

# TOOLKIT ON GOVERNANCE OF OPIOID AGONIST MEDICATION TREATMENT:

Methadone and Buprenorphine

June 2008

**DISCLAIMER**

The views expressed in this publication are those of the authors and not necessarily those of the Australian Agency for International Development (AusAID).

# Acknowledgements

This Toolkit, supported by the Australian Government through the AusAID Illicit Drugs Initiative, was developed by Drug and Alcohol Services South Australia's WHO Collaborating Centre for Research in the Treatment of Drug & Alcohol Problems at the University of Adelaide, with the assistance of AIDS Projects Management Group. The main authors were Palani Narayanan, Robert Ali and Robyn Vial, assisted by agencies and individuals in several countries. Peter Lawrinson authored the section on Monitoring and Evaluation. The authors would like to acknowledge all the people who contributed by providing data, facilitating site visits, reviewed drafts and provided valuable comments and suggestions. In particular the authors would like to thank the following:

## **CAMBODIA**

- i. Prof. Ka Sunbaunat - Director, National Programme for Mental Health, Ministry of Health
- ii. Dr. Chhit Sophal - Deputy Director, National Programme for Mental Health, Ministry of Health
- iii. Dr. Meas Vyrith - Director, Laboratory, Secretariat-General, National Authority for Combating Drugs (NACD)
- iv. Dr. Thong Sokunthea - Deputy Director, Department of Legislation, Education and Prevention, Secretariat - General, National Authority for Combating Drugs (NACD)
- v. H. E. Dr. Teng Kunthy - Secretary-General, National AIDS Authority (NAA)
- vi. H. E. Dr. Ly Penh Sun, Deputy Director, National Centre for HIV/AIDS, Dermatology and STI's (NCHADS)

## **LAO PDR**

- i. Dr. Kou Chansina - Acting Vice-Chair of LCDC
- ii. Dr. Bounpheng Sodouangdenh - Dep. Director –Dept of Curative Medicine
- iii. Dr. Vannareth Thammavongsa - Director of Drug Control Unit
- iv. Assoc. Prof. Dr. Sisouk Vongphachanh - Head of Mental Health Department
- v. Dr. Bouavanh Southivongh – Ministry of Health



## **MYANMAR**

- i. Dr. Aung Thaw – Senior Consultant Psychiatrist/ Project Manager (substance Abuse), Drug Dependency Treatment and Research Unit, Mental Health Hospital

## **THAILAND**

- i. Dr. Prat Boonyawongvirot - Permanent Secretary, Ministry of Public Health
- ii. Dr. Sriwanna – Drugs Specialist, Ministry of Public Health
- iii. Dr. Sithisat Chiamwongpaet – Director, Bangkok Metropolitan Administration
- iv. Ms. Aumphorpun Buavirat – Bangkok Metropolitan Administration
- v. Dr. Viroj Sumyai - Ass.Sec Gen of Food and Drugs Administration, MOPH.
- vi. Dr. Apinun Aramrattana - Deputy Director, Research Institute for Health Sciences, Chiang Mai University
- vii. Dr. Viroj Verachai – Deputy Director, Thanyarak Institute
- viii. Ms. Sivalee Kasemsilpa – Thai Harm Reduction Network



## **UN AGENCIES**

- i. Mr. Gray Sattler – UNODC Regional Office, Bangkok
- ii. Ms. Sonia Bezziccheri – UNODC Regional Office, Bangkok
- iii. Mr. Patrick Brenny - UNAIDS, Bangkok
- iv. Dr. Graham Shaw – WHO, Cambodia
- v. Dr. Phauly Tea – UNODC, Cambodia
- vi. Dr. Leik Boonwat – UNODC, Lao PDR
- vii. Dr. Khamnoan Hsam – UNODC, Lao PDR
- viii. Dr. Michael Hahn – UNAIDS Lao PDR
- ix. Dr. Michael Hassett - AusAID Lao PDR
- x. Dr. Michael Hahn - UNAIDS Lao PDR
- xi. Dr. Oscar Barreneche – WHO, Myanmar
- xii. Ms. Hlaing Hlaing Htun – WHO Myanmar
- xiii. Mr. Chawalit Tantinimitkul – WHO Thailand
- xiv. Dr. David Jacka, WHO Vietnam
- xv. Dr. Nicolas Clark – WHO Geneva

## **AUSTRALIA**

- i. Mr. Dave Burrows, APMG
- ii. Dr. Alex Wodak, St. Vincent's Hospital
- iii. Ms. Jo Hayter, Turning Point

## **OTHER**

- i. Dr. Ratna Mardiaty – Indonesia
- ii. A/Prof. Min Zhao – China



## ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ARV	Anti Retro Viral
AOD	Alcohol and Other Drugs
BBV	Blood Borne Viruses
BSS	Behaviour Surveillance Survey
CBT	Cognitive Behaviour Therapy
DOT	Directly Observed Therapy
FDA	Food and Drug Administration
GP	General Practitioner
HIV	Human Immunodeficiency Virus
Hep C	Hepatitis C
ID	Identity
INCB	International Narcotics Control Board
LCDC	Lao Commission for Drug Control
MMT	Methadone Maintenance Treatment
MOH	Ministry of Health
MOPH	Ministry of Public Health
MoU	Memorandum of Understanding
M&E	Monitoring and Evaluation
NIH	National Institute of Health - USA
NAA	National AIDS Authority
NACD	National Authority for Combating Drugs
NGO	Non-Governmental Organisation
ONCB	Office of the Narcotics Control Board
OAM	Opioid Agonist Medication



OAMT	Opioid Agonist Medication Treatment
QMS	Quality Management Systems
SEA	South East Asia
SOP	Standard Operating Procedures
STI	Sexually Transmitted Infections
UNODC	United Nations Office of Drugs and Crime
UNAIDS	United Nations AIDS Program
WHO	World Health Organization





# Contents

<b>INTRODUCTION</b>	<b>9</b>
Purpose of this Toolkit	9
Target Audience	10
Principles of Effective Treatment for Opioid Dependence	10
Governance of Opioid Agonist Medication Treatment Programs	12
Case Study: Singapore	13
<b>SECTION 1: METHADONE &amp; BUPRENORPHINE</b>	<b>15</b>
1.1 What is Methadone?	15
1.2 What is Buprenorphine?	15
1.3 Why use Opioid Agonist Medication Treatment?	15
1.4 What are the benefits of Opioid Agonist Medication Treatment?	15
1.5 What is the difference between substitution treatment and maintenance treatment?	16
1.6 What level of participation should we expect from family members of drug users?	17
1.7 How can a drug user/patient be involved in the program?	18
1.8 WHO has included methadone and buprenorphine in the WHO Model list of Essential Medicines. What does this mean?	18
<b>SECTION 2: ISSUES IN IMPLEMENTATION</b>	<b>21</b>
2.1 Stages of implementation	21
2.2 Location of services (Sites)	23
2.3 Staff	24
2.4 Informed Consent	28
2.5 Documentation and Confidentiality	28
2.6 Milestones in Treatment	29



2.7	Linking Opioid Agonist Medication Treatment Programs to HIV Treatment	30
2.8	Psychosocial support programs	31
2.9	Ensuring continuity and suitable linkages in the process of opioid agonist medication treatment implementation	33
2.10	Summary: Minimum Required Components for an Opioid Agonist Medication Treatment Program	34
<b>SECTION 3: GOVERNANCE TOOLS</b>		<b>37</b>
Tool 1: Guidance Note on Roles and Responsibilities of Government Ministries and Agencies		37
Tool 2: Guidance Note on Roles and Responsibilities of Non-Government Agencies		48
Tool 3: Guidance Note on Development of National Policies and Guidelines		50
Tool 4: Guidance Note on Importation, Storage and Distribution of Opioid Agonist Medication		54
Tool 5: Guidance Note on Accreditation of Opioid Agonist Medication Clinics		56
Tool 6: Guidance Note on Training, Authorisation and Review Process for Prescribers		59
Tool 7: Guidance Note of Clinical Supervision		64
Tool 8: Guidance Note on Costs and Budget for Opioid Agonist Medication Treatment Programs		72
Tool 9: Guidance Note on Monitoring and Evaluation		75
<b>SECTION 4: CHECKLISTS</b>		<b>84</b>
Checklist 1: Introduction of a Pilot Opioid Agonist Substitution Treatment Program		85
Checklist 2: From pilot to scale-up		90
Checklist 3: Opioid Agonist Substitution Treatment Program in Prison Settings		94
<b>SECTION 5: GLOSSARY</b>		<b>97</b>



# Introduction

## PURPOSE OF THIS TOOLKIT

The purpose of this toolkit is to document the systems and governance mechanisms that need to be in place when a country decides to;

- i. Introduce opioid agonist medication treatment programs such as methadone or buprenorphine for the treatment of heroin addiction
- ii. Scale-up opioid agonist medication treatment programs
- iii. Introduce opioid agonist medication in correctional facilities such as prisons and drug rehabilitation centres.
- iv. Ensure the high quality and sustainability of opioid agonist medication treatment programs

The Toolkit aims to assist governments and policymakers in introducing opioid agonist medication treatment programs that are safe and effective and of the highest quality. It provides National and Provincial Governments as well as Clinical Directors with:

- > A framework for treating opioid dependence that integrates HIV prevention, treatment and care
- > A framework for clinical governance which includes;
  - i. Legislative requirements, quality control and accreditation
  - ii. Guidance for infrastructure and clinical requirements
  - iii. Principles for staff mentoring and supervision
  - iv. Program monitoring, evaluation and reporting.

This toolkit is not a clinical guideline for methadone or buprenorphine prescribers. Such guidelines exist within countries that have already started implementing opioid agonist medication treatment programs such as Thailand and Myanmar. Clinical Guidelines from WHO will also become available in the near future and found at [http://www.who.int/substance\\_abuse/en/index.html](http://www.who.int/substance_abuse/en/index.html)



## TARGET AUDIENCE

This toolkit is produced to assist senior government officials in the key agencies that are involved in the introduction and implementation of methadone or buprenorphine treatment programs. The toolkit can be used by Senior Health Officials as a tool to develop a Methadone or Buprenorphine Treatment Strategy or a National Policy on Drug Treatment. The Toolkit is also helpful in assisting the management of drug treatment programs at the national, provincial and district levels.

The toolkit will be useful to multisectoral, national level committees which oversee the development and implementation of national opioid agonist medication treatment programs, such as methadone and buprenorphine, by defining the roles and responsibilities of different government and non-government agencies involved in such programming.

## PRINCIPLES OF EFFECTIVE TREATMENT FOR OPIOID DEPENDENCE

- i. The first principle of effective treatment is the fact that there is no single treatment that is appropriate for all individuals who are dependant. Simply said, countries need to invest in a range of drug treatment options including opioid agonist medication treatment programs where heroin addiction is a significant public health problem.
- ii. Drug users are people with multiple needs, problems and issues. Effective treatment must attend to all the multiple bio-psychosocial needs of the individual, not just their drug use. In this regard, detoxification is not an effective drug treatment as it is a short-term intervention that only deals with the removal of the drug and does not tend to the other needs and causes of drug use. Detoxification is only the first stage of treatment and by itself does little to change long-term drug use. However, ready access to detoxification should be part of the range of interventions available as it may help introduce some drug users to the variety of other interventions.
- iii. Drug treatment must be readily available and accessible for individuals who need it. It is important that treatment is available in all provinces and districts where there are affected communities and not just in capital cities. The availability and accessibility of drug treatment will also depend on the laws and regulations within the country. For example, for methadone treatment programs to be effective there needs to be legislation that will enable the importation and use of methadone in the country. If there are laws that prevent methadone from being imported, the program cannot be introduced or scaled up to reach the necessary coverage of drug users.
- iv. It has also been proven that drug treatment is most effective when patients are retained in treatment for an adequate period of time. When compared, patients who stayed in treatment for a period longer than a year did better than patients who were in treatment for a few weeks or a few months. This is in part because when patients stay longer in treatment, the opportunities for behavioural interventions to take effect is also higher, resulting in better treatment outcomes.

- v. In treatment of opioid dependence, medications are an important element but they are not the only component. Years of research and experience show that counselling and other psychosocial support programs that deal with psychological and behavioural aspects of drug use are critical to effective treatment. The Cochrane Review of drug treatment found that adding counselling to methadone programs added a 30% improvement to the retention in treatment which in turn produced better outcomes.
- vi. Effective treatment results from close monitoring and appraisal of the treatment methodology and outcomes. Treatment regimens and plans need to be assessed and modified continually to accommodate changes in drug use patterns and behaviour among users.
- vii. Patients' progress and continuation of drug use in treatment should also be monitored. However, it must be remembered that such monitoring should be done for the benefit of the patient and not for the purpose of disciplinary action against the patient. For example, when a methadone patient returns a positive urine test sample, the result should be used to discuss the possible reasons for his/her continued drug use and to find solutions to these problems rather than resulting in recrimination against the patient or discontinuation of treatment.
- viii. Treatment programs should also provide assessment for HIV, hepatitis, TB, sexually transmitted infections and other infectious diseases and provide help and the means to modify behaviour. Once again, counselling and psychosocial support can be an excellent means of preventing infections.
- ix. When patients are diagnosed with co-morbid conditions, it is important that strategies for the treatment of co-morbidities be integrated with drug treatment programs. For example, HIV positive methadone patients will benefit greatly by receiving an integrated methadone and HIV treatment modality.
- x. Finally, it is important to remember that recovery from addiction can be a long-term process and often requires multiple episodes of treatment. Most drug users experience frequent relapse and remission.



## **GOVERNANCE OF OPIOID AGONIST MEDICATION TREATMENT PROGRAMS SUCH AS METHADONE MAINTENANCE TREATMENT AND BUPRENORPHINE MAINTENANCE TREATMENT**

Governance is recognised as an important component of improving the safety and quality of health care as poor treatment outcomes are often the result of health care system failures. Without proper governance systems, health services become vulnerable to abuse.

Good governance often makes the difference between good and poor treatment programs. Treatments can be interrupted due to lack of coordination among agencies and individuals involved. Treatment outcomes can be severely affected by low quality services.

In opioid agonist medication treatment programs, governance can be described as the institutions, processes, policies and laws affecting the way people direct, control and administer Methadone Maintenance Treatment (MMT) or Buprenorphine Maintenance Treatment (BMT). It defines the process of decision-making and the process by which those decisions are implemented. It also includes the relationship among the stakeholders and how they work together to achieve the goals of the program.

This toolkit focuses on the key themes in the governance of opioid agonist medication treatment programs including:

- i. Focus on accountability at all levels: describing the roles and responsibilities of governmental and non-governmental agencies
- ii. Implementing clinical care improvement processes: including accreditation processes and providing evidence-based practices
- iii. Ongoing workforce mentoring, support and supervision: providing training and authorisation of methadone prescribers and other staff involved in the program; and ensuring that staff capacity is continuously improved and maintained
- iv. Data and information to assist in decision-making: collecting key performance indicators and comparing these with other health care services to ensure that the treatment is of the highest quality; and stressing the importance of monitoring and evaluation
- v. Consumers at the centre of efforts to improve quality and safety: providing opportunity for responding to patient-related issues is key to quality improvement.



## **CASE STUDY: SINGAPORE**

The importance of good governance mechanisms can be demonstrated by analysing the implementation and subsequent ban on the use of buprenorphine in Singapore.

In the year 2000, concerned with increasing heroin use in the island republic, the Ministry of Health introduced buprenorphine as a treatment for addicted heroin users. This was seen as a good move considering the documented success of buprenorphine elsewhere in the world.

However, the implementation of the buprenorphine substitution program was not preceded by good governance mechanisms. Doctors who were not experienced with opioid treatment generally were not given in-depth training and supervision. There was a lack of monitoring and support for these doctors in implementing the program. Patients were allowed large take-away doses which created diversion and abuse.

By 2003, buprenorphine had become the widespread drug of choice among opioid users. Drug users had begun to mix buprenorphine with midazolam for its synergistic effect. More worryingly, they started to inject the drugs.

In 2006, reacting to media and community concern, the government of Singapore reclassified buprenorphine as a Class A drug similar to heroin which effectively removed it as a treatment option. This unfortunate turn of events was the direct result of the lack of a good governance system for oral substitution treatment including a lack of training and supervision for prescribers, and a lack of policy guidelines, national implementation policy or an effective monitoring mechanism.

This case study highlights the critical emphasis that should be placed on forward planning and governance mechanisms for the safe and effective implementation of oral substitution programs.

(source: Winslow, CAMP. Paper presented at Effective Approaches to Drug Treatment Workshop, Siem Reap, Cambodia, 2007)





# Section 1:

## Methadone & Buprenorphine

### 1.1 WHAT IS METHADONE?

Methadone belongs to the opioid family of drugs which includes morphine, codeine and heroin. Opioids are classed as depressant drugs as they work by slowing down the functions of the central nervous system. Methadone was developed in Germany in 1941 for the relief of pain. It was used as a treatment for heroin dependence in New York, USA, in 1964 and it is now recognised internationally as an effective method for treating opioid dependence.

### 1.2 WHAT IS BUPRENORPHINE?

Buprenorphine is a partial opioid agonist derived from the morphine alkaloid, thebaine. It has been used for the relief of pain in many countries since the 1980s and was first used as a substitution treatment in 1996 in France. Buprenorphine has similar efficacy to methadone in reducing illicit opioid use and has a superior safety profile, fewer adverse effects and less potential for drug interactions. Compared to methadone, retention in treatment appears to be of a lesser duration.

### 1.3 WHY USE OPIOID AGONIST MEDICATION TREATMENT?

Many people believe that it is preferable for heroin users to stop taking drugs altogether. Although for some heroin users this is achievable, for many others there is a high risk of relapse into heroin use. Research shows that drug addiction is not the failure of one's strength or will but is a chronic, relapsing medical condition that could affect any human being (WHO 2003, 2004). Opioid Agonist Medication Treatment has helped many people reduce the recurrence of compulsive heroin use.

### 1.4 WHAT ARE THE BENEFITS OF OPIOID AGONIST MEDICATION TREATMENT?

Research has shown that it can improve the health of heroin dependants in a number of ways:

- i. When administered in appropriate doses, patients are less likely to use heroin which is often contaminated with other substances.
- ii. Methadone and buprenorphine are taken orally (methadone) or sublingually (buprenorphine) which is safer than injecting heroin. This reduces the risks of sharing needles and other injecting equipment. This further reduces the chances of becoming infected with blood borne viruses such as HIV and hepatitis C.

- iii. Methadone and buprenorphine are legal and longer lasting than heroin and other opioids, and a patient needs only one dose a day which is often administered in a clinic. The patient is required to come to the clinic once a day, every day to take his/her dose. She/he is in constant contact with medical and other support staff. This routine encourages the patient to lead a balanced and stable lifestyle – including improved diet and sleep.
- iv. The routine also reduces stress among patients as they don't have to worry about their next 'hit' of heroin. The routine also means that patients have more time in their days and are healthier to look for work and maintain paid employment.
- v. When patients are able to secure employment, and the need to use heroin every 6-8 hours is eliminated, there is less reason to commit crimes. Criminal activities conducted to obtain heroin are reduced which means lower crime rates in the community as well as lower potential burden on the criminal justice system in the country.
- vi. Patients are also able to manage their withdrawal from heroin without serious illness or discomfort.
- vii. It is cheaper for both individuals and communities – for individuals, while there may be a dispensing fee at certain clinics, it is still cheaper than the cost of purchasing heroin for a few 'hits' in a day. For communities, treating drug users with methadone or buprenorphine is cheaper than the cost of crime within the community.

## **1.5 WHAT IS THE DIFFERENCE BETWEEN SUBSTITUTION TREATMENT AND MAINTENANCE TREATMENT?**

The two terms are usually used interchangeably. Substitution Treatment highlights the fact that methadone or buprenorphine is prescribed to the heroin user as a replacement drug. It identifies the fact that methadone or buprenorphine treatment does not necessarily eliminate the use of drugs (opiates) but substitutes one dangerous drug (heroin) with another less problematic drug (methadone or buprenorphine) to reduce the harmful consequences to the drug dependent person.

Opioid maintenance however highlights the fact that this treatment is a long term treatment where a drug user is given methadone or buprenorphine to replace his/her heroin addiction. The methadone or buprenorphine will be administered to the patient for as long as the patient may need it. Thus, the patient is 'maintained' on methadone until s/he decides in the future to stop using it. For some, that time will be measured in years and for a few it will mean for the rest of their life, much the same as a diabetic may be maintained on insulin.

## **1.6 WHAT LEVEL OF PARTICIPATION SHOULD WE EXPECT FROM FAMILY MEMBERS OF DRUG USERS?**

When a drug user enrolls in an opioid agonist medication treatment program, s/he may require a lot of support from family members (siblings, parents, partners, children). Their level of participation can sometimes mean the difference between success and failure of the patients' attempt to stay in treatment.

Families can be involved or can participate in the following ways:

- i. Financial support – this is especially important at the beginning stages of the treatment. The patient might not have a job and may need to depend on family members to pay for the cost of the treatment. Sometimes, even when the cost of the treatment is free, the patient may need to pay for transport to and from home and the clinic. There may also be a cost for the various tests that the clinic may require such as liver function tests or a HIV test. Other expenses include food, accommodation and/or clothes.
- ii. Physical Support. Once again, in the early stages of treatment, the patient may not have secured accommodation or employment. They may need help from family members to secure a job and earn a regular income. While searching for employment, they may need accommodation for themselves and children, if there are any. Another type of physical support could be periodically attending the clinic with the patient and meeting with the doctor to talk about the treatment and the progress made by the patient.
- iii. Emotional support. Some people say, 'once a junkie, always a junkie'. This derogatory saying also means that people are very suspicious of drug users even when they are in, or have been through, treatment. Drug users, who have come out of treatment, and methadone or buprenorphine patients, complain that very often their family members do not trust them even after their full recovery from heroin use. It is usually the case of "guilty before proven innocent" as the ex-drug user/patient is always the prime suspect when something goes missing at home. Situations like this can make patients feel unaccepted by family members. Their efforts in recovery are not appreciated and finally a lack of purpose to staying 'clean' develops. This can lead to relapse.

## **1.7 HOW CAN A DRUG USER/PATIENT BE INVOLVED IN THE PROGRAM?**

Drug users should not be seen as the problem. They are in fact, the key to the success or failure of the opioid agonist medication treatment program. As patients and consumers, they hold lots of information that is important for the development and success of the substitution treatment program.

Drug users / patients can be involved in the following ways:

- i. Providing information about the heroin using 'scene';
- ii. Feedback to clinicians about the patient perspective on the treatment and clinic staff;
- iii. Feedback about reasons for drop-outs among patients;
- iv. Feedback on the presence and influence of drug dealers at the treatment site;
- v. Developing a peer support group among patients that can provide psychosocial support.

## **1.8 WHO HAS INCLUDED METHADONE AND BUPRENORPHINE IN THE WHO MODEL LIST OF ESSENTIAL MEDICINES. WHAT DOES THIS MEAN?**

According to the World Health Organization Expert Committee on the Use of Essential Drugs 1999, drugs on the Essential Medicines list should:

- > Satisfy the health care needs of the majority of the population with a specific condition;
- > Be available at all times;
- > Be available in adequate amounts and in the appropriate dosage forms;
- > Be available at a price that individuals and the community can afford.

The inclusion of methadone on the Essential Drugs List took place in 2006. It is a global recognition that methadone is an effective treatment for heroin dependence. It is an agreement that methadone treatment produces many benefits that have been discussed earlier including the reduction in HIV transmission and crime.

By including methadone and buprenorphine in its Essential Drugs List, WHO recommends that all countries experiencing problems with heroin dependence and related HIV infections provide methadone as a possible treatment modality.

WHO also urges governments to make methadone and/or buprenorphine available and accessible for heroin dependent people. The world's leading health body also recommends that methadone is made available at a price that is affordable for drug users and their families who are seeking this treatment.

## REFERENCES:

1. Neuroscience of Psychoactive Substance Use and Dependence, WHO, 2004.  
[www.who.int/substance\\_abuse/publications/en/Neuroscience\\_E.pdf](http://www.who.int/substance_abuse/publications/en/Neuroscience_E.pdf)
2. Management of Substance Dependence (Fact Sheet), WHO, 2003.  
[www.who.int/substance\\_abuse](http://www.who.int/substance_abuse)
3. Legislating on Health and Human Rights: Model Law on Drug Use and HIV/AIDS. Canadian HIV/AIDS Legal Network, 2006.
4. Drug Info Clearinghouse, Australian Drug Foundation, Drug facts – Methadone.  
[www.druginfo.adf.org.au](http://www.druginfo.adf.org.au)
5. National Drug Strategy: National Pharmacotherapy Policy for people dependent on opioids. January 2007. Australian Government Department of Health and Ageing.
6. Opioid Treatment Program: Clinical Guidelines for methadone and buprenorphine treatment. November 2006. NSW Department of Health [www.health.nsw.gov.au](http://www.health.nsw.gov.au)
7. Canadian Health Network – Drug Info. [www.canadian-health-network.ca](http://www.canadian-health-network.ca)
8. The Methadone Handbook. Third Edition. Preston and Doerty, Australian Drug Foundation, 2006
9. Methadone Research Webguide, National Institute of Drug Use (NIDA), 2006.
10. Policy Brief: Reduction of HIV Transmission Through Drug Dependence Treatment – Evidence for Action on HIV/AIDS and Injecting Drug Use, WHO, 2004.  
[http://www.wpro.who.int/sites/hsi/documents/policy\\_brief\\_04\\_04.htm](http://www.wpro.who.int/sites/hsi/documents/policy_brief_04_04.htm)





# Section 2:

## Issues In Implementation

### 2.1. STAGES OF IMPLEMENTATION

The countries in South East Asia are at different stages of Opioid Agonist Medication Treatment Programs implementation. There are:

- i. Countries which are about to trial/implement methadone maintenance treatment such as Cambodia and Vietnam;
- ii. Countries which have implemented pilot programs in the last few years such as Myanmar;
- iii. Countries that are scaling-up their pilot programs such as Indonesia, PR China and Malaysia;
- iv. Jurisdictions which have an established program such as Hong Kong in PR China, and Thailand;
- v. Countries that have not begun to plan any methadone program such as the Lao PDR.

Thailand and Hong Kong are the only two examples where MMT was established before there was an HIV epidemic within the country/ jurisdiction. Hong Kong developed an island-wide methadone program in the 1970s as a national response to increasing crime rates. Experts believe that although public health was not the main motivation for the introduction of the program in Hong Kong, the wide scale implementation may have prevented an epidemic of HIV among drug users in Hong Kong today.

### PILOT PROJECTS

Countries in South East Asia have typically begun their opioid agonist medication treatment program implementation by first introducing a pilot project. Pilot projects are important and serve a particular purpose which is to identify the challenges and the feasibility of the treatment within the country's cultural context. However, pilot projects are inadequate to address public health priorities such as the rapid spread of HIV among injecting drug users. Pilot projects should be time limited (6 months to one year); their feasibility evaluated and scaled up to match the scale of the epidemic as soon as possible.

There is an abundance of research data available now to show that opioid agonist medication treatment programs such as methadone and buprenorphine work in various settings including in many Asian countries. Therefore, an implementation pilot of an opioid agonist medication treatment program should be a strategy to learn **how to operate the program** in the country rather than find out if it works in the country. Countries should be aware that during pilot period, the implementation of the program is being adapted to make it more effective.

An important contributor to the success of methadone or buprenorphine maintenance treatment is the duration of treatment. The longer the patient stays in treatment, the better the treatment outcomes. As such, it is important for governments to ensure the continuity of methadone treatment availability when starting a pilot project. A pilot project that is designed for 6 months should not mean that the project will stop at the end of the 6 months for evaluation. Governments should ensure the continuance of methadone or buprenorphine programs whilst the evaluation is being carried out; otherwise, the patients fall back to injecting heroin.

It is also important that pilot methadone or buprenorphine projects involve an adequate number of drug users. It is important to have at least 200 participants in the pilot project to have outcomes that can be assessed to determine issues of implementation. Similarly, the pilot project should enlist as many drug users as possible to ensure valid and sound feasibility data.

Sometimes, pilot MMT programs are seen as failures not because oral substitution treatment is ineffective but because the implementation of the pilot project was done in a poor and unsystematic manner. Some pilot projects fail to implement good training programs for prescribers or supervision of prescribers which makes the pilot vulnerable to abuse. This is clearly demonstrated by the case examples given in the Introduction section of this document.

## 2.2. LOCATION OF SERVICES (SITES)

As amended by the 1972 Protocol (6, 8), the 1961 Single Convention on Narcotic Drugs, is the principal international treaty regulating availability of opioids and methadone is regulated under this Convention. Buprenorphine is controlled under another international treaty – the Convention on Psychotropic Substances, 1971; some of the controls applied to buprenorphine are therefore less strict than those which apply to narcotic drugs such as methadone. For example, imports and exports of buprenorphine need not be reported to International Narcotics Control Board (INCB) on a quarterly basis but only on annual basis. For practical purposes, however, it is not crucial to differentiate between the control measures for methadone and buprenorphine, since, under the national legislation of many countries, buprenorphine tends to be controlled as a narcotic drug. This classification makes it difficult for methadone or buprenorphine to be distributed without the strict supervision of trained personnel. As such, OAMT is often implemented through government health centres and hospitals in Asia.

However it is important to note that globally, OAMT is dispensed successfully at the following locations or sites:

- i. **Government Health Centres or Primary Health Centres** – In Thailand and Indonesia, there are successful models of OAMT treatment implemented through these centres.
- ii. **General Hospitals** – In Malaysia, Myanmar and Indonesia, drug users receive treatment in hospitals.
- iii. **Mental Health Institutions** such as in China.
- iv. **Drug Treatment Centres** – In Thailand (Chiang Mai and Bangkok) Indonesia (Jakarta), Myanmar and some areas of China, these centres demonstrate good results in providing OAMT.
- v. **Prisons** – Prisons are an important place to provide methadone services as proven by many developed countries. In Asia, only Iran and Indonesia have methadone programs in prisons. However, there is now an increased awareness of this need in Asia and the world generally.
- vi. **NGO Drop In Centres** – Many drug users seek treatment in NGO centres because they receive non-judgemental treatment from staff who are often their peers. In Australia and Netherlands, some NGOs provide OAMT services.
- vii. **Private Clinics** – Private doctors can play an important role in scaling up OAMT. However, without proper accreditation and supervision this can also be open to abuse.
- viii. **Pharmacies** – Similar to private doctors, pharmacies are well placed in the community to dispense OAMT with proper supervision and monitoring.



- ix. **Village/Community structures** – At village level (in remote areas), OAMT can be delivered through the support of the local hospital. An example of this can be found in Northern Thailand where MMT is delivered to the Akha community in the Mae Chan province.

It is important to remember that the methadone dispensing systems outlined above have different strengths and weaknesses. For instance, Primary Health Care Clinics may be advantageous because they are easily accessed within communities. However these clinics are often also dealing with many other community health issues and can often be overwhelmed by the needs of drug users and OAMT patients. Nurses may not view drug users favourably and this may impact on patients coming to the clinic regularly to receive their doses. In some instances, OAMT programs commenced in hospitals are slow to expand to the community thus limiting the access to the services.

It is, therefore, important that suitable systems and sites are identified within a country with the participation of drug users, community groups, NGOs, and medical personnel.

### **2.3. STAFF**

#### **2.3.1 IN THE OPIOID AGONIST MEDICATION TREATMENT CLINIC, A TREATMENT TEAM USUALLY CONSISTS OF THE FOLLOWING PERSONNEL:**

- i. Medical doctor as prescriber
- ii. Nurses
- iii. Dispensers
- iv. Counsellors

Currently, no undergraduate or postgraduate courses exist for competencies in addiction and the treatment of addiction in Asia. Additional training and courses need to be provided for all the above staff to enable them to implement the programs effectively.

### **2.3.2 THE ROLE OF THESE HEALTHCARE PROVIDERS IN A METHADONE TREATMENT PROGRAM ARE AS FOLLOWS:**

#### **DOCTOR (MEDICAL DOCTOR AS PRESCRIBER)**

- > Medical and psychological assessment to identify the drug-related problems faced by patients
- > Development of a treatment plan which will include identifying the initial dosage and subsequent dose increment for patients
- > Management of intoxication and withdrawal by patients
- > Pharmacotherapy treatments
- > Treatment of medical co-morbidities
- > Management of psychiatric co-morbidities
- > Referral to clinicians with special skills for patients who may need it ( for example, referring patients who may need specialist care for HIV or for other illnesses)
- > Care of pregnant women and their newborn child

#### **NURSES**

- > Assistance to the doctor in screening and assessment of patients
- > Provision of information about drugs, methadone, buprenorphine and related issues to all patients
- > Management of intoxication and withdrawal – nursing aspects
- > Nursing support and assisting the doctor in all other aspects of treatment and care for patients: this includes primary care, immunisations, clinical observations, wound care and dressings
- > Provision of health education and additional information about medications
- > Undertaking home visits to discuss strategies with parents and co-dependents
- > Coordinating care, patient follow-ups and monitoring



## **DISPENSERS**

- > Ensuring that the right medication preparation (strength and quantity) is dispensed to the right patient (2 dispensers are required for this task)
- > Ensuring that patients have consumed their methadone or buprenorphine and chances of diversion are minimal or none
- > Observing patients for toxicity and withdrawal before and after dispensing
- > Provision of feedback to doctors regarding toxicity and withdrawals experienced by patients
- > Management of methadone and buprenorphine records and storage of medicines

## **COUNSELLORS**

- > Assistance in the assessment process including identifying drug and alcohol related issues among patients
- > Counselling, including motivational interviewing and relapse prevention
- > Provision of continued information and support regarding treatment, side effects and strategies to overcome challenges related to drug use
- > Patient follow-up monitoring and review
- > Case management of patients
- > Working with families of patients to ensure adherence to treatment
- > Referrals to clinicians with special skills especially in the area of mental health
- > Referrals to social welfare services

### **2.3.3**

Additional staff at a methadone clinic/site could involve;

- i. Social worker(s);
- ii. Peer worker(s);
- iii. Security guard(s).

#### **2.3.4**

The number of staff needed for each clinic or site will depend on the agreed staff-patient ratio. Again, this varies from place to place. However, for a site or clinic that treats 300 patients the following number and designation of staff are recommended;

- > 2 doctors
- > 2 dispensers
- > 2 nurses
- > 5 counsellors

It is important that additional doctors and nurses are identified to cover sick or annual leave and weekends.

Clinics operate most effectively when they cater for between 200-300 patients. Clinics with more than this number of patients may face overcrowding and logistical problems. One way of dealing with overcrowding is by having satellite dispensing sites. At satellite sites, only methadone and/or buprenorphine are dispensed. When patients require additional services, they are referred back to the main clinic to meet with the doctor or counsellor.

#### **2.3.5**

Apart from trained staff, adequate infrastructure is also important in ensuring effective service delivery. The opioid agonist medication treatment clinic should have:

- > A consultation room for the doctor
- > A medical check up room ( could be the same as the consultation room if big enough)
- > Counselling rooms
- > A room for peer activity
- > Toilets for male and female patients
- > Methadone/buprenorphine dispensing counter
- > A resting area

## 2.4 INFORMED CONSENT

Informed consent is a process in which a person learns key facts about a clinical trial or treatment, including potential risks and benefits, before deciding whether or not to participate in a study, research or treatment. Informed consent continues throughout the treatment.

Opioid agonist medication treatment (OAMT) should not be given to patients unless informed consent is obtained from patients. This means that before MMT or BMT can commence patients should be informed about:

- > the nature of treatment (including the aims, what methadone or buprenorphine can and cannot achieve, known benefits and disadvantages)
- > the service provider's "house rules" (including frequency of pick-up, urine testing, dosing hours, takeaway doses, clinic or pharmacy schedule of appointments, and rules regarding illegal behaviour such as violence, drug dealing and drug use)
- > how long the treatment will last
- > side effects and risks associated with taking methadone
- > how methadone or buprenorphine may affect activities such as driving motor vehicles and operating machinery
- > when patients will receive their first dose and subsequent doses
- > the risks of other drug use (including alcohol) while taking methadone or buprenorphine
- > how to obtain further information.

## 2.5 DOCUMENTATION AND CONFIDENTIALITY

The development and maintenance of accurate, complete and confidential medical records is a crucial component of care in MMT and BMT. Confidentiality of medical records of patients on opioid agonist medication treatment programs should receive special consideration so that these records are used for the clinical management of the individual and not for punitive purposes.

Staff from the opioid agonist medication treatment programs should not discuss patients or their condition with anyone unless required for referral or to receive a clinical second opinion. When this is necessary, the information should only be shared after receiving written approval from patient.

## 2.6. MILESTONES IN TREATMENT

Historically, drug treatment programs have had punitive approaches so that any drug use during treatment is seen as failure of the treatment. The ultimate goal of methadone programs in the 1960s and 1970s was to get patients to stop using heroin completely. Urine analysis was used regularly to ensure patients were not using heroin and to determine the success of the program. Patients who continued using heroin were deemed failures of the treatment program. Sometimes these patients were 'kicked out' of the program. However, research and experience now shows that opioid and heroin addiction is complicated and that many people relapse even after abstaining from drugs for many years.

Many OAMT patients will continue to use heroin during the induction phase (the first 3 months) of the methadone program. This is because, during the early stages, the methadone dose prescribed by the doctor is still low and is often inadequate to completely suppress the withdrawal symptoms of heroin addiction. The patient's drug use during this time often reduces as the dose of methadone prescribed by the clinic is increased. There is good evidence now to show that drug use among patients during treatment is related to the dose of methadone prescribed and the duration of treatment

A substantial proportion of patients become abstinent in the first 6 months of treatment or when the maintenance phase of the treatment is reached. During this time, the doctor and patient should have decided on a dose that is suitable for the patient, a dose high enough to suppress the withdrawal symptoms of heroin/opioid use, reduce cramps and increase tolerance to opiates so that any additional use of heroin has no significant effect, but not high enough to cause troublesome side effects.

Internationally, MMT and BMT programs have moved towards using urine drug screening to monitor program performance and as an indicator of the safety and quality of the program. Some programs also use it to monitor individual patients but do it in a way that improves their treatment retention and compliance, not for punishment.

Therefore, it is recommended that, should a drug urine test be conducted during treatment and should a patient's urine sample returns a positive result for morphine (indicating consumption of heroin), s/he should not be viewed as a failure. Instead the doctor/prescriber can take the following action:

- i. Discuss with the patient the reason for the patient's continued heroin use. It could be that the maintenance dose of the drug user is too low. Perhaps the patient has a particular problem that could be easily solved?
- ii. Discuss with the patient his/her mode and frequency of heroin use. It is very possible that the patient is using less heroin and injecting less frequently than before. This in turn reduces the risk of transmitting and contracting HIV.
- iii. Discuss patient's risk exposure and provide advice about reducing HIV risk behaviour.



## 2.7 LINKING OPIOID AGONIST MEDICATION TREATMENT PROGRAMS TO HIV TREATMENT

It is not necessary for governments to require HIV testing of all drug users who seek to attend a methadone treatment program. However, many patients would voluntarily accept this test if it is offered to them in a safe and non-judgemental manner together with pre-test counselling. Plus, patients who are stabilised on OAMT will probably want to know their HIV status as they start rebuilding their lives. Some drug users seek OAMT after discovering their positive HIV status.

Opioid agonist medication treatment programs can play an important role in supporting treatment for HIV-positive drug users and there is increasing evidence that being in MMT or BMT improves compliance with HIV treatment. ARV treatments require the patient to strictly adhere to the treatment regimen. These medications must be taken every day without fail, much like methadone itself. Since drug users in opioid agonist medication treatment programs already attend the clinic everyday to receive medication, it makes sense to integrate HIV services within the same premises where possible. Equally important is the incorporation of treatment for tuberculosis and other opportunistic infections. When this is done, the patient does not have to go elsewhere to access HIV services and the program becomes a much more attractive option. This increases attendance and participation at the clinic and decreases drop-out from both MMT/BMT and ARV programs.

The following are some ways to integrate HIV services at opioid agonist medication treatment programs:

- i. Provide pre- and post-test counselling at the clinic. This could be done by a social worker.
- ii. Provide testing facilities. Blood can be taken at the clinic and sent to the hospital laboratory for testing.
- iii. Provide options for patients to store and consume ARV medications at a methadone clinic. Patients can be given methadone, buprenorphine and ARV at the same time through Directly Observed Treatment (DOT). This can also work well in a prison setting.
- iv. The prescriber of OAMT also taking responsibility for prescribing ARVs.
- v. Provide a HIV-positive peer support group at the clinic as part of a psychosocial program to support both opioid agonist medication treatment and HIV treatment.

## 2.8 PSYCHOSOCIAL SUPPORT PROGRAMS

Experience and research show that effective treatment attends to the multiple needs of individuals, not just their drug use.

Research also shows that good psycho-social support services for patients increases the success of opioid agonist medication treatment programs. This includes counselling services. Methadone or buprenorphine is administered once a day. Many heroin users are used to hectic and chaotic lifestyles which include searching for money, searching for drugs, searching for a place to use/inject drugs and a place to be 'high'. This process is repeated about 3-4 times daily due to the short duration of action.

Both methadone and buprenorphine are long-acting and patients do not crave the drug every 5-6 hours. They don't have to search for the money, or spend time trying to 'score' the drug. Often this means they have extra time on their hands once they get onto methadone programs. This can present various problems if not handled effectively.

Some of the problems faced by methadone and buprenorphine patients are:

- i. Unemployment and boredom – when patients are enrolled in methadone or buprenorphine programs, their lives are stabilised. However without a job, they can spend much of their time at home watching TV. This leads to boredom and can result in relapse to heroin use.
- ii. Frustration with the routine – some patients will find the routine of coming to a clinic every morning, every week frustrating and tiring.
- iii. Remembering or facing the problems that led them to drug use in the first place.
- iv. Panic, fear and sadness about HIV illness.
- v. Sexual dysfunction – methadone and buprenorphine can cause some men to experience lowered sexual drive and libido. However, very few men discuss this side effect with their doctors or nurses for fear of embarrassment. It can also be embarrassing to discuss this with a spouse or girlfriend.
- vi. Dealing with distrust from family and neighbours.
- vii. Legal problems due to crimes committed while using heroin.
- viii. Financial problems including money for transportation to attend clinic and fees for medication (in many cases patients are required to pay a small fee to the clinic/service each time methadone or buprenorphine is dispensed: although small, it can sometimes be a significant factor that can contribute to drop-out among patients).
- ix. Family members unsure how they can help.



Any of these problems can contribute to relapse if not handled effectively. Therefore, it is important that governments plan for psychosocial support, including counselling, for patients as part of their treatment program.

*The present evidence suggests that adding any psychosocial support to Standard MMT significantly improves the non-use of heroin during treatment.*

(Amato. L et al, Cochrane Review, 2004)

Some possible ways of ensuring psychosocial support are:

- i. Ensure counselling services are available at the clinic. A trained and empathetic counsellor can assist patients to rebuild their lives. Counsellors will assist patients to develop coping mechanisms to resist heroin relapse and deal with personal and family issues. Adding counselling to an opioid agonist medication treatment program can lead to a 30% improvement in retention in treatment.
- ii. Employ a peer counsellor. This can be a recovered heroin user (currently on methadone or not) to provide support for patients. This peer worker could discuss issues such as sexual dysfunction, dealing with family members and neighbours and also living with HIV (especially if the peer counsellor is also HIV-positive).
- iii. Create a patient support group – a facilitated discussion can highlight the similarities in problems faced by patients and can build solidarity. In Indonesia, a patient support group conducts community projects to raise awareness and build trust.
- iv. Create a family support group – parents and family members also need help in supporting their sons/daughters and siblings. They need to understand the patient's behaviour change and treatment process. This will enable them to trust the patient better and in turn provide better support. During family support group meetings, difficulties faced by parents and other family members can be addressed by learning from others who may have gone through the same experience.

## 2.9 ENSURING CONTINUITY AND SUITABLE LINKAGES IN THE PROCESS OF OPIOID AGONIST MEDICATION TREATMENT IMPLEMENTATION

### Ensuring the availability of opioid agonist medication (methadone and/or buprenorphine) nationwide

As discussed previously, patients who start on methadone or buprenorphine need to have access to their medicine daily until they complete their treatment. Treatment interruption can result in relapse to heroin use which would in turn mean a loss of the gains made from being on treatment in the first place.

In starting MMT or BMT, governments are faced with a few questions and challenges regarding the location of the treatment. What is obvious is that opioid agonist medication treatment programs should be implemented in places with significant need for the treatment. However, should the treatment be located in:

- i. places with high or low HIV prevalence?
- ii. areas with high levels of injecting drug users or in areas where injecting drug use is emerging?

Often the choice that is made is to implement opioid agonist medication treatment programs in high HIV prevalence areas where there are large numbers of injecting drug users. However, planning for these services to be in places where there are emerging epidemics of injecting drug use can be a wise move too.

It is important that the number of locations or sites for opioid agonist medication treatment programs should match the scale of the problem. It is also important to recognise that drug users are a mobile population. Patients often move once their lives are stable. They may find jobs in other cities and they may want to return to their hometowns to look after their elderly parents. They may get married and want to start a family in a different town. When methadone or buprenorphine are available in various settings and cities, patients can continue to be in treatment and treatment interruptions can be avoided.

### Ensuring methadone and/or buprenorphine are available within prison systems and other closed settings

Some drug users may continue to use some heroin while on opioid agonist medication treatment. The reasons for this have been discussed above. Some may still break the law for one reason or another and others may have prior criminal offences that catch up with them when they are in treatment. When this happens, they may be caught and sent to prison. If opioid agonist medication treatment programs are not available within the prison system, their treatment will be interrupted. Once again, this can lead to them relapsing to heroin, increasing the possibility of injecting and sharing needles. Therefore WHO recommends that *“prisoners on methadone maintenance prior to imprisonment should be able to continue this treatment while in prison”*. *In countries in which methadone maintenance is available to opiate-dependent individuals in the community, this treatment should also be available in prisons.*” (WHO Guidelines on HIV Infection and AIDS in Prisons)



Making opioid agonist medication treatment programs available within the prison system has many benefits. Among them are:

- i. Ensuring the continuity of treatment for patients who have been on methadone or buprenorphine treatment outside;
- ii. Providing medicated detoxification for drug users who enter prison. This will ensure they are not withdrawing 'cold turkey' and actively seeking heroin inside the prison (or creating more demand for heroin inside prison);
- iii. Providing a drug treatment option for prisoners who continue using drugs in prison (especially for prisoners who are ready to quit);
- iv. Providing a treatment option for prisoners who are about to be released: they can be started on methadone or buprenorphine inside the prison and referred to a clinic on the outside upon their release to reduce the chance that they go back to using heroin. This also reduces their chance of having a drug overdose soon after release or returning to drug related crime and coming back to prison.

## **2.10 SUMMARY: MINIMUM REQUIRED COMPONENTS FOR AN OPIOID AGONIST MEDICATION TREATMENT PROGRAM**

Opioid agonist medication treatment programs should not be viewed as only the provision of the medication for patients. They should be implemented as comprehensive programs to ensure safety, efficacy and successful outcomes. Opioid agonist medication treatment programs therefore should contain at least the following components:

- i. Methadone and/or buprenorphine provision
- ii. Counselling
- iii. Psychosocial interventions.

The nature and extent of the psychosocial interventions vary based on local needs. In Indonesia, peer group support proved beneficial. In Southern China, a support group for family members was identified as an important intervention. Needs assessments and continued monitoring of programs help to highlight the needs for each country and setting.

## REFERENCES

1. Australian Government Department of Health and Ageing. National Pharmacotherapy Policy for people dependent on opioids. National Drug Strategy. January 2007.
2. UNODC Regional Centre for East Asia and the Pacific. Internal Document No. 3/2007. "A Step-by Step Algorithm for the Procurement of Controlled Substances For Drug Substitution Treatment" provides additional detail on the procurement process. Available at <http://www.unodc.un.or.th/drugsandhiv/publications/2007/Step-by-Step.pdf>
3. European Monitoring Center for Drugs and Drug Addiction, Legal aspects of substitution treatment: an insight into nine EU countries. 2003.
4. Methadone Maintenance Treatment, Essential Information, NSW Drugs Program Bureau, NSW Health 2000. [www.regenthouse.com.au](http://www.regenthouse.com.au)
5. Amato L, Minozzi S, Davoli M, Vecchi S, Ferri M, Mayet S. Psychosocial combined with agonist maintenance treatments versus agonist maintenance treatments alone for treatment of opioid dependence. Cochrane Database of Systematic Reviews 2004, Issue 4.
6. WHO, Guidelines on HIV Infection and AIDS in prisons, UNAIDS/99.47E, 1993
7. K. Dolan et al, Methadone Maintenance reduces injecting in prisons. British Medical Journal 312, 1996.
8. Canadian HIV/AIDS Legal Network. Legislating on Health and Human Rights: Model on Drug Use and HIV/AIDS. 2006.





# Section 3:

## Governance Tools

### **TOOL 1: GUIDANCE NOTE ON THE ROLES AND RESPONSIBILITIES OF GOVERNMENT MINISTRIES AND AGENCIES**

The role of the government in the introduction of opioid agonist medication treatment programs is more prominent than in any other HIV prevention program among drug users such as needle exchange programs or peer-based outreach programs. Methadone is under international control as a narcotic drug. It is included in Schedule I of the Single Convention on Narcotic Drugs of 1961 (Single Convention). Other narcotic drugs in the same schedule are, for example, fentanyl, morphine, oxycodone or pethidine. Buprenorphine is under international control as a psychotropic substance included in Schedule III of the Convention on Psychotropic Substances, 1971. Further information on these Conventions along with Guidelines for National Competent Authorities can be found on the website of the International Narcotics Control Board (INCB) at [www.incb.org](http://www.incb.org)

Methadone has strict regulation for importation and distribution. It can also be misused, resulting in severe consequences. Overdose is also a possibility which calls for strict guidelines for its distribution and raises issues around responsibility of the state and physicians.

The Single Convention contains provisions for the control of import and domestic distribution of narcotic drugs, which have to be complied with by all Parties to this treaty. Governments have to estimate every year the requirements of their countries for narcotic drugs and submit those estimates for confirmation to the INCB. Imports of narcotic drugs can only be made within the limits of the total of the estimates of the importing country. Furthermore, each import of a narcotic drug must be specifically authorized by the competent authorities of the importing country. Exporting countries authorize exports of narcotic drugs only on the basis of import authorizations/certificates issued by the competent authorities of the importing countries. The role of governments in the importation and domestic distribution of methadone and buprenorphine is very important.

It is critical that governance issues are address at all levels of government structure – the national, provincial and where appropriate, at district level. Coordination between these levels of governments ensures reduced confusion about program goal and implementation methods. This is important for the successful and efficient delivery of the program.

It must also be stressed that NGOs can play a significant role in the delivery of OAMT. NGOs can act as both a distribution site and as a support service to government-run programs. The role of NGOs and other agencies are discussed in Tool 2.

## 3.1 ROLE OF MINISTRIES AND RELATED AGENCIES

### 3.1.1 MINISTRY OF HEALTH / PUBLIC HEALTH

The Ministry of Health or Public Health (MoH/MoPH) has the overall management responsibility for the opioid agonist medication treatment program at a national level. Both Buprenorphine Maintenance Treatment (BMT) and Methadone Maintenance Treatment (MMT) as an HIV prevention strategy should be viewed as a medical intervention for patients (drug users).

Typically the role of the MoH/MoPH includes:

- > Authorising the supply of the medication
- > Approving the formulation and registration of the medication
- > Preparing national policies and clinical guidelines on the use of the medication
- > Developing clinic accreditation standards
- > Monitoring the use of the medication
- > Recalling faulty products, should there be problems with the medication

The main responsibilities of the MoH/MoPH are:

- i. To include MMT as part of the National AIDS Strategy
- ii. To convene a multisectoral National Advisory Board consisting of all key government agencies including the police: this advisory board will oversee the development and implementation of the methadone program
- iii. To appoint the National Coordinator for the methadone program. The role of the National Coordinator will be to ensure the successful implementation of the methadone program;
- iv. To direct the National Advisory Board and the National Coordinator to develop a National Methadone and/or Buprenorphine Program Strategy. This strategy will highlight the following:
  - a) Rationale for the development of MMT/BMT within the country. This will include a situation assessment report of drug use and HIV in the country
  - b) Identification of target numbers of drug users to be reached by the program
  - c) Identification of sites for clinics in various geographical locations within the country
  - d) Method of services delivery including the overall structure of the program
  - e) Ensuring linkages with other programs such as VCCT, TB and hepatitis
  - f) Training needs analysis and training plan for staff of methadone sites

- g) Development of an appropriate budget and allocation of funds for the methadone program. This should include the estimation of funds for a minimum of 3-5 years.
- v. To develop the National Guidelines for the implementation of the methadone program
- vi. To develop a monitoring and evaluation framework for the methadone program
- vii. To develop an accreditation process for methadone prescribers
- viii. To develop a training structure for the continuous professional development of methadone prescribers, nurses, counsellors and dispensers
- ix. To monitor and supervise the implementation of methadone in the country

In Thailand, the Department of Medical Services performs the duties mentioned above. This department also works in close collaboration with The Food and Drug Administration (see below) to provide:

- a. Training of physicians to prescribe methadone;
- b. Registration of clinics which have methadone prescribers
- c. Supervision of methadone implementation by both governmental and non-governmental doctors
- d. Investigation of complaints against methadone prescribers
- e. Providing policy advice to the government in relation to MMT.

(source: Dr Viroj Verachai, personal communications)

### **3.1.2 NATIONAL AIDS AUTHORITY**

The National AIDS Authority (NAA) has the responsibility to develop a National Strategy on HIV/AIDS in the country that includes strategies for HIV prevention among injecting drug users. MMT/BMT should be an integral part of the National AIDS Strategy as recommended by WHO.

However, it is important that before such a strategy is implemented, the NAA secure the support of various government agencies. The most important of these is the National Agency Against Drug Abuse (NAADA). The cooperation of NAADA is crucial for the success of MMT implementation as has been highlighted elsewhere in this document.

There are several examples in the region of how such cooperation can be built. A Memorandum of Understanding (MoU) is often the most common form. The NAA can also form a National Committee on Harm Reduction. This sub-committee can supervise and monitor the implementation of all harm reduction programs in the country including needle-syringe programs and opioid agonist medication treatment programs.

### **3.1.3 FOOD AND DRUG ADMINISTRATION**

The Food and Drug Administration (FDA) plays a key role in methadone and buprenorphine programs across Asia. The weight of responsibility however varies according to countries. In Thailand, the FDA is the key administration body that regulates controls and supervises the implementation of opioid agonist medication treatment programs in the country. The FDA is responsible for:

- > Estimation and projection of methadone and/or buprenorphine use (demand) in the country and the submission of estimates for confirmation to INCB
- > Purchase of methadone and or buprenorphine
- > Registration of methadone and or buprenorphine
- > Storage and distribution of methadone and or buprenorphine within the country



### **3.1.4 PHARMACEUTICAL DEPARTMENT**

The pharmaceutical department has a key role to play in the implementation of opioid agonist medication treatment programs. The department receives, stores and distributes methadone and or buprenorphine to all the sites within the country. Safety during storage and distribution is a key issue for this department and needs special attention. The department will need to develop a data collection system to track the use of methadone and or buprenorphine across the country. In this regard the department needs to work closely with the FDA to keep national records of the use of methadone and/or buprenorphine in the country. An integrated, tightly controlled and monitored opioid agonist medication recording system along with restricted take-away doses is the best prevention against widespread diversion of methadone and or buprenorphine.

### **3.1.5 MINISTRY OF LAW**

Legislation that enables access to methadone and/or buprenorphine within a country is key to the development of a national OAMT program. If the laws prohibit the use of methadone or buprenorphine for drug treatment, then an opioid agonist medication treatment programs cannot be implemented, let alone scaled up to reach optimum coverage. As such, the role of the Ministry of Law is important:

- i. To review the laws related to the importation and provision of methadone and/or buprenorphine as a treatment within the country;
- ii. To support the development of an enabling environment for the implementation of methadone and/or buprenorphine within the country. This could be a policy framework in the form of a MoU or a Presidential Decree. A MoU between MoH/MoPH and the National Police usually provides a legal environment for opioid agonist medication treatment programs to take place.



### 3.1.6 NATIONAL AGENCY AGAINST DRUG ABUSE

The National Agencies Against Drug Abuse (NAADA) such as LCDC (Lao PDR), NACD (Cambodia) and the ONCB (Thailand) play a key role in the introduction and implementation of MMT.

In jurisdictions such as Thailand and Hong Kong, MMT was started as a form of drug addiction treatment. In Hong Kong especially, the treatment was introduced by the National Drug Control Agency. This proved to be a highly effective method of drug treatment and crime prevention.. Even more significantly, it has proven to be a very useful tool in the prevention of HIV among drug users on the island.

In many other countries, the MoH/MoPH has introduced methadone and/or buprenorphine as part of its HIV control measures. However, considering that these medications are under international control as a narcotic drug, the implementation of the program requires the support and cooperation of the NAADA.

The NAADA can perform the following roles:

- a. Develop an internal policy regarding the use of opioid agonist medication treatment programs for drug addiction treatment and HIV prevention;
- b. Develop a MoU with the NAA that will enable the wide-scale implementation of opioid agonist medication treatment programs in the country;
- c. Provide policy advice to the Home Ministry/ National Police and State Welfare Department regarding the use of methadone and/or buprenorphine as method of preventing heroin use and HIV transmission;
- d. Include opioid agonist medication treatment programs as part of the Demand Reduction Strategy which forms the larger drug policy or drug strategy for the country;
- e. Support the MoH/MoPH in the implementation of opioid agonist medication treatment programs.

### 3.1.7 HOME MINISTRY/ NATIONAL POLICE

The role of the police is to uphold and to implement the law. In many South-East Asian countries, the police play a crucial role in the success of a HIV prevention program. Programs such as needle-syringe programs cannot be successful when police continue to arrest drug users who carry needles and syringes. Similarly with opioid agonist medication treatment programs, the role of the police is vital to success.

- i. The National Police/ Home Ministry must develop an internal policy that supports HIV prevention work within the country. This will include policies which recognise that HIV is a public security issue that needs the support of police. An example of this is available in Australia where the Australian police has collaborated on the development of a National Drug Strategy which includes supply reduction, demand reduction and harm reduction, with opioid agonist medication treatment programs playing an important role in both demand and harm reduction. This policy must then be communicated with all levels of police in the country to allow the uninterrupted implementation of harm reduction programs.
- ii. The National Police/ Home Ministry should actively participate in the National Advisory Board created by the MoH/MoPH as an equal partner.
- iii. The Police should develop a MoU with MoH/MoPH. This will provide a framework in which the opioid agonist medication treatment programs will be implemented.
- iv. At the field level, police and opioid agonist medication treatment programs implementation agency need to develop mechanisms to work together. This will include the following:
  - a. Provision of patient identification cards to MMT and/or BMT patients: this will allow police to identify patients of the program when stopped on the street.
  - b. Police liaison with the treatment programs implementing agency when a patient is arrested. For patients, police can contact the counsellor of the MMT/BMT program to intervene. This can result in less incarceration of drug users.
  - c. Police liaison with the treatment programs implementing agency when a patient is caught for minor offences and kept in police lock-up, to ensure the continued administration of methadone and/or buprenorphine for the patient. For example in Indonesia, parents of methadone patients are contacted immediately upon arrest to enable the parents to bring methadone to the patients at the police lock-ups to avoid treatment interruption (Dr. Ratna Mardiati, personal communications). Treatment interruptions in situations like this can result in the patient relapsing to heroin use. This will increase the likelihood of injection, sharing of needles, HIV infection and crime in the future.
  - d. Police response to violence or crime at the treatment clinic. Sometimes violence does occur at OAMT clinics. A good relationship between the police and the methadone clinic can result in better patient behaviour and swift intervention by police when any untoward behaviour is experienced. Sometimes drug dealers



operate at the doorsteps of treatment clinics, encouraging patients back to heroin use. A good relationship between police and the clinic can decrease this activity. However, this should be done carefully with involvement and knowledge of patients and without creating a culture of fear among patients.

### **3.1.8 MINISTRY OF JUSTICE**

The Ministry of Justice is often responsible for the development and implementation of programs in prisons. This can vary according to countries. In Cambodia the Ministry responsible is the Ministry of Interior.

Opioid Agonist Medication Treatment Programs such as Methadone programs can be highly successful for prisoners as demonstrated by programs in Iran, Indonesia and Australia. The responsibilities of this Ministry include:

- i. Undertaking a situation assessment of drug use and HIV within prisons;
- ii. Participating in the National behavioural surveillance survey (BSS) to identify infection rates and prevalence of HIV among prisoners;
- iii. Undertaking feasibility studies of OAMT programs within the prison system: as part of this, a study visit to countries where programs have been successfully implemented is highly recommended;
- iv. Developing a Committee for the Prevention of Drugs and HIV in Prisons: this multisectoral committee can include MoH/MoPH, Police, NAA, NAADA, NGOs and parents of prisoners with the objective to develop a national strategy and related activities to prevent HIV and drug use in prisons;
- v. Developing a Prison Strategy on Drug Use and HIV: this strategy will among others, identify the following activities:
  - a. Capacity building of prison staff to participate in drug prevention, treatment and HIV prevention activities;
  - b. Drug use prevention (demand reduction strategies) within prisons among prisoners;
  - c. Drug detoxification, treatment and rehabilitation for prisoners who may be using drugs within the prison system;
  - d. HIV prevention among prisoners: this can include development of information sessions, bleach programs, condom distribution programs;
  - e. Development of opioid agonist medication treatment programs such as MMT as part of drug treatment and HIV prevention strategies;
  - f. Development of TB, OI and ARV treatment for prisoners with HIV.
- vi. Developing a MoU or other policy agreements with MoH/MoPH and NAADA to deliver MMT within the prison systems.



In the longer term, Ministry of Justice should spearhead the reform of drug and HIV laws (if it does not already include effective treatment methods such as OAMT programs) and the implementation of alternative sentencing options.

### **3.1.9 NATIONAL PRISONS DEPARTMENT**

Drug users make up a large proportion of the prison population in Asia and many other parts of the world. Many prisoners are sentenced to short stays in prison for petty crimes under the influence of drugs. This large concentration of drug users in prison often increases the demand for drugs within the prison. Many prisoners report continued drug use and injecting within the prison systems. Drug treatment programs inside prisons are increasingly recognised as an integral prison program component. Opioid Agonist Medication Treatment Programs such as methadone in prisons can be beneficial for the following reasons:

- i. Continued accessibility of treatment within prison reduces the likelihood of relapsing on release. This, in return, increases the chances of the patient not continuing to commit crime upon his/her release from prison, based on the need to access heroin or other opiates.
- ii. For long-term drug users who have served long prison sentences, starting OAMT before being released will increase the chance of his/her continued stabilisation when they are returned to the community.
- iii. For pregnant female drug users imprisoned, it can bring stability and better health outcomes for mother and baby.
- iv. For prisoners serving long sentences who would like to give up heroin, OAMT represents an option of proven effectiveness.

The role and responsibilities of the Prisons Department in a national methadone program are:

- i. Develop a partnership with the MoH/MoPH to implement OAMT programs for prisoners. This partnership will:
  - a. Produce a MoU or similar between the Prisons Department, MoH/MoPH and NAADA that will provide policy guidelines to the program;
  - b. Develop clinical guidelines, protocols and standard operating procedures for use within the prison OAMT Clinic;
  - c. Develop a training plan to provide ongoing capacity building for doctors, nurses and other prison staff;
  - d. Develop a mechanism for the transportation and storage of methadone and/or buprenorphine within the prison clinic: this will include stock-keeping procedures and procedures to account for any loss of methadone or spillage;
  - e. Develop strategies for TB, HIV, urine and STI testing for patients.



- ii. Develop a partnership with local NGOs to provide services for prisoners. This partnership will:
  - a. Develop a comprehensive service package on HIV prevention and treatment for prisoners. The NGOs would provide the following support to the prison:
    - i. Staff training on drug use and HIV;
    - ii. Drug use prevention programs for prisoners such as cognitive-behavioural and other therapies which build the capacity of prisoners to avoid relapse upon release;
    - iii. HIV prevention programs which can include information sessions and counselling.
  - b. Develop psychosocial support for OAMT patients. Similar to the programs conducted in the community, prisoners on OAMT need psychosocial support to deal with challenges and issues faced whilst on methadone treatment. Prisoners will also need to talk about possible side effects and receive peer counselling and support which can be provided by NGOs.

### **3.1.10 NATIONAL CUSTOMS AND IMMIGRATION DEPARTMENT**

The National Customs and Immigration Department should be involved during the planning stages of the opioid agonist medication treatment programs to ensure that customs clearance of methadone and/or buprenorphine is swift and undertaken appropriately. MoH/MoPH should involve this department at early stages to ensure there is no confusion as to why this internationally controlled drug is suddenly being brought into the country. This can avert unnecessary delays in accessing opioid agonist medication and unnecessary treatment interruptions.



### 3.1.11 STATE WELFARE DEPARTMENT

Many drug users live a chaotic lifestyle when they are using drugs. This often means not having regular employment and loss of skills to gain such employment. Drug users also often lose their important documents such as national identity cards which are often crucial to gain any kind of employment or other social benefits. These ID cards may also be necessary to start treatment on methadone and/or buprenorphine.

Opioid agonist medication treatment programs reduce the chaos in a patient's life. They bring back stability and prepare the patient for reintegration with society. However securing lawful employment without skills and proper documents is extremely difficult.

The State Welfare Department can therefore assist in the following ways:

- i. Developing a partnership with MoH/MoPH to provide skills training to opioid agonist medication treatment patients;
- ii. Developing a partnership with the treatment programs site to provide 'reintegration' services for patients which can include providing national identity cards to patients who need them;
- iii. Developing support services for family members who may need financial support to continue caring for the patient.

#### REFERENCES:

1. Dolan KA, 2001, Can hepatitis C transmission be reduced in Australian prisons? *Medical Journal of Australia (EMJ)*, 2001
2. Dolan KA, Hall W, Wodak A. Methadone maintenance reduces injecting in prison. *BMJ* 1996; 312: 1162.
3. Dolan K. The epidemiology of hepatitis C infection in prison populations [discussion paper]. Canberra: Commonwealth Department of Health and Aged Care, 2000.



## **TOOL 2: GUIDANCE NOTE ON ROLES AND RESPONSIBILITIES OF NON-GOVERNMENT ORGANISATIONS AND PROFESSIONAL INSTITUTIONS**

### **3.2 ROLE OF NON-GOVERNMENTAL ORGANISATIONS (NGOS)**

#### **3.2.1 NGOS WORKING ON HIV PREVENTION AMONG INJECTING DRUG USERS**

NGOs can perform roles both as an opioid agonist medication prescribing site and/or as a support agency.

As an opioid agonist medication treatment programs site, NGOs can:

- i. Incorporate methadone and/or buprenorphine provision as part of their package of comprehensive services provided to injecting drug users. It is, however, important that the NGO takes into consideration that providing opioid agonist medication and needle-syringe programs (NSP) at the same site can produce problems. NSP clients who are still using heroin might try to influence opioid agonist medication patients who are trying to quit using heroin. Being in such close proximity to current users may also increase the chance of relapse.
- ii. Develop a special site for methadone and/or buprenorphine distribution. Patients who come for opioid agonist medication may be treated separately to those who may still be using heroin. A specific site for opioid agonist medication might work better. This site would function similar to other sites with a treatment team that includes counsellors and dispensers.

As a support agency, the NGO can:

- i. Provide peer counselling at the opioid agonist medication treatment site (dealing with relapse prevention, transportation, boredom etc);
- ii. Provide information and help with side effects of methadone and/or buprenorphine;
- iii. Organise opioid agonist medication patients to form a support group;
- iv. Provide support to partners and family members of patients (assisting family members to understand MMT/BMT, how they can support their sons/daughters/siblings);
- v. Provide vocational training for patients (often patients have more free time on their hands than they previously did as well as needing to develop skills for employment).

### **3.2.1 NATIONAL ORGANISATION OF PARENTS AGAINST DRUG ABUSE**

- i. Begin a discussion on OAMT within the organisation;
- ii. Develop an internal policy in regards to the use of OAM for drug treatment;
- iii. Support the NAADA and NAA in developing strategies for drug treatment and drug policy which include MMT/BMT;
- iv. Provide information to parents regarding MMT/BMT;
- v. Advocate for the use of MMT/BMT in drug treatment.

### **3.2.2 NATIONAL YOUTH ORGANISATIONS**

- i. Discuss advocacy for the use of opioid agonist medication for drug use and HIV prevention and treatment;
- ii. Consider supporting the NAADA in developing a national drug strategy that will include opioid agonist medication as part of demand reduction and harm reduction;
- iii. Provide information regarding opioid agonist medication treatment programs to society through the various drug campaigns that are conducted in the country;
- iv. Refer families affected by opioid drugs and their use to opioid agonist medication treatment programs.

### **3.2.3 INSTITUTES OF HIGHER LEARNING OR UNIVERSITIES**

- i. Develop a module on drug treatment for medical students at university;
- ii. Develop a module on Opioid Agonist Medication Treatment Programs for medical students who wish to specialise in the area of mental health.

**Note:** In several countries, the role and cooperation of religious institutes and religious leaders is key to the success of opioid agonist medication treatment programs. Where this is the case, advocacy activities including site visits, workshops and inclusion of religious leaders in policy and planning meetings are highly recommended.



## **TOOL 3: GUIDANCE NOTE ON THE DEVELOPMENT OF NATIONAL POLICIES AND GUIDELINES**

### **3.3 INTRODUCTION**

It is clear that opioid agonist medication treatment programs such as methadone and buprenorphine treatment programs cannot be implemented in any country if there are national laws and regulations that prohibit the use of these medications. In many cases, methadone and buprenorphine are not yet approved for the use of addiction treatment among heroin dependent people.

Legislation for MMT and/or BMT is required to enable maintenance of a person on a class of drug on which they are already dependent .. This legislation is important to ensure safety in the use of the drug in treatment and the protection of staff and patients who are involved in the program.

This section of the toolkit aims to provide examples of legislation and policies that have allowed several countries in the region to implement opioid agonist medication treatment programs. This section also aims to define the various policy documents and guidelines that are important to the implementation of methadone treatment.

For the purpose of this document:

- > Policy – is the vision of what you want to do: this is often developed and enacted through a national governing body;
- > Legislation – is the legal framework which gives you permission;
- > Regulation – is the guidance by which the permission is enacted or implemented.

#### **3.3.1 POLICY**

A country can develop a national policy on OAMT to treat drug users and to prevent HIV. This vision can be articulated in documents such as the National Drug Treatment Policy, National Drug Strategy or the National AIDS Strategy. These policy documents should provide answers to the following questions:

- > What OAMT and why should they be used for drug addiction treatment?
- > What are the aims and objectives of the opioid agonist medication treatment programs?
- > How will the opioid agonist medication treatment programs program be implemented?
- > Who will guide and supervise the opioid agonist medication treatment programs program?
- > How will OAMT programs be monitored, evaluated and expanded?

The national policy is the vision for the program and will be further developed and defined in other policy documents such as the National Clinical Guidelines for MMT and/or BMT. These clinical documents will guide doctors and treatment personnel in developing safe and effective clinical practices and implementing these programs. While a National Drug Treatment Policy provides the framework for the entire program, the National Clinical Guidelines are technical documents which highlight the detailed procedure for doctors and treatment practitioners.

### **3.3.2 NATIONAL GOVERNING BODY**

A national governing body such as a National Committee on Drug Treatment or a National Working Group on HIV/AIDS and Drug Use is an important management body to ensure the safe and high-quality implementation of opioid agonist medication treatment programs. The body should be multisectoral including law enforcement agencies, health departments and other key stakeholders in the country. This national body ensures that stakeholders understand and accept a common goal for the implementation of opioid agonist medication treatment programs in the country.

The body can also provide supervision and monitoring of the program to ensure that the implementation is conducted according to international standards and reaches national objectives. By meeting regularly, the body can also ensure that a safe and effective program can be scaled up to reach more drug users across the country. It can also deal with concerns, media reports and community expectations and complaints.

An example of this national governing body in the Asian region is the Illicit Drugs related HIV/AIDS Working Group (DHAWG) of Cambodia, established in 2007. The DHAWG is co-chaired by National Authority for Combating Drugs (NACD) and the National AIDS Authority (NAA). Together, the NACD and NAA through the DHAWG have formulated a five-year master plan (2005-2010) to address, among other issues:

- > Coordination of stakeholders to reduce HIV transmission related to drug abuse and enhance care, treatment services for and prevention of illicit drug and substance use in Cambodia;
- > Give advice and monitor all activities related to dissemination, education, treatment, rehabilitation and other programs involved in drug use and HIV prevention.



### 3.3.3 LEGISLATION

Governments should ensure that in implementing methadone programs there is legislation that provides mechanisms for;

- > Drug dependent patients to have access to maintenance medications;
- > Defining the framework for supply, storage, prescription, labelling, packaging and handling of methadone;
- > Authorising medical practitioners to be opioid agonist medication treatment prescribers (including the tasks required of them);
- > Review, amend, and cancel medical practitioners' authority to prescribe;
- > Investigate complaints (generic legislation);
- > Medication record keeping (generic legislation).

An example of an enabling legislation specifically governing the use of methadone to treat drug dependence can be found in Iran where there is now an Executive Order from the Head of Judiciary which states:

“One of the interventions by the Ministry of Health and Medical Education includes the provision of needles, syringes and other materials used individually by drug addicts and AIDS patients as well as Methadone Maintenance Treatment programs as means of combating HIV and hepatitis infections among drug addicts”

The order No 1-83-14434 also states that:

“The said interventions are clearly void of malicious intent but clearly motivated by the will to protect society from the spread of deadly contagious diseases”

The order goes on to order authorities of law enforcement not to impede the provision of such services.

### 3.3.4 REGULATION

Under the national legislation, regulations are required to ensure that implementation of the opioid agonist medication treatment programs is conducted according to international standards and reaches national objectives. Setting regulations and assessing whether clinics and prescribers are abiding by these regulations is one of the principal roles of the national governing body described above.

Regulations ensure that:

- > MMT and/or BMT is based on principles of good medical practice;
- > Evidence-based guidelines are used to define who is considered eligible for opioid agonist medication treatment programs as well as contraindications for MMT/BMT;
- > Government (legislative) requirements are met;
- > Acceptable and unacceptable practice is defined;
- > Prescriber and clinic licensing procedures are related to adequate training, and meet specific standards of care, logistics, hygiene, etc
- > The process and criteria for removing prescriber and clinic licences

These regulations should be widely disseminated, and monitoring treatment quality and outcomes need to also be put in place. This is an important role of the national governing body.



## **TOOL 4: GUIDANCE NOTE ON THE IMPORTATION, STORAGE AND DISTRIBUTION OF METHADONE AND/OR BUPRENORPHINE**

### **3.4 IMPORTATION, STORAGE AND DISTRIBUTION OF METHADONE AND/OR BUPRENORPHINE**

The importation process of opioid agonist medications may be lengthy and complicated for countries starting treatment programs. If not properly undertaken, it can cause delays in methadone and/or buprenorphine arriving into the country and at the clinics. The interruption in treatment can be highly detrimental to the success of the program as well as the well-being of the drug dependent person attempting to access treatment.

In this regard, the following steps are recommended:

- i. The Ministry of Health/ Public Health (MoH/MoPH) conducts a situation assessment on drug use and HIV in the country. Data from this assessment is used to estimate the number of drug users for Opioid Agonist Medication Treatment.
- ii. This estimation and a proposal to implement an opioid agonist medication treatment programs is developed and sent to the Food and Drug Administration.
- iii. The estimation and target is developed into a proposal by FDA and the estimates of requirements for methadone and/or buprenorphine are sent to INCB for confirmation. The estimates have to be submitted to INCB for confirmation for each calendar year well in advance (by 30 June of the year preceding the year to which these estimates apply). However, if necessary, governments may at any time submit supplementary estimates to INCB for confirmation.
- iv. INCB will review the estimates and confirm them or request additional clarifications. The confirmed estimates are published by INCB.
- v. The competent authorities of the importing country will issue the import authorization/certificate for methadone and/or buprenorphine to the company authorized by them to import the medication into the country. The importer will send this import authorization/certificate and a purchase order to the company that sells the medication and has won any open and competitive tendering.
- vi. The export authorization for the consignment is issued by the competent authorities of the exporting country based on the import authorization/certificate issued by the competent authorities of the importing country. The company sends the required amount of methadone and/or buprenorphine to the country.

The FDA receives the medication stock from the private company and has the responsibility to store and distribute to dispensing sites. Often this duty is also delegated to the National Pharmaceutical Department which may already possess a stock-keeping mechanism for other medications brought into the country.

Opioid Agonist Medication Treatment sites will be required to provide an estimation of methadone and/or buprenorphine needed per quarter to the FDA. The FDA approves this request and authorises the National Pharmaceutical Department to distribute the medication to the sites.

It is also possible, where there is more than one site in a state or province, that the State Health Department's Pharmaceutical Branch will store the medication for the provincial need. This mechanism must be discussed and agreed upon before the start of the opioid agonist medication treatment program to ensure smooth distribution of medication and prevent interruption to the medication supply.

The importation process and responsible agencies can be summarised as follows:

STEPS TO TAKE	ACTIVITIES	RESPONSIBILITY
Preparation for application to obtain International Narcotics Movement License (INML)  <b>Steps 1-4</b>	Situation assessment	MoH/MoPH – FDA
	Specifications of methadone and/or buprenorphine	FDA – WHO
	Source company: name, contact information and price	FDA (MoH/MoPH)
	Total cost of methadone/buprenorphine estimated	FDA (MoH/MoPH)
	Set datelines for applications	MoH/MoPH
	Complete application forms	MoH/MoPH with assistance from WHO
Placing the order for methadone/buprenorphine with the supplier  <b>Steps 5-6</b>	Place the order for the purchase of methadone/buprenorphine with the supplier	MoH/MoPH / FDA
	Budget and payments for the shipment of methadone/buprenorphine	Internal funding / external funding
Transportation and storage of methadone/buprenorphine	Shipment into country	MoH/MoPH / National Pharmaceutical Department/ FDA
	Customs clearance	FDA and National Customs Department
	Storage at the national level and stock-keeping	National Pharmaceutical Department
Distribution and dispensing at clinics	Transportation within the country	FDA
	Storage within provinces/districts/state	State Health Departments/ pharmaceutical divisions
	Transportation to methadone sites	State Health Departments + methadone sites/clinics

Note:

WHO treatment guidelines for opioid dependence [http://www.who.int/substance\\_abuse/en/index.html](http://www.who.int/substance_abuse/en/index.html)

The UNODC document entitled "A Step-by Step Algorithm for the Procurement of Controlled Substances For Drug Substitution Treatment" provides additional detail on the procurement process. Available at <http://www.unodc.un.or.th/drugsandhiv/publications/2007/Step-by-Step.pdf>



## TOOL 5: GUIDANCE NOTE ON THE ACCREDITATION OF OAMT CLINICS

### 3.5 ACCREDITATION

**3.5.1** Accreditation is a major component in the governance of an opioid agonist medication treatment programs such as Methadone Maintenance Treatment (MMT) and Buprenorphine Maintenance Treatment (BMT) program because it ensures that the systems that are adopted are consistent and of high quality. It also ensures that the organisation that provides treatment as well as the prescribers meet standards that ensure safe and effective delivery of the treatment.

There are a few accreditation processes that take place during the implementation of OAMT programs. In Australia, these include:

- i. Pharmaceutical Branch accreditation – ensures that proper storage of methadone is undertaken;
- ii. Prescriber Review Committee accreditation– a multisectoral committee that ensures all prescribers are trained and skilled in medication prescription;
- iii. System accreditation - an independent quality assurance accreditation of the organisation and clinics that provide OAMT.

The organisation that is responsible for the development and implementation of a OAMT program should be reaccredited regularly to ensure that it is:

- > Efficient
- > Legal
- > Accountable
- > Sustainable
- > Reflective
- > Integrated
- > Working with consumer participation

### 3.5.2 GOOD QUALITY ORGANISATION

When an organisation is accredited, it demonstrates that the organisation is of a high quality. An organisation that has 'high quality' should fulfil the following standards:

- i. Safety** – Ensuring that the OAMT is providing a safe treatment program is the number one priority. In this regard, the accreditation process will consider the number of deaths which may have occurred among patients which may be directly related to opioid agonist medication treatment. It will also analyse the number of dosing errors the clinic/site made over the course of a year. The higher the number of errors, the lower the standard of the clinic.
- ii. Effectiveness** – Ensuring that the patients that start on opioid agonist medication treatment stay in the treatment for the entire duration of the treatment and are not dropping out of the program. If there are many patients not completing their treatment or dropping out soon after commencing treatment, there could be something amiss about the treatment at the clinic/site. The proportion of patients retained in treatment 12 months after commencing is a guide to the effectiveness of an opioid agonist medication treatment program. Eighty percent retention is a very good result while less than 60% retention would be cause for concern.
- iii. Appropriateness** – Ensuring that the treatment service is appropriate for the patients. This can be assessed by looking at data induction into treatment. If patients are still experiencing withdrawal symptoms long after admission to the program, then the clinic could be administering lower doses than are medically required by the patients.
- iv. Access** – Ensuring the patient has appropriate access to the doctors and other clinic staff and that the time between first contact with the clinic and admission into the program is not too long. If there is a long gap, the drug user (patient) may lose interest in treatment.
- v. Acceptability** – Ensuring that the treatment service is well accepted by the patients. This can be assessed by looking at patient feedback – both complaints and appreciation letters. Acceptability of the program by the surrounding community should also be assessed.
- vi. Efficiency** – Ensuring that the treatment service is serving as large a number of patients as possible using the available resources and infrastructure.



Accreditation of the opioid agonist medication treatment clinics and organisations will demonstrate evidence that the organisation has sound systems in place for the implementation of programs. It will also provide evidence that the organisation has high quality:

- > Policies – descriptions of what the organisation intends to do;
- > Procedures – descriptions of how they will do it;
- > Practices – what is actually done.

### **3.5.3 ACCREDITATION TEAM**

An accreditation process should be guided and implemented by an accreditation team. Each country should develop an accreditation team that comprises individuals from various disciplines. This team could be part of the process that countries use for accreditation of their hospitals as is the case in Thailand where methadone clinics are accredited through the same process used for public hospitals. The accreditation team will develop the plan and standards for accreditation. This will include developing the standards that organisations /clinics must achieve.

### **3.5.4 POST ACCREDITATION**

An accreditation report is produced which will contain the results of the accreditation process and the recommendations for any improvement. This highlights areas where the organisation has demonstrated high quality and confirms that it has achieved the standards set by the government. The report also identifies areas where there are opportunities for improvement. The recommendations should be discussed with staff of the organisation and an action plan developed to overcome any areas of concern.



## **TOOL 6: GUIDANCE NOTE ON THE TRAINING, AUTHORISATION AND REVIEW PROCESS FOR METHADONE AND/OR BUPRENORPHINE PRESCRIBERS**

### **3.6 TRAINING, AUTHORISATION AND REVIEW PROCESS FOR PRESCRIBERS**

In previous chapters, it has been discussed that opioid agonist medication treatment programs such as MMT and BMT can be implemented through various sites. These include government-run hospitals, health centres, NGO drop-in centres, pharmacies and private GPs. In all of these sites, a range of professionals including doctors, nurses and pharmacists are involved in providing treatment. While the mix of professionals and the services they provide can vary from site to site, it has been noted that a major contributor to treatment effectiveness is the approach and skills of those providing the service. The relationship between the doctor and the patient is critical to enhancing treatment outcomes.

The National Policy on Opioid Agonist Medication Treatment Programs for every country should include a requirement for mandatory training and authorisation of prescribers. An example of this can be found in the Australian National Pharmacotherapy Policy, 2007, which states

*A medical practitioner intending to prescribe pharmacotherapies for the treatment of opioid dependence should have knowledge and skills in the assessment and treatment of drug dependence.*

*Jurisdictions should develop professional training programs for prescribers intending to prescribe methadone and buprenorphine and assess the competence of medical practitioners wishing to be approved as prescribers.*

#### **3.6.1 THE NEED FOR PRIVATE GPs AND NGO DOCTORS**

In many parts of Asia, opioid agonist medication treatment programs are started by the Ministry Of Health or Public Health (MoH/MoPH) with support from international agencies such as the World Health Organization (WHO) and United Nations Office of Drugs and Crime (UNODC). At the early stages, the services are run through the public health system such as in hospitals or government drug treatment centres. While this is a good start, experience shows that as demand for the treatment increases the hospital may struggle to cope with the influx of new patients. Patients are often kept on a waiting list or turned away. Even when there are places available, the services/site might be physically inaccessible or unattractive to some patients. Some drug users may also wary of attending government services whilst others may receive discriminatory treatment from hospital staff.

It is therefore important to make OAMT available through other outlets such as community based primary health care as well as private doctors and NGOs. Some patients who may not want to be identified, such as well-known community members or public servants might choose to go to private GPs. Drug users who are already accessed by NGOs may be better served through NGO clinics. However, it is imperative that private GPs and NGO staff involved in methadone prescribing are trained, authorised and monitored effectively to avoid negative consequences.

### 3.6.2 TRAINING AND AUTHORISATION PROCESS

A high quality training and authorisation program should consist of the following elements:

- i. Good selection procedure
- ii. High quality training
- iii. Clinical placement
- iv. Post authorisation support
- v. Ongoing training

#### **i. Good Selection Procedure**

Each country has its own ways of recruiting potential prescribers. Some of these are through professional contact that the MoH/MoPH may have with doctors throughout the country. Potential prescribers can also be recruited through other methods – advertisement in medical journals or newsletters or by targeting specific individuals in specific geographic areas. In selecting potential prescribers, it is important to screen out medical practitioners who have had problems with illicit or prescription drug use themselves or who have engaged in prescribing behaviour that may have been of concern to authorities in the past (perhaps prescribing buprenorphine or benzodiazepines to drug users).

#### **ii. High Quality Training**

There are various training methodologies currently being used for training doctors and other staff involved in OAMT programs. Each country may have a consultant trainer within the country or a consultant from another country. Length of the training also varies from two days to two weeks. In any case, for the purpose of good governance, it is important to develop a checklist to ensure that the most important aspects of the program are covered.

Before training commencement, participants (potential prescribers) should be given the following documents as pre-course reading:

- > National Policy on OAMT;
- > Aims and Objectives of the training;
- > A brief outline of the concept of opioid agonist medication treatment;
- > Information on methadone and/or buprenorphine and the rationale for its use.

A manual or Clinical Guidelines for Opioid Agonist Medication Prescribers should also be developed. This manual will include the following:

- > Required competencies;
- > Information on opioid dependence;

- > Framework for opioid agonist medication treatment;
- > Pharmacology;
- > Assessment and stabilisation process;
- > Treatment review process;
- > Dosage and side effects;
- > Statutory requirements.

During the training (conducted through lectures, small group exercises and case studies) the following subjects should be covered:

- > Models of addiction behaviour;
- > Treatment goals and strategies to achieve them;
- > The pharmacological principles for delivering effective treatment;
- > Managing difficult situations including complex cases.

At the end of the training, participants should be required to sit for a written exam. This assesses knowledge of the policies, procedures and practices involved in the effective and safe treatment using OAM.



### **iii. Clinical Placement**

Upon successful completion of the training and written exam, participants should be engaged in a clinical placement supervised by an accredited doctor. This placement provides participants with the opportunity to have one-on-one discussions with a more experienced doctor and to also focus on any weaker areas identified during the written exam. During this placement, the potential prescriber is to:

- a. Observe an assessment and then conduct an assessment under supervision;
- b. Observe and then conduct, under supervision, two or more medical prescription reviews.

A Certificate of Completed Training should be given to participants upon successful completion of the training, written exam and the clinical placement. It is recommended that authorisation should only be provided to doctors who have completed all of the above steps.

In giving authority for prescribers, the MoH/MoPH or the governing body should restrict the newly authorised prescribers to initially seeing a limited number of patients to ensure safe and effective treatment. This can also potentially overcome situations where private GPs dispense methadone without proper assessment and counselling of patients. Newly authorised prescribers should be restricted to seeing two new patients per week for the first two months, to a maximum of 50 patients.

### **iv. Post Authorisation Support**

The national governing body or the MoH/MoPH should have regular contact with the prescribers in the private and public sectors. A government liaison officer is recommended. This could be a health officer from the Department of Public Health. Their role is to provide ongoing support and advice to prescribers. They should also identify further training needs for prescribers.

It is also important that the prescriber's practice and authorisation is reviewed by the governing body at regular intervals. Practice audits can be undertaken at the request of the prescriber or the MoH/MoPH if there have been concerns raised about clinical standards. During the practice audits, the officer in charge should inspect the following:

- > Physical surroundings including clinical facilities such as reception and waiting rooms;
- > Storage and safety of medication and case notes;
- > Case notes – selected at random and reviewed for initial dose, rates of dose increase and management of other drug use.

The prescriber should be present at the audit and feedback must be given immediately. Should there be any concerns, it should be raised with the MoH/MoPH or the governing body. If malpractice is identified or concerns are raised, the authority to prescribe should be suspended or removed.

#### **v. Ongoing training and recertification**

Ongoing education for opioid agonist medication treatment prescribers is necessary as patients often present prescribers with various situations and challenges that may not have been addressed at the initial training. Also prescribers may need to update their medical knowledge on various issues such as hepatitis C, drug interactions between new ARV medications and methadone. It is highly recommended that regular updates and ongoing training strategies be developed as part of the opioid agonist medication treatment training strategy.

Note: Another publication, from the Australian organisation Turning Point, will provide additional information on developing capacity and providing training for methadone programs in Asia. See: [www.turningpoint.org.au](http://www.turningpoint.org.au)

### **3.6.3 THE NEED FOR AN OPIOID AGONIST MEDICATION TREATMENT PROGRAMS PRESCRIBERS REVIEW COMMITTEE**

In most countries in Asia, the MoH/MoPH holds responsibility for the implementation of the opioid agonist medication treatment program. For example in Thailand, the Thanyarak Institute is responsible for the training and supervision of the prescribers throughout the country. However the Institute also runs a treatment centre, conducts research and develops many other programs related to drug use.

The process of training, accrediting and authorising prescribers following the steps mentioned above is best managed through a special committee. This committee - representing various professional, ethical and regulatory interests should be tasked with the responsibility to accredit, recommend authorisation as a OAM prescriber and review the prescriber practice. A Prescribers Review Committee is recommended for this task. This committee could be the governing body mentioned above.



## TOOL 7: GUIDANCE NOTE ON CLINICAL SUPERVISION

### 3.7 INTRODUCTION

In Asia and elsewhere, problems associated with substance misuse are becoming increasingly complex as drug use patterns change and co-occurring mental health disorders are seen more frequently. Treatment for drug addiction is also rapidly changing and becoming more complex. Complex treatment issues call for more sophisticated clinicians including prescribers, dispensers, nurses and counsellors. To meet increasing demands, modern treatment organisations must now be able to:

- > Monitor, evaluate, and promote clinical competence directly and objectively;
- > Ensure fidelity to evidence-based practices;
- > Increase treatment efficacy and cost-effectiveness.

Treatment centres are often faced with a multitude of needs such as dealing with co-morbidities and patient-family issues so that a lot of resources are focused on providing direct patient care. All too often, clinicians and supervisors alike have heavy caseloads and a variety of program management responsibilities and very little time for staff development activities. This means that other activities, such as clinical supervision that are critical to ensuring quality service and effectiveness are often neglected. Supervision then often becomes more administrative than clinical.

#### 3.7.1. WHAT IS CLINICAL SUPERVISION?

There are several definitions of clinical supervision. Bernard and Goodyear (1998) offer this definition that has come to be accepted within the counselling profession:

“Supervision is an intervention that is provided by a senior member of a profession to a junior member or members of that same profession. This relationship is evaluative, extends over time, and has the simultaneous purposes of enhancing the professional functioning of the junior member(s), monitoring the quality of professional services offered to the patients she, he, or they see(s), and serving as a gatekeeper of those who are to enter the particular profession.”

Clinical supervision is an in-depth regular exploration of the clinician’s (supervisee’s) work with patients in a systematic and planned way. It integrates into practice:

- > Self-understanding;
- > Relevant theory;
- > Up-to-date knowledge;
- > Skills development.

It is important to recognise that clinical supervision is quite distinct from administrative supervision. Clinical supervision does not seek to meet administrative or managerial goals beyond achieving ‘best practice’ or the best way to provide treatment services for the patient. The clinician should not ideally be accountable operationally or professionally to the supervisor.

The table below summarizes the difference between clinical supervision and administrative supervision

CLINICAL SUPERVISION	ADMINISTRATIVE SUPERVISION
Clinical supervision emphasizes improving the counselling skills and effectiveness of the supervisee	Administrative supervision emphasizes conformity with administrative and procedural aspects of the agency’s work (eg. using correct formats for documentation, and complying with agency leave policies).
Clinical supervision emphasizes developing counsellor effectiveness through positive changes in knowledge, attitudes and skills.	
Both supervisor and supervisee should know that the supervisor will only intervene to improve performance, not to be unnecessarily critical or arbitrary.	The supervisee is accountable operationally and professionally to the supervisor
<p>A clinical supervisor has a role as expert, authority, mentor and representative of the treatment agency in relationship to the counsellor.</p> <p>Quality supervision is based on a relationship that is respectful, is clear regarding authority and accountability, and involves clear expectations for each person.</p>	

In organizations that have limited resources, it is acknowledged that clinical supervision will often be conducted by managers within the organizations. On such occasions both a worker and manager may be comfortable and satisfied with the dual roles of operational and clinical supervision, provided clarity is retained with respect to the different functions (i.e. both parties are clear which ‘hat’ is being worn at any given time).

However, there remains much potential for a blurring of boundaries between operational concerns and clinical/professional development. Therefore, the ideal situation is to have supervisors that are external to an organization, and yet have some knowledge of the working of that organization/agency (achieved as part of an orientation when contracted to provide supervision).



Whilst clinical supervision does not have a primary aim of satisfying of worker obligations in an operational sense, greater adherence to organisational requirements may occur as a by-product of clinical supervision.

Unfortunately supervision can become a 'cozy club of complicity' in which no more than a superficial review of cases occurs. Supervision is not fulfilling its potential unless the clinician explores new perspectives and advances his/her knowledge and skills

### **3.7.2 WHAT ARE THE BENEFITS OF CLINICAL SUPERVISION?**

Research in the field of mental health shows that there are several benefits to clinical supervision. It seems reasonable to generalize these benefits to the alcohol and other drugs field given that clinical supervision is a generic process. The benefits are:

- > Improved service to patients;
- > Higher practitioner job satisfaction;
- > Less burnout;
- > Decreased staff turnover;
- > Lower administration costs;
- > New skills learnt;
- > Improved staff communication;
- > Improved patient outcomes.

Given that the benefits above are interrelated, it is likely that quality clinical supervision will consistently contribute to good outcomes. Having said that, supervision cannot be expected to be a panacea for workers in a dysfunctional organization with other impediments to 'best practice'.

### **3.7.3 DEVELOPING A SUPERVISION POLICY**

An organization needs to develop a supervision policy in conjunction with its workers to ensure:

- > Common understanding of the purpose and process of supervision to mutually benefit the clinician and their organization (consistent with the organisation's overall philosophy and development program);
- > Clear and consistent goals;
- > Structure for how, when, where and how often the clinical supervision will take place;
- > Removal of barriers to supervision.

A supervision policy is best incorporated into an organization's clinical procedures manual (or its equivalent), so that it is consistent with all related policies.



### 3.7.4 WHAT ARE COMMON BARRIERS TO SUPERVISION?

Some of the common barriers to clinical supervision are:

- > Managers not understanding the benefits of such supervision;
- > Supervisors not trained/experienced in providing clinical guidance and feedback to supervisee;
- > Supervision program not articulated/written in policy documents;
- > Confusion between clinical and managerial (administrative) supervision;
- > Lack of common understanding of concepts and terminology;
  - > Clinical supervision inadequately funded;
  - > Access difficult.

Many barriers to clinical supervision relate to a lack of understanding of the value, goals and process of the supervision. Therefore, it is of critical importance that a program be designed to orient managers to clinical supervision and to help them in developing a program of supervision. In situations where there is a lack of experienced clinical supervisors in the alcohol and other drugs field, it is possible to recruit supervisors from other fields, and trained in groups, to ensure that they are familiar with the nuances of alcohol and other drugs work.

### 3.7.5 SUPERVISORY AGREEMENT /CONTRACT

Due to the barriers discussed above, and to prevent negative supervisory experience, a supervision contract is recommended. This supervisory contract helps prepare the supervisee for the supervisory experience.

Contracts are created by the supervisor with the supervisee, and are designed to orient the supervisee to supervision as well as to serve as a roadmap for the entire experience. The contract will define the mutual goals and agendas of both parties involved in the supervision. Supervision contracts should include the following:

**Purpose, goals, and objectives.** The guiding principle here is promoting supervisee development and ensuring best outcomes for patients.

**Context of services.** This part defines when and where supervision will take place, the type of monitoring and supervision model that will be used.

**Evaluation.** It is important to identify the criteria to be used in assessing performance plus the evaluation methods, instruments, and schedules that will be followed.

**Duties and responsibilities of the supervisor and supervisee.** This section outlines the actions that both the supervisor and supervisee are committed to in order to make supervision successful.



**Procedural considerations.** At a minimum the treatment centre's standard operating procedures and record keeping format should be clarified. An additional statement can be added that defines how conflicts within supervision will be resolved.

### 3.7.6 THE RIGHTS OF THE SUPERVISEE

Although supervision contracts establish explicit tasks and responsibilities for the supervisor and supervisee, there can be situations where the supervisee is uncomfortable with the situation. The supervisee may be:

- > Uncertain about what is involved in the clinical supervision especially when no orientation to the supervision is provided;
- > Afraid and resistant to losing independence and autonomy in treatment;
- > Anxious about being scrutinised, spied on or interrogated;
- > Uncomfortable about being open to criticism by others about his/her method of working with patients or providing treatment.

It is therefore important to recognise that being the person who is being evaluated, the supervisee has the right to:

- i. A supervisor who supervises consistently and at regular intervals
- ii. A growth-oriented supervision that respects personal privacy
- iii. A supervision that is technically sound and theoretically grounded
- iv. Criteria that are made clear in advance, and evaluations based on actual observation of performance, and
- v. A supervisor who is adequately skilled in clinical practice and trained in supervisory methods

### 3.7.7 THE ROLE OF THE SUPERVISOR

Clinical supervision is a highly skilled activity. Being a supervisor entails developing a positive relationship with the supervisee. A high-quality supervisory relationship entails a combination of facilitating attitudes, behaviours and practices. Falander and Shafranske (2004) state that facilitating attitudes *consist of supervisor empathy toward the supervisee's developmental process and the creation of a sense of teamwork between them. Facilitating behaviours from the supervisor include warmth, understanding, affirmation, acceptance, and respect along with a non-judgemental outlook.* A supervisor also needs to be encouraging as well as skilled in developing a comfortable relationship where the supervisee may feel secure to disclose important matters. As such, a supervisor is someone not just with clinical skills but also good 'people' skills. Some excellent clinicians will not necessarily be excellent supervisors.



The main responsibilities of a supervisor can be categorized in 4 main areas:

SUPERVISOR RESPONSIBILITIES	TASKS
Skills Development	<ul style="list-style-type: none"> <li>• Evaluate clinical interactions</li> <li>• Identify and reinforce effective actions</li> <li>• Teach and demonstrate counselling techniques</li> <li>• Explain the rationale for strategies and interventions</li> <li>• Interpret significant events</li> </ul>
Support	<p>Encourage, reduce feelings of isolation, normalise the difficulty of alcohol and other drugs work and feelings of professional uncertainty</p> <p>“The supportive functions of clinical supervision include handholding, cheerleading, coaching, morale building, burnout prevention, and encouragement of personal growth. In certain respects the supervisor may be said to befriend the supervisee, although the boundaries of the professional situation make a close personal relationship between the two inappropriate.”</p> <p>(Powel 1980 <i>Clinical supervision: Skills for substance abuse counsellors</i> (Trainee’s Workbook). New York: Human Sciences Press.)</p>
Administrative	<ul style="list-style-type: none"> <li>• Keep (confidential) notes relating to the sessions</li> <li>• Confirm to management that supervision did take place according to schedule and that supervision has conformed to the agency’s guidelines</li> <li>• Notify relevant authorities of potential for imminent harm and/or unethical conduct as per mandatory reporting requirements</li> </ul>
Evaluative	<ul style="list-style-type: none"> <li>• Assess and monitor worker’s skills and development</li> <li>• Clarify clinical performance standards</li> <li>• Negotiate goals and monitor achievement</li> <li>• Provide clear and constructive feedback               <ul style="list-style-type: none"> <li>– focus on strengths unless dangerous, unethical behaviour</li> <li>– workers are often anxious re their supervisor’s evaluation; the supervisor needs to be skilled in their evaluation and feedback so that it increases motivation and empowers the supervisee.</li> </ul> </li> </ul>



### **3.7.8 DEVELOPING AND IMPLEMENTING A CLINICAL SUPERVISION PROGRAM**

In developing and implementing a clinical supervision program, organisations should follow the same principles for establishing any new program. The principles and processes are:

- > 'Needs assessment' first
- > Engage the alcohol and other drugs workers in the process
- > Plan the program in detail before launching
- > Find suitable supervisors
- > Establish contractual obligations
- > Establish conditions conducive for quality outcomes
- > Review

A needs assessment should occur after the staff has been given a clear rationale for the process, and a guarantee that a program will follow. Raising expectations, and then not delivering, is very bad for staff morale.

A critical factor is securing an adequate number of highly competent clinical supervisors (they can be in short supply). Search and recruitment of supervisors should begin early in the process, so that unnecessary delays are avoided. Clear contractual obligations consistent with the organisation's policy should be established with external supervisors.

### **3.7.9 EVALUATION**

Clinical supervision programs require ongoing evaluation (developed at the planning stage) to ensure objectives are achieved and to refine delivery. The main rationale for program evaluation is to determine whether a program is efficacious, and for implementing further improvements. An additional role of evaluation may be to justify further funding of a program. The use of external clinical supervisors can cost a considerable amount (e.g. fees, the need to cover the supervisee's absence, costs incurred in planning and setting up the program), unless some reciprocal funding arrangement is put in place. Therefore, it is vital that the program be evaluated from the outset to help further planning and justify funding. (This is not to argue that clinical supervision should only occur if proven to be cost-effective, as it is a professional requirement that registered health workers receive clinical supervision. But, if tangible benefits of a program can be demonstrated, then the agency can justify a fully-fledged program without compromises.)

**REFERENCE:**

1. UCLA Integrated Substance Abuse Programs 2006 [www.uclaisap.org](http://www.uclaisap.org)
2. Powel 1980 *Clinical supervision: Skills for substance abuse counsellors* (Trainee's Workbook). New York: Human Sciences Press.
3. Addiction Messenger eNewsletters - [www.nfattc.org/addictionMessenger](http://www.nfattc.org/addictionMessenger)
4. NCETA Clinical Supervision Resource Kit for the Alcohol and Other Drugs Field 2005 - [www.nceta.flinders.edu.au/csrk/](http://www.nceta.flinders.edu.au/csrk/)



## **TOOL 8: GUIDANCE NOTE ON COSTS AND BUDGET FOR OPIOID AGONIST MEDICATION TREATMENT PROGRAMMING**

### **3.8 INTRODUCTION**

The cost of Opioid Agonist Medication Treatment Programs is often the foremost question and challenge faced by policymakers when starting the program. In developing countries where there are numerous competing public health priorities, policymakers may worry that they will not be able to continue the program after a few years due to financial burdens. While it is true that a substantial amount of money is needed to cover the various aspects of the program, it is also true that the opportunity cost of not implementing these programs is substantial.

When thinking about cost, it's important to think about both the cost of implementing the opioid agonist medication treatment programs and the opportunity cost of not implementing the program. The cost for implementing the program will be discussed further in this chapter. The opportunity cost of not implementing the program is worth a serious discussion here and within each country.

Hong Kong, as an example, developed a wide-scale methadone program in response to escalating crime rates within the jurisdiction. The policymakers, especially the law enforcement agency, realised that it was cheaper to treat heroin users with methadone which reduces the need for drug users to commit crimes, than to provide no treatment and face increased criminal justice costs. This strategy has proven extremely beneficial for Hong Kong because, apart from reducing crime and making the island a safe place, it has also kept HIV infections at a low level among drug users.

Even in developed countries such as Australia, authorities are often asked why taxpayers' money should be used for drug users to continue using some form of drug. The answer is simply because it is an effective legitimate treatment and it is cheaper to treat drug users with methadone and/or buprenorphine than to bear the cost of the health and social and economic consequences of heroin addiction including crime in the community and medical treatment for HIV infected persons.

The cost of developing an opioid agonist medication treatment program will vary from country to country depending on many internal and external factors. These factors include;

#### **3.8.1 MEDICATION**

- i. Where the methadone and/or buprenorphine is purchased from.

There are several companies that sell these medications. Some countries use a tendering process whereby companies are invited to submit a tender for the program and the vendor is chosen from those who tender. However, in doing so, it is important to not compromise on the quality of the medication. A reliable and reputable company is important to ensure the methadone and/or buprenorphine is delivered on time and to specification.

- ii. How much medication is purchased.

Economies of scale in some cases apply for the purchase of methadone and/or buprenorphine. The more medication that is purchased, the lower the unit cost can be. So countries need to decide if they would prefer buy a few months' supply or a one-year supply or more. However, it is also important that countries do not purchase too large an amount that storage becomes a problem. Methadone and buprenorphine also have a shelf life and therefore, it is not useful to purchase large amounts if it will not be used before its expiry date.

- iii. Shipment costs.

Bulk purchase also allows for lower shipment costs per unit of medication.

- iv. The type of methadone purchased.

Methadone can be purchased in liquid or powder form. The liquid form comes in 1mg, 5mg and 10mg strengths. Powdered methadone is easier to transport and store and is also cheaper than liquid methadone. It is possible to purchase the powdered methadone and liquefy in the country. The National Pharmaceutical Department can perform this task which is not complicated. Buying powdered methadone also improves shelf life which allows countries to buy in large amounts and reduce the purchase price.

- v. Some countries have moved to domestic manufacture of these medicines as it has proved to be relatively cost-effective and offset some of the costs associated with shipment and storage. However, it needs to be recognised that there is a significant investment required to tool up for such manufacture and it is also a time-consuming process.

### **3.8.2 STAFF**

- i. Number of sites or clinics – the larger the number of sites that are started for the program, the higher the cost will be in regards to the staff salaries.
- ii. Number of staff in each site or clinic.

### **3.8.3 INFRASTRUCTURE**

- i. The cost of building or rental of clinic or sites.
- ii. The need for renovation of clinics to suit the program.
- iii. The cost of laboratory testing kits, machines.



### **3.8.4 POLICY DEVELOPMENT**

- i. Advocacy – including the cost of holding multisectoral meetings to develop a national consensus on methadone programming.
- ii. Cost of workshops and seminars to be held regularly to discuss policy matters at national, provincial and local levels.
- iii. Policymaker education – including the cost of study visits, workshops and trainings.

### **3.8.5 CAPACITY BUILDING**

- i. Training of doctors and other medical personnel.
- ii. Training of counsellors.
- iii. Training of non-medical personnel in methadone program implementation.
- iv. Training of policymakers.
- v. Patient and parent education.
- vi. Ongoing information for the community.
- vii. International technical support – including cost of international consultants for capacity building purposes.
- viii. Study visits for medical personnel.
- ix. Allocation for clinical supervision.

### **3.8.6 MONITORING PROGRAMS**

- i. Monitoring and evaluation of programs –especially important during the start-up phase of the program. An allocation for monitoring including visits to Opioid Agonist Medication Treatment Programs sites is recommended.
- ii. Where possible allocation for a specific staff member to conduct monitoring duties.

## **TOOL 9: GUIDANCE NOTE ON MONITORING AND EVALUATION**

### **3.9 INTRODUCTION**

Methadone and buprenorphine, administered to patients in Opioid Agonist Medication Treatment Programs, have been consistently shown in clinical studies to decrease opioid and other illicit drug use; HIV/hepatitis C exposure risks; criminal activity; risk of overdose; and to result in improvements in physical and psychological health, as well as social functioning. Despite these encouraging findings, program managers; and funding, accreditation and licensing bodies need up-to-date, objective and reliable evidence that their own programs are producing beneficial outcomes for their patients. Studies have also shown that some programs are much more effective than other programs.

Furthermore, not all programs or patient groups are the same. Programs are likely to differ in the level of staffing and resources, and the range of services that they can offer patients. The characteristics of opioid dependent persons seeking treatment may differ from one country to the next or from region to region within a country, e.g. patients from rural regions are likely to differ from patients that live in large cities. Any of these treatment-related or patient-related factors may influence how well a patient benefits from Opioid Agonist Medication Treatment Programs.

The aim of conducting a process and outcome evaluation of a program by external investigators and clinician-mediated (process and outcome) monitoring is to describe in detail the nature and level of clinical services provided to the patients; to describe the characteristics of the patients; and to ascertain that treatment goals are being achieved.

#### **3.9.1 WHAT IS PROCESS EVALUATION?**

A process evaluation aims to describe how a treatment or a program operates. It is concerned with detailing the efficiency and quality of treatment services; identifying areas where improvements can be made; how treatment services or systems operate; and ways in which resources are used to produce outputs (i.e., number of patients treated).

The main aims of process evaluation are:

- To describe the implementation of the program, including information on factors facilitating or impeding the implementation;
- To describe service performance and service quality;
- To describe the acceptance of the programme by patients, by staff and in the community environment;
- To develop recommendations on the basis of process evaluation for service management and staff training; and
- To contribute to an interpretation of findings in outcome evaluation.

The key focuses for Opioid Agonist Medication Treatment Programs process evaluation are:

**Program implementation:**

- Service location;
- Service infrastructure;
- Staff qualifications;
- Program management; and
- Program funding.

**Service performance:**

- *Agonist maintenance treatment:* treatment regime (dosages, dosage policy, urine controls, take-away policy, medical and psychosocial care, patient's rights and responsibilities, sanctions), staff training, staff attitudes
- *Integration of HIV/AIDS and hepatitis prevention:* preventive activities (pre-test and post-test counselling), provision of information on HIV/AIDS in individual and/or group sessions, hepatitis B vaccinations where available), staff attitudes
- *Management of infectious diseases (HIV/AIDS, hepatitis):* available treatment options (medical care, psychosocial interventions, links to other services, ARV medication where available), attitudes of staff.

**Commitment to service quality:**

- Quality assurance procedures;
- Patient satisfaction surveys;
- Staff knowledge/satisfaction surveys; and
- Links of programme to other services.

Acceptance of programme: neighbourhood reactions to the programme.

### 3.9.2 WHAT IS OUTCOME EVALUATION?

The aim of conducting an outcome evaluation is to systematically measure patients' responses to treatment, in order to establish if treatment has been successful, and to identify aspects of treatment that could be improved. The choice of outcome measures reflects the explicit goals of the treatment program, and the harms and disruptions to a patient's life, risked by exposure to the harm causing agent; in this case illicit opioid use. Whereas a process evaluation aims to describe, in detail, the nature of the treatment program; an outcome evaluation aims to establish the overall effectiveness of the program for the patients receiving treatment.

In treatment outcome evaluation, groups of patients are interviewed, using standardized measures, soon after they commence treatment. This establishes a "baseline" level of patient functioning from which change can be measured over the course of the patient's treatment. Patients are then re-interviewed (or followed-up) at designated time-points (usually of not less than three months) over the course of their treatment. Patient performance, as determined by their rating on the individual measures, at follow-up can be compared with their baseline level of functioning.

Patient interviews are ideally conducted by trained interviewers who are not directly involved with the provision of treatment to the patient group under examination. Patients are much more likely to give honest answers regarding their illicit drug use, other criminal activities and injecting behaviour if they can assure that the information they give will be treated confidentially and, in particular, will not be communicated to their treatment providers and will not influence the treatment they receive. They will not tell the truth if they think that their answers will get them into trouble, such as being removed from the program.

Reporting on program performance requires the aggregation of patient data, and data can only be aggregated if it is collected in the same way, using the same measures, for each patient. For this to happen, it is important that interviewers are properly trained in the administration of the measures.

In order to measure Opioid Agonist Medication Treatment Programs outcomes it is first necessary to identify the outcomes that are to be measured. This is typically determined by the goals of treatment. The key goals of Opioid Agonist Medication Treatment Programs are to:

- Reduce harmful opioid use and other drug use;
- Help reduce the spread of HIV and other blood-borne viral infections (BBVs) associated with injecting drug use;
- Improve the physical and psychological health of patients;
- Reduce deaths associated with opioid use;
- Reduce crime associated with opioid use; and
- Facilitate an improvement in social function.

These goals determine the domains of measurement for an outcome evaluation. Standardized measures (instruments or tools), in the form of patient self-report questionnaires, exist that can measure change over time for each of these domains. These measures will be discussed in section 9.5 and 9.6.

Whilst individual patients differ in the extent to which they improve or even decline over the course of the treatment, as the data collected from individual patients is aggregated into grouped patient data, overall there would be an expectation of improvement. If there are sufficient numbers of patients ( $n > 100$ ) involved in the outcome evaluation, it should be possible to relate the extent of improvement to patient and treatment-related factors (derived from the process evaluation or independently). For instance, it may be worth determining whether gender, age, marital status, or the provision of ancillary services such as mental health or vocational counselling influence treatment outcome. Determining which specific treatment components work best with different patient groups can provide valuable information that can be used to improve treatment processes.

### **3.9.3 METHODOLOGIES FOR CONDUCTING PROCESS AND OUTCOME EVALUATION: PROCESS AND OUTCOME EVALUATION OF A PROGRAM CONDUCTED BY EXTERNAL INVESTIGATORS, AND CLINICIAN-MEDIATED MONITORING**

Treatment processes and outcomes can be investigated in two ways:

- i. A population approach for the process and outcome evaluation of a program conducted by external investigators, that is, a formal “one-off” treatment services evaluation study; and
- ii. Clinician-mediated monitoring, that is, ongoing, routine monitoring of clinical outcomes that is integrated into routine clinical practice.

These two approaches to program assessment can be conducted separately or together. They are not mutually exclusive activities. The choice of which method to use, or indeed whether to adopt both methods, will be determined by the aim of the evaluation and the level of resources available to conduct the evaluation. A brief description of the two main methods follows:

#### **1. PROCESS AND OUTCOME EVALUATION OF A PROGRAM CONDUCTED BY EXTERNAL INVESTIGATORS:**

- Used primarily to report on program performance;
- Minimal demand placed upon clinicians;
- “Independent” (persons not directly involved in the patients treatment) trained interviewers used to collect data and follow-up subjects;
- A discrete “one-off” longitudinal cohort study of limited duration (e.g. 12 months);

- Subjects recruited on consecutive presentation to OST (n = approximately 100);
- Measurements of interest made at commencement of treatment (baseline) and at defined intervals for the duration of the study;
- Comprehensive suite of measures utilized (taking up to one hour to administer);
- Attempts made to follow-up patients who have dropped-out of treatment;
- Subject performance (as a group) at follow-up compared with baseline.

## **2. CLINICIAN-MEDIATED MONITORING:**

- Requires greater involvement of clinical staff;
- Feedback progress to individual patients;
- Conducted in conjunction with individual patient case management;
- Fully integrated into routine clinical practice;
- Standardized, on-going, routine collection of treatment outcome data either at the local, state or national level;
- Utilizes measures that are brief (10-15 minutes) and easy to administer;
- Administered to patients by clinicians upon entry into OST (baseline) and at specified review point(s), of not less than X months whilst still in treatment, in conjunction with case management reviews or script renewals;
- No attempt made to follow-up patients who have left treatment;
- Tailor data collection to harmonise with current data collection requirements and differences in service provision;
- Relate outcomes to patient and treatment program-related factors;
- Facilitated by automation of data collection, collation and reporting.

**COMPARISON OF AN EXTERNALLY CONDUCTED PROCESS AND OUTCOME EVALUATION STUDY AND CLINICIAN-MEDIATED MONITORING**

	<b>PROCESS AND OUTCOME EVALUATION OF A PROGRAM</b>	<b>CLINICIAN-MEDIATED MONITORING</b>
<b>Aim</b>	program evaluation (PE)	patient case management
<b>Focus</b>	program	patients (s)
<b>Measures</b>	comprehensive	brief
<b>Patients</b>	discrete cohort	“all”
<b>Status of patient</b>	anonymous	identified
<b>Interviewers</b>	independent	clinicians
<b>Duration</b>	limited	ongoing
<b>Demands on clinician time</b>	minimal	time & resource intensive
<b>Follow-up rates</b>	good (70-80%)	poor (<50%)

Given that clinician-mediated monitoring usually relies upon clinicians to collect the data from patients, it is suggested that questioning on sensitive topics, such as, criminal activities, be avoided.

In summary, externally conducted process and outcome evaluation studies are primarily used for reporting on overall program performance and thus require accurate and complete data collection. Clinician-mediated monitoring enables an individual's patient's progress in treatment to be followed and is firmly sited within routine clinical practice, thus promoting a clinical culture that views evaluation as a central component of clinical practice. Both of these approaches provide important information for optimising the provision of treatment and there is clearly an advantage in conducting both activities together if resources permit.



### **3.9.4 CHOOSING CONTENT DOMAINS FOR OUTCOME EVALUATION AND MONITORING**

The domains for measurement are determined by the goals of treatment, as previously mentioned. The key domains for Opioid Agonist Medication Treatment Programs are:

- Opioid use
- HIV and other BBV exposure risk (injecting)
- Crime
- Health (physical and mental)
- Social functioning (relationships, financial concerns)
- Alcohol, tobacco & other drug use

Other domains may include:

- Blood-borne virus exposure risk (sexual and skin penetration)
- Dependence severity
- Quality of life

Additionally, it is important to collect enough patient and treatment-related information to provide meaning to the outcome data collected and to allow for investigation into factors that may be affecting the extent to which groups of patients respond to Opioid Agonist Medication Treatment Programs. Conducting process evaluation at the same time as outcome evaluation will greatly assist in the interpretation of the findings of both studies. Process evaluation provides information on what constitutes treatment. Outcome evaluation provides information on the effectiveness of treatment. Table 9.2 summarises the type of data items that could be useful for monitoring and evaluation.



## POTENTIAL PATIENT AND TREATMENT VARIABLES FOR TREATMENT MONITORING AND EVALUATION

PATIENT VARIABLES		
ADMINISTRATIVE	PREDICTORS	BASELINE/OUTCOME
Patient identifier	Demographics	AOD use frequency
Referral Sources	Education	AOD use amount
Payment Source	Vocational history	Route of drug administration
	Social history	BBV risk behaviours
	AOD use history	AOD dependence symptoms
	AOD treatment history	Physical health
	Medical history	Psychological health
	Psychiatric history	Employment
	Legal problems	Financial stability
	Motivation	Legal problems
	Treatment readiness	Family/social relationships
TREATMENT VARIABLES		
ADMINISTRATIVE	PREDICTORS	
Program identifier	Setting/level of care	
Admission date	Therapeutic modality	
Discharge date	Context	
Length of stay	Treatment components	
Charges	Staffing	
	Discharge status	
	Patient satisfaction	
	Post-treatment services	

### **3.9.5 CHOOSING AND USING MEASURES FOR OUTCOME EVALUATION AND MONITORING**

There are many hundred of measures and instruments that have been developed for use in the alcohol and other drug (AOD) treatment field. A discussion on the relative merits of one instrument over another is beyond the scope of this toolkit. It is recommended that patient self-report measures be utilized over measures that rely upon clinician rating and that these measures are administered verbally in a face-to-face contact with the patient by a trained interviewer. Ideally, questionnaires should not be given to patients to complete themselves. This often results in incomplete, poor quality data. Furthermore it is recommended that the measures chosen for use should have good psychometric properties, i.e., there should be published accounts in the peer-reviewed literature attesting to the measure's reliability, validity and sensitivity in comparable cultural contexts. Measures validated for use in the United States or Australia may not be suitable for use in other countries.

Both a population approach to process and outcome evaluation of a program, conducted by external investigators, and clinician-mediated monitoring may include the same domains for measurement. The difference lies in the choice of measures. Process and outcome evaluation studies conducted by external investigators will more often utilize longer, more comprehensive measures, whereas clinician-mediated monitoring will more likely contain only one or a small number of questions in each domain. An example of an instrument that is being used for clinician-mediated monitoring is the Treatment Outcome Profile (TOP) developed by the National Treatment Agency for Substance Abuse in the United Kingdom. This one-page instrument and instructions for use can be found at the website: [http://www.nta.nhs.uk/areas/outcomes\\_monitoring/](http://www.nta.nhs.uk/areas/outcomes_monitoring/).

The WHO lists a number of the most commonly used AOD instruments, translated into a range of languages, on the Management of Substance Abuse section of its website: [http://www.who.int/substance\\_abuse/research\\_tools/en/](http://www.who.int/substance_abuse/research_tools/en/). These instruments are suitable for externally conducted process and outcome evaluation of programs, conducted. Some of these tools have been used in the WHO Collaborative Study on Substitution Therapy of Opioid Dependence and HIV/AIDS – a recently completed externally conducted process and outcome evaluation. The key aim of this study was to establish whether OST could be as effective in developing countries as has shown to be the case in developed countries. An important secondary aim of the study was demonstrate the feasibility of conducting an evaluation of treatment outcomes and processes that could inform program managers, service providers and local oversight bodies of the nature and effectiveness of their Opioid Agonist Medication Treatment Program delivery sites. Both of these aims were achieved. These measures, accompanying user's manuals and final report on the study's findings will be available on the W.H.O. website in the form of a toolkit – The Process and Outcome Evaluation Toolkit for Opioid Substitution Therapy – for other nations to use and to replicate the findings from this study.



# SECTION 4: CHECKLISTS



**CHECKLIST 1: INTRODUCTION OF A PILOT OPIOID AGONIST SUBSTITUTION TREATMENT PROGRAM**

ACTIVITIES/ AREAS	AVAILABLE/ NOT AVAILABLE	RESPONSIBLE	ACTIONS TO TAKE
<p>Drug Use and HIV situation identified</p> <ul style="list-style-type: none"> <li>- Have you conducted a situation assessment on drug use and HIV?</li> <li>- Do you have a national estimate of the number of drug users and injecting drug users?</li> </ul> <p>Do you have a needs analysis?</p>			
<p>National Committee</p> <ul style="list-style-type: none"> <li>- Is there a national body that is in charge of the development of OST in your country?</li> <li>- Which is the most senior body in charge?</li> </ul>			
<p>Legislation and policies</p> <ul style="list-style-type: none"> <li>- Does the current law prohibit the importation and use of methadone in your country?</li> <li>- Do you need to amend the laws to allow access to methadone?</li> <li>- Is there a clear understanding between the law enforcement agency and the health departments regarding OST? E.g. MoU?</li> <li>- Do you have a National Drug Treatment Policy?</li> <li>- Do you have a National Policy on OST?</li> </ul>			
<p>Preparations of estimates to be submitted for confirmation to INCB</p> <ul style="list-style-type: none"> <li>- Have you developed a proposal for the OST which will include the number of drug users you will reach every year and the amount of methadone and/or buprenorphine you will need per year?</li> </ul>			



ACTIVITIES/ AREAS	AVAILABLE/ NOT AVAILABLE	RESPONSIBLE	ACTIONS TO TAKE
<p>Identification of methadone and/or buprenorphine suppliers and pricing</p> <ul style="list-style-type: none"> <li>- Do you have a list of suppliers and the prices of methadone and/or buprenorphine they offer?</li> <li>- Have you decided if you would tender out or choose the most reputable supplier?</li> </ul>			
<p>Methadone and/or buprenorphine importation mechanisms</p> <ul style="list-style-type: none"> <li>- Do all key stakeholders understand the importation process and mechanisms?</li> <li>- Have you elicited the cooperation and support of the Customs Department to ensure smooth importation?</li> </ul>			
<p>Cooperation of WHO, UNODC, UNAIDS</p> <ul style="list-style-type: none"> <li>- Have you received support from these organisations?</li> </ul>			
<p>Storage and distribution systems developed</p> <ul style="list-style-type: none"> <li>- Who will be in charge of the storage and distribution of methadone and/or buprenorphine once received in the country?</li> <li>- Has the pharmaceutical branch been involved in the planning process?</li> </ul>			



ACTIVITIES/ AREAS	AVAILABLE/ NOT AVAILABLE	RESPONSIBLE	ACTIONS TO TAKE
<p>Budget</p> <ul style="list-style-type: none"> <li>- Have you calculated the budget for this program – per year and for the first 3 years?</li> <li>- What mechanisms did you use to calculate this?</li> <li>- Has the money been secured?</li> <li>- How will the program be funded?</li> </ul>			
<p>Identification of Sites</p> <ul style="list-style-type: none"> <li>- Have you identified the site for OST implementation?</li> <li>- How many sites have you identified for the start up?</li> <li>- How many patients can this site accommodate?</li> <li>- Has the site met the minimum standards for methadone and/or buprenorphine implementation?</li> </ul>			
<p>Training of prescribers and other staff</p> <ul style="list-style-type: none"> <li>- Has all the staff at the site been trained?</li> <li>- Is there a training needs analysis and a training plan?</li> <li>- Which organisation or agency will be in charge of the trainings in the country?</li> <li>- Do you have a Prescribers Review Committee?</li> </ul>			
<p>Accreditation process for sites</p> <ul style="list-style-type: none"> <li>- Have you developed an accreditation mechanism for clinics or sites?</li> <li>- Do you have a minimum required standard for clinics to prescribe methadone and/or buprenorphine?</li> </ul>			



ACTIVITIES/ AREAS	AVAILABLE/ NOT AVAILABLE	RESPONSIBLE	ACTIONS TO TAKE
<p>Supervision roles within government system identified</p> <ul style="list-style-type: none"> <li>- What is the lead agency in the country to monitor the program?</li> <li>- Is there a National OST program coordinator?</li> </ul>			
<p>Monitoring and evaluation</p> <ul style="list-style-type: none"> <li>- Have you developed an M&amp;E system?</li> <li>- Do you have an identified team or person to be responsible for and implement the M&amp;E?</li> <li>- Are the objectives and aims of the pilot project reasonable and understood by all key stakeholders?</li> </ul>			
<p>Standard Operating Procedures (SOP)</p> <ul style="list-style-type: none"> <li>- Have you developed the Clinical Guidelines for the OST pilot?</li> <li>- Is there a SOP that has been discussed with all relevant parties including staff?</li> </ul>			
<p>Advocacy</p> <ul style="list-style-type: none"> <li>- Have you developed a media strategy to explain the program to the public</li> <li>- Are there any particular groups or agencies that are against the pilot program and, if so, have you developed advocacy strategies to deal with this opposition?</li> </ul>			
<p>Methadone information booklets</p> <ul style="list-style-type: none"> <li>- Have you developed a methadone information booklet for patients/drug users?</li> <li>- Have you developed a methadone information booklet for parents and family members of patients?</li> </ul>			



ACTIVITIES/ AREAS	AVAILABLE/ NOT AVAILABLE	RESPONSIBLE	ACTIONS TO TAKE
Psychosocial Programs <ul style="list-style-type: none"> <li>- Have you identified other needs and challenges faced by the patients in accessing the treatment? This could be problems related to transport, accommodation, employment, marital issues?</li> <li>- Do you have psychosocial and other behaviour change interventions to address the above?</li> <li>- Have you identified challenges and needs of the parents and family members of patients?</li> <li>- Do you have programs to address the above?</li> </ul>			
Cooperation with Law enforcement agencies. <ul style="list-style-type: none"> <li>- Have you consulted and involved relevant law enforcement agency in the development of the pilot project?</li> <li>- Is there any form of formal or informal agreement to cooperate in this program? E.g. a MoU</li> <li>- Have you identified the role of the police and other law enforcement agencies in the implementation of the project?</li> </ul>			
Ongoing education for policy makers and program implementers. <ul style="list-style-type: none"> <li>- Study visits</li> <li>- Conference attendance</li> <li>- Workshops</li> <li>- Trainings</li> </ul>			
Others			



**CHECKLIST 2: FROM PILOT TO SCALE-UP**

ACTIVITIES/ AREAS	AVAILABLE/ NOT AVAILABLE	RESPONSIBLE	ACTIONS TO TAKE
Monitoring and evaluation report of the pilot project analysed and agreed upon			
Situation assessment / Needs assessment is updated			
Provinces / cities and towns requiring methadone treatment programs have been identified			
Population of IDU requiring the treatment in each province has been identified. Targets set.			
Methadone and/or buprenorphine sites at the provinces also identified			



ACTIVITIES/ AREAS	AVAILABLE/ NOT AVAILABLE	RESPONSIBLE	ACTIONS TO TAKE
Legislation and policies have been developed to enable scale up			
Preparations for submission of estimates to INCB for confirmation			
Application for Methadone and/or Buprenorphine Importation submitted			
Methadone and/or buprenorphine supplier identified. (same supplier as pilot or new supplier identified)			
Budget for 3 – 5 years has been developed and ear-marked.			
Accreditation systems for clinics and sites have been adopted			



ACTIVITIES/ AREAS	AVAILABLE/ NOT AVAILABLE	RESPONSIBLE	ACTIONS TO TAKE
Training for prescribers and other staff <ul style="list-style-type: none"> <li>- Training institution</li> <li>- Training needs analysis</li> <li>- Module</li> <li>- Training schedule</li> </ul>			
Standard Operating Procedure Manual has been adopted for use at the National Level <ul style="list-style-type: none"> <li>- Provincial adaptation made</li> <li>- Additions based on pilot project</li> </ul>			
Referral systems between sites in different provinces developed and adopted			
National Committee <ul style="list-style-type: none"> <li>- National Committee for Drug Use and HIV</li> <li>- National Committee on OST</li> </ul>			
National Coordinator for OST			
Management Structure for National Program developed and accepted by National Committee			



ACTIVITIES/ AREAS	AVAILABLE/ NOT AVAILABLE	RESPONSIBLE	ACTIONS TO TAKE
National Advocacy Strategy <ul style="list-style-type: none"> <li>- Media relations</li> <li>- Religious groups</li> <li>- Drug treatment centres</li> </ul>			
Psychosocial support for Patients and Parents scaled up using lessons learnt from Pilot projects			
Monitoring and Evaluation Systems <ul style="list-style-type: none"> <li>- M&amp;E Teams</li> <li>- Data collection mechanisms</li> <li>- Reporting mechanisms</li> </ul>			
Others			



**CHECKLIST 3: OPIOID AGONIST SUBSTITUTION TREATMENT PROGRAM IN PRISON SETTINGS**

ACTIVITIES/ AREAS	AVAILABLE/ NOT AVAILABLE	RESPONSIBLE	ACTIONS TO TAKE
<p>A participatory assessment of the situation of drug use and HIV among inmates</p> <ul style="list-style-type: none"> <li>- BSS reports</li> <li>- Needs assessment</li> </ul>			
<p>A consultative process on the issues of HIV among inmates between MOH, Ministry of Justice, Law enforcement</p>			
<p>Development of a National Committee on Drug Use and HIV in Prisons</p>			
<p>Development of National Policy /legislation for the use of methadone and or buprenorphine within prison settings</p>			
<p>Development of a National Strategy for comprehensive Drug Use and HIV prevention among prisoners</p>			
<p>Development of SOP and protocol</p>			



ACTIVITIES/ AREAS	AVAILABLE/ NOT AVAILABLE	RESPONSIBLE	ACTIONS TO TAKE
Training of Prison officials regarding MMT			
Training and authorisation of doctors and prison staff			
Accreditation of prison clinic			
Preparation of clinic and infrastructure within prison system			
Development of methadone and/or buprenorphine distribution between the Local Health Department and the prison.			



ACTIVITIES/ AREAS	AVAILABLE/ NOT AVAILABLE	RESPONSIBLE	ACTIONS TO TAKE
Development of methadone and/or buprenorphine distribution and storage system within the prison setting			
M&E System - data collection system - reporting			
Supervision roles between Health Department and Prison Department			
Others			



# GLOSSARY

Abstinence	The voluntary self-denial of something, such as drugs, sex or food.
Accreditation	Give official authorization to; the act of granting credit or recognition.
Addiction	Persistent compulsive use of a substance known by the user to be physically, psychologically, or socially harmful; compulsive physiological need for and use of a habit-forming substance (as heroin, nicotine, or alcohol) characterized by tolerance and by well-defined physiological symptoms upon withdrawal.
Adherence	Stick fast to; remain faithful to.
Agonist	A chemical substance (as a drug) capable of combining with a receptor on a cell and initiating the same reaction or activity typically produced by the binding of an endogenous substance.
Antenatal care	Concerned with the care and treatment of the unborn child and of pregnant women.
AOD	Alcohol and Other Drugs.
ARV	Anti-Retroviral medication; acting, used, or effective against retroviruses, i.e. any of the family Retroviridae of single-stranded RNA viruses; also called RNA tumor virus.
BBV	Blood-Borne Virus.
BMT	Buprenorphine Maintenance Treatment
Benzodiazepine	Any of a group of aromatic lipophilic amines (as diazepam and chlordiazepoxide) used especially as tranquilizers, i.e. a drug used to reduce mental disturbance (as anxiety and tension).
BSS	Behavioural Surveillance Survey.
Buprenorphine	A semisynthetic narcotic analgesic that is derived from thebaine and is administered in the form of its hydrochloride $C_{29}H_{41}NO_4HCl$ intravenously or intramuscularly to treat moderate to severe pain and sublingually to treat opioid dependence.



Case management	Person (as a social worker or nurse) who assists in the planning, coordination, monitoring, and evaluation of medical services for a patient with emphasis on quality of care, continuity of services, and cost-effectiveness.
CBT	Cognitive Behavioural Therapy; psychotherapy especially for depression that emphasizes the substitution of desirable patterns of thinking for maladaptive or faulty ones.
Central nervous system	The part of the nervous system which in vertebrates consists of the brain and spinal cord, to which sensory impulses are transmitted and from which motor impulses pass out, and which supervises and coordinates the activity of the entire nervous system.
Child-resistant containers	A container that cannot be easily opened by a child.
Chronic	Marked by long duration, by frequent recurrence over a long time, and often by slowly progressing seriousness; suffering from a disease or ailment of long duration or frequent recurrence.
'Clean'	Free from drug addiction.
Clinician	An individual qualified in the clinical practice of medicine, psychiatry, or psychology as distinguished from one specializing in laboratory or research techniques or in theory.
'Cold turkey'	Abrupt complete cessation of the use of an addictive drug; the symptoms experienced by one undergoing withdrawal from a drug.
Constipation	Abnormally delayed or infrequent passage of dry hardened feces, i.e. bodily waste discharged through the anus.
Contraindications	Something (as a symptom or condition) that makes a particular treatment or procedure inadvisable.
Counselling	To advise especially seriously and formally after consultation.
Counsellors	A person engaged in counseling.
Craving	A powerful desire for something.
Diazepam	A synthetic tranquilizer C <sub>16</sub> H <sub>13</sub> ClN <sub>2</sub> O used especially to relieve anxiety and tension and as a muscle relaxant.



Depressants	One that depresses; specifically, an agent that reduces bodily functional activity or an instinctive desire.
Dispensers	A person, or equipment, to supply medicine according to a doctor's prescription.
Dose increment	The amount or degree by which there is a change in the measured quantity of a therapeutic agent to be taken at one time.
DOT	Directly Observed Treatment.
Empathetic	The action of understanding, being aware of, being sensitive to, and vicariously experiencing the feelings, thoughts, and experience of another of either the past or present without having the feelings, thoughts, and experience fully communicated in an objectively explicit manner.
Epidemic	Affecting or tending to affect an atypically large number of individuals within a population, community, or region at the same time.
Ethical	Conforming to accepted professional standards of conduct.
Feasibility	Possible and practical to achieve easily or conveniently.
Feedback	The return to a point of origin of evaluative or corrective information about an action or process.
GP	General Practitioner; Doctor.
Gynaecomastia	Excessive development of the breast in the male.
Hepatic impairment	Any loss or abnormality of psychological, physiologic, or anatomic structure or function relating to the liver.
Hepatitis	A disease or condition (as hepatitis A, B or C ) marked by inflammation of the liver.
Hepatitis B	A sometimes fatal hepatitis caused by a double-stranded DNA virus (species hepatitis B virus of the genus Orthohepadnavirus, family Hepadnaviridae) that tends to persist in the blood serum and is transmitted especially by contact with infected blood (as by transfusion or by sharing contaminated needles in illicit intravenous drug use) or by contact with other infected bodily fluids (as semen); also called serum hepatitis.



Hepatitis C	Hepatitis caused by a single-stranded RNA virus of the family Flaviviridae (species hepatitis C virus of the genus Hepacivirus) that tends to persist in the blood serum and is usually transmitted by infected blood (as by injection of an illicit drug, blood transfusion, or exposure to blood or blood products) and that accounts for most cases of non-A, non-B hepatitis.
HIV	Human Immunodeficiency Virus; any of several retroviruses and especially HIV-1 that infect and destroy helper T cells of the immune system causing the marked reduction in their numbers that is diagnostic of AIDS; also called AIDS virus.
Hypersensitive	Excessively or abnormally sensitive; abnormally susceptible physiologically to a specific agent (as a drug or antigen).
Impotence	An abnormal physical or psychological state of a male characterized by inability to copulate because of failure to have or maintain an erection; also called erectile dysfunction, i.e. a chronic inability to achieve or maintain an erection satisfactory for sexual intercourse.
INCB	International Narcotic Control Board, based in Vienna, Austria.
Induction phase	The period when the patient has just begun treatment.
Informed consent	Consent to surgery by a patient or to participation in a medical experiment by a subject after achieving an understanding of what is involved.
INML	International Narcotics Movement License.
Intoxication	An abnormal state that is essentially a poisoning; the condition of being drunk.
In-utero	In the uterus; before birth.
Jurisdictional requirements	What is needed from a legal perspective.
Legal consent	Agreement to a principle, rule or law.
Libido	Sexual drive; instinctual psychic energy that in psychoanalytic theory is derived from primitive biological urges (as for sexual pleasure or self-preservation) and that is expressed in conscious activity.
Longitudinal cohort study	Following a group of people and taking information from them over time.

Menstrual irregularities	Irregularities of, or relating to, menstruation or the menses.
Miscarriage	Spontaneous expulsion of a human fetus before it is viable and especially between the 12th and 28th weeks of gestation.
MMT	Methadone Maintenance Therapy; Methadone Maintenance Treatment
MoH	Ministry of Health.
MoU	Memorandum of Understanding; agreement.
Monoamine oxidase inhibitors	Medicines that relieve certain types of mental depression.
Nausea	A stomach distress with distaste for food and an urge to vomit.
Neonatal	Of, relating to, or affecting the newborn and especially the human infant during the first month after birth.
Neonates	A newborn infant; especially, an infant less than a month old.
NGO	Non-Governmental Organisation.
NSP	Needle / Syringe [Exchange] Programme
OI	Opportunistic Infection(s)
Opportunity cost	Cost in terms of foregoing alternatives.
OST	Opiate Substitution Therapy; Opiate Substitution Treatment.
Outcome evaluation	Provides information on the effectiveness of treatment.
OAM	Opioid agonist medication
OAMT	opioid agonist medication treatment
Overdose	Too great a dose; a lethal or toxic amount (as of a drug).
PE	Program evaluation.
Peer worker	A person who works with a group of people of approximately the same age, status, and interests.
Pharmacology	The properties and reactions of drugs especially with relation to their therapeutic value; the science of drugs including their origin, composition, pharmacokinetics, therapeutic use, and toxicology.

Pharmacotherapy	The treatment of disease and especially mental disorder with drugs.
Poly drug use	The use of two, or more, drugs.
Postnatal care	Assistance occurring or being after birth; of or relating to an infant immediately after birth.
Premature labour	Labour beginning prior to the 37th week of gestation.
Prescriber	A person who writes or gives medical prescriptions.
Process evaluation	Provides information on what constitutes treatment.
Psychiatric	Engaged in the practice of psychiatry; dealing with cases of mental disorder; a branch of medicine that deals with the science and practice of treating mental, emotional, or behavioral disorders especially as originating in endogenous causes or resulting from faulty interpersonal relationships.
Psychometric properties	The technique of mental measurements; the use of quantitative devices for assessing psychological trends; a measure's reliability, validity and sensitivity in comparable cultural contexts.
Psychosocial support	Assistance relating to both social conditions and mental health.
Punitive	Inflicting or intended as punishment.
Reintegration	Integrate back into society; a renewing, or making whole again.
Raised intracranial pressure	Increased pressure within the skull.
Relapse	A recurrence of illness; especially a recurrence of symptoms of a disease after a period of improvement.
Relapse prevention	Efforts to stop a recurrence of illness; especially a recurrence of symptoms of a disease after a period of improvement.
Retention	The act of retaining; to hold or keep in.
Secondary consultation	To seek information or advice from someone coming after, or less important than, or resulting from someone else.
Sedative	Tending to calm, moderate, or tranquilize nervousness or excitement.

Serostatus	Status with respect to being seropositive or seronegative for a particular antibody.
Sexual dysfunction	When a person is unable to experience enjoyable sexual activity..
Shelf life	The period of time during which a material (as a food or drug) may be stored and remain suitable for use.
Side effect	A secondary and usually adverse effect.
Social worker	Work carried out by trained personnel with the aim of alleviating the conditions of those people suffering from social deprivation.
Spouse	A person's partner in marriage; a husband or wife.
Staff-patient ratio	The quantitative relation between the number of staff and the number of patients and the number of times one value contains or is contained within the other.
Statutory requirement	Required, permitted, or enacted by statute, i.e. a rule of an organization or institution or a written law passed by a legislative body.
STD	Also referred to as Sexually Transmitted Infection – STI; any of various diseases or infections that can be transmitted by direct sexual contact including some (as syphilis, gonorrhea, chlamydia, and genital herpes) chiefly spread by sexual means and others (as hepatitis B and AIDS) often contracted by nonsexual means.
STI	Sexually Transmitted Infection; also referred to as Sexually Transmitted Disease – STD; any of various diseases or infections that can be transmitted by direct sexual contact including some (as syphilis, gonorrhea, chlamydia, and genital herpes) chiefly spread by sexual means and others (as hepatitis B and AIDS) often contracted by nonsexual means.
Take-away doses	The measured quantity of a therapeutic agent capable of being borne or carried, easily transported, or conveyed without difficulty.



TB	Tuberculosis: A usually chronic highly variable disease that is caused by a bacterium of the genus <i>Mycobacterium</i> ( <i>M. tuberculosis</i> ) and by a related mycobacterium ( <i>M. bovis</i> ), is usually communicated by inhalation of the airborne causative agent, affects especially the lungs but may spread to other areas (as the kidney or spinal column) from local lesions or by way of the lymph or blood vessels, and is characterized by fever, cough, difficulty in breathing, inflammatory infiltrations, formation of tubercles, caseation, pleural effusion, and fibrosis.
Tolerance	The capacity of the body to endure or become less responsive to a substance (as a drug) or a physiological insult especially with repeated use or exposure.
TOP	Treatment Outcome Profile.
'Top up'	An amount needed to restore something to its former level.
Toxic	Poison.
Toxicity	The quality, state, or relative degree of being toxic or poisonous.
Treatment outcomes	The results of care provided to improve a situation, especially medical procedures or applications that are intended to relieve illness or injury.
Ulcerative colitis	A chronic inflammatory disease of the colon that is of unknown cause and is characterized by diarrhea with discharge of mucus and blood, cramping abdominal pain, and inflammation and edema of the mucous membrane with patches of ulceration.
Vasodilation	Widening of the lumen of blood vessels.
Vendor	Someone who promotes or exchanges goods or services for money.
Vocational training	Training for a specific vocation in industry or agriculture or trade.
WHO	World Health Organization.
Withdrawal	The syndrome of often painful physical and psychological symptoms that follows discontinuance of an addicting substance.

# SOURCES

Merriam-Webster Medical Dictionary, on-line version, 2007;  
[www2.merriam-webster.com/cgi-bin/mwmedhlm](http://www2.merriam-webster.com/cgi-bin/mwmedhlm)

Lexic.us:  
[www.lexic.us](http://www.lexic.us)

Oxford Shorter English Dictionary online:  
[www.askoxford.com/dictionaries/?view=uk](http://www.askoxford.com/dictionaries/?view=uk)

[Healthline.com](http://Healthline.com)



