors

- Black MSM encounter stifling structural problems (employment, stigma, discrimination, incarceration, drug and alcohol use)
 - What is the place for addressing survival needs as well as sexual, primary and HIV health care needs for Black MSM?
 - Attributable risk to stimulant use for HIV incidence in MSM cohort studies is 16% (EXPLORE) to 33% (MACS).

Youth

- Sexual debuts well within high school range for incident cases;
 - 9/10 graduated high school perhaps signaling a place for prevention interventions/information
- Youth culture
 - Experiences of being Black male youth who have sex with men diminish trust with dominant culture

UCLA Vine Street Team

- Judith Currier, MD, CTU Grant Investigator
- Steve Shoptaw PhD, Site Principal Investigator
- Pamina M. Gorbach, DrPH, MPH, Co-Investigator
- Nina T. Harawa, PhD., Co-Investigator
- Cathy J. Reback, PhD, Co-Investigator
- John K. Williams, MD, Co-Investigator
- Christopher Hucks-Ortiz, MPH, Project Manager
- Jackie Benavente, MFT, Clinical Therapist
- Traci Bivens, Qualitative Interviewer
- Christopher Blades, Peer Health Navigator
- Miguel Bujanda, Peer Health Navigator
- Adam Carranza, Peer Health Navigator
- Pedro Chavez, Risk Reduction Counselor
- Christian Fleming, Peer Health Navigator
- Maria Sipin, Community Health Representative
- Gregory D. Victorienne, Community Educator
- Demetria Villanueva, Lab Technologist



910 N. Vine St
Los Angeles, CA 90038