Crook, A. M. (2008). Assessing the reliability of self reported gel use compared to used applicator returns in the ongoing mdp 301 phase iii trial <u>Microbicides 2008</u>. Delhi.

Background: Accurate measurement of exposure to study product is an essential safety component of all drug trials and a regulatory requirement for licensing submissions. The Microbicides Development Programme (MDP301) Phase III trial is assessing the safety and efficacy of the unlicensed PRO2000 microbicide gel. This analysis aims to assess the reliability of the gel usage data being collected in this trial by comparing two different measurements of gel use: self reported usage from participant interviews on sexual behaviour compared to the number of used applicators returned at follow-up. Methodology Blinded data on 4110 study participants were available for analysis as of 15th September 2007. The average number of gel applicators used per week was estimated from the total number of used applicators returned at four separate follow up visits after enrolment, adjusting for the time since the participant was last seen. This was compared to the number of times gel was reported to have been used in the last week prior to that visit. Results Gel applicators were reported to have been used an average of 3.4 times per week compared to an average of 3.6 used applicators returned at 4 weeks. Overall 99% of participants were reported to be using between 0 and 10 applicators by both methods. The distribution of the difference between the measures was symmetric around a mode of zero (24%, perfect agreement); 59% agreed to within ±1 applicator and 79% agreed to within ±2 applicators (1 standard deviation of the difference). These findings were consistent across all four follow up visits where both sets of data are collected. Conclusion: The relative concordance of the two measures provides some assurance that the data being collected on gel use in MDP301 are reliable enough to enable product exposure to be estimated with a reasonable level of accuracy.