

HPTN 075 STUDY OVERVIEW & EXTERNAL STAKEHOLDER ENGAGEMENT

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PURPOSE

- To determine the feasibility of recruiting and retaining men who have sex with other men (MSM) in a multi-country prospective cohort study in preparation for HIV prevention studies in Sub-Saharan Area (SAA)

STUDY POPULATION & DESIGN

- MSM regardless of HIV infection status
- Aged 18-44 years living in SAA
- Who report anal sex with a man in the past 3 months
- An observational study
- Six months accrual period across all sites
- No replacement for participants lost to follow-up
- Follow-up period of 12 months/participant
- Five study visits including enrolment & quarterly visits).
- Participants who do not complete 12 months of follow-up will be contacted to explore reasons for no longer participating.

STUDY SIZE

- A total of approximately 400 men, about 100 per site, are to be enrolled
- Enrolment of HIV-infected men will be capped at 20 men per site.

STUDY DURATION

- Total study duration in the field is 21 months:
 - > 3 months of implementation
 - > 6 months of accrual
 - > 12 months of follow-up

PRIMARY OBJECTIVE

- To assess study recruitment and retention of a prospective cohort of approximately 400 MSM in SSA to inform feasibility, power calculations and sample size calculations for future HIV prevention studies.

BLANTYRE SITE

- Established in 1989
- Implements studies for all networks
- First ever MSM study
- Start dates 19 Jan 2016 (screening)
- Number screened - 129
- Number enrolled – 100 (Pos17 Neg83)
- 100th participant June 6, 2016

STAKEHOLDER ENGAGEMENT

- Stakeholders:
 - > Site staff
 - > Site CAB
 - > Media
 - > Govt staff (health, police & local govt)
 - > Community gate keepers
 - Chiefs
 - Faith leaders
 - Others

CAB



POLICE AS A STAKEHOLDER



STAFF CONSULTATION



MEDIA CONSULTATION



IMPORTANCE OF STAKEHOLDER ENGAGEMENT

- Referrals
- Retention
- Community trust
- Security purposes
- Resource mobilization

BEST PRACTICES

- Good relationship with IRB – oral consent
- Engaging the community throughout the study
- PAC members identification (strategic)
- CAB membership diversification
- Referral system e.g. linking with referral centres such ART, HTC, STI and Skin clinics.
- MSM friendly clinic (including excluded potential participants)
- Retention activities

LESSONS LEARNT

- Community preparedness is key to a successful implementation of a study
- External stakeholder involvement is the foundation for community trust

ACKNOWLEDGEMENTS

- Stakeholders
- Study participants
- JHP staff
- Sponsors

COMMENTS/QUESTIONS