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STANDARD OPERATING PROCEDURES

MEDICATION-ASSISTED TREATMENT FOR OPIOID DEPENDENCE IN NIGERIA: METHADONE AND BUPRENORPHINE

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Medication-assisted treatment for opioid dependence in Nigeria: Methadone and Buprenorphine

2022


These Guidelines have been developed with funding from the European Union (EU) under the framework of the UNODC implemented project 'Response to Drugs and Related Organized Crimes in Nigeria'

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Foreword

It is important to keep in mind that medication-assisted treatment (MAT) is a drug replacement harm reduction intervention that entails providing services to clients who find it difficult to abstain from drug use. However, in this case, the client receives a substitute drug from a health-care worker following informed consent. As such, trust must be established and treated with the utmost care and diligence.

During treatment, the health-care provider is obliged to use judgement and to act in the best interest of the client. These decisions largely revolve around behavioural assessments that are crucial for attainment of targets that are mutually agreed upon by both provider and client. Failure for one results in overall failure for both. Considering this, familiarity with the established standards for MAT contained in this document is the minimum requirement for the provider.

This Standard Operating Procedures (SOP) manual provides a step-by-step approach through a treatment cascade that makes it clear that MAT is not appropriate for all individuals. The criteria set within the eligibility determination sections contained herein ensure that only persons requiring the services are inducted. Other aspects of treatment ensure maximum benefit for clients and their families.

While treatment for some clients can be lifelong, a significant proportion of those undergoing MAT treatment, approximately three-quarters, are eventually weaned off methadone. The likelihood of achieving such desirable outcomes increases by providing quality MAT services.

It is, however, noteworthy that the overall goal of drug harm reduction is not to wean off methadone, but to prevent adverse social, economic and health outcomes including mortality and morbidity, especially infection with blood-borne viruses like HIV and viral hepatitis. Therefore, reintegration with the family and remaining sober and free of blood-borne viral infections during MAT are the desired outcomes for clients, their partners/ families and the society at large.

To ensure optimum adherence, the provider must be familiar with the standards in this SOP manual and apply those during all interactions with the client. Matters relating to assessment and counselling of the client, clinic timing, recording and reporting of events as well as housekeeping are all discussed herein. This document is therefore recommended to providers of medication-assisted treatment in Nigeria.

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Nigeria 2022

Contributors

In partnership with the Government of Nigeria, UNODC is implementing the large-scale, EU-funded project "Response to Drugs and Related Organized Crime in Nigeria". The project aims to support Nigeria's efforts in fighting drug production, trafficking and use, and curbing related organized crime. The project adopts a balanced approach to drug control, with equal attention paid to drug interdiction and drug demand reduction, including drug prevention, treatment and care (DPTC).

These medication-assisted treatment guidelines were delivered as part of this project.

The following are acknowledged for their immense contribution to the development and publication of these guidelines:

The group of Nigerian experts from various organizations and professional backgrounds that provided relevant technical advice and consultation on this document. From the Federal Ministry of Health these included: Kazeem O Ayinla, Felicity Jinga, Hadiza Agabi and Pharm. Farida Tukur. From the National Drug Law Enforcement Agency: Abubakar Garba and Angela O. Nweke. From National AIDS Control Agency: Ezinne Okey-Uchendu. This group also included experts from designated Model Treatment Centres: Dr. Auwal Sani Salihu of the Aminu Kano Teaching Hospital in Kano, Dr. Ibrahim Adamu Mshelia and Dr. Ibrahim Wakawa Abbu of the Federal Neuro Psychiatric Hospital in Maiduguri, Dr. Aborlo Kennedy Nkporbu of the University of Port Harcourt Teaching Hospital in Port Harcourt, Dr. Duwap Makput of the Jos University Teaching Hospital, Dr. Nkereuwem and William Ebiti of the Federal Neuro Psychiatric Hospital in Kaduna, Dr. Olusola Ephraim-Oluwanuga of the National Hospital Abuja, Dr. Shehu Sale of the Federal Neuro Psychiatric Hospital in Sokoto, Dr. Olanrewaju Olugbenga Sodeinde and Dr. Sunday Mauton Amosu of the Federal Neuro Psychiatric Hospital in Abeokuta, Dr. Andrew Orovwigho of the Federal Neuro Psychiatric Hospital in Enugu, Dr. Bukola Arigbede of the Federal Neuro Psychiatric in Benin, Dr. Moses D. Auduof Quintessential Health Care Centre in Jos, Dr. Boniface Effiong Ukpong of the Mobile Manna Foundation, John Akinola of Freedom Foundation in Lagos, Evelyn Chioma Joseph of the Society for Improvement of Rural People in Enugu, Miracle Onyeonoro of the Centre for Right to Health in Abuja, Nanribet Gabriel Mwoltu of the Heartland Alliance, Mr. Nsidibe Esiien of the Centre for Response and Info on Substance Abuse in Uyo, Oluwafisayo Alao of the Youth Initiative for Drug Research Info Support and Education in Abuja, and Ruth Boma Ebiti of Milestones Foundation in Kaduna. From the networks of people who use drugs: James Eghaghe of the Nigerian Network of People Who Use Drugs, Aniedi Emah Akpan of the Drug Harm Reduction Advocacy Network and Godwill Agada of FHI 360 GF project. From the World Health Organization: Dr. Ehab Salah.

The UNODC international consultant who was the lead author of this document: Gary Reid. We are grateful for his support and guidance in this process.

Vanessa Barchfield edited the document and Netra Shyam provided the layout and design.

The staff of UNODC Country Office Nigeria for their dedication and support throughout the process of developing this document, including: Dr. Akanidomo Ibanga, Dr. Abiola Olaleye and Mohammad Azim Arshad.

Acronyms and abbreviations

ART	Antiretroviral therapy
ATS	Amphetamine-type stimulants
COWS	Clinical Opiate Withdrawal Scale
HIV	Human immunodeficiency virus
HTC	HIV testing and counselling
MAT	Medication-assisted treatment
OST	Opioid substitution treatment
OAMT	Opioid agonist maintenance treatment
SOP	Standard Operating Procedures
STI	Sexually transmitted infections
TB	Tuberculosis
PWID	People who inject drugs
PWUD	People who use drugs
HBV	Hepatitis B virus
HCV	Hepatitis C virus

INTRODUCTION

About the Standard Operating Procedures

In Nigeria, medication-assisted treatment (MAT) is used for the treatment of opioid dependence and is combined with psychosocial support to provide sustainable change. Not all countries or international institutions use the term MAT. Other terms used include opioid agonist maintenance treatment (OAMT), opioid agonist treatment (OAT) and opioid substitution therapy (OST). The medications used in MAT eliminate withdrawal, control or eliminate cravings, and lessen or block the euphoric effect of further opioid use. This Standard Operating Procedures (SOP) manual was developed to provide a series of easy-to-follow steps for the delivery of MAT with the use of methadone or buprenorphine, from the time the patient presents for treatment to the time treatment is stopped voluntarily or involuntarily. These SOP outline processes and procedures of agreed-upon work practices around the management of opioid use disorders with MAT in Nigeria. The SOP manual aims to provide consistency, quality and efficiency in service provision, clarity on roles and responsibilities of staff, and safety of MAT delivery. These SOP additionally outline the fundamentals of the supply chain mechanism, key points for record maintenance for stock management of MAT, and the essential forms to be used for patient and MAT-related documentation. They are based on international best practices for management of opioid dependence and were developed in consultation with experts in the field in Nigeria to complement and provide an additional resource to the *Guidelines for Medication-Assisted Treatment for Opioid Dependence in Nigeria: Methadone and Buprenorphine, 2022*.

Target audience

These SOP are appropriate for all health-service providers offering MAT for opioid-dependent people who use drugs (PWUD). These SOP are also relevant to senior policymakers and administrators, national programme coordinators, project managers and health workers – in the government and non-government sector – that offer services to patients with opioid dependency within the health-care system.

Guiding principles

The implementation of a MAT service will be closely aligned with a set of core guiding principles that should complement national health and social welfare policies that support the right to health.

Many opioid-dependent PWUD are highly stigmatized and, as a consequence, may have limited access to health care. When establishing a MAT service, it is essential to ensure that:

- All PWUD have the same rights to health services as the general population.
- PWUD and their families are respected and treated with dignity without any discrimination due to their drug-using behaviour or mental status.

- Enrolment in MAT service is voluntary and should be free of threats or coercion.
- All persons should be informed about the benefits and risks of MAT.
- All patients have a right to discontinue treatment, and treatment staff should facilitate treatment cessation without undue discomfort.
- All persons receiving treatment for substance use disorders have rights to privacy and confidentiality of their health records.
- MAT services should not be used to arrest or harass persons who are seeking services or engaged in treatment.

The delivery of MAT should be accompanied by monitoring and documentation in order to continually improve the quality of the service and protect against misuse of methadone or buprenorphine.

1 **STEP 1:** Establishing the clincal setting, clinic times and staff

1.1 Location and infrastructure

Ideally, MAT clinics should be located where people with opioid dependence are present. If this is not possible, the MAT clinic should be easily accessible to the majority of patients. As patients in the early phases of treatment on methadone need to visit the clinic every day (for those receiving high doses of buprenorphine, it is often every other day) to receive their doses, the clinic should be easily accessible to reduce the drop-out rate among patients.

A health clinic should aim to have three to four rooms designated for the provision of MAT services. At some sites, consultation with a doctor and the process of methadone or buprenorphine induction may be located elsewhere from the primary, long-term dispensing site. All rooms need to be spacious enough to avoid overcrowding. A room should be available for the doctor to interact with the patient during intake and during follow-up. This room needs to be large enough to accommodate two to three seated people (which may include a family member or guardian) and have adequate space for physical examination of the patient. A room should be available for the nurse to dispense methadone or buprenorphine to patients and be of sufficient size for the dispensing equipment, storage for methadone or buprenorphine stock, and for basic record keeping and files. Any room selected for methadone or buprenorphine stock must always have adequate security measures in place, as methadone and buprenorphine are narcotics. Apart from basic furniture required for staff and patients, the clinic should have medical equipment for basic medical examinations. This includes: a stethoscope, blood pressure apparatus, torch, disposable gloves, thermometer, examination table, etc.

A counselling room should be available to ensure privacy and maintain confidentiality during patient and counsellor interactions. Each clinic should have a waiting area where patients can be seated while awaiting their turn for dispensing of methadone or buprenorphine and introduction or follow-up for other health services.

For liquid methadone, the clinic should have the equipment necessary for manually dispensing methadone solution. This includes graduated pipettes to measure the exact amount of methadone to be dispensed or manual dispensers. Disposable cups are required to dispense the methadone to the patients, and rubbish bins should be available for the disposal of used cups. The clinic should provide clean drinking water for patients in close proximity to where the methadone or buprenorphine is dispensed. Patients receiving methadone must rinse their mouths with water after consuming the medicine, and patients on buprenorphine should drink water to moisten their mouths prior to dosing.

1.2 Clinic timings

During the early phases of treatment, until the patient is stable, methadone is commonly dispensed on a daily basis; consequently, the methadone site should be open seven days a week. When the patient is stable, take-away doses are recommended, and clinic timings for the patient are more flexible. When dispensing buprenorphine only, the prolonged duration of its effect at high doses enables alternate-day and, for some patients, even three-days-a-week dispensing regimens following stabilization. Consequently, the MAT site may not need to open seven days a week if buprenorphine only is dispensed. In Nigeria, MAT clinics should be open to accommodate patients that need to take their medicines before work, and be able to accommodate patients that may attend after work (if and when a patient is employed). On any given day, MAT sites should be open for six to eight hours, depending on the number of enrolled patients. Some sites may have longer operating hours, depending on patients' needs. On Sundays and public holidays, clinics should open normal hours. However, if opening hours are to be different or changed, this information needs to be communicated to patients beforehand. It is best to prominently display opening hours for weekdays, weekends and public holidays in writing at the clinic site.

The opening and closing hours for dispensing methadone or buprenorphine can be decided by the MAT site treatment team, based on patients' needs. Once patients are stabilized on methadone or buprenorphine, some of patients may start working, making it difficult for them to come to the clinic at their usual time. The methadone or buprenorphine dispensing site should try to be flexible and find suitable times to accommodate such patients. Another alternative is to assess the patient's suitability for take-away doses of methadone, which renders daily attendance at a MAT clinic unnecessary **[refer to Step 8 in this SOP**]. Patients stabilized on buprenorphine will transition faster towards not requiring daily attendance at a MAT clinic than those receiving methadone. For take-away doses and adjustments of methadone or buprenorphine doses, another site may be appropriate. If this is the case, clinic opening times can be determined by treatment staff, taking patient convenience into consideration.

1.3. Staff roles and responsibilities

Medical doctor

The doctor is the head of the clinical unit and plays a lead role in the medical aspects of the MAT clinic. The doctor should have a minimum qualification of Bachelor of Medicine and Bachelor of Surgery (MBBS). Not all MAT clinics have a psychiatrist on site; therefore, a consultant psychiatrist should be on call and available when psychiatric assessment and treatment of comorbid psychiatric illness is required. Only physicians trained in methadone or buprenorphine treatment may prescribe these medicines.

Pharmacist

Registered pharmacists import, manufacture, procure, store, distribute, sell, compound and dispense controlled medicines and substances (such as MAT) in accordance with

extant rules and laws in Nigeria. The pharmacist ensures rational dispensing and use of controlled medicines. The pharmacist should receive training in pharmacotherapy to understand the benefits and processes involved in providing a MAT service.

Nurse

The nurse is in charge of dispensing methadone or buprenorphine and, in the absence of the doctor, can also be in charge of the day-to-day management of the clinic. A basic degree and experience in general nursing is required for nursing staff. A minimum of one nurse per site is essential. Only a nurse trained in methadone or buprenorphine treatment shall dispense these medicines.

Counsellor or social worker

The counsellor or social worker is responsible for providing psychosocial intervention services to patients. The counsellor or social worker should ideally have a graduate degree in psychology, social science or humanities; alternatively, a counsellor with lived experience (i.e., a recovered addict) with two years of sobriety can be considered for the role. A counsellor or social worker that has experience working with PWUD is highly preferred. Sometimes a nurse serves a dual role as counsellor; when this is the case, the nurse should receive training in counselling.

Outreach workers/peer educator

Outreach workers/peer educators should have good interpersonal skills and be interested in health-related learning.

Laboratory technician

The laboratory technician conducts laboratory tests as requested by the medical doctor following an assessment of the patient. Some MAT sites may have a dedicated laboratory technician while others make referrals for laboratory services.

Important characteristics of all staff

Staff attitudes towards patients largely determine the success of the MAT clinic and client retention in the programme. It is critically important to establish a strong therapeutic relationship with the patient to ensure effective treatment. Many people are uncomfortable when giving a history of their drug dependence, and most have experienced prolonged stigma and discrimination by family members and the wider community, including health services. The staff needs to be non-discriminatory, non-judgmental, positive and exhibit caring attitudes towards the patients. A strong, respectful rapport between patients and staff will improve patient retention in the MAT programme.

Refer to **Appendix 1** for detailed roles and responsibilities of staff members within the MAT clinic or centre.

2 **STEP 2:** Initiating MAT service, establishing eligibility, and identifying and diagnosing opioid dependence

Prior to the actual delivery of MAT, the general community and potential patients should be informed about the MAT programme to attract patients to the centre. This will encourage either patients seeking treatment to visit the centre or family members to bring the prospective patients to the centre. Other centres treating opioid dependence, including detoxification and rehabilitation centres, prisons and existing outreach services targeting PWUD, should also be informed about the MAT programme.

2.1 Eligibility

It is important to confirm that person seeking assistance is eligible to receive MAT. Assess for the following:

- Dependent opioid use for at least six months with at least one serious attempt at withdrawal over that period (for those dependent on tramadol, codeine and pentazocine, a minimum of two failed attempts at detoxification and rehabilitation).
- Engaging in harmful use of opioids (for example, injecting drugs).
- Previous treatment failures (medical or non-medical), including previous methadone or buprenorphine use.
- Ability to access methadone on a daily basis. With methadone, it is commonly recommended that patients be in stable treatment for at least three months before non-daily or take-away doses are considered. Access to buprenorphine on a daily basis for at least two weeks during early treatment is recommended.
- Motivation to undergo longer-term treatment.
- Strong desire to give up opiate use.
- Opioid-dependent and HIV-positive people receiving antiretroviral therapy (ART), TB-infected and receiving anti-TB treatment, or pregnant.
- 18 years of age or older (need flexibility with younger patients based on risk behaviour assessment).

2.2 Non-eligibility

(Important: there are no fixed exclusion criteria, so flexibility during assessment is needed)

Assess for the following:

- Acutely psychotic.
- Only dependent on alcohol, benzodiazepines, amphetamine-type stimulants (ATS) or cannabis. However, polydrug use should not exclude people who are dependent to opioids from receiving MAT.

- Acute medical conditions (severe hepatic disease, respiratory illness or head injury).
- High risk of overdosing. However, it is important to note that overdosing can be reduced once patients are stabilized on MAT.

There are occasional circumstances when methadone or buprenorphine maintenance may not be preferable in the context of opioid use dependency. These may include:

- Individuals who refuse consent.
- Minors (those under 16 years of age) or individuals with only recent evidence of mild opioid use dependency and with strong psychosocial supports – a trial of detoxification with maintenance may be considered.
- Individuals with dependency to tramadol, codeine or pentazocine. First-line treatment for tramadol, codeine or pentazocine dependency would normally be detoxification and rehabilitation. MAT should only be considered if a minimum of two previous detoxification and rehabilitation efforts have failed, or if the harms associated with ongoing opioid use warrant use of a *higher* potency opioid, in addition to more intensive, longer-term clinical interventions.

Individuals who use opioids, but who do not fulfill opioid-use dependency criteria should be offered other treatment options, including:

- Psychosocial interventions.
- Admission for detoxification and rehabilitation.

2.3 Conducting identity requirements

It is important to confirm the identity of all people who seek MAT services. On first presentation, examine the patient's identity documents and confirm their validity. Identity requirements include at least one of the following: national identity card/driver's license/voter's card/international passport. Additional information to assist with identity requirements are as follows:

- Recent photographs (up to six photographs may be needed: for registration at the MAT site; to be attached to medical records; to be attached to the drug user registration card; to be attached to the methadone/buprenorphine dispensing record book at dosing point; and two may be kept in reserve for possible future patient transfer or miscellaneous needs).
- In some countries, the health-care provider and the patient agree on a personal code to be used for patient identification.

2.4 Diagnosing opioid dependence

Dependency on opioid use is a chronic physical and psychological state resulting from neuroadaptation to recurrent opioid use. Physiological tolerance develops, so the individual requires opioids to achieve a 'normal' physical and psychological state.

Methadone or buprenorphine treatment is usually appropriate for people who are dependent on opioids. When opioid use dependency is not present, methadone or buprenorphine is not indicated.

There are two assessment tools available to determine opioid dependency: WHO International Classification of Diseases [ICD]-10 and the Diagnostic and the American Psychiatric Association's Statistical Manual of Mental Disorders (DSM-5). The following will assist a medical doctor to confirm opioid dependency:

DEPENDENCE (ICD-10) *	DEPENDENCE (DSM 5) +
Presence of three or more of the following in the last 12 months	Presence of at least two or more of the following in the last 12 months
1. Evidence of tolerance.	1. Taking more opioid drugs than intended. 2. Tolerance for opioids.
2. A physiological withdrawal state when substance use has ceased or reduced.	3. Withdrawal symptoms when opioids are not taken.
3. A strong desire or sense of compulsion to take the substance.	4. Cravings for opioids.
4. Difficulties in controlling substance-taking behaviour in terms of its onset, termination or levels of use.	5. Wanting or trying to control opioid drug use without success.
5. Progressive neglect of alternative pleasure or interests, increased amount of time necessary to obtain or take the substance or to recover from its effects.	6. Failing to carry out important roles at home, work or school because of opioid use. 7. Giving up or reducing other activities because of opioid use. 8. Spending a lot of time obtaining, taking or recovering from the effects of opioid drugs.
6. Persisting with substance use despite clear evidence of overtly harmful consequences.	9. Continuing to use opioids, despite use of the drug causing relationship or social problems. 10. Knowing that opioid use is causing a physical or psychological problem but continuing to take the drug anyway. 11. Using opioids even when it is physically unsafe.

* Adapted from WHO ICD-10 diagnostic guidelines for substance use disorders.

\+ Adapted from American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, fifth edition, DSM-5™.

A comprehensive medical history is the most important component of the assessment, and beneficial insights are dependent on an open dialogue between patient and doctor.

Additionally, a review by a medical doctor can determine if the patient is experiencing opioid intoxication or opioid withdrawal. Refer to **Appendix 2**.

3 **STEP 3:** Assessment, sharing information, consent and registration

3.1 Comprehensive clinical assessment

When conducting a comprehensive clinical assessment, there is a need to fully evaluate the patient's physical, social and psychological (mental health) conditions to collect adequate baseline information for the commencement of MAT. It is recommended that this clinical assessment be conducted by the medical doctor.

It is important to explore with the individual the reasons for seeking treatment, as this will effect treatment goals and help in determining if treatment is acceptable and appropriate for the patient. Some sites may have well established and trained counsellors that offer counselling services to determine if a person is a good candidate for MAT and provide an explanation about the medicine. This should be followed by another counselling session after two to three days to confirm that the information conveyed earlier was understood. Based on the counselling sessions, a health provider will assist a person to connect with a health service for a more comprehensive assessment and potential commencement of MAT.

It can sometimes be difficult to establish whether opioid dependence is causing or exacerbating mood disturbance, or vice versa. Assessment of the patient may reveal that the use of other substances (such as methamphetamines or alcohol) and sedative (such as benzodiazepines) withdrawal may be associated with psychiatric problems. A comprehensive clinical assessment should determine if psychiatric and medical comorbidity exist, and if this is the case, a referral for a psychiatric review should be made.

3.2 Investigations

It is **NOT ESSENTIAL** to perform any laboratory test before initiating a patient on methadone or buprenorphine. If the doctor has conducted a clinical examination and has not detected any significant detrimental condition, methadone or buprenorphine can be safely started. However, it is a good practice to conduct routine laboratory tests (such as hemogram, liver function tests and renal function tests) in the initial days of assessment and treatment as a 'baseline' test. When there are noted findings on a physical examination, the relevant laboratory tests are warranted. Other recommended tests include: sexually transmitted infection (STI) screening, HIV testing and counselling, screening for viral hepatitis, a pregnancy test and urine drug screening.

3.2.1 Urine screening

Urinalysis is most useful in the following circumstances:

- Patients in the early stages of treatment.
- When clarity of drug use is required for diagnostic purposes.

Urine toxicology can be useful on a monthly basis, when feasible, but should never be used for punitive purposes. No patient should ever be dismissed or excluded from MAT for ongoing drug use, but results from the urine tests can help identify ongoing drug use and additional needs for support, such as increases in methadone or buprenorphine doses, counselling interventions for polydrug or alcohol use and others.

3.3 Providing information to patients

After confirming opioid use disorder and completing a comprehensive clinical assessment, a medical doctor, senior nurse or counsellor trained on MAT issues should provide the patient with the following information both verbally and in writing, if the patient is literate:

- Information on the side effects of current and past drugs used (including alcohol).
- The risks associated with sharing injecting equipment and information on safe injecting practices.
- The risks associated with polydrug use, drug interactions and overdose.
- Information about HIV, viral hepatitis, TB and other common medical conditions associated with substance use.

Prior to commencing MAT, patients should be provided with an explanation and information about methadone or buprenorphine, including the following:

- The rules/regulations, clinic opening times and procedures to be followed while on MAT.
- The causes of opioid use dependency.
- An explanation that the peak effect occurs two to four hours after administration of methadone, and one to four hours after administration of buprenorphine.
- An overview of interaction with other sedatives (e.g., alcohol, benzodiazepines) and antiretroviral drugs, particularly nevirapine and efavirenz (specific to those receiving methadone).
- The fact that it may take two to eight weeks to achieve the ideal stabilizing dose with methadone and one to three weeks with buprenorphine.
- Expected behavior when undergoing treatment.
- Expected duration of treatment (at least six months for best outcomes). Twelve months is recommended.
- How to avoid overdose during treatment: risks related to combining methadone with the unsupervised use of other central nervous system (CNS) depressant drugs (alcohol, opioids, benzodiazepines and tricyclic antidepressants).
- How to avoid HIV and other infections through other harm reduction (not sharing needles and syringes if injecting drugs) and sexual health measures.
- Information about other relevant services and referral when necessary.
- Procedures of addressing complaints during treatment, if required.
- An explanation that methadone and buprenorphine may affect the patient's capacity to drive or operate machinery during the early stages of treatment, after an increase in dose, or when patients are also taking other drugs.

For frequently asked Questions and Answers about MAT refer to **Appendix 3.**

3.4 Obtaining consent for treatment

- Patient must be provided with information about MAT, precautions, side effects and associated services (i.e., HIV, TB, hepatitis).
- Consent should be voluntary: consent form should be signed by patient and dated.
- For minors under the age of 16 years, obtaining consent from a parent, guardian or significant other is recommended.

3.5 Registering a patient when prescribing methadone or buprenorphine

People who use drugs must be registered and a notification of the registration should be sent to the coordinating health facility in the state for transfer to the Federal Ministry of Health (FMOH), and/or designated institution(s). Treatment should not be commenced until the prescriber has registered the user and confirmed that they are not already receiving methadone or buprenorphine treatment from another MAT site. The FMOH should also be notified of the initiation of methadone or buprenorphine treatment through the same channel used for transferring the notification of registration at the time of commencement and this should be documented in the monthly summary report of new patients commenced on MAT.

Prescribing is the sole responsibility of the doctor who signs the prescription. This responsibility cannot be delegated to others.

Each patient prescribed MAT must be registered at a MAT centre, first as a new patient to the service, and then as a patient receiving maintenance treatment. This information recorded must include a registration number, the type of MAT received, the patient's name and contact details, and some demographic information.

3.6 Requirements for methadone and buprenorphine prescriptions

Methadone is a Schedule 1 Narcotic under the National Policy for Controlled Medicines. As a result, MAT providers need to adhere to legal and good practice requirements. Prescriptions are valid provided they are written on standardized MAT prescription forms. Medical personnel prescribing MAT should be trained to deliver the service.

The following information needs to be included on prescriptions:

- Prescriber's registration number and address.
- Unique patient identification number.
- Strength of the preparation.
- Daily dose and start date.
- Total quantity, written in words and numbers.
- Signature of prescriber.

NOTE: prescription is only valid if presented within 10 days from date of signature or proposed start date.

4 **STEP 4:** Methadone and Buprenorphine induction

4.1 Induction into treatment with methadone

- Advise patient to avoid sedatives (including alcohol) for 24 hours before the commencement of methadone treatment.
- Be aware of any signs of drug use on the day of commencement.
- The first dose of methadone should not be delayed because of a patient's use of heroin (or other opioids) the same day. The time of first dose maybe postponed an hour or two if there are signs of sedation.
- It is commonly the nurse at the MAT clinic who distributes methadone doses as prescribed by the doctor.
- Check pupils for dilatation. If pupils are dilated, the patient has some withdrawal symptoms.
- Use caution when dosing for new patients. Initial doses should be 5-20 mg, and commonly the first dose is 15-20 mg. The initial dose should never exceed 30 mg. If there is any doubt regarding the patient's recent intake of opioids, the initial dose can be lowered to 5-10 mg (**see Table 1**).
- The patient should rinse their mouth with water; this helps them swallow the entire dose and ensures they are not hiding the medicine inside their mouth (this should be done each time a patient takes methadone).
- Review the patient three to four hours after the first dose for signs of withdrawal or intoxication. This can inform dose changes in the first week of treatment.
- An additional 5-10 mg can be given three to four hours after the induction dose if the Clinical Opiate Withdrawal Scale (COWS) tool (refer to **Appendix 4**) indicates moderate or severe withdrawal.
- A nurse may need to see the patient and enquire about their well-being on a daily basis in the early stages of treatment. After the first day, ensure the patient spends three days on each dose before considering an increase in dosage. It may take up to five days for a change in the dose to have its full effect owing to the long half-life of methadone.
- Patients should be reviewed by the doctor three to four days after the first dose to determine whether the initial dose needs to be increased. If the patient has been experiencing withdrawal symptoms for most of that period, the dose can be increased by a maximum of 10 mg.
- The daily dose should not exceed 40 mg in the first seven days of treatment to avoid significantly exceeding opioid tolerance that could lead to risk of over-sedation and even fatal consequences.

During the stabilization phase, the key phrase is "start low – go slow".

TABLE 1. Induction doses of methadone and clinical conditions

Induction initial dose	Situation/clinical condition
5-20 mg	In general, start low. The dose can always be increased. Prescribe this dose for people with low or uncertain levels of opioid dependence, high risk polysubstance use, or with other severe medical conditions.
20-25 mg	Moderate level of opioid tolerance or some lower-level risk factor. Using opioids regularly for more than six months and using twice a day or more in the past two weeks.
25-30 mg	Higher level of opioid tolerance with minimal use of other drugs; patient with no special risk factors and is well known to doctors; prior methadone treatment with no special risk factors.

The induction phase usually lasts 10 to 14 days and the patient can be inducted as an **outpatient**, which is internationally the most common approach. However, if *necessary*, the patient may also be admitted to a drug treatment centre if that is considered more suitable and appropriate for the patient (for some patients who live far from the induction site, a short-term residential programme may prove more convenient).

4.2 Induction into treatment with buprenorphine

- Counsel patient not to consume opioids within six hours of the first dose of buprenorphine (if the patient had been prescribed methadone but is being shifted to buprenorphine, they should not consume opioids within 24 hours).
- Ensure the patient has experienced precipitated withdrawal before induction with buprenorphine. Clinically, this presents as rapid onset of significant opioid withdrawal symptoms one to four hours after the first buprenorphine dose, as buprenorphine reaches its peak effects. The recommended treatment is to continue with buprenorphine dosing and provide symptomatic medication as needed. Precipitated withdrawal is not dangerous but can be extremely uncomfortable and can result in the patient refusing treatment.
- It is commonly the nurse at the MAT clinic who distributes buprenorphine in doses as prescribed by the doctor.
- Commence the patient on buprenorphine-naloxone unless pregnant or breastfeeding (or has a proven allergy to naloxone). The combination of buprenorphine-naloxone is less likely to be injected than buprenorphine-mono.
- Defer the first dose of buprenorphine until the patient is experiencing mild to moderate withdrawal (anxiety, abdominal or joint pain, dilated pupils, sweating). The COWS tool can be helpful. (**Refer to Appendix 4**).
- Ensure that the induction dose is determined by the situation/clinical condition of the patient. (**See Table 2**).

- On subsequent days, the buprenorphine dose can be increased by 2, 4 or 8 mg increments, with upper limits of 16 mg on day two and 24 mg on day three. Slower dose increments (as used for methadone) are not required and, indeed, dose increments that are too slow are associated with higher rates of treatment drop-out.

TABLE 2. Induction doses of buprenorphine and clinical conditions

Initial daily dose	Situation/clinical condition
2-4 mg	Clients with low or uncertain levels of opioid dependence, high risk polysubstance use, or with other severe medical conditions.
2-4 mg initial dose Further supplementary dose after one to two hours, up to maximum 8 mg for first day	Clients with mild opioid withdrawal. (Split dosing reduces risk of precipitated withdrawals).
Up to 8 mg	Moderate to severe opioid withdrawal at time of first dose.

4.3 Awareness of risks with methadone or buprenorphine toxicity

Some patients are at a greater risk of methadone toxicity, particularly during induction into treatment. Toxicity of methadone resembles that of other opioids: sedation, coma, respiratory depression and pinpoint pupils can occur following an overdose. The risks of overdose and death are the highest in the first 10 days of treatment. All staff need to be aware that a patient may continue with illicit drug use in an effort to minimize the withdrawal symptoms before becoming stabilized in treatment. As a partial agonist, buprenorphine is safer than methadone with less risk of toxicity that can result in over-sedation, respiratory depression and overdose. The respiratory depression associated with an overdose of buprenorphine may be linked to the effects of alcohol or benzodiazepines. Methadone or buprenorphine toxicity does not occur only in the induction phase but can also happen during the maintenance phase of treatment.

Be aware of factors that contribute to high methadone toxicity, as follows:

- Alcohol-dependent patients or those consuming heavy amounts of alcohol.
- Recent use of benzodiazepines and/or other sedatives.
- Age >60 years.
- Respiratory illnesses.
- Taking drugs that inhibit methadone metabolism or lower opioid tolerance.
- Recent discharge from inpatient drug use treatment/rehabilitation centre.
- Recent incarceration.
- Severe liver disease.

5 **STEP 5:** Effective maintenance dose with methadone or buprenorphine and awareness of overdose

5.1 Establishing an effective maintenance dose with methadone

- The maintenance dose should be individualized to the patient's needs and it is best to adopt flexibility with the dose.
- A maintenance dose of at least 60 mg per day is more effective than lower doses (a higher dose results in less chance of ongoing illicit drug use and better retention).
- Reaching an effective maintenance dose usually takes two to three weeks, but for some individuals it may take up to eight weeks.
- If patient is still using illicit opioids, be prepared to increase the methadone dose.
- Methadone should be increased by 5-10 mg every four to five days to achieve a dose of at least 60 mg daily over the following two to four weeks.
- Keep the patient on each dose for at least three days before deciding to increase the dose again.
- Higher doses may be needed, especially if the patient is receiving ART or TB treatment.
- When the patient reaches a daily dose of 50 mg, it is safe to increase the dose by 10 mg/day after five to seven days on the stable dose.
- Ensure flexibility with methadone doses and provide treatment on a case-by-case basis.

The two most important findings of a clinical assessment that guide methadone dose changes are:

- Presence of withdrawal symptoms or signs of intoxication.
- Ongoing use of illicit opioids despite being on methadone.

5.2 Establishing an effective maintenance dose with buprenorphine

- The maintenance dose commonly ranges between 8-24 mg/day. Some patients require higher (e.g., up to 32 mg/day) or lower (4-8 mg/day) doses. A maintenance dose is generally achieved within the first week of treatment if the patient adheres to the treatment plan.
- Buprenorphine dose can be increased by 2, 4 or 8 mg increments daily, with upper limits of 16 mg on day two and 24 mg on day three. Adjust doses following review of the patient – assessing side effects, features of withdrawal (suggesting not enough buprenorphine) or intoxication (suggesting too much buprenorphine or other drug use), and ongoing cravings and substance use.
- Dose increments that are too small are likely to lead to higher rates of treatment drop-out.

- Typically, effects will continue to be experienced for up to 12 hours at low doses (2 mg), and as long as 48-72 hours at higher doses (16 or 32 mg).
- The prolonged duration of effect at high doses enables double (alternate-day dosing) or even triple (third-day dosing) dispensing regimens.

5.3 Treatment of overdose

5.3.1 *Methadone overdose*

Patients who are on long-term methadone treatment and appear to be suffering from a methadone overdose can be observed for four to six hours at the dispensing site. If there are no signs of toxicity, the patient can be discharged and asked to return the next day. Patients who are unaware of the effects of methadone or are experiencing a clinical overdose of methadone should be referred to a drug dependency treatment hospital for observation and further assessment.

Naloxone should be used, if available, but be aware that methadone will continue to produce respiratory depression after the effects of naloxone have worn off. It is important to monitor the patient for around two hours after administration of naloxone. Inform the patient that taking any opioid drugs after naloxone is dangerous as it can result in a second overdose. Naloxone only stays in the body for around 60 to 90 minutes. Opioid drugs stay in the body much longer.

A patient suffering from a methadone overdose should be treated as follows:

- Provide respiratory support.
- Administer naloxone, if appropriate, for intramuscular (IM) or intravenous (IV) use. Naloxone should be stocked at the MAT clinic.

5.3.2 *Buprenorphine overdose*

Doses of buprenorphine many times greater than normal therapeutic doses appear to be well-tolerated. Clinically significant respiratory depression is rare, except in individuals who are not opioid tolerant. However, if treatment of overdose is needed, it is more difficult as naloxone, an opioid antagonist that reverses opioid overdose, does not readily reverse the effects of buprenorphine. If respiratory depression occurs as a result of overdose, management in a hospital using ventilation is recommended, as is examining the underlining causes.

For further information on treating opioid overdose and respiratory support refer to **Appendix 5**. For further information on naloxone refer to **Appendix 6**.

6 STEP 6: Review patient regularly

With both methadone and buprenorphine, every review should include the patient's drug history, a physical examination, mental state examination and modification of the management plan if required.

6.1 Patients on methadone

Patients should be clinically reviewed by the treating doctor and treating team on:

- Day one, four hours after the first dose.
- Day three or four.
- End of week one.
- At least once a week for the first month or until a stable dosage has been achieved.
- At least every two weeks for the first two and three months.
- At least monthly thereafter.

This schedule should be revised if a patient's condition deteriorates.

6.2 Patients on buprenorphine

Patients should be clinically reviewed by the treating doctor and treating team on:

- Day one, four hours after the first dose.
- Day three – by this stage, the likely stabilization dose should be reasonably clear.
- End of week one.
- At least weekly for the first month or until a stable dosage has been achieved.
- At least every two weeks for the first three months of treatment.
- At least monthly thereafter.

If a patient's clinical condition deteriorates, revise the schedule.

For both methadone and buprenorphine, the patient can be visiting the MAT clinic on a daily basis, particularly during induction and early phases of treatment. At this time, the nurse can do the following:

- Identify the patient by name and ascertain their identification.
- Enquire whether the patient has consumed any illicit opioid in the last 24 hours.
- Examine the patient's pupils and check for pupil dilation.
- Enquire about the general well-being of the patient.
- Confirm the dose of opioid for the patient from the dispensing register.

If the nurse is satisfied, then the patient should be given their daily dose of methadone or buprenorphine and asked to sign the dispensing register. The nurse should also make sure that the patient visits the doctor and counsellor for follow-up.

7 **STEP 7:** Addressing adherance, retention and common side effects

7.1 Adherence and retention

The treatment team should make every effort to maximize patient adherence and retention. This includes:

- Achieving a stable methadone dose, commonly at 60 mg and above daily for methadone; with buprenorphine, a stable dose is commonly in the range of 8-24 mg/day, with dosing administered every two or three days.
- Having a strong therapeutic relationship between the treatment team and patient.
- Encouraging psychosocial individual and group therapy sessions, as well as drug education classes for all MAT patients.
- Addressing individual adherence concerns on a continuing basis.
- Addressing transportation and other access issues.
- Encouraging psychosocial sessions for families (codependents) of MAT patients once a month.
- Providing peer support, social work support and other services to match a patient's needs.
- Providing a low threshold service (minimizing barriers for access) to recommence methadone if a patient drops out of treatment.
- Ensuring access to take-away doses when appropriate.

Good rapport between the staff and patient is vital for the success of the treatment. Confidentiality is of paramount importance in the provision of good clinical care and can also increase retention.

7.2 Addressing common side effects of methadone and buprenorphine

Patients should be educated on the potential side effects of methadone and buprenorphine before the commencement of treatment. This will allow for early detection and management. Side effects, how they can be self-managed and suggested clinical management are outlined in Table 2.

TABLE 3. Managing common side effects of methadone and buprenorphine

Side effect	Self-management	Clinical management
Sedation, disturbed sleep, drowsiness.	Avoid sedatives while on methadone or buprenorphine.	Only a doctor can prescribe additional sedatives to a patient.

(contd) TABLE 3. Managing common side effects of methadone and buprenorphine

Side effect	Self-management	Clinical management
Headaches – common in first week of buprenorphine treatment. Side effect is transient and generally mild.	Relaxation techniques. If persistent, consider aspirin or paracetamol.	If ongoing, check for other causes.
Constipation and sweating. Dry mouth (specific to methadone).	Increase fluid intake. Encourage fibre intake (fruit, cereals and vegetables), fluids and regular exercise.	Stimulant laxatives if necessary.
Nausea and possibly vomiting.	Attempt to avoid foods or smells that trigger nausea.	May indicate that dosage is too high.
Dental caries specific to methadone (secondary to decreased saliva secretion).	Drink fluids regularly. Brush teeth twice daily. Encourage oral hygiene, use of dental floss and sugar-free gum. Reduce intake of sugary drinks and sweet food.	Active dental treatment if available. Dental check-up.
Lowered sex drive.	Reflect on other psychological factors (such as anxiety, poor relationship with partner, etc.).	Review dose. Consider investigation for opioid-induced hypogonadism.

8 **STEP 8:** Take-away [take-home] doses of methadone and burprenorphine

Take-away doses can help stable patients normalize their lives, integrate into the community, and meet work and family commitments. Patients prescribed methadone or buprenorphine should be assessed for stability before take-home dosing is commenced. That assessment should take the following into account:

- Current adherence to supervised dosing.
- Current adherence to appointments with the treatment team.
- Infrequency of use of additional illicit opioids or other drugs (may or may not be confirmed with a random urinary drug screen).
- No evidence of recent (e.g., in prior three months with methadone and two weeks with buprenorphine) intoxicated presentations or overdoses.
- Stability of mental health.
- Stability of accommodation.
- The availability of a secure area to store medication at home (particularly if there are children at the home).
- Little evidence of intention to divert or inject take-home doses.

Take-away dosing might progress as follows:

- No take-home doses in the first three months of treatment with methadone; no take-home doses in the first two weeks with buprenorphine.
- Assess social and economic stability and family support.

Take-home doses of buprenorphine-mono are generally not recommended as there is a high risk of injecting this substance. Take-home dosing for those patients on a combination of buprenorphine-naloxone may be more appropriate and may be considered after a continuous period of stability in treatment.

8.1 Take-away dose with methadone

Steps for prescriber-authorized take-away (take-home) doses with methadone are as follows:

- No take-home doses in the **first three months** of treatment.
- Assess stability and family support.
- Assess stability – one take-home dose per week.
- Assess stability over one month – two take-home doses per week.
- Assess stability over one month – three take-home doses per week.
- Assess stability over one month – four take-home doses per week.
- Maximum of four take-home doses given each week for **highly stable** patients, meaning patients will have supervised dosing three times a week.

8.2 Diluting take-away doses of methadone

> doses greater than 25 mg should be diluted to 100 mL.
> doses less than 25 mg should be diluted to 50 mL.

Diluting doses has a few advantages:

- Reduces the value of diverted methadone.
- Discourages injection.
- Reduces the chance of an entire dose being accidentally swallowed by someone other than the client, with possibly fatal consequences.

8.3 Take-away dose with buprenorphine-naloxone

Take-away doses of buprenorphine-naloxone may be considered after a continuous period of stability (a minimum of two weeks) in treatment. Steps for prescriber-authorized take-away doses are as follows:

< Two weeks	No take-away doses
Two weeks - two months	Zero to two take-away doses per week
Two months - six months	Zero to five take-away doses per week
> Six months	Zero to six take-away doses per week

To encourage MAT retention, the treatment team can consider take-away doses with methadone or buprenorphine-naloxone in some circumstances on a case-by-case basis, reviewing the patient's individual circumstances and examining the distance between the patient's home and the clinic.

8.4 Safety of take-away dose and rules

With all take-away doses it is essential to inform patients or guardian/s about the potential risks of methadone or buprenorphine, and to stress that take-away doses need to be locked up and kept out of reach of children.

Each container for methadone or buprenorphine should have a **label** that highlights the following: (1) Poison; (2) Keep out of Reach of Children; (3) Name of Patient; (4) Dispensing Unit; (5) Date; and (6) Not to be Transferred to Others.

Each take-away dose is placed in a separate container (preferably with a childproof locking device). If a patient is receiving four take-away doses, they should be provided with four separate containers of methadone. For methadone (commonly dispensed as liquid), each take-away dose should be diluted with water. Buprenorphine-naloxone (as tablet or film) doses can also be provided in separate containers or in one container, as assessed and determined by the treatment team.

Take-away dosing is not recommended in the following situations:

- Polysubstance use.
- Recent overdoses or presenting for dosing in an intoxicated state.
- Unstable psychiatric conditions.
- Risk of injecting take-home doses.

Rules and messages that should be communicated to the patient and understood by the dispenser include:

- It is a criminal offence to provide methadone or buprenorphine to a non-methadone/buprenorphine patient.
- Fatal accident can occur if a person that is not prescribed methadone consumes it by accident. Respiratory depression can happen if a person not prescribed buprenorphine consumes by accident, and more so if taken in combination with alcohol or benzodiazepines.
- Both methadone and buprenorphine are only to be consumed according to the prescription.

9 **STEP 9:** Services offered, referrals and linkages to other services

Staff from the treatment team should be focused on linking patients to other health and social services as and when required. Whether or not the MAT clinic has an integrated one-stop-shop model, staff should encourage referrals and access to other services. An inventory of available services should be undertaken and contact information circulated so that existing treatment staff can provide specific services at the MAT centre or refer patients to the following as needed:

- HIV testing and counseling (HTC).
- If living with HIV, and required, antiretroviral therapy (ART).
- Condom distribution programmes for people who use drugs and their sexual partners.
- Targeted information, education and communication (IEC) for people who use drugs and their sexual partners.
- Needle and syringe programmes (if available) for people who may continue to inject drugs.
- Hepatitis B testing and vaccination.
- Hepatitis C testing.
- Prevention, diagnosis and treatment of tuberculosis.
- Detection and management of sexually transmitted infections.
- Support groups/self-help groups.
- Welfare agencies, charitable/government organizations and drop-in centres that provide food, shelter, clothes and income-generation programmes for people who use drugs.

Treatment staff should always make an effort to assist any patient to access other services smoothly and efficiently as required. If a referral service is outside of the MAT dispensing site, it is best to have the patient accompanied (commonly by an outreach worker or peer educator) to ensure improved connectivity between patient and service provider. A multidisciplinary approach to methadone or buprenorphine treatment is essential.

During induction and when receiving MAT, the injecting of drugs among some patients can take place. Consequently, each patient needs to be aware of and be referred to services that provide information about safer injecting, which is a key intervention for the prevention of HIV and other blood-borne viruses. A record of services offered or referral to other services should be maintained at the MAT centre.

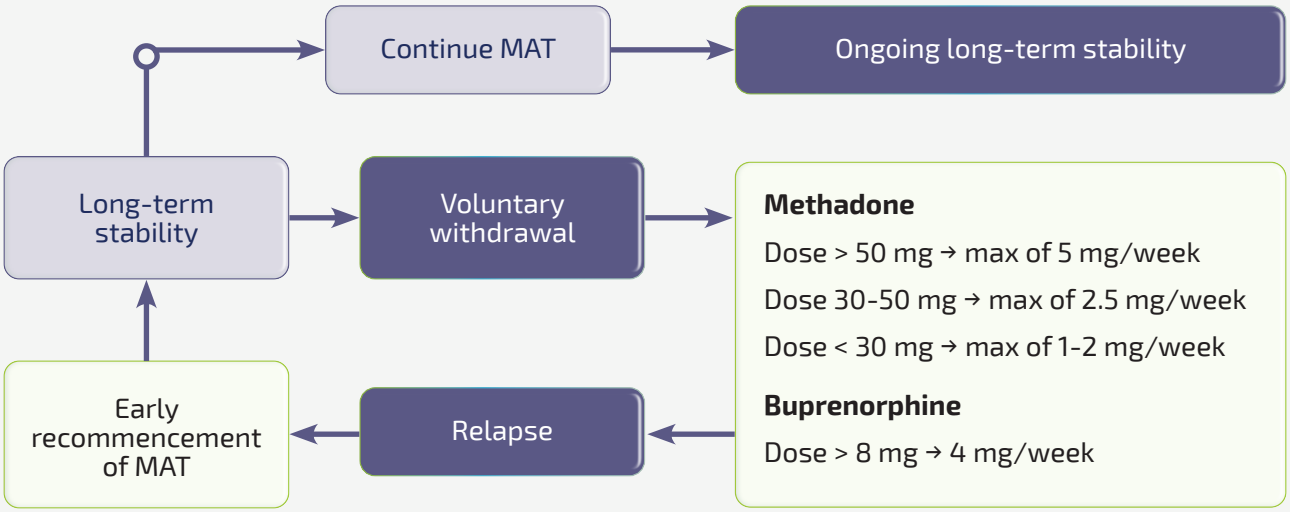
Counselling of patients receiving MAT is an important part of ongoing supportive treatment throughout the maintenance process, and the frequency of the sessions is determined on a case-by-case basis. Individual counselling has added therapeutic benefits as it provides an opportunity for the patient to voice any concerns or issues with MAT, and it also supplies the service providers valuable insights on patient progress. MAT services

can also offer patients the opportunity to participate in group discussions with others also receiving treatment. Group discussions are commonly facilitated by a counsellor or another qualified treatment team member. Individual counselling sessions or group discussions should be documented in a register.

10 **STEP 10:** Termination of treatment – voluntary and involuntary

Patients need to be repeatedly informed that MAT is a long-term treatment. Termination of treatment should be based on stabilization of psychosocial functioning more than duration of treatment. Continuing on MAT for a long period of time produces the best outcomes. **Benefits increase when the patient remains in treatment for more than 12 months.** All decisions related to termination of methadone or buprenorphine should be taken jointly by the treating doctor and the patient.

VOLUNTARY WITHDRAWAL FROM METHADONE AND BUPRENORPHINE



Patients may experience withdrawal symptoms for a number of weeks after cessation of methadone despite very gradual tapering of the dose during the final 5 mg of therapy. Patients on methadone can be transferred to buprenorphine as the dose is reduced as cessation from buprenorphine may be better tolerated than from methadone. Transfer may occur when the daily methadone dose is less than 30 mg, though transfer at higher doses (up to 80 mg) has been shown to be feasible. The final dose of methadone should be followed by a day without either methadone or buprenorphine. Buprenorphine should be commenced the following day in accordance with the buprenorphine induction regimen. Warn patients that they may experience moderate to severe withdrawal during transfer, which should settle once the buprenorphine dose is therapeutic.

The smallest dose available as buprenorphine-naloxone film is 2 mg; many patients find it difficult to cease from this level. Options at this dosage include either:

- Alternate day dosing (although lower doses may not hold the patient for 48 hours).
- Switching to buprenorphine tablets and dividing the tablets (which are scored for half doses).

As part of the cessation of treatment, it is important for the treating doctor to assess if the patient is ready to successfully 'wean' or taper their dose to eventually stop methadone or buprenorphine outright (refer to **Appendix 7**). Complete cessation is recommended only when the patient is socially engaged with family or friends, has employment or is engaged in regular extracurricular activities, and is not engaging in opioid and, ideally, other drug use. Cessation is usually not recommended in the first 12 months of treatment.

Involuntary cessation of methadone

The treatment team may decide to discontinue a patient's methadone or buprenorphine treatment because of unsatisfactory progress (for example repeated failure to attend treatment or diversion of methadone or buprenorphine) or if the patient is putting themselves or others at risk.

An abrupt termination of treatment or a dramatic reduction in dosage is associated with a marked deterioration in behaviour, drug use and emotional stability, and is rarely warranted.

Key reasons for terminating maintenance treatment with methadone or buprenorphine are as follows:

- Violence, threats or abuse to staff or other clients.
- Diversion of methadone or buprenorphine from the clinic.
- Confirmed drug dealing or other illegal activities around the clinic.
- Continued use of dangerous quantities of other central nervous system (CNS) depressant drugs.
- Trafficking take-away doses.

NOTE: Concurrent use of illicit drugs while on MAT is not a sufficient reason for discontinuation of treatment. It is important for the staff to fully investigate the reasons a patient may have returned to using drugs, and possibly injecting, while supporting them to better comply with MAT. If a patient continues to use illicit drugs, staff should encourage them to attend further counselling and link them to appropriate drop-in centres that offer targeted interventions for people who inject drugs (PWID).

11 **STEP 11**: Transfer of patient to another MAT site

Some patients may move from one geographical location to another and may want to continue MAT in their new location. It is possible for the treating doctor to transfer the patient to another MAT site. A referral letter prepared by the treating doctor should contain the following information:

- Name, date of birth, address and contact details of the patient.
- Patient identification number.
- Dose of methadone/buprenorphine.
- Other medical or psychiatric problems and prescribed medications (for example TB medication, ART or antidepressants).
- Adherence, retention and psychosocial issues.
- A copy of the patient's photo identification must be enclosed with the referral letter.

12 **STEP 12**: Dealing with specific clinical situations of patients

12.1 Missed doses

It is not uncommon for patients to miss supervised doses of methadone or buprenorphine. If a patient misses their doses intermittently (once or twice a month), it does not necessarily indicate instability. Patients who regularly miss one or more doses a week should be reviewed by the treatment team to determine the reason for the missed doses.

Missed doses of methadone or buprenorphine should be dispensed according to the following schedule:

Number of days missed	Recommended action
1 day	Continue current dose, review at next appointment.
2 days	» Review by treatment team. » Continue at current dose.
3 days	» Review by treatment team. » Give half dose of methadone and resume normal dosing the following day. » Continue current buprenorphine dose.
4 days	» Review by treatment team. » Give half dose of methadone and resume normal dosing the next day. » Give half buprenorphine dose and resume normal dosing the following day. » Keep patient under close observation the next few days.
5 days	**Begin new induction.**

12.2 Vomited doses

Vomited doses are only relevant to methadone as buprenorphine is administered sublingually. Despite methadone being absorbed rapidly, vomited doses should be managed as follows:

Time of vomiting	Witnessed or unwitnessed	Action
Vomiting more than 20 minutes after dose	Witnessed or unwitnessed vomiting	Methadone has probably already been absorbed, so no action required.

Time of vomiting	Witnessed or unwitnessed	Action
Vomiting less than 20 minutes after dose	Witnessed vomiting of methadone dose Unwitnessed vomiting of methadone dose	Re-administer same dose of Methadone. Review patient in four hours to assess whether or not the patient is experiencing withdrawal. Signs of withdrawal: give normal dose. No signs of withdrawal: do not administer an additional dose; resume normal dosage the following day.

12.3 Pregnancy

Methadone or buprenorphine should be offered to all pregnant opioid-dependent women. It is the most effective treatment for opioid use and will provide the least harmful outcome for the foetus. For buprenorphine treatment during pregnancy, in some countries, buprenorphine-mono is preferred to buprenorphine-naloxone. It is reported that with the buprenorphine-naloxone film, the absorption of naloxone is minimal when administered sublingually. However, the effect of long-term, low-level naloxone exposure on the foetus is unknown. Research shows methadone to be associated with greater treatment satisfaction and retention for pregnant women, despite higher risk linked to drug interactions and adverse events.

- In general, methadone or buprenorphine treatment for pregnant women should consist of the following:
- Stabilize the patient on an appropriate dose that is sufficient to cease their use of illicit drugs.
- Maintain the patient at a level that is comfortable and that avoids drug withdrawal during pregnancy. Do not encourage a reduction of the dose.
- All pregnant women should be actively referred to antenatal care.
- Reassess the dose in the days immediately following delivery to avoid over-sedation.
- Keep the patient on the maintenance dose for a minimum of two to three months postpartum before reducing the dose.
- Consider the need to address other substance abuse problems (smoking, alcohol or benzodiazepines) that have adverse effects on pregnancy outcomes.

13 **STEP 13**: Record keeping and dispensing MAT

13.1 Key steps to take when dispensing methadone or buprenorphine

- Correctly identify the patient before dosing: check photo identification (ID) card (if this is the approach adopted to confirm identification of patients).
- Ensure that the dose is authorized by the prescriber.
- Confirm whether it is safe to administer the dose. If the patient is intoxicated, consider whether the dose should be refused.
- Confirm that the correct dose has been measured. **NOTE:** methadone prescriptions are usually written in milligrams, but it is dispensed as a syrup containing 5 mg/ml. Thus a 30 mg dose is given as 6 ml of syrup.
- Measure the required dose into a disposable cup, using the syringe, pump or dispensing measure.
- Observe that the client swallows the dose and follows it with a sip of water. Then ask the patient to speak to you.
- Communicate with the prescriber regarding any irregularities in the patient's attendance.
- Maintain proper records.

Right person - right drug - right dose - right time - write down!

Note: Equipment used for methadone should be regularly checked for accuracy of dose delivery.

Training programme for dispenser

It is strongly recommended that all dispensers employed in the clinic or dispensary be required to complete a training programme to ensure that they are familiar with the guidelines on the methadone or buprenorphine programme and the principles of methadone or buprenorphine administration. It is recommended that proof attendance be provided and kept on file. A copy should be readily available to all dispensers for reference.

13.2 Storage

Methadone and buprenorphine are controlled drugs and must be kept in a secure location and placed in the locked cabinet or safe when not being used. Methadone solution does not require refrigeration, but should be located in a cool, dark place to avoid damage to the shelf life.

13.3 Supply chain mechanism and stock register of MAT

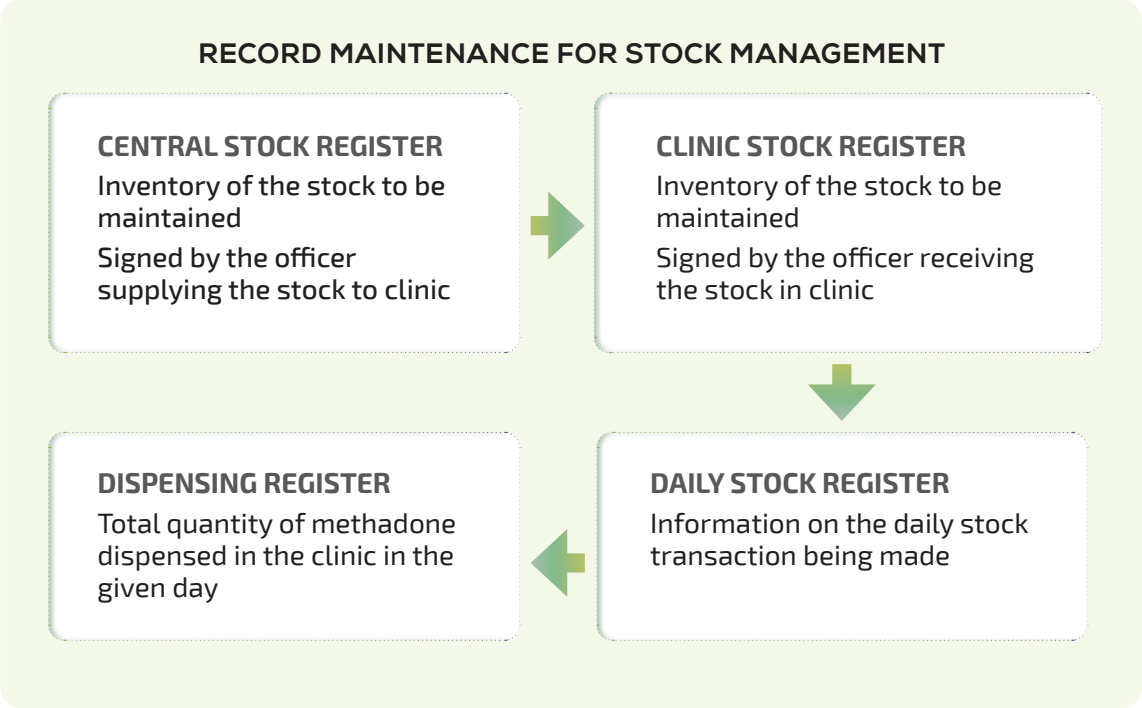
Methadone and buprenorphine are regulated narcotics. If a patient does not receive their dose, they will suffer from physical withdrawals. As a result, the supply chain for methadone and buprenorphine should not only be tightly monitored, but it should also be responsive enough to ensure uninterrupted stock. There are three key steps in the supply chain management. At every step, there should be a designated officer-in-charge of the stock with clearly established responsibilities. In addition, there should be a designated storage place at every point in the supply chain. The storage place should have designated access rights, and no one except the authorized officer/s should be allowed in.

The Federal Ministry of Health National Agency for Food and Drug Administration and Control Pharmacists Council of Nigeria is the nodal agency for regulating the flow of narcotic/psychotropic drugs in Nigeria.

13.4 Supply of methadone and buprenorphine to MAT clinic

Every MAT clinic must estimate the quantity of methadone or buprenorphine required. To make this calculation, follow these steps:

Average dose per patient per day
X
Number of patients on methadone or buprenorphine in a day
X
Number of days for which the stock is to be supplied
=



Generally, one to two months of supply can be held at a MAT clinic, depending upon the centre's storage capacity and safety precautions in place for securing methadone or buprenorphine. In addition, a buffer stock of at least two weeks should be kept at the MAT clinic to cover any unforeseen delays in the supply chain (such as unrest, natural disasters, etc.). The officer-in-charge should conduct periodic 'stock projections' and forecast accordingly to ensure that sufficient stock is on site. In addition, the officer should also keep track of methadone and buprenorphine expiration dates. If the expiration dates on some methadone or buprenorphine are approaching, then those stocks should be prioritized for immediate consumption.

13.5 Methadone- and buprenorphine-related documentation

Inventory tools are necessary for the monitoring and controlling of MAT. At a pharmacy level, MAT can be used and deployed at wholesale community pharmacies, secondary and tertiary hospital pharmacies as well as MAT-specific clinics/centres. When a patient arrives for the first time as a 'new' patient to receive MAT, they should be registered and added to a registration form for regular patients of MAT. **Refer to Appendix 8 and 9**.

Methadone and buprenorphine are controlled drugs and therefore accurate and secure records must be maintained regarding inventory, strength, batch numbers, expiration dates, and quantity of stock received and returned. Records must be maintained on how much stock is received at each MAT centre. When the data is reviewed, it must be signed off by the appropriate authority to ensure accountability. **Refer to Appendix 10** for the Controlled Medicine Record Keeping Book. The MAT centre must also have a MAT Stock Register of its methadone and buprenorphine. **Refer to Appendix 11.** The centre must also maintain a Daily Stock Register of MAT. **Refer to Appendix 12 and 13.** Additionally, there is a need to maintain a Daily Patient Dose Sheet for Methadone and Buprenorphine. **Refer to Appendix 14.**

A dispensary must maintain accurate records of each dose administered to each patient. These records may be computerized or manually prepared. The volume of methadone solution (expressed in millilitres) should be recorded, and the records should also clearly mention the dose of methadone (expressed in milligrams) to avoid misinterpretation. Methadone or buprenorphine dispensers should also record the remaining stock on a daily basis.

13.6 Stock management at MAT centres

At each MAT clinic or centre, the nurse is responsible for maintaining stocks and ensuring a regular supply of methadone and buprenorphine. The nurse is also responsible for daily dispensing and stock management. The nurse should document every dosage of methadone or buprenorphine, including any wastage. On every dispensing day, before dispensing, the nurse/other designated staff should collect the average daily required supply of medicines from the storage cabinet and transfer these to the dispensing room. Any leftover supply must be returned to the storage cabinet at the end of the day.

Consumed and in-stock medicines should be reviewed periodically. In addition, records should be regularly checked to ensure accuracy of entries.

13.7 Patient-related documentation

An individualized file should be kept on each patient in which information and records are maintained as follows:

Clinical assessment form: Baseline information on the client's sociodemographic profile, history of drug use and drug-related complications, risky behaviour practices, history of physical and psychological problems, and current psychosocial status. This should also include a record of the physical examination performed by the doctor and the subsequent diagnosis. **Refer to Appendix 15.**

Counselling: Before beginning MAT, a patient should be counselled about the treatment. During this session, they should be informed about the medicines and benefits of MAT, and their motivation for treatment should be assessed. Documentation of this session is to be kept in their personal file. **Refer to Appendix 16.**

Consent form: Once deemed suitable for MAT, a patient is provided clear information regarding the treatment. When it is clear that the patient fully understands the MAT process, they should sign a consent form, to be kept in their file. **Refer to Appendix 17.**

Referral services: Many opioid-dependent patients are commonly in need of other health or mental health services. To facilitate access, MAT centres should either provide such services in-house or assist patients in accessing services offsite. **Refer to Appendix 18.**

A **Patient Prescription Book, Dispensing Record Book and Identification Card** are documents that should be provided to and maintained on each patient. **Refer to Appendix 19, 20 and 21.**

Staff working at MAT clinics should attempt to adhere to the following requirements:

- All attempts should be made to keep all patients' methadone or buprenorphine dispensing records confidential.
- Each patient's records should include the dates for which the prescription is valid.
- All prescriptions should be written in milligrams (mg) to avoid confusion in dosing when methadone is mixed at variable concentrations.
- Record each dose dispensed and signed by the dispenser and the patient.
- Record any notes on adverse events or situations with patients.
- Encourage patients to bring their personal identification card upon each visit to the MAT centre.

13.8 MAT-related documentation and record maintenance

MAT-related documentation and record maintenance is an integral part of the MAT programme. Basic record maintenance is necessary to document the services offered to

patients and track their progress. Records are also necessary for programme supervisors to review how the programme is being implemented and are important for research activities.

Each dispenser should have access to all relevant details of each patient, including communications with their prescriber, variations in dosage and the authorization of take-away doses. It is recommended that such details be recorded in a permanent, readily retrievable and consistent manner, and that they should not be easily accessible to patients.

13.9 Administration of doses

- To avoid stigma and ensure confidentiality, dispensing areas should be discrete.
- Supervised doses should always be directly observed to prevent diversion.
- Engage patient in conversation to ensure that they have consumed the dose.
- There should be no remaining methadone or buprenorphine visible in the patient's mouth.
- Observe the patient for signs of toxicity from methadone or buprenorphine or other drugs.
- Dosing must be delayed if patient appears intoxicated.

Diversion of supervised doses can be minimized when the following procedures are followed:

For both methadone and buprenorphine:

- Dose one patient at a time.
- Do not allow other people in the dosing area while a patient is being dosed.
- Do not allow a patient's bags, drinks or other containers in the dosing area.
- Ensure each patient throws away (into a designated bin) or returns any items used during dosing.
- Observe the patient throughout the dosing process, especially when the dose is placed in their mouth and immediately after.
- Once the dose is placed in their mouth, ensure that the patient's hands are kept away from their mouth.

14 MONITORING AND EVALUATION

14.1 Important information for data collection

Monitoring and evaluating of MAT services and programmes are essential at all MAT clinics. The following items are considered important components of a minimum dataset, to be collected and assessed by service providers on an ongoing basis:

The number of patients registered in treatment should be monitored and broken down by:

- Site of treatment.
- Age.
- Sex (male, female, transgender).
- Proportion of patients entering treatment for the first time, re-admissions, ongoing treatment.
- Retention in treatment.
- Average duration of treatment.
- Average dose of methadone or buprenorphine.
- Death rates (patients in active treatment at the time of death); number of deaths from all five main causes/categories (HIV/AIDS, liver disease, overdose, TB, accident and other).
- Dropout and duration – record the category of dropout as one of the following: imprisoned, loss to follow-up, social problems, psychosis, hypersensitivity.

14.2 Documenting cumulative numbers

Cumulative data of patients on MAT must be recorded on a monthly basis. Each MAT site records the number of registered patients from the first day of operations. 'Cumulative' is defined as the total number of patients from the previous months plus new patients. For example, a MAT clinic first opened in January 2021, and by September 2021 the total number of patients enrolled at the clinic is 140. In October 2021, an additional 10 new patients are registered. The cumulative number of registered patients for October 2021 is 150.

14.3 Patient satisfaction

Patient involvement in the planning, delivery and evaluation of MAT can bring benefits for methadone or buprenorphine consumers, service providers and communities at large. A simple survey administered by treatment staff over five days every six to 12 months will provide useful insights. Patients complete the anonymous questionnaire and place completed forms into a box for review by staff. The information will help service providers identify any areas that need improving. Satisfied patients are more likely to adhere to and be retained in MAT and can encourage other individuals in need of treatment to seek it out. **Refer to Appendix 22.**

APPENDICES

Appendix 1
Roles and responsibilities of staff

Roles and responsibilities of the DOCTOR

- Must have thorough clinical knowledge of MAT management.
- Conducts a basic assessment and medical examination of patients to determine eligibility for MAT.
- Determines patient suitability for MAT on the basis of inclusion and exclusion criteria.
- Prescribes appropriate doses of methadone and additional medications, as required by patients, and supervises the dispensing of methadone or buprenorphine doses, if required.
- Discusses the risks and benefits of methadone or buprenorphine therapy with patients prior to commencing treatment.
- Responsible for induction to MAT and take-away doses of MAT.
- Conducts basic health-education sessions for patients and their family members.
- Provides a clearly documented initial management plan.
- Follows up with patients and their families and assesses and regularly reviews the progress of patients on MAT.
- Asks patients about last use of illicit opioids, any cravings or withdrawals while on methadone or buprenorphine, any side effects of methadone or buprenorphine, any medical or psychiatric problems, and general well-being.
- Encourages and orders laboratory tests as required, including screening for HIV and hepatitis B and C.
- Provides referrals for HIV testing and counselling and to other centres (such as TB services or ART clinics) as and when required.
- Provides referrals to a psychiatrist if a client presents with signs and symptoms of psychiatric illness or if the physician suspects a comorbid psychiatric illness.
- Provides routine health check-ups as well as general health care, including appropriate management of abscesses, overdoses and STIs, as per the services available at the MAT clinic.
- Conducts regular educational classes for other team members on health-related topics, including those related to MAT – benefits of MAT, duration of treatment, importance of long-term adherence, etc.
- Maintains appropriate records, as required in the MAT clinic.
- Conducts case discussions and record review of MAT patients with other clinic staff. Consults with other staff on patient health issues.
- Assists in advocacy and other meetings related to MAT and other health issues of PWUD, as and when required.

Roles and responsibilities of the CONSULTANT PSYCHIATRIST

- Conducts psychiatric assessments of patients referred by the physician.
- Treats comorbid psychiatric illness in patients receiving MAT.
- Provides referrals to various support services, as and when required.
- Supervises the clinical MAT programme, as and when required.
- Attends staff treatment meetings when appropriate and requested.

Roles and responsibilities of the PHARMACIST

- Must receive training in pharmacotherapy to understand the benefits and processes involved in providing a MAT service.
- Ensures rational dispensing and use of controlled medicines and takes all appropriate steps to prevent diversion of controlled medicines and substances in their custody.
- Stocks narcotics and checks prescription orders, ensuring all information is complete.
- Administers MAT to patients when a nurse is not on staff or not available:
  - Patients collect and swallow their dose of methadone or dissolve the buprenorphine dose sublingually in clear view of and to the satisfaction of the pharmacist.
  - Ensures dosing of methadone/buprenorphine be provided in private and discrete manner.
  - Before dispensing, identifies patients by referring their records and photos attached to identification sheets.
  - Speaks to patient before dosing. If the patient is intoxicated, they should not be dosed; instead, pharmacists should notify the prescriber of intoxicated presentations to prompt a clinical review of the patient. If unable to contact the prescriber, delay dosing and ask the patient to return later and for reassessment. If still intoxicated upon return, the dose should be refused for safety reasons.
  - Refers to patient's prescription and confirms the correct dose to be measured.
  - If a patient has missed more than five consecutive days of dosing, they should be referred to the prescriber for the reinduction into treatment.
  - With methadone, ensures the measuring device is accurately calibrated and hygienically maintained and that disposable cups of water are available. With buprenorphine, ensures patients have access to water (patients may drink water before their dose to moisten the mouth).
  - For buprenorphine, closely observes as patients place the dose sublingually to avoid diversion. Checks that patients have consumed the dose prior to leaving the pharmacy by asking them to speak or open their mouths.
- Keeps sufficient stocks of pharmacotherapy treatment in an approved safe, which must be locked when not in use.

- Prepares all take-away doses and labels them accordingly.
- Maintains written dosing procedures.
- Provides verbal and written information and advice to patients and the general public on pharmacotherapies, when appropriate or requested.
- When the pharmacy does not open (e.g., for public holidays) it is important that alternative measures be in place so that there is no interruption in patient treatment.
- Maintains confidentiality of information acquired about patients, families and others.

Roles and responsibilities of the NURSE

- Dispenses methadone or buprenorphine to patients as prescribed by the doctor and follows protocols (checks for signs of withdrawal or intoxication, obtains patients' signatures on the dispensing sheet, conducts a general enquiry of patients' psychosocial and health conditions, listens to patients' concerns, and, when possible, addresses any misunderstandings about treatment).
- Manages day-to-day clinic in the absence of the doctor.
- Immediately reports any signs of withdrawal or intoxication to the doctor.
- Ensure care for the patient is coordinated to avoid duplication and misunderstanding.
- Provides patients with support, when necessary.
- Supports other staff members in their roles, when necessary
- Actively engages with patients from first presentation to encourage continued attendance at the clinic and adherence to therapy.
- Provides general and focused supportive counselling and education to patients, including on basic methadone treatment, HIV/AIDS, HIV testing and counselling, STIs, viral hepatitis, TB, overdose and any other medical conditions. Assists with various types of referrals as required (can also include referrals for increasing or decreasing doses and take-home doses).
- Participates in regular clinical care discussion meetings, as required.
- Clearly documents all information gathered on a regular basis: methadone dispensing record book, daily utilization record book and computer records. Records patients that are absent from dosing and those that drop out (by not attending the service).
- Maintains the stock of medicines (ensures adequacy of stocks of methadone and other medicines, indenting for methadone stocks as and when required, and maintains appropriate records). Ensures that the safe for methadone is always secure.
- Maintains the stock of drinking water and disposable cups inside the clinic for patient use.
- Provides emergency health services in the absence of the treating doctor (for example overdose management).
- Maintains clinic cleanliness and enforces a no smoking policy in the clinic.

Roles and responsibilities of the COUNSELLOR OR SOCIAL WORKER

- Conducts psychosocial assessment of patients visiting the MAT centre.
- During initial sessions, assesses high-risk injecting and sexual behaviours. Assesses patients' employment, legal, marital and psychological problems.
- Supports treatment adherence and provides motivational counselling. Provides intensive support during the patient's initial days on MAT.
- Provides counselling on improvement in psychosocial status (including craving management, behaviour change, relapse prevention and rehabilitation).
- Provides counselling services to the sexual partners of patients on MAT; counsels family members on the treatment process so they understand and can help in the patient's recovery.
- Follows up on patient attendance or dropout (if a patient drops out, explore the reasons for this outcome and document them).
- Maps existing services, which may be required by patients, and builds a network with agencies that can be potential 'referral' agencies. This is more relevant for MAT centres that do not have services on site.
- Provides referral services for STIs, HIV testing and counselling, vocational and other relevant services. This is more relevant for MAT centres that do not have services on site. Motivates patients to seek referral services and provides accompanied referrals, if required.
- Maintains records as required.
- Liaises with the doctor and nurse and carries out periodic assessment of patients.
- Conducts home visits, as and when required.

Roles and responsibilities of the OUTREACH WORKER/PEER EDUCATOR (if part of the MAT site team)

- Serves as a communication link between the treatment team and patients.
- Provides education to patients, including treatment literacy.
- Strengthens drug using networks and participants.
- Develops good relationships with the physician, nurse and treating team.
- Develops relationships with family members.
- Addresses questions or issues from the community.
- Helps and empowers patients in their care and addresses stigma.
- Identifies challenges and issues of the programme, particularly around the community acceptance of the programme, and is involved in problem-solving these issues.
- Develops relationships with other PWUD in the community and, when appropriate, guides PWUD to treatment at local health services or the drug treatment centre.
- Provides health information to PWUD in the community.
- Provides information and facilitates access to harm reduction interventions.

To maintain a strong ethical framework, outreach workers/peer educators should:

- Provide accurate, unbiased information to PWUD.
- Provide information that is helpful to PWUD in maintaining their health.
- Provide PWUD with information in a respectful, confidential manner.
- Maintain confidentiality except within the treatment team.

Roles and responsibilities of the LABORATORY TECHNICIAN

- Provides advice to the MAT clinic on the standard procedure of collecting blood and urine samples (if the latter is required).
- Analyzes blood and urine samples (if the latter is required).

Appendix 2
Identification of opioid intoxication and opioid withdrawal

Opioid intoxication

A. Recent use of an opioid.

B. Clinically significant problematic behavioural or psychological changes (e.g., initial euphoria followed by apathy, dysphoria, psychomotor agitation or retardation, or impaired judgement) that developed during or shortly after opioid use.

C. Pupillary constriction (or pupillary dilation due to anoxia from severe overdose) and one (or more) of the following signs or symptoms developing during or shortly after opioid use:
   - Drowsiness or coma.
   - Slurred speech.
   - Impairment in attention or memory.

D. Signs and symptoms are not attributable to another medical condition and are not better explained by another mental disorder, including intoxication with another substance.

Opioid withdrawal

A. Presence of either of the following:
   - Cessation of (or reduction in) opioid use that has been heavy and prolonged (i.e., several weeks or longer).
   - Administration of an opioid antagonist after a period of opioid use.

B. Three (or more) of the following developing within minutes to several days of Criterion A:
   - Dysphoric mood.
   - Nausea and vomiting.
   - Muscle aches.
   - Lacrimation or rhinorrhea.
   - Pupillary dilation, piloerection, or sweating.
   - Diarrhea.
   - Yawning.
   - Fever.
   - Insomnia.

C. The signs or symptoms in Criterion B cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.

D. The signs and symptoms are not attributable to another medical condition and are not better explained by another mental disorder, including intoxication or withdrawal with another substance.

Source: American Psychiatric Publishing. *Diagnostic and Statistical Manual of Mental Disorders, 5th Edition*. Arlington, USA. 2013.

Appendix 3
Frequently Asked Questions on MAT

1. Q: What is opioid substitution therapy (OST)? Is it different from MAT?

A: In opioid substitution therapy, the illicit drug a drug user is taking is substituted with another prescribed medication that produces similar drug effects (e.g., replacing heroin with methadone or buprenorphine). Administering methadone or buprenorphine for treatment of opioid dependence combined with psychosocial support and intervention is commonly referred to as medication-assisted treatment (MAT).

2. Q: How is methadone or buprenorphine administered as MAT?

A: Methadone is commonly available as a liquid or powder, which is mixed with water and dispensed as an oral liquid to people who are opioid dependent. To prevent diversion of this substance, it is recommended that people drink methadone under direct observation of a health team member at MAT clinics. Buprenorphine is commonly available as a tablet or film and both are administered sublingually (under the tongue). Once administered, the health team member directly observes the patient for full absorption, which may take five minutes.

3. Q: When should the initial MAT dose of methadone or buprenorphine be taken?

A: Ideally the first dose of methadone should be administered six to 12 hours after the last illicit heroin/opioid intake. Patients in opioid withdrawal (with dilated pupils) can safely be given methadone. For buprenorphine, the person should experience precipitated withdrawal (onset of withdrawal symptoms) before induction with buprenorphine. Ideally a person should not have consumed opioids within six hours of the first dose of buprenorphine.

4. Q: What is the right maintenance dosage of methadone or buprenorphine?

A: The maintenance dose can vary from person to person. The correct dose is determined by the health-care provider (doctor) in consultation with the patient. The doctor will consider several factors before deciding on the correct dose. The first dose is low (commonly 5-25 mg), and it may take two to eight weeks to achieve an ideal maintenance dose for the patient. Maintenance doses of at least 60 mg per day are more effective than lower doses of methadone, though may be lower or higher depending on the individual. With buprenorphine, maintenance doses commonly range from 8-24 mg/day. Some patients require higher (e.g., up to 32 mg/day) or lower (4-8 mg/day) doses.

5. Q: What is the relationship between the methadone or buprenorphine dose and its effect?

A: Even a smaller dose of methadone (e.g., 10-20 mg) helps to relieve opioid withdrawal symptoms. A moderate dose (usually 40-60 mg) is required to control cravings for opioids. A higher dose (60+ mg) may be needed to suppress the effects of further use of opioids. At these levels, the brain is saturated and if one uses illicit opioids such as heroin, the effect is blocked, and the user does not experience the high. With buprenorphine, the effects will continue to be experienced for up to 12 hours at low doses (2 mg), and as long as 48 to 72 hours at higher doses (16 or 32 mg). The effect of higher dosing with buprenorphine reaches a ceiling, after which higher doses result in a longer duration of action. This does not happen with methadone.

6. Q: What happens if a person misses a dose of their MAT drug?

A: If a person misses taking methadone or buprenorphine for five days in a row, he or she must return to the clinic for a medical examination and to begin a new induction. If one to two days are missed, the current dose may be continued but review is required. If a person misses the dose for three to four days, the dose is commonly halved and normal dosing potentially could resume the following day, with close monitoring in subsequent days.

7. Q: What are the side effects of methadone and buprenorphine?

A: The medical effects of methadone and buprenorphine are similar to those of other opioids, including: constipation, dizziness, drowsiness, headaches, constriction of pupils, nausea, sweating and vomiting. Other side effects can include: insomnia or disturbed sleep and decreased libido or sexual performance. Opioid-dependent individuals do not exhibit many of these side effects.

8. Q: What are the withdrawal symptoms from methadone and buprenorphine?

A: The withdrawal effects from drugs such as heroin, morphine, methadone or buprenorphine are severe when they are abruptly withdrawn. The withdrawal symptoms that may appear after about 72 hours include: cold or flu-like symptoms, headaches, anxiety, sweating, aches and pains, sleeping difficulties, stomach cramps, dilation of pupils, nausea and loss of appetite.

9. Q: What are the benefits of MAT?

a. MAT is an appropriate substitution treatment for people with mild to moderate opioid dependence.
b. It is an attractive treatment for opioid users.

c. Methadone is a long-acting drug that can be taken only once a day while buprenorphine may be taken every other day (depending on the dose).
d. Reduces illicit drug use.
e. Maintains most patients in treatment for longer durations.
f. Improves the patients' physical well-being.
g. Improves psychological, social functioning and quality of life.
h. Reduces new infections of HIV and hepatitis B and C.
i. Significantly reduces criminality.

Appendix 4
Clinical Opiate Withdrawal Scale (COWS)

COWS flowsheet for measuring symptoms over a period of time during MAT induction

For each item, write in the number that best describes the patient's signs or symptoms. Rate those only as they pertain to an apparent relationship to opiate withdrawal (for example, if heart rate is increased because the patient was jogging prior to assessment, the increased pulse rate would not add to the score).

Patient's Name: _____ Date : _____

MAT induction:

Enter scores at time zero, 30min after first dose, 2 hours after first dose, etc.

Times_____/_____/_____/_____

1. **Resting pulse rate:** (Record beats per minute) *Measured after patient is sitting or lying for one minute.* 0 pulse rate 80 or below 1 pulse rate 81-100 2 pulse rate 101-120 4 pulse rate greater than 120				
2. **Sweating:** *Over past ½ hour not accounted for by room temperature or patient activity.* 0 no report of chills or flushing 1 subjective report of chills or flushing 2 flushed or observable moistness on face 3 beads of sweat on brow or face 4 sweat streaming off face				
3. **Restlessness:** *Observation during assessment.* 0 able to sit still 1 reports difficulty sitting still, but is able to do so 3 frequent shifting or extraneous movements of legs/arms 5 Unable to sit still for more than a few seconds				
4. **Pupil size:** 0 pupils pinned or normal size for room light 1 pupils possibly larger than normal for room light 2 pupils moderately dilated 5 pupils so dilated that only the rim of the iris is visible				
5. **Bone or joint aches:** *If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored.* 0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/ muscles 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort				

(contd) COWS flowsheet for measuring symptoms over a period of time during MAT induction.

6. Runny nose or tearing: *Not accounted for by cold symptoms or allergies.* 0 not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks				
7. GI upset: *Over last ½ hour.* 0 no GI symptoms 1 stomach cramps 2 nausea or loose stool 3 vomiting or diarrhea 5 Multiple episodes of diarrhea or vomiting				
8. Tremor: *Observation of outstretched hands.* 0 No tremor 1 tremor can be felt, but not observed 2 slight tremor observable 4 gross tremor or muscle twitching				
9. Yawning: *Observation during assessment.* 0 no yawning 1 yawning once or twice during assessment 2 yawning three or more times during assessment 4 yawning several times/minute				
10. Anxiety or irritability: 0 none 1 patient reports increasing irritability or anxiousness 2 patient obviously irritable anxious 4 patient so irritable or anxious that participation in the assessment is difficult				
11. Gooseflesh skin: 0 skin is smooth 3 piloerection of skin can be felt or hairs standing up on arms 5 prominent piloerection				
Total scores **Observer's initials**				

Score:

5-12 = Mild;

13-24 = Moderate;

25-36 = Moderately severe;

more than 36 = Severe withdrawal

Source: Wesson, D. R., & Ling, W. *The Clinical Opiate Withdrawal Scale (COWS).* J Psychoactive Drugs, 35(2), 253-9.2003.

Appendix 5
Overdose and providing respiratory support

While an opioid overdose is most common in the first two weeks of methadone treatment, it can also take place among those involved in poly substance use with other sedatives (such as benzodiazepines or alcohol). With buprenorphine, doses many times greater than normal therapeutic doses appear to be well-tolerated in most individuals. However, respiratory depression can occur if an individual is also using benzodiazepines, alcohol or is not opioid tolerant. With buprenorphine-naloxone, if treatment of overdose is needed, it is more difficult becausenaloxone, an opioid antagonist that reverses opioid overdose, does not readily reverse the effects of buprenorphine. If respiratory depression occurs as a result of overdose, management in a hospital using ventilation is recommended, as well as an examination of the underlining causes.

SIGNS	SYMPTOMS	TREATMENT
• Pinpoint pupils • Hypotension • Bradycardia • Hypoventilation • Unsteady gait • Slurred speech • Sedation/coma Symptoms may last for 24 hours or more. Death may result from respiratory depression.	• Cannot be woken up by noise or pain. • Blue lips and fingernails due to lack of oxygen. • Slow breathing (less than 1 breath every 5 seconds). • Gasping, gurgling or snoring. • Choking sounds. • Passing out. • Vomiting. • Pale face. • Tired body.	• Try to wake the person by shouting their name, shaking their body or pressing the breastbone with your knuckles. • Check whether the person is breathing by placing your ear near their mouth to listen to the person's breath and watching their chest to see if it is rising and falling. • If the client is not breathing and does not respond to noise, movement or pain, immediately call for medical help. • Put the person in recovery position (on their side with a hand under their head) so that he/she does not choke in case of vomiting. • Make sure there is nothing in the throat and that the airway is clear of blockage. If necessary, remove any contents inside the mouth with your finger. • Commence cardiopulmonary resuscitation if no response: perform mouth-to-mouth resuscitation and chest compressions – 30 compressions after every 2 breaths until breathing resumes. • Prepare and administer 0.4-0.8 mg dose of naloxone IM or IV. • Repeat dose 0.4-0.8 mg IV/IM every 1-2minutes, up to maximum dose of 10 mg in a day, until there is sufficient arousal and adequate ventilation. • Possible overdose could return after 60-90 minutes when the effects of naloxone wear off. • Monitor the client for at least 4-6 hours afterwards; inpatient support is sometimes needed.

NOTE: Initial doses of naloxone above 2 mg can induce severe withdrawal, with the risk of vomiting and aspiration; very high doses above 10 mg may even be life threatening.

Appendix 6
Facts about Naloxone

1. Naloxone is a safe, effective antidote to opioid overdose. It has no effect on persons dependent on non-opioid drugs (such as methamphetamines or alcohol).

2. Naloxone has no potential for abuse and has been included in the WHO Model List of Essential Medicines as a first aid or emergency drug.

3. It can be given by intramuscular injection or subcutaneously in case intravenous injections are not feasible. It is best to inject in the upper arm or thigh.

4. A normal dose is 1-2 ml (0.4-2 mg); it is safe to repeat the first dose if there is no initial response.

5. Naloxone may cause withdrawal feelings, especially at higher doses or if given intravenously.

6. It takes one to five minutes to act, and lasts for 60-90 minutes; it is possible for overdose symptoms to return after this time because naloxone wears off faster than heroin and other opiates.

7. It is important to continue supporting the person for four to six hours following overdose.

8. Naloxone will not cause any harm if injected in a person who is not having an overdose.

9. Naloxone should be stored at room temperature and should be kept away from light.

10. Naloxone has a limited "shelf life." Trained responders need to be aware of the expiry date stamped on the box and to obtain replacement naloxone before that date.

Appendix 7
'Weaning off' of MAT

Are you ready to 'WEAN OFF' of MAT?

The more questions the patient can *honestly* answer by checking "yes," the greater the likelihood that the patient is ready to taper off MAT. Consider that each "no" response represents an area that the patient needs to work on to increase the odds of a successful taper and recovery. This list of questions could be asked by the treating doctor, nurse or a counsellor that is familiar with the patient.

1.	Have you been abstaining from illegal drugs like heroin, cannabis and 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.	Are you living in a non-drug user neighbourhood?	YES/NO
6.	Are you comfortable living in such a neighbourhood?	YES/NO
7.	Are you living in a stable family relationship?	YES/NO
8.	Do you have non-user friends that you spend time with?	YES/NO
9.	Do you have friends or family who would be helpful while weaning off?	YES/NO
10.	Have you been participating in counselling that has been helpful?	YES/NO
11.	Have you been attending psychosocial work ups and benefitted from them?	YES/NO
12.	Do other members of the treatment team think you are ready to wean off?	YES/NO
13.	Do you think you would ask for help when you are feeling bad during wean off?	YES/NO
14.	Have you stabilized on a relatively low dose of MAT?	YES/NO
15.	Have you been on MAT for a long time (at least a year)?	YES/NO
16.	Are you in good mental and physical health?	YES/NO
17.	Do you want to get off MAT?	YES/NO

Source: M. Suresh Kumar, Ravindra Rao, M.N. Chengappa. *Methadone Maintenance Therapy, SOP*. United Nations Office on Drugs and Crime, Regional Office for South Asia. 2012.

Appendix 8

Patient Register: New Patients (Methadone or Buprenorphine)

Client Register: New Patients (Methadone or Buprenorphine)										
Name of the MAT centre including address and code:										
Date	Patient registration #	Name	Sex	Age	Marital status*	Occupation	Level of education	Address and phone number	Source of referral	MAT type (meth or bup)

***Marital status** – Write Single (S), Married (M), Divorced (D), Widow (W)

Date of initiation: ……

Maintained by (name and designation)

1. …… (e.g., physician)
2. ……..(e.g., nurse)
3. ……..(dispensing pharmacy)
4. ……..(case manager)

INSTRUCTIONS FOR USE

- This register should be maintained at the MAT centre/hospital/pharmacy and should be kept in a locked cupboard when not in use.
- The register should be maintained regularly and should be accessible only to authorized staff maintaining it and to the nodal officer/medical officer at the MAT centre.
- Authorized staff is required to sign in the relevant space provided after making entries in the register. Please refer to the MAT Record Maintenance Guide for information on maintaining the register.
- The register should be provided upon request during mentoring/evaluation visits by experts.
- Please write legibly and avoid corrections in the register. Any corrections or changes in entry should be signed by the concerned person and countersigned by the medical officer/supervising officer.
- If an item is not applicable, please put a "N/A" in the box.
- Dates should be written in the dd/mm/yy format. For example, 4 July, 2021 should be written as 04/07/21.

Appendix 9

Patient Register: Regular MAT Patients (Methadone or Buprenorphine)

Patient Register: MAT Patients (Methadone or Buprenorphine)										
Name of the MAT centre including address and code:										
Date	MAT file #	Patient registration #	Date of registration	MAT type (meth or bup)	Name and contact number	Age	Sex	Marital status*	Occupation	Level of education

***Marital Status** – write Single (S), Married (M), Divorced (D), Widow (W)

Date of initiation: _____

Maintained by (name and designation)

5. _____ (e.g.,physician)

6. _____ (e.g., nurse)

7. _____ (dispensing pharmacy)

8. _____ (case manager)

INSTRUCTIONS FOR USE

- This register should be maintained at the MAT centre/hospital/ pharmacy and should be kept in a locked cupboard when not in use.
- The register should be maintained regularly and should be accessible only to authorized staff maintaining it and to the nodal officer/medical officer at the MAT centre.
- Authorized staff is required to sign in the relevant space provided after making entries in the register. Please refer to the MAT Record Maintenance Guide for information on maintaining the register.
- The register should be provided upon request during mentoring/ evaluation visits by experts.
- Please write legibly and avoid corrections in the register. Any corrections or changes in entry should be signed by the concerned person and countersigned by the medical officer/supervising officer.
- If an item is not applicable, please put a "N/A" in the box.
- Dates should be written in the dd/mm/yy format. For example, 4 July, 2021 should be written as 04/07/21.

Appendix 10

Controlled Medicine Record Keeping Book

FEDERAL MINISTRY OF HEALTH

Controlled Medicine Record Keeping Book

(Schedule I and Related Narcotics Record Book)

Name of MAT facility:

Location address:

Name of medicine/strength/dosage form:

Unit of Issue:

Date	SRV / SIV /Inv #	Received from / issued to	Quantity received	Quantity issued	Balance	Batch #	Expiry date	Pharmacist name/registration #/signature	Remarks

Appendix 11
MAT STOCK REGISTER

MAT STOCK REGISTER
(Bin Card for Controlled Substances/Medicines)

Name of facility:

Name of medicine/strength/dosage form:

Unit of issue: Ledger Folio number:

Maximum stock: Minimum stock: Re-order level:

Date	SRV/SIV (INV.) #	Received from/ issued to	Batch #	Expiry date	Quantity received	Quantity issued	Losses	Adjustment		Stock balance	Name/signature	Remarks
								+ve	-ve			

Appendix 12
Daily Stock Register – Buprenorphine

Name of the MAT centre including address and code:					
Date	Stock	Number of buprenorphine tablets			Signature of nurse/ pharmacist
		XXMG	XXMG	XXMG	
	Opening stock				
	Stock dispensed				
	Remaining stock				
	Opening stock				
	Stock dispensed				
	Remaining stock				
	Opening stock				
	Stock dispensed				
	Remaining stock				

Date of initiation:……

Maintained by (name and designation)

9. …… (e.g.,physician)

10. ……(e.g., nurse)

11. ……(dispensing pharmacy)

12. ……(case manager)

INSTRUCTIONS FOR USE

- This register should be maintained at the MAT centre/ hospital/pharmacy and should be kept in a locked cupboard when not in use.
- The register should be maintained regularly and should be accessible only to authorized staff maintaining it and to the nodal officer/medical officer at the MAT centre.
- Authorized staff is required to sign in the relevant space provided after making entries in the register. Please refer to the MAT Record Maintenance Guide for information on maintaining the register.
- The register should be provided upon request during mentoring/evaluation visits by experts.
- Please write legibly and avoid corrections in the register. Any corrections or changes in entry should be signed by the concerned person and countersigned by the medical officer/ supervising officer.
- If an item is not applicable, please put a "N/A" in the box.
- Dates should be written in the dd/mm/yy format. For example, 4 July, 2021 should be written as 04/07/21.

Appendix 13
Daily Stock Register – Methadone

Name of the MAT centre including address and code:					
Date of entry	Total # of bottles (1 litre) of methadone existing	Total # of bottles (1 litre) received	Total # of bottles (1 litre) remaining	Received by (name, signature and designation)	Any remarks

Date of initiation: ……..

Maintained by (name and designation)

13. …….. (e.g., physician)

14. ……..(e.g., nurse)

15. ……..(dispensing pharmacy)

16. ……..(case manager)

INSTRUCTIONS FOR USE

- This register should be maintained at the MAT centre/hospital/pharmacy and should be kept in a locked cupboard when not in use.
- The register should be maintained regularly and should be accessible only to authorized staff maintaining it and to the nodal officer/medical officer at the MAT centre.
- Authorized staff is required to sign in the relevant space provided after making entries in the register. Please refer to the MAT Record Maintenance Guide for information on maintaining the register.
- The register should be provided upon request during mentoring/evaluation visits by experts.
- Please write legibly and avoid corrections in the register. Any corrections or changes in entry should be signed by the concerned person and countersigned by the medical officer/supervising officer.
- If an item is not applicable, please put a "N/A" in the box.
- Dates should be written in the dd/mm/yy format. For example, 4 July, 2021 should be written as 04/07/21.

Appendix 14

Patient dose sheet for methadone and buprenorphine

Patient name: _____

MAT #: _____

Enter dose of methadone in ml/day: _____

Enter dose of buprenorphine in mg/day: _____

DATE	JAN	FEB	MARCH	APRIL	MAY	JUNE	JULY	AUG	SEPT	OCT	NOV	DEC
1												
2												
3												
4												
5												
6												
7												
8												
9												
10												
11												
12												
13												
14												
15												
16												
17												

(contd) Appendix 14

Patient dose sheet for methadone and buprenorphine

Patient name: _____

MAT #: _____

Enter dose of methadone in ml/day: _____

Enter dose of buprenorphine in mg/day: _____

DATE	JAN	FEB	MARCH	APRIL	MAY	JUNE	JULY	AUG	SEPT	OCT	NOV	DEC
18												
19												
20												
21												
22												
23												
24												
25												
26												
27												
28												
29												
30												
31												

Appendix 15
Clinical assessment form

No. _____

DRUG DEPENDENCY TREATMENT HOSPITAL/MEDICAL CLINIC/MAT CENTRE

In-depth interview form

Patient name		Age		Hospital/medical clinic/MAT centre name	
		Sex			
Identification #		Permanent address of patient		Home address	
Father's name				Village	
Occupation				Township	
Education				District	
Ethnic group		Family/ guardian address		Name	
Religion				Relationship	
Marriage		Single		House number	
Widow		Separated		Street	
Divorced				Ward	
		Telephone number			
Registration date		Referred by			
Police station (if relevant)					
Admission date and hour				Discharged date and hour	
Diagnosis					
Associated condition					

Discharge status	Recovered		Improved		Not improved		Died	
Types of discharge	With approval		Signed and went		Absconded		Transferred	
	Dead		Other (Specify)					
Follow up	Doctor……		Date ……		Place ……			
Body weight on admission:				Body weight on discharge:				
Signature of doctor in-charge:								

DRUG DEPENDENCY TREATMENT

1. SOURCE OF REFERRAL

- Self referred
- General hospital
- Social agency
- Private physician
- Parents/guardian
- Friend
- School/college
- Police
- Employer
- Drug treatment centre (Specify……..……..centre)

2. REASON FOR REFERRAL

- Detoxification
- Residential
- Day care
- Outpatient
- Inpatient
- Counselling
- MAT

3. DRUG TYPE(S) USED

- Heroin
- Opium
- Pethidine
- Morphine
- Tramadol
- Codeine (promethazine)
- Methadone
- Cannabis
- Methaqualone
- ATS
- Barbiturates
- Benzodiazepines (e.g.diazepam)
- Other (specify)

4. MOTIVE FOR DRUG TAKING

- Experimentation
- To satisfy curiosity
- To achieve a sense of belonging
- Peer pressure
- To express independence/hostility
- To have pleasurable or thrilling experience
- Self– treatment
- To escape from something
- Delinquent or deviant behavior

5. WHICH TYPE OF DRUG/S HAS PATIENT STARTED MISUSING

(SPECIFY_____)

6. AGE OF FIRST DRUG USE _____

7. DURATION OF DRUG USE _____

8. TYPES OF DRUG(S) USING AT PRESENT _____

9. PRIMARY DRUG PROBLEM AT PRESENT _____

10. AGE OF FIRST USE _____

11. DURATION OF USE _____

12. DURATION OF PHYSICAL HARM _____

13. FREQUENCY OF USE

- No use during last month
- Once per month
- Once per week
- Two– three times per week
- More than three-times/week
- Once daily
- Two–three times daily
- More than three times daily

14. MOST RECENT USUAL ROUTES OF ADMINISTRATION

- Oral
- Smoking
- Inhalation
- I.M.
- I.V.
- Other (specify .....)

15. DOSAGE AND AMOUNT USED (IF AWARE)

- In one day (_____) mg.
- In one dose (_____) mg.

16. LAST DOSE

Date: (_____) Time: (_____)

17. HAVE YOU EVER LOST CONSCIOUSNESS WHILE USING DRUGS?

– No _____ – Yes _____ How many times? _____

18. DOSE ANY MEMBER OF YOUR FAMILY HAVE A DRUG PROBLEM?

– No _____ – Yes _____

– Indicate

Name(s)	xx	Relationship
1.	xx	1
2.	xx	2.
3.	xx	3

19. HOW MANY OF YOUR PRESENT FRIENDS ARE PEOPLE WHO USE DRUGS?

– All – Most – Few – None

20. WHEN USING DRUGS/ALCOHOL, ARE YOU GENERALLY:

– Alone – With one or two others – In a group

21. HOW MANY TIMES HAVE YOU STOPPED USING DRUGS "ON YOUR OWN"?

– Never – Once – Twice – Three or four times – More than four-times

22. EXPENDITURE ON DRUGS

– Per day _____ – Per week _____

23. PATIENT'S OCCUPATION _____

24. PATIENT'S INCOME _____ Per month

25. SOCIAL CLASS

– Higher
– Lowest
– Impossible to estimate
– Above Average
– Average
– Below Average

26. FAMILY HISTORY

– Father – Alive/dead – Age _____ – Occupation _____
– Mother – Alive/dead – Age _____ – Occupation _____
– Siblings – Brother(s) _____
– Sister(s) _____

– History of drug abuse in the family _____

– History of psychiatric illness in the family _____

27. LIVING ARRANGEMENT

– Living alone
– Living with parents
– Living with spouse
– Living with others

28. POLICE ARREST

– Never
– Once
– Twice
– Three or more

29. REASON FOR ARREST(s)

– Drug-related offenses _____ – When? _____

– Crime for gain _____ – Violence

30. NUMBER OF CONVICTIONS

– Once
– Twice
– Threetimes
– Four times or more

31. IF CONVICTED AND JAILED

– Duration of last sentence _____
– Date of release from jail _____

32. WHY HAVE YOU ENROLLED IN TREATMENT AT THIS TIME?

(CHECK ALL THAT APPLY)

– Want to get off drugs
– Want to avoid arrest
– Forced by the courts
– Cannot support habit
– Disgusted with lifestyle
– Want to improve physical health
– Pressured by family/friends
– Shortage of drug on the street
– Other (specify) – _____
_____

33. ADMITTED AS

– Inpatient
– Outpatient
– Daycare
– Residential (social welfare)

34. TREATMENT

– Methadone or buprenorphine maintenance
– Withdrawal
– Detoxification
– Others (specify) _____

PHYSICAL EXAMINATION

Patient name _____ **MAT SITE:** _____

1. GENERAL APPERANCE

– Normal: – Abnormal: – Drowsy: – Confused:
– Neglected self– care:

2. SKIN (check findings)

– Tattoo
– Track Marks _____New x Old
– Thrombosed veins
– Oedema
– Subcutaneous abscesses _____ Acute x Healed

3. EYES (check findings)

– Sclera _____ Normal x Icteric
– Pupil sizes
– Normal
– Myotic
– Mydriatic
– Reactive
– Nonreactive
– Nystapmus
– Absent
– Present

4. CARDIOVASCULAR SYSTEM

– Blood pressure _____Normal x Abnormal = _____ mm Hg.
– Heart _____N.A.D. x Abnormal (specify)
_____

5. RESPIRATORY SYSTEM

– Lungs _____N.A.D x Abnormal (specify)
_____

6. ABDOMEN

– Liver _____ Palpable Tender
Not palpable Not tender
Enlarged
– Spleen _____ Palpable
Not palpable
– Kidneys _____ Palpable
Not palpable

7. C.N.S.

– Gait	_____	Normal	x	Abnormal
– Babinski sign	_____	(+)		x (_____)
– Coordination	_____	Normal	x	Abnormal
– Romberg sign	_____	(+)	x	(_____)
– Deep tendon reflexes (D.T.R)	_____	Normal	x	Abnormal

8. MENTAL STATE

– Alert
– Somnolent
– Noticeably high

9. SPEECH

– Clear
– Slurred

10. WITHDRAWAL STATUS : Check if present

: Nil

– NARCOTICS: : Yawning
: Perspiration
: Lacrimation
: Rhinorrheas
: Piloerection
: Mydriasis
: Diarrhea
: Fever
: Nausea/vomiting
: Aches and pain

–SEDATIVE : Anxiety
: Tremulousness
: Insomnia
: Orthostatic hypotension
: Delirium
: Convulsions
: Fever

: Lethargy
: Tension
: Anxious
: Inattentive
: Aggressiveness
: Depressed

ADDITIONAL NOTES

_____

_____

_____

_____

_____

_____

Appendix 16
Suggested counselling forms prior to MAT

COUNSELLING 1

Code No: _____ Date: _____

- ☐ Health education on effects of substance misuse
- ☐ Health education on methadone or buprenorphine
- ☐ Methadone or buprenorphine taking model
- ☐ Discussion on benefits of therapy

Next appointment: _____ for C2

Counsellor's name and signature _____

COUNSELLING 2

Code No: _____ Date: _____

Assessment

- Information on substance misuse
- Methadone or buprenorphine therapy and its benefits

Knowledge: good ☐ C1 again ☐

_____

Information given

- Nature of methadone/buprenorphine
- Side effects
- Benefits of methadone/buprenorphine therapy
- Harmful polydrug use

Discussion

- Questions on methadone or buprenorphine knowledge
- Current drug use
- Future plan
- Necessary documents

Motivation good ☐ fair ☐ poor ☐ (if poor → C2 again)

_____

READY FOR REFERRAL TO HEALTH SERVICE FOR COMPREHENSIVE ASSESSMENT AND POTENTIAL COMMENCEMENT OF MAT

- Availability of necessary documents
- Good understanding of methadone or buprenorphine therapy
- Enthusiasm
- Being able to attend health service regularly

REFERRAL DATE: _____

FOLLOW-UP DATE: _____

Name and signature of counsellor: _____

Appendix 17
Consent form

Patient name: _____ **Prescriber name:** _____

As a participant in medication-assisted treatment (MAT) for opioid dependence, I understand that the success of my treatment can only be achieved if I comply with the requirements. I freely and voluntarily agree to undergo MAT at _____ centre as follows:

1. I agree to keep and be on time for all my scheduled appointments with the doctor and the health-care team at the clinic/treatment centre.
2. I understand that the staff at the clinic/treatment centre will need to confirm my identity every time I receive my medication.
3. I agree to conduct myself in a courteous manner at the clinic/treatment centre.
4. I agree not to arrive at the clinic/treatment centre 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.
5. I agree not to sell, share or give any of my medication to another person. I understand that such mishandling of my medication is a serious violation of this agreement and will result in my treatment being terminated without recourse for appeal.
6. I agree not to deal, steal or conduct any other illegal or disruptive activities in the clinic/treatment centre.
7. I agree to collect my medication personally at my regular clinic/treatment centre through daily visits and to consume the whole dose under direct observation of dispensing staff.
8. I understand that if I miss an appointment and fail to collect my medication on any day, I will not be given an extra dose the following day.
9. I understand that if I miss two or more consecutive doses of my medication, the prescription will be cancelled and can only be renewed after another full medical check-up.
10. I agree that it is my responsibility to swallow the full dose of the medication I receive from the clinic/treatment centre staff. I agree that there is no guarantee that any medication that spills while being taken will be replaced, regardless of the reasons for the loss.
11. I understand the dangers of taking more than my prescribed dose of methadone. I agree not to obtain similar medications from any other physicians, pharmacies or other sources without informing my primary treatment providers.
12. I understand that mixing my medication with other substances, especially alcohol, benzodiazepines, such as valium, or other drugs of abuse can be dangerous. I also understand that death can occur among persons mixing methadone with benzodiazepines.
13. 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.
14. I understand that MAT alone is not sufficient treatment for my medical condition, and I agree to participate in the patient education and relapse prevention programme, as provided, to assist me in my treatment.

_____ _____

Patient (or guardian) signature Prescriber signature and date

Appendix 18

Other services and referrals

OTHER SERVICES																
Name of the MAT centre including address and code:																
Date	Name	MAT FILE #	Services received (record actual utilization of services by clients e.g., commodities distributed, testing done, etc.) TICK BOXES AS REQUIRED													
			ICTC*	ART**	STI Test***	TB DOT ****	General OPD (medicine, skin, surgery, etc.)	Drug detox	Community care centre	HCV test*****	Lab test	Legal service	Occupation services	Mental health service	Reproductive health	

*Integrated counselling and testing Centre
** Antiretroviral therapy
*** Sexually transmitted infection
**** Tuberculosis directly observed treatment
*****Hepatitis C virus

Date of initiation: _____

Maintained by (name and designation): _____

17. _____ (e.g.,physician)

18. _____ (e.g., nurse)

19. _____ (dispensing pharmacy)

20. _____ (case manager)

INSTRUCTIONS FOR USE

- This register should be maintained at the MAT centre/hospital/pharmacy and should be kept in a locked cupboard when not in use.
- The register should be maintained regularly and should be accessible only to authorized staff maintaining it and to the nodal officer/medical officer at the MAT centre.
- Authorized staff is required to sign in the relevant space provided after making entries in the register. Please refer to the MAT Record Maintenance Guide for information on maintaining the register.
- The register should be provided upon request during mentoring/evaluation visits by experts.
- Please write legibly and avoid corrections in the register. Any corrections or changes in entry should be signed by the concerned person and countersigned by the medical officer/supervising officer.
- If an item is not applicable, please put a "N/A" in the box.
- Dates should be written in the dd/mm/yy format. For example, 4 July, 2021 should be written as 04/07/21.

Appendix 19

Example of a methadone or buprenorphine dispensing record book to be kept for each patient

COVER

Methadone or Buprenorphine Dispensing Record Book

Name of the MAT centre including address and code _____

_____

Patient name _____

Registration number _____

Inside the book

Date	Time	Dose (mg)	Dose (ml) if methadone	Patient's signature	Dispenser's signature	Comments

The dispensing record book for each patient should be kept at the MAT centre.

Appendix 20
Example of patient prescription book

PATIENT PRESCRIPTION BOOK

MAT centre _____

Patient name _____

Methadone solution _____ 5 mg/ml _____

Buprenorphine: _____ XX mg

Dispense_____mg _____ in words)

From _____ start date

To _____ end date

At _____ dispensary

_____

Prescriber's signature

Appendix 21
Example of patient identification card (ID)

FRONT

PHOTO

Name: _____

Date of birth: _____

Card number: _____

Address: _____

BACK

Date of issue: _____

Name of MAT centre: _____

Name, address and code of MAT dispensing centre: _____

Remarks:

- Always bring this card when you visit the methadone dispensing centre.
- Do not give this card to another person.
- Inform the MAT centre when you lose your card so that a new card can be issued.

Appendix 22

Assessment for patient satisfaction with service

PATIENT SATISFACTION

A. Sex ☐ Male ☐ Female ☐ Transgender

B. Age (years) ☐ 24 and less ☐ 25–30 ☐ 31–44 ☐ 45–54 ☐ 55 and over

C. Time on (tick the box)

Methadone or buprenorphine ☐ Less than 6 months ☐ 6-12 months

☐ 13-24 months ☐ More than 2 years

HOW DO YOU FEEL ABOUT YOUR OVERALL EXPERIENCES OF THE MAT – METHADONE OR BUPRENORPHINE – SERVICE IN THE LAST SIX MONTHS

(Place an 'x' over the face that most closely matches your feelings)

Question	Terrible	Mostly unsatisfactory	Neither good nor bad	Mostly satisfactory	Excellent
1. How do the staff at the clinic treat you?					
2. How much have you been included in decisions on your treatment(including dosing and management of your needs)?					
3. How is the clinic's physical space for patients?					
4. How does the clinic respond to complaints from patients?					
5. How effective has the clinic been with helping with your problems?					
6. How do you feel about the amount of information the clinic gives you about your treatment?					
7. Would you recommend the clinic to a friend who needed treatment?					

8. What is the one thing you would most like to see changed at this clinic?

_____

_____

9. Is there anything else you would like to say about this clinic?

_____

_____

10. Thinking about ALL your experiences at this clinic (not just the past six months), please give this clinic an OVERALL rating by placing an 'X' on one of the boxes below (the number 1 = TERRIBLE and number 10 = EXCELLENT).

1 2 3 4 5 6 7 8 9 10

Any further comments

_____

_____

_____

_____

_____

_____

Source: Kehoe, P and Wodak, A. *Patient Satisfaction in a NSW Public Opioid Pharmacotherapy Clinic: Management and Responses.* Technical Report Number 194, National Drug and Alcohol Research Centre, University of New South Wales.Sydney, Australia. 2004.

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European Union

UNODC
United Nations Office on Drugs and Crime