

Cairns, J. (2008). Evaluation of a dual HIV rapid testing strategy for screening into the MDP301 trial. *Microbicides 2008*. Delhi.

Background: MDP301 is a six centre trial evaluating the safety and efficacy of 0.5% and 2% PRO 2000/ 5 microbicide gels for the prevention of vaginally acquired HIV infection. The initial HIV status is determined using HIV rapid antibody kits. This analysis estimates the sensitivity and specificity of the Abbott Determine rapid test and investigates the value of using a dual rapid testing strategy. Methodology: Data from five sites were used in this analysis including KwaZulu Natal, Durban, Johannesburg, Mazabuka in Zambia, and Mwanza in Tanzania. The MDP301 HIV testing algorithm for these sites uses two rapid tests in parallel. All sites use Abbott Determine in conjunction with one other FDA or WHO approved assay. If a participant has discordant rapid results they are not eligible for enrolment and an HIV ELISA is performed for confirmation. Results: As of September 15th 2007 10,272 women had undergone HIV rapid testing. Of these 269 (2.6%) had discordant rapid results. 2959 tested positive with Abbott Determine including 161 discordant results that were confirmed positive by ELISA. 11 discordant results were found to be negative with the local confirmatory ELISA (sensitivity 99.73%). 7313 participants tested negative with Abbott Determine including 108 discordant results that were confirmed negative by ELISA. 8 discordant results were found to be positive after the local confirmatory ELISA (specificity 99.85%). Conclusion: The results show that only a small number of women would be randomised in error if the Abbott Determine test was the only indicator of HIV status, saving 10,272 rapid tests. The high specificity and sensitivity of the test therefore questions the need for a dual rapid testing strategy in clinic. A more cost effective strategy would be to establish HIV status using a single Abbott Determine test, confirming with a second rapid test only if the result was positive.