HPTN 035 LILONGWE SITE

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LOCATION

1. Study Site

- Located at Tidziwe Centre, Kamuzu Central Hospital (KCH), Lilongwe, Malawi

2. Accessibility to potential participants

- Close to the centre of town and very accessible by mini buses and bicycles which operate where clients live.

3. Centrality to anticipated recruitment/ catchment area

- Study recruits clients from within 20 Kilometre radius of Lilongwe District. Population is rural and semi-urban

4. Existence healthcare service infrastructure

- KCH the main tertiary hospital in the central region.
- Five other government health centres are within 20 kilometre radius from the site.
- All these centres have been debriefed about HPTN 035.
- 0ther Private Health facilities / clinics

CATCHMENT AREA MAPunc1.wmf

Potential for establishment of referral linkages for care and support

- General Clinical service
  -There are other health care institutions e.g. Bwaila Hospital, Likuni Mission Hospital, Area 18, Area 25, Kawale health centres
- Specialised Clinical service
  - Lighthouse,PMTCT, Family Planning, STI and Reproductive Health Clinic, TB Clinic, all at KCH and/or Bwaila Hospital
- HIV Counselling & Related services
  - National Association of People living with HIV/AIDS in Malawi (NAPHAM)
  - Malawi AIDS Counselling & Resource Organization (MACRO)
  - Home Based Care Programme.

POPULATION CHARACTERISTICS

- Malawi pop –
  - ~ 12 million people
  - rural/urban split of 87% to 13%.

  Lilongwe population : 1.3 million
- Pop male/female ratio of 49%: 51%.
- Average household size is 4.3, 25% female headed.
- Country's GDP per capita is estimated to be US$ 190 with a poverty head count of 65.3%.
- Levels of literacy 74% for males and 49% for females.

HEALTH STATISTICS

- HIV prevalence in Malawi
  - 13% in women and 10.2% in men of 15-49 age group
  - 23% urban vs. 12.4% rural
  - 47% in STI patients at KCH
  - Amongst cohabiting couples: 83% negative, 7% positive, 10% discordant
  - Estimated prevalence for Lilongwe: 10.3%. 11.5% and 9.2% for Women and Men respectively of 15-49 age group
- The contraceptive prevalence rate 28% in 2004
- Condom use prevalence during last sexual intercourse with a non-cohabiting partner 29.8%.
- Life expectancy 37 years

Identification of high risk women

- **Local Site definition of high risk women:**
  Moderate-high risk:
  All young, sexually active women residing in Lilongwe within a 20 km radius.
  Highest risk: Women who work around men drinking alcohol. Bar girls. Identified by place.

- **Categories of high risk women:**
  - Bargirls
  - STI patients
  - Reproductive age ; peak in 30-34 yrs
  - Population of security forces; army/ police
  - Urban population

MAXIMIZING RECRUITMENT OF HIGH RISK WOMEN

- **Prior recruitment trials**
  - Older age, too many women from one low prevalence village
- Current challenges

- Poor response of high risk women in reporting for screening.

- Women in high transmission areas frequently relocate (eg. Army/ Police)

- Urban working class women could not stand long waiting hours at the study site.

- Slow in recruitment of high risk women as most of them were ineligible due to high HIV prevalence.

- Competing of studies to recruit from the same subset of women.

MAXIMIZING RECRUITMENT OF HIGH RISK WOMEN

- **Probable strategies for future trials :**

- More study staff & bigger space for recruitment to minimize long waiting time

- Prescreening activities e.g. HIV testing, PT evaluation outside consenting process to minimize time spent consenting ineligible women

- Group consenting than individual consent to minimize time spent (less waiting hours)

- Special preference for participants needing to get back to work

- Regular clinic flow evaluation to develop a more efficient client flow and minimize participant clinic time

- Transport to communities for participants who over stay in clinic

RETENTION CHALLENGES

1. Relocation of participants outside catchment area
2. Drop outs that result from husbands/partners refusing spouse's further participation
3. Difficulties to locate houses for participants (false locator information)
4. Misconceptions to blood draws and pelvic exams
5. Slow response for males getting involved in the study
6. Uncertainity / Unwillingness of some women to inform spouses about study

3 Key lessons learned to maximise retention

1. Male involvement is important to ensure retention

2. Timely dispelling of rumors and misconceptions is essential in maximizing retention

3. Good locator information and strong vibrant community/outreach team

MAJOR CHALLENGES WITH PRODUCT & CONDOM ADHERENCE

- Lack of male involvement
  - unacceptability of study product
  - Social harm
  - Temporary break down of marital union

- Safety of study product
  - Gel thrown away in bush
  - Cartons of gel found with playing children in the street
  - Gel swap between study participants
  - Stigma attached to study product bags
  - Gel left with client colleague or unattended at the clinic

- Movements away from home
  - Funerals
  - Farming

LESSONS LEARNT FROM THESE CHALLENGES

- Male involvement strategy essential in product adherence
- Group and targeted counseling on study product safety and use
- Involvement of ppts in study operational issues e.g. tote bags, how to carry gel on emergency trips

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