The Feasibility of HIV Prevention Cohort Studies among Men Who Have Sex with Men in sub-Saharan Africa

HPTN 075

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HPTN 075: Main Aim

To determine the feasibility of recruiting and retaining men who have sex with men (MSM) in a multi-country prospective cohort study in preparation for HIV prevention studies in sub-Saharan Africa (SSA) to inform feasibility, power calculations and sample size calculations for future HIV prevention studies.
Penalties targeting gays and lesbians in Africa

- Death penalty
- Imprisonment from 11 years to a lifelong sentence
- Imprisonment from 1 month to 10 years
- Imprisonment, no precise indication of length

Countries that recognize gay and lesbian rights
- Recognition of same-sex marriage
- Unclear/no data

*Only parts of Nigeria and Somalia carry out the death penalty.*
Introduction

• Same-sex sexuality is criminalized in most African countries and socially not accepted
• HIV transmission among African MSM has been overlooked for a long time
• Studies have now shown that among MSM HIV prevalence is disproportionally high
• Although there are some open cohort studies, not clear whether cohorts can be maintained
Primary Endpoints HPTN 075

• Recruitment rate within a 6-month period, overall and by site
• Cumulative retention rate, measured by the percent of participants who remain in the study at the end of the one-year (Week 52 Visit) follow-up period, overall and by site
Study Sites

- KEMRI/CDC, Kisumu, Kenya
- Blantyre CRS, Blantyre, Malawi
- Groote Schuur HIV CRS (Desmond Tutu HIV), Cape Town, South Africa
- Soweto HPTN CRS, Soweto, South Africa
Community Preparation and Risk Mitigation Plans

- Preparation for study implementation
  - Establishing relationships
  - MSM community buy-in
  - Development recruitment strategies
- Creating broader community support for study (CABs and beyond)
- Preparing for mitigation of potential problems that study participants might encounter
Eligibility Criteria

• Biologically male at birth, according to self-report
• 18-44 years old
• Having engaged in anal intercourse in the previous 3 months (12 weeks) with a man
• Willing to undergo HIV testing throughout the study and to receive test results
• And additional ones

• Positive HIV status not an exclusion criteria, but participation was capped
Recruitment

• Strategies varied per site, based on:
  – Input CAB and MSM community informants
  – Earlier experiences

• Common factor:
  – Informal networks
Accrual Overview

Target: 100 Per Site

<table>
<thead>
<tr>
<th>Site</th>
<th># weeks</th>
<th>Average per week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 1</td>
<td>18.7</td>
<td>5.3</td>
</tr>
<tr>
<td>Site 2</td>
<td>33.6</td>
<td>3.0</td>
</tr>
<tr>
<td>Site 3</td>
<td>33.1</td>
<td>3.0</td>
</tr>
<tr>
<td>Site 4</td>
<td>39.1</td>
<td>2.6</td>
</tr>
</tbody>
</table>
### Screening, Enrollment, Study Completion

<table>
<thead>
<tr>
<th>Category</th>
<th>Count/Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screened</td>
<td>624</td>
</tr>
<tr>
<td>Ineligible</td>
<td>223/624 = 35.7%</td>
</tr>
<tr>
<td>Enrolled</td>
<td>401/624 = 64.3%</td>
</tr>
<tr>
<td>Deaths</td>
<td>5/401 = 1.2%</td>
</tr>
<tr>
<td>Completed final visit (5)</td>
<td>368/396 = 92.9%</td>
</tr>
<tr>
<td>Missed visits (2, 3 and/or 4)</td>
<td>36*/1155 = 3.1%</td>
</tr>
</tbody>
</table>

* Consecutively missed visits of men who did not complete Visit 5 are excluded.
Study Participation Flow

- Screened, N = 624
  - Ineligible: n = 223
  - Visit 1
    - Eligible and enrolled: n = 401
    - Visit 2
      - Participated: n = 381
        - Missed: n = 9
        - Did not return: n = 8
        - Deceased: n = 3
      - Visit 3
        - Participated: n = 370
          - Missed: n = 15
          - Did not return: n = 5
          - Deceased: n = 2
        - Visit 4
          - Participated: n = 368
            - Missed: n = 12
            - Did not return: n = 12
      - Visit 5
        - Participated: n = 368
        - Did not return: n = 3
        - Deceased: n = 12
## Reasons* Early Terminations (N = 28)

<table>
<thead>
<tr>
<th>Reason</th>
<th>% (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unable to adhere to schedule (including because of relocation)</td>
<td>46.4 (13)</td>
</tr>
<tr>
<td>Unable to contact</td>
<td>32.1 (9)</td>
</tr>
<tr>
<td>Refused further participation</td>
<td>17.9 (5)</td>
</tr>
<tr>
<td>Incarcerated</td>
<td>3.6 (1)</td>
</tr>
</tbody>
</table>

* Reasons overlap: 13 men (46.4%) who had relocated (nationally and internationally) could not be contacted, could not adhere to schedule, or refused further participation.
<table>
<thead>
<tr>
<th>Percentage</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>33.5%</td>
<td>Receiving HIV counselling and testing; knowing one’s status</td>
</tr>
<tr>
<td>30.9%</td>
<td>Receiving HIV risk reduction education</td>
</tr>
<tr>
<td>20.5%</td>
<td>Knowing more about MSM as a community; meeting new people, gaining support from other MSM or being empowered as MSM</td>
</tr>
<tr>
<td>16.4%</td>
<td>Learning more about one’s own health: getting tested for other things than HIV, getting free check-ups and receiving treatment</td>
</tr>
<tr>
<td>14.8%</td>
<td>Improving one’s general knowledge of health, beyond HIV and STI</td>
</tr>
<tr>
<td>10.5%</td>
<td>Learning about MSM research or contributing to MSM research</td>
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</table>
HIV Prevalence Based on Screening

- HIV prevalence: 30.4% (183/601)
- Newly diagnosed: 43.7% (80/183)
Independent Risk Factors for HIV Infection at Screening

- Older age
- Identifying as female/transgender (versus male)
- Last HIV test less recent
- Study site
HIV Care Continuum for HIV-infected Persons Screened for Participation in HPTN 075

![Graph showing the HIV Care Continuum](chart.png)
Independent Correlates of Newly-diagnosed HIV Infection at Screening

- Younger age
- Last HIV test less recent
- Study site
Transgender Women (TGW)

20.1% (79/395)

More likely to:
- Be only attracted to men
- Have experienced child sexual abuse
- Have engaged in transactional sex
- Have experienced forced sex
- Have experienced homophobic discrimination
- Prefer and only have had receptive anal sex
- Test HIV positive
Men/TGW Who Had Sex with Men and Women in Preceding 3 Months

21.7% (84/387)

More likely to:
- Be older and be married
- Have children
- Identify as bisexual
- Identify as male (versus female or transgender)
- Prefer insertive anal sex (versus receptive)
- Have less lifetime sexual partners and more recent sexual partners
Summary

• Recruitment and retention of MSM and TGW in sub-Saharan Africa is feasible
• Few social harms. Little impact, could have been prevented. All successfully addressed. No social harms on community level
• Development risk-mitigation plans: meaningful exercise
• High HIV prevalence (30.4%)
• African MSM & TGW constitute a diverse population
Next Steps

• Implementing and intensifying HIV prevention addressing MSM and TGW
• PrEP trials?
• Mental health promotion?
• Network intervention and community mobilization?
HPTN 075 Protocol Team

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