PC47 Developing a community entry strategy: preparing for a Phase III microbicide trial

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ABSTRACT TEXT

Background:

Community involvement in clinical trials is essential to the success of the trial, and may well enhance community support and advocacy for the introduction of effective HIV prevention technologies such as vaginal microbicides.

Methods:

Initially, research staff initiate a process for documenting all governmental and non-governmental organizations in the community. This information is documented in a database. Community members are also asked to participate in a cognitive mapping exercise which assists in describing the social context of the community. Representatives from idenitifed organizations, as well as community members are then invited to an open community meeting where the needs around HIV prevention, research and the role of the community are discussed. Volunteers from this meeting are invited to become part of a community advisory group (CAG). The CAG is formal structure, which meets monthly and which operates within terms of reference, developed and agreed by the members. CAG members receive formal training in a number of topics including research ethics, specific protocol and additional health education information. Research teams interact with the broader community through community radio programmes, public events and campaigns, and community drama events. All these activities are aimed at informing community members about the trials, but also respond to the demand for greater information about sexual and reproductive health.

Results:

Since adopting this methodology, we have engaged with four different communities in the greater Johannesburg area. Each of these communities has established an active CAG which have each been trained and participate in regular monthly meetings. Research staff and community members participate in health education programmes on two local community radio stations. Several successful public awareness campaigns have been held in each of these communities. Recruitment and retention of trial participants appears to have been enhanced through these activities.

Conclusion:

Despite challenges, a structured approach to community entry and ongoing involvement of the community in research has enhanced the conduct clinical trials in these four communities. Additional tools need to be developed to monitor and evaluate these processes in more detail, and to demonstrate potential additional public health benefits from these interactions.

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