

PD40 Challenges in collating community involvement experiences from sites in Africa preparing for the Microbicides Development Programme (MDP) multi-centre Phase III clinical trial

Richard Mutemwa, Neetha Morar, William Stones, Charles Shagi, Viincent Basajja, Ntombikayise Mncwango, Julie Bakobaki, Nicola Kaganson, Kennedy Mundia, Jonathan Staedler

ABSTRACT TEXT

Issues:

The MDP301 effectiveness trial is comparing each of two concentrations of PRO 2000 gel against placebo in the prevention of acquisition of HIV infection during vaginal intercourse. The trial is being conducted at six sites with very different population characteristics. Community involvement has been a key requirement in preparation for the trial at the sites, with the aim of promoting community participation and involvement in the research process. Co-ordination presented challenges, given the need to work with rather than replace existing systems, the absence of a 'gold standard' for community activities in clinical trials, and the lack of defined competencies for clinical trial community liaison officers (CLO).

Description:

The six trial sites include South Africa, in Durban (MRC SA), rural KwaZulu Natal (Africa Centre), Johannesburg (RHRU); Zambia in Mazabuka (UTH Lusaka), Tanzania in Mwanza (NIMR/AMREF/LSHTM) and Uganda in Masaka (MRC UK). The MDP Community Liaison Co-ordinator was responsible for ensuring that information about community activities in the trial sites was collated, for the purposes of reporting as well as identification of capacity building requirements. Experiences and activities were documented during the feasibility (12-24 months) and pilot (3 months) study phases leading up to the trial. Three practical issues arose from working with reports. First, the six sites started preparation for the trial from different levels of readiness; Secondly, the diversity in site characteristics, operational systems and processes for involving the community impacted on the way community activities were recorded and reported. Lastly, community liaison staff across the sites had different academic and experiential backgrounds which had an impact on the depth and breadth of the reports. This presented a challenge when merging material into summaries community activities. A set of standardised approaches for documentation were developed and implemented at the sites in preparation for Phase 3 trial initiation. The potential for capacity building through facilitating visits of CLOs to other sites was also identified and piloted.

Conclusion:

Further work is required to streamline the reporting of activities, so that sites and their communities can continue to benefit from the cross site comparisons which help to identify training needs and can inform south-south capacity building during Phase III.

Richard Mutemwa - Research Fellow: University Of Southampton, r.i.mutemwa@soton.ac.uk, tel 442380594748, fax 442380598743, Centre For AIDS Research, University Of Southampton, SOUTHAMPTON, SO17 1BJ, UNITED KINGDOM