Abstract

PRE-SCREENING AND 'BANKING' PARTICIPANTS FOR CLINICAL RESEARCH – EXPERIENCE FROM KENYA AIDS VACCINE INITIATIVE (KAVI)

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Introduction: Participation in clinical research is a voluntary exercise whereby a participant makes an informed choice to join a study. Clinical trials are robust experiments that require efficiency. HIV vaccine clinical trials pose a special challenge due to the associated stigma and misconceptions. Participant recruitment into HIV vaccine clinical trials therefore requires special attention to the informed consent process resulting in slow participant recruitment rate. To address this, KAVI designed a study aimed at 'banking' participants for potential participation in future studies at KAVI.

Methods: Following informed consent a questionnaire was administered to obtain information on demographics, lifestyle, medical history and willingness to receive information about upcoming studies. VCT was offered and blood drawn for HIV testing and storage. HIV infected participants were excluded and referred for care. Follow-up was scheduled six-monthly for 2 years; HIV counseling and testing were repeated at follow-up visits. Participants that consented to roll-over into new recruiting studies were discontinued from the 'banking' study.

Results: A total of 336 participants were screened and 306 enrolled with a male: female ratio of about 1:1.2.Majority were young (25-29 years), single (77%), and unemployed or students.
Most described their health as good (71%), were heterosexual (92%) and sexually active (78%); 49%and 10% had one or no sexual partner respectively. Condom use was high (regular partner 81%, casual partners 86%); 88% believed that they were HIV-uninfected. A total of 77 participants (23%) consented and rolled over to new studies, 50 of these consented for 2 HIV vaccine clinical trials that required 80 participants.

Conclusion: Pre-screening and 'banking' participants for future studies can supplement direct recruitment from the community and increase recruitment efficiency, reduce recruitment effort,and improve participant retention and compliance with procedures. There is need for further studies to understand the participants' decision-making process in volunteering for clinical research.