



**HPTN**

HIV Prevention  
Trials Network

# **The Feasibility of HIV Prevention Cohort Studies among Men who have Sex with Men (MSM) in sub-Saharan Africa**

**HPTN 075**

**Protocol Chair: Theo Sandfort**

**New York State Psychiatric Institute and Columbia University**

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**Youth Prevention Research Working Group (YPRWG),**

**HIV/AIDS Office of Network Coordination (HANC)**

## Sponsored by

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## Purpose:

To determine feasibility of recruiting and retaining men who have sex with men (MSM) in a multi-country prospective cohort study in preparation for HIV prevention studies in sub-Saharan Africa (SSA)

# Design

- HPTN 075 is an observational cohort study
- Participant accrual over six months at four sites in SSA using convenience sampling strategies
- Each participant will be followed for 12 months, including five study visits
- Assessments: structured HIV behavioral assessments, medical examinations, and collection of biological samples
- Reasons for drop out will be collected

# Study Population

Men, regardless of HIV infection status, aged 18-44 years living in SSA who report anal sex with a man in the past 3 months

# Study Size

Approximately 400 men, about 100 per site  
Enrollment 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 preparation
  - 6 months of accrual
  - and 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

# Secondary Objectives (1)

- To identify factors related to study participation and retention among MSM in SSA, including potential barriers for study participation
- To assess the experience of MSM in SSA of participating in a cohort study that includes biomedical and behavioral assessments
- To evaluate the social impact of participating in a biomedical and behavioral cohort study on participants
- To assess prevalence and incidence of HIV and sexually transmitted infections (STIs), and the prevalence of hepatitis B virus (HBV) infection in the study cohort

## Secondary Objectives (2)

- To obtain baseline laboratory data (chemistry and hematology) to evaluate the cohort's suitability for possible future pre-exposure prophylaxis (PrEP) intervention studies
- To identify demographic, behavioral, and socioeconomic factors related to prevalence of HIV infection, newly diagnosed HIV infection, HBV infection, and STIs
- To identify demographic, behavioral, and socioeconomic factors related to uptake of standard HIV prevention interventions; accessing HIV- and non-HIV-related care and treatment; as well as interest in potential HIV prevention strategies and participation in future HIV intervention trials

## Secondary Objectives (3)

- To explore the possibility of including female sex partners of MSM participants in future HIV intervention trials
- To compare substance use data obtained by self-report to data obtained by retrospective testing for substances of abuse in stored urine samples

## Primary endpoints

- Recruitment rate within a 6-month period, overall and by site.
- Cumulative retention rate, measured by the percent of participants who remain in the study at the end of the one-year (Week 52 Visit) follow-up period, overall and by site.

## Secondary Endpoints (1)

- Completed study visits over the full course of the study
- Self-reported potential barriers to study participation, including internalized homophobia, experienced homophobia, limited social capital, alcohol and drug use problems, mental distress
- Self-reported experience of study participation, including experienced intrusiveness of biomedical procedures, participation burden, and satisfaction with study participation
- Self-reported number and types of positive and negative social impact as experienced by participants
- Prevalence of HIV infection and STIs at baseline

## Secondary Endpoints (2)

- Incidence of HIV infection and STIs during follow-up
- Prevalence of HBV infection at baseline
- Frequency of abnormal chemistry or hematology results that might exclude participation in a future PrEP study
- Self-reported uptake of standard of HIV prevention interventions and self-reported access to HIV- and non-HIV-related care and treatment
- Self-reported interest in future HIV prevention strategies and participation in future HIV intervention trials.

## Study Sites

- KEMRI/CDC, Kisumu, Kenya
- Blantyre CRS, Blantyre, Malawi
- Groote Schuur HIV CRS (Desmond Tutu HIV), Cape Town, South Africa
- Soweto HPTN CRS, Soweto, South Africa

## Inclusion Criteria (1)

- Biologically male at birth, according to self-report
- 18-44 years old (inclusive)
- Willing and able to provide informed consent
- Willing to undergo HIV testing throughout the study and to receive those test results
- Reporting at least one act of anal intercourse in the previous 3 months (12 weeks) with a person reported by the participant to be biologically male
- Able to provide complete locator identification for themselves and at least two other personal contacts

## Inclusion Criteria (2)

- Willing to participate in all scheduled study assessments, including specimen collection, laboratory assessments, and sample storage
- Committing to not participate in any HIV intervention or vaccine study while participating in HPTN 075
- Planning to remain in the study area for at least one year
- For HIV-uninfected men: All HIV test results must be non-reactive/negative at both the Screening and Enrollment Visits
- For HIV-infected men: All HIV test results must be reactive/positive at both the Screening and Enrollment Visits

## Exclusion Criteria (1)

- Unwilling to adhere to study procedures
- Past or current participation in a biomedical and/or behavioral HIV/STI intervention or cohort study, including HIV vaccine studies
- HIV-infected men who report that they are already on ART or in HIV care

## Exclusion Criteria (2)

- Any other reason or condition that in the opinion of the Investigator of Record (IOR) would interfere with participation, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives
- Men who have discordant HIV test results at Screening and Enrollment (i.e., at least one reactive or positive result and at least one non-reactive or negative result). These men will receive HIV counseling and will be referred for further diagnostic tests and care.

# Laboratory

- HIV testing
- CD4 cell count testing
- HIV viral load
- Hematology testing (CBC with platelets and differential)
- Chemistry testing (creatinine, phosphate, ALT/AST, bilirubin)
- Urine dipstick for protein and glucose
- HBV serology (HBsAb, HBsAg, HBcAb)
- Syphilis testing
- GC/CT testing (urine, rectal swabs, and pharyngeal swabs)
- Plasma storage
- Urine storage for substance use testing
- Rectal swab storage

# Recruitment

- Peer outreach: MSM hired and trained as peer outreach workers to approach MSM based on their personal connections to and knowledge of the MSM population
- Participant referral: eligible participants will be asked to refer their friends to participate in the study
- Indirect recruitment: distribution of announcements via actual and virtual “gay” venues and events
- Key figures referral: trusted persons with access to MSM networks who can distribute study information and encourage MSM to participate