HPTN 064
HIV Seroincidence Study in Women

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On behalf of the HPTN 064 Study Team
Presentation Overview

- Epidemiology of HIV in US Women
- ISIS Rationale
- ISIS Methodology
- Preliminary Results
- Conclusions
Diagnoses of HIV Infection and Population among Adult and Adolescent Females, by Race/Ethnicity, 2008—37 States

Diagnoses of HIV Infection
N=10,332

- 1% American Indian/Alaska Native
- <1% Asian
- <1% Black/African American
- 13% Hispanic/Latino
- 67% White
- Multiple races

Female Population, 37 States
N=89,735,021

- 3% American Indian/Alaska Native
- 1% Asian
- 1% Black/African American
- 11% Hispanic/Latino
- 14% White
- 70% Multiple races

Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. Data from 37 states with confidential name-based HIV infection reporting since at least January 2005. All displayed data have been estimated. Estimated numbers resulted from statistical adjustment that accounted for reporting delays, but not for incomplete reporting.
*Hispanics/Latinos can be of any race.
Death Rates for Females Diagnosed with HIV, by Race/Ethnicity: 2007—37 States

Rationale for ISIS

• Scant data exist on HIV incidence in US women, impeding ability to design robust HIV prevention trials
• Need to identify women in the US who are at risk for HIV acquisition
  – Seroincidence rates in past studies ~1% per year
  – Novel recruitment strategies needed
• Need for improved assays/algorithms for accurate identification of incident HIV infections in cross-sectional studies
Study Design

• Prospective and retrospective observational cohort study with 6-12 months follow-up
• HIV testing
• Quantitative behavioral data (ACASI)
  – Condom use, concurrency, substance use, mental health, financial security, etc.
• Qualitative data in 4 of 10 communities
  – Semi-structured interview (women)
  – Focus groups (men and women)
Inclusion Criteria for Women

- Self identifies as a woman
- Women ages 18-44 years at screening
- Residence in High Risk Area (HRA)
- Unprotected sex with a man during the previous 6 months
- AND at least one additional risk factor
Inclusion Criteria for Women

- At least ONE of the following:
  - **Individual Risks**
    - Illicit drug use (injecting and non-injecting)
    - ETOH dependence and/or binge drinking
    - Incarceration – within past 5 years
    - STI (GC, Chlamydia, Trichomoniasis, Syphilis)
    - Exchange of sex for commodities
  
  - **Partner Risks**
    - Illicit drug use (injecting and non-injecting)
    - ETOH and/or dependence or binge drinking
    - Incarceration – within past 5 years
    - STIs
    - HIV diagnosis
Primary Endpoint

• Estimate the overall HIV-1 incidence rate among enrolled women from specific geographic areas

• Three components comprise HIV Incidence
  Recent infections + seroconversions + acute infections at last visit

Key:
- X = enrollment visit
- Red = follow-up visit
- Green dotted line = retrospective
- Blue line = prospective
Qualitative Component

• 4 of 10 sites (Bronx, NYC; Washington, DC; Dekalb County, GA; Wake County, NC)

• ISIS Participants
  – 120 interviews with women across 4 sites (30 per site)
  – 32 focus groups with women

• Men recruited from ISIS communities
  – 31 focus groups
## Qualitative Topics

<table>
<thead>
<tr>
<th>Interviews and Focus Groups with Women</th>
<th>Focus Groups with Men</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Focus:</strong> Social, Structural and Contextual Factors</td>
<td><strong>Focus:</strong> Barriers and Facilitators to HIV Testing</td>
</tr>
<tr>
<td><strong>Key Domains Explored:</strong></td>
<td><strong>Key Domains Explored:</strong></td>
</tr>
<tr>
<td>• Environment, inc. safety</td>
<td>• Knowledge and experiences with HIV testing</td>
</tr>
<tr>
<td>• Social support</td>
<td>• Facilitators and barriers to HIV testing</td>
</tr>
<tr>
<td>• Children</td>
<td>• Attitudes around condom use</td>
</tr>
<tr>
<td>• Financial characteristics</td>
<td>• Perceptions of HIV/AIDS and STIs</td>
</tr>
<tr>
<td>• STIs</td>
<td>• Access to care (HIV)</td>
</tr>
<tr>
<td>• Perceptions of risk</td>
<td></td>
</tr>
<tr>
<td>• Condom use</td>
<td></td>
</tr>
<tr>
<td>• Concurrency</td>
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</tbody>
</table>
Study Sites

10 distinct communities within 6 geographic locations
Recruitment

- Venue-based sampling in locations frequented by women who live in study census tracts/zip codes
- Suitable venues and recruitment times determined by ethnography
Community Engagement

- Community participation has been robust at all stages of development and implementation:
  - Community representatives on protocol team
  - Community consultation
  - Active presence at community events and in day to day activities
  - Identification of key stakeholders (civic leadership, NGO leadership, etc.)
  - Community contacts/advocates
  - Ongoing community feedback via CABs and CWGs
Rapid Recruitment and Strong Retention

- 2,098 women enrolled in 14 months
- 93% retention/6 month follow-up
- 94% retention/12 month follow-up
# ISIS Female Cohort Demographics

<table>
<thead>
<tr>
<th>RACE</th>
<th>Cohort (n=2098)</th>
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<tbody>
<tr>
<td>Black or African American</td>
<td>1850 (88%)</td>
</tr>
<tr>
<td>White</td>
<td>163 (8%)</td>
</tr>
<tr>
<td>ETHNICITY</td>
<td></td>
</tr>
<tr>
<td>Latina or Hispanic Origin</td>
<td>245 (12%)</td>
</tr>
<tr>
<td>Age (Median)</td>
<td>29 years</td>
</tr>
</tbody>
</table>
High Levels of Poverty

<table>
<thead>
<tr>
<th>Total household income pre-tax</th>
<th>Cohort (n=2098)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10K or less</td>
<td>932 (44%)</td>
</tr>
<tr>
<td>10,001-20K</td>
<td>225 (11%)</td>
</tr>
<tr>
<td>20,001-40K</td>
<td>144 (7%)</td>
</tr>
<tr>
<td>40,001-60K</td>
<td>36 (2%)</td>
</tr>
<tr>
<td>&gt;60K</td>
<td>17 (&lt;2%)</td>
</tr>
<tr>
<td>Refused</td>
<td>98 (5%)</td>
</tr>
<tr>
<td>Don’t know</td>
<td>616 (29%)</td>
</tr>
<tr>
<td>Concerned about having enough food for self/family in last 6 months</td>
<td>970 (46%)</td>
</tr>
</tbody>
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## Low Formal Education Levels

<table>
<thead>
<tr>
<th>Education</th>
<th>Cohort (n=2098)</th>
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<tbody>
<tr>
<td>Less than high school</td>
<td>776 (37%)</td>
</tr>
<tr>
<td>High school graduate</td>
<td>772 (37%)</td>
</tr>
<tr>
<td>Some college</td>
<td>410 (20%)</td>
</tr>
<tr>
<td>Finished college</td>
<td>35 (2%)</td>
</tr>
</tbody>
</table>
## High Rates of Substance Use at Baseline

<table>
<thead>
<tr>
<th>Substance</th>
<th>Ever Used % (n=2058)</th>
<th>In last 6 months % (of ever used)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Daily</td>
</tr>
<tr>
<td>Alcohol</td>
<td>84</td>
<td>23</td>
</tr>
<tr>
<td>Cannabis</td>
<td>67</td>
<td>31</td>
</tr>
<tr>
<td>Cocaine</td>
<td>34</td>
<td>23</td>
</tr>
<tr>
<td>Amphetamine type stimulants</td>
<td>19</td>
<td>4</td>
</tr>
<tr>
<td>Sedatives/Sleeping Pills</td>
<td>14</td>
<td>14</td>
</tr>
<tr>
<td>Opioids</td>
<td>21</td>
<td>43</td>
</tr>
</tbody>
</table>
Alcohol Use at Study Entry (Baseline)
n= 1753 (84%)

# of drinks containing alcohol on a typical day

- 1 or 2: 40%
- 3 or 4: 27%
- 5 or 6: 19%
- 7 or more: 13%

Frequency of Binge Drinking (4+ drinks)

- Never/ < Monthly: 52%
- Monthly: 18%
- 2 to 3 times/week: 10%
- 4+ times/week: 19%
Conclusions

• It is feasible to recruit a population of low income women living in high HIV prevalence areas

• Retention was excellent
  – Suggests effective community engagement

• Women in the ISIS cohort have high rates of alcohol and substance use

• Analyses are ongoing
  – Primary endpoint anticipated September 2011
Acknowledgements

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