

# **PC74 Evaluation of informed consent procedures and reasons for participation in a pilot study for a vaginal microbicide trial among women in SW Uganda.**

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## **ABSTRACT TEXT**

### **Background:**

This work is part of the multi-centre Microbicides Development Programme that aims to conduct an efficacy trial for the evaluation of a vaginal microbicide in several African sites. The objective of the study reported here was to evaluate women's understanding of the informed consent content and procedures in a pilot study in preparation of the main trial.

### **Methods:**

HIV-negative sexually active women living in HIV-discordant (50) and HIV-negative concordant (10) couple relationships were identified from the general rural population through a sero-survey and invited to participate in a pilot study using a placebo gel prior to sexual intercourse. Study information was provided during group workshops followed by one-to-one or couple sessions where information leaflets were given and explained. Leaflets focussed on: the gel used in the study does not prevent HIV infection or pregnancy; safety of gel during pregnancy is yet unknown, proper and consistent condom use can prevent HIV infection. Other information referred to risks and benefits of participation, voluntary participation, details of study procedures (genital examination, HIV, syphilis and pregnancy tests and an interview on health and sexual behaviour). Women gave written consent. In-depth interviews (IDIs) were conducted among consenting women, approximately 1-2 weeks after completion of the study. Data was analysed using NVIVO.

### **Results:**

57 women aged 21-54 years participated in the IDIs. 52/57 (91%) were aware the study gel would not prevent HIV or pregnancy. Condom use was reported as a main HIV prevention strategy (92%) although abstinence (3%) and faithfulness (5%) were also reported. Women easily recalled HIV and syphilis testing and genital examinations, while interviews on sensitive sexual behaviour were only remembered after probing. Being in HIV discordance was still a surprise to 4 (7%) of the women at end of study. Main reasons for participation were: wish to contribute to HIV prevention research (60%), learning about HIV status (23%) and accessing medical care (11%).

### **Conclusion:**

There is good comprehension and retention of consent information among these rural women. These findings imply that it will be feasible to conduct a phase III microbicide trial in this population.

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