

Kalumbilo, S. N. (2008). Issues affecting understanding of key informed consent messages in the mdp 301 trial in mazabuk,zambia Microbicides 2008. Delhi.

Background: Informed consent (IC) is important in microbicide trials because it explains key messages about the study including potential benefits and risks. Three key messages are emphasized during the IC process in the MDP 301 trial: gel may not prevent HIV, it is not known whether gel is safe to use in pregnancy, and condoms are effective in preventing HIV. This study explored issues influencing the understanding of these key messages. Method: In-depth interviews were conducted with a random sub-sample of 30 participants 4 weeks after receiving IC. They were asked about their understanding of key messages using openended questions. In addition, six IC sessions were recorded in the clinic. All transcripts were analysed thematically. Results: Of the 30 participants, 28 thought that gel prevented HIV because they had not seroconverted at follow-up visits. Others claimed that gel was already known to have worked elsewhere. Recorded sessions also revealed that some study counsellors interpreted safety studies as efficacy studies. All participants were aware that the gel did not prevent pregnancy because they had seen other participants get pregnant and were told by study staff. Two mentioned that condoms did not prevent HIV because infection rates were still high and condoms easily break or expire. Recorded sessions revealed that the study staff did not interpret some terminologies such as 'study' and 'placebo' in the participant information sheet (PIS) correctly. Conclusion: Participants' belief that the gel prevents HIV is influenced by their HIV sero-negative status at follow-up visits and misunderstanding that it 'worked' elsewhere. Participants and clinical staff need to be educated that the gel is not known to have prevented HIV elsewhere. Participants need education that remaining HIV negative may not mean that the gel prevents HIV. There is also need to resolve the interpretation of key terminologies in the PIS.