Engaging a Hidden Population to Stop HIV

HPTN 078

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Study Rationale

- In the US, MSM remain the most affected by HIV
  - 67% of new HIV diagnoses are MSM (2014)

- US MSM have low rates of viral suppression
  - 34% in White MSM, 16% in Black MSM
• MSM who are HIV+ and virally unsuppressed serve as the reservoir for HIV and drive the epidemic
• If every one became virally suppressed, HIV transmission would stop

Study Rationale

HIV-

HIV+, unsuppressed
(detectable, infectious)

HIV+, suppressed
(undetectable, non-infectious)
Study Rationale

Who makes up the HIV reservoir?

HIV+, Virally Unsuppressed

- HIV+ Unaware Of Status
- HIV+ Aware, Not In Care
- HIV+ Aware, In Care, Not Suppressed
Study Rationale

Who makes up the HIV reservoir?

HIV+, Virally Unsuppressed

EASY TO FIND

HIV+ Aware, In Care, Not Suppressed
Study Rationale

Who makes up the HIV reservoir?

HIV+, Virally Unsuppressed

HIV+ Unaware Of Status

HIV+ Aware, Not In Care

HARD TO FIND (HIDDEN POPULATION)
Study Rationale

HPTN 078 tests two critical ideas

• How can we find MSM who are HIV+ and unsuppressed (detectable and infectious)

• When we find them, how can we help these MSM become suppressed (undetectable and non-infectious)
HPTN 078: Enhancing Recruitment, Linkage to Care and Treatment for HIV-Infected Men Who Have Sex with Men (MSM) in the United States

<table>
<thead>
<tr>
<th>Screened population</th>
<th>Enrolled participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>2700</td>
<td>356</td>
</tr>
<tr>
<td>MSM &gt;= 16 yo</td>
<td>MSM HIV+, Unsuppressed</td>
</tr>
</tbody>
</table>

Study Duration: 24 M Follow-up

Deep-Chain Respondent Driven Sampling (DC-RDS)

Individual Randomization

Case Manager Intervention Package

SOC for Linkage and Treatment
Deep-Chain Respondent Driven Sampling (DC-RDS)

Looking for a hidden population

Hope to find it after 6th wave

MSM, HIV+ Unsuppressed

Example Coupons

TURN IT!
Call or text (443) 310-6738 for more information or to schedule an appointment (days, nights or weekends)

Golden Ticket
You have just received a Golden Ticket
Ticket Expires: __________

We have an IDEA...

Contact Us Now:
(857) 206-5178 call or text
(617) 927-6440 call only
### Deep-Chain Respondent Driven Sampling (DC-RDS)

<table>
<thead>
<tr>
<th>Seed</th>
<th>Wave 1</th>
<th>Wave 2</th>
<th>Wave 3</th>
<th>Wave 4</th>
<th>Wave 5</th>
</tr>
</thead>
</table>

![Network Diagram](image-url)
In DC-RDS, things get interesting past wave 6.
Case Manager (CM) Intervention

Site Standard-of-Care for Linkage and Treatment

CM Intervention

24 months

Control

I need help.

How much?

MSM+

Offer:

- Face-to-face meetings
- Linkage assistance
- ART adherence counseling
- Appropriate referrals

The CM intervention includes patient choice, motivational interviewing and automated phone/email/text messages
Study Objectives

• Assess the ability of DC-RDS to identify and recruit HIV-infected MSM in the US who are unsuppressed.

• Compare the efficacy of the two study arms (CM intervention vs. SOC control) in achieving durable viral suppression 24 months after enrollment.
Clinical Research Sites

Sites

- Alabama CRS (Birmingham, AL)
- Fenway Health CRS (Boston, MA)
- Johns Hopkins University CRS (Baltimore, MD)
- Ponce de Leon Center CRS (Atlanta, GA)
Current Study Status

• DC-RDS is working – all sites have recruitment trees that have reached waves 10 - 12

• In order to fully enroll, we have added direct recruitment activities in parallel to DC-RDS
  – Clinic/hospital referrals
  – Support group referrals
  – Alliances with testing programs
  – Study advertisements (flyers, social media posts)
  – Limited venue-based recruitment
## Current Study Status

<table>
<thead>
<tr>
<th></th>
<th>S1 DC-RDS Visits</th>
<th>S1 Direct Recruitment Visits</th>
<th>Total Screened</th>
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<tbody>
<tr>
<td>Fenway</td>
<td>156</td>
<td>17</td>
<td>173</td>
</tr>
<tr>
<td>JHU</td>
<td>108</td>
<td>40</td>
<td>148</td>
</tr>
<tr>
<td>Ponce</td>
<td>78</td>
<td>52</td>
<td>130</td>
</tr>
<tr>
<td>Alabama</td>
<td>103</td>
<td>61</td>
<td>164</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>445 (72%)</strong></td>
<td><strong>170 (28%)</strong></td>
<td><strong>615</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Enrolled via DC-RDS</th>
<th>Enrolled via Direct Recruitment</th>
<th>Total Enrolled</th>
<th>Randomized to CM Arm</th>
<th>Randomized to SOC Arm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fenway</td>
<td>12</td>
<td>5</td>
<td>17</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>JHU</td>
<td>7</td>
<td>3</td>
<td>10</td>
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<td>5</td>
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<tr>
<td>Ponce</td>
<td>21</td>
<td>6</td>
<td>27</td>
<td>14</td>
<td>13</td>
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<tr>
<td>Alabama</td>
<td>2</td>
<td>8</td>
<td>10</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>42 (66%)</strong></td>
<td><strong>22 (34%)</strong></td>
<td><strong>64</strong></td>
<td><strong>33</strong></td>
<td><strong>31</strong></td>
</tr>
</tbody>
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Community Engagement

- DC-RDS did not require special community engagement

- Direct recruitment does – sites have worked to form alliances for referrals and are starting to conduct venue-based activities.
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Question and Answer Session