

## Demonstrating effective delivery of daily oral HIV pre-exposure prophylaxis (PrEP) as part of an HIV combination prevention intervention among young women at high HIV risk, female sex workers and men who have sex with men in Kenya (PrEP Demonstration Project)

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### Introduction

According to the 2009 Modes of Transmission Study (2009), key populations – on average - contributed to 33% of all new HIV infections in Kenya. These high rates of new infections suggest that existing methods of HIV prevention and interventions are not sufficient and additional modalities are needed. While combination prevention has been offered as a tool for reducing new HIV infections, the concept of “combination” is not properly defined, standardized nor clearly understood. The bio-medical toolkit for HIV prevention offered in Kenya includes male circumcision, male and female condoms, STI treatment, use of ARVs for those who are HIV positive and to prevent vertical transmission and ARVs as pre and post exposure prophylaxis medication (PrEP and PEP). Despite the existence of standard of care in Kenya, there lacks defined package of interventions tailored to the needs of diverse subgroups such as young women at high HIV risk, Female sex workers (FSW) and MSM. This project will focus on MSM, FSW and young women.

### HIV Pre- Exposure Prophylaxis (PrEP)

HIV PrEP is the use of an antiretroviral drug to block the acquisition of HIV infection in uninfected people. Currently, Truvada™ has been established as an effective drug for HIV PrEP. As promising as PrEP may be as a HIV prevention tool, it has brought with it many questions and new challenges regarding its implementation in a theoretical world and within HIV behavioral interventions. There is little agreement on the clinical protocols, public health infrastructure required, community education, provider training, need for medical monitoring and adherence, optimal delivery package and clinical capacity necessary for PrEP to be implemented successfully on a national level. With financial support from the Bill and Melinda Gates Foundation, this project will begin to provide answers necessary for the scale up of PrEP including: a) who needs HIV PrEP; b) what is required in public and private facilities to effectively deliver PrEP as part of a combination of HIV prevention packages; c) the optimum adherence and retention strategies in delivering PrEP in routine service delivery settings; d) the cost of implementing HIV PrEP.

### Aim

This project aims to demonstrate how daily oral HIV pre-exposure prophylaxis (PrEP) might be delivered as part of an HIV combination prevention package among young women at high HIV risk, FSWs and MSM.

### Outcomes

The targeted outcomes are: (a) Correct identification of young women, FSW and MSM at high risk of HIV and in need of PrEP correctly, (b) Demonstrate the Effective delivery of oral HIV PrEP in a real world setting, and (c) Sustained uptake and adherence to oral PrEP among young women (YW) at high risk of HIV, MSM and FSW

### Demonstration project design

The demonstration project will use a prospective cohort design, enrolling 2,100 eligible participants and following them up at multiple intervals over the course of 12 months. Individuals will attend 6 visits at the project sites over the course of the project. In between some visits, they will return to the pharmacy to obtain a refill of PrEP and counselling on adherence and medication side effects