Project Title: Prevalence and distribution of active sexually transmitted infections and bacterial vaginosis among symptomatic patients attending public health facilities in Soshanguve, South Africa

Project Overview:
Setshaba Research Centre, based in Soshanguve, Tshwane, South Africa, conducts HIV vaccine and prevention trials under the HIV Vaccine Trials Network and HIV Prevention Trials Network. For this project, the scholar will work with an immunologist as the mentor, and will be supported by the community engagement and laboratory staff, other experienced researchers at our center, and a collaborating statistician at the South African Medical Research Council. The project will require about 10 months at our center. The scholar will have the opportunity to interact with potential participants who are symptomatic for sexually transmitted infections (STIs), obtain their consent, administer a questionnaire and manage specimens with the guidance and support of the community engagement team. She/he will then learn to process the specimens to prepare it for conducting molecular testing. This involves firstly isolating nucleic acids (DNA/RNA) using an automated nucleic acid extraction system. The scholar will then perform Real-Time multiplex PCR assay that will be able to detect a wide range of pathogens that cause the essential STIs and bacterial vaginosis. Thereafter, the scholar will analyze the data with guidance from the mentor and statistician, and will prepare an oral/poster presentation and a manuscript for publication with assistance from the other investigators.

Project Summary:
This study aims to conduct STI screening to investigate the prevalence and distribution of essential STIs and bacterial vaginosis among symptomatic patients attending public health facilities in Soshanguve, South Africa. The objectives of the study are:
- To identify suspected cases of essential STIs and/or bacterial vaginosis among patients attending Department of Health STI clinics by collecting clinical and socio-demographic data.
- To perform molecular testing to determine possible etiological agents by using two different panel assays to cover majority of essential STIs and bacterial vaginosis.
- To determine the prevalence of essential STIs and bacterial vaginosis among the sub-groups (gender, age groups) included in the study.

We will aim to enroll 500 participants into the study. After a written informed consent has been obtained from each study participant, a semi-structured questionnaire will be used to collect socio-demographic and clinical data. For male participants, 10–30 ml of first-catch urine will be self-collected by each participant. For female participants, a vaginal swab will self-collected by each participant. Samples will be labelled and transported at a temperature of 2–25 °C to the laboratory where it will be processed to prepare it for conducting molecular testing. This involves firstly isolating nucleic acids (DNA/RNA) using an automated nucleic acid extraction system. Real-Time multiplex PCR assay using one panel of tests for male participants and two panels for female participants will then be performed that will be able to simultaneously detect a wide range of pathogens that cause the essential STIs and bacterial vaginosis. Panel A (STI Essential Assay) will detect *C. trachomatis*, *N. gonorrhoeae*, *T. vaginalis*, *M. genitalium*, *M. hominis*, *U. urealyticum* and *U. parvum*. Panel D (Bacterial vaginosis) will detect *G. vaginalis* (GV), *A. vaginae* (AV), *Megasphaera type 1* (Mega1), *BV-associated bacteria 2*, *Mobiluncus spp.* (Mob), *B. fragilis* (BF), *Lactobacillus spp.* (Lacto).

The results will be reported as:
- Frequency and percentages of reported clinical symptoms and socio-demographics (age, sex, etc.)
- Proportion of patients with a suspected essential STI and/or bacterial vaginosis confirmed by PCR
- Possible etiological agents based on the two different panel assays.
- Prevalence of STIs and bacterial vaginosis among the sub-groups (gender, age-groups)

If COVID-19 restricts the scholar from working onsite, then all data collection and PCR testing will be performed by site staff. The scholar will subsequently work with the statistician and other investigators to analyze and interpret the data, prepare a poster/oral presentation and write up the findings for a publication remotely. Alternatively, the samples can be collected by site staff, batched and stored, and the scholar will be able to conduct PCR testing and subsequent processes onsite when COVID-19 restrictions are lifted sufficiently.

Regulatory requirements for the project and plans for completing them:
The proposal will be submitted to the University of Witwatersrand Human Research Ethics Committee in January 2022. Approval will be obtained before the project starts in May as it generally takes 3 months for approval. The scholar will be required to complete GCP training; virtual or online courses are available.

Expected Deliverables:
The scholar will receive training on all study and reporting procedures:
- Obtaining informed consent
- Collection of clinical and socio-demographic data
- Processing of samples and performing of real-time PCR
- Analysis of data and preparation of results
- Manuscript writing

A poster/oral presentation at an HVTN Full Group meeting (May 2023)
Publication in a peer-reviewed journal.

Project Contact Person(s) (Name, Email):
Dr Ayman Osman (AOsman@setshaba.org.za) - Mentor
Dr Athmanundh Dilraj (ADilraj@setshaba.org.za)