Understanding Clinical Trials and How to Get Involved

UNITED STATES CONFERENCE ON AIDS
MONDAY, SEPTEMBER 9, 2013
NEW ORLEANS, LA
Overview

- HPTN Overview
- Community Engagement
  - Site-Level Engagement
  - National Engagement
- Developing Leadership
- Case Study
- Taking Action
HIV Prevention Trials Network Overview
<table>
<thead>
<tr>
<th>Variable</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>HIV Status</td>
<td>HIV negative, acute infection, established HIV infection</td>
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<tr>
<td>Populations</td>
<td>Adolescents, MSM, women, IDU, communities</td>
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<tr>
<td>Interventions</td>
<td>Behavioral, HIV testing, PrEP, ART, male circumcision, substitution/antagonist therapy, financial incentives, integrated strategies</td>
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<tr>
<td>Types of Studies</td>
<td>Observational, individual randomized, site randomized, community randomized, implementation science</td>
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</tbody>
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Community Engagement
The United States National Institutes of Health, Division of AIDS (NIH-DAIDS) defines community by the population in and for which the research is being conducted.
Partnerships in Research

- Concept Development
- Protocol Development
- Research Implementation
- Information Dissemination
Research Trial Stakeholders

- Global Stakeholders
  - International Organizations
- National Stakeholders
  - Legislators
  - National NGOs
- Broader Stakeholders
  - NGOs
  - Media
- Community Stakeholders
  - CBOs/Advocacy Groups
  - Traditional leaders
- Trial Participants
Guiding Principles

- Respect
- Mutual Understanding
- Integrity
- Transparency
- Accountability
- Autonomy
Site-Level Community Engagement
Community Advisory Boards (CAB)

• Group that speaks for the concerns of the community on issues related to research
• Interact with researchers and participate in the "behind-the-scenes" happenings of research studies
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Community Advisory Boards (CAB)
CAB History

- **1980s: AIDS activists in the U.S. and Europe**
  - Demanded that researchers and regulatory authorities move more quickly to find medications to fight HIV.
  - A group of activists looked for opportunities to review trial proposals.
  - By protesting, letter-writing, and lobbying the U.S. government they succeeded.

- This process resulted in the creation of CABs
CAB Membership

• Now comprised of individuals representing:
  – Various parts of the local community such as: religious groups, schools, and universities
  – Media
  – Non-government organizations/community-based organizations

• Non-paid volunteers
• Set their own guidelines
• Mandatory representation from the research target population
Community Working Group

- Facilitate community input into science generation and the research process.
- Build community capacity to provide input into research.
- Develop mechanisms for sharing experiences, lessons learned and best practices.
- Assess the impact of community involvement on community participation in research.
Capacity Building

- Understanding the research process (clinical trial design, informed consent development, ethical considerations, IRB review, study implementation, results interpretation, and messaging following study results)
- Cultural humility/responsiveness training for CRS working with BMSM
- Scientific plenary focusing on adherence in HIV prevention research
- HPTN 068 community advisory group training
- HPTN 071 community engagement manual
Input on Scientific Agenda

- Community voice key component in science generation and review process
- Consultative meetings
- Training on “How to Review a Protocol and Provide Feedback”
- Routine conference calls
- Pre-implementation assessment visits and education is critical
- Online questionnaires
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Input on Scientific Agenda
Develop Study-Specific Resources

• Study FAQs
  – HPTN 069
  – HPTN 071 and 073

• Study Fact Sheets and Brochure
  – HPTN 069
  – HPTN 071
  – HPTN 073

• Study websites
  – HPTN 069 www.nextprepstudy.org
  – HPTN 073
BE PREPARED FOR THE FUTURE.
Volunteer for an HIV prevention study.

Are you 18 or older and HIV negative?
Find out how you can help PrEP for the future and be reimbursed for your time and travel.
National Community Engagement
Increasing ‘Research’ Health Literacy

• Research awareness shapes
  – Policy and programming decisions
    • Preventing misplaced spending on disproven approaches
    • Encouraging support for beneficial programming
  – Advocacy for community needs
    • Understanding of ability to guide future research directions
    • Ownership of roles in disseminating information through constituency networks
National Engagement Objectives

• Building national-level engagement in HIV prevention research among members of focus communities by:
  – Transferring specific knowledge about HPTN’s domestic and international studies through interactions with key organizations and community groups
  – Promoting inclusion of HPTN’s research agenda within the national HIV prevention dialogue
Social Media as a Communication Venue

• Low cost engagement for increased visibility
• Open forum for national dialogues
• Build national stakeholder /advocate partnerships
• Search engine optimization
Education/Dissemination Efforts

• Webinars
• Twitter Chats
• Presence at National Conferences
  – Trainings/workshops
  – Plenaries
  – Exhibiting
• Materials development for national partner blogs, newsletters and websites
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Education/Dissemination Efforts
BE THE
GENERATION BRIDGE

NATIONAL PARTNERS

AIDS United-Mapping Pathways
1424 K Street, NW, Ste. 200
Washington, DC 20005
www.aidsunited.org

ASPIRA Association, Inc.
1441 1 Street, NW Suite 800
Washington, DC 20005
www.aspira.org

AVAC
423 West 127th Street, 4th Fl
New York, NY 10027
www.avac.org

Black AIDS Institute
1833 West 8th Street, Ste. 200
Los Angeles, CA 90057
www.blackaids.org

Gay and Lesbian Latino AIDS Education Initiative (GALAEl)
1207 Chestnut St, 5th Floor
Philadelphia, PA 19107
www.galael.org

Latino Commission on AIDS
24 West, 25th Street, 5th Floor
New York, NY 10010
www.latinoids.org

National Minority AIDS Council & National Black Gay Men’s Advocacy Coalition
NMAC: 1931 13th Street, NW
Washington, DC 20009
NBGMAC: 3636 Georgia Ave, NW
Washington, DC 20010
www.nmac.org
www.nbgmac.org

REACH LA
1400 E. Olympic Blvd, Ste. 240
Los Angeles, CA 90021
www.reachla.org

The AIDS Institute
1705 DeSales Street NW
Suite 700
Washington, DC 20036
www.theaidsinstitute.org

MTN microbicide trials network
HIV VACCINE TRIALS NETWORK
HIV Prevention Trials Network
We’ve launched a new PrEP demonstration project for Black men who have sex with men. Find out what it is all about on Wednesday, August 14th.

🌟 Participate in the #HPTN073 Twitter chat at 10 am PT / 1 pm ET by sending your questions and comments to @HIVptn @JonPaulLucas or @cchauncey using the hashtag #PrEPChat.

🌟 Join the HPTN 073 Webinar at 11 am PT / 2 pm ET by registering at http://bit.ly/073Webinar
What Can You Do to Help Increase Research Engagement?

- Share information about research within your networks’ HIV discussions
- Participate in dialogue process with researchers
- Investigate ways to integrate research related work in your career
- Integrate discussions about research in programming and policy decisions
Developing Leadership
Executive Committee

Prevention Management Group

Network Oversight and Operations Committees
- Science Review Committee
- Study Monitoring Committee
- Manuscript Review Committee
- Performance Evaluation Committee
- Endpoint Adjudication Committee
- Policies and Procedures Group

Scientific Committees and Working Groups
- Adolescents Committee
- Men who have Sex with Men (MSM) Committee
- Substance Users Committee
- Women at Risk Committee
- Biomedical Sciences for Prevention Working Group
- Combination Interventions for Prevention Working Group
- Community Working Group
- Ethics Working Group
Community Representation

- Network Executive Committee
- Scientific Committees
- Ethics Working Group
- Protocol Teams
- Performance Evaluation Committee
- Science Review Committee
- HANC Cross Network Community Groups
The HPTN Black Caucus is 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.
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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
- Network resource (i.e. HPTN leadership, MSM committee)
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 Scholars Program

- Mentorship program funded through a supplement from NIAID and NIMH
- Seeks early career US minority investigators who have received their degree (MD, PhD, etc.)
- Develop a project based upon existing domestic HIV research study in the HPTN
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Case Study
Case Study

• Phase II placebo controlled injectable PrEP study in preparation for phase III injectable PrEP study

• Focus on
  – HIV negative MSM
  – Ages 18-45
  – In the US
  – Four metropolitan cities
Case Study #2

• We’ve described the reasons why increasing research literacy and engagement can help communities in their fight to reduce the impact of HIV. What recommendations do you have for researchers in increasing community engagement?

• Focus on
  – Existing local and regional HIV-specific organizations
  – Population specific, non-HIV health equity organizations
  – Faith-based groups
  – Membership-related groups (By Occupation, Fraternity, Sorority, Civic Group, Etc.)
Conclusions
Taking Action

- Collaboration with, and inclusion of, community representatives in all aspects of the research process is critical.

- Meaningful community engagement increases the likelihood that affected communities are invested and supportive.
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.fhi360.org](http://www.fhi360.org)

- [http://www.avac.org](http://www.avac.org)
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Questions or Comments?

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Twitter/HIVptn