HPTN 061 and HPTN 073

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Darrell Wheeler

HPTN Plenary
25 June 2012
HPTN 061 Acknowledgements

- National Institutes of Health: NIAID, NIDA, NIMH
- Protocol Co-Chairs:
  - Beryl Koblin, PhD
  - Kenneth Mayer, MD
  - Darrell Wheeler, PhD
- HPTN 061 Protocol Team Members
- HPTN 061 Study Participants
- HPTN Network Laboratory, Johns Hopkins Medical Institute
- Statistical and Data Management Center, SCHARP
- HPTN CORE Operating Center, FHI 360
- Black Gay Research Group

Clinical Research Sites, Staff and CABs

- Emory University
- Fenway Institute
- GWU School of Public Health and Health Services
- Harlem Prevention Center
- New York Blood Center
- San Francisco Department of Public Health
- UCLA
The HIV Hyper-Epidemic among U.S. Black MSM

High HIV prevalence despite significantly lower rates of high risk behaviors

- Young Black MSM less likely than young white MSM to engage in unprotected anal sex
- Black MSM less likely than white MSM to use drugs associated with risk of HIV infection
- Black MSM are more likely to engage in sex with other Black MSM, than other racial partners
- High rates of Bacterial and Viral STI potentiate HIV transmission
- Impact of dual stigmas?

Interventions focusing solely on traditional individual risk behaviors may not be the most effective

Millett, AIDS, 2007
HPTN 061 Methods

- HPTN 061 was a multi-site study to determine the feasibility and acceptability of a multi-component intervention for Black MSM in Atlanta, Boston, LA, NYC, San Francisco and Washington.
- Black MSM were recruited directly from the community or as sexual network partners referred by index pts
- Index participants were HIV-uninfected or, either:
  - HIV infected but unaware of their infection
  - Previously diagnosed with HIV infection, but
    - not engaged in HIV care, and/or
    - having unprotected sex with partners who were uninfected or of unknown HIV status

Community recruitment methods included community outreach, engagement of key informants and local community-based groups, advertising, and use of online strategies.
HIV System Navigation: An Emerging Model to Improve HIV Care Access

- Near Peers
- Structured training
  HRSA-funded evaluation:
  Helpful for engagement in care, adherence, retention
  Associated with ↓ PVL
- Unique feature of HPTN 061:
  assessment of HSN for HIV Prevention and Care

*Bradford, AIDS Pt Care & STDs, 2007*
## HPTN 061 Milestones

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
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<tbody>
<tr>
<td>Nov 28, 2007</td>
<td>Concept reviewed/approved for protocol development by HPTN EC</td>
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<tr>
<td>Apr 3-5, 2008</td>
<td>HPTN Community Workshop and protocol consultation</td>
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<tr>
<td>Sept 24, 2008</td>
<td>Protocol V. 1.0 approved by DAIDS</td>
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<tr>
<td>July 17, 2009</td>
<td>First participant Enrolled</td>
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<td>Oct 20, 2010</td>
<td>Last Participant Enrolled</td>
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<tr>
<td>Dec 09, 2011</td>
<td>Last participant follow-up visit</td>
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<tr>
<td>2012</td>
<td>Database lock including all laboratory values underway</td>
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<tr>
<td>Currently</td>
<td>Analyses underway (8 presentations at AIDS 2012)</td>
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Variables Studied

- Age
- City, Country of Origin
- Latino identity
- Education
- Household income
- Marital status
- Sexual orientation
- Gender identity
- # and type of sex partners
- Transactional sex
- Substance use
- Internalized homophobia
- Perceived racism
- Religious identity
- Incarceration history
- STDs
Variables Studied

- Use and perceptions of health care
- Awareness/use of PEP/PrEP
- HIV testing history
- HIV/AIDS conspiracy theories
- Integration of race and sexuality
- Treatment optimism
- Treatment adherence
- Mental health
- Social support
- Internalized HIV stigma
- Childhood physical and sexual abuse
- Intimate partner violence
- Stressful life events
Social Reality of the Men in HPTN 061

- Of 1553 participants
  - Majority identified as gay/homosexual
  - Almost ¾ had an annual household income of < $30,000
  - Over 1/2 had a high school education or less
  - Majority were unemployed
  - Many had been incarcerated
  - Asymptomatic STDs were common
Engaging at risk Black MSM in community-based research was very feasible

Undiagnosed HIV and STD’s were common

Men were reluctant and/or unable to refer >1 network partner (only 5.8% referred >1 partner)

Health system navigation was helpful for many of the men, associated with increased retention

Support for significant social needs, e.g. housing and employment was needed by many of the men
<table>
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<tr>
<th>Day</th>
<th>Title &amp; Author</th>
<th>Location</th>
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<tbody>
<tr>
<td>23 Mon</td>
<td><strong>An Evolving Concentrated Epidemic: Comparison of Socioeconomic, Behavioral and Biological Factors among Newly Diagnosed, Previously Diagnosed and HIV-Uninfected Black Men Who Have Sex with Men in 6 U.S. Cities</strong>&lt;br&gt;K.H. Mayer, et al.</td>
<td>Presentation&lt;br&gt;MOACO105&lt;br&gt;11:00am - 12:30pm</td>
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<tr>
<td>23 Mon</td>
<td><strong>Sexual Networks and HIV Risk among Black Men Who Have Sex with Men (BMSM) in the U.S.</strong>&lt;br&gt;H.V. Tieu, et al.</td>
<td>Poster&lt;br&gt;MOPE265&lt;br&gt;Poster Exhibition Area</td>
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<tr>
<td>24 Tues</td>
<td><strong>The high prevalence of incarceration among Black men who have sex with men (BMSM): associations and implications</strong>&lt;br&gt;R. Brewer, et al.</td>
<td>Poster&lt;br&gt;TUPE451&lt;br&gt;Poster Exhibition Area</td>
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<td><strong>Sociocultural and Psychological Factors as Predictors of HIV Sexual Risk Behavior in Black Men Who Have Sex with Men (MSM) from 6 US cities</strong>&lt;br&gt;L. Wilton, et al.</td>
<td>Poster&lt;br&gt;TUPE547&lt;br&gt;Poster Exhibition Area</td>
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<td><strong>Lessons Learned from Implementing a Black Caucus into HPTN 061: Demonstrated Community Engagement</strong>&lt;br&gt;S. Fields, et al.</td>
<td>Poster&lt;br&gt;TUPE730&lt;br&gt;Poster Exhibition Area</td>
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| 25 Wed | 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, et al. | Poster WEPE313  
Poster Exhibition Area |
| 26 Thurs | A Study of Perceived Discrimination in Black MSM and its Association with Healthcare Utilization and HIV Testing  
R. Irvin, et al. | Poster THPE495  
Poster Exhibition Area |
|        | Nonadherence to HIV Testing Guidelines and Late HIV Diagnosis Is Common Among US Black Men Who Have Sex with Men (MSM)  
S. Mannheimer, et al. | Presentation  
THABO301  
4:30pm - 6:00pm |
HPTN-073

• Pre Exposure Prophylaxis Adherence and Uptake among BMSM

  – Open label demonstration study with PrEP
  – Client-centered care coordination (C4)
  – Once daily oral Tenofovir-FTC
  – Implemented in local health care facilities
Primary Objectives – HPTN073

• Define rates of PrEP initiation and adherence
  – Self report
  – Pill counts
  – Dried blood spots
  – PBMCs & plasma concentrations
  – Determine differences in initiation and adherence of daily PrEP by sociodemographics, including age, education and risk practices
  – Describe side effects and toxicities among participants that initiate PrEP
Secondary Objectives – HPTN073

- Describe reasons for choosing to initiate PrEP or choosing to decline PrEP among BMSM
- Describe number of seroconversions in participants who initiated PrEP
- Describe HIV drug resistance patterns among persons who become HIV infected while participating in HPTN073
- Assess self-reported diversion (selling or sharing) of PrEP
- Determine logistics (space & staff) for administering PrEP in a local health care setting.
HPTN073 Projected Timeline

• Early July submission of budget
• Late July submission of full protocol to DAIDS
• Study implementation late 2012/early 2013
HPTN 061/073 Conclusions

• The rates of newly diagnosed HIV and STD infections among Black MSM in the U.S. greatly exceed that of the general population

• Structural, behavioral, and biological factors (e.g. unemployment, unprotected anal sex, and STDs) were associated with new infections among American BMSM

• To optimize uptake of PrEP and treatment for prevention for Black MSM, underlying social and structural issues must be addressed.
HPTN073 Development Team

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