Project Brief: Integrating expedited partner STI therapy during PrEP delivery for young women

Full Title of Study/Programme	Integrating expedited partner STI therapy during PrEP delivery for young women Short Title: (In development)
Technical Focus Area/Key Words	Sexually transmitted infections, pre-exposure prophylaxis, point of care testing, expedited partner therapy
Rationale	Rates of curable sexually transmitted infections (STIs) are on the rise, with South Africa having some of the highest STI rates globally. South Africa is also home to the highest HIV-1 incidence in the world, which peaks among young women ages 15-24 years of age. With the advent of oral pre-exposure prophylaxis (PrEP) as a highly effective strategy to prevent HIV-1 infection, South Africa and other high incidence countries are actively working to provide PrEP to key populations at highest risk for HIV-1. However, PrEP is not effective against other STIs and untreated STIs can increase susceptibility to HIV-1 infections. A 2019 WHO technical brief highlighted the importance of utilizing PrEP programs to optimize efforts to reduce STIs among those at highest risk, including adolescent girls and young women (AGYW). This proposal supports global efforts to substantially reduce STIs in key populations as part of the 2030 Sustainable Development Goals (goal 3.3) and the South African National Strategic Plan [NSP] for HIV, Tuberculosis and STIs 2017-2022 (goal #1). We aim to advance the field by implementing a multidisciplinary approach to inform point-of-care (POC) diagnostic STI screening combined with expedited partner therapy (EPT) for AGYW using PrEP for HIV-1 prevention. Our findings will provide essential knowledge for clinicians and policy makers to make improvements in STI screening and treatment that will lead to reductions in rates of persistent STIs and improvements in AGYW sexual reproductive health.
Primary Objectives	• To estimate the incidence of STIs (*Chlamydia trachomatis* -CT, *Neisseria gonorrhoeae* - NG, and *Trichomonas vaginalis* - TV) among AGYW initiating PrEP who received POC STI testing plus EPT and those who received POC STI testing and declined EPT. • To assess the acceptability of POC STI testing plus EPT for women initiating oral PrEP and their partners who received EPT and its impact on exposure to related social harms. Estimate the cost of implementing rapid POC diagnostic STI testing and EPT for AGYW in South Africa using PrEP compared to standard syndromic management.
Secondary Objectives	In development
Tertiary Objectives	In development
Primary Endpoints/Outcomes	• Incidence of recurrent STIs among AGYW who received POC STI testing with and without EPT • Acceptability of POC STI testing plus EPT for women initiating oral PrEP and their partners who received EPT and its impact on exposure to related social harms

	Cost of implementing POC STI testing plus EPT for women using PrEP
Secondary Endpoints/Outcomes	In development
Tertiary Endpoints/Outcomes	In development
Study Design	Prospective cohort study with a qualitative component
Study arms	AGYW initiating PrEP receiving POC STI testing and EPT AGYW initiating PrEP receiving POC STI testing and declining EPT
Study population	Sexually active, HIV-negative AGYW, 16-24 years old, positive for NG/CT at screening, interested in initiating PrEP, not desiring pregnancy for the duration of study participation, willing to return for quarterly study visits and with no contraindications to emtricitabine (FTC) or Tenofovir Disoproxil Fumarate (TDF).
Study sample size	400 AGYW
Follow up/duration	12 months per woman
Study/Programme sites	Hillbrow, Johannesburg
Study/Programme duration	In development
Intervention	POC STI testing and EPT
Operations	The study team will define key metrics for trial conduct
Investigators	Wits RHI Dr. Thesla Palanee-Phillips, Co-Principal Investigator Dr. Yuthika Naidoo, Co-Investigator Ms. Krishnaveni Reddy, Co-Investigator
Other Partners & Collaborators	University of Washington • Assistant Prof. Jennifer Balkus, Co-Principal Investigator • Dr. Jennifer Velloza, Co-Investigator • Associate Prof. Ruanne Barnabas, Co-Investigator • Assistant Prof. Jennifer Ross, Co-Investigator • Prof. Elizabeth Brown (also Fred Hutchinson Cancer Research Center) , Co-Investigator Prof. Jane Simoni, Contributor
Sponsors/Donors	National Institutes of Health (NIH); Grant No.: 1R01AI155000-01A1
Linked Sub Studies and post grad projects	In development
Publications/key presentations to date	N/A
Progress Update as at 21 Oct 20	Formative research protocol, informed consent forms and interview guides developed and submitted to Wits RHI Research Review Committee (RRC). Ethics submission pending
Frequency of donor narrative report	Every 3-6 months (To be decided)
Overall Study/Project Contact	Dr. Thesla Palanee-Phillips (tpalanee@wrhi.ac.za)
Briefing owner and date	Krishnaveni Reddy, 21 October 2020