

Project Title:

Demonstration of Pre-Exposure Prophylaxis (PrEP) among MSM, TG, and PWID with substantial risk of HIV

The rationale of the project:

Myanmar has a concentrated HIV epidemic among key populations. Based on Integrated Bio- Behavioral Surveillance (IBBS), HIV prevalence rates are estimated as high as 34.9% among people who inject drugs (PWID)¹, and 14.6% among female sex workers (FSW)² and 11.6% for men who have sex with men (MSM).³ Prevalence data among Transgender Women (TG) in Myanmar is unknown. Globally, transgender women have some of the highest concentrated HIV epidemics in the world with laboratory-confirmed prevalence up to 40%.⁴ Moreover, these populations have a higher estimated prevalence in specific regions- states of the country, showing the urgent need to reinforce prevention at the sub-national level to sustain the reduction in new infections among key populations.

Among the general adult population, there has been good progress towards reducing the HIV prevalence from 0.9% in 2000 to 0.6% in 2017.⁵ In addition, progress was also made in reducing the number of new HIV infections from 29,000 in 2000 to 11,000 in 2018. However, there is a missed opportunity to prevent new infections among those at substantial risk with nearly 28% of new infections among PWID, 13% among MSM, 23% among clients of sex workers, and 24% among 'low-risk women'.⁷ New infections among TG in Myanmar is unknown.

Therefore, effective HIV prevention in the country hinges on the implementation of a range of evidence-informed "combination prevention" strategies. Myanmar has reinforced its commitment to HIV prevention through joining the Global HIV Prevention Coalition in May 2018, which includes priority focus on prevention among key populations as well as the adoption of PrEP.

In September 2015, WHO recommended the use of PrEP for people at substantial risk of HIV as part of a combination HIV prevention strategy. These recommendations were released following a number of trials on PrEP showing that when taken consistently and correctly, PrEP reduced the chances of HIV infection by more than 90% from condom-less sex²⁴ and by over 70% from injecting drugs²⁵. In addition to high personal protection, PrEP confers significant public health benefits through rapid scale-up to populations at substantial risk. New approaches for HIV prevention are still required in Myanmar as it is estimated that around 11,000 people were infected in 2018 and there are approximately 30 new infections per day²⁶. The national technical consultation on PrEP in April 2019, therefore, came to a consensus on the adoption of PrEP as one of the options for HIV combination prevention, augmenting the ongoing prevention initiatives in the country.

This project aims to develop, implement and evaluate the uptake, feasibility and effectiveness of PrEP among MSM, TG in Yangon, and PWID in Kachin State and Northern Shan State with a substantial risk of HIV.

Methodology:

The project will be a mixed method prospective cohort study to demonstrate the feasibility of delivering PrEP as a component of combination prevention with the additional qualitative

method to explore users' perspectives on acceptability, adherence and risk behaviors, also providers' perspectives on barriers to delivering PrEP.

Brief stepwise explanation of the procedure of the project

With the funding support from USAID/PEPFAR and Global Fund, and the technical support and guidance from Ministry of Health (MoH), National AIDS Program (NAP) and USAID HIV/AIDS Flagship (UHF) Project will implement a demonstration project to provide PrEP as a component of combination prevention for key populations including MSM, TG, and PWID with substantial risk of HIV infection in Myanmar. Aligned with recommendations from the National HIV Technical Strategic Group (TSG) meeting and National PrEP SOP, the PrEP demonstration project will be led by the National AIDS Program (NAP) and implemented under the UHF Project by its implementing partners, Population Services International (PSI) and Medical Action Myanmar (MAM) in Yangon for MSM and TG population and Asian Harm Reduction Network (AHRN) in Kachin for PWID population.

Community sensitization, awareness-raising, health education, and demand creation will be provided through a peer-led and community-based approach including the use of social media campaigns. The PrEP demonstration project will be implemented by partners under the close supervision of NAP using (Tenofovir 300mg/ Emtricitabine 200mg) or (Tenofovir 300mg/ Lamivudine 300mg) to a total of 2200 PrEP users in Yangon, Kachin and Northern Shan State including MSM, TG, and PWID with substantial risk of HIV infection.

Potential ethical issues

PrEP demonstration projects are primarily aimed at identifying the best practices to implement and scale-up PrEP delivery in Myanmar to prevent new infections. There is already extensive research and evidence available globally.

Demonstration projects on PrEP will adhere to all principles of the ethical conduct, including confidentiality of all participants' data, informed consent (though will be different and adapted context due to the nature of the project and target population), confidentiality, privacy, and data protection. Participation would be voluntary and ensure that the participants fully understand the implication of their decision to use PrEP.

Privacy and confidentiality will be given utmost priority building on the current system of working with key populations who are often criminalized and discriminated against in their local communities. While analyzing data for the purpose of the study, data obtained from the facilities would be anonymized and mechanisms will be put in place to ensure that confidentiality is maintained.

The projects will also address key ethical issues specific to demonstration projects that arise during the planning, implementation, and post-project phase including meaningful community engagement and wide dissemination of the findings and lessons learned.

Ethical committee approval for the implementation of the demonstration project will be sought from the Institutional Review Board (IRB) in Myanmar.

Expected outcomes and utilization

The results will be analyzed and utilized to support the development of the National PrEP policy to scale up the coverage of PrEP among the key populations and people with substantial risk of HIV in Myanmar.