**Case 2: Feasibility of HIV Prevention Cohort Studies among Men who have Sex with Men in Sub-Saharan Africa (case adapted from Jerome Singh)**

**Introduction**

Daily Pre-Exposure Prophylaxis (PrEP) with oral TDF-FTC (Truvada) has demonstrated *efficacy* in reducing the risk of HIV infection in high risk individuals.. On-demand PrEP with oral TDF-FTC has also been proven to have a good safety profile and highly *effective* in reducing the incidence of HIV-infection in high risk men who have sex with men (MSM), in a European setting. The feasibility of introducing oral PrEP amongst African MSM is unknown.

MSM have been identified as a “key population” in HIV epidemics, globally. Even in African countries with generalized epidemics and high HIV prevalence overall, the HIV prevalence among MSM is 3-4 times higher than in the general population. Because of the high levels of bisexual sexual activity and bisexual concurrency in this population it has been argued that efforts to address generalized HIV epidemics will be unsuccessful unless they also address nested, concentrated HIV epidemics among MSM. MSM in Sub-Saharan Africa (SSA) are at alarmingly high risk of HIV acquisition and transmission. MSM in Africa also face two distinct disadvantages to accessing prevention and treatment. First, the major HIV prevention programs in SSA target heterosexual persons and pregnant women, and thus do not meet the specific prevention needs of MSM. Second, in many parts of SSA, MSM cannot safely seek HIV prevention or treatment services because of the social, cultural, and legal aspects of stigma, discrimination, and criminalization.

**Proposed study**

The primary objective of this study was to determine the feasibility of recruiting and retaining MSM in a multi-country prospective cohort study in preparation for HIV prevention studies in SSA. Members of a community-based organization propose accruing approximately 400 MSM, regardless of HIV infection status, aged 18-44 years, who report anal sex with a man in the past 3 months. Faculty from a US University will provide technical oversight for the implementation of the study and data analysis. The research team propose recruiting participants at their health clinics in four sites across three SSA countries. A total of approximately 400 men, about 100 per site, will be enrolled, with enrolment of HIV-infected men being capped at 20 men per site. Each participant is to be followed for 12 months, during which five study visits will be conducted and will involve structured HIV behavioural assessments, medical examinations, and collection of 10 ml plasma sample for testing for HIV, hepatitis B and syphilis. Participants who do not complete 12 months of follow-up will be contacted to explore reasons for no longer participating. The proposed study’s duration in the field is 21 months. Secondary objectives of the study include: (a) identifying factors related to study participation and retention among MSM in SSA, including potential barriers for study participation; (b) evaluating the social impact of participating in a biomedical and behavioural cohort study on participants; and (c) comparing substance use data obtained by self-report to data obtained by retrospective testing for substances of abuse in stored urine samples. Ethical approval from a local IRB will be sought. MSM behaviour is classified as unlawful in 2 of the 3 proposed host countries, while MSM behaviour is deemed socially unacceptable and culturally inappropriate in all four of the proposed host settings. Furthermore, substance use is classified as unlawful in all 3 settings.

**Ethical issues**

1. Should a study be conducted in country where the behaviour(s) in question – in this case, homosexuality is? Should a governing IRB (local and/or international) approve the study if the study focus in question constitutes criminalised activities?
2. What engagement strategy with the community should be followed pursuant to this study?
3. How should privacy, confidentiality, disclosure obligations to third parties or authorities in terms of relevant domestic law, and study-related social harms (such as stigma and discrimination) be managed during recruitment, during the study, and after the study?
4. What are the post-trial benefits implications of this study?