Women and HIV Prevention Research: How is the HIV Prevention Trials Network Working to Bridge Gaps in Research for Women in the United States and Around The World?

September, 2013
United States Conference on AIDS (USCA)
New Orleans, Louisiana

Overview

- Introductions
- What is the HPTN?
  - StoryCorps Conversation with HPTN’s Leadership
- HPTN’s Research with Women
  - United States
    - Seroincidence and PrEP Research
  - Thailand, India, South America and Africa
    - Treatment as Prevention (TASP)
    - Combination Research and Financial Incentives (Including US HPTN 065)
- Panel Discussion
Panel Participants
- Dazon Dixon Diallo
- Deirdre Grant
- Naina Khanna
- Wairimu Chege
- Vanessa Elharrar

Panel Facilitator
Melissa Turner

Introductions and Opening Questions
What is your role?

1. Case Manager
2. Executive Director
3. Community Member
4. Advocate/Activist
5. Researcher
6. Medical Provider
7. Other

How long have you done paid and/or volunteer work related to HIV?

A. 0-2 years
B. 3-5 years
C. 6-8 years
D. 9-11 years
E. 12-20 years
F. 21 years or more
How would you rate your current levels of knowledge about HIV prevention clinical research?

A. Pretty High Levels of Knowledge
B. Moderate Levels – I feel very comfortable with this topic
C. Low Levels, But Learning
D. Not Much At All – I’m just beginning to explore this topic.

Knowing about current and completed research is important because it helps in making informed decisions about…

A. Policy Planning
B. Program Planning
C. Finding Funding Resources
D. Personal Health Choices
E. All Of The Above
What is the HIV Prevention Trials Network (HPTN)?

Introducing The HPTN

The HPTN is a partnership between scientists and communities around the world to develop, evaluate and implement cutting-edge biomedical, behavioral and structural interventions to reduce the transmission of HIV. Those interventions include PrEP, treatment as prevention and combination research.
HPTN receives its funding from three National Institute of Health (NIH) divisions:

- The National Institute of Allergy and Infectious Diseases (NIAID),
- The National Institute of Mental Health (NIMH), and;
- The National Institute on Drug Abuse (NIDA)
HPTN’s Mission

To discover and develop interventions that can be used to prevent sexual and/or parenteral transmission of HIV in populations at risk around the world.

HPTN Community Working Group (CWG)

- Representatives from all sites worldwide
- Ensures community input into science generation and the research process.
- Builds community capacity to provide input into research.
- Develops mechanisms for sharing experiences, lessons learned and best practices.
- Assesses the impact of community involvement on community participation in research.
Community Advisory Boards (CAB)

- Ensures that recruitment and retention plans are developed
- Informs clinical research staff of potential social harms
- Assists in the development of study specific educational tool kits and communication plans
- Keeps community members informed of research activities
- Conducts community preparedness and ongoing involvement

HPTN 2012-2013 HPTN Scholars
Latino ethnicity, HIV risk correlates, and high-risk sexual behavior among HIV-negative Black MSM (HPTN 061) Dr. Andres Bedoya

Typologies of Testing: A Qualitative Analysis of HIV Testing Patterns Among Black MSM in Atlanta, (HPTN 061) Dr. Sophia Hussen

Tell me who your sex partners are and I will tell you who you are: A Comparison of Sexual Network Partners with Community-Recruited Participants from the HPTN 061 Project Dr. Grace (Chela) Hall

Racial/ethnic differences in injector networks & factors associated with membership in networks w/ HIV (HPTN 037) Dr. Chevy Williams

The Association Between Venues where Women at Risk of HIV Meet Sexual Partners and Partner HIV Risk Characteristics (HPTN 064) Dr. Malika Roman Isler

Attitudes and Believes about Individual and Community HIV/STI Risk among Women at Risk for HIV Acquisition in HPTN 064 Dr. Oni Blackstock
Prevalence and HIV Risk-Related Correlates of Emotional, Physical, and Sexual Violence Among Women at Risk in the US (HPTN 064)
Dr. Brooke Montgomery

Differences in Substance Use, Psychosocial Characteristics and HIV-Related Sexual Risk Behavior Between Black Men Who Have Sex with Men Only (BMSMO) and Black Men Who Have Sex with Men and Women (BMSMW) in Six US Cities (Journal of Urban Health. June, 2013)
Dr. Typhanye Penniman Dyer

HPTN’s Portfolio

- 80 research sites in 15 countries
- 50 clinical trials ongoing or completed
- 50,000 study participants followed
- 300 publications
HPTN’s Leadership

Former Principal Investigators
Dr. Sten Vermund
Dr. Quarraisha Abdool Karim

Current Principal Investigators
Dr. Wafaa El-Sadr
Dr. Myron Cohen

HPTN Presents

Wafaa El-Sadr
And
Quarraisha Abdool Karim
A StoryCorps Conversation
HPTN’s HIV Prevention Research With Women

Today’s Presentation Will Highlight HPTN Research With Women In:

- United States
- South America
- Africa
- Thailand
- India
- China
HIV Prevention Tool Box

- Expanded HIV Testing
- Male Circumcision
- Treatment as Prevention
- Treatment of STIs
- Behavioral Interventions
- Prevention for Positives
- PrEP
- Interventions for Injection Drug Users
- Cash Incentives
- Comprehensive Safer Sex Practices, Including Use of Condoms
- Microbicides
- Vaccines

HPTN's Current Research with Women

- Treatment as Prevention
- PrEP
- Combination Interventions
- Behavioral Interventions
- Expanded HIV Testing
- Expanded HIV Testing
- Expanded HIV Testing
- Cash Incentives
- Prevention for Positives
- Comprehensive Safer Sex Practices, Including Use of Condoms
- Interventions for Injection Drug Users
In 2010, what percentage of new HIV infections in the United States were among women?

A. 10 %
B. 20 %
C. 50 %
Fill in the blank: At some point in their lifetimes, an estimated 1 in ____ Black women will be diagnosed with HIV infection, compared with 1 in 106 Hispanic/Latino women and 1 in 526 white women.

A. 32
B. 72
C. 92


<table>
<thead>
<tr>
<th>Population</th>
<th>New HIV Infections</th>
</tr>
</thead>
<tbody>
<tr>
<td>White MSM</td>
<td>11,200</td>
</tr>
<tr>
<td>Black MSM</td>
<td>10,600</td>
</tr>
<tr>
<td>Hispanic/Latino MSM</td>
<td>6,700</td>
</tr>
<tr>
<td>Black Heterosexual Women</td>
<td>5,300</td>
</tr>
<tr>
<td>Black Heterosexual Men</td>
<td>2,700</td>
</tr>
<tr>
<td>White Heterosexual Women</td>
<td>1,300</td>
</tr>
<tr>
<td>Hispanic/Latino Heterosexual Women</td>
<td>1,200</td>
</tr>
<tr>
<td>Black Male IDUs</td>
<td>1,100</td>
</tr>
<tr>
<td>Black Female IDUs</td>
<td>850</td>
</tr>
<tr>
<td>Hispanic/Latino Heterosexual Men</td>
<td>780</td>
</tr>
</tbody>
</table>

Source:
Challenges of a Hidden Epidemic: HIV Prevention Among Women in the United States

Sally L. Hodder, MD,* Jessica Justman, MD,† Danielle E. Hales, MPH,‡ Adaora A. Adimora, MD, MPH,§ Catherine I. Fogel, PhD, WHCNP,‖ Carol E. Golin, MD,¶ Ann O’Leary, PhD##
Lydia Soto-Torres, MD, MPH,** Gina Wingo, PhD,†† and Wafaa M. El-Sadr, MD, MPH††† on behalf of the HIV Prevention Trials Network Domestic Prevention in Women Working Group

HPTN 064: ISIS
The Women’s HIV Seroincidence Study

Rationale

• To understand rate of new HIV infections (“incidence”) in US women in order to design new HIV prevention trials
• Earlier studies may not have found women most at risk for new HIV infections
  – New recruitment strategies needed
• Need for improved lab tests to identify most recent HIV infections
Objectives

• To measure rate of new HIV infections (“incidence”) in a group of women at risk for HIV in the US
• To evaluate new lab methods for identification of most recent HIV infections
• Describe what happens in participants’ lives that might affect HIV risks
  – For example, partner risks, alcohol/drug use, financial factors, condom use

Inclusion Criteria

• Women (self identified) ages 18-44 years
• Live in an area with high rates of HIV and poverty
• Not aware of being HIV-infected
• Report unprotected sex with a man during the previous 6 months
• AND report at least one additional personal or partner risk factor, such as binge drinking, drug use, or incarceration history...
Venue-Based Recruitment

• Women recruited from “venues”, or locations, where those who live in selected areas often go
• Suitable venues and recruitment times carefully chosen after community input
• Van transportation provided by some sites

Study Locations

10 distinct communities within 6 geographic locations

- Bronx and Harlem, NY
- North and South Newark, NJ
- Baltimore, MD
- Washington, DC
- Durham and Raleigh, NC
- Decatur and Atlanta, GA
Study Procedures

• Enrollment visit, 6-month visit and 12-month visit:
  – Informed consent
  – HIV counseling and testing
  – Complete questionnaire using a computer

Composition of Qualitative Component

ISIS Participants
N=2099

Individual Interviews of 120 women

31 Focus Groups with women

32 Focus Groups with men
Results

• 2,099 women enrolled over 14 months
  – 88% black
  – 12% Hispanic/Latina Ethnicity
• 94% women completed study

Important Characteristics of Women Entering ISIS

• Drug use in the past 6 months...............27%
• Binge drinking in the past 6 months.........39%
• Condom use at last sex..........................18%
• HIV status of last sex partner unknown.....41%
• Average # of partners in past 6 months.....1-3
HIV in the ISIS Cohort

38 women were identified as HIV-infected:

- 32 (1.5%) participants first learned about HIV infection at study entry
- 2 of the 32 women had “recent infections” per new lab test, most likely in past 6 months (1/400 or 0.25%)
- 2 women had “acute” HIV infection at study entry, most likely acquired in past 2 weeks (1/40 or 2.5%).
- 4 women acquired HIV during study (1/400 or 0.24%)

What Might Lead to Women’s HIV Risk?

- **Societal**
  - Health inequalities
  - Housing
  - Healthcare access
  - Judicial policies

- **Community**
  - Poverty
  - Violence
  - Access to resources

- **Relational**
  - Concurrency (overlapping partners)
  - Domestic violence
  - Condom use
  - Social support

- **Individual**
  - Financial insecurity
  - Resource-driven survival behaviors
  - Health status and Self-esteem issues
Summary

• ISIS succeeded in recruiting over 2000 women from communities with high rates of HIV and poverty
• HIV incidence was 1 in 400 women per year
  • ~five times higher than rate previously estimated by the CDC for general population of black women in the US
• New lab tests did well in predicting incidence rates
• 1.5% (3 of 200 women) unaware of HIV + status
• Drug and alcohol use & lack of knowledge about partner’s HIV status common, while condom use low
ISIS Video Trailer

PrEP Studies: A Global Perspective
PrEP stands for…

1. Post Exposure Prophylaxis
2. Pre- Exposure Prophylaxis
3. Preparing for Research Evaluation Process

![Bar Chart](image)

Which drug has been approved by the US FDA to be prescribed now as PrEP?

1. Moraviroc
2. Truvada
3. Tylenol Extra Strength
4. Truelenol
5. None of the above

![Bar Chart](image)
Research has shown that PrEP does not work for women?

1. True
2. False

<table>
<thead>
<tr>
<th>Study (reference)</th>
<th>Study population</th>
<th>Design</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEM-PrEP</td>
<td>2120 Women in Kenya, South Africa and Tanzania</td>
<td>TDF/FTC (Truvada®) vs. placebo</td>
<td>Product not proven effective in preventing HIV due to low adherence (approximately 33% adherent)</td>
</tr>
<tr>
<td>MTN-003 (VOICE)</td>
<td>5,029 Women in South Africa, Uganda, and Zimbabwe</td>
<td>TDF (Viread) vs. placebo TDF/FTC (Truvada®) vs. placebo TDF gel vs. placebo</td>
<td>No product proven effective in preventing HIV due to low adherence (23%-29% adherent)</td>
</tr>
</tbody>
</table>
HPTN 069/ACTG 5305
NEXT-PREP:
Novel Exploration of Therapeutics for PREP

HPTN 069 Sites

• Baltimore, MD
• Boston, MA
• Chapel Hill, NC
• Cleveland, OH
• Los Angeles, CA
• Newark, NJ
• New York City, NY
• Philadelphia, PA
• Pittsburgh, PA
• San Francisco, CA*
• San Juan, PR
• Seattle, WA
• Washington, DC.

Enrolling combined total of 600 Men, Women, Transgender Women, and Transgender Men who have sex with men.
* Enrolling only Men and Transgender Women who have sex with men.
There are 3 active drugs:
- maraviroc (MVC)
- emtricitabine (FTC)
- tenofovir (TDF)

Study Regimens (3 pills/arm):
- maraviroc + FTC placebo + TDF placebo
- maraviroc + emtricitabine + TDF placebo
- maraviroc + tenofovir + FTC placebo
- tenofovir + emtricitabine + MVC placebo
HPTN 067
The ADAPT Study:
Alternative Dosing to Augment PrEP pill-Taking
Clinical Research Sites for HPTN 067

- Harlem, New York
  - 180 MSM and transgender women
- Bangkok, Thailand
  - 180 MSM and transgender women
- Cape Town, South Africa
  - 180 women who have sex with men (WSM).

Study Groups

1. Daily
2. Event-driven (before and after sex)
3. Time-driven (2 times a week and a booster after sex)

No more than
- 2 tablets in a 24-hour period
- 7 tablets in a week.
Main Study Questions

- How does taking oral Truvada® tablets intermittently compare to taking the tablets daily? Will participants in the intermittent groups:
  - have the same coverage of sex events,
  - need fewer tablets for coverage, and
  - report fewer side effects compared to participants who take their tablets daily?
Desmond Tutu HIV Foundation
ADAPT Study Video

HPTN 076: Injectable Pre-Exposure Prophylaxis (PrEP)
Study in Development

- Total of 132 participants
  - 48 at each of two international sites
    - Cape Town, South Africa
    - Harare, Zimbabwe
  - 18 at each of two US sites
    - Bronx, New York
    - Newark, New Jersey
- Injectable PrEP vs placebo

HPTN 076 Main Study Questions

- Is injectable PrEP safe for women?
- Will women find injectable PrEP acceptable for use?
- Is injectable PrEP tolerable for women?
Treatment as Prevention (TasP) Studies: A Global Perspective

Thailand, India, South America and Africa
It is estimated that in 2011, 34 million people around the world were living with HIV. What percentage of those people were women?

A. 25% (8.5 Million)
B. 49% (16.7 Million)
C. 62% (21 Million)
### Global summary of the AIDS epidemic | 2011

<table>
<thead>
<tr>
<th>Number of people living with HIV</th>
<th>Total</th>
<th>34.0 million [31.4–35.9 million]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>30.7 million [28.2–32.3 million]</td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>16.7 million [15.4–17.6 million]</td>
<td></td>
</tr>
<tr>
<td>Children (&lt;15 years)</td>
<td>3.3 million [3.1–3.8 million]</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>People newly infected with HIV in 2011</th>
<th>Total</th>
<th>2.5 million [2.2–2.8 million]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>2.2 million [1.9–2.4 million]</td>
<td></td>
</tr>
<tr>
<td>Children (&lt;15 years)</td>
<td>330 000 [280 000–390 000]</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>AIDS deaths in 2011</th>
<th>Total</th>
<th>1.7 million [1.5–1.9 million]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>1.5 million [1.3–1.7 million]</td>
<td></td>
</tr>
<tr>
<td>Children (&lt;15 years)</td>
<td>230 000 [200 000–270 000]</td>
<td></td>
</tr>
</tbody>
</table>

The research site in Pune, India created a video discussing the impact of HIV in their region. The video will be made available on-line.
HPTN 052: Serodiscordant Couples Study

Clinical Research Sites for HPTN 052

Africa
• Gaborone, Botswana
• Kisumu, Kenya
• Blantyre, Malawi
• Lilongwe, Malawi
• Johannesburg, South Africa
• Harare, Zimbabwe

Asia
• Chennai, India
• Pune, India
• Chiang Mai, Thailand

South America
• Manguinhos, Brazil
• Nova Iguacu, Brazil
• Porto Alegre, Brazil
• Rio de Janeiro, Brazil
HPTN 052 Study Design

Randomization
- Stable, healthy, serodiscordant couples, sexually active
  - CD4 count: 350 to 550 cells/mm³
- Immediate ART
  - CD4 350-550
- Delayed ART
  - CD4 < 250

Primary Transmission Endpoint
- Virally linked transmission events

Primary Clinical Endpoint
- WHO stage 4 clinical events, pulmonary tuberculosis, severe bacterial infection and/or death

1,763 serodiscordant couples (97% heterosexual)
HIV infected partners: 890 men, 873 women

39 HIV Transmissions
- 28 linked HIV transmissions
- 11 unlinked transmissions

Immediate ART
- 1 transmission

Delayed ART
- 27 transmissions

96% Protection
Results of the HPTN052 trial announced on 12 May 2011 show that if an HIV-positive person adheres to an effective antiretroviral therapy regimen, the risk of transmitting the virus to their uninfected sexual partner can be reduced by 96%.

“Treatment for prevention is a game changer.”
Michel Sidibe
Executive Director of UNAIDS
DHHS revised their HIV Treatment Guidelines in February 2012

• ART recommended for all HIV-infected individuals, irrespective of CD4-cell count, for their own health and to prevent HIV transmission

• Changes based on
  – Growing body of evidence demonstrating harmful effects of ongoing HIV replication and clinical benefit
  – HPTN 052 – ART significantly reduces the likelihood of HIV transmission

In April 2012, WHO issued new guidance for couples

“For couples where only one partner is HIV positive, the guidelines recommend offering antiretroviral therapy to the HIV positive partner, regardless of his/her own immune status (CD4 count), to reduce the likelihood of HIV transmission to the HIV negative partner.”
Effective Implementation of TasP

Effective implementation of TasP requires addressing barriers to:
• Expanded testing,
• Improved care linkage and engagement
• Earlier ART initiation and adherence

The final sets of studies that we'll discuss today all address various issues that may help overcome some of those barriers.

### Antiretroviral therapy coverage in low- and middle-income countries, adults and children [combined], December 2011

<table>
<thead>
<tr>
<th>Geographical region</th>
<th>Estimated number of people receiving ARV therapy</th>
<th>Estimated number of people needing ARV therapy</th>
<th>Antiretroviral therapy coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sub-Saharan Africa</td>
<td>6 200 000</td>
<td>11 000 000</td>
<td>56%</td>
</tr>
<tr>
<td>Latin America and the Caribbean</td>
<td>660 000</td>
<td>850 000</td>
<td>77%</td>
</tr>
<tr>
<td>East, South and South-East Asia</td>
<td>1 100 000</td>
<td>2 400 000</td>
<td>46%</td>
</tr>
<tr>
<td>Europe and Central Asia</td>
<td>137 000</td>
<td>520 000</td>
<td>26%</td>
</tr>
<tr>
<td>North Africa and the Middle East</td>
<td>16 000</td>
<td>100 000</td>
<td>16%</td>
</tr>
<tr>
<td>Total</td>
<td>8 100 000</td>
<td>14 800 000 [13.7–15.6 million]</td>
<td>55% [52–69%]</td>
</tr>
</tbody>
</table>
Number of people receiving antiretroviral therapy in low- and middle-income countries, 2002–2011

HPTN 043:
NIMH Project Accept
Study Hypothesis

Increase in knowledge of HIV status in a community will be associated with decreased HIV incidence

Project Accept (HPTN 043)

Chiang Mai, Thailand
Kisarawe, Tanzania
Mutoko, Zimbabwe
Soweto, South Africa
Vulindlela, South Africa
Communities randomized to two approaches:
Mobilization, Testing, Support, and Access to Services

<table>
<thead>
<tr>
<th>Community-based VCT</th>
<th>Standard VCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>(CBVCT N = 24 communities)</td>
<td>(SVCT N = 24 communities)</td>
</tr>
<tr>
<td>• Community preparation, outreach, mobilization</td>
<td>• Standard VCT services normally provided in that community</td>
</tr>
<tr>
<td>• Mobile VCT</td>
<td></td>
</tr>
<tr>
<td>• Post-test support services</td>
<td></td>
</tr>
<tr>
<td>– Stigma-reduction skills training</td>
<td></td>
</tr>
<tr>
<td>– Coping effectiveness training</td>
<td></td>
</tr>
<tr>
<td>– Ongoing counseling</td>
<td></td>
</tr>
<tr>
<td>• Ongoing data feedback and field adjustments</td>
<td></td>
</tr>
</tbody>
</table>

Van Rooyen et al, AIDS and Behavior, 2012

86,720 HIV tests

- 69,987 in CBVCT communities
- 7,636 in SVCT communities

50,000 individuals when repeat tests are excluded

140,755 post-test support visits

Sweat et al, Lancet ID, 2011
The goal was to affect the entire community and not just a study cohort.

Outcomes evaluated at the end of the intervention among a probability sample of 54,326 community residents 18 to 32 years of age.

Incident rates were estimated using a multi-assay algorithm.

Primary outcome: HIV incidence, evaluated at the community level

An almost 4-fold increase in the detection of previously undiagnosed HIV cases.

Increase in HIV testing by 45% among men and 15% among women.

Number of sexual partners reported by HIV-infected individuals significantly lower by 8% 95% CI: 1% - 15%, p = 0.03.

Number of sexual partners among HIV-infected men significantly lower by 18% 95% CI: 5% to 28%, p = 0.009.

Multiple sexual partners significantly lower by 30% 95% CI: 0.54 – 0.92, p = 0.01.

Multiple sexual partners among HIV-infected men significantly lower by 29% 95% CI: 0.57 to 0.89, p = 0.0006.

Sweat et al, Lancet ID, 2011
HPTN 071: PopART
Population Effects of ART to Reduce HIV Transmission

HPTN 071 (PopART) Hypothesis

Integrated strategy of

• Universal voluntary HIV testing

• Appropriate combination prevention offered to all those testing HIV negative

• Immediate ART for all those testing HIV positive

will have a substantial impact on HIV incidence at population level
• 12 communities in Zambia

• 9 communities in the Western Cape of South Africa

• Total study population 1.2 million persons

Primary Objective

– To measure the impact of the PopART intervention in reducing HIV incidence

– HIV incidence to be measured in a cohort of 52,500 adults over 3 years
HPTN 071: PopART Study Randomization Ceremony

Delft South (Metro District)
As of 2010, 3.9 million youth aged 15-24 in Sub-Saharan Africa were living with HIV. How many of those youth were women?

A. One Quarter
B. Two Quarters
C. Three Quarters
3.9 million young people in Sub-Saharan Africa aged 15 – 24 years are living with HIV. Three-quarters are young women.

HPTN 068:
Effects Of Cash Transfer For The Prevention Of HIV In Young South African Women
HPTN 068 Study Design

- A Phase III individually randomized design
- A total of 2,536 young women enrolled
- Structural Intervention Arm
  - Young woman and her parents receive monthly cash transfer payments conditional on the young woman’s school attendance (must be ≥ 80% of in-session days)
- Control Arm
  - No payments given to the participant

Main Study Question

Does providing cash transfers to young women and their household, conditional on school attendance, reduce structural barriers to education and thereby reduce young women’s risk of acquiring HIV?
HPTN 065 was designed to evaluate the feasibility of an enhanced Test, Link to Care, Plus Treat approach for HIV prevention in the United States.

- Study was not designed to evaluate changes in HIV acquisition rates.
- Study is using laboratory data reported through existing surveillance systems. People did not need to enroll in linkage-to-care or viral suppression portions of the study; individual level data was not collected from community members.
HPTN 065 Intervention Communities

- Washington, DC and Bronx, NY
  - Both communities already had well developed HIV testing and linkage-to-care programs
  - Hospitals agreed to participate in expanded HIV testing portion of study
  - All other activities carried out in existing community testing and treatment locations, not in research centers
- Required intensive engagement by those providers and fostered close communication with community organizations

HPTN 065 Non-Intervention Communities

- Chicago, IL
- Houston, TX
- Miami, FL
- Philadelphia, PA

No intervention related to this study took place in these communities; data about the epidemic was gathered from current epidemiology systems to be used in developing the data analysis for the study.
HIV Testing and Linkage-to-Care (L2C)

18 HIV Testing Sites in the Bronx, and 19 in DC, were randomized into either a Financial Incentive (FI) Test Site group or a Standard of Care (SOC) Test Site group.

FI Test Sites gave Linkage to Care coupons to anyone who received a new HIV+ test result, or who was reconfirmed to be HIV+ but out of care for at least one year.

- **Financial Incentives**
  - Linkage to Care

- **Standard Of Care**
  - Linkage to Care

Traded 1st half of coupon for $25 gift card for getting lab work done (CD4 and VL) within three months of referral.

Traded 2nd half of coupon for $100 gift card for returning within three months of referral to review lab results and develop an HIV care plan.

HIV Viral Suppression (VS)

20 HIV Care Sites in the Bronx, and 19 in DC, were randomized into either a Viral Suppression (VS) Financial Incentive Care Site group or a Standard of Care (SOC) Care Site group.

To receive $70 VS gift cards, patients at Viral Suppression Care Sites needed to be eligible for the program and then qualify for each gift card.

- **Financial Incentives**
  - Viral Suppression

- **Standard Of Care**
  - Viral Suppression

- **Viral Suppression Financial Incentives**

- **Viral Suppression Standard Of Care**

To qualify, patients were eligible if they were an established patient and they were on ART.

Patients qualified for a gift card if they had a suppressed viral load (<400 copies/mL) and had not earned a gift card in the last 3 months.
HPTN 065 (TLC Plus) Study Design

**HIV Testing & Linkage to Care**
- Expanded HIV Testing
  - Social Mobilization
  - Universal offer of testing in ED/hospital admission
- HIV Testing Sites
  - 37 Randomized HIV Test Sites to link HIV positives
  - Financial incentive plus SOC
  - Standard of care (SOC)

**HIV Treatment**
- Initiate ART per guidelines
- 39 Randomized HIV Care Sites
  - Financial incentive plus SOC
  - Standard of care (SOC)

**Prevention for Positives**
- Select HIV Care Sites
  - Individual randomization of 660 patients in each community (1,230 total)
  - CARE plus Standard of Care
  - Standard of Care

HPTN 065: Timeline

- Expanded HIV Testing
- Social Mobilization
- Linkage-to-Care & Viral Suppression
- Prevention for Positives

* Provider Surveys
* Patient Surveys (part of PfP)
Looking Forward

HPTN researchers continue to develop new and innovative studies for women and men, all geared to reducing the incidence of new HIV infections around the world.

For updates on current and new studies, or to find information about findings from completed studies, subscribe to the HPTN newsletter, check the HPTN.org website, or follow HPTN on Facebook or Twitter at HIVptn.

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Questions or Comments?
Georgette King, MPA
HPTN Senior Community Engagement Officer
• 919-544-7040 ext 11448
• gking@FHI360.org

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