

## **Proposal Summary**

### **a) STUDY TITLE:**

EFFECTIVENESS AND EFFICACY OF IMPLEMENTATION PROJECT  
ON BUPRENORPHINE MAINTENANCE TREATMENT FOR OPIOID DEPENDENCE  
IN MYANMAR

### **b) RATIONALE OF THE STUDY**

It has been estimated that there are about 93,000 people who inject drugs (PWID) in Myanmar, almost all of whom inject heroin. Heroin dependence is a devastating, chronic disorder with adverse consequences in almost all the areas of patients' lives including enhanced vulnerability to blood borne viral infections like HIV. In Myanmar, a sizeable number of PWID are living with HIV.

In response to the rising epidemic of HIV associated with drug use, Myanmar has initiated comprehensive programs aimed at preventing HIV transmission among PWID. Among these, Opioid substitution Therapy (OST) using Methadone is especially important, which at present covers about only 20000 PWID.

Some of the reasons cited for low coverage of methadone include long distance to travel, long induction period, difficulty in accessing take-home dose, and limited availability of satellite dispensary models<sup>1</sup>. Buprenorphine as OST comes across as a very promising option in this regard. Buprenorphine has shorter induction period, and better safety profile particularly in the combination formulation of Buprenorphine-Naloxone (BPN-N). Thus, there is possibility of take-home dispensing. There is substantial research available showing effectiveness of buprenorphine<sup>2</sup>. In view of this, it has been decided to implement buprenorphine-based OST as a pilot project in two locations in Myanmar.

### **c) OBJECTIVES**

- 1) To recruit the clients selected for receiving buprenorphine-based OST at the participating clinics in Yangon Region, Mandalay Region and Kachin State
- 2) To initiate the clients with buprenorphine-based OST at the assigned hospitals in Yangon Region, Mandalay Region and Kachin State
- 3) To document the effectiveness and feasibility of implementation of buprenorphinebased opioid substitution therapy for opioid-dependent people who inject drugs in Myanmar (with the overall goal to enhance the coverage of OST in Myanmar).

### **d) METHODOLOGY**

**Study Design:** Prospective observational design (based on review of routinely maintained clinical records)

**Setting:** The project will be implemented at three sites: (a) Yangon Mental Health Hospital (b) Myitkyina Drug Treatment Hospital, Kachin (c) Mandalay Drug treatment hospital.

<sup>1</sup> The National Strategic Framework on Health and Drugs (under publication)

<sup>2</sup> Connock M, et al (2007). Methadone and buprenorphine for the management of opioid dependence: a systematic review and economic evaluation. Health Technology Assessment. 11:1-171.

**Participants:** As this is not a study with an experimental design, all participants would be those who have been selected for receiving buprenorphine-based OST at the participating clinics. The criteria for eligibility of OST with buprenorphine will be similar to the criteria currently being employed in Myanmar for suitability of OST using methadone:

**Instruments:**

• **Drug Treatment Information Card**

The information of socio-demographic profile, substance use history, details of injecting drug use, risk behaviours, diagnosis of opioid dependence, types of treatment and outcome of treatment are included.

Treatment related details will be captured during each follow-up assessments. This will include mean dose of BPN used, retention on BPN, adherence rates on BPN, side-effects of BPN (using a side-effect checklist).

**e) BRIEF STEPWISE EXPLANATION OF THE PROCEDURE OF THE STUDY**

The staff recruited at each of the implementation sites will be trained in all the aspects of delivery of OST using buprenorphine with the help of standard treatment guidelines, including the process of record maintenance using the formats (listed above). This data will be accessed and analysed to provide information about feasibility of implementation of OST with buprenorphine in Myanmar. The record maintenance schedule will be as per follows:

**Time period Records to be filled-in**

**At the entry into treatment** • Intake Assessment comprised of structured questionnaire

- WHO ASSIST
- Maudsley Addiction Profile (MAP)

**Detailed Follow-up**

**assessment (Every month)**

**while the treatment is**

**ongoing till 18 months**

- Maudsley Addiction Profile (MAP)
- Clinical Opioid Withdrawal Scale (COWS)
- Treatment related details

This data will be digitally entered and analyzed to explore the feasibility of implementing OST with buprenorphine in Myanmar.

**f) POTENTIAL ETHICAL ISSUES**

Standard guidelines for MMT in Myanmar will be adopted and customized for implementing OST with Buprenorphine. All patients entering the treatment will provide written informed consent. Privacy and confidentiality will be ensured.

**g) EXPECTED OUTCOMES AND UTILIZATION:**

The expected outcomes of the study would include information on the feasibility of implementation of OST using buprenorphine

3 Department of Medical Services, Ministry of Health and Sports and World Health Organisation, Myanmar (2019). Guidelines on Methadone Maintenance Therapy in Myanmar (3rd Edition). Yangon: World Health Organisation