HPTN 065
TLC-Plus
Study Update

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June 6, 2011
ART for Prevention

- Annual testing by all >15 year old individuals
- All HIV+ individuals started on ART immediately
- 99% decrease in infectiousness
- High adherence with ART
- Low failure with first line ART

- 95% reduction in new HIV cases in 10 years
- HIV Incidence reduced from 15-20,000 to 1000 per million
- Prevalence decreases to less than 1% by 2050

Granich et al Lancet 2009; 373:48-57
Granich et al, Lancet 2009
Test and Treat

Test

Adoption of safer behaviors by HIV+ persons

Treat with ART

+ Adherence

Maintain viral suppression

Decrease in HIV Transmission
HPTN 065: TLC-Plus Study

Test

HIV Positive

Adopt safer behaviors

Positive Prevention

Linkage to care sites

Enroll in Care

Initiation of ART

Treat

Adherence to ART

Maintain viral suppression

Decrease in HIV Transmission
<table>
<thead>
<tr>
<th>Study Component</th>
<th>Design</th>
<th>Outcomes</th>
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<tbody>
<tr>
<td>Expanded HIV Testing</td>
<td>Descriptive, ecologic study</td>
<td>Feasibility</td>
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<td>Linkage-to-Care</td>
<td>Two-arm, site-randomized, prospective</td>
<td>Feasibility and effectiveness</td>
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<td>Viral Suppression</td>
<td>Two-arm, site-randomized, prospective</td>
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<td>Prevention for Positives</td>
<td>Two-arm, individual-randomized, prospective</td>
<td>Effectiveness</td>
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<td>Patient and Provider Surveys</td>
<td>Quantitative survey</td>
<td>Knowledge, attitudes, practices</td>
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# HPTN 065: Timeline

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<td>Expansion of HIV testing in hospitals</td>
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<td>Linkage to Care</td>
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<td>PfP and Patient Survey*</td>
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* Anticipated to Begin in October 2011
HPTN 065: Social Mobilization Campaign

- Social mobilization campaign targeting MSM
  - Began November 19, 2010 in Washington, DC
  - Began April 1, 2011 in the Bronx
HPTN 065: DC Campaign

- Web-based Ads
  - Facebook.com
  - Manhunt.com
  - Blacklabelads.com
  Ad on Adam4Adam had 10 million impressions and 4,055 clicks

- Print Ads
  - Washington Informer
  - DC Agenda

- Metro Ads
  - Posters and exterior bus ads

- Radio Ads
HPTN 065: Bronx Campaign

- Web-based Ads
  - Blabbeando (Latino LGBT blog)
  - Manhunt.com
  - Google ads (local targeting of key search terms)

- Print Ads
  - Next Magazine
  - Posters distributed by NYC DOHMH
HPTN 065: Universal HIV Testing in EDs and In-patient Admissions

- 16 hospitals are participating in the study
  - Bronx: 9 hospitals
  - Washington, DC: 7 hospitals

- All hospitals are being asked to expand testing in the Emergency Department and in-patient admissions

- 7 of the 16 hospitals are now submitting study data
  - The study team is working with the remaining 9 sites to ensure study data reporting requirements are met
TLC-Plus Team efforts thus far

- Bronx: Introductory phone calls with investigators and hospital coordinators in February with regular status-reports from sites
- D.C. Introductory meeting with investigators and hospital coordinators/staff in February, follow-up phone calls, review each site’s monthly HIV testing data from ED and IP since February
- Database with hospital-based HIV testing data being built at SCHARP.
37 HIV Test Sites were randomized as part of the L2C component
- Bronx: 18 test sites
- Washington, DC: 19 test sites

Study-specific training was conducted in March 2011 at all HIV Test Sites randomized to the FI arm of the study

All HIV Test Sites (except one) were activated for the L2C component at the beginning of April 2011
- The remaining site is working on operational logistics and will be activated shortly
<table>
<thead>
<tr>
<th>Location</th>
<th>No. of Coupons Dispensed</th>
<th>Percentage of Sites Who Have Dispensed a Coupon</th>
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<tbody>
<tr>
<td>Washington, DC</td>
<td>25</td>
<td>70%</td>
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<tr>
<td>Bronx, NY</td>
<td>10</td>
<td>55%</td>
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</table>
HPTN 065: Viral Suppression (VS)

- 39 HIV Care Sites were randomized as part of the VS component
  - Bronx: 20 care sites
  - Washington, DC: 19 care sites

- Study-specific training was conducted between January and March at all HIV Care Sites

- All HIV Care Sites were activated for the VS component between February 1 and April 14, 2011
### HPTN 065: Viral Suppression (VS)

<table>
<thead>
<tr>
<th>Location</th>
<th>No. of $70 Gift Cards Dispensed</th>
<th>Percentage of Sites Who Have Dispensed a $70 Gift Card</th>
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<tbody>
<tr>
<td>Washington, DC</td>
<td>477</td>
<td>89%</td>
</tr>
<tr>
<td>Bronx, NY</td>
<td>196</td>
<td>70%</td>
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</tbody>
</table>

- Note: Half of the DC FI Care Sites began on February 1, 2011, while the majority of the Bronx FI Care Sites began after April 1, 2011
HIV Surveillance

**Measures of HIV morbidity and mortality**

- HIV Infection
  - HIV diagnosis (1st positive confidential test)
  - 1st CD4 Count Test
  - 1st Viral Load Test
  - 1st Drug Resistance test
  - 1st CD4 Count <200 (IMM-AIDS)

- AIDS-OI
  - Death

- Entry to care
- Retention in care and viral load

**HIV Prevention Trials Network**
Surveillance Data
Key data elements

Study intervention outcome measures

• CD4 result
• CD4 date
• VL result
• VL date
• Name of facility of diagnosis
• Name of treatment facility (lab order)
• Type of HIV test
• HIV test date
• HIV test result
• HIV diagnosis date
• AIDS diagnosis date

Stratification, adjustment, and other outcomes

◆ Date of birth (DOB)
◆ Race/ethnicity
◆ Transmission category
◆ Sex at birth
◆ Date of death
◆ Cause of death
◆ Previous negative test, lab based
◆ Previous negative test, self-reported
◆ Place of residence at diagnosis
◆ Current place of residence
HIV Surveillance Information Flow
HPTN 065 TLC-Plus

Sources of Reports
- Hospital Practitioners
- Private Practitioners
- Public Clinics
- Laboratories

Local and/or State Health Department

CDC

SCHARP
- Aggregate surveillance data
- Also receives:
  - Aggregate testing data
  - Aggregate behavioral data

Active Case Finding

People with HIV
Example: Linkage to care of persons newly diagnosed with HIV within 3, 6, and 12 months

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Residents diagnosed in jurisdiction</th>
<th>Non-Residents Diagnosed in Jurisdiction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Y1, Q1</td>
<td>Y1, Q1</td>
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<tr>
<td></td>
<td>Y1, Q2</td>
<td>Y1, Q2</td>
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<tr>
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<td>Y1, Q3</td>
<td>Y1, Q3</td>
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<tr>
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<td>Y1, Q4</td>
<td>Y1, Q4</td>
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</tbody>
</table>

- **Number of diagnosed cases**
- **Number of cases alive at 3 months after diagnosis**
- **Number of cases alive at 6 months after diagnosis**
- **Number of cases alive at 12 months after diagnosis**
- **No known linkage within 12 months**
- **First VL/CD4 within 3 months**
- **First VL/CD4 4-6 months**
- **First VL/CD4 7-12 months**
HPTN 065: Provider Surveys

- Overview of the Provider Surveys:
  - Administered twice during the study - at baseline & after completion of VS component
  - Collects information including:
    - ART knowledge, attitudes, and use
    - Use of FI for L2C and VS

- Baseline Provider Survey Update
  - Data was collected between September 2010 and May 2011
  - Rates of participation
    - Washington, DC response rate: 80/111 (72%)
    - Bronx response rate: 94/177 (53%)
    - Overall: 174/288 (60%)
Site and DOH Surveys

- Annual HIV test site and HIV care site surveys at each participating sites:
  - Bronx: 18 test sites, 20 care sites
  - DC: 19 test sites, 19 care sites

- Annual Department of Health (DOH) survey in both intervention and non-intervention cities: 6 DOHs (NYC, Washington DC, Chicago, Miami, Houston, Philadelphia)

- Data collection starting with year 2009 and thereafter.
**Patient Characteristics**

**Question #16**

Questions 7-22 summarize characteristics for all HIV care patients 13 years and older at your facility.

Please complete the table below with the requested information on the gender breakdown of HIV-positive patients in care at your site, down to the level of detail that is collected at your site. If data in a certain category or section are not available, please leave blank:

<table>
<thead>
<tr>
<th>Gender</th>
<th>Total number of HIV+ patients in care</th>
<th>Total number of HIV+ patients currently on ART in care</th>
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<tbody>
<tr>
<td>Male</td>
<td>611</td>
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</tr>
<tr>
<td>Female</td>
<td>457</td>
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<td>Transgendered or Transexual</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>1094</strong></td>
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**Remember:** You previously entered that there were **1094** HIV-positive patients under HIV primary medical or physician’s care and **765** HIV-positive patients under primary medical or physician’s care who are currently on ART.
HPTN 065: Prevention for Positives (PfP)

- Computer-based intervention to assess and change risk behavior
- 1320 patients will be recruited from 12 HIV Care Sites
- All 12 PfP sites have been identified- 6 sites in DC and 6 sites in the Bronx)
- Anticipated to start this component in Sept/Oct 2011
HPTN 065: Patient Surveys

- **Purpose of the Patient Surveys:**
  - Administered twice during the study - at before & after completion of PfP component
  - Collects information including:
    - ART knowledge, attitudes, and use
    - Use of FI for L2C and VS

- Patient surveys are incorporated into the PfP component

- Baseline patient surveys anticipated to start in September/October 2011
Community Engagement

- Establishment of Community Advisory Group
- Broad representation
- Unique issues relevant to communities
- Participation in community fora and communication groups
- Presentations at various community settings
Unique Features of HPTN 065 TLC-Plus

- Partnerships
  - Between NIH and CDC
  - Across NIH institutes
  - With departments of health in major cities
- Community and program sites (rather than research site) focus
- Combination of feasibility and effectiveness outcomes
- Use of routine HIV surveillance data for key outcomes
- Bring together large number of stakeholders
Acknowledgements

- HPTN 065 protocol team
- NYC and Washington, DC Departments of Health
- Houston, Philadelphia, Chicago, and Miami Departments of Health
- All participating sites
- Community advisors and CAB members

CDC
NIH