



ACT Methadone Treatment Guidelines



Policy and Planning Division

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FOREWORD

The health, economic, social and personal harms caused by drug use in our communities are well recognised. In identifying these harms, the problems associated with opioids are disproportionately represented. Opioid use is associated with greater rates of morbidity, greater rates of mortality and greater rates of psychosocial disadvantage than any other illicit drug of dependence.

The ACT Government is committed to enhancing the health, well being and safety of the community. With this in mind, the Government is determined to reduce the harm caused by the misuse of alcohol and other drugs in the ACT community. This commitment requires the Government to address the harmful consequences of all drug use, including opioid use.

The *ACT Methadone Treatment Guidelines* outline current service delivery and broad directions for the future development of methadone treatment services in the ACT and provides a basis for coordinated action between different providers and consumers. The guidelines emphasise the partnership required between government agencies, non-government agencies and the community in providing services that can appropriately and adequately assist individuals experiencing difficulties because of their opioid use.

The ACT Pharmacotherapy Program is an integral part of the ACT Government's harm minimisation strategy to manage the community and individual harms associated with opioid dependency. This document provides another tool with which to further the reduction of drug related harm within the community.

The Government would like to thank all those community members who made contributions, suggestions or who otherwise assisted in the production of this document. Appreciation is especially due to the members of the Methadone Advisory Committee, for their valuable input into this framework and without whom this document would not have been possible.

Simon Corbell MLA

Minister for Health

March 2003

LIST OF ABBREVIATIONS

ACT	Australian Capital Territory
AIDS	acquired immune deficiency syndrome
BZD	benzodiazepine
CHO	Chief Health Officer
CNS	central nervous system
DoDA	<i>Drugs of Dependence Act (Australian Capital Territory) 1989</i>
DSM-IV-TR	Diagnostic and Statistical Manual of Mental Disorders (4 th ed.) Text Revision
HBV	hepatitis B virus
HCV	hepatitis C virus
HIV	human immuno-deficiency virus
ICD-10	International Classification of Diseases (10 th ed.)
IDU	injecting drug user
IGCD	Intergovernmental Committee on Drugs
JACS	Department of Justice and Community Safety
LAAM	levo- α -acetylmethadol
M&OTS	Methadone and Other Treatments Subcommittee
MCDS	Ministerial Council on Drug Strategy
MMT	methadone maintenance treatment
MTC	methadone treatment centre
NSP	needle and syringe program
NSW	New South Wales

METHADONE TREATMENT IN THE MANAGEMENT OF OPIOID DEPENDENCY

Methadone Hydrochloride

Methadone is a synthetic, long-acting opioid agonist that was developed by German pharmacists in the early 1940's as an analgesic. Its application as a treatment for heroin dependence was developed at Rockefeller University in the United States in the early 1960's. By 1969 it had been adopted for similar purposes in Australia. It is most commonly indicated for the treatment of opioid dependency and the management of chronic pain.

Methadone is most commonly available in two forms: a clear flavourless liquid or in a tablet form. Methadone liquid may be prepared into a linctus for oral administration or administered as an injection. It is rapidly absorbed with high degrees of bioavailability across many different routes. Onset is approximately 30 minutes to 4 hours after oral dosage with a steady-state elimination half-life of approximately 25 hours.

The most common administration route, especially in dependency treatment, is orally. However it may be administered with comparable efficacy across epidural, intramuscular, intrathecal, intravenous or subcutaneous routes. Therapeutic doses allow trough plasma levels of approximately 100 mg/mL. However due to differences in metabolism and tolerance, there is significant overlap between therapeutic and toxic doses from case to case.

There are numerous benefits of methadone over other opioids in the treatment of dependency:

- the extended half-life of methadone in comparison with other opioids permits an accumulation of the drug in the body with an associated maintenance of steady-state serum levels;
- these characteristics ensure a far less rapid onset of effect with an associated reduction in euphoria, and the far less rapid onset of withdrawal which permits much less frequent dosing; and
- the slight alterations in efficacy across routes permits the majority of consumers to suspend injecting behaviour in favour of oral dosing, with little alteration to their perception of the drug's impact.

*For further reading on **Methadone Hydrochloride** see:*

- Hurlbut 2000.
- Somogyi 2000.
- Graham 2000.

Terminology

In the ACT Methadone Program, it is usual for the doctor involved in managing a case to be referred to as “the prescriber”. The pharmacist member of a case management team is referred to as “the dispenser”. Other workers are often involved in case management teams, such as counsellors or parole officers.

Prescribers and dispensers usually refer to individuals in their care as “patients”. Non-medical members of management teams more frequently refer to the same individuals as “clients”. Recipients of care more often refer to themselves as a group as “consumers”.

These differences in terminology indicate differences in approach to the management of opioid dependence, either as psychosocial or medical issue, and should be respected. It is suitable for all members of a case management team to understand the reasons that other workers may use different terminology. While terminology is related to the organisation, it should be acknowledged that such terms have role implications.

For the purposes of uniformity, this text will adopt the term “consumer ” in any situation where “client”, “patient”, “consumer” or “customer” would refer to the individual recipient of care from the case management team.

In several sections these guidelines refer to the need for deviation from the guidelines by a prescriber to be conducted in review with a *suitably qualified, experienced and licensed peer from a different practice or organisation than [one’s] own*. For the purposes of this document the following minimum requirements must be met for a physician to be considered under this clause:

- the clinician providing the correlate opinion must be a currently active methadone prescriber and have at least three years experience prescribing methadone; and
- the clinician providing the correlate opinion must have a current methadone consumer base of at least 15 consumers.

Correlate opinions for the purposes of such clauses should be provided in the form of a signed letter indicating that the clinician has reviewed the patient and the case and is of the opinion that the consumer would benefit from the deviation to the guidelines.

In the instance that a clinician cannot find a colleague to act in this role, they may choose to correlate their clinical opinion through the Chief Health Officer. The Senior Medical Officer, Alcohol and Drug Program, may also be contacted in this regard.

Methadone Withdrawal Management

Methadone can be employed to assist opioid dependent persons in withdrawal management. This process entails the provision of a low end dosage tapered over a three to six week period. The regimen is designed to lessen the severity of opioid withdrawal symptoms.

While this process is generally effective in achieving an initial withdrawal, it is generally ineffective in preventing relapse to opioid use in the longer term. Maintenance therapies appear to be more effective in the long term treatment of opioid dependence.

Methadone Maintenance Treatment

Methadone can be suitably employed to assist opioid dependent persons in stabilising their dependency and to slow or prevent the emergence of a typical pattern of increasing illicit opioid use. This process entails the determination of a safe and stable dosage maintained over an extended treatment period of months or years. It must be recognised that for a sub-population of opioid dependent persons who begin maintenance programs, eventual detoxification from methadone may never become a realistic clinical goal notwithstanding their stability during maintenance.

The use of methadone in assisting opioid dependent persons to achieve a degree of stability in their use of opioids is known as methadone maintenance treatment [MMT].

Maintenance therapies appear to be more effective than withdrawal management in preparing opioid dependent persons for more comprehensive psychosocial rehabilitation. Methadone is one of a range of maintenance pharmacotherapies that are now available to help manage opioid dependence. Alternative maintenance therapies are described below from page 53.

PURPOSE OF METHADONE TREATMENT GUIDELINES

Needs Analysis

Methadone treatment is recognised in Australia and internationally as an effective method for treating opioid dependence and reducing the individual and social harms associated with dependent opioid use. Methadone treatment services are well established in the ACT and currently operate under a range of existing procedures and protocols.

A need existed for a document to assist the coordination of contributions from the several agencies and many individuals that liaise to provide methadone treatment services within the ACT. The *ACT Methadone Treatment Guidelines* establish a common set of standards for providing methadone treatment in the Territory.

Current methadone treatment services in the ACT have also operated without an overarching set of guidelines to shape and direct change and innovation within the program. The need for a steering document has become increasingly salient with a number of recent changes in the circumstances surrounding methadone treatment service delivery. These changes in circumstances include:

- The development of alternate pharmacotherapies for the treatment of opioid dependence, such as naltrexone, levo- α -acetylmethadol [LAAM] and buprenorphine, and the associated need for guidelines to assist consumers and providers develop suitable links between these new treatments and the existing pharmacotherapy of methadone treatment;
- the possible establishment of an ACT Prison and the associated need for guidelines to assist the delivery of methadone treatment services in this and other ACT corrective environments, such as the Belconnen Remand Centre; the Periodic Detention Centre and Quamby Juvenile Detention Centre;
- the increasing inclusion of community service providers, such as general practitioners and pharmacists, in methadone service provision;
- the increasing recognition of opioid dependent persons as a specific population with definite epidemiological characteristics; and
- the associated need for guidelines to assist consumers and providers develop suitable links between methadone treatment, alternate pharmacotherapies and the wider health requirements of opioid dependent persons.

Legislative Framework

In accordance with the requirements of the *Drugs of Dependence Act (Australian Capital Territory) 1989* [the Act], ACT Health in cooperation with private prescribers and dispensers makes methadone available to opioid dependent persons who have been assessed as suitable to participate in methadone treatment.

This legislation can be purchased in hard copy by contacting the Department of Urban Services Publishing Services Unit on 02) 6205 0552 or downloaded for free from one of the following online legislation archives:

- Australian Legal Information Institute AustLII www.austlii.edu.au
- Commonwealth Attorney General's Department ScalePLUS scaleplus.law.gov.au

Under the Act, the Chief Health Officer [CHO] and the Director of ACT Community Care Alcohol and Drug Program [ACTCC-ADP] are the ACT Health agents charged with the responsibility of ensuring that methadone prescribing and dispensing practices comply with the specific requirements and regulations of the Act.

Under the Act it is an offence to be in possession of (§§164, 169) or supply (§§76-83) a drug of dependence, including methadone, unless the person possessing or supplying the drug is licensed or authorised to do so under the Act.

Under §58 of the Act it is an offence for a medical practitioner to prescribe or supply a drug of dependence to a person who, in the opinion of the medical practitioner, is a dependent person or to a person for therapeutic use for more than two months unless the medical practitioner has a written authority to do so from the CHO.

Under §59 of the Act a medical practitioner may be approved by the CHO to prescribe methadone to opioid dependent persons who are registered consumers

Methadone may be dispensed to registered consumers through community pharmacies which have been approved as methadone treatment centres [MTC] following an inspection by an authorised inspector in accordance with the Act.

For specific information about the requirements for registration and licensing to participate in methadone service delivery, please contact the CHO:

Office of the Chief Health Officer
ACT Health
GPO Box 825
CANBERRA ACT 2601

Phone: +61 (2) 6205 0883
Facsimile: +61 (2) 6205 1884

Policy Framework

A range of strategies are in place both nationally and locally to address complex drug issues such as methadone maintenance treatment. In particular, the *National Drug Strategic Framework 1998-99 to 2002-03* provides a nationally consistent framework under which State and Territory activities may be developed. The *ACT Drug Strategy 1999: From Harm to Hope* articulates the ACT directions laid down in the national framework.

The *National Policy on Methadone Treatment* lays down more specific Commonwealth guidelines for the delivery of MMT within the constraints of the national framework.

The *National Drug Strategic Framework 1998-99 to 2002-03* was developed by the Ministerial Council on Drug Strategy [MCDS]. This document contains two operating principles which are important foundations for the *ACT Drug Strategy 1999*. These principles are described in both policies as harm minimisation and social justice.

The *National Drug Strategic Framework 1998-99 to 2002-03* defines the principle of harm minimisation as follows:

Harm minimisation aims to improve health, social and economic outcomes for both the community and the individual and encompasses a wide range of approaches, including supply reduction, demand reduction and harm reduction strategies.

With regard to social justice, the *National Drug Strategic Framework 1998-99 to 2002-03* states that:

Although drug-related harm can affect any individual, family or community, patterns of such harm show that particular communities and population groups are more affected than others. Strategies for tackling drug-related harm not only must target the particular drug or drugs causing problems but must also be developed with regard to the broader context of the needs of, and problems facing, the affected community. Levels of employment, health status (including mental health status), homelessness, remoteness, recreation opportunities, cultural considerations, family support, community development and access to services must all be taken into account.

The National Drug Strategic Framework seeks to develop strategies that recognise the unique settings of local communities, are culturally responsive, meet the needs of marginalised population groups, and improve access to services. Local communities will be partners in the development of local strategies, and client groups should be involved in the continuing design and evaluation of service models.

The basis of the ACT policy framework in harm minimisation and social justice well reflects the World Health Organisation understanding of health promotion activity as outlined in the 1986 *Ottawa Charter for Health Promotion*. In this document, health promotion is defined as:

the process of enabling people to increase control over, and to improve, their health.

The ACT Government recognises the importance of the concept of health promotion and supports the philosophy put forward in the Ottawa Charter.

Philosophy of Service

Following the principles of harm minimisation and social justice, the following statements describe the philosophy of service supporting methadone treatment in the ACT:

- opiate dependant persons have basic human rights and needs;
- the provision of clinical management for opioid dependence should be centred on care for the individual person and undertaken without prejudice regarding the nature of their substance use;
- the provision of care for a person's opioid dependency should address both:
 - their own treatment goals; and,
 - their broader health requirements as ascertained in concert with appropriate health care professionals; and
- methadone maintenance treatment is only one method of clinically managing opioid dependence. Opiate dependent persons should be encouraged to access all services appropriate to their clinical requirements.

Goals

This philosophy of service allows the following basic goals to be set for methadone treatment in the Territory:

- to improve the health of consumers;
- to improve the social functioning of consumers;
- to reduce harmful opioid and other drug use;
- to reduce the spread of bloodborne disease;
- to reduce opioid related mortality and morbidity; and
- to reduce opioid related criminal activity.

Principles

The following principles support and guide efforts towards realising the basic goals of methadone treatment:

- **Access** – where a need for methadone treatment services exists these services should be made available. Every effort should be made to ensure an appropriate range and distribution of services to facilitate equity of access for all consumer groups. To be accessible to those who seek care, services should be located at appropriate sites, treatment should be affordable to consumers, and opening hours should optimise service utilisation;
- **Acceptability** – the operation of methadone services should be acceptable to major stakeholders including consumers, service providers and the community
- **Quality of care** – quality of care includes:
 - ⇒ the provision of information to consumers about methadone treatment (including side effects and drug interactions), program rules, their rights and responsibilities as consumers, and special issues such as driving and operating machinery during treatment;
 - ⇒ mechanisms for ensuring consumer confidentiality;
 - ⇒ consumer appeals procedures;
 - ⇒ mechanisms for monitoring and reporting on program performance and effectiveness; and
 - ⇒ a commitment to staff training and development programs.

Strategies

- **Access** – given the continued and increasing demand for methadone treatment services in the ACT, these services should continue to be provided at increasing levels. Every effort should be made to ensure an appropriate range and distribution of services to facilitate equity of access for all consumer groups.

ACT Methadone provision has been managed to date through a combination of public and community streams out of ACT Community Care. The streams are:

- Public clinic assessment and stabilisation, public clinic prescribing and dosing;
- Public clinic assessment and stabilisation, GP prescribing and community pharmacy dosing; and
- Public clinic assessment and stabilisation, public clinic prescribing and community pharmacy dosing.

It is essential that a strong public stream remain both for stabilising some consumers before accessing the community stream, and to care for those consumers who may not be able to manage in a more autonomous community environment.

- Acceptability – the development of the ACT Methadone Treatment Guidelines including recommended procedures for the operation of methadone services in the ACT, has been developed through consultation with all major stakeholders including consumers and service providers. A schedule of those groups involved through the Methadone Advisory Committee, and a schedule of the consultation process, can be found in **Appendix B: Consultation Process**; and
- Quality of care – quality of care strategies include:
 - ⇒ the development of accredited training for clinicians and pharmacists participating in MMT;
 - ⇒ an ongoing commitment to consumer education and empowerment through initiatives such as this document;
 - ⇒ an ongoing commitment to best practice stakeholder consultation in the development of policy and procedure through bodies such as the Methadone Advisory Committee;
 - ⇒ the development of further comprehensive and consultative policy documents addressing health promotion activities that parallel MMT, such as the General Practice based Opioid Dependant Persons Health Service or programs for the delivery of alternate pharmacotherapies.

Ethics of Service Delivery: Rights and Responsibilities

Consumers

Rights	Responsibilities
Consumers have the right to	Consumers have the responsibility to
be respected and receive treatment without prejudice from all health professionals;	respect health professionals involved in the prescription and dispensing of methadone;
receive high quality service which is consistent with this document;	access treatment in a manner which is consistent with this document;
have access to all relevant information regarding treatment options so they can make informed decisions;	consider all information provided regarding methadone and alternate treatments and make realistic decisions about their participation;
privacy and confidentiality regarding their health status and treatment;	respect the privacy and confidentiality of other consumers;
be protected from all forms of discrimination or treatment which creates an intimidating, hostile or offensive treatment environment;	use behaviours that would be considered acceptable by any reasonable person when participating in treatment;
be honestly engaged in consultation about any aspect of the treatment program so it can more fully meet consumers' needs;	honestly engage in consultation about any aspect of the treatment program so it can more fully meet consumers' needs;
a complaints and review mechanism if they feel they have been treated unlawfully, inappropriately or unfairly.	act within the law at all times

Providers

Providers (including prescribers, dispensers, and members of the care management team) engaged in the methadone program can legitimately expect to hold the following rights in respect to their role.

Providers have the right to:

- maintain the full complement of professional rights and responsibilities that they would bear in professional practice outside their role within the program;
- fulfil their duties with respect suitably reciprocated from individuals and other professionals within the program;
- practice their speciality without perception of threat from program consumers or other program providers;
- be informed as to all aspects of the program and its operation, be informed of aspects of the consumer's case that may effect the efficacy of their clinical decision making, and be consulted by other members of the case management team when decisions are made that may effect the clinical outcomes of the case; and
- access avenues of review in cases where they believe the program, other providers or consumers have compromised their rights as providers.

Providers are expected to accept certain obligations that allow them to insist upon the rights already discussed above. The code of ethics for providers in methadone treatment is based on the following fundamental values:

Equity:	the consumer receives equal treatment for equal needs;
Access:	the consumer has ready access to the services needed;
Effectiveness:	achievement of intended benefits from the services provided;
Appropriateness:	relevance of services to the consumer's needs, gender, and social and cultural background;
Efficiency:	use of available resources to achieve the best possible effect;
Responsiveness:	services reflect reasonable expectations on the part of consumers.

Code of Ethics

Many professionals involved with the delivery of MMT, such as clinicians, pharmacists, nurses, counsellors and public administrators are bound by their own professional codes of ethics that regulate their professional conduct. However consumers are often concerned to understand the rights they can expect under these codes. In addition many workers involved with the delivery of MMT, such as volunteers, may not be bound by a professional code of ethics.

For these reasons, the Alcohol and Other Drugs Council of Australia has developed a generic code of ethics for alcohol and other drug workers. This is reproduced for the information of providers and consumers at **Appendix A: Code of Ethics**.

While this code of ethics is not binding in any way to persons employed in the delivery of MMT in the ACT, it is a very good guide to the general responsibilities of workers in the drug and alcohol field and may assist MMT workers in clarifying their obligations to consumers. It may also assist consumers in understanding their general rights and the reasonable expectations they might hold of their service providers.

It is important to note that this Code of Ethics is a resource and a reference. It is neither comprehensive nor intended in any way to replace, augment or override any existing ethical guidelines that are in place for professionals working in MMT delivery.

RECOMMENDED TREATMENT PROTOCOLS

The recommended treatment protocols detailed in this section should enable the majority of suitably indicated persons to be safely and successfully maintained on methadone. Where in the clinical opinion of providers it becomes necessary to deviate from these guidelines, the prescriber responsible should:

- with the permission of the consumer, correlate opinions with a suitably qualified, experienced and licensed peer from a different practice or organisation than their own;
- clearly justify and document all exceptional, pertinent clinical circumstances in the appropriate records; and
- follow any other protocols for deviation from these guidelines as indicated in the relevant sections of this document.

Suitability for Methadone Treatment

Indications for Methadone Treatment

Admission into methadone treatment should be voluntary and the clinical indications necessary to benefit from treatment should be the same across all treatment models and delivery streams. As the clinical indications for MMT may be very similar to indications for other opioid dependency treatments it is also important for prescribing clinician to be satisfied that MMT is the most appropriate treatment from the available range.

Methadone treatment is only suitable for opioid dependent persons. Opioid dependence syndrome is characterised by:

- neuroadaptation as evidenced by opioid tolerance and/or the development of withdrawal symptoms upon cessation of use or the application of a naloxone test;
- the use of opioids and/or other drugs to avoid the development of withdrawal symptoms;
- a continued desire to use opioids despite persistent and recurrent problems associated with their use;
- a narrowed repertoire of behaviours associated with, or fixated on, opioid use;
- a narrowed circle of social interaction focussed on opioid using peer groups;
- repeated, unsuccessful attempts to reduce or cease opioid use; and
- the priority of opioid use over other life activities.

It is not necessary for all of these indications to be present for a diagnosis of opioid dependency. DSM-IV criteria for the identification of opioid dependence require at least three of the conditions described above to be present within the previous twelve months. These criteria are reproduced in **Appendix C: Diagnostic Screening Instruments**.

Physical dependency as indicated by neuroadaptation is neither necessary nor sufficient for a diagnosis of opioid dependency. However, where there is no evidence of neuroadaptation or physical dependence careful consideration should be given to the range of interventions available other than MMT. Opioid dependent persons without signs of neuroadaptation tend to be younger users with a shorter duration of using history. For the majority of such consumers, all alternative treatment options should be fully investigated prior to considering MMT. In any event, such cases tend to present more frequent incidence of relapse during or following MMT.

The absence of neuroadaptation should not exclude a person from MMT. For example, a pregnant woman with a past history of regular use but no evidence of neuroadaptation may still be indicated in order to minimise the risks of illicit drug use for her self and her child. Similarly, users who are brought into the justice system may be indicated notwithstanding any evidence of neuroadaptation in order to minimise the likelihood of problems associated with injecting drug use within the prison system. Where there is no evidence of either neuroadaptation or an extended history of drug use, clinicians should correlate opinions with a suitably qualified, experienced and licensed peer from a different practice or organisation than their own before prescribing MMT.

Contraindications for Methadone Treatment

Certain circumstances require special consideration in determining whether a person is suitable for induction into methadone treatment. The following factors should be carefully weighed as contraindications for methadone treatment:

- the consumer is not opioid dependent;
- the treatment is not voluntary;
- the consumer is not able to give informed and written consent to treatment.

The *National Policy on Methadone Treatment* recommends that persons under 16 years of age should also be contraindicated for methadone treatment. This position is not consistent with current legislation governing rights to consent to medical treatment. The *Medical Treatment Act (Australian Capital Territory) 1994* limits the right to consent to medical treatment to persons aged over 18 years. In the case that a person under the age of 18 is clinically indicated for MMT, written and informed consent to treatment should be sought from the person's parent or legal guardian.

In the case that a clinician diagnoses opioid dependency in a person under 18 years of age and determines that MMT is the most appropriate form of treatment they should carefully consider whether there are any criteria present in the person's presentation that may invoke mandatory reporting obligations. While there is certainly no direct correlation between opioid dependence and physical or sexual abuse in the home, it is important to remember that the rate of sexual and physical abuse amongst opioid dependent persons is substantially

higher than amongst the community considered as a whole. It is also important to remember that gender is not a barrier to exposure to physical or sexual abuse. Clinicians are advised to seek specialist advice from the appropriate welfare agency in circumstances where they have reason to suspect the consumer has been subject to physical or sexual abuse in the home. Information regarding clinician's mandatory reporting obligations are reproduced in **Appendix E: Guidelines for Mandatory Reporting.**

In the case of a consumer of any age being contraindicated solely on the absence of informed and written consent, treatment may still be able to proceed with informed and written legal consent obtained from the consumer's parent or legal guardian.

There are also a number of common drug regimens which are contraindicated for concurrent use with methadone. **Appendix F: Important Pharmacokinetic and Pharmacodynamic Contraindications.** presents a schedule of some of the most important pharmacokinetic and pharmacodynamic contraindications. This appendix is not comprehensive and is intended as a guide only. Clinicians must employ their usual methods for assessing potential drug interactions when determining the suitability of methadone treatment for their consumers and must not issue clinical decisions regarding potential drug interactions based solely upon the information contained in this document. Clinicians can obtain further advice regarding drug and food interactions with methadone by contacting one of the following sources of information:

- Therapeutic Advice and Information Service
1300 138 677 9am-7pm AEST Mon-Fri excl. Pub Hols.
- Senior Medical Officer at the Public Methadone Program
02) 6205 4545

Assessment for Methadone Treatment

Admission to MMT should always be voluntary and only ever proceed after an individual has been assessed by an approved methadone prescriber.

With appropriate consent and permission the assessment process should involve:

- the collection of all relevant medical, social and personal details;
- a psychiatric and psychological history;
- a drug use history including previous treatment attempts;
- an assessment of risk taking behaviour associated with drug use;
- assessment of clinical symptoms associated with drug use such as intoxication, withdrawal or venipuncture;
- assessment of secondary diagnoses associated with drug use such as thrombosis, infected injecting sites, viral infections or dietary deficiency; and

- identifying the consumer's treatment goals.

There are two main methods for approaching the assessment of the consumer's needs and determining their suitability for treatment:

Clinical Assessment

Careful clinical observation of the consumer for signs of opioid intoxication or withdrawal and clinical interview regarding the consumer's history of drug use together offer the simplest tool for gauging the suitability of a consumer for MMT.

In addition to simple observation and interview, or where doubt remains as to the clinical status of a consumer, an opioid withdrawal scale and/or a severity of dependence index can be used to assist in objectively establishing the degree of dependence. Examples of such assessment instruments can be found in **Appendix C: Diagnostic Screening Instruments**. With the consent of the consumer, other useful information regarding a consumer's history of drug use may be obtained from pathology testing of blood, urine or hair samples although these procedures are frequently more expensive and time consuming than warranted by any increase in assessment accuracy.

Pharmacological Assessment

If there is still difficulty in establishing the existence or severity of opioid dependence syndrome, further assessment guidance is available through clinical appraisal of results from pharmacological assessments such as methadone or naloxone testing. Pharmacological assessment methods are not generally recommended as they may be very hazardous if misapplied and are generally more expensive and time consuming than warranted by any increase in assessment accuracy. If clinicians are considering employing tests of this nature they should be conducted with the informed and written consent of the consumer and with reference to appropriate clinical procedures beyond the recommendations of this document.

Methadone tolerance testing involves administering a small dose of methadone and observing the toxicological responses over the period leading to peak serum levels. Acute toxic responses such as miosis or cardiovascular depression would suggest a lower tolerance than the absence of such responses. Clinicians should be careful to monitor for signs of hazardous intoxication, and be prepared to administer an antagonist or similar antidote should it become necessary.

Naloxone testing involves administering a dose of naloxone and observing the antagonistic response in the period following the precipitation of withdrawal. The presentation of acute withdrawal symptoms such as lacrimation, rhinorrhea, piloerection, mydriasis or diaphoresis would suggest higher levels of dependency than the absence of such symptoms. Clinicians

should be careful to monitor for signs of hazardous withdrawal, and be prepared to administer an agonist or similar preparation should it become necessary to reverse the withdrawal reaction. For this reason, it is imperative to only utilise antagonists such as naloxone with a short half life that will permit the withdrawal process to be reversed. Under no circumstances should such a procedure be attempted using a longer acting, irreversible antagonist like naltrexone.

Generally speaking, clinical methods should be preferred as less intrusive, less hazardous, less time consuming and less expensive. In the case that pharmacological testing is agreed to be desirable, methadone testing is the simpler test to perform. Naloxone testing is not widely practiced in dependency treatment. It is generally considered more hazardous and intrusive than warranted by any improvement in the accuracy of results. In the case that assessment using a naloxone test is performed, the clinician should carefully document the reasons it is considered necessary.

*For further reading on **Assessment for Methadone Treatment** see:*

- Bell 2000.
- Quigley 2000.

Induction

Methadone maintenance treatment offers many health advantages to opioid dependent persons. Some of the greatest benefits are in substantially reduced rates of drug related morbidity and mortality. However, it is important to note that in the first two weeks of induction to methadone maintenance there is in fact a marked increase in the rate of mortality ¹.

Because of the long half-life, the serum level of methadone increases on a given dose to reach a steady state in about 7 days. Most of the increase occurs in the first three days. It becomes a matter of fine clinical judgement to select an appropriate initial dose. If it is too low the patient may use (heroin or other drugs) and be at risk of mixed drug overdose. If it is too high then symptoms of methadone overdose may occur - usually after the first two or three days. For this reason the patient needs to be very carefully assessed on a daily basis prior to dosing with methadone during the first week. If dosing staff have any concerns at all the prescriber must be contacted. There should be no rises in methadone dose during the first three days unless the prescriber has personally seen and assessed the patient. A small routine rise in dose (5mg) may be authorised for day four. After the first week the risk declines rapidly.

¹ See Caplehorn and Drummer (1999).

Dosage

Commencement Dosage

Initial doses of methadone should be based on a history of the quantity, frequency and route of administration of opioids and should take into account the likely purity of that substance. In general, the initial dose will be in the range of 20–30mg but should not be more than 40mg. Caution should be exercised if a starting dose any greater than 30mg is to be used because of the risk of overdose. The appropriateness of the commencement dose needs to be decided in light of the biochemical estimates of hepatic and renal function when clinically indicated, as well as other drug use. A consumer who re-presents, on the first day, at least four hours after the administration of an initial dose of methadone may be considered for a supplementary dose where there is evidence of persistent opioid withdrawal. These cases need to be assessed by an experienced medical practitioner.

Appropriate dosage is particularly critical during the induction period when the majority of deaths associated with methadone occur ². Many of these deaths appear to result from iatrogenic methadone toxicity ³. However it is important to note that most of these deaths also present polydrug toxicologies ⁴.

A meta-analysis of Australian and overseas studies has demonstrated that an opioid dependent person in methadone maintenance is one quarter as likely to die as an untreated opioid dependent person ⁵. However a recent cross-sectional study of New South Wales coronial reports on methadone related mortality found that the relative risk of fatal accidental drug toxicity during the first two weeks of treatment was in fact 6.7 times as high as that for heroin users not in treatment, and 97.8 times as high as that for consumers with two weeks or more of treatment history ⁶.

The problem of determining the appropriate induction dosage for a particular consumer is related to the difficulties in assessing the degree of opioid dependence and tolerance ⁷. Self-reports of recent drug use are generally an unreliable measure of opioid tolerance for applicants without an established therapeutic relationship ⁸. These reports are therefore by themselves an unreliable indicator for appropriate induction dosage.

Consumers being inducted must be clear as to the possible dangers of misleading their physician about their drug use during the establishment of induction dosages ⁹. Given all these variables it is not possible to define a generically safe and effective induction dose of methadone ¹⁰.

2 (Zador and Sunjic 2000; Ali and Quigley 1999; Caplehorn and Drummer 1999).

3 (Caplehorn and Drummer 1999: *passim*).

4 (Zador and Sunjic 2000: 80 f.).

5 (Caplehorn and Drummer 1999: 104).

6 (Caplehorn and Drummer 1999: 104).

7 (Ali and Quigley 1999: 100; Zador and Sunjic 2000).

8 (Caplehorn and Drummer 1999: 106).

9 (Caplehorn and Drummer 1999: 106; Zador and Sunjic 2000: 81).

10 (Caplehorn and Drummer 1999: 106).

There are however two ways to approximately determine a person's level of opioid dependence and tolerance.

- clinical assessment through careful observation and interview, including diagnostic screening instruments
- pharmacological assessment through methadone or naloxone testing.

These techniques for assessing tolerance are discussed above from p.21 in the section entitled “Suitability for Methadone Treatment”. Naloxone testing is no longer widely practiced in dependency assessment ¹¹. The primary method remains careful clinical assessment and this is sufficient in the vast majority of cases.

Stabilisation Dosage

The aim of MMT is to arrive at an effective maintenance dose for the consumer using safe dose increments. Effective here means a dose that prevents the consumer from developing withdrawal symptoms, fails to produce a toxic response, and minimises the consumer's harmful use of opioid drugs.

Clinicians need to be aware of the pharmacokinetics ¹² of methadone which determine the time taken to achieve a steady state plasma level of the drug. Steady state is the situation where the rate of drug elimination equals the rate of drug administration. Methadone has an average half-life in the body of 15 to 30 hours, which means that it takes an average of five to seven days to achieve the steady state plasma level associated with a particular dose.

The implications of this are that it may take between two to four days before toxic and potentially fatal drug levels are achieved. Accordingly, research indicates that the overwhelming number of deaths associated with methadone induction and stabilisation occur within this timeframe after the dose change.

It is also important to advise consumers that although they may not feel as though their discomfort is totally alleviated by initial dosage, they will feel progressively more comfortable after subsequent days at that dosage until steady state plasma levels are achieved by about the fourth day. Consumers should also be advised of the risk of overdose if they attempt to alleviate their discomfort using other drugs with a central nervous system depressive effect – such as alcohol, benzodiazepines or other opioids.

- First seven days

11 For a useful discussion of the merits and difficulties of administering and interpreting the naloxone test, see (Bell 2000; Quigley 2000).

12 The action of drugs in the body over a period of time, including the processes of absorption, distribution, localisation in tissues, biotransformation and excretion.

In the first seven days of stabilisation, dose increases should be conditional upon the consumer being assessed by an experienced clinician for signs of intoxication. Where doses need to be increased within the first week, the increment should be no more than 5mg on any one day. With this in mind, the maximum dose achieved at the end of the first week should not exceed 40mg.

- Subsequent stabilisation
After the first week of treatment, if a dosage increase is considered appropriate it should always be accomplished gradually and at no more than 10mg per week. During this later stage of stabilisation, consumers should be clinically assessed on a regular basis to identify symptoms of opioid toxicity. This procedure should be followed and repeated prior to any dose increment.

There is evidence to recommend that prescribers and dispensers advise consumers on an incremental regime against driving or operating machinery. Consumers should also be made aware of the risks associated with driving or operating machinery whilst experiencing polydrug effects that include a methadone component.

Consumers on a stabilised dose and with no evidence of polydrug use are unlikely to be impaired and can in most cases safely drive a motor vehicle or operate machinery.

Maintenance Dosage

Consumers receiving a daily dose of 60mg or more are less likely to use illegal opioids and are more likely to remain in treatment than those receiving a dose of less than 60mg. Each consumer should be prescribed the dose that is best suited to the clinical management of their case.

Generally it is accepted that doses in excess of 120mg per day do not confer additional benefit in the majority of cases. However there will be consumers who, due to exceptional opioid tolerance or very rapid methadone metabolism, may require dosages above 120mg per day.

In these cases it is recommended that the clinician:

- with the permission of the consumer, correlate opinions with a suitably qualified, experienced and licensed peer from a different practice or organisation than their own; and,
- clearly justify and document all exceptional, pertinent clinical circumstances in the appropriate records.

If after these procedures it still appears as if a daily dose in excess of 120mg is in the best clinical interests of the consumer, the clinician seeking to prescribe the dose should:

- apply to the Chief Health Officer,
- include in their application their own clearly justified and documented opinion and the clearly justified and documented correlate opinion; and
- subject the high dose regimen to clinical review at least every 12 weeks to ascertain any indications of clinical improvement.

In instances where very high doses are indicated and prescribed, the clinician should monitor consumers very closely for signs of methadone toxicity at the point of peak serum level. Split dosage might be considered to maintain appropriate steady state serum levels in consumers who experience excessive peak serum level due to their requirement for higher than normal doses to prevent withdrawal symptoms. In most cases, split dosing can be safely and conveniently dispensed with one half administered under usual supervision and one half dispensed for unsupervised oral administration. For details regarding the dispensing of doses intended for unsupervised oral administration see the section below.

Missed Dosage

When consumers miss methadone doses they may rely upon other drugs to alleviate the discomfort of withdrawal symptoms. Most frequently these other drugs are illicit diacetylmorphine, benzodiazepines or alcohol. While it is procedure to assess consumers for signs of intoxication before any administration of methadone, it is essential to take special care in monitoring consumers who have missed a dose for signs of intoxication before resuming their regimen.

If a client misses two consecutive doses but present for dosing on the third day they may be dispensed a half dose. If a consumer misses more than three consecutive doses they should not resume their regimen until they have consulted with their prescribing physician. It may be appropriate for the prescriber to reduce a consumer's dose in the case that the regimen compromise has reduced the consumer's opioid tolerance.

In the case that a consumer misses their dosing for seven consecutive days they shall be deemed to have withdrawn from the program and will require reassessment and replacement by their prescriber before they are able to resume their treatment.

Emergency Dosage

On occasion a consumer may miss a number of consecutive doses. In this situation it is likely that they may begin to experience withdrawal symptoms. In such a case they may feel a very urgent need to resume their regimen.

In the case that this occurs while the consumer's usual dispensary is open, they should present as usual and the procedures discussed above regarding missed dosage should be followed.

In the case that this occurs while the consumer's usual dispensary is closed, it is not usual practice to administer emergency dosing and there are no facilities in the ACT to accommodate such emergency dosing. In the case of extreme withdrawal after consecutive missed doses where the condition may be life threatening, consumers are urged to immediately contact their nearest hospital emergency department or available drug and alcohol service provider. Workers in these situations should then contact the Senior Health Officer at the Public Methadone Program to determine the way to progress.

Unsupervised Oral Administration

Some of the initial benefits of entering MMT accrue from the process of supervised daily oral administration. This procedure permits:

- a reduction in the time spent participating in drug seeking behaviour;
- the establishment of a regular pattern of behaviour; and
- the opportunity for more frequent contact with health workers.

However once a consumer is suitably stabilised on a program, the requirement for daily presentation to receive a supervised dose may represent a disadvantage to the maintenance of their current stability or their efforts to achieve further stability. Such disadvantage may accrue when daily dosing begins to:

- represent an inappropriate focus on drug seeking behaviour;
- interfere significantly with established employment or educational responsibilities; or
- interfere significantly with caring or other household responsibilities.

To reduce the disadvantages of supervised administration, stable consumers may be offered opportunities to take doses away from their dispenser for daily unsupervised oral administration.

Unsupervised oral dosing is not suitable for all consumers and should only be considered by the case management team in terms of the accepted clinical indicators of stability. The decision about whether unsupervised oral dosing is appropriate is a matter to be determined by a prescriber in consultation with the consumer. In the majority of cases a limit of 3 doses per seven day period should be imposed upon access to unsupervised oral dosing to ensure that the consumer is still able to appropriately engage with the rest of their case management team. Such limits are also necessary to ensure consumers retain access to suitable clinical advice and support from their prescriber and dispenser.

There are two situations in which the prescriber may consider allowing a consumer access to more than 3 unsupervised oral doses per week. First, a consumer may request a one-off special, extra unsupervised oral dose to meet a particular exigency, such as family emergency,

special employment situation etc. It should be noted that clinicians should monitor the frequency with which consumers are attempting to access special extra unsupervised doses and it should be reiterated that these cases should be ad hoc and expeditious. Such special cases should be generally restricted to one case per four week period. In such cases it is recommended that the clinician clearly justify and document all exceptional, pertinent circumstances in the appropriate records.

Second, there are a percentage of long term consumers who have exhibited such long term levels of clinical stability that the case management team may consider it appropriate to allow access to more than 3 unsupervised oral doses per week under special circumstances for limited periods. In these cases it is recommended that the clinician:

- with the permission of the consumer, correlate opinions with a suitably qualified, experienced and licensed peer from a different practice or organisation than their own;
- apply to the Chief Health Officer;
- include in their application their own clearly justified and documented opinion regarding all exceptional, pertinent circumstances; and
- subject the unsupervised dose regimen to clinical review at least every 8 weeks to ensure the regime of unsupervised oral administration remains clinically appropriate.

All doses released for unsupervised oral administration should be presented in amber containers with child resistant and tamper evident seals. In addition, suitable cautionary labelling should be attached to each container. The following represent examples of best practice labelling and should serve as a useful guide to the requirements for suitable cautions. The ability of pharmacies to reproduce such labelling will depend on the size of the pharmacy, the level of staffing and the type of labelling equipment available.

KEEP OUT OF REACH OF CHILDREN

METHADONE LIQUID

This bottle contains (dose) mg of methadone.
Take the contents of this bottle in a single dose
on (date to be consumed)
(name of patient)

TO BE TAKEN ONLY BY MOUTH BY THE PATIENT
NAMED ON THE LABEL ON THE DAY STATED ON THE LABEL

DO NOT INJECT

MAY CAUSE DEATH OR SERIOUS INJURY
IF INJECTED OR TAKEN BY ANOTHER PERSON

In addition, the name and address of the dispensing pharmacy, the prescription number and a cautionary label for drowsiness must always be included on the container.

Indications of Stability

In monitoring progress towards a consumer's clinical goals, there are several processes that may be used to indicate the degree of stability that consumers have managed to achieve.

Examples of such indications of stability may include:

- improved management of close personal relationships;
- improved engagement in either paid work, unpaid work or education;
- improved ability to manage a residence;
- development of and progress towards non-drug related life goals;
- development of personal and professional relationships with non-drug dependent individuals and groups;
- reductions in hazardous drug taking behaviour;
- reductions in other risk taking behaviours; and
- reductions in illegal or otherwise socially inappropriate behaviours.

Each possible factor indicating stability needs to be weighed on the merits of the individual case. For instance: a failure to demonstrate improved engagement in either paid work, unpaid work or education would not be an indication of instability if other criteria were present, such as reductions in hazardous drug taking behaviour and improvements in close personal relationships that, when considered together, indicated an improvement in consumer stability and progress towards the realisation of the consumer's clinical goals.

While we must recognise that there are a number of issues that may contribute to an understanding of a consumer's stability, there are particular activities that may compromise treatment to such an extent that it is important for these particular indications of stability to be very closely monitored.

Such activities in need of especial attention may include:

- hazardous drug use; or
- dose diversion.

The issues of hazardous drug use and dose diversion are discussed individually in more detail below. While for many consumers the consideration of factors such as hazardous drug use and dose diversion may be appropriately approached through relatively unobtrusive means such as self-reporting, for consumers in less stable situations or without a well established therapeutic relationship it may be necessary to suggest more objective means such as pathology testing.

Stability and Pathology

It is current practice in the Alcohol and Drug Program to insist upon a regular regimen of urinalysis to aid in the monitoring of patient stability. Urinalysis has the advantage of objectivity in determining certain facts about recent drug use. While it is not “foolproof” or “demonstrative”, urinalysis holds many advantages over other pathological and non-pathological testing methods:

- it has well established methods for administration and interpretation;
- it is relatively accurate for identifying many commonly used compounds of clinical concern in MMT;
- it is relatively cheap and accessible compared to other pathological testing methods; and
- it is relatively unobtrusive compared to other pathological testing methods.

Pathology methods such as serum testing give improved accuracy for some indications, however serum testing is more costly and significantly more obtrusive. Other tests exist for the analysis of hair, sweat and saliva although these pathologies are not commonly used in MMT in the ACT. Prescribers should consult the appropriate clinical literature to determine what pathology testing would be most appropriate for the consumer being assessed. Information on urinalysis testing within the Public Program is available by contacting the Alcohol and Drug Program on 6205 4545.

Community prescribers may develop their own position on the frequency and status of urinalysis within their procedures for ascertaining consumer stability. It should be noted that testing frequency has implications for the accuracy of results and thus the utility of urinalysis in clinically indicating stability.

No matter what set of factors are finally determined to be the best indicators of stability for a particular consumer, and regardless of what procedures are agreed upon as the most suitable for determining the status of these indications, it is important for the case management team to work together in developing these factors and procedures.

Hazardous Drug Use

Some pharmacological interactions with methadone are potentially fatal.

While this means that clinicians should exercise caution when prescribing medications for other conditions that require treatment for the consumer, it is also true that the continued hazardous use of drugs by program consumers is a major contributor to methadone related fatalities¹³. Such hazardous drug use can compromise the harm minimisation goals of methadone treatment. For this reason, continued hazardous drug use by consumers whilst engaged in MMT is considered an indication of poor stability.

¹³ (Scott et al. 1999: 1791 f.; Avi Bleich et al.).

It is important to reiterate that while drug use is not encouraged at all amongst MMT consumers, not all illicit drug use can be seen as equally hazardous. For this reason it is important to develop differential responses to drug use that reflect the relative instability indicated. Undifferentiated responses tend to encourage the use of more addictive drugs with shorter half-lives and consequently with less likelihood of detection in serum or urine testing ¹⁴. This effect has been observed in British studies of the mandatory random drugs testing in prison populations ¹⁵. As the authors of these studies suggest, the perceived need to punish all drug use has compromised opportunities to retain the clinical trust of individuals, as well as to obtain quality data on drug use patterns from which to determine policy ¹⁶. These results are difficult to align with the policy imperatives of harm minimisation.

The misuse of benzodiazepines, alcohol or illicit opioids while in MMT are the most common examples of hazardous drug use. It should also be emphasised that benzodiazepine, alcohol or illicit opioid use while in MMT is extremely hazardous. All these agents have depressive effects on the central nervous system that may synergistically enhance each other and markedly increase the likelihood of cardiac or respiratory failure.

Dose Diversion

It is important to ensure that the prescribed dosage of methadone is being correctly consumed. If a consumer is unsatisfied with their present dose and will not discuss this issue with members of their case management team, it is possible they may engage in the consumption of additional, illicitly obtained methadone or the diversion of excess, legal methadone to the illegal market.

Repeated failure to adhere to the established dosage regimen is a serious indication of instability in a consumer. Such failure may indicate that the current regimen is inappropriate for the consumer and that they experience episodes of intoxication or withdrawal on their current dosage.

In addition, regardless of the consumer's subjective appraisal of the regime, instability as evidenced by failure to maintain their regimen may seriously compromise the clinical goals as determined by the consumer and clinician. Finally, instability as evidenced by failure to maintain their regimen – especially where this results in the diversion of methadone to the street market – has the potential to seriously compromise the integrity of the methadone program in general and, subsequently, the well being of all persons suitable to receive MMT in the ACT.

Serum or urine levels of methadone metabolite can be used to determine either excessive dosage through illicit consumption or inadequate dosage through diversion ¹⁷.

¹⁴ (Gore and Bird 1998: 1257).

¹⁵ (Gore and Bird 1998; Gore Bird and Ross 1996).

¹⁶ (Gore Bird and Ross 1996: 1413).

¹⁷ (Fountain et al. 2000: 401).

Management for Periods of Instability

It is often considered appropriate to place special conditions upon the services offered to consumers who incur periods of instability, especially as evidenced by hazardous drug use or dose diversion.

Such special conditions might appropriately include:

- if the consumer is engaged in a community based stream of service provision, the referral of their case back to the Public Clinic to enable closer clinical management and greater support than can often be made available in the community setting;
- the renegotiation of those factors and procedures agreed to provide the best indication of stability for the consumer to include more rigorous use of pathology such as urinalysis in the assessment of the consumer's stability; or
- reduction or removal of rights to access unsupervised oral doses.

In cases where a consumer is so unstable that their behaviour threatens the safety of other consumers, program staff or the public, or where it is demonstrable that the consumer is persistently diverting their dose to the illegal market, it may be necessary to remove them from the program through a period of withdrawal management.

Intravenous Administration and Volume Expansion

Given the personal and public health risks posed by unchecked and/or preventable injecting, one of the greatest benefits offered by MMT is the opportunity for consumers to reduce or suspend injecting behaviour. Such reduction or cessation carries health benefits for the consumer by reducing potential exposure to bloodborne diseases, reducing the risks of acquiring systemic infections and reducing the likelihood of sustaining venous damage. The reduction in health risks for the individual consumer has public health benefits for the entire community.

While reductions in injecting behaviour can greatly assist the implementation of harm minimisation principles, there are a number of consumers for whom the process of injection remains a part of their acculturated identity.

For these consumers it may not be possible to access the other benefits of MMT if they are required to cease injecting behaviour as a criteria for involvement with the program. If these consumers are likely to encounter less harm in contact with MMT providers despite their persistence in injecting behaviour then it may seem pertinent to permit their involvement in order to maximise the impact of harm minimisation policies.

Volume expansion and the provision of prescribed injectable opioids are the two main methods for managing the health risks presented by persistent injecting behaviour amongst MMT consumers.

Volume Expansion

The *National Policy on Methadone Treatment* recommends the expansion of take away doses to a volume of 200mL as a possible strategy to:

- reduce the likelihood of intravenous administration; and,
- reduce the likelihood of the opioid naïve, especially small children, accidentally consuming sufficient preparation to produce a toxic reaction ¹⁸.

While such a policy may reduce the likelihood of these types of incidents, it cannot eliminate the risk. In the case of intravenous administration, volume expansion may in fact increase the health risks associated with dosage.

According to current practice and experience in the ACT, volume expansion may only be of limited benefit. Accordingly, volume expansion is not compulsory in the ACT and decisions to volume expand should be made on a clinical basis by the prescribing doctor in consultation with the consumer, dispenser and other relevant persons.

In the case that volume expansion is considered appropriate, the diluent should be formulated as follows:

0.1% sodium benzoate w/v

0.2% citric acid w/v

Purified water to 100 ml

This preparation is available through wholesalers and has a long date of expiry. When using this preparation to volume expand doses the following procedure is recommended:

- Full strength diluent should not be used. The preparation described above should be further diluted to a factor of two using purified water prior to dispensing. Such further dilution results in a concentration of 0.05% sodium benzoate and 0.1% citric acid in purified water. **A FIVE DAY EXPIRY DATE SHOULD BE APPLIED;**
- It is recommended that consumers take volume expanded doses by sipping over 20 minutes during the course of a meal;
- Consumers should be aware that volume expanded doses prepared in the manner described above should not be taken as a bolus dose;
- Doses of 25 mg (or 5 ml) or less should be diluted to a volume of 50 ml. Doses of greater than 25 mg (or 5 ml) should be diluted to a volume of 100 ml;
- Pregnant consumers or consumers with an concurrent gastric condition may experience difficulties in orally administering volume expanded doses.

¹⁸ NPMT 15.

Injectable Opioid Prescription

Injectable opioid prescription is an historical phenomena in the United States and is a continuing, if limited, feature of opioid dependency treatment in the United Kingdom. The provision of injectable diacetylmorphine and methadone to consumers is nonetheless a contentious practice amongst providers, consumers and the community, even in those jurisdictions where the practice is officially accommodated.

In the ACT, injectable opioid prescription is not available for the treatment of opioid dependence.

*For further reading on **Injectable Opioid Prescription** see:*

- Sarfraz and Alcorn 1999.

Adjunct Therapies

Adjunct therapies are supportive approaches that may assist in the improvement of well-being of people undergoing methadone maintenance treatment.

Counselling/Case Management

Talking to someone else, whether it be in a group or individually, often helps people to find new ways of dealing with problems. Counselling is a way of addressing and resolving issues. It can involve identifying options and choosing between them, learning new skills to cope better with problems, gaining greater understanding of what is occurring, or being supported while recovering from a significant life event.

Case Management involves undertaking a detailed assessment of consumer needs and working together to identify goals and strategies to address these in the short and long term. Case management provides support and help in accessing the services and resources suited to the individual.

Relaxation Techniques

Learning to relax body and mind can assist in feeling better and more in control.

Acupuncture affects the physiological functioning of the body by the insertion of fine needles into specific points all over the body. Medically, acupuncture works by regulating various systems in the body - hormonal, nervous, immune, circulatory, muscular.

Acupuncture is good for more than just pain. It can also be used for health enhancement, to assist in addiction withdrawal, and to improve sense of well-being and vitality.

Massage can help people to cope with stress and pain. It can be extremely relaxing and will often relieve symptoms such as tension and discomfort.

Meditation is a technique for quietening the mind and emptying it of thoughts. Muscles of the body become calm and relaxed and heart and breathing slow down.

Hypnotherapy can relax the body and mind and help to deal with anxiety and solve problems more effectively. It may also help to control pain and treatment side effects.

Methadone to Abstinence Residential Model

Research on methadone maintenance shows that this treatment produces immediate decreases in criminality and drug use, however as consumers taper off methadone they are prone to relapse. Some of the aspects of treatment that appear to prevent relapse include minimising withdrawal symptoms during methadone reduction, and support during and after completing maintenance. While the philosophies and methods of residential and methadone treatment programs are different, there exist many commonalities that lay the groundwork for a collaborative effort between the two modalities.

The strengths of the methadone program and the residential or therapeutic community environment have been combined in programs both in Australia and overseas to enable consumers to taper off methadone maintenance in a supportive environment and remain drug-free. Whilst there is no single treatment of drug dependence adequate for all consumers, there are a number of approaches which can be utilised alone or in combinations. In designing the most appropriate treatment for any given individual, it has been found that mid- to low-severity consumers show substantial improvement in either methadone maintenance or therapeutic community treatment, while high-severity consumers are more affected by the treatment modality. In both modalities, mid-severity consumers showed the most dramatic effects of improvement with increased treatment duration, while low-severity consumers showed little additional improvement with longer treatment.

Research also appears to indicate that where detoxification to abstinence is the goal, the consumer may be catered for in a therapeutic community or residential treatment environment, where group and individual counselling, stress management, leisure activities, education and work training, and administration of methadone away from the residential program are included. Where the goal is maintenance, it may well be that the best method of treatment involves day-patient attendance or half-way house environment.

Information relating to alternative pharmacotherapies may be found in the section “Alternate Pharmacotherapies” on page 53.

Treatment Termination

Most treatment terminations are initiated at the request of the consumer. However, decisions to cease treatment always remain the responsibility of the prescriber in consultation with the consumer. The CHO must be notified in writing of any treatment termination within seven working days of the final dosage.

Voluntary Termination

Generally, more gradual dose reductions produce less severe withdrawal symptoms. Dose reductions should be made in consultation with the consumer.

Dose reduction regimes that invoke physical or psychological distress in the consumer are usually counterproductive. During voluntary withdrawal it is important to ensure the rate of reduction does not allow physical or psychological stress to develop in the consumer. It may be most appropriate to maintain a consumer at a reduced dose for some period until they feel comfortable to resume the reduction regime.

The following reduction regimes are generally well tolerated by consumers:

- for consumers on doses over 50 mg – dose reduction should occur at a rate no faster than 10mg per week until a 40mg dose is achieved; and
- for consumers on doses under 50mg – dose reduction should be no faster than 5mg a week.

Where relapse occurs or seems likely, reduction should be suspended or the dose may even need to be increased for a period.

Involuntary Termination

Certain behaviours may result in the involuntary removal of consumers from the program. Such behaviours might include proven episodes of:

- violence or threats of violence against program staff or their families, and other consumers or their families, including consumers not involved with methadone maintenance treatment delivery;
- involvement in damage or theft from prescriber's, dispenser's or clinic premises;
- involvement in illicit drug dealing or couriership on or near prescriber's, dispenser's or clinic premises;
- diversion of medication; or
- repeated refusal to pay for prescriber's, dispenser's or clinic services.

Dispensers have the right to refuse service to a consumer if, in their opinion, the consumer's behaviour is inappropriate to the continuation of the consumer's attendance at the pharmacy.

Depending on the severity of the offending behaviour, there are a number of responses that can be employed short of involuntary termination. Such alternative avenues for redress should always be thoroughly examined and exhausted before resort to involuntary termination. Alternate responses may include:

- formal warning or report;
- transfer to another prescriber or dispenser;
- closer supervision; or
- more frequent review of stability indicators.

Consumers should bear in mind that they can get advocacy and other support to assist in resolving these types of issues from national and local peer support networks. If all alternate avenues have been exhausted and it is still considered necessary to involuntarily withdraw a consumer from methadone treatment, the reduction in dosage should be gradual and enacted with counselling support. Rapid dose reduction or abrupt cessation may only be warranted in cases of violence, assault or threats of physical interference towards staff or other consumers.

In general, involuntary withdrawal should not proceed at a rate greater than a 5mg reduction in dose each 3 days and reduction should always commence from the consumer's full dose. Consumers who are discharged from treatment must be counselled as to the risks of illicit drug use and informed of other treatment options.

After Care

After the completion of methadone treatment it is important the consumer has access to continued follow-up assistance, or after care. Such after care may include:

- skills maintenance sessions;
- progress monitoring; and/or
- support counselling.

The benefit of continued contact with counsellors and clinicians should be stressed to the consumer.

Appeals and Conflict Resolution Mechanisms

Appeal and Conflict Resolution Mechanisms

In the instance that a consumer feels that a decision made by a member of their case management team is not suitable or in error, they have the right to appeal that decision. The process to be followed in such an instance is:

STEP 1

As soon as you have been informed of a decision that you don't agree with, discuss it with the clinic staff or contact the Medical Officer and discuss it with him/her. If you are satisfied with the outcome, there should be no need for further action. If you are not satisfied with the outcome, then take step two.

STEP 2

The complaint should be put in writing and sent to the Medical Officer. Complaint forms are available from the clinic. The address is below. You should receive a reply within seven working days. If you are satisfied with the outcome, there should be no need for further action. If you are not satisfied with the outcome, then take step three.

STEP 3

Write to the Program Director, Alcohol & Drug Program and inform him/her of what steps you have taken, and why you are not satisfied. The address is below. You should receive a reply within seven working days. If you are satisfied with the outcome, there should be no need for further action. If you are not satisfied with the outcome, then take step four.

STEP 4

Write to the Community and Health Complaints Commissioner. This is a unit set up by the ACT Government to investigate complaints about ACT Health Services. The address is below.

Relevant addresses are:

**Senior Medical Officer
Alcohol & Drug Program**
PO Box 11
WODEN ACT 2606
Ph: 6205 4545

**Director
Alcohol & Drug Program**
PO Box 825
CANBERRA ACT 2601
Ph: 6205 1611

**Community and Health Complaints Commissioner
ACT Health**
GPO Box 825
CANBERRA ACT 2601
Ph: 6205 2222.

In the instance that a member of a case management team has a grievance with any professional aspect of another member of the case management team, they should at first attempt address it through direct dialogue. If dialogue is not successful, the case should be referred to the Director of Drug and Alcohol Services in ACT Community Care. In most cases the Director of Drug and Alcohol Services will be able to assist parties in reaching a satisfactory resolution. In the event that the Director of Drug and Alcohol Services is unable to assist in finding a satisfactory resolution, the Director may appoint a mutually acceptable mediator with appropriate qualifications to adjudicate on the matter. The decision of such a mediator appointed by the Director of Drug and Alcohol Services and mutually accepted by both parties to the conflict will in each case be binding.

Cross-stream and Interprovider Co-ordination and Communication

MMT in the ACT is a complex system bringing together disparate contributions from a wide range of people. There are a number of offices established to facilitate cross-stream and interprovider co-ordination and communication. Some of the key contacts are reproduced below with a brief synopsis of the role they play in cross-stream and interprovider co-ordination and communication.

ACT Health Alcohol & Other Drug Unit	6205 0909	Coordinates policy and purchasing decisions with whole of system implications.
ACT Methadone Case Client Coordinator	6205 1000	Coordinates liaison for consumers with prescribers and dispensers both within the ACT and in cases of interstate transfer.
Alcohol & Drug Program – ACT Community Care (24 hrs)	6205 4545	Coordinates operations and policy within the Public Clinic.
Chief Health Officer	6205 0883	Coordinates licensing and regulation of prescribers, dispensers and treatment centres.

Program Transfers: Intraterritory, interstate and international

Intraterritory Transfers

As consumers chose to move between treatment streams, as more conveniently located MTCs open or as consumers relocate their residence within the territory, it may become necessary or desirable to transfer consumers to another ACT registered prescriber or dispenser.

In such cases, prescribers should contact the Methadone Client Case Coordinator to facilitate transfer to the most suitable placement. The Methadone Case Client Coordinator can be contacted on **02) 6205 1000**.

Interstate Transfers

Permanent Transfer to the ACT

Consumers registered for MMT in other states may arrange a permanent transfer to the ACT program. Consumers seeking such a permanent transfer should note that ACT residents have priority access to placements in the event that there is a waiting list for treatment.

Consumers seeking such a transfer should contact the ACT Methadone Case Client Coordinator. Consumers can obtain assistance in arranging such transfers by contacting their local prescriber, local public methadone clinic or local consumer organisation.

Temporary Transfer to the ACT

Consumers registered for MMT in other states may arrange a temporary transfer to the ACT program. Consumers seeking such a transfer should contact the ACT Methadone Case Client Coordinator.

Consumers can obtain assistance in arranging such transfers by contacting their local prescriber, local public methadone clinic or local consumer organisation.

Transfers out of the ACT

Consumers registered for MMT in the ACT may arrange a temporary or permanent transfer to programs in other jurisdictions, both interstate and internationally. It must be appreciated that there is a great variety of circumstance surrounding the delivery of MMT in different jurisdictions. Consumers should make inquiries to determine what circumstances they may need to accommodate that are different to their treatment protocols in the ACT.

Consumers seeking such a transfer should ask their dispenser for a form. When complete, the consumer or the dispenser should forward the form to the ACT Methadone Case Client Coordinator.

It should be noted that the time required to arrange a transfer differs markedly from jurisdiction to jurisdiction, especially in the case of international transfers. In most cases as much time as possible should be used to effect a smooth transfer. Consumers can obtain advice as to the minimum transfer times for different jurisdictions by contacting their local prescriber, local public methadone clinic or local consumer organisation. The minimum time required to organise a transfer to New South Wales is one week, although it is preferable for applications to be made three weeks before the transfer is required. Consumers should consider factors such as the time of year, the latent demand for methadone services at the new location and the capacity of the local program to accommodate an additional consumer when planning a transfer.

Consumers can obtain assistance in arranging such transfers by contacting their local prescriber, local public methadone clinic or local consumer organisation.

International Transfers

It is essential that consumers carrying opioid medications overseas hold a letter from their prescribing doctor describing the quantity and nature of the medications. Travellers should also check with an embassy or consulate for each country they intend to visit to ensure that their entry into these countries whilst in possession of prescribed opioids complies with the relevant local laws.

It is important to note that the Therapeutic Goods Administration no longer issues travellers' letters for people intending to take prescribed opioid medications overseas. In addition, prescribers should note the requirement to apply to the Chief Health Officer for approval to prescribe methadone for the purposes of travel.

Further information regarding the requirements and procedures for international program transfers can be obtained by contacting the Methadone Case Client Coordinator on **02) 6205 1000**.

Skill Acquisition and Maintenance for Providers

MMT is a multidisciplinary field, bringing together various clinical and non-clinical areas. While it is recognised that each of the disciplines engaged make vital contributions to the successful operation of MMT, methadone remains a very specialised area within each discipline. None of the contributions can stand alone and all parties should hold specialist knowledge from within their field regarding methadone and its delivery.

Medical practitioners, pharmacists, nurses, counsellors, psychiatrists, corrections officers and parole officers intending to participate in methadone service provision all require differing types and levels of specialised information regarding the way methadone and MMT will effect their working environments. As a consequence, all such provider groups should have

demonstrated knowledge and skills concerning methadone treatment before being authorised to participate in MMT.

The acquisition, demonstration and maintenance of provider skills is always a stronger and more relevant process when it occurs in cooperation between the Government and the appropriate key peak professional bodies. The ACT Government encourages a partnership approach to ensuring MMT providers can honestly assure consumers to best standards of skill acquisition and maintenance.

The ACT Government has minimum standards of training required for prescribers and dispensers to participate in MMT delivery. These standards are set by ACT Health in consultation with the Methadone Advisory Committee or coordinated by the Alcohol and Drug Program. To obtain accreditation, prescribers and dispensers are required to participate in both an initial training and periodic refreshing activity to ensure that the skills of MMT service providers are current. Details regarding the requirements for obtaining and retaining accreditation are available from the Chief Health Officer.

**Office of the Chief Health Officer
ACT Health
GPO Box 825
CANBERRA ACT 2601**

**Phone: +61 (2) 6205 0883
Facsimile: +61 (2) 6205 1884**

The *National Policy on Methadone Treatment* recommends the following protocol to determine the optimal provider to consumer ratio:

The number of consumers that doctors are approved to treat should be determined by:

- *the expertise and experience of the doctor in treating drug dependence;*
- *the accessibility of the doctor to the client;*
- *whether the doctor is working full-time or part-time in MMT; and*
- *the type of consumers and/or type of setting in which the doctor is providing MMT.*

The national policy makes no such recommendations for the optimum provider to consumer ratio for other professional contributors to MMT service delivery.

Consumer Records and Program Monitoring

Consumer Records

Case records detailing consumers' clinical history and treatment progress should be established and adequately maintained. Such records are necessary to ensure the most appropriate and highest quality care can be provided for each individual case.

Appropriate procedures should be implemented to ensure the security and confidentiality of records. Such procedures are vital to engendering trust between consumers and providers, and to demonstrating the integrity of the MMT system.

Consumers and staff should be made aware that records may be accessed by legal means under certain circumstances, such as the serving of subpoenas. While a service may attempt to restrict the public use of a consumer's records, such restricted access cannot be universally guaranteed.

Program Monitoring

The Commonwealth Government has responsibility for collating and maintaining national methadone treatment data. Besides meeting Commonwealth reporting obligations, the careful maintenance of consumer records and program performance measures can provide very useful information for monitoring the progress of the program towards its goals. Such monitoring is essential to ensure innovation within the program is targeted to the areas of greatest need.

It is recognised that data collection can be intrusive for the consumer and arduous for service providers, especially in community settings. In order to make the administration of MMT as easy as possible for providers and consumers, the least amount of data as possible should be routinely collected for the purposes of program monitoring.

The *National Policy on Methadone Treatment* recommends the following items of data as most important elements of a meaningful minimum dataset.

- **Number of registered consumers in treatment, broken down by:**
 - age by five year range;
 - gender identity;
 - employment status;
 - previous treatment status; and
 - treatment stream status.

- **Retention in treatment**
 - mean, mode and standard deviation of duration of current episode for consumers registered in treatment at the time of the annual census; and
 - number of consumers entering MMT during the year of report who dropped out of treatment within 12 weeks, grouped by previous treatment attempt status.
- **Dosage rates**
 - mean dose of methadone.
- **Mortality rates**
 - Number of deaths from all causes, of consumers in treatment at the time of death, during the reporting year and the proportion that are opioid related.

Other information such as rates of consumer satisfaction with service delivery or rates of consumer progress towards clinical goals can also give important indications of program strengths and weaknesses.

Needle and Syringe Programs

Needle and syringe programs [NSP] are an integral aspect of harm minimisation and thus a basic component of the ACT's strategy for addressing the problems associated with injecting drug use. In this regard, NSP shares many philosophies and goals with MMT. Where service provision models share such important foundations, it is necessary to ensure they work closely to support each other's efforts to provide the most appropriate services to consumers.

It is recognised that MMT consumers often have special requirements for assistance from NSP facilities. These special requirements may include information about IDU and BBV while engaged in MMT, or the provision of specific types of equipment to reduce the impact of harmful drug taking practices. Where any consumer group presents a special requirement in order to maximise the harm minimisation benefit of a service, the special service should be made available as fully as possible.

METHADONE TREATMENT AND PAIN MANAGEMENT

Methadone Maintenance Treatment in Chronic Pain Management

People with chronic pain conditions who become iatrogenically dependent on analgesia may benefit from MMT as a last line of treatment. Such consumers should be managed by pain clinics or appropriate clinicians in consultation with the Alcohol and Drug Program. The Pain Management Clinic at The Canberra Hospital may be contacted on 6244 2222.

Pain Management for Opioid Dependents

MMT consumers admitted to hospital must have their treatment continued.

Due to their tolerance of opioids these consumers will require larger doses of analgesia for adequate pain relief. The analgesic agent, dose and administration route should be discussed with appropriate pain management specialists.

Injectable analgesia should not be withheld from MMT consumers in hospital, but orally administered analgesics should be preferred if equally appropriate in all other regards.

MMT consumers who have a painful condition may need an increased methadone dosage for a period to deal with the pain. However increased methadone dose by itself is unlikely to provide sufficient analgesia in most acute, painful conditions.

*For further reading on **Pain Management for Opioid Dependents***

- Newman 2000.

CONSUMER GROUPS WITH PRIORITY ACCESS AND OTHER CONSUMER GROUPS WITH SPECIAL NEEDS

Priority Access Groups

Certain consumer profiles qualify individuals for priority access to MMT. The Alcohol and Drug Program recognises the following groups of people as being in special circumstances that make them suitable for priority access to the Public Program:

- opioid dependent persons who are HIV positive and their opioid dependent partners;
- opioid dependent women who are pregnant and their opioid dependent partners;
- opioid dependent persons who have a serious concurrent illness that requires hospitalisation; and
- people who have been inducted into MMT while in detention and who have recently returned to the community.

Other individuals may be assessed by an Alcohol and Drug Program Medical Officer as suitable for priority treatment.

In addition to those groups identified as suitable for priority treatment, there are a number of recognised opioid dependent sub-populations that present special needs for successful case management. Some of the most prominent consumer groups with special needs are discussed in more detail below. It should be noted that not all consumer groups with special needs as discussed below are also considered priority access groups as identified above.

Groups with Special Needs

Opioid Dependent Persons during Pregnancy and Childbirth

Maternal participation within MMT during pregnancy is unlikely to pose a substantial teratogenic risk. There are many studies of children of women who have participated in MMT over their pregnancy, but the data are insufficient to categorically deny any teratogenic risk associated with MMT participation.

Antenatal care for opioid dependent women should be managed, where possible, in collaboration with obstetric services which specialise in the management of drug dependency during pregnancy. Some women may be initially reluctant to advise other health practitioners of the fact that they are on a methadone program. Consumers with such reservations should be counselled about the need for a partnership approach between drug and alcohol services and other relevant health and social services.

As pregnancy alters the metabolism of methadone, consumers may need an increase in dosage and/or to have divided doses. Many women may want to reduce their dose during pregnancy, but withdrawal during pregnancy or a return to unsanctioned opioid use are in themselves associated with greater risks. These issues need to be discussed with the consumer, and consumers in such situations need to be closely monitored. If a reduction in dose does occur it should be undertaken during the second trimester.

There is compelling evidence of a neonatal abstinence syndrome associated with children who have been repeatedly exposed to methadone in utero. The syndrome is characterised by hypertonia, tremor, diarrhoea, and vomiting; although other symptoms have been described. There is some clinical research to indicate that the final level of dose of methadone does not correlate well with the occurrence or severity of neonatal abstinence syndrome.

Further information regarding opioid dependent women in maternity and opioid dependent infants can be obtained from:

Maternal & Child Health Services: Phone 02) 6207 1043
Alcohol & Drug Program: Phone 02) 6205 4545

Opioid Dependent Persons Under Eighteen Years of Age

Age in itself is not a contraindication for MMT, although opioid dependent persons under eighteen years of age will present special requirements in their case management. Some of these issues are discussed above at pp.23-4.

Further information regarding opioid dependent persons less than eighteen years of age can be obtained from:

Alcohol & Drug Program: Phone 02) 6205 4545

Opioid Dependent Persons Living with a Concurrent Legal Condition

Further information regarding opioid dependent persons in custody can be obtained from:

Alcohol & Drug Program: Phone 02) 6205 4545

- *In police custody*

If a MMT consumer is taken into police custody, it is the responsibility of the consumer to inform the custodial officer of their status as a MMT consumer and the responsibility of the custodial officer to ensure the continuity of treatment.

Officers in custodial charge of a MMT consumer should contact that person's usual methadone prescriber to facilitate the transferral of the consumer's dispensing requirements to a pharmacy operated by the Medical Officer in charge of corrective health services for the custodial facility.

- *In juvenile detention*

It should be noted that for persons under the age of eighteen years in juvenile detention are able to continue any MMT they are currently receiving. It is not current policy for people to commence MMT whilst in juvenile detention in the ACT. See also *Opioid Dependent Persons Under Eighteen Years of Age* at p.52.

- *In remand*

If a MMT consumer is remanded in custody, their treatment must be continued through the Medical Officer in charge of corrective health services for the remand facility.

- *In prison*

The ACT Corrective Services system currently does not offer imprisonment within the ACT, with all detainees receiving a prison sentence requiring transfer to the New South Wales custodial system. ACT prisoners in NSW institutions must follow the procedures and guidelines governing MMT in the NSW custodial system.

In the event that the ACT develops a local prison facility, MMT may be suitable for certain types of prisoners such as:

- MMT consumers who are sentenced to prison; or
- untreated opioid dependent persons who are sentenced to prison.

Opioid Dependent Persons Living with a Concurrent Bloodborne Viral Condition

Injecting drug use is one of the greater risk behaviours for contracting several bloodborne viruses. The most epidemiologically important of these are HIV/AIDS and HBV-HCV. Carriage of HIV/AIDS antibodies is recognised as criteria for priority entry into MMT.

Such priority must be afforded for a number of reasons. Firstly, there are the personal risks consumers enjoin through the combined immunosuppressant effects of their viral load and their drug use. In addition there are the public health risks that attend the unchecked spread of HIV/AIDS through the community in general.

Opioid Dependent Persons Living with a Concurrent Polydrug Use Condition

Consumers who are using alcohol or other non-opioid drugs in a potentially harmful way at the time of their entry to MMT should be counselled on and alerted to the dangers of intoxication while on methadone, the harms of polydrug use and on ways to reduce or cease hazardous use of alcohol and other drugs.

Service providers also need to be aware that methadone consumers may develop significant alcohol and other drug use habits whilst receiving MMT. Some consumers mistakenly believe that once on methadone, they will not develop other drug dependencies. This view should be clearly discouraged during induction. Service providers should be alert to the possible development of new dependencies and the need for appropriate interventions with such consumers.

Consumers who have multiple drug dependence should, where possible, be managed in specialist services that provide comprehensive, quality care. Options for such consumers include selective detoxification. Careful consideration should be given to a controlled program of prescribing and dispensing of the drugs of dependence.

Opioid Dependent Persons Living with a Concurrent Mental Health Condition

People presenting for MMT are often living with a concurrent mental health condition. The combination of a substance use issue together with a mental health condition is also known as “dual diagnosis”.

In most instances, the presence of a mild mental health condition should present no barrier to participation in MMT. However, special care may be required in cases where significant conditions are suspected, particularly where psychotic symptoms are present. In such cases it is appropriate to seek the opinion of a suitably qualified mental health clinician before proceeding with induction.

In situations where a consumer is living with a significant mental health condition, there should be a process of shared care with appropriate mental health workers fully involved in case management. All clinicians involved in the management of such cases should be aware of the potentially hazardous interactions between methadone and several drugs commonly prescribed in the treatment of mood, personality and psychiatric disorders. Some commonly occurring pharmacokinetic contraindications are outlined in **Appendix F: Important Pharmacokinetic and Pharmacodynamic Contraindications**.

Appropriate treatment for underlying mental health issues has been found to contribute to the likelihood that a person will remain in treatment. The role of motivation and structure is also important, particularly where the person's past lifestyle has been chaotic, often with irregular eating and sleeping patterns. Supportive therapy, including formal teaching of relapse prevention techniques, are considered to be of vital importance in developing new positive coping mechanisms, both for consumers with mental health issues, and those without these types of confounding problems.

Further information regarding opioid dependents with concurrent mental health conditions can be obtained by contacting the Alcohol and Drug Program on:

02) 6205 4545

*For further reading on **Opioid Dependent Persons Living with a Concurrent Mental Health Condition** see:*

- Mason et al. 1998.

ALTERNATE PHARMACOTHERAPIES

Naloxone and Naltrexone

Naloxone and naltrexone are related drugs that act as pure opioid antagonists. In blocking the μ , κ and δ receptors from accepting opioids, naloxone and naltrexone not only remove the euphoric effects of opioids, but reverse the CNS depressive effects as well.

In opioid dependent persons, naloxone and naltrexone precipitate withdrawal syndrome as they aggressively displace any bound opioids already in place and prevent the binding of any further administered opioids.

Naloxone is a short acting agent, with an elimination half life of approximately 0.5 to 1.6 hours. Naltrexone is a longer acting relative with an elimination half life of approximately 10 hours.

Naloxone

Naloxone, known by its proprietary name of Narcan[®], is indicated for the treatment of both narcotic overdose and postoperative narcotic depression. It has achieved a high public profile in its application for the former.

Naloxone is very successful at immediately reversing the effects of opioid intoxication. However, due to its short duration of effect, it must be used cautiously in cases where longer-acting opioid agonists such as methadone or dextropropoxyphene are suspected as the toxic agents. In such cases, the effects of the naloxone may cease before the action of the opioid agonist. Such a situation risks allowing a relapse into opioid intoxication. In cases such as these, continuous intravenous infusion can be used to overcome the danger of relapse to intoxication.

Naloxone will not produce adverse effects or exacerbate CNS depression following administration where the diagnosis of opioid overdose is in error.

Naltrexone

Naltrexone aggressively binds with opioid sites in the brain. It has approximately double the antagonistic effect of naloxone and a considerably longer half life. The severity and length of its action requires caution when administering to suspected opioid dependents. In cases where the patient has been opioid free for less than seven days there is considerable risk of precipitating a severe and irreversible withdrawal syndrome that may endanger the patient.

In some instances where naltrexone is used as the agent to precipitate a rapid or ultra rapid detoxification from opioids, clinicians have found it necessary to employ adjuncts ranging from high doses of benzodiazepines to full anaesthesia in order to ameliorate the severe effects of the compressed withdrawal. These effects range from episodes of extreme agitation and psychosis to aggression and violence reported in many such cases.

Naltrexone is registered in Australia for use within a comprehensive treatment program in the management of alcohol dependence and as an aid in the maintenance of previously opiate-dependent patients who have ceased the use of opioids such as heroin and morphine. It is currently being used in clinical trials at a number of sites across Australia. The trials are being evaluated under the National Evaluation of Pharmacotherapies for Opioid Dependence (NEPOD) project.

The major benefit of naltrexone in opioid dependency treatment is its ability to prevent post-detoxification use of opioids from realising any opioid effects. While this result seems attractive to abstinence based alcohol and drug treatment programs, there are several serious disadvantages:

1. the inability of opioid class drugs to take any effect when consumed after naltrexone means that most individuals demonstrate very poor retention on naltrexone maintenance programs;
2. the period of absolute abstinence required before induction into naltrexone maintenance, and the period of negligible stimulus of the opioid receptor sites whilst on naltrexone maintenance, combine to severely lower opioid tolerance amongst users who have been inducted onto naltrexone; and
3. lower levels of retention and lower levels of tolerance generally result in higher rates overdose in post-detoxification relapse.

*For further reading on **Naloxone and Naltrexone** see:*

- Bell 2000.
- DRUGDEX via MICROMEDEX Healthcare Series Vol. 106.

Buprenorphine

Buprenorphine is a member of the opioid class along with drugs such as diacetylmorphine and methadone. Buprenorphine is a partial opioid agonist having a maximum effect that is less than that of morphine. It binds strongly to the opioid receptors and can block the action of other opioid drugs.

This mixed agonist/antagonist action appears to make buprenorphine safer in overdose and less likely to be diverted. There is also evidence that suggests buprenorphine presents an easier withdrawal phase than other, pure opioid agonist agents. Some consumers may find other advantages in terms of the relative ease of transition to other treatments, the need for less frequent administration than methadone and flexibility of treatment.

Buprenorphine is now registered in Australia for use in the management of opioid dependence. It is being trialed throughout Australia and is considered to be as effective as methadone in the treatment of opioid dependence. Buprenorphine offers an alternative treatment for opioid dependent people not suited to treatment with methadone, and thus offers the possibility of retaining more people in treatment.

*For further reading on
Buprenorphine see:*

- DRUGDEX via MICROMEDEX Healthcare Series Vol. 106.

Levo- α -acetylmethadol

Levo- α -acetylmethadol [LAAM] is a synthetic opioid that acts similarly to methadone. However, while methadone presents an elimination half-life of approximately 25 hours, LAAM has a substantially extended elimination half life of approximately 72 hours. This extended half life removes the need for daily administration.

While the reduction in face to face management time for LAAM has many advantages over traditional “short-life” methadone maintenance, there are issues which prevent it from being suitable for all consumer groups. New or unstable consumers may benefit from the more regular clinical contact possible under a daily dosing methadone regime. The long effects of LAAM also increase the risks of synergistic interaction with other agonist agents, thus increasing the risks of overdose for consumers who persist in the use of illicit opioids. Levo- α -acetylmethadol is also counterindicated in pregnancy where opioid tolerance may be lowered and opioid clearance raised due to alterations in metabolism.

Levo- α -acetylmethadol is not currently approved for use in Australia. Under the Drugs of Dependence Act, levo- α -acetylmethadol is not currently able to be prescribed in the ACT for the treatment of opioid dependence.

For further reading on

Levo- α -acetylmethadol see:

- DRUGDEX via MICROMEDEX Healthcare Series Vol. 106.

BIBLIOGRAPHY AND REFERENCES

Policy Documents

The following table presents a list of key policy documents dealing with methadone pharmacotherapy and the best practice for its delivery. These documents have been sourced from several jurisdictions both within Australia and internationally.

The list is ordered alphabetically by name of jurisdiction.

Table I Bibliography - Policy Documents.		
Jurisdiction	Year	Title
Commonwealth	1998	National Drug Strategy - National Policy on Methadone Treatment
New South Wales	1999	NSW Methadone Maintenance Treatment - Clinical practice guidelines
New Zealand	1996	National Protocol for Methadone Treatment in New Zealand
Tasmania	2000	Tasmanian Methadone Policy 2000
United Kingdom	2000	Drug Misuse and Dependence - Guidelines on clinical management
Victoria	2000	Methadone Guidelines: Prescribers and pharmacists
Western Australia	2000	Evidence Based Practice Indicators for Alcohol and Other Drug Interventions: Literature review

Clinical and Research Literature

The following list presents a survey of recent clinical and other research dealing with methadone pharmacotherapy and the best practice for its delivery. These documents have been sourced from a selection of key journals, government publications and independent research. The list is ordered alphabetically by surname of primary author. Year of publication is indicated by shading the entry in accordance with the following key:

	2000-2001	1999	1996 -1998	< 1996
1	Addy D, Ritter A, Lang E, Swan A and Engeland M. (et al.) 2000. <u>Clinical Treatment Guidelines for Alcohol and Drug Clinicians: 1 – Key principles and practices.</u> Turning Point Drug and Alcohol Centre: Melbourne.			
2	Ali R and Quigley A. 1999. <i>Editorial: Accidental drug toxicity associated with methadone maintenance treatment.</i> <u>Medical Journal of Australia</u> 170 (3) 100-1.			
3	Bell J 1999 <i>Assessment of Methadone Tolerance: Trigger paper.</i> Humeniuk, R. et al. ed. 2000 135-45.			
4	Bell J, Chan J and Kuk A. 1995. <i>Investigating the Influence of Treatment Philosophy on Outcome of Methadone Maintenance.</i> <u>Addiction</u> 90 (6) 823-30.			
5	Bird A, Gore S, Hutchinson S, Lewis S, Cameron S and Burns S. (et al.) 1997. <i>Harm Reduction Measures and Injecting Inside Prison versus Mandatory Drugs Testing: Results of a cross-sectional anonymous questionnaire survey.</i> <u>British Medical Journal</u> 315 (7099) 21-4.			
6	Birkett D 1999 <i>Factors Affecting the Disposition of Methadone: Discussion paper.</i> Humeniuk, R. et al. ed. 2000 87-92.			
7	Bleich A, Gelkopf M, Schmidt V, Hatward R, Bodner G and Adelson M. (et al.) 1999. <i>Correlates of Benzodiazepine Abuse in Methadone Maintenance Treatment: A one year prospective study in an Israeli clinic.</i> <u>Addiction</u> 94 (10) 1533-40.			
8	Bochner F 1999 <i>Drug Interactions with Methadone - Pharmacokinetics: Trigger paper.</i> Humeniuk, R. et al. ed. 2000 93-110.			
9	Brienza R, Stein M, Chen M-H, Gogineni A, Sobota M, Maksad J, Hu P and Clarke J. (et al.) 2000. <i>Depression amongst Needle Exchange Program and Methadone Maintenance Clients.</i> <u>Journal of Substance Abuse Treatment</u> 18 (2000) 331-7.			
10	Canadian HIV/AIDS Legal Network. 1999. <u>Fact Sheet 5 - Injection Drug Use and HIV/AIDS: Prescription of opiates and controlled stimulants.</u>			
11	Canadian HIV/AIDS Legal Network. 1999. <u>Fact Sheet 9 - Injection Drug Use and HIV/AIDS: Methadone maintenance treatment.</u>			
12	Caplehorn J and Drummer O. 1999. <i>Mortality Associated with New South Wales Methadone Programs in 1994: Lives lost and saved.</i> <u>Medical Journal of Australia</u> 170 (3) 104-9.			
13	Chou C-P, Hser Y-I and Anglin D. 1998. <i>Interaction of Client and Treatment Program Characteristics on Retention: An exploratory analysis using hierarchical linear models.</i> <u>Substance Use and Misuse</u> 33 (11) 2281-301.			
14	Darke S and Ross J. 2000. <i>Fatal Heroin Overdoses Resulting from Non-injecting Routes of Administration.</i> <u>Addiction</u> 95 (4) 569-73.			
15	Darke S and Ross J. 2000. <i>The Use of Antidepressants among Injecting Drug Users in Sydney, Australia.</i> <u>Addiction</u> 95 (3) 407-17.			
16	Dawe S and Mattick R. 1997. <u>National Drug Strategy: Review of diagnostic screening instruments for alcohol and other drug use and other psychiatric disorders.</u> AGPS: Canberra.			

17	Day R 1999 <i>Drug Interactions with Methadone - Pharmacokinetics: Discussion paper.</i> Humeniuk, R. et al. ed. 2000 111-16.
18	Doran C, Mattick R, Shanahan M, Ali R and White J. (et al.) 2000. <i>Buprenorphine vs Methadone Maintenance: A cost-effectiveness analysis.</i> Unpublished paper presented to <u>Combined APSAD-National Methadone Conference</u> Melbourne 20-22 Nov 2000.
19	Foster D 1999 <i>Factors Affecting the Disposition of Methadone: Trigger paper.</i> Humeniuk, R. et al. ed. 2000 67-86.
20	Fountain J, Strang J, Gossop M, Farrell M and Griffiths P. (et al.) 2000 <i>Diversion of Prescribed Drugs by Drug Users in Treatment: Analysis of the UK market and new data from London.</i> <u>Addiction</u> 95 (3) 393-406.
21	Gaughwin M and Ryan P. 1999. <i>Heroin Addiction: The science and ethics of the new treatment pluralism.</i> <u>Medical Journal of Australia</u> 170 (3) 129-30.
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At the time of printing of the ACT Methadone Guidelines, the phone number and the location details for the existing ACT methadone outlet and the phone numbers for the ACT and Australian contact points are current.

If due to unforeseen circumstances these details change we will notify you by means of an Amendment Sheet to the Guidelines

EXISTING METHADONE OUTLETS

Wruwallin Clinic Methadone Program (Government Program):

The Wruwallin Clinic provides daily management and dosing of consumers receiving methadone treatment and liaises closely with local and interstate pharmacies and methadone programs in coordinating consumer care. The service is provided from Woden.

Woden	Monday-Friday	7.15am – 9.30am	Saturday-Sunday	7.15am – 9.30am
Bldg 7		10.00am – 12.00pm		10.00am – 12.00pm
ACT Community Care		2.00pm – 3.00pm		1.00pm – 3.00pm
Alcohol & Drug Program				
Palmer Street				
GARRAN				

Pharmacy Outlets:

There are many community pharmacies in all areas of the ACT that participate in the delivery of MMT services. These dispensaries operate within various times as determined by the pharmacist. For details regarding the location and opening hours of community pharmacies offering MMT dispensing, contact the Alcohol and Drug Program on 02) 6205 4545.

ACT CONTACT POINTS

ACT Health	6205 0909
• Alcohol & Other Drug Unit (policy area)	
ACT Methadone Case Client Coordinator	0416 295 055
Alcohol & Drug Program – ACT Community Care (24 hrs)	6205 4545
Chief Health Officer	6205 0883
Chief Pharmacist	6207 3974
Co-Morbidity/Dual Diagnosis Project Officer	0417 256 982
Maternal & Child Health Services	6207 1043
Pain Management Clinic – The Canberra Hospital	6244 2222

AUSTRALIAN CONTACT POINTS

Government Departments and Agencies

• Commonwealth Department of Health and Aged Care	02) 6289 1555
• New South Wales Health	02) 9391 9000
• Northern Territory Health Service	08) 8999 2400
• Queensland Health	07) 3234 0111
• South Australian Department of Human Services	08) 8226 8800
• Tasmanian Department of Health and Human Services	03) 6233 3530
• Victorian Department of Human Services	03) 9616 7777
• Western Australian Health Department	08) 9222 4222

Non-government Organisations

• Alcohol & other Drugs Council of Australia (ADCA)	02) 6281 0686
• Australian Drug Foundation (ADF)	03) 9278 8100
• Australian National Council on Drugs (ANCD)	02) 6260 5791
• Australian Professional Society on Alcohol & Drugs (APSAD)	02) 9399 7061

Research Centres

• National Centre for Epidemiology & Population Health (NCEPH)	02) 6125 2378
• National Drug & Alcohol Research Centre (NDARC)	02) 9398 9333
• National Drug Research Institute (NDRI)	08) 9426 4230
• National Health and Medical Research Council (NHMRC)	02) 6289 9184
• Queensland Alcohol & Drug Research & Education Centre (QADREC)	07) 3365 5189
• Turning Point Alcohol & Drug Centre	03) 9254 8061

APPENDIX A: CODE OF ETHICS

Many professionals involved with the delivery of MMT, such as clinicians, pharmacists, nurses, counsellors and public administrators are bound by their own professional codes of ethics that regulate their professional conduct. However consumers are often concerned to understand the rights they can expect under these codes. In addition many workers involved with the delivery of MMT, such as volunteers, may not be bound by a professional code of ethics.

For these reasons, the Alcohol and Other Drugs Council of Australia has developed a generic code of ethics for alcohol and other drug workers. This is reproduced with slight amendment for the information of providers and consumers below.

While this code of ethics is not binding in any way to persons employed in the delivery of MMT in the ACT, it is a very good guide to the general responsibilities of workers in the drug and alcohol field and may assist MMT workers in clarifying their obligations to consumers. It may also assist consumers in understanding their general rights and the reasonable expectations they might hold of their service providers.

It is important to note that this Code of Ethics is a resource and a reference. It is neither comprehensive nor intended in any way to replace, augment or override any existing ethical guidelines that are in place for professionals working in MMT delivery.

The Code of Ethics ***Alcohol and Other Drugs Council of Australia***

1. *Service providers owe a duty of care to their clients. That is, service providers will take reasonable care in exercising their professional responsibilities and skills when working with, and for, their clients.*
This means that service providers will do what they can to:
 - *achieve and maintain appropriate standards of proficiency in their work – for example, through attendance at relevant courses*
 - *ensure that their clients have relevant and sufficient information about the programs in which the clients are participating so that their participation is on the basis of informed consent*
 - *maintain appropriate client confidentiality at all times*
2. *Service providers will apply their skills towards assisting with the identification, early intervention, treatment, rehabilitation and social integration of their clients, and will work towards prevention of drug problems.*
3. *Where appropriate, service providers will commit themselves to help others who are involved in assisting in the treatment of their clients, particularly health and other workers. By doing this, service providers recognise that they will be able to participate in a widely supportive approach to care and support.*

4. *Service providers will take steps to ensure that their clients are referred to more appropriate care as soon as it becomes apparent that such referral is necessary in the interests of providing optimum standards of care.*
5. *Service providers will respect the human and legal rights of their clients, including the client's right to make decisions on their own behalf and to participate in planning for their treatment or rehabilitation.*
6. *At all times service providers will carry out their duties and responsibilities to their client without prejudice in regard to gender, age, ethnicity, religious or political affiliation, any disability, sexual preference, or socio-economic and cultural background.*
7. *Service providers will do their utmost to preserve the dignity, respect, health and safety of their clients; and will not enter into a sexual relationship of any kind with any of their clients.*
8. *Service providers will participate in any reasonable review of their professional standards or skills, and in any processes that relate to the resolution of conflicts with their clients, or the handling of complaints made by, or on behalf of, their clients.*
9. *Service providers will endeavour to conduct themselves as a positive role model for their clients and colleagues.*

For further information on professional ethics in MMT see:

- Addy et al 2000
- or*
- contact the Alcohol and Other Drugs Council of Australia
- or*
- contact the relevant professional association

APPENDIX B: CONSULTATION PROCESS

Schedule of Stakeholders and Consumer Groups

The following organisations were consulted during the drafting of these *ACT Methadone Guidelines 2001*.

- **Schedule I:**
Stakeholders and Consumer Groups Consulted over Drafting.

Organisation	Representative / Contact
◀ ACT Community Care Pharmaceutical Services	Ms Jane Strang (Deputy Chief Pharmacist)
◀ ACT Community Care Drug and Alcohol Program	Ms Julie Perrin (Director) Ms Deborah Felton (Methadone Project Officer) Dr Jo Mazengarb (Senior Medical Officer)
◀ Canberra Clinical School Academic Unit of General Practice	Ass. Prof. Nicholas Glasgow (Chair)
◀ ACT Division of General Practitioners	Dr Clare Willington
◀ ACT Pharmacy Guild	Mr Peter Downing
◀ Assisting Drugs Dependents Inc	Ms Maureen Cane (Chief Executive) Mr Ivan Cooper
◀ ACT Health Alcohol & Other Drug Unit	Ms Fran Barry (Manager) Ms Rebecca Scrivener (MAC Secretariat) Mr Christopher Killick-Moran (MAC Research Assistant)
◀ Canberra Injectors Network	Ms Tarquin McPartland
◀ Methadone Action Consumer Empowerment	Mr Michael Rimmer

Schedule of Consultation

The following organisations and individuals were consulted or made submissions during the drafting of these *ACT Methadone Guidelines 2001*.

Schedule 2

Calendar of Stakeholder and Consumer Group Consultations.

Organisation / Individual	Date	Consult. No.	Rep 1	Rep 2	Rep 3
ACT Division of General Practitioners	Fri 08 Sep '00	1	Clare Willington		
ACT Community Care Drug and Alcohol Program	Thu 14 Sep '00	1	Julie Perrin	Jo Mazengarb	Deborah Felton
Canberra Injectors Network	Tue 19 Sep '00	1	Tarquin McPartland		
ACT Community Care Pharmaceutical Services	Wed 20 Sep '00	1	George Stefanoff	Jane Strang	
ACT Pharmacy Guild	Wed 27 Sep '00	1	Paul O'Connor		
Methadone Action Consumer Empowerment	Mon 30 Oct '00	1	Michael Rimmer		
Mr John Gregan Pharmacist	Wed 01 Oct '00	1			
Dr Michael Tedeschi General Practitioner Public Prescriber	Thu 02 Nov '00	1			
Assisting Drug Dependents Inc		1	Elizabeth Skinner	Ivan Cooper	

APPENDIX C: DIAGNOSTIC SCREENING INSTRUMENTS

A Note on DSM and ICD.

The first section of this appendix reproduces the DSM-IV-TR and ICD-10 criteria for the diagnosis of various syndromes associated with opioid use. The DSM has been developed by the American Psychiatric Association and the ICD by the World Health Organisation.

The research community has long found standardised diagnostic criteria useful. Such criteria provide agreement as to the constellation of symptoms that indicate dependence syndrome and allow researchers all over the world to communicate clearly as to what kinds of disorders are being studied.

Standardised diagnostic criteria are equally important and useful to clinicians. In the dependency treatment field, there have been many different ways by which clinical staff might arrive at a diagnosis, sometimes differing among staff within the same program. Although the use of standard diagnostic criteria may seem somewhat burdensome, it provides many benefits: more efficient assessment and placement, more consistency in diagnoses between and within programs, enhanced ability to measure the effectiveness of a program, and provision of services to people who most need them.

Against these benefits, it should be remembered that these diagnostic criteria are human constructs and reflect particular clinical and social theories regarding the nature of dependency that are by no means uncontested. They should be used as a guide only.

DSM-IV-TR Criteria for Substance Related (Substance Use and Substance Induced) Disorders

OPIOID INTOXICATION SYNDROME

292.89

- A Recent use of an opioid.
- B Clinically significant maladaptive behavioural or psychological changes (e.g. initial euphoria followed by apathy, dysphoria, psychomotor agitation or retardation, impaired judgement, or impaired social or occupational functioning) 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, developing during, or shortly after, opioid use:
 - 1 Drowsiness or coma
 - 2 Slurred speech
 - 3 Impairment in memory or attention
- D The symptoms are not due to a general medical condition and are not better accounted for by another mental disorder.

Specify if: **With Perceptual Disturbances**

OPIOID INTOXICATION DELIRIUM

292.81

- A Disturbance of consciousness (i.e. reduced clarity of awareness of the environment) with reduced ability to focus, sustain or shift attention
- B A change in cognition (such as memory deficit, disorientation, language disturbance) or the development of a perceptual disturbance that is not better accounted for by a preexisting, established, or evolving dementia
- C The disturbance develops over a short period of time (usually hours to days) and tends to fluctuate during the course of the day
- D There is evidence from the history, physical examination, or laboratory findings of either of the following:
 - 1 The symptoms in criteria A and B developed during opioid intoxication
 - 2 Medicinal opioid use is aetiologically related to the disturbance

Note: This diagnosis should be made instead of a diagnosis of Opioid Intoxication (292.89) only when the cognitive symptoms are in excess of those usually associated with intoxication syndrome and when the symptoms are sufficiently severe to warrant independent clinical attention

SUBSTANCE ABUSE SYNDROME

- A A maladaptive pattern of substance use leading to clinically significant impairment or distress, as manifested by one (or more) of the following, occurring within the same twelve month period:
 - 1 Recurrent substance use resulting in a failure to fulfil major role obligations at work, school or home (e.g. repeated absences or poor work performance related to substance use; substance-related absences, suspensions, or expulsions from school; neglect of children or household)
 - 2 Recurrent substance use in situations in which it is physically hazardous (e.g. driving an automobile or operating a machine when impaired by substance use)
 - 3 Recurrent substance-related legal problems (e.g. arrests for substance-related disorderly conduct)
 - 4 Continued substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance (e.g. arguments with spouse about consequences of intoxication, physical fights).
- B The symptoms have never met the criteria for Substance Dependence for this class of substance.

SUBSTANCE DEPENDENCE SYNDROME

A maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by three (or more) of the following occurring at any time in the same twelve month period.

- 1 Tolerance, as defined by either of the following:
 - (a) A need for markedly increased amounts of the substance to achieve intoxication or the desired effect
 - (b) Markedly diminished effect with continued use of the same amount of the substance
- 2 Withdrawal, as manifested by either of the following:
 - (a) The characteristic withdrawal syndrome for the substance
 - (b) The same (or closely related) substance is taken to relieve or avoid withdrawal symptoms
- 3 The substance is often taken in larger amounts or over a longer period than was intended
- 4 There was a persistent desire or unsuccessful efforts to cut down or control substance use
- 5 A great deal of time is spent in activities necessary to obtain the substance (e.g. visiting multiple doctors or driving long distances), use the substance (e.g. chain-smoking), or recover from its effects
- 6 Important social, occupational, or recreational activities are given up or reduced because of substance use

*This entry **DSM-IV-TR Criteria for Substance Dependence Syndrome**
continued on next page.*

DSM-IV-TR Criteria for Substance Dependence Syndrome

continued from previous page

- 7 The substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to be caused or exacerbated by the substance (e.g. recurrent cocaine use despite recognition of cocaine-induced depression, or continued drinking despite recognition that an ulcer was made worse by alcohol consumption)

Specify if: **With Physiological Dependence** – evidence of tolerance or withdrawal (i.e. either item 1 or 2 is present)

Without Physiological Dependence – no evidence of tolerance or withdrawal (i.e. neither item 1 nor 2 is present)

Course specifiers:

Early Full Remission

Early Partial Remission

Sustained Full Remission

Sustained Partial Remission

On Agonist Therapy

In a Controlled Environment

OPIOID WITHDRAWAL SYNDROME

292.0

- A Either of the following:
 - 1 Cessation of (or reduction in) opioid use that has been heavy and prolonged (several weeks or longer)
 - 2 Administration of an opioid antagonist after a period of opioid use
- B Three (or more) of the following, developing within minutes to several days after criterion A
 - 1 Dysphoric mood
 - 2 Nausea or vomiting
 - 3 Muscle aches
 - 4 Lacrimation or rhinorrhea
 - 5 Pupillary dilation, piloerection, or sweating
 - 6 Diarrhoea
 - 7 Yawning
 - 8 Fever
 - 9 Insomnia
- C The symptoms in criterion B cause clinically significant distress or impairment in social, occupational, or other important areas of functioning
- D The symptoms are not due to a general medical condition and are not better accounted for by another mental disorder

ICD-10 Criteria for Harmful Substance Use and Substance Dependence Syndrome

HARMFUL SUBSTANCE USE

A pattern of psychoactive substance use that is causing damage to health. The damage may be physical (as in cases of hepatitis from the self-administration of injected drugs) or mental (e.g. episodes of depressive disorder secondary to heavy consumption of alcohol).

Diagnostic Guidelines: The diagnosis requires that actual damage should have been caused to the mental or physical health of the user.

Harmful patterns of use are often criticised by others and frequently associated with adverse social consequences of various kinds. The fact that a pattern of use of particular substance is disapproved of by another person or by the culture, or may have led to socially negative consequences such as arrest or marital arguments is not in itself evidence of harmful use.

Acute intoxication or “hangover” is not in itself sufficient evidence of the damage to health required for diagnosing harmful use.

Harmful use should not be diagnosed if dependence syndrome, a psychotic disorder, or another specific form of drug- or alcohol-related disorder is present.

SUBSTANCE DEPENDENCE SYNDROME

Diagnostic Guidelines: A definite diagnosis of dependence should usually only be made if three or more of the following have been experienced or exhibited at some time during the previous year:

- (i) A strong desire or compulsion to take the substance;
- (ii) Difficulties in controlling substance-taking behaviour in terms of its onset, termination or level of use;
- (iii) A physiological withdrawal state when substance use has ceased or been reduced, as evidenced by: the characteristic withdrawal syndrome for the substance; or use of the same (or closely related) substance with the intention of relieving or avoiding withdrawal symptoms;
- (iv) Evidence of tolerance such that increased doses of the substance are required in order to achieve efforts originally produced by lower doses (clear examples of this are found in alcohol- and opiate-dependent individuals who may take daily doses sufficient to incapacitate or kill nontolerant users);
- (v) Progressive neglect of alternative pleasures or interests because of psychoactive substance use, increased amounts of time necessary to obtain or take the substance or recover from its effects;
- (vi) Persisting with substance use despite clear evidence of overtly harmful consequences, such as harm to the liver through excessive drinking, depressive mood states consequent to periods of heavy substance use, or drug-related impairment of cognitive functioning; efforts should be made to determine that the user was actually, or could be expected to be, aware of the nature and extent of harm.

Narrowing of the personal repertoire of patterns of psychoactive substance use has also been described as a characteristic feature (e.g. a tendency to drink alcoholic drinks in the same way on weekdays and weekends, regardless of social constraints that determine appropriate drinking behaviour).

It is an essential characteristic of the dependence syndrome that either psychoactive substance taking or a desire to take a particular substance should be present; the subjective awareness of compulsion to use drugs is most commonly seen during attempts to stop or control substance use. This diagnostic requirement would exclude, for instance, surgical patients given opioid drugs for the relief of pain, who may show signs of an opiate withdrawal state when drugs are not given, but who have no desire to continue taking drugs.

The dependence syndrome may be present for a specific substance (e.g. tobacco or diazepam), for a class of substances (e.g. opioid drugs); or for a wider range of different substances (as for those individuals who feel a sense of compulsion regularly to use whatever drugs are available and who show distress, agitation and/or physical signs of a withdrawal state upon abstinence).

*This entry ICD-10 Criteria for Substance Dependence Syndrome
continued on next page.*

ICD-10 Criteria for Substance Dependence Syndrome

continued from previous page

The diagnosis of the dependence syndrome may be further specified by the following:

- Currently abstinent
- Currently abstinent, but in a protected environment (e.g. in a hospital, in a therapeutic community, in prison, etc.)
- Currently on a clinically supervised maintenance or replacement regime (e.g. with methadone; nicotine-gum or patch)
- Currently abstinent, but receiving treatment with aversive or blocking drugs (e.g. naltrexone or disulfiram)
- Currently using the substance (active dependence)
- Continuous use
- Episodic use (dipsomania)

A Note on Diagnostic Screening Instruments

The following notes on diagnostic screening instruments have been reproduced with only minor alteration from Sharon Dawe's and Richard Mattick's excellent *Review of Diagnostic Screening Instruments for Alcohol and Other Drug Use and Other Psychiatric Disorders*. This work is readily accessible and a very useful point for further information on the material contained in this section of the appendix.

There are two important aspects to consider in relation to diagnostic screening instruments and what use they may serve in the delivery of any human service including MMT. These aspects are termed the reliability and validity of the instrument and considered together are known as the psychometric properties of the instrument. Broadly speaking the concept of reliability refers to the ability of the instrument to measure a construct consistently, while the term validity is used to describe how accurately an instrument measures what it purports to measure. Reliability is generally more easily established than validity.

Reliability

The reliability of an instrument is determined by the stability of the measurement across time, that is, test-retest reliability; and by internal consistency, or the extent to which items on an instrument measure the same construct.

Test-retest reliability is determined by administering the same instrument on two well-specified occasions and assessing how similar the scores are using correlative techniques.

The internal consistency of an instrument may be determined in a number of ways. One frequently used method is referred to as split-half reliability. An instrument is administered and divided into halves that are scored separately. The results of one half of the test can then be correlated with the results of the other. An alternative method used for determining the internal consistency of an instrument is the use of a statistic known as Cronbach's alpha which is based on the average correlation of the items within a test. If an instrument appears to be measuring more than one construct or domain, a factor analysis may be performed. In this procedure it is possible to determine whether the test items fall into distinct groups and may represent separate factors.

Validity

The validity of an instrument is usually ascertained by reference to independent, external criteria and may be divided into content validity, construct validity and criterion validity.

An instrument is considered to have content validity if it measures all aspects of the particular condition; for example an instrument designed to assess the severity of alcohol withdrawal symptoms would need to include items addressing the broad range of changes which are known to occur on cessation of the use of alcohol.

Construct validity refers to the extent to which an instrument measures a particular construct.

The criterion validity of an instrument refers to the extent to which it corresponds to another accurate measure of the construct. In the context of screening and diagnostic instruments, concurrent validity is one aspect of criterion validity that is particularly important. Studies on concurrent validity look at the relationship between an instrument and the criterion, e.g. a diagnosis. For example, if researchers developed a brief instrument to measure the severity of alcohol dependence they may compare the scores on the new instrument with other standardised measures of alcohol dependence or against a major diagnostic system such as the DSM-IV. In addition to knowing whether an instrument compares favourably with a previously validated instrument, it is important for clinicians to be able to interpret the scores with confidence. Using a statistical procedure (receiver operating characteristics; ROC's) it is possible to determine the score obtained that produces maximum sensitivity (i.e. the instrument correctly identifies subjects with a current diagnosis) and specificity (i.e. it correctly identifies those who do not meet diagnostic criteria). A ROC curve is obtained by plotting sensitivity against false positive rate for all possible cut-off points of the instrument.

Sample Diagnostic Screening Instruments

Severity of Dependence Scale [SDS]

Primary Reference: Gossop, M., Darke, S., Griffiths, P., Hando, J., Powis, B., Hall, W. and Styrang, J. 1995. The Severity of Dependence Scale (SDS): Psychometric properties of the SDS in English and Australian samples of heroin, cocaine and amphetamine users. *Addiction* **90** 607-614.

Possible Score = 15

Scoring:

Each item is scored on a four point scale.

For items 1 to 4:		For item 5:	
Response	Score	Response	Score
Never/almost never	0	Not difficult	0
Sometimes	1	Quite difficult	1
Often	2	Very difficult	2
Always/nearly always	3	Impossible	3

The greater the score, the higher the degree of psychological dependence.

.....
A copy of the Severity of Dependence Scale questionnaire is reproduced overleaf. Providers and consumers should feel free to copy, distribute and use this questionnaire as required.

Severity of Dependence Scale

This questionnaire is going to ask you five questions about your drug use. For each of the five questions we want you to tick the most appropriate response answer.

	Never/ almost never	Sometimes	Often	Always/ nearly always
Do you think your use of opioids is out of control?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the prospect of missing a dose or fix make you anxious or worried?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you worry about your use of opioids?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you wish you could stop?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Not difficult	Quite difficult	Very difficult	Impossible
How difficult do you find it to stop or go without opioids?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Severity of Opioid Dependence Scale [SODQ]

Primary Reference: Sutherland, G., Edwards, G., Taylor, C., Gossop, M. and Brady, R. 1986. The Measurement of Opiate Dependence. *British Journal of Addiction* **81** 479-484.

Possible Score = 63

Scoring:

Each item is scored on a four point scale.

For items 1, 2 and 3 (a-b, d):		For item 3(c):		For item 3(e):	
Response	Score	Response	Score	Response	Score
Never or almost never	0	Not at all	0	Impossible	3
Sometimes	1	A little	1	Very difficult	2
Often	2	Quite a lot	2	Quite Difficult	1
Nearly always	3	A great deal	3	Not difficult	0

.....
A copy of the Severity of Opioid Dependence Scale questionnaire is reproduced overleaf. Providers and consumers should feel free to copy, distribute and use this questionnaire as required.

Severity of Opioid Dependence Scale

AGE: years
GENDER:
 M F

First of all, we would like you to recall a recent month when you were using opiates heavily in a way which, for you, was fairly typical of a heavy use period. Please fill in the month and the year:

MONTH: YEAR:

This questionnaire is going to ask you questions about the way you feel about your drug use for the period you have just nominated. For each of the questions we want you to tick the most appropriate response answer.

I On waking, and before my first dose of opiates:

	Never or almost never	Sometimes	Often	Nearly always
a My body aches or feels stiff	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b I get stomach cramps	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c I feel sick	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d I notice my heart pounding	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e I have hot and cold flushes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f I feel miserable or depressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g I feel tense or panicky	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h I feel irritable or angry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i I feel restless and unable to relax	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j I have a strong craving	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2 Please complete all sections (a-f) of this question:

		Never or almost never	Sometimes	Often	Nearly always
a	I try to save some opiates to use on waking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b	I like to take my first dose of opiates within two hours of waking up	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c	In the morning, I use opiates to stop myself feeling sick	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d	The first thing I think of doing when I wake up is to take some opiates	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e	When I wake up I take opiates to stop myself aching or feeling sick	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f	The first thing I do after I wake up is to take some opiates	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3 Please think of your opiate use during a typical period of drug taking for these questions:

		Never or almost never	Sometimes	Often	Nearly always
a	Did you ever think your opiate use was out of control?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b	Did the prospect of missing a fix (or dose) make you very anxious or worried?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

		Not at all	A little	Quite a lot	A great deal
c	Did you worry about your opiate use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

		Never or almost never	Sometimes	Often	Nearly always
d	Did you wish you could stop?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Impossible	Very difficult	Quite difficult	Not difficult
e	How difficult would you find it to stop or go without?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Subjective Opioid Withdrawal Scale [SOWS]

Primary Reference: Handelsman, L., Cochrane, K., Aronson, M. et al. 1987.
Two New Rating Scales for Opiate Withdrawal *American Journal of Alcohol Abuse* **13** 293-308.

Possible Score = 64

Scoring:

Each item is scored on a four point scale.

For items 1 to 16:	
Response	Score
Not at all	0
A little	1
Moderately	2
Quite a bit	3
Extremely	4

.....
A copy of the Subjective Opioid Withdrawal Scale questionnaire is reproduced overleaf.
Providers and consumers should feel free to copy, distribute and use this questionnaire as required.

Subjective Opioid Withdrawal Scale [SOWS]

Please score each of the 16 items below according to how you feel

NOW

Please tick the most appropriate response.

	SYMPTOM	Not at all	A little	Moderately	Quite a bit	Extremely
1	I feel anxious	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	I feel like yawning	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	I am perspiring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	My eyes are teary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	My nose is running	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	I have goosebumps	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	I am shaking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	I have hot flushes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9	I have cold flushes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	My bones and muscles ache	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11	I feel restless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12	I feel nauseous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13	I feel like vomiting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14	My muscles twitch	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15	I have stomach cramps	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16	I feel like using now	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Objective Opioid Withdrawal Scale [OOWS]

Primary Reference: Handelsman, L., Cochrane, K., Aronson, M. et al. 1987.

Two New Rating Scales for Opiate Withdrawal *American Journal of Alcohol Abuse* **13** 293-308.

Possible Score = 13

Observe the patient during a
5 MINUTE OBSERVATION PERIOD
 then indicate a score for each of the opioid withdrawal signs listed below (Items 1-13).
 Add the scores for each item to obtain the total score.

	SIGN	MEASURES		SCORE
1	Yawning	0 = no yawns	1 = ≥ 1 yawn	<input type="text"/>
2	Rhinorrhea	0 = < 3 sniffs	1 = ≥ 3 sniffs	<input type="text"/>
3	Piloerection (observe arm)	0 = absent	1 = present	<input type="text"/>
4	Perspiration	0 = absent	1 = present	<input type="text"/>
5	Lacrimation	0 = absent	1 = present	<input type="text"/>
6	Tremor (hands)	0 = absent	1 = present	<input type="text"/>
7	Mydriasis	0 = absent	1 = ≥ 3 mm	<input type="text"/>
8	Hot and cold flushes	0 = absent	1 = shivering/ huddling for warmth	<input type="text"/>
9	Restlessness	0 = absent	1 = frequent shifts of position	<input type="text"/>
10	Vomiting	0 = absent	1 = present	<input type="text"/>
11	Muscle twitches	0 = absent	1 = present	<input type="text"/>
12	Abdominal cramps	0 = absent	1 = holding stomach	<input type="text"/>
13	Anxiety	0 = absent	1 = mild – severe	<input type="text"/>
TOTAL SCORE				<input type="text"/> <input type="text"/>

Short Opiate Withdrawal Scale [SOWS]

Primary Reference: Gossop, M. 1990. The Development of a Short Opiate Withdrawal Scale *Addictive Behaviours* **15** 487-490.

Possible Score = 40

Scoring:

Each item is scored on a four point scale.

Response	Score
None	1
Mild	2
Moderate	3
Severe	4

Mark the appropriate box if the patient has suffered from any of the following conditions in the last 24 hours.

RATING	None	Mild	Moderate	Severe
Feeling sick	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Stomach cramps	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Muscle cramps/twitching	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Feeling of coldness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Heart pounding	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Muscular tension	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Aches and pains	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Yawning	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Runny eyes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Insomnia/sleeping problems	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Glossary of Clinical Terms Used in the Assessment of Opioid Dependence and Withdrawal.

Clinical Term	Common Corollary
Anorexia	appetite loss
Diaphoresis	excessive perspiration
Diarrhoea	excessively frequent and liquid bowel movement
Gastralgia	abdominal cramps
Hypertension	high blood pressure
Insomnia	abnormal wakefulness
Lacrimation	weeping eyes
Malaise	general aches and pains
Mydriasis	pupillary dilation
Piloerection	gooseflesh
Rhinorrhea	running nose
Tachycardia,	rapid pulse

APPENDIX D: CONSUMER CONSENT AND ACKNOWLEDGMENT FORMS

Methadone is a drug of dependence, and persons in MMT transfer their dependence on illicit opioids to methadone. While methadone dependency is generally less hazardous than dependency on illicit opioids, MMT is not altogether free of risks for the consumer.

For these reasons is compulsory for providers of MMT to obtain the full consent of consumers before initiating treatment. It is also important to ensure consumers understand certain issues surrounding MMT and its successful delivery.

Such consent and acknowledgment of receipt of information can be formalised using a document such as reproduced on the following pages. Providers should feel free to copy and use this pro forma as they require.

ACT HEALTH - COMMUNITY HEALTH
ALCOHOL AND DRUG PROGRAM



CONSENT TO OPIOID AGONIST TREATMENT

I, _____, do hereby authorise and give voluntary consent to
(Name of Consumer)

Dr _____ of _____
(Name of Clinician) (Name of Clinic)

and/or any appropriately authorised assistant personnel to prescribe for me and/or administer to me the addictive,
opioid drug(s): ☐ methadone ☐ buprenorphine ☐ levo- α -acetylmethadol.

This prescription and administration is an element of the treatment for my diagnosed dependency on opioids. The treatment procedures have been explained to me and I understand that I will be required to take the prescribed opioid according to the schedule determined by the prescriber in order to aid in controlling my dependence on opioids.

It has been explained to me that methadone, levo- α -acetylmethadol and buprenorphine are drugs that can be harmful if taken without medical supervision or in ways contrary to medical direction. I further understand that methadone, levo- α -acetylmethadol and buprenorphine are addictive medications and they may produce adverse effects. I have had alternate treatment methods explained to me, and I desire to receive opioid agonist treatment to help manage the risk of my dependent opioid use.

I understand that I may withdraw my consent for treatment, withdraw from the treatment program and discontinue the use of the drug at any time. If I choose to do this I shall be provided with detoxification from the opioid agonist under medical supervision.

I declare that I have not knowingly supplied and false information to the prescribing doctor today regarding my opioid use.

I agree to participate in methadone treatment at _____ and to abide by the
conditions of the program. (Name of Clinic)

I certify that no guarantee has been given as to the clinical outcome of opioid agonist treatment. With full knowledge of the potential benefits and attendant risks, I consent to receive the opioid agonist treatment detailed on this declaration.

SIGNATURE OF CONSUMER

DATE OF BIRTH

DATE

_____/_____/_____
SIGNATURE OF PARENT(S) OR GUARDIAN(S)

_____/_____/_____
RELATIONSHIP

_____/_____/20____
DATE

SIGNATURE OF WITNESS

NAME OF WITNESS

_____/_____/20____
DATE

ACT HEALTH - COMMUNITY HEALTH
ALCOHOL AND DRUG PROGRAM



**ACKNOWLEDGEMENT OF RECEIPT OF INFORMATION REGARDING
OPIOID AGONIST TREATMENT**

I, _____, do hereby acknowledge receiving and
(Name of Consumer)

understanding of the following information regarding opioid agonist treatment with an approved opioid.

- Methadone, levo- α -acetylmethadol and buprenorphine are drugs of dependence and I will be transferring my dependence on other opiates to dependence on one of these drugs;
- The use of other drugs such as alcohol, benzodiazepines or other opiates may be hazardous in combination with methadone, levo- α -acetylmethadol or buprenorphine, and could lead to overdose, coma, respiratory failure and death;
- My dose of methadone, levo- α -acetylmethadol or buprenorphine may be reduced or withheld in the event that I present to collect my dose intoxicated with alcohol or other drugs;
- It is an offence to drive a motor vehicle whilst under the influence of a drug so that the influence impairs my capacity to control a motor vehicle. Methadone, levo- α -acetylmethadol or buprenorphine may impair my ability to drive a motor vehicle, operate machinery or engage in sporting activity, especially during periods of dose change;
- I have been provided with an information brochure regarding opioid agonist treatment, and a booklet regarding the program;
- Where applicable, I agree that I will transfer to the Community Methadone program once staff at the Public Clinic feel that it is appropriate for me to do so. I understand that a fee of \$15.00 per week applies to the Community Methadone program.

I understand that my treatment may be terminated without my consent for any of the following reasons:

- Violence, threatened violence or verbal abuse towards other consumers or staff;
- Failure to attend treatment for 7 or more consecutive days;

• Unlawful entry onto premises, diversion or attempted diversion of methadone from the clinic or pharmacy, or theft from other consumers, staff, the clinic or pharmacy.

SIGNATURE OF CONSUMER

DATE OF BIRTH

DATE

SIGNATURE OF PARENT(S) OR GUARDIAN(S)

RELATIONSHIP

DATE

SIGNATURE OF WITNESS

NAME OF WITNESS

DATE

_____/_____/20____

APPENDIX E: GUIDELINES FOR MANDATORY REPORTING OF CHILD ABUSE

Sources for Information

The following information regarding mandatory reporting requirements in the ACT has been collated from the document *Mandatory Reporting – Keeping Children Safe, A Shared Responsibility: Reporting Child Abuse – A guide for health care workers* published by the Department of Education and Community Services. This publication is available from the Department of Education and Community Services website at www.decs.act.gov.au or by contacting the Child Abuse Prevention and Education Unit on 02) 6207 1382. Some information has also been included from the *Children and Young People Act (Australian Capital Territory) 1999*. This legislation can be purchased in hard copy by contacting the Department of Urban Services Publishing Services Unit on 02) 6205 0552 or downloaded for free from one of the following online legislation archives:

- Australian Legal Information Institute AustLII www.austlii.edu.au
- Commonwealth Attorney General's Department ScalePLUS scaleplus.law.gov.au

Introduction

Keeping children safe and ensuring that they grow up in environments in which they can "fare well" is a responsibility shared by governments and the whole community.

By and large, the prevention of child abuse and the protection of children from abuse is carried out by those people closest to the child; the family. When the family is unable to protect children the responsibility is taken up by the community and finally at the extreme end of the continuum, the statutory agencies.

The investigation of reports of child abuse by ACT Family Services is one component of a much greater national strategy to address the problem of child abuse and neglect of Australian children.

The ACT's Child Abuse Prevention Strategy developed in conjunction with the many Family Support agencies in the ACT will continue to develop a focus on prevention which provides opportunities for all members of the community to assist families in their difficult task of raising children.

The following text reproduces the current ACT legislative basis for compulsory reporting:

CHILDREN AND YOUNG PEOPLE ACT 1999

SECT 158

Voluntary reporting

A person who believes or suspects that a child or young person is in need of care and protection may report the circumstances on which the belief or suspicion is based to the chief executive.

SECT 159

Mandatory reporting

(1) This section applies to a person who is-

- (a) a doctor; or
- (b) a registered dentist within the meaning given by the *Dentists Act 1931*, section 3; or
- (c) a person who is an enrolled nurse or a registered nurse within the meaning of the *Nurses Act 1988*, section 3; or
- (d) a teacher at a school; or
- (e) a police officer; or
- (f) a person employed to counsel children or young people at a school; or
- (g) a person caring for a child at a child-care centre; or
- (h) a person coordinating or monitoring the provision of home-based care on behalf of a family day care scheme licensee; or
- (i) a public servant who, in the course of his or her employment, provides services related to the health or wellbeing of children, young people or families; or
- (j) the community advocate; or
- (k) the official visitor; or
- (l) a prescribed person.

(2) If-

- (a) an adult to whom this section applies reasonably suspects that a child or young person has suffered, or is suffering, sexual abuse or non-accidental physical injury; and
- (b) those grounds arise during the course of or from the persons work (whether for remuneration or otherwise); the person must, as soon as practicable, report to the chief executive the name, or a description, of the child or young person and the grounds for the persons suspicion.

Maximum penalty: 50 penalty units, imprisonment for 6 months or both.

SECT 160

Report other than in good faith

A person must not make a report under section 158 or 159 other than in good faith.

Maximum penalty: 50 penalty units, imprisonment for 6 months or both.

Principles of Intervention - Keeping the Balance

It is important that mandated professionals understand key principles of practice in the system providing care and protection services.

- The overall well being and long term interests of children are generally best met within their own families. Every effort should be made to help children remain safely at home.
- Where ever possible children requiring out of family care should be assisted to maintain and develop links with their natural families.
- Any intervention with children and families should be the least invasive as the circumstances allow
- Service delivery must be responsive to individual needs and be culturally sensitive
- People affected by decisions, particularly children and young persons, have a right to be included in the decision making process
- The needs of children are best met when professionals work together to promote a cooperative partnership which fosters trust and mutual respect for each other's roles.

Identifying Child Abuse

Under the law, as a mandated notifier you are obliged to notify ACT Family Services when you have formed a suspicion based on reasonable grounds that a child has been physically or sexually abused.

What are reasonable grounds?

There may be reasonable grounds to notify when:

- a child tells you he or she has suffered non accidental physical injury or has been sexually abused
- someone else tells you that a child has been abused, or
- your own observations of the child's physical condition or behaviours lead you to believe that the child has suffered non accidental physical injury or sexual abuse.

You do not have to prove that abuse has occurred. Your role as a mandated person is to report your suspicion or ensure that it is reported in accordance with your agency protocol.

Categories of child abuse

In most situations, child abuse is not an isolated incident but a pattern of behaviour occurring over a period of time, the effects of which are cumulative.

The abuse of children falls into several categories: physical abuse, sexual abuse, emotional abuse, and neglect. Most children who come to the attention of ACT Family Services are suffering harm as a result of a combination of these categories of abuse.

- Physical Abuse

Physical abuse refers to non accidental injury to a child.

It includes any injury caused by excessive discipline, severe beatings or shakings. Physical abuse may result in a range of injuries from soft tissue injuries to dislocations and fractures. It may also include poisoning, attempted suffocation or strangulation and death.

There are three types of indicators of physical abuse to children.

1. verbal disclosures by the child.
2. physical injuries found in locations where it is unlikely a child has injured himself or herself, or where the very nature of the injury itself is of concern.
3. behavioural indicators which reflect:
 - emotional problems eg. signs that the child may be extremely anxious or depressed (such behaviours are non specific and very often reflect childhood problems other than abuse), and/or
 - the need the child has to "deal with" violent behaviour by mimicking it or expressing it in ways that are outside the normal boundaries of childhood aggression.

- Sexual Abuse

Child sexual abuse refers to any sexual behaviour between a child and an adult or an older, bigger, or more powerful person, for that person's sexual gratification.

The range of sexual behaviours that are considered harmful to children is very broad. It includes:

- any form of sexual touching (fondling genitals, buttocks, breasts, abdomen, thighs; any oral/genital contact; penile or digital penetration);
- any form of sexual suggestion to children, including the showing of pornographic videos;
- the use of children in the production of pornographic videos or films;
- exhibitionism; and
- child prostitution.

Sexual abuse often involves a progression in behaviour from fondling to intercourse; this may occur quickly or over a period of years.

Child sexual abuse is difficult to detect because of the secrecy that surrounds it. Children are frequently threatened or coerced into remaining silent and are frightened of the consequences if they disclose the abuse. Adults are often reluctant to openly discuss sexuality with children, or to interfere in what they see as private family matters. These factors all contribute to a climate of secrecy which means that a child will not often disclose sexual abuse directly.

There are three types of indicators of child sexual abuse:

1. verbal disclosures
2. physical signs or injuries; and
3. behavioural indicators, which reflect:
 - emotional problems eg: signs that the child is extremely anxious or depressed (such behaviours are often non specific and may reflect childhood problems other than abuse), and/or
 - the need the child has to "deal with" the sexual behaviour by mimicking it; or expressing it in some way which is outside the boundaries of normal childhood sexual behaviour.

The most likely sign that a child has been sexually abused is a disclosure from the child. All other signs or indicators need to be carefully considered within a context of other signs, and in consultation with experienced professionals.

Confidentiality.

Confidentiality and privacy are important but must not override the safety of children. It is important, however to respect the privacy of the child and family so sharing of information should be strictly on a need to know basis.

Where a person in good faith notifies Family Services the notification shall not be taken to be a breach of confidence or of professional etiquette or ethics or of a rule of professional conduct. (Sect 29, *Children and Young Persons Act (Australian Capital Territory) 1999*).

Should my client/patient be forewarned that I may be compelled to notify?

It is fair and ethical to make clear to people legal responsibilities of this kind. Many agencies currently address this issue by:

- including a verbal explanation of the limitations on confidentiality at the beginning of their relationship with a client or patient, and/or
- placing a sign in the agency reception area or in agency newsletters which clearly state the legislative responsibilities in relation to mandatory reporting.

Contacts

Mandatory reporting is a difficult area to negotiate for professionals with limited experience dealing with cases of suspected child abuse. Before any professional engaged with MMT delivery in the ACT suspects that they may be in a position of obligation to notify, it is strongly recommended that they contact one of the agencies below for free and confidential advice as to how they should proceed.

ACT Family Services	02) 6207 1069 (Northside)
	02) 6207 1466 (Southside)
After Hours Crisis Service (NSW Residents)	02) 6207 0720

APPENDIX F: IMPORTANT PHARMACOKINETIC AND PHARMACODYNAMIC CONTRAINDICATIONS.

CNS Depressants

It should be noted that all CNS depressant substances are extremely dangerous in combination with methadone. Drug use involving opioid, benzodiazepine and alcohol class substances is frequently encountered in MMT management and should be very closely monitored. Tricyclic antidepressant class substances also increase the CNS depressant effects of methadone and their use should be very carefully monitored in cases where a client in MMT also requires antidepressant therapy.

CYP 3A- Mediated Metabolism

The hepatic cytochrome P450 (CYP) 3A4 is one of the key mechanisms by which methadone is N-demethylated within the body to produce the major metabolite EDDP. Accordingly, other important groups of drugs with significant methadone interaction include those that reduce or increase drug clearance through interactions with the metabolism mediated by the CYP 3A- group of enzymes, particularly CYP 3A4.

Inhibitors of CYP 3A4 mediated metabolism have the potential to reduce the clearance of methadone from the body and thus increase the chance of a particular dosage producing overdose effects. CYP 3A4 inhibitors significant for many MMT clients include groups of modern HIV/AIDS antiretroviral and protease inhibition pharmacotherapies, SSRI and SNRI ¹⁹ antidepressant pharmacotherapies, some hormone therapies, calcium channel antagonists and some antibiotics.

Inducers of CYP 3A4 mediated metabolism have the potential to increase the clearance of methadone from the body and thus increase the chance of a particular dosage producing withdrawal effects. CYP 3A4 inducers significant for many MMT clients include some groups of antiepileptics, glucocorticoids and some groups of tuberculosis pharmacotherapies.

¹⁹ SSRI = selective serotonin reuptake inhibitors

SNRI = serotonin / norepinephrine reuptake inhibitors

Schedule of Major Contraindicated Drugs

The following schedule is reproduced with permission extant from Andrew Preston's widely distributed *The Methadone Briefing*. It has been previously reproduced with amendment in the *National Policy on Methadone Treatment*. The items are arranged alphabetically. It is very important to remember that while this list is a good guide to major potential reactions with methadone it is not exhaustive. Pharmacy is a rapidly evolving field with new drugs and new information about established drugs becoming available every day.

Clinicians should follow their usual procedures for determining the potential risk of various drug therapies in combination with methadone and should not rely solely upon the information contained in this document. Consumers should always check with their clinician or pharmacist before starting any drug therapy in combination with their methadone regimen and should not rely solely upon the information contained in this document.

Drug	Degree of interaction	Effect	Mechanism
Alcohol		Increased sedation	Additive CNS depression
Barbiturates	Moderate	Reduced methadone levels, raised sedation	Raised hepatic metabolism, additive CNS depression
Benzodiazepines		Enhanced sedative effect	Additive CNS depression
Buprenorphine		Antagonist effect	Can only be used safely in low-dose (20mg or less daily) methadone treatment
Carbamazepine	Moderate	Reduced methadone levels	Raised hepatic metabolism; methadone may need BD dosing regime
Chloral hydrate		Increased sedation	Additive CNS depression
Chlormethiazole		Increased sedation	Additive CNS depression
Cimetidine	Moderate	Possible increase in methadone levels	Inhibits hepatic enzymes involved in methadone metabolism
Cisapride		Morphine has an increased rate of onset of action and increased sedative effect when used with these drugs	Unknown
Domperidone			
Metoclopramide			
Cyclizine	Severe	Injection with opiates causing hallucinations reported	Unknown

This entry ***Schedule of Major Contraindicated Drugs***
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Schedule of Major Contraindicated Drugs
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Drug	Degree of interaction	Effect	Mechanism
Codeine		Enhanced sedative effect	Additive CNS depression
Desipramine	Moderate	Raised desipramine levels (x2)	Unknown – interaction not seen with other tricyclic antidepressants
Dextropropoxyphene		Enhanced sedative effect	Additive CNS depression
Disulfiram (Antabuse)	Dependant on methadone formulation	Full 'therapeutic' alcohol adverse reaction	Some methadone preparations contain alcohol
MAOI antidepressants including moclobemide and selegiline	Severe with pethidine, although rare with methadone concurrent use should be avoided	CNS excitation – delirium, hyperpyrexia, convulsions or respiratory depression	Unknown
Naltrexone	Severe	Reverses the effects of methadone in overdose (long acting)	Opiate antagonist, works by competing for opiate receptors
Naloxone	Severe	Reverses the effects of methadone in overdose (short acting)	Opiate antagonist, works by competing for opiate receptors
Phenobarbitone	Moderate	Reduced methadone levels	Raised hepatic (liver) metabolism – see carbamazepine
Phenytoin	Moderate	Reduced methadone levels: withdrawal symptoms	Raised hepatic (liver) metabolism – see carbamazepine
Rifampicin	Severe	Reduced methadone levels: withdrawal symptoms	Raised hepatic (liver) metabolism
Tricyclic antidepressants e.g. amitriptyline	Moderate	Increased sedation	Unknown
Urine acidifiers e.g. ammonium chloride		Reduced methadone levels	Raised urinary excretion
Urine alkalinisers e.g. sodium bicarbonate	Moderate	Raised methadone levels	Reduced urinary excretion
Zidovudine		Raised levels of zidovudine possible	Unknown
Zopiclone		Increased sedation	Additive CNS depression