HIV PREVENTION RESEARCH UNIT

SINDAWONYE
Clinical Trials Unit
(we are together)

GI TA RAMJE
MTN Regional Meeting, Cape Town, South Africa
21-24 May 2007
CHATSWORTH CRS

- approximately 19 miles south of the main Westville CTU office

- Chatsworth is an urban area with about 20 informal (makeshift housing erected on vacant land) and 15 formal settlements

- It has a total population of 500,000 people from primarily the Indian (Asian) and African ethnic groups
HIV Prevalence Among Women Screened and HIV Incidence Cases Among Women Enrolled in the HPTN 055 HIV Prevention Preparedness Study By Neighbourhood Cluster

055 Data

Prevalence % Among Women Screened By Neighbourhood Cluster Assessed

- 40 to 50: (143/319)
- 30 to 40: (9/29)
- 10 to 20: (23/131)
- 0: (0/9)

HIV Incidence Cases
HIV Prevalence Among Women Screened in the HPTN Trial in Eleven Neighbourhood Clusters

Chatsworth
N = 1456

Participants excluded from prevalence calculation:
- Screened out (ineligible): 107
- No locator data: 4
- Outlying data (positives): 25
- Outlying data (negatives): 15

2005 / 2006
HIV Prevalence % Among Women Screened by Neighbourhood Cluster Assessed:
- 30 to 40 (392)
- 20 to 30 (460)
- 10 to 20 (305)
- 0 to 10 (148)
- Areas not targeted
Baseline Demographics of participants enrolled in the HPTN 055: Chatsworth CRS

<table>
<thead>
<tr>
<th>Ethnic Group</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Zulu</td>
<td>43%</td>
</tr>
<tr>
<td>Indian</td>
<td>37%</td>
</tr>
<tr>
<td>Coloured</td>
<td>1%</td>
</tr>
<tr>
<td>White</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Other African ethnic group</td>
<td>19%</td>
</tr>
</tbody>
</table>

| % Married                     | 30%   |
| Mean Age                      | 27.6 yrs |

<table>
<thead>
<tr>
<th>Highest level of education</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No schooling</td>
<td>5%</td>
</tr>
<tr>
<td>Primary (incomplete)</td>
<td>13%</td>
</tr>
<tr>
<td>Primary (complete)</td>
<td>6%</td>
</tr>
<tr>
<td>Secondary (incomplete)</td>
<td>55%</td>
</tr>
<tr>
<td>Secondary (complete)</td>
<td>20%</td>
</tr>
<tr>
<td>Tertiary</td>
<td>2%</td>
</tr>
</tbody>
</table>

| % Employed                   | 21%   |
Baseline Sexual characteristics and sexual behaviour of participants enrolled in the HPTN 055 trial: Chatsworth CRS

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean # of male sexual partners, past 3 months</td>
<td>1.1</td>
</tr>
<tr>
<td>Vaginal sex without condom in past 3 months (%)</td>
<td>83%</td>
</tr>
<tr>
<td>Mean typical # sex acts in past 1 week</td>
<td>2.0</td>
</tr>
</tbody>
</table>
BOTHA’S HILL CRS

- 19 miles northwest of the central unit in Westville, Durban
- Within the 9 mile radius of the research site, there is access to a total population of 462,531, of whom 218,799 (47.3%) are male and 243,732 (52.7%) are female.
HIV Prevalence Among Women Screened in the MIRA Trial in Nine Neighbourhood Clusters

Botha’s Hill
N = 1799

2005 / 2006
HIV Prevalence % Among Women Screened by Neighbourhood Cluster Assessed

- 40 to 50 (774)
- 30 to 40 (826)
- 25 to 30 (0)
- 10 to 20 (0)
- 0 to 10 (0)
- Areas not targeted

Participants excluded from prevalence calculation:
- Screened out (ineligible): 157
- Outlying data (positives): 23
- Outlying data (negatives): 19
HIV Incidence Among Women Enrolled in the MIRA Trial in Nine Neighbourhood Clusters

Botha’s Hill
N = 754

2005 / 2006
HIV Incidence % Among Women Enrolled by Neighbourhood Cluster Assessed

- Areas not targeted
- 20 to 30 (76)
- 10 to 20 (143)
- 0 to 10 (519)

Seroconversions (83)
UMKOMAAS CRS

- Semi rural area
- 40 miles south of Durban
- Formal and informal areas are populated mainly by African, Indian (Asian) and Colored ethnic groups
- Population of 121,448 of whom 56,898 (46.9%) are male and 64,550 (53.1%) are female within a 9 mile radius of the clinic and 349,243 (46.8% male and 53.2% female) within a 15 mile radius
HIV Prevalence Among Women Screened in the MIRA Trial in Eleven Neighbourhood Clusters

Umkomaas
N = 1889

Participants excluded from prevalence calculation:
Screened out (ineligible): 140
No locator data: 4
Outlying data (positives): 25
Outlying data (negatives): 15

2005 / 2006
HIV Prevalence % Among Women Screened by Neighbourhood Cluster Assessed

- 60 to 70 (188)
- 50 to 60 (368)
- 40 to 50 (368)
- 30 to 40 (176)
- 20 to 30 (265)
- 10 to 20 (0)
- 0 to 10 (0)
- Areas not targeted

Map showing distribution of HIV prevalence in Umkomaas.
HIV Incidence Among Women
Enrolled in the MIRA Trial in
Eleven Neighbourhood Clusters

Umkomaas
N = 761

Participants excluded from incidence calculation:
No locator data: 1
Outlying data (enrolled): 15
Outlying data (seroconversions): 1

2005 / 2006
HIV Incidence % Among Women Enrolled by Neighbourhood Cluster Assessed
- 20 to 30 (19)
- 10 to 20 (150)
- 0 to 10 (576)
- Areas not targeted

Seroconversions (70)
Baseline Demographics of participants enrolled in the MIRA trial: Umkomaas and Botha’s Hill CRS

<table>
<thead>
<tr>
<th>Home language spoken (N = 1741)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>English</td>
<td>90</td>
</tr>
<tr>
<td>Zulu</td>
<td>1271</td>
</tr>
<tr>
<td>Xhosa</td>
<td>9</td>
</tr>
<tr>
<td>Multi-lingual</td>
<td>137</td>
</tr>
<tr>
<td>% Married</td>
<td>23.47%</td>
</tr>
<tr>
<td>Mean Age</td>
<td>28.69 yrs</td>
</tr>
<tr>
<td>Mean years of education</td>
<td>9.10 yrs</td>
</tr>
<tr>
<td>% Employed</td>
<td>19.79%</td>
</tr>
</tbody>
</table>
HIV Prevalence and Incidence data from Chatsworth, Botha’s Hill and Umkomaas

<table>
<thead>
<tr>
<th>Clinical Research Site</th>
<th>Chatsworth</th>
<th>Umkomaas</th>
<th>Botha’s Hill</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completion date</td>
<td>Mid 2008</td>
<td>Completed MI RA</td>
<td>Complete MI RA</td>
</tr>
<tr>
<td>HIV Prevalence (%) – Preparedness Study</td>
<td>Preparedness 37 (n=240)</td>
<td>43 (n=761)</td>
<td>43.5 (n=754)</td>
</tr>
<tr>
<td>HIV incidence cases (per 100 women years) – Preparedness Study</td>
<td>5.0/ 100wy</td>
<td>Estimated 6-6-8/ 100wy</td>
<td>Estimated 6-8/ 100wy</td>
</tr>
</tbody>
</table>
MOU Provincial Department of Health

- HIV-related network of care services
- Management of non-trial related events
- Assessment of HIV + participant need for ART
- Enrolment in ARV programme for participants with CD4 <200
- Treatment of opportunistic infections and chest x-rays

MOU (Scaling up ARV)

- 2 sites

MOU Prince Mshiyeni
- Assess HIV + participant need for ART
- Counselling and initiation of ART for participants with CD4 <200
- Treatment of opportunistic infections including chest x-ray
- On-going monitoring of infection
- Regular reporting to MRC on number of women seen and care provided

MOU Osindsweni

MOU Mahatma Gandhi

MOU G J Crooks

MOU Hlabisa

MOU R K Khan

NB: MOU to be set up prior to study initiation
MAXIMIZING RECRUITMENT

Community Entry
- (Community Leaders, local health care providers, NGOs, CBOs, women’s groups)

Community Education & Awareness
- (General HIV/STI prevention and home-based care education, education on clinical trials and informed consent)

Development of Referral Strategies

Participant Recruitment, Screening
- HIV +ve – screened out – referred to health service
- HIV –ve - enroll

Accrual & retention

Follow-up
- HIV testing
- Pregnancy testing
- Safe sex & HIV/STI prevention counseling
- STI testing
- Safety testing

Study Completion

Regular Feedback
Community Support

- Participant accrual
- Peer education programme
- Regular community meeting attendance
- Door-to-door, NGO, CBO
- Referrals from partners
RETENTION STRATEGIES

COMMUNITY
- Community Feedback

TRACK
- Database

ENCOURAGE
- Staff
- Clinic Flow
- Reward system

FOLLOW-UP
- Locator Information
- Peer Educators
- GPS

FACILITATE
- Weekend Clinic
- Appointment Cards
- Toll Free Line
- Suggestion Box

95%
Major challenges with product and condom adherence

- Disclosure of trial participation to partner
- Women may not be happy with their randomisation assignment
- Condom negotiation still a problem
- Clear messaging around use of product with condoms

Key lessons learned from previous trial experience in addressing adherence problems

- Need for male partner involvement
- Ascertain full understanding of product assignment before randomisation
- Reiteration of adherence messages at every visit