

PARTICIPANTS RETENTION IN HPTN 035 MICROBICIDE STUDY IN ZIMBABWE “AGAINST ALL ODDS”

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MTN Regional meeting 10 September
2008



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Background

- N= 484
 - Seke South= 261
 - Spilhaus= 223
- Sites were mixed of rural, peri-urban and urban; with formal and informal settlements

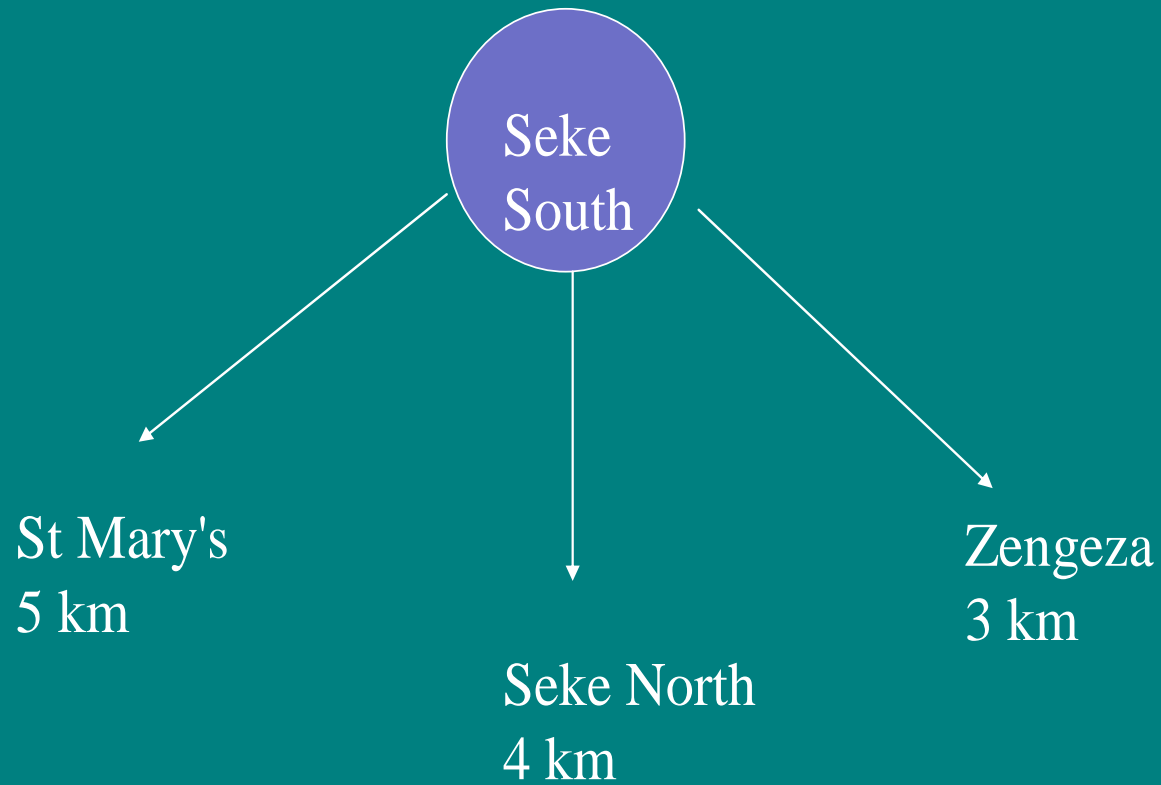


Seke South



- Located within a primary health care clinic
- Low income urban community
- Popln= 190 000 women of child bearing age.
- 3 other primary health care clinics within 5km radius

Location of Seke South Clinic

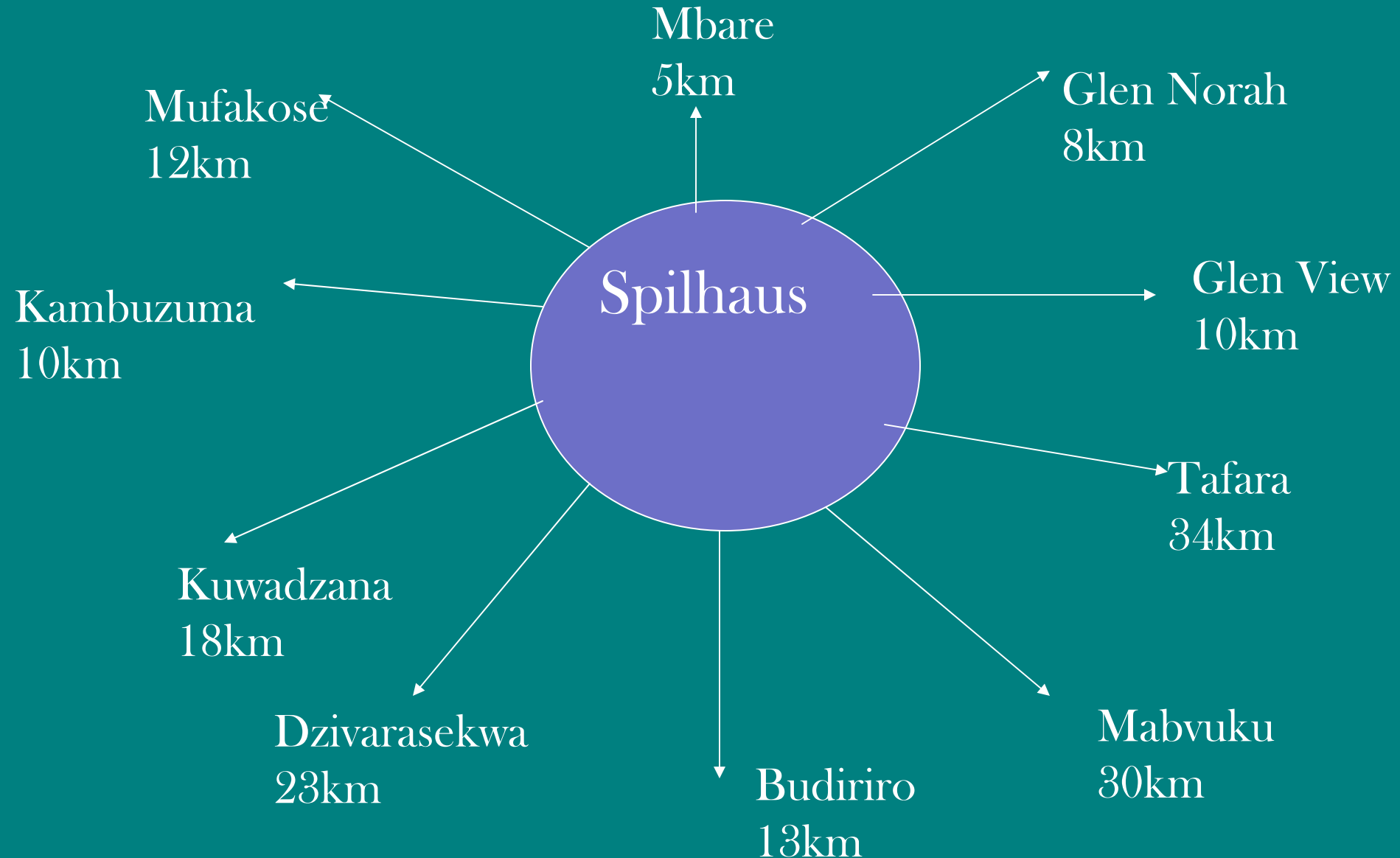


Spilhaus Clinic



- Located within a reproductive health complex
- Southern part of urban Harare
- Serves 13 low income suburbs
- Popln= 130 000 women of reproductive age

Location of Spilhaus Clinic



Retention and LTFU

Considerations

- Loss to follow-up (LTFU) defined as no closing visit with HIV endpoint data
- Protocol assumed 19% LTFU per year over 3 years given an overall expected HIV incidence in the trial of 4.42 per 100 PY
- Minimizing LTFU is essential in clinical trials to ensure the validity of trial results
- Important not only to limit LTFU, but to ensure that LTFU is not different by study group

Retention Challenges

- Political and economical challenges
- Include:
 - fuel shortages which led to public transport unreliability
 - frequent increases in bus fares due to high cost of fuel
 - limited access to basic commodities resulting in participants spending a lot of time in queues
 - Political Polarization made it difficult to go to some rural areas

Retention Challenges(cont)

- High loss of jobs leading to permanent relocation to rural areas
- Erratic supplies of water and electricity which lead to participants failing to come for their visits
- Seasonal rural migration for farming purposes to supplement inadequate income
- Cross border trading to supplement income

Retention Strategies

- Community
- Outreach
- Database
- Clinic Staff
- Clinic Flow
- Participant Incentives

Community

- Educate CAB members continuously about the importance of study completion
- Educate partners of study participants through male involvement campaigns and quarterly retention meetings
- Bimonthly meeting with the local CAB to update them and get feedback

Outreach

- Ensure that accurate and appropriate information is disseminated during the recruitment process so that participants understand what they are getting involved in
- Recruit participants from areas where there is adequate transportation to get to the clinic site, and/or where they pass by the clinic on their way into town

Outreach

Before enrollment

- Ensure that accurate and appropriate information is disseminated during the recruitment process
- Home visit to verify locator information before enrolment

Locator Information

- Home address and phone number
- Husband's name, work address and phone number
- Parent or nearest relative's name, address and phone number
- Second contact after parent or relative
- Rural address of the participant

Extensive follow-up

- Issue visit reminders before scheduled visits
- Immediate follow-up on any missed scheduled visit
- Courteous home visits

Focusing On Hard to Reach Participants

- Rural outreach



- Provided transport

- participants with limited time
- limited access to transportation
- employed participants (arriving late, extended lunch time, etc)

- Rural outreach

Data Base

- Generate list of participants requiring a reminder letter/visit
- Generate list of participants who had defaulted or missed their scheduled visit
- Track courteous visits to ensure that they are done effectively and equitably
- Flagging of difficult participants and those going outside the study areas

Data Base (cont)

- *Weekly reconciliation*
 - Data and outreach
 - Data and reception records
- *Weekly retention meetings*
 - Management
 - Data
 - Outreach

Clinic staff

- Be sensitive and appreciative of the participants' effort to come to the clinic and the distance travelled
- Daily “Client liaison officers” at each clinic site to inform participants of any delays, problems, shortages
- Continuous participant education on importance of the need to attend all follow-up visits

Clinic Staff

- Encourage participants to be honest about their whereabouts, activities that might affect their attendance at clinic visits, their preferred schedules, etc
- Inform participants at check-in for every visit approximately how long that visit will be
- Update locator information at every contact.

Clinic Flow

- Reducing clinic times to minimum possible
- Group education
- Cross-training of study staff
 - Counseling
 - Outreach
- ‘Gold star’ system
 - flagging of binders for participants in a hurry

Participant Incentives

- Television in the reception area.
- Offer childcare, to the extent possible by general hands.
- Provide refreshments
 - Tea and bread or biscuits
 - Meals for long visits

Participant Incentives cont



- Quarterly participant retention meetings
- Prizes for completing significant milestones in the study
- Regular and timely increments of the reimbursement money to cater for the increasing transport costs

Retention Meeting



Zimbabwe – Study exit visit retention and LTFU (as of 29JUL08)

	Seke South	Spilhaus
Expected	138	117
Completed scheduled closing visit	129 (93%)	107 (91%)
Early withdrawals ††	9 (7%)	10 (9%)
Lost to follow up	4 (3%)	2 (2%)

Key Lessons

- CHALLENGES

- Seasonal migration to rural areas
- Cross border traders
- Rural migration due to economic reasons

- KEY LESSONS

- Retention is a process that starts at recruitment.
- Use of the data base
- Participant Retention meetings.
- Male partner involvement also key

Conclusions

- Pre-emptive planning and continuous monitoring of retention rates, combined with additional tracking time ensured high return of participants
- Achieving high retention is resource intensive and requires proper allocation of financial, administrative and human resources
- Many of our successful strategies were staff-driven, therefore it's important to involve all members of staff in retention discussions, and to share ideas across sites

Acknowledgements

- The Participants
- The Harare and Chitungwiza CABs
- The HPTN 035 Zimbabwe Team
- UZ-UCSF Admin
- FHI
- MTN
- NIAD