PrEP and Black MSM

ANTIRETROVIRALS AND HIV PREVENTION: A CONVERSATION WITH KEY OPINION LEADERS ABOUT A NEW PARADIGM

FENWAY HEALTH, 10/29/13
Overview

• HPTN 061
  – Lessons Learned
• HPTN Black Caucus
• HPTN 073
  – Client Centered Care Coordination (C4)
• Next Steps
HPTN 061: The BROTHERS Study
Study Overview

- The first and largest prospective study of BMSM conducted in the U.S.
- Enrolled a total of 1,553 men in six U.S. cities
- First study to clearly define HIV incidence rate for BMSM in the U.S.
Study Population

- 34% were 30 years or younger
- 26% identified as gay/homosexual
- 2% transgender
- 46% had some college education or more
- 58% had annual income less than $20,000
- 31% worked full or part time
• HIV incidence among BMSM was 2.8% per year, 50% higher than rates in white MSM in the U.S.

**Study Findings**

• Young BMSM (< 30) acquired HIV infection at a rate of 5.9% per year, three times that of U.S. white MSM

• At enrollment, of those who self-reported being HIV-negative or not knowing their status, 12% were HIV-positive

• Peer health navigation = 100% retention
Lessons Learned: Retention

Retention Retreat and Report
Where are the **BROTHERS** – Released March 8, 2011

- http://www.hptn.org/research_studies/HPTN061StudyDocuments.asp#BlackCaucus

- **3 Major Areas of Concern**
  - **Burden/Benefit Analysis**
    - Transportation, Visit length, ACASI, Reimbursement,
  - **Intervention Delivery**
    - Cultural competency, Confidentiality, Staffing, Recruitment, Contacts
  - **Community Engagement**
    - Locator form, Dedicated retention staff, Staff support and feedback, monthly communications
Lessons Learned:

• Black MSM have competing life demands
  Prioritize their lives differently

• Black MSM Retention must be:
  – Proactively Planned: Not at afterthought
  – Benefits must outweigh the study burden

• Logistical Issues of Concern for Black MSM
  – Length of interviews, Clinic/lab hours, Transportation, Compensation

• More counselor engagement between study visits

• More mental health support

• Historical Mistreatment Addressed
  – Racism and Homophobia
Lessons Learned: Black Caucus

• The HPTN Black Caucus Ensured
  – That the design, implementation, analysis and interpretation of study data were racially and culturally appropriate
  – That the study was responsive to the needs of BMSM

• Contributions of the Black Caucus can be divided into two distinct areas
  – Cultural Competence
  – Design/implementation
Lessons Learned: Next Steps

- HPTN 061 was the first study of its type to establish a Black Caucus to serve as a key informant group
- The formation of the Black Caucus was based in CBPR concepts
- The Black Caucus functioned to provide a vehicle whereby the silent voices of BMSM can be heard, respected and understood
- 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
HPTN Black Caucus
A highly respected interdisciplinary group of Black professionals with unique expertise in conducting research on, about, and related to the lives of Black men who have sex with men who are at risk for HIV/AIDS
Mission / Purpose

- Support Community Engagement Activities
- Advise on staff diversity and cultural responsiveness for CRS and protocol team
- Provide feedback on study design, protocol implementation and information dissemination
- Serve as advisory group for Study Co-PI's
- Resource to HPTN leadership and the HPTN MSM SWG
Contributions

• Garner the scientific expertise of the BMSM communities
• Assist with and enhance study implementation to ensure success
• Interpret and disseminate study data
• Enhance BMSM cultural competencies
• Provide culturally relevant technical assistance to improve study retention
HPTN 073: PrEP Adherence and Uptake Among BMSM in Three US Cities
HPTN 073 Study Design

- Demonstration project
- Once daily oral emtricitabine 200 mg / tenofovir disoproxil fumarate 300 mg (FTC/TDF)
- Client-centered care coordination (C4)
HPTN 073 CLINICAL RESEARCH SITE LOCATIONS
HPTN 073 Study Questions

- Will BMSM initiate PrEP?
  - Why or why not?
- Will BMSM use PrEP daily?
  - If not how often?
- Is it safe for BMSM to use PrEP?
- Will BMSM sexual practices change with uptake of PrEP?
• Is it acceptable for local health care facilities to administer client-centered care coordination (C4) along with PrEP to BMSM?

• How much Truvada® is in the blood of BMSM who become infected with HIV?

• How often does HIV drug resistance occur?
Client Centered Care Coordination (C4)

- A clinical model maximizing resources and expertise of a healthcare team to develop a unique healthcare plan based on client needs.
- Considers experiences of BMSM in the U.S. related to biomedical interventions, psychosocial issues, and barriers to accessing health care.
Core Elements of C4

• **Care Coordination**: provides individualized prevention counseling, support, and service coordination working closely with service providers

• **Client-Centered Approach to Care**: an approach in which each client’s realities are taken into consideration with the goal of optimizing retention and adherence

• **Provider for Clinical Oversight**: different providers will perform different functions related to care coordination, the client-centered approach to care, and PrEP discussions/administration
Chapel Hill, NC
75 Participants
- 5 PrEP Uptake Interviews
- 5 PrEP Non-Initiator Interviews
- Site Staff C4 Focus Group

Los Angeles, CA
75 Participants
- 5 PrEP Uptake Interviews
- 5 PrEP Non-Initiator Interviews
- Site Staff C4 Focus Group

Washington, DC
75 Participants
- 5 PrEP Uptake Interviews
- 5 PrEP Non-Initiator Interviews
- Site Staff C4 Focus Group
Community Engagement

- Community engagement has been key at all stages of development and implementation:
  - Community input on protocol design
  - Community representatives on protocol team
  - HPTN 073 Community Working Group
  - Community consultations at each site
  - Community contacts/advocates
  - Ongoing community feedback
HPTN 073 Main Study Questions

• Will BMSM use PrEP?
• Is it safe for BMSM to use PrEP?
• Is it acceptable for local health care facilities to administer client-centered care coordination (C4) along with PrEP to BMSM?
HPTN 073 Research Team

- Dr. Darrell Wheeler, PhD, MSW, LCSW  
  - *National PI*
- Dr. Sheldon D. Fields, PhD, APRN, FNP-BC, FAANP  
  - *National Co-PI*
- Dr. LaRon Nelson, PhD, NP  
  - *Lead C4 Design Expert*
- Dr. Leo Wilton, PhD  
  - *Qualitative Lead Scientist*
HPTN 073: Black Caucus

- **Chair:** Christopher Chauncey Watson
- **Membership:** Two from each study site
  - Two at large community members
    - Blake Rowley, BA (NASTAD)
    - Craig S. Hutchinson, MPH (CA. Department of Public Health)
- **Work plan areas:**
  - Area 1: Scientific and community expertise
  - Area 2: Implementation
  - Area 3: Data Analysis, Interpretation and dissemination
  - Area 4: Technical Assistance
  - Area 5: Cultural Competency
Conclusions
Additional Information

- [www.hptn.org](http://www.hptn.org)
  - [www.facebook.com/HIVptn](http://www.facebook.com/HIVptn)
  - [www.twitter.com/HIVptn](http://www.twitter.com/HIVptn)

- [www.nih.gov](http://www.nih.gov)

- [www.cdc.gov](http://www.cdc.gov)
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