



HIV PREVENTION TRIALS NETWORK



HPTN
061

What is HPTN 061?

HPTN 061 is a research study conducted by the HIV Prevention Trials Network (HPTN) to examine certain strategies which may show promise for slowing the spread of HIV among black gay, bisexual and other men who have sex with other men (MSM*). The study also sought to better understand the lives of black MSM and how factors in their lives relate to HIV risk. The study began enrolling participants in July 2009 and completed follow up in December 2011.

The research study was open to MSM and transgender-- both HIV infected and uninfected-- who were 18 years old or older and self-identified as black. Most participants had three visits spaced out over a year. At these visits, participants were asked questions about their past and current lives. They were offered testing for HIV and other sexually-transmitted infections, as well as an opportunity to work with a "peer health navigator" who could assist them in getting connected to resources available in their community, such as medical care and social services.

**Note: In research the term "MSM" is used to describe men who have sex with men, which includes men who identify as gay, bisexual, same gender loving, transgender, and other terms.*

Why black men?

Although it is estimated that black MSM make up less than half of one percent of the U.S. population, data from the Centers for Disease Control and Prevention show that in 2009 over 20% of new HIV infections were diagnosed among black MSM. In addition, data from 2006-2009 showed that the number of new infections among young black MSM (18-24 years old) increased by nearly 50% between 2006 and 2009.

Who participated?

A total of 1553 men enrolled in six cities. These cities (and the local name of the study) were: Atlanta, GA (BROTHERS), Boston, MA (Project SOS), New York, NY (Brothers' Project), Los Angeles, CA (The Brothers' Project), San Francisco, CA (Unity), and Washington, DC (061). The participants in the study came from a variety of backgrounds in terms of age, education, income and other characteristics. A snapshot of participant demographics shows:

- 34% were 30 years or younger (n=519)
- 46% had some college education or more (n=706)
- 31% worked full or part time (n=481)
- 20% were full or part time students (n=317)
- 60% had annual income less than \$20,000 (n=920)
- 2% identified as transgender (n=31)

Study status and early results

The study completed participant enrollment in December 2011 and initial results were first presented at the International AIDS Conference in July 2012. Initial analyses of the data revealed greatly elevated HIV infection rates among young black MSM in the U.S. The study was first to determine the rate of new HIV infection among such a large prospective cohort of U.S. black MSM (referred to as HIV incidence). Other early analyses showed that HIV infection in this study population was associated with high rates of sexually transmitted infections, poverty and low and/or delayed rates of HIV testing.

A key question at the beginning of the study was whether black MSM would agree to participate in this research. The number of men enrolled clearly shows that black MSM were willing to volunteer their time, information and samples for an HIV study. In addition, more than 350 men worked with a peer health counselor at one or more study sites, and over 97% of men enrolled were willing to have an HIV test. This success speaks to the generosity of the participants and the dedication and support of staff and community partners at each site.

As of January 2014, four HPTN 061 manuscripts have been published in peer-reviewed scientific journals. Specific citations for these papers can be found at HPTN.org, along with short summaries of their findings. As future results are published, they will also be shared on HPTN.org. Results from HPTN 061 are also being shared through webinars, presentations, workshops and social media.

What results are still to come?

This project began with the goal of answering several specific questions:

- Would participants be interested in using HIV prevention components offered in this study, such as HIV testing, working with a peer counselor, receiving referrals for health care or other supportive services?
- Would these HIV prevention components show promise for slowing HIV infection?
- What individual sexual behaviors may be affecting risk for HIV?
- What other factors of men's lives may be affecting their risk for HIV?

Some of these questions are beginning to be answered by the findings shared at the International AIDS Conference 2012 and in the already-published scientific papers, but further analysis is needed. For example, researchers are preparing papers identifying factors which were associated with having HIV vs. being uninfected and determining who used peer counselors and what effect peer counselors may have had.

In addition to answering the main study questions, the project team is investigating many other questions that the data from HPTN 061 can answer. For example, team members are exploring how HIV risk among black MSM might be affected by their religious experiences, or perceptions of racism and experience of homophobia, or a history of child sexual abuse.

What happens next?

Additional study data analysis will be necessary to fully evaluate the intervention explored in HPTN 061. In the meantime, recent HIV prevention studies have shown that MSM could lower their risk of HIV infection if they took a pill once a day containing medicine usually used to treat people already infected with HIV. This prevention approach is called pre-exposure prophylaxis, or PrEP. The FDA recently approved the drug Truvada to be used for PrEP. Could PrEP be an effective tool to help lower the risk of HIV for black MSM? The HPTN 073 study is investigating this very question at three U.S. research sites, two of which were HPTN 061 study sites. While PrEP is one tool that holds promise for helping in the fight against HIV, results emerging from HPTN 061 indicate that stopping this epidemic will require many strategies to effectively address the different factors that put black MSM at risk.

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