Kasse, M. J. (2008). Recruitment and retention in a vaginal microbicide efficacy trial: experiences with hiv negative women living in discordant couple relationships in rural sw uganda Microbicides 2008. Delhi.

Background: We describe recruitment and retention rates among women living in HIV discordant and some HIV-concordant negative couple relationships in a phase III vaginal microbicide trial. This study is part of the Microbicides Development Programme (MDP), a multi-centre collaboration involving African and UK institutions. Methods: Discordant couples are identified at HIV voluntary counseling and testing (VCT) clinics and through house-to-house surveys. After obtaining informed consent, participants are enrolled and receive instructions on gel use and a 4-week gel supply. Further dispensing is done through monthly home visits. Clinical follow-up visits are conducted every 3 months including STI screening, pregnancy test, family planning counseling and couple VCT. Results: Between Jan 2005 and June 2007 a total of 663 M+F- discordant couples were identified. Of these, 618 women (93%) were screened and 472 (76%) met the study inclusion criteria (16/month). Reasons for exclusion were: HIV sero-conversion before enrolment (31); pregnancy (25); clinical/laboratory abnormalities (19); reporting not to be sexually active (10); no regular sexual partner (11); unwilling to share HIV results with partner (6); unwilling to use condoms (4); refusal to participate (17); and other reasons (23). Overall 29% of identified couples were not enrolled. So far, the trial is recruiting at 80% of the target. The overall retention rate at one year was 96% and rates at 3, 6 and 9 months were 96%, 98%, 94% respectively. A total of 24 women have been withdrawn due to personal decision (16), influenced by the death of partner in 7 women and relocation (8) Conclusions: We demonstrated that good recruitment and high retention rates among women living in discordant couple relationships are achievable in this community. The trial is ongoing.