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# METHADONE MAINTENANCE TREATMENT

*in The Republic of Maldives*


STANDARD OPERATING PROCEDURE

**Year of Publication: 2012**

**Published by:**

United Nations Office on Drugs and Crime, Regional Office for South Asia

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**Cover photo:** World AIDS Day Graffiti at Tsunami Point, Male, Maldives.

**Designed & Printed by:** Mensa Design Pvt. Ltd., New Delhi.
E-mail: design.mensa@gmail.com

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# METHADONE MAINTENANCE TREATMENT IN THE REPUBLIC OF MALDIVES

# Preface

In 2008, the first clinic providing long term medical treatment for drug dependence in the form of Methadone Maintenance Treatment (MMT) was initiated in Male, Maldives in partnership with the United Nations Office on Drugs and Crime, Regional Office for South Asia (UNODC ROSA). Today, about 80 clients are receiving methadone from the clinic.

Reviews of the performance of the clinic have demonstrated the efficacy of methadone in Maldivian settings as a long term treatment for clients dependent on opioids. The positive response to the first clinic has encouraged the UNODC ROSA to develop this Standard Operating Procedure (SOP) for centres implementing Methadone Maintenance Treatment.

The document outlines the standards in terms of processes and procedures to be followed during the setting up of an MMT clinic, including the staffing structure with respective responsibilities; initiating MMT services, registration into MMT, delivery of Methadone, follow up, termination of MMT, transfer to another MMT facility, supply chain mechanism and record maintenance.

A special feature of this document is that a set of sample formats for record keeping, consent form, requisition slip, medical test requisition form, MMT registration, dispensing register, client dose sheet, stock register and wean off questionnaire have been included. Besides, a glossary for abbreviations has been added for ease of reference.

This is the first time that Standard Procedures in MMT that are specific to local conditions in Maldives have been established. By their very nature, procedures in medical care undergo constant change. In view of this, every effort has been made to update this document, both in content and presentation.

It is a great honour for the UNODC ROSA to have developed the "Standard Operating Procedure for Centres Implementing Methadone Maintenance Treatment in Maldives". I am confident that this document will be of great use for service providers and will encourage the wider use of methadone in clinic settings as a long term treatment for clients dependent on opioids in the spirit of providing evidence-based treatment options.

I would like to thank those who have contributed to this important tool, including the drafting team and the reviewers for making this document a reality.

Cristina Albertin

**Cristina Albertin**

Representative

# Foreword

Maldives has seen a rise in drug use among its adolescents and youths. Since the first case of heroin abuse was detected in 1993, drug use has escalated among the youth. The problem of drug use is a serious national concern which affects the country's social well-being and national security. The National Health Policy of Maldives recognizes this as one of its major challenges. Though the exact number of drug users is not known, a survey on drug use is underway, the results of which will be soon published. Anecdotal reports suggest injecting drug use is on the rise, which will exacerbate the HIV epidemic. Drug use not only affects the health of the individual but also has a bearing on the family, society and the workforce of the country.

Tackling the problem of drug use is a major pledge of the Government, which formulated a five-year strategic plan. The Drug Control Master Plan was launched in 2008, which aimed to tackle all dimensions of the problem of drug use in Maldives. A multi-pronged strategy was designed to address the issue of both supply as well as demand of drugs in Maldivian context. This also meant providing drug users with treatment options, which are well researched and found to be acceptable in Maldivian context.

In this regard, the Methadone Maintenance Treatment (MMT) Clinic 'Gagan' initiated in the year 2008 has shown to be evidence based treatment for opioid drug users. From the time of the inception of the clinic, its effectiveness has been proven in both self-reports from the drug users and reports from their families as well as through independent evaluations conducted. The experience has shown that it is possible to initiate and replicate MMT in Maldives.

Standardizing of MMT services is critical for efficient management as well as to ensure consistency and quality in service delivery. I am glad that with technical support and guidance from the UNODC through project "Prevention of transmission of HIV among drug users in SAARC Countries" Standard Operating Procedure has been prepared which builds from the robust experiences of implementing MMT in Maldives. The UNODC has come forward to prepare this document through its team of experts, which has been vetted by the national experts as well as the Government of Maldives.

I would like to thank the UNODC, the National Drug Agency Team in the Gagan clinic,the beneficiaries of the MMT program, and especially Journey and Society for Health Education (SHE), two very vital NGOs, for supporting this program. I thank them for the many successes of the MMT program which I believe will be further strengthened with the operationalization of this SOP by the service providers.

**Lubna Mohamed Zahir Hussain**
Minister of State for Health
Government of Maldives

# Abbreviations

| | |
|---|---|
| **ART** | Anti-Retroviral Therapy |
| **BCC** | Behaviour Change Communication |
| **DDPRS** | Department of Drug Prevention and Rehabilitation Services |
| **DU** | Drug User |
| **HIV** | Human Immunodeficiency Virus |
| **IDU** | Injecting Drug User |
| **MMT** | Methadone Maintenance Treatment |
| **OST** | Opioid Substitution Treatment |
| **RSA** | Rapid Situation Assessment |
| **SHG** | Self Help Groups |
| **SOP** | Standard Operating Procedure |
| **STI** | Sexually Transmitted Infections |
| **TB** | Tuberculosis |
| **UNODC** | United Nations Office on Drugs and Crime |
| **VCTC** | Voluntary Counselling and Testing Centre |

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# 1

# INTRODUCTION

The drug use situation in Maldives is unclear. No nationwide estimates of the drug use prevalence have been carried out that would provide an understanding of the extent, pattern and trends of drug use in the country. Maldives has, however, a high proportion of people who are young. As per the census 2009 estimates carried out by the Government of Maldives, about 43 percent of the population comprises youth between the ages of 15 and 34 years[1]. Thus, a high rate of drug use and its accompanying complications could have a greater implication.

Some small-scale studies conducted on the issue provide an understanding of the type of drugs consumed in Maldives. As per the rapid situation assessments (RSAs) carried out in 2003 and 2007, heroin and hash oil are the commonly used drugs in Maldives along with a variety of pharmaceutical preparations[2]. The number of drug users in the country, as reported in many of the documents, ranges from 10,000 to 30,000. The proportion of people who inject drugs has been reported to be 8 percent in the RSA conducted in 2003. The RSA conducted in 2007 reported that 28 percent injected drugs at some point of time. The Bio-Behavioural Survey was carried out in 2008 among 275 injectors in Male` and Addu.

## Convention Adherence

The Government of the Republic of Maldives has ratified all the three UN conventions related to narcotic drugs, namely, the Single Convention on Narcotics Drugs, 1961 (as amended by the 1972 Protocol), the United Nations Convention on Psychotropic Substances, 1971 and the United Nations Convention against Illicit Traffic in Narcotics Drugs and Psychotropic Substances, 1988

## History of Opioid Substitution Treatment in Maldives

Detoxification and rehabilitation has been the mainstay of treatment for drug related problem in Maldives. In 2008, the first clinic providing long-term medical treatment for drug dependence in the form of Methadone Maintenance Treatment (MMT) was initiated in Male in technical partnership with UNODC Regional Office for South Asia. Currently, about 80 clients are receiving methadone from the clinic. Reviews of the performance of the clinic carried out both by UNODC and externally demonstrate the efficacy of methadone in Maldivian settings as a long term treatment for clients dependent on opioids. The clients on MMT fared better in terms of reduction of drug use and high risk behaviour as well as improvement in psychosocial status and overall quality of life. The retention rate of the clients on MMT is comparable to other parts of the world[3,4].

## National Policy on Drugs and HIV

The Maldives National AIDS Program (NAP) is government-led and is strongly supported by United Nations agencies. The National Strategic Plan on HIV in the Maldives 2007-2011 (NSP) provides program direction and aims to limit HIV transmission, provide care for

[1] Ministry of Health & Family, Republic of Maldives, 2009, *The Maldives Health Statistics.*

[2] UNICEF and Journey, 2007, *Voices From the Shadow.*

[3] Kumar M.S., 2010, *Evaluation of MMT Programme in Maldives.*

[4] Mortimore G., Stimson G., 2010, *A process and systems evaluation of the drug treatment and rehabilitation services in the Maldives.*

infected people, and mitigate the impact of the epidemic through the following seven strategic directions:

- Provide age- and gender-appropriate prevention and support services to key populations at higher risk: drug users, sex workers and men who have sex with men
- Reduce and prevent vulnerability to HIV infection in adolescents and young people
- Provide HIV prevention services in the workplace for highly vulnerable workers
- Provide treatment, care and support services to people living with HIV
- Ensure safe practices in the healthcare system
- Build and strengthen capacity and commitment to lead, coordinate and provide a comprehensive response to the epidemic
- Strengthen the strategic information system to respond to the epidemic.

## Opioid Substitution Treatment

Opioid substitution treatment (OST) is a medical treatment used worldwide for the treatment of opioid dependence and prevention of HIV among injecting drug users (IDUs). OST has clearly emerged as the main treatment modality for opioid dependence and has been included as one of the essential services under the comprehensive package of services advocated by the WHO/UNODC/UNAIDS[5].[6].

Substitution treatment is defined as the administration under medical supervision of a prescribed psychoactive substance, pharmacologically related to the one producing dependence, to people with substance dependence for achieving defined treatment aims. OST involves treatment of the individual dependent on opioids with opioid medicines under the supervision of a trained medical staff. For example, dependency on an opioid (such as heroin) which is unsafe and requires repeated administration through unsafe/hazardous route is treated with an opioid medication (such as buprenorphine or methadone) which is long acting, safer and administered through oral/sublingual route. The client does not experience either withdrawal or euphoria ('high') as a result of the medicines. With regular use of OST, the client achieves a comfort level in which he/she stops using illicit drugs, thus preventing the potential harm of contracting HIV infection and other diseases transmitted through the injecting route (e.g. Hepatitis B, Hepatitis C). While on OST, the clients do not spend all their time looking for their next 'fix' or injection. Thus, they can be engaged in other activities, including counselling and other psychosocial interventions. In addition, there is also an improvement in the psychosocial status of the clients, leading to an overall improvement in quality of life.

OST, especially MMT, decreases opioid and other illicit drug use, criminal activity and risk of overdose; and it results in improvement in physical and psychological health and social functioning, including level of employment[8]. Buprenorphine has been shown generally to be as effective as MMT, producing similar changes in all aspects of treatment outcome[9]. Reductions in injecting drug use, unsafe injection practices, unsafe sexual practices and sero-conversion rates for Human Immunodeficiency Virus (HIV) have been reported for clients receiving MMT. Participating

[5] World Health Organization, United Nations Office on Drugs and Crime, UNAIDS, 2004, 'Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention': Position paper.

[6] WHO, UNODC, UNAIDS, 2009, *Technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users.*

[7] World Health Organization, United Nations Office on Drugs and Crime, UNAIDS, 2004, 'Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention': Position paper.

[8] Mattick R P et al., 2003a 'Methadone maintenance therapy versus no opioid replacement therapy for opioid dependence' (Cochrane Review). In: *The Cochrane Library*, Issue 1, 2003, Oxford: Update Software.

[9] Mattick R P et al., 2003b, 'Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence' (Cochrane Review). In: *The Cochrane Library*, Issue 1, 2003, Oxford: Update Software.

in MMT has been shown to reduce the clients' risk of acquiring HIV infection in communities experiencing high rates of HIV transmission. The longer the patients are retained in OST, the better are their treatment outcomes. The provision of a range of ancillary services, including primary and specialist medical treatment and psychosocial support services is also associated with improved outcomes. Additionally, it has been demonstrated that stopping injecting drug use slows the progression of HIV in infected subjects.

# 2

# MMT – STANDARD OPERATING PROCEDURE

The document on Standard Operating Procedure (SOP) for MMT will outline the standards that are to be followed for the use of methadone as an opioid substitution treatment in Maldives. The document outlines the standards in terms of processes and procedures to be followed during the establishment of an MMT clinic, initiation, dispensing and termination of methadone and other issues associated with MMT, including record keeping and maintaining a supply chain mechanism.

## A. Setting up an MMT clinic

An MMT clinic should ideally be located in an island where opioid dependent users are present. In case this is not possible, the MMT clinic should be easily accessible to the majority of clients residing in adjoining areas/islands. As the clients have to visit the clinic daily for their doses, the clinic should not be too far; otherwise, it may result in higher drop-out among the clients.

In terms of infrastructure, an MMT clinic should have, at the minimum, three to four rooms designated for use of MMT services specifically. The clinic should have a doctor's room for the doctor to interact with the client during intake and during follow-up. The room should have enough space for two to three persons to be seated and adequate space for physical examination of the client.

A dispensing room should be available for the nurse to dispense methadone to the clients. The dispensing room should have enough space for the nurse, dispensing equipment, storage for holding methadone stock for seven to ten days and for a basic record keeping system. The room should have adequate security measures for dispensing and stocking methadone. Rooms for counselling the clients on methadone should be provided. These rooms should have adequate audio-visual privacy to maintain confidentiality of the client-counsellor interaction. The clinic should have a designated storage room for holding methadone stock for a period of about a month. Additionally, a waiting area for the clients to be seated while awaiting their turn for follow up/dispensing of methadone and an area for record maintenance of the MMT clients should be available in the MMT clinic.

Apart from the basic furniture required for the staff and clients, the clinic should have medical equipment for basic examination. This includes stethoscope, BP apparatus torch, disposable gloves, thermometer, examination table, etc. For dispensing liquid methadone, the centre should have equipment necessary for manual dispensing of methadone solution. This includes graduated pipettes to measure the exact amount of methadone to be dispensed or manual dispensers. In addition, plastic dispensing cups are required to dispense the medicine to the clients. Dustbins for disposal of used cups should also be provisioned for. The centre should provide for clean drinking water for the clients alongside the dispensing of methadone, which the clients require for rinsing their mouth after consuming methadone.

## B. Clinic timings

As methadone has to be dispensed on a daily basis to the clients, the MMT centre should be open seven days a week. On a given day, the optimal duration for functioning would be for seven to eight hours. During public holi-

days, the clinic may be open for a limited duration. However, such information should be conveyed to the clients beforehand and, if possible, should be prominently displayed in writing at the centre. The actual dispensing of medicines should be done for at least 60 percent of the centre's timings.

The opening and closing hours for dispensing can be decided by the MMT centre as per the clients' needs. Once the clients are stabilized on methadone, some of them may start working, making it difficult for them to come at the usual time. The centre may have to open early in the day to accommodate such clients. The dispensing time can also be split into morning and evening dispensing, so that some clients can come in the morning while some others can visit the clinic in the evening for intake of methadone dose.

## C. Staffing in MMT centre

MMT involves two broad types of activities – clinical care and psychosocial care. The staff involved in clinical care includes doctor and nurses, whereas the psychosocial care is led by a team of counsellors and includes social workers/outreach workers. In Maldives, apart from these staff, the head counsellor and peer volunteers are also involved in providing care and support to the MMT clients.

### 1. Medical Doctor

The doctor is the head of the clinical unit. He plays a lead role in the medical aspects of the MMT clinic. The doctor should have a minimum qualification of MBBS. A psychiatrist would be preferable, wherever possible.

#### Roles/Responsibilities

- Conduct a basic assessment and medical examination of the client for determining whether he/she is eligible for MMT.
- Determine the suitability for MMT on the basis of inclusion and exclusion criteria.
- Prescribe appropriate doses of methadone and additional medications as required by the client (for e.g. analgesics, sedative/hypnotics), and supervise the dispensing of methadone doses, if required.
- Conduct basic health-education sessions for the clients and their family members.
- Follow up with the clients and their family members and assess the progress of the clients on MMT.
- Request for laboratory investigations (including basic investigations such as haemogram, liver and kidney function tests, or screening for HIV, Hepatitis B and C, etc).
- Provide referrals to counselling and testing centres for screening for HIV, as well as referrals to other centres (e.g., TB services, ART clinics) as and when required.
- Provide referrals to the psychiatrist if the client presents with signs/symptoms of psychiatric illness or if the physician suspects a co-morbid psychiatric illness.
- Provide routine health check-up as well as health care, including appropriate management of abscesses, overdoses and STIs, as per the facilities available at the MMT centre.
- Conduct regular educational classes on health related topics, including those related to MMT – benefits of MMT, duration of treatment, importance of long-term adherence, etc.
- Maintain appropriate records as required in the MMT clinic.
- Conduct case discussions and record review of the MMT clients with other staff of the MMT clinic.
- Assist in advocacy and other networking meetings, as and when required.

### 2. Nurse

The nurse is the staff in charge of the daily dispensing of the OST medicines. He/she is also in charge of the day-to-day management of the clinic in the absence of the doctor. A basic degree and experience in nursing is required for the nursing staff.

### Roles/Responsibilities

- Dispense methadone to the clients on a 'daily observed treatment' basis as prescribed by the doctor following protocols (e.g. checking the pupil size to determine the withdrawal state, obtaining signature of the patient on the dispensing sheet, conducting general enquiry of the patient's psychosocial and health related condition).
- Provide basic treatment education to the clients.
- Report early warning signs of adverse conditions to the doctor/team leader.
- Maintain the patient related records appropriately.
- Maintain the stock of medicines (including ensuring adequacy of stocks of methadone and other medicines, indenting for methadone stocks as and when required, and maintaining appropriate records).
- Provide emergency health services in the absence of the treating doctor.

## 3. Counsellor/s

The counsellor is responsible for the psychosocial intervention services for the clients. The counsellor should ideally have a graduate degree in psychology/social science/humanities. Those who have received training in counselling and have prior experience of working with drug users are preferred.

### Roles/Responsibilities

- Conduct psychosocial assessment of the clients visiting the MMT centre.
- Register new clients who are found fit for MMT.
- Explain the treatment contract and obtain signatures on the contract form.
- Increase treatment adherence and provide motivational counselling.
- Provide psycho-education sessions for clients and their family members (one-to-one and in group settings).
- Provide counselling on improvement in psychosocial status (including craving management, behaviour change, relapse prevention and rehabilitation).
- Provide counselling services to the female partners of the clients on MMT as well as the family members to involve them in treatment process.
- Map the existing services, which may be required for the clients and building a network with such agencies that can be potential 'referral' agencies.
- Provide referral services for STIs, HIV counselling and testing, vocational and other relevant services.
- Maintain records as required.
- Liaise with the medical doctor as well as nurse and carry out periodic assessment of the progress of the clients' treatment.

## 4. Social workers/Volunteers

The social workers/volunteers are the role models for the MMT clients. These staff members can be those who are currently on MMT or have completed methadone treatment. He/she should have good communications skills and should be acceptable to the DU/IDU community they have to work with. As required by the Government of Maldives, the volunteers should have at least a diploma or an advanced certificate in social work or related disciplines.

### Roles/Responsibilities

- Identify new clients, provide information on MMT and motivate them to visit the OST centre.
- Provide intensive support during the client's initial days on MMT.
- Follow up on attending/drop out clients.
- Maintain regular contact with the clients on MMT.
- Conduct BCC sessions in the field as well as for participants in the group discussions at the MMT centre.

- Motivate DUs/IDUs to seek referral services; and provide accompanied referrals, if required.
- Assist in formation of support group/Self Help Group.
- Assist the counsellor in conducting home visits as well as other follow-up activities.
- Conduct home visits, as and when required.

## 5. Head counsellor/Case manager

The head counsellor is also the case manager of the MMT clients. He/she assumes overall responsibility for the psychosocial welfare of the clients as well as managing the team of counsellors.

### Roles/Responsibilities

- Overall in-charge of the psychosocial component of the MMT treatment in the clinic.
- Provide various counselling services, including motivational enhancement therapy, craving management, relapse prevention and other similar interventions in individual and group setting.
- Conduct sessions with families and care givers of MMT clients.
- Supervise counselling sessions conducted by other counsellors in the MMT clinic.
- Monitor and conduct psychosocial work-ups and classes for MMT patients in liaison with NGOs and volunteers.
- Identify religious scholars and arrange for religious sessions on the Islamic perspective on harms of drug abuse.
- Set up and maintain referral network with various NGOs/social support groups.
- Coordinate with various client-centred social support services.
- Coordinate with the general physician and the psychiatrist in their respective assessment of patients, including case discussions and periodic review of the cases.
- Manage the crisis, if any, faced by the clients in the MMT clinic.
- Supervise and assist in maintenance of the case records of the MMT clients, counselling based registers, and other records.
- Manage the day-to-day running of the MMT clinic.

## 6. Consultant psychiatrist

A psychiatrist is not essential in every MMT clinic; however, referrals to the consultant psychiatrist should be made on a regular basis. A psychiatrist may cover more than one MMT clinic periodically.

### Roles/Responsibilities

- Conduct a psychiatric assessment of the client referred by the physician.
- Treatment of co-morbid psychiatric illness in MMT client.
- Referral to various support services, as and when required.
- Overall supervision of the MMT program in the clinic.
- Attend staff meetings regularly.

## 7. Laboratory technicians

- Advise the MMT clinic on the standard procedure of collecting urine samples.
- Analysis of urine samples.

An important determinant of successful outcome of the MMT clinic and client retention in the program is the attitude of the staff towards the clients. The staff should have a non-discriminatory, positive and caring attitude towards the clients. A strong rapport with the MMT clients should be established by the staff, which helps greatly in improving the client retention. Dealing with clients who relapse and drop out of the program is very difficult, and should be handled effectively. Knowing that drug use is a chronic, relapsing medical condition helps. Staff burn out is a common problem in agencies providing services for drug users and should be addressed by the team leader. The team leader should look out

for signs and symptoms of burnout. If necessary, the staff can be shifted out of the centre for a short period of time.

## D. Initiating MMT services

Prior to the actual delivery of MMT, the general community and the potential clients should be informed about the MMT program to attract clients to the centre. This will ensure that either the clients will themselves visit the centre seeking treatment or their family members will bring the clients to the centre. Additionally, other centres treating opioid dependent drug users should also be informed about the MMT program. This includes detoxification and rehabilitation centres, prison authorities, health corporations, etc. Finally, some clients can also be initiated into the MMT program through the outreach mechanism.

## E. Registration into MMT

Upon entry to the MMT centre, the client should undergo a brief screening-cum-counselling by one of the counsellors, following which the client can be registered at the MMT centre. The staff concerned should briefly interact with the client and address the following issues:

- Understand the client's perception regarding the treatment modality and expectations from it
- Assess the motivational level of the client
- Dispel myths/misconceptions of the client towards MMT
- Explain that assessments will be made by the counsellor and doctor prior to initiation on MMT to determine whether he/she (the client) fits the criteria for MMT initiation
- Explain the rules and regulations, clinic timings, procedures to be followed while on MMT (e.g. to meet the doctor and counsellor regularly, to participate in group discussions, to involve family members in the program, etc.)
- Inform the clients that it may not be possible to initiate the treatment immediately upon registration if the MMT slot is full and there is a waiting list
- Inform the client about the DOs and DON'Ts while he/she is on MMT (e.g. to come daily for MMT, to report any side effects, being honest about drug use status, etc.).

After the screening, if the client is found suitable for MMT, he/she will be registered for MMT. A register detailing the client's name and his/her contact details should be maintained for this purpose. Upon registration, if the slot for MMT is not available, the client should be assured that he/she will be contacted as soon as a slot is vacant.

In case a slot for MMT is available, a file should be created for the client. The client should then be assessed by the treating doctor and counsellor. The assessment should include detailed history, physical examination and a brief mental status examination. The assessment and observations should be noted in the client intake form (attached as Appendix), which should be maintained in the client file.

Upon confirming that the client is suffering from opioid dependence and fulfils the inclusion criteria for MMT enrolment, the client is then asked to read the consent form along with his/her family member/s. After the client has understood the implications of being in MMT,

### Inclusion criteria for entry of a client into MMT program

1. Age more than 18 years
2. Established diagnosis of opioid dependence syndrome (preference should be given for injecting drug users and female clients)
3. Having a strong motivation for treatment

he/she is asked to sign the consent form (attached as Appendix). After the consent form is signed, the doctor prescribes medications for the client, which includes the dose of methadone as well as any other concomitant medications required. In addition, any investigations and medical referrals required are ordered by the doctor. The client is then referred to the nurse.

## F. Delivery of methadone

On the first day, the nurse ascertains the client's name and identification mark. The last dose of consumption of opioids is enquired about. The pupils are checked for dilatation. If the pupils are dilated and the client has some withdrawal symptoms, the nurse institutes methadone in doses prescribed by the doctor. Following the consumption of methadone, the nurse asks the client to consume water and rinse his/her mouth. This will help the client to swallow the entire dose of methadone orally; it will also ensure that the client has indeed swallowed methadone and is not hiding the medicine inside his/her mouth. Finally, the nurse asks the client to sign the dispensing register.

The nurse informs the client that he/she may experience some withdrawal symptoms, especially in the later part of the day. The client should be assured that this is a normal phenomenon in the initial days, as it takes time to titrate the dose of methadone.

The client is then asked to visit the nurse on a daily basis. During the daily visit, the nurse:

- Identifies the client by name and ascertains his/her identification.
- Enquires whether the client has consumed any illicit opioid in the last 24 hours
- Examines the client's pupils and checks if the pupils are dilated
- Enquires about the general well-being of the client
- Confirms the dose of opioid for the client from the dispensing register

If the nurse is satisfied, then the client is given his daily dose of opioid and asked to sign on the dispensing register. The nurse also makes sure that the client visits the doctor and counsellor for follow-up.

## G. Follow-up

Follow-up with the doctor and counsellor is not on a daily basis.

**Doctor:** For the initial week to ten days, the client has to visit the doctor daily or on alternate days till the dose is stabilized. After the dose is stabilized, the client may visit the doctor less frequently. During every follow-up, the doctor will enquire from the client about his/her last use of illicit opioids, any cravings or withdrawals while on methadone, any side effect of methadone, any medical or psychiatric problem, and general well-being. If required, the doctor may ask for investigations and refer the client to other facility for associated co-morbidities.

The client, in addition to drug use *per se*, would also have problems in other areas, including familial (discord in the family with frequent fights and quarrels: distrust among the family members), occupational (loss of job; unemployment), and legal (involvement in illegal activity such as pick-pocketing, thefts, and incarceration). The counsellor should address these issues in the counselling sessions.

**Counsellor:** The counsellor should have periodic individual sessions with each client. During the initial sessions, the counsellor must focus on assessing the high-risk behaviour of the client, including both injecting and sexual. Also, the psychosocial status of client, including his/her employment, legal, marital, psychological problems must be assessed. The counsellor should set goals, with

active participation from the client. The client must also be encouraged to undergo voluntary counselling and testing for HIV. During the follow-up, the counsellor must try to address the areas that were defined as problematic during the assessment. The goals that have been set should be revisited during each follow up, and the client should be encouraged to achieve them. In addition, the counsellor should actively encourage the client to engage his/her family members in the treatment decision. The family members should be interviewed to make them understand the treatment process and solicit their help in the client's recovery. The sexual partners of the client should be contacted and advised to go to the VCTC. They should also be counselled for high risk behaviours and safer practices.

**Group discussions:** In addition to the above, the social workers should carry out group discussions wherein issues such as 'basics of HIV and AIDS', 'drug related harms and ways to reduce them', 'benefits of methadone', 'relapse and relapse prevention', 'experience sharing', etc. may be taken up.

The NGOs working in the area and associated with drug treatment can be involved in the process of providing psychosocial care. Support groups can be formed among the methadone clients, and the NGOs can be asked to take a lead in the same.

### H. Termination of MMT

It has to be conveyed to the client repeatedly that MMT is a long-term treatment and the end-point of treatment is based not upon its

## Follow-up of Client in MMT

- The patient is encouraged to take his/her Methadone dose regularly and on time
- The nurse makes it a point to ask about the previous day's activities on a daily basis, specifically with respect to cravings for heroin or other drugs
- The physician holds regular follow-up with the patients
- The importance of psychosocial classes is stressed
- Regular counselling sessions are conducted by the counsellors
- Urine testing is done at regular intervals

## Psychosocial Activities in MMT Clinic: Summary

- Individual sessions
- Group therapy sessions for all MMT patients
- Drug education classes for MMT patients
- Religious classes once a week/ alternate week
- Special group therapy sessions for all female MMT patients
- Sessions for families (co-dependents) of MMT patients, once a month

duration but upon stabilization of psychosocial functioning. The client should be encouraged to continue MMT for a long period of time.

In case the client wishes to discontinue MMT, he/she will need time to be prepared for the same. The dose should be tapered gradually, and adequate psychosocial services should be provided on a regular basis. The clients will require follow-up even after they have stopped methadone. Patients willing to terminate methadone, at times, prefer to undergo detoxification on an outpatient or inpatient basis. All decisions related to termination of methadone should be taken jointly by the treating physician and the patient.

## Criteria for Premature Termination from MMT Program

### (These are not strict criteria but should be decided by MMT team* on a case-by-case basis)

- Violence, threats or abuse to staff or other clients
- Diversion of methadone from the clinic
- Engaged in drug dealing or any other illegal activities in or around the MMT clinic
- Continued use of street heroin/ other CNS depressants/cannabis/any other banned substance in spite of repeated reminders/ advice about the risks associated with using them with Methadone (based on urine test results)
- Repeatedly testing urine positive for banned substances

* The MMT team comprises personnel involved in the treatment of the patient on methadone. They are the treating physician, counsellors and the nurses.

In case of clients dropping out without informing the centre, efforts should be made by the outreach team to trace them and ascertain their reasons for dropping out. Such clients should be motivated to restart MMT. However, if the client does not wish to restart MMT and has resumed drug use, he/she can then be referred to other drug treatment services.

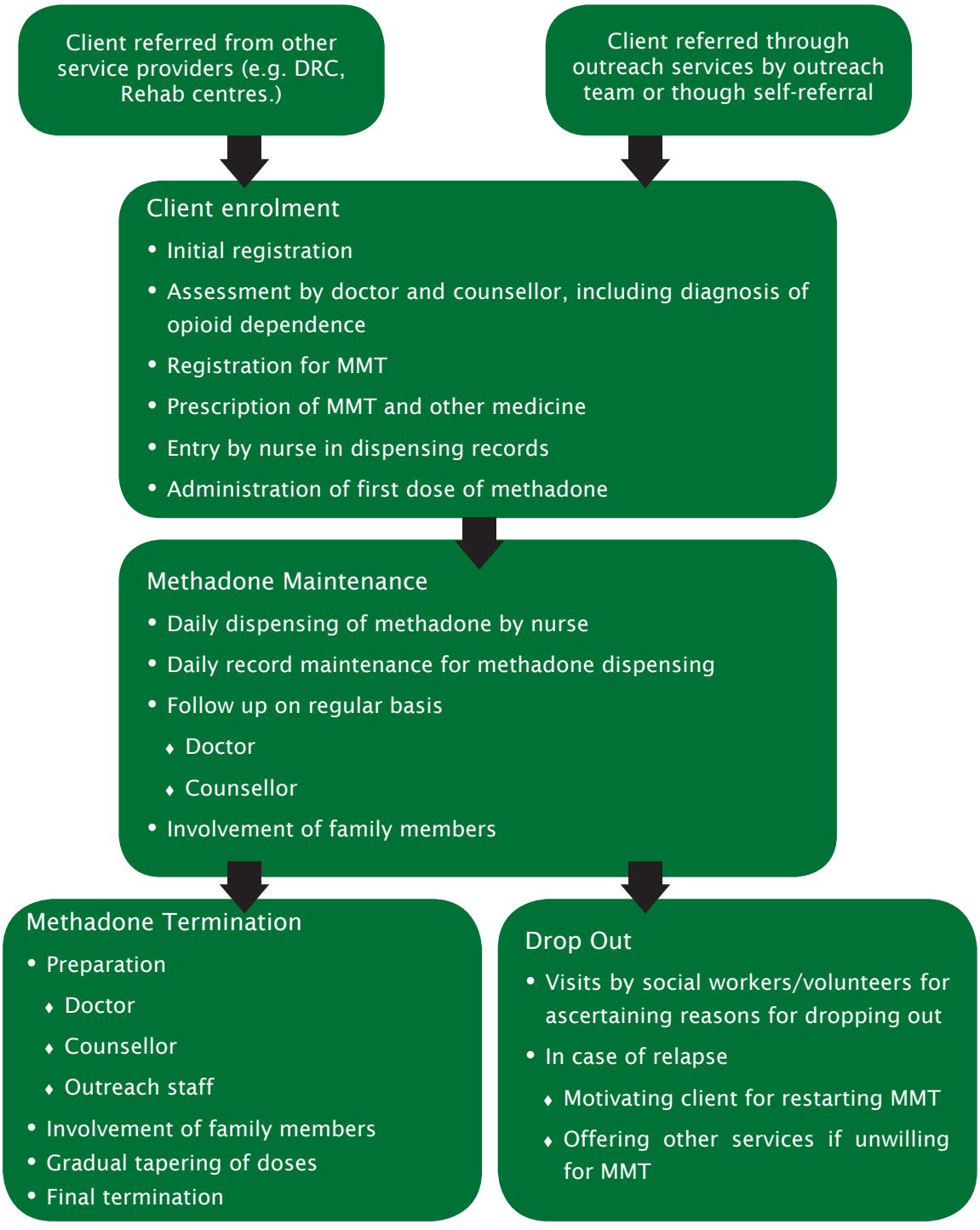
In some cases, the clients may have to be terminated from MMT on disciplinary grounds. However, this option should be exercised rarely and should not become the standard practice.

### I. Transfer to another MMT facility

Some patients may migrate from one geographical location to another and may want to continue MMT in their new location. Patients may be transferred to another MMT facility by the treating physician. The referral letter by the physician to another MMT facility should contain the following information:

- Name, date of birth, address and contact details of the patient
- Dose of methadone
- Other medical or psychiatric problems and medication for these (e.g., receiving TB medication, antidepressants, etc.)
- Adherence and psychosocial issues

A copy of the photo identification of the patient has to be enclosed with the referral letter.




## J. Supply chain mechanism

As methadone is a narcotic, it is regulated under the law. However, it is also true that if the client does not get his/her daily dose, he/she suffers from physical withdrawals. Thus, the supply chain for methadone should not only be tightly monitored, but it should also be responsive enough to ensure uninterrupted stock.

There are three main steps in the supply chain management. At every stage and step, there should be a designated officer-in-charge of the stock with clearly laid down responsibility. In addition, there should be a clearly designated storage place at every point of storage. The storage place should have minimum access rights, and no one except the authorized officer/s should be allowed in. The stor-

age should be located in a dark and cool place to avoid damage to the shelf life of methadone. The store should be secured properly with provision of round-the-clock manned security. Finally, some form of record should be kept for every transaction made, from receipt to supply.

### 1. Central procurement and storage of methadone

The Department of Drug Prevention and Rehabilitation Services (DDPRS), Ministry of Health, is the nodal agency for regulating the flow of narcotic/psychotropic drugs in the country. The DDPRS procures methadone through a central agency called the State Trading Organization, which is the designated Government organization for procurement of the medicines.

### 2. Supply to MMT clinic from central store

Before supply to the MMT clinic, an estimation of the quantity of methadone required by the centre should be made. This can be arrived at in the following manner:

Average dose per patient per day

X

No. of patients on methadone in a day

X

No. of days for which the stock is to be supplied

Generally, one to two months of supply can be given to the MMT clinic, depending upon the capacity of the centre and safety provisions in the centre to stock methadone. In addition, a buffer stock for at least two weeks should be kept at the MMT clinic to take care of any unforeseen delays in supply (such as unrest, natural calamities, etc).

The officer-in-charge of the central store should ensure that enough stocks remain at the central store through periodic 'stock projection' and forecast accordingly. In addition, the officer should also keep a tab on the expiry dates of methadone to ensure that methadone stocks are within the expiry period. If the expiry dates of some of the stocks of methadone are close, then such stocks should be prioritized for immediate consumption.

### 3. Stock management at MMT centre

At the MMT centre, the nurse is in-charge of maintaining the stocks and ensuring regular supply of methadone at the centre. The nurse will be the staff responsible for the daily dispensing and day-to-day stock management. The nurse should also document every transaction of methadone, including any wastage.

On every dispensing day, before dispensing, the nurse/other designated staff should collect the average daily requirement of medicines from where they have been stored. This stock for the day should then be stored in the dispensing room. The stock of methadone remaining at the end of the day should be stored back in the storage room. There should be periodic checks and supervision regarding the stock consumption as well as stock in hand. In addition, the records should be regularly checked to establish the accuracy of the entries made.

## K. Record Maintenance

Record maintenance is an integral part of the MMT program. If the record keeping is extensive, then it becomes cumbersome and the staff spends significant time in record maintenance rather than in actual service delivery. However, basic record maintenance is necessary to document the services being rendered to the clients. Due to the legal restrictions on methadone, record keeping is important. In addition, the records are also necessary for the program supervisors to check how the program is being implemented. Finally, records are also necessary for conducting research activities. There are mainly two types of records to be maintained in the OST program. The first is documentation of the client's progress, while the second is documentation of stocks

of the OST medicines. A suggested pro-forma of the records is provided in Appendix.

### 1. Client related documentation

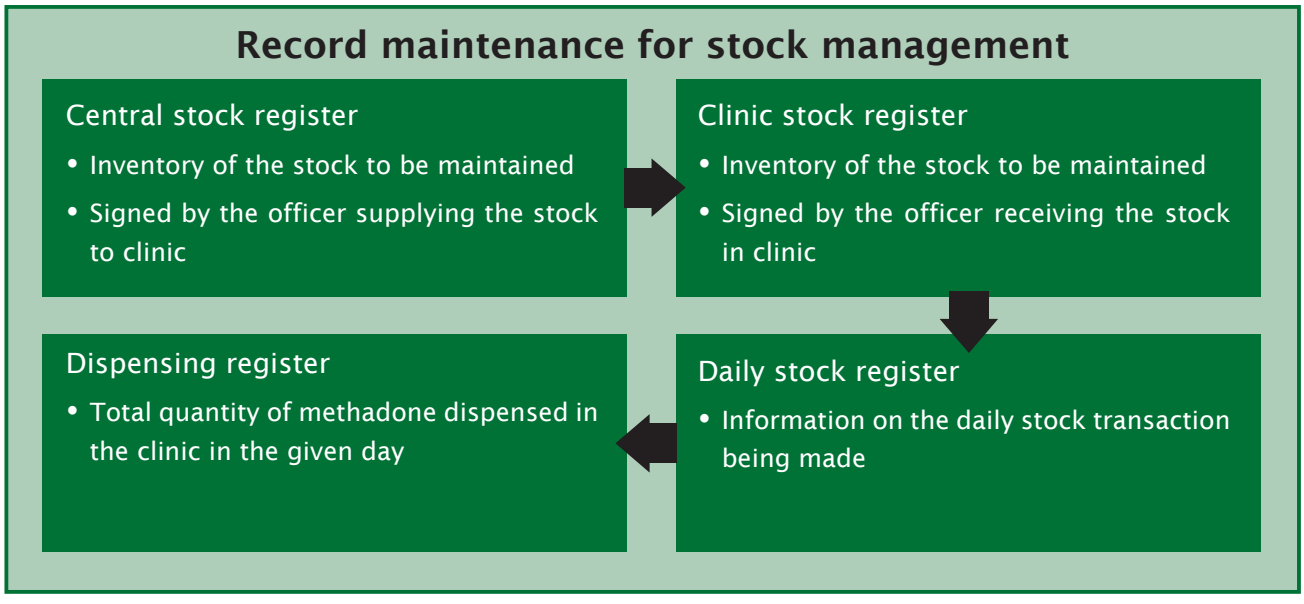
A separate file should be maintained for each client where information and records pertaining to the client is maintained.

- **Client intake form:** Herein, a baseline information on the client's socio-demographic profile, history of drug use and drug-related complications, risky behaviour practices including sexual risk, history of physical and psychological problems, and current psychosocial status of the client is recorded. In addition, a record of the physical examination performed by the doctor and diagnosis is maintained.
- **Consent form:** Once the client is found to be suitable for OST, he/she is provided clear information regarding OST. After it is ensured that the client has fully understood the information, he/she is expected to provide his/her signature/thumb impression on the consent form, which is then maintained in the client file.
- **Follow-up records:** During follow up by the doctor and the counsellor, a record of the progress made by the client, referrals made and the test results thereof, his/her current physical and psychosocial status as well as drug intake should be made. Further plans for the client should also be mentioned.

### 2. Methadone related documentation

These records are required to document the stocks of methadone. Some of the basic medicine related documentation is as follows:

- **MMT registration:** A simple register with details of all the clients initiated on MMT should be maintained during the initial intake of the clients into the MMT program.
- **Dispensing register:** This is used for recording the quantity of methadone dispensed in a single day. A register containing the client's name, dose dispensed to the client with his/her signature is maintained by the nurse.
- **Client dose sheet:** A sheet in which a record of the client's daily dose of medicine that he/she receives should be maintained by the nurse. At the end of the month, the sheet should then be transferred to the client's file.
- **Daily stock register:** A simple register mentioning the amount of methadone remaining in the MMT centre store at the morning, amount dispensed during the day, and the final amount remaining at the end of the day should be maintained. The total amount shown as dispensed in the daily stock regis-



ter should tally with that mentioned in the dispensing register.

- **Central stock registers:** Similar stock registers should be maintained at the MMT centre as well as the central store and tallied on a periodic basis by the respective officers-in-charge.

A periodic review of all the above mentioned records should be made to ensure that the records are tallying and are updated regularly.

## L. Conclusion

Methadone Maintenance Treatment has been well established as an effective modality of long-term treatment for opioid dependence and HIV prevention among drug users who are dependent on opioids, including injecting drug users. The implementation of MMT requires a multi-disciplinary team of medical, paramedical and outreach staff. MMT centres have minimal requirements in terms of infrastructure as well as staff. In addition, running an MMT clinic requires basic training and knowledge and skill in program management. A robust supply chain mechanism and diligent record maintenance is required to make the OST program infallible to public as well as Government scrutiny.

It has been well documented that the two most important factors which determine the successful outcome in terms of client acceptability and retention in MMT programs are the flexibility of the MMT centres during MMT service delivery, as well as staff attitude in dealing with the clients. Centres which are flexible and accommodating and have a positive and caring attitude towards clients have been found to retain clients on methadone much longer than others. A client-oriented service also results in minimal friction between the staff and the clients as well as in lesser staff burnout.

# APPENDIX: RECORD-KEEPING FORMATS

A suggestive format for maintenance of the records mentioned above is shown below. It is to be noted that these formants are merely suggestive; the OST centre can adapt these formats in accordance with the local requirements and feasibility.

## SAMPLE FORMAT 1: CLIENT INTAKE FORM

**Name:** **Age/Sex:** **MMT Reg. No:**

**Parent's name:** **Phone:** **Date:**

- **Address:** **Referred by:**
- **Reasons for consultation:**
- **Accompanied by:**
- **Presenting complaints:**
- **Family history:**
  - Mental illness/Drug abuse/Suicide/Epilepsy
- **History of drug use:**

| Type | Year of first use | Age of first use | Quantity | Dependence? (Yes/No) | Route of use | Current use (last one month)? (Yes/No) | Amount consumed in last 24 hours |
|---|---|---|---|---|---|---|---|
| **Heroin** | | | | | | | |
| **Cannabis**(Ganja/ Charas/Hashish/Bhang) Cannabis(Ganja/ Charas/Hashish/Bhang) | | | | | | | |
| **Benzodiazepines** | | | | | | | |
| **Alcohol** | | | | | | | |
| **Barbiturates** | | | | | | | |

contd...

| Type | Year of first use | Age of first use | Quantity | Dependence? (Yes/No) | Route of use | Current use (last one month)? (Yes/No) | Amount consumed in last 24 hours |
|---|---|---|---|---|---|---|---|
| **Other opioids** (Opium,Pentazocine, Codeine, Dextroproppoxyphene) (*Please specify*): | | | | | | | |
| **Sedative/Hypnotics** (Diazepam, Nitrazepam, Chlordiazepoxide, Chlorpheniramine (Avil), Phenargan, etc.) | | | | | | | |
| **Amphetamines & other ATS** | | | | | | | |
| **Cocaine** | | | | | | | |
| **Inhalants** | | | | | | | |
| **Tobacco/Nicotine** | | | | | | | |

- **Any History of injection drug use:** **YES/NO**

⇨If YES,

- Started since:
- Reasons for shifting to injecting drug use:
- Any history of sharing needles/syringes:
- Any history of reuse of needles/syringes:
- Any complications of injecting (abscesses, wound/ulcer, blocked veins, gangrene, HIV, Hepatitis B/C) (please mention details):

- **Any history of unprotected sexual intercourse:**

- **History of treatment taken:**

| Year/month of treatment seeking | Type of intervention | Place of intervention | Duration of treatment | Duration of abstinence | Reason for relapse |
|---|---|---|---|---|---|
| | | | | | |
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- **Medical History:**
  - Allergic to any medicines: No/If yes, specify:
  - Medicines currently taking: No/If yes, specify:
- **Personal History:**
  - Divorce & re-marriage in parents:
  - School dropout: If so, reason
  - Jail history & reasons:
  - Marriage & divorce history:
  - Children:
- **Occupational History:**
  - Date of joining & leaving: .....
  - Drug consumption while on duty: .....Yes/No
  - Drug-related accidents: .....Yes/No
  - Relationship with colleagues, superiors:.....
  - H/O change of jobs: No/If yes, specify:
- **Social History:**
  - Number of people in the house:.....
  - Other earning members:.....
  - Marital disharmony: .....Yes/No
  - Sexual problems:.....Yes/No

- Overall social support:.....Good/Poor
- Leisure time activities and hobbies:.....

- **Legal History:**

- **General Physical Examination:**

| Vital signs | |
|---|---|
| Pulse | |
| BP | |
| Temperature | |
| Weight | |
| Pupils | |

| Examination for | |
|---|---|
| Pallor | |
| Icterus | |
| Clubbing | |
| Koilonychias | |
| Lymphadenopathy | |
| Edema | |

**Skin (Needle marks, Abscess, Open wounds): Describe in detail**

- **Has any physical disability:** No/If yes, specify:

- **Systemic Examination:**

- **Mental Status Examination (Positive findings):**
  - Attitude, Appearance, Behaviour
  - Mood:
  - Thought:
  - Perception:

- Orientation: Date/Time/Place/Person
- Intelligence:
- Memory:
  - Immediate:
  - Recent:
  - Remote:

- Insight:
- Judgment:
- Motivation:
  - Reasons: Financial/Physical illness/Mental illness/Others (SPECIFY):
  - Reason why the patient wants to give up drugs now:
  - Level of motivation of the patient: Good/Doubtful/Poor/De-motivated
- **Diagnosis: (ICD-10)**
- **Recommended Investigations:**
- **Treatment**

**Doctor's name:** **Date:** **Signature:**

## SAMPLE FORMAT 2: OBJECTIVE OPIATE WITHDRAWAL SCALE

**Objective Opiate Withdrawal Scale (OOWS)** (For Heroin & other Narcotic drugs):

The withdrawal assessment has to be carried out by a medical professional or a trained nurse. This assessment for monitoring withdrawal symptoms requires approximately 5 minutes to administrator. Rate the patient on the basis of what you observe during a timed 10 minutes period.

| S. No. | Item | Points |
|---|---|---|
| 1 | Yawning | |
| 2 | Rhinorrhoea | |
| 3 | Piloerection (Observe patient's arm or chest) | |
| 4 | Perspiration | |
| 5 | Lacrimation | |
| 6 | Mydriasis | |
| 7 | Tremors (hand) | |
| 8 | Hot and cold flashes (shivering or huddling warmth) | |
| 9 | Restlessness (frequent shifts of positions) | |
| 10 | Vomiting | |
| 11 | Muscle twitches | |
| 12 | Abdominal cramps (holding stomach) | |
| 13 | Anxiety (observe manifestations like finger-tapping, fidgeting, agitation) | |
| | **TOTAL OOWS SCORE (1-13)** | |

Score 1 point for each item if present. The maximum score is 13.
Patients scoring less than 3 do not usually need additional medication for withdrawal.

*Source:* L. Handelsman, K.J. Cochran, M.J. Aronson, R. Ness, K.J. Rubinstein and P.D. Kanof, 1987, 'Two New Rating Scales for Opiate Withdrawal', American Journal of Drug and Alcohol Abuse, 13:293-308.

# SAMPLE FORMAT 3: COUNSELLOR INTAKE FORM

## A. PSYCHOSOCIAL COMPLICATIONS

- **Legal:**
- **Marital:**
- **Familial:**
- **Occupational:**
- **Financial:**
- **Psychological:**

## B. HIGH RISK BEHAVIOUR

- **Injection related (if ever injected drugs):**
  - Sharing of injecting equipment (needles and syringes/other paraphernalia) (EVER):

| | | |
|---|---|---|
| 1 | YES | |
| 2 | NO | |

- **Sex related:**
  - No. of sexual partners (last 30 days):
  - Last sexual encounter, whether:

| | | |
|---|---|---|
| 1 | Protected | |
| 2 | Unprotected | |

## C. CURRENT LIVING ARRANGEMENT

## D. REASONS FOR WANTING TO SEEK TREATMENT

## E. CURRENT MOTIVATIONAL LEVEL

- **Areas For Psychosocial Intervention:**

- **Psychosocial Intervention Plan:**

**Counsellor's name:** **Date:** **Signature:**

# SAMPLE FORMAT 4: CONSENT FORM

## TREATMENT CONTRACT

As a participant in the methadone for opioid abuse and dependence treatment, I freely and voluntarily agree to accept this treatment contract, as follows:

(1) I agree to keep, and be on time for, all my scheduled appointments with the doctor and the clinic staff.

(2) I agree to conduct myself in a courteous manner in the methadone clinic.

(3) I agree not to arrive at the clinic intoxicated or under the influence of drugs. If I do, the doctor will not see me and I will not be given any medication until my next scheduled appointment.

(4) I agree not to sell or deal in any kind of banned substances, share or give any of my medication to another person. I understand that such selling of or dealing in drugs and mishandling of my medication is a serious violation of this agreement and would result in my treatment being terminated without recourse for appeal.

(5) I agree not to steal or conduct any other illegal or disruptive activities in the methadone clinic.

(6) I agree that my medication (or prescriptions) can only be given to me at my regular clinic visits. Any missed clinic visits will result in my not being able to get medication until the next scheduled visit.

(7) I agree that the medication I receive is my responsibility and that I will adhere to the prescribed treatment.

(8) I agree not to obtain medications from any doctor, pharmacies, or other sources without informing my treating doctor. I understand that mixing methadone with other medications, especially benzodiazepines such as Calmpose or Valium and other drugs of abuse can be dangerous. I also understand that a number of deaths have been reported among persons mixing methadone with benzodiazepines.

(9) I agree to take my medication as the doctor has instructed and not to alter the way I take my medication without first consulting the doctor.

(10) I understand that medication alone is not sufficient treatment for my drug use and I agree to participate in all the psychosocial interventions like counselling, patient education, after care and 'relapse-prevention' program as provided to assist me in my treatment.

(11) I agree to take any other medicines prescribed by the doctor that he/she may deem fit for me.

(12) I understand that the MMT clinic will not be responsible for and will not intervene in any way in any of my legal issues.

(13) I agree to take the MMT for a minimum of 1 year, failing which I can restart the treatment only after 1 year from the last day of receiving my methadone dose.

(14) I agree to follow all the policies of the MMT clinic and respect the treatment providers unconditionally.

**Client Name:**

**Client Signature:** **Witness Signature:** **Date:**

## SAMPLE FORMAT 5: DISPENSING REGISTER

| Date | Sl. No. | MMT registration No. | Name | Dose dispensed (in ml/day) | Signature/ thumb impression of the client |
|---|---|---|---|---|---|
| | | | | | |

## SAMPLE FORMAT 6: STOCK REGISTER

The format for stock register at the OST centre as well as the main storage site is the same.

| Date of entry | Total No. of bottles (1 litre) of methadone existing | Total No. of bottles (1 litre) received | Total no. of bottles (1 litre) remaining | Received by (Name, Signature and Designation) | Any Remarks |
|---|---|---|---|---|---|
| | | | | | |
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## SAMPLE FORMAT 7: CLIENT DOSE SHEET

| Name of the client: | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| OST No.: | | | | | | | | | | | | |
| Pl. enter dose of methadone in ml/day: | | | | | | | | | | | | |
| **Date** | **Jan** | **Feb** | **March** | **April** | **May** | **June** | **July** | **Aug** | **Sept** | **Oct** | **Nov** | **Dec** |
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| 29 | | | | | | | | | | | | |
| 30 | | | | | | | | | | | | |
| 31 | | | | | | | | | | | | |

## SAMPLE FORMAT 8: "WEAN OFF" QUESTIONNAIRE

### Are you ready to 'WEAN OFF' from MMT ?

1. Have you been abstaining from illegal drugs like heroin, cannabis & benzodiazepines? YES/NO
2. Do you think you are able to cope with difficult situations without using drugs? YES/NO
3. Are you employed? YES/NO
4. Are you staying away from contact with users and illegal activities? YES/NO
5. Have you gotten rid of your "works"/"outfit"? YES/NO
6. Are you living in a non-drug user neighbourhood? YES/NO
7. Are you comfortable living in such a neighbourhood? YES/NO
8. Are you living in a stable family relationship? YES/NO
9. Do you have non-user friends that you spend time with? YES/NO
10. Do you have friends or family who would be helpful during wean off? YES/NO
11. Have you been participating in counselling that has been helpful? YES/NO
12. Have you been attending psychosocial work ups and benefitted from them? YES/NO
13. Do your doctor, nurse and counsellor think you are ready to wean off? YES/NO
14. Do you think you would ask for help when you are feeling bad during wean off? YES/NO
15. Have you stabilized on a relatively low dose of methadone? YES/NO
16. Have you been on methadone for a long time (at least >1year)? YES/NO
17. Are you in good mental and physical health? YES/NO
18. Do you want to get off methadone? YES/NO

The more questions you can honestly answer by checking "yes," the greater the likelihood that you are ready to taper off from methadone. Consider that each "no" response represents an area that you probably need to work on to increase the odds of a successful taper and recovery.