PC6 A comparison of retention figures in Microbicides Development Programme feasibility and pilot studies: before and after introduction of a study product

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ABSTRACT TEXT
Background:
Microbicide trials are currently recruiting large numbers of participants. Sample size calculations are based on estimates of HIV incidence data and retention rates derived from population surveys or cohort studies.

Methods:
MDP feasibility studies have been completed at 6 sites in Africa (coordinated by Africa Centre, MRC HPRU (Durban), and RHRU (Johannesburg) in South Africa, AMREF/NIMR/LSHTM in Mwanza Tanzania, MRC/UVRI in Masaka Uganda, and UNZA in Mazabuka Zambia) where participants were followed three-monthly for a minimum of 12 months. Following this a Pilot Study was implemented in 6 sites to assess acceptability of and barriers to using placebo gel, and study procedures including measurement tools. Retention data from the 3-month follow up in Feasibility were reviewed with the retention rates after 4 weeks of follow up in the Pilot Study where participants used placebo gel.

Results:
3174 women were enrolled into feasibility studies at the 6 sites giving 2294 person years of follow up. 308 women were enrolled into the pilot study. Retention at each of the sites in after 3 months in the feasibility and after 4 weeks in the pilot studies was as follows:

Site	Retention at 3 mth timepoint in feasibility study	Retention after 4 weeks in pilot study
Durban	94%	100%
Johannesburg	84%	92%
Africa Centre	63%	98%
Mazabuka	87%	98%
Masaka	93%	95%
Mwanza	83%	100%

Although it is only possible to make a descriptive comparison of these results, they are reassuring in that one of the objectives of Feasibility was to identify strategies to improve retention. A number of other factors could explain the increased retention seen in the Pilot Study including: the fact that women received a placebo gel and condoms, the shorter follow-up period, higher reimbursements, and education of participants through a more detailed consent process.

Conclusions:
Preparatory work in target populations prior to Phase III is highly recommended, not only to collect accurate data on incidence but also to develop strategies to retain women in follow-up for long periods.

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