

Luwugge, H. S. (2008). Adherence to gel and condom use among women participants in a phase iii microbicide trial of pro2000/ 5 in rural sw uganda Microbicides 2008. Delhi.

Introduction: Vaginal microbicides currently being evaluated in phase III clinical trials could have considerable impact on HIV transmission. This study aimed to assess adherence to gel and condoms among rural women participating in a phase III microbicide trial. The study is part of the Microbicide Development Programme (MDP), an international collaboration of African and UK research institutions.

Methodology: 456 eligible HIV-negative women living in HIV discordant and concordant negative couple relationship were enrolled after written informed consent. At enrollment and follow-up visits, they were provided with gel and condoms and requested to use both at every sex act. Detailed data on gel and condom use per sex act were collected by means of structured questionnaires and pictorial coital diaries (CDs) at 4, 24 and 40 weeks of follow-up. 73 women participated in 8 FGDs, 100 in IDIs, and 100 completed CDs. Results: A total of 2720 sex acts were reported by participants at week 4, 24 and 40 using sexual behavior questionnaires. Rates of reported gel and condom use Week 4 N=1365 Week 24 N=843 Week 40 N=512 Gel and condom 75% 75% 86% Gel only 18% 17% 7% Condom only 5% 7% 8% None 2% 1% 1% >From IDIs and FGDs data, gel was reported to be easy to insert, convenient to use and led to increased lubrication and sexual pleasure. Conclusion: Approximately 90% of women accepted to use gel either alone or in combination with condoms as recommended. The rate of non-condom use was still substantially high although trial information provided emphasized that lack of condom use increases HIV risk. However, our findings indicate good study progress and this is expected to lead to valid assessment of the efficacy and safety of the PRO2000 microbicide gel.