
Background: Defining a reliable measure of adherence is critical for all efficacy microbicide trials. Using data from the ongoing Microbicides Development Programme Phase III trial, this analysis compares information collected at the last sex act to the previous sex acts reported at that visit, to investigate whether the last sex act could be used to measure of adherence to gel use. Methodology Blinded data on 5350 study participants with a week 4 visit were available for analysis as of 15th September 2007. Condom and gel use defined as Condom only, Gel Only, Both or Neither at the last sex act was compared to up to the last 6 previous sex acts reported at that visit. Results 4193 (78%) women reported having at least two sex acts at their week 4 visit and 1222 (23%) reported 6 sex acts or more at week 4. There was 91% agreement between the condom and gel used at the last sex act compared to the previous sex act (from n= 4193 women). For the third most recent sex act and the last sex act this figure was 88% (from 3115 women). The figures for the fourth, fifth and sixth sex acts were 86%, 84% and 85% (from 2272, 1659 and 1222 women respectively). Conclusion: There is a high concordance of reported gel and condom use over recent sex acts. Although agreement appears to drop over time, there is still high agreement between the last and 6th last sex act and therefore condom and gel use reported at the last sex act could be considered a reasonable indicator of condom and gel use overall.