

Abstract:

Comparison of sexual behaviour data collected from a coital diary and a clinic based interview in the microbicides development programme (MDP) pilot study, Mwanza, Tanzania

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Background: MDP conducted a feasibility study in six sites, including Mwanza, Tanzania, in preparation for a Phase III clinical trial of vaginal microbicides. In clinical trials there is a need to collect accurate sexual behaviour data, to measure per act efficacy of microbicides, and to show the behavioural conditions under which trial results were achieved.

Methods: Fifty-nine women working in bars and similar facilities were enrolled in a 4-week pilot study in September 2004 to assess the acceptability of the gel and study procedures. Each woman was provided with a coital diary (CD) weekly by a fieldworker and advised to complete one page every day. At the end of 4 weeks the women attended for clinical review and participated in a structured interview with a counsellor about their sexual behaviour over the last week, or four weeks if they had no sex in the previous week.

Results: Results are presented for 56 women for whom full data were available, and for the week previous to the interview. The mean number of sex acts reported was 2.1 in the interview and 4.0 in the CD (median: 2.0 and 4.0 respectively [$p < 0.0001$]). For the 41 women who reported sex acts in both methods, 100% condom use was reported by 17 (41%) at interview and 13 (32%) in the CD ($p = 0.3$). and 100% gel use by 35 (85%) at interview and 15 (37%) in the CD ($p < 0.001$).

Conclusions: Lower numbers of sex acts and a higher proportion of sex acts with gel use were reported in the structured interview than in the CDs. This may indicate social desirability bias or be the result of poor recall. A simple aide memoire based on the CD has been designed for women to use in the phase III trial to assist recall of sexual behaviour when attending clinical visits.