OVERVIEW OF SiVET STUDY DESIGN

The success of any HIV prevention trial depends on the identification of a suitably large population of persons at high risk of HIV seroincidence that is willing to participate in the trial (Seage et al 2001). Studies in Kenya have demonstrated that men who have sex with men (MSM) and female sex workers (FSW) are at disproportionately high risk of HIV infection (Sanders et al 2007, McKinnon et al 2013). The purpose of this study is to evaluate if FSW and men who have sex with men (MSM) who sell sex (MSM-SW) are willing to participate in a simulated vaccine clinical trial. The trial is designed to mirror the procedures of an actual HIV vaccine trial but will use a registered hepatitis B vaccine as a proxy. This will enable assessment of volunteer compliance with protocol procedures while identifying potential barriers to participation in an actual vaccine trial. Retention of study volunteers is of critical importance in randomized clinical trials and this study will determine retention rates in this mixed cohort of MSM-SW and FSW.

The MSM cohort that will be enrolled in this study has an estimated HIV incidence of 10.9% (McKinnon et al 2013). MSM-SW and FSW are part of the Sex Worker Outreach Programme (SWOP), a prevention, treatment and care program that was established in the early 1980s. From 2005, the program was awarded a CDC-PEPFAR grant that facilitated access to much needed ART services and allowed scale up of HIV prevention services for sex workers residing within Nairobi County. Currently, the program has reached over 26,000 sex workers and enrolled at least 21,000 in seven sex-worker dedicated clinics in Nairobi. Those reached and enrolled into the program access a comprehensive HIV prevention and care package as per the MOH guidelines. Throughout its lifespan, the program has been setting the pace and best practice in community engagement and health care services for sex workers. The existing seven sex worker dedicated clinics have minimized the stigma and discrimination encountered by key populations when seeking health care, greatly improving access to friendly and acceptable HIV prevention and care. Additionally, these clinics have improved the proportion of sex workers screened for HIV in Nairobi County creating a critical mass that is influencing changes to their health seeking behaviours. The hotspot based, peer led model used for community engagement, where peer educators trained and certified by NASCOP-MOH spearhead activities in the field, has greatly improved the existing partnerships and ownership of the funded activities within the targeted communities.

Through these cordial and genuine partnerships, we will be able to refine recruitment strategies for these key populations and define optimal eligibility criteria for future HIV vaccine studies.