

Moffat, C. (2008). Are previous enrollees in a feasibility study a suitable study population from which to recruit for an HIV prevention trial. *Microbicides 2008*. New Delhi, India.

Objectives: To explore the association between enrolment in a feasibility study and risk of HIV infection during an HIV prevention trial. Methods:: Between August 2002 and October 2003 we conducted a study to assess the feasibility of implementing a vaginal microbicide study among recreational workers in Mwanza, Tanzania. In February 06 we began enrolment into a randomized, placebo controlled vaginal microbicide study to assess the safety and efficacy of PRO 2000/5 vaginal microbicide gel for HIV prevention, recruiting from the same target population. Willingness to receive HIV test results was an inclusion criteria in the clinical trial but not in the feasibility study. Results: Baseline HIV prevalence among women screened into the clinical trial was 18.6% compared to 25.5% at enrolment into the feasibility study. 512/1573 (32.5%) enrolled in the feasibility study were unwilling to know their HIV status. Of women screened for enrolment into the randomized clinical trial, 183/1520 (12.0%) had previously participated in the feasibility study. Women previously enrolled in the feasibility study were older (median age 35 vs. 30 years, $p < 0.001$) and more likely to be Mamalishe or working in Pombe shops (79.2% vs. 69.9%, $p = 0.01$), both factors associated with lower risk of HIV infection in the feasibility study. Odds, adjusted for age and facility, of being HIV positive at screening for the randomized trial were 42.6% lower for women previously enrolled in the feasibility study. ($p = 0.01$, 95% C.I. 10.8%-63.0%). Conclusions: Recruiting women previously enrolled in an HIV prevention feasibility study may result in a sample population at lower risk of HIV than the sample population of the feasibility study with important implications for deciding on the target population and exclusion criteria for HIV prevention trials.