

NATIONAL PHARMACOTHERAPY POLICY

For people dependent
on opioids

January 2007



Foreword

These guidelines were prepared by a working group of the Intergovernmental Committee on Drugs, and funded by the Australian Government.

These guidelines have been prepared to provide a broad policy context and a framework for State and Territory policies and guidelines that are concerned with the treatment of opioid dependence with methadone, buprenorphine and naltrexone. For clinical matters associated with pharmacotherapy treatments please refer to respective national clinical guidelines.

The contribution of various individuals in the drafting and review process is gratefully acknowledged. In particular, thanks are due to the members of the working group:

Associate Professor Robert Ali (Chair, Drug and Alcohol Services South Australia); Professor Bob Batey (New South Wales Department of Health); Ms Lynne Biggs (Queensland Department of Health); Chris Boag (Victorian Department of Human Services); Dr Jeremy Hayllar (Queensland Department of Health); Dr Allan Quigley (Western Australian Department of Health) and Mr Bruce Wight (Australian Government Department of Health and Ageing).

Both methadone and buprenorphine are listed in Australia as Schedule 8 drugs under the *Standard for the Uniform Scheduling of Drugs and Poisons No. 21*. As drugs of dependence, they have strict regulatory frameworks around their use, particularly with respect to their use in the management of opioid dependence. In contrast, naltrexone is listed as a Schedule 4 drug and, as such, has fewer regulatory controls associated with its use. For this reason this policy document is divided into three sections:

Section 1: general treatment issues, common across all pharmacotherapies;

Section 2: the use of the Schedule 8 drugs – methadone and buprenorphine – in the management of opioid dependence; and

Section 3: the use of naltrexone in the management of opioid dependence.

The information contained in this policy should be read in conjunction with agreed National Clinical Guidelines for the use of methadone¹, buprenorphine² and naltrexone maintenance³.

1 *Clinical Guidelines and Procedures for the use of Methadone in the Maintenance Treatment of Heroin Dependence*, Commonwealth of Australia (2003)

2 *National Clinical Guidelines and Procedures for the use of Buprenorphine in the Treatment of Opioid Dependence*, Commonwealth of Australia (2006)

3 *Clinical Guidelines and Procedures for the use of Naltrexone in the Management of Opioid Dependence*, Commonwealth of Australia (2003)

The following pharmacotherapies for opioid dependent people are registered in the *Australian Register of Therapeutic Goods*:

Methadone oral liquid – Methadone Syrup® is registered for the treatment of dependence on opioid drugs, and Biodone Forte® is registered for the detoxification and maintenance treatment of dependence on opioid drugs.

Buprenorphine sublingual tablet (Subutex® and Suboxone®) – buprenorphine is registered for the treatment of opioid dependence, including maintenance and detoxification, within a framework of medical, social and psychological treatment. (Note that Suboxone® is a combination product containing both buprenorphine and naloxone).

Naltrexone tablet (ReVia®) – naltrexone is registered as adjunctive therapy in the maintenance of formerly opioid-dependent patients who have ceased the use of opioids such as diamorphine (heroin) and morphine.

ReVia® tablets are listed in the Pharmaceutical Benefits Schedule (PBS) for use within a comprehensive treatment program for alcohol dependence with the goal of maintaining abstinence. The PBS notes that naltrexone is contraindicated in patients receiving opioid drugs.

Table of Contents

FOREWORD	iii
INTRODUCTION	1
Management of Drug Dependence	1
Pharmacotherapies for Opioid Dependence	2
1. Methadone	2
2. Buprenorphine	3
3. Naltrexone	4
SECTION 1 TREATMENT WITH PHARMACOTHERAPIES	7
1.1 Goals of Treatment	7
1.2 Optimising the Benefits of Pharmacotherapy Treatment	7
1.2.1 Quality of Care	7
1.3 Assessment for Treatment	8
1.4 Informed Consent	8
1.5 Rights and Responsibilities	9
1.6 Monitoring Drug Use	9
1.7 Maintenance of Client Records	9
1.8 Aftercare and Assertive Follow-up	10
1.9 Accreditation/Service Standards	10
1.10 Safe Storage and Transport	10
1.11 Management of Special Client Groups	10
1.11.1 HIV/AIDS	10
1.11.2 Hepatitis A and B	11
1.11.3 Hepatitis C	11
1.11.4 Prisoners	12
1.11.5 Polydrug Use	12
1.11.6 Comorbidities	13
1.11.7 Pregnancy	13
1.11.8 Driving	13
1.11.9 Aboriginal and Torres Strait Islander Peoples	14

SECTION 2	TREATMENT WITH SCHEDULE 8 DRUGS – METHADONE AND BUPRENORPHINE	15
2.1	Approval of Pharmacotherapy Prescribers	15
2.2	Other Service Providers	15
2.3	Authorisation of Prescribing Methadone and Buprenorphine	16
2.4	Facilitated Entry	16
2.5	Methadone	16
2.6	Buprenorphine	16
2.6.1	Buprenorphine Dosing	16
2.6.2	Buprenorphine Withdrawal	17
2.6.3	Buprenorphine Maintenance	17
2.7	Acute Pain	18
2.8	Chronic Pain	18
2.9	Takeaway Doses	18
2.9.1	Preparation and responsibility for takeaways	19
2.9.2	Dilution of methadone takeaway doses	20
2.9.3	Takeaway doses of buprenorphine	20
2.10	Transfers - Interstate	20
2.11	Overseas Travel	20
2.12	Treatment Termination	21
2.12.1	Voluntary termination	21
2.12.2	Involuntary termination	22
2.13	Monitoring and Regulation	22
SECTION 3	NALTREXONE	23
3.1	Suitability of Naltrexone Treatment	23
3.2	Opioid Withdrawal Treatment	23
3.3	Naltrexone Relapse Prevention Treatment	23
3.4	Medication compliance	24
3.5	Overseas Travel	24
3.6	Diverted Naltrexone	24

Introduction

The purpose of the *National Pharmacotherapy Policy for People Dependent on Opioids* is to provide a broad policy context and framework for State and Territory policies and guidelines. These jurisdictional policies and guidelines will address clinical issues and jurisdictional/legislative requirements. Where there is any conflict between jurisdictional policies and the national policy, the jurisdictional policy and clinical guidelines shall prevail.

In addition, detailed national clinical guidelines for the prescribing of methadone, buprenorphine and naltrexone for the management of opioid dependence have been developed under the auspices of the (former) National Expert Advisory Committee on Illicit Drugs. These guidelines form companion documents to the *National Pharmacotherapy Policy for People Dependent on Opioids*.

Management of Drug Dependence

Drug dependence is a condition characterised by a strong desire to use a drug, with repeated use that takes priority over other activities despite drug-related legal, interpersonal and health problems. The opioid dependence syndrome may appear in varying degrees in different individuals and is characterised by a maladaptive pattern of opioid use, leading to clinically significant impairment or distress, as manifested by three or more of the following occurring in the same 12 month period⁴:

- 1) Tolerance, as defined by either of the following:
 - a) need for markedly increased amounts of the opioid to achieve intoxication or desired effect; and
 - 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; and
 - b) the same (or closely related) opioid is taken to relieve or avoid withdrawal symptoms.
- 3) The opioid is often taken in larger amounts or over a longer period than was intended.
- 4) Unsuccessful efforts or a persistent desire to cut down or control opioid use.
- 5) A great deal of time is spent in activities necessary to obtain opioids (e.g. visiting multiple doctors or driving long distances), use the opioid, or recover from its effects.
- 6) Important social, occupational, or recreational activities are given up or reduced because of opioid use.
- 7) Continued opioid use despite knowledge of having had a persistent or recurrent physical or psychological problem that is likely to be caused or exacerbated by the opioid.

The severity of dependence can range from mild to severe. Most heroin users report one to two years between their first use of heroin and their first period of dependent use.

⁴ This definition of dependence is based on *The diagnostic and statistical manual of mental disorders*, 4th edition (DSM-IV)

The 2004 National Drug Strategy Household Survey found that 0.5% of Australians aged 14 years and older had used heroin, methadone (not for maintenance treatment) or other opioid drugs in the previous 12 months. Of these users, 45% used opioids daily or weekly. Approximately one in four people who use heroin will become dependent. Opioid dependence can result in a range of problems for the user, their family and friends and for the wider community. These problems include health and social costs, including the risk of overdose, spread of blood borne viruses, and family breakdown; health costs (to both the individual and the community); economic costs associated with morbidity, mortality and absenteeism related to illicit drug use; and the cost of law enforcement for drug related crime.

The availability of treatment services for drug users remains integral to the National Drug Strategic Framework. It is recognised that the provision of treatment services for people who are drug dependent reduces drug use and prevents drug-related harm. As outlined in the Framework, there is an expectation in the community and among drug users and their families that treatment services will be accessible, regardless of age, race, gender, sexual preference and location. Pharmacotherapies need to be considered within this broader context of drug treatment.

The range of services available should be comprehensive and address the individual nature and different stages of people's drug use. This is especially important when considering treatment for Aboriginal and Torres Strait Islander Peoples, as they may be reluctant to leave their family and country for treatment. Lack of choice for individuals seeking treatment has been identified as a common concern, particularly where no Aboriginal and Torres Strait Islander organisations provides services⁵.

Pharmacotherapies for Opioid Dependence

There are now a number of pharmacotherapies for the management of opioid dependence available in Australia:

Methadone

Methadone was developed in Germany in 1941 for the relief of pain. It was used as a treatment for heroin dependence in New York in 1964 and was subsequently introduced in Australia for the same purpose in 1969. Methadone is currently the most common pharmacotherapy used in Australia and is recognised nationally and internationally as an effective method for treating opioid dependence.

Methadone is a synthetic opioid **agonist** primarily used in maintenance therapy and may also be used as a withdrawal agent for those dependent on opioids. Methadone reduces the use of heroin through cross tolerance which results in a reduction of heroin withdrawal symptoms, less desire to use heroin, and reduced euphoric effect when heroin is used. Methadone is taken orally on a daily basis.

Methadone is listed under Schedule 8 of the *Standard for the Uniform Scheduling of Drugs and Poisons* and is registered on the Australian Register of Therapeutic Goods as Methadone Syrup (5mg/mL) for the treatment of dependence on opioid drugs, and Biodone Forte (5mg/mL) for the detoxification and maintenance of dependence on opioid drugs. Methadone tablets and injections are registered in Australia for analgesia but not for the treatment of opioid dependency.

5 *National Drug Strategy Aboriginal and Torres Strait Islander Peoples Complementary Action Plan 2003-2006*
Commonwealth of Australia 2003

There is consistent evidence from controlled trials, longitudinal studies and program evaluations that methadone substitution treatment for heroin users is associated with reductions in heroin use, criminal activity, deaths due to overdose, and behaviours associated with a high risk of HIV transmission⁶. Methadone substitution treatment has been found to be more effective than no treatment, placebo, detoxification alone, and drug-free treatment in retaining opioid-dependent people in treatment and reducing heroin use⁷.

For those retained in treatment, daily illicit opioid use reduces from 100% of persons entering treatment to less than 20% of persons within one year. Higher doses of methadone are associated with greater reductions in heroin use than either moderate or low doses.

At June 2005 there were approximately 39,000 clients in pharmacotherapy treatment in Australia. Since 1985-86 the number of people receiving pharmacotherapies for opioid dependence has increased by around 14% per annum. This rate of growth appears to be slowing, possibly reflecting recent interruptions to heroin supplies in Australia. Arrangements differ in each jurisdiction, but there has generally been an increasing reliance on the private sector for the provision of pharmacotherapy services in Australia. Among clients receiving pharmacotherapy treatment at June 2005, 70% received the treatment from a private prescriber, 24% from a public prescriber and 7% from a correctional facility. The number of clients attending private prescribers has increased by approximately 20% per annum since 1985-86.⁸

Buprenorphine

Buprenorphine (Temgesic^{®9}) has been used in many countries (including Australia) since the 1980s as a pain-relieving drug. The use of buprenorphine for treating opioid dependence started in the 1980s and buprenorphine (Subutex[®]) has since been approved for the treatment of opioid dependency in several countries, including France, which became the first country to use buprenorphine as a substitution therapy in 1996. By 1998, 55,000 patients were in buprenorphine treatment in France.

Buprenorphine is often called a mixed opioid agonist/antagonist drug but is more accurately described as a partial opioid **agonist** with high receptor affinity. It has actions similar to the full agonist drugs but with less efficacy such that increases in dose have progressively less increase in effect. Dose increases beyond that required to saturate all receptor sites will cause a prolonged duration of action with the consumption of other opioids having little or no further effect .

This receptor blockade state is reached in opioid tolerant people below the threshold of loss of consciousness and suppression of respiration which is usually associated with opioid overdose. This action appears to make buprenorphine safer than methadone in overdose and also protects from overdose effects if other opioids are taken in addition to prescribed buprenorphine. Higher receptor

-
- 6 Teesson M, Ross J, Darke S, Lynskey M, Ali R, Ritter A et al. One year outcomes for heroin dependence: Findings from the Australian Treatment Outcome Study (ATOS). *Drug & Alcohol Dependence* 2006; 83(2):174-180.
Gossop M, Marsden J, Stewart D, Rolfe A. Patterns of improvement after methadone treatment: 1 year follow-up results from the National Treatment Outcome Research Study (NTORS). *Drug & Alcohol Dependence* 2000; 60:275-286.
National Institutes of Health. Consensus Development Statement: Effective Medical Treatment of Heroin Addiction (1997). Available from: http://odp.od.nih.gov/consensus/cons/108/108_intro.htm .
Gowing, L, Farrell M, Bornemann R & Ali R (2004). Substitution treatment of injecting opioid users for prevention of HIV infection [Cochrane Review]. In: *The Cochrane Library*, Issue 4. Chichester, UK: John Wiley & Sons, Ltd.
- 7 Mattick RP, Breen C, Kimber J, Davoli M. Methadone maintenance therapy versus no opioid replacement therapy for opioid dependence. *Cochrane Database of Systematic Reviews: Reviews* 2003 Issue 2. Chichester, UK: John Wiley & Sons, Ltd. DOI: 10.1002/14651858.CD002209.
- 8 Australian Institute of Health and Welfare. 2005 National Opioid Pharmacotherapy Statistics Annual Data (NOPSAD) statistical report, June 2006.
- 9 Not used for treatment of opioid dependence.

affinity causes displacement of other opioids from the opioid receptor. This may be observed as withdrawal in a person who is opioid dependent.

Buprenorphine (as Subutex®) was included on the Australian Register for Therapeutic Goods in October 2000. A second sublingual tablet preparation, Suboxone®, containing buprenorphine and naloxone (the combination product) was approved by the Therapeutic Goods Administration on 27 July 2005. Both preparations are listed under Schedule 8 of the *Standard for the Uniform Scheduling of Drugs and Poisons* for the management of opioid dependence within a framework of medical, social and psychological treatment. Buprenorphine is indicated for use in maintenance and detoxification treatment of opioid dependence.

Buprenorphine is considered an important alternative to methadone for the treatment of opioid dependence, and may attract more people into treatment. Buprenorphine offers potential advantages in terms of safety, the relative ease of withdrawal, the need for less frequent administration, ease of transition into other treatments and flexibility of treatment.

The effectiveness of buprenorphine is similar to that of methadone in terms of reduction of illicit opioid use and improvements in psychosocial functioning; however buprenorphine may be associated with lower rates of retention in treatment¹⁰.

Naltrexone

In the 1970s there was much enthusiasm in the United States of America about the use of naltrexone for the treatment of opioid dependence. However, research evidence on the effectiveness of oral naltrexone maintenance treatment remains limited¹¹ and recent experience indicates that this treatment has limited acceptability and rates of dropout from treatment are relatively high. In a recent study in Melbourne¹² only 30% of people screened entered naltrexone treatment, and only 30% of those remained in treatment for the full 12 weeks of the study. Patient motivation and supervision of daily naltrexone dosing by a responsible adult appear to be important predictors of success. To date, best results have been obtained with groups such as health professionals and prisoners. Young people whose family networks have remained intact are also good candidates for naltrexone maintenance treatment.

Naltrexone is an opioid **antagonist**. Antagonists bind to opioid receptors, without producing opioid effects, and block both the analgesic and euphoric effects of opioid agonists, such as heroin, on the receptor sites. Naltrexone is long acting with few side effects; however patients need to become opioid free before naltrexone is taken as it induces strong withdrawal symptoms in people who are opioid dependent. Naltrexone is quickly absorbed after oral administration. Naltrexone does not cause dependence and for most people its side effects are minimal.

Naltrexone is listed in Schedule 4 of the *Standard for the Uniform Scheduling of Drugs and Poisons*. Naltrexone was entered in the Australian Register of Therapeutic Goods in January 1999, as ReVia film coated tablets (50mg). ReVia is registered in Australia for use as part of a comprehensive treatment program for alcohol dependence and as an adjunctive therapy in the maintenance of formerly opioid dependent patients who have ceased the use of opioids (detoxified).

10 Mattick RP, Kimber J, Breen C, Davoli M. Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. *Cochrane Database of Systematic Reviews: Reviews 2003 Issue 2*. Chichester, UK: John Wiley & Sons, Ltd. DOI: 10.1002/14651858.CD002207.pub2

11 Minozzi S, Amato L, Vecchi S, Davoli M, Kirchmayer U, Verster A. Oral naltrexone maintenance treatment for opioid dependence. *Cochrane Database of Systematic Reviews: Reviews 2006 Issue 1*. Chichester, UK: John Wiley & Sons, Ltd. DOI: 10.1002/14651858.CD001333.pub2

12 Tucker T, Ritter A, Maher C, Jackson H. Naltrexone maintenance for heroin dependence: uptake, attrition and retention. *Drug & Alcohol Review* 2004; 23(3):299-309.

Naltrexone is not registered for use in accelerated opioid withdrawal (detoxification) methods, known as rapid opioid detoxification or ultra-rapid detoxification. The approved Australian Product Information for naltrexone contraindicates its use in “patients in acute opioid withdrawal.”

A systematic review concluded that the use of opioid antagonists combined with alpha2 adrenergic agonists (such as clonidine) under minimal sedation is a feasible approach to the management of opioid withdrawal. However, it is unclear whether this approach reduces the duration of withdrawal symptoms or facilitates transfer to naltrexone treatment to a greater extent than withdrawal managed primarily with an adrenergic agonist¹³.

Antagonist-induced withdrawal under heavy sedation, compared to light sedation, does not confer additional benefits in terms of less severe withdrawal symptoms or increased rates of commencement on naltrexone maintenance treatment. Given that the adverse events are potentially life-threatening, the value of antagonist-induced withdrawal under heavy sedation or anaesthesia is not supported. The high cost of anaesthesia-based approaches, both in monetary terms and use of scarce intensive care resources; suggest that this form of treatment should not be pursued.¹⁴

13 Gowing L, Ali R, White J. Opioid antagonists with minimal sedation for opioid withdrawal. *Cochrane Database of Systematic Reviews: Reviews 2006 Issue 1*. Chichester, UK: John Wiley & Sons, Ltd. DOI: 10.1002/14651858.CD002021.pub2

14 Gowing L, Ali R, White J. Opioid antagonists under heavy sedation or anaesthesia for opioid withdrawal. *Cochrane Database of Systematic Reviews: Reviews 2006 Issue 2*. Chichester, UK: John Wiley & Sons, Ltd. DOI: 10.1002/14651858.CD002022.pub2



Section 1 Treatment with pharmacotherapies

1.1 Goals of Treatment

The broad goal of treatment for opioid dependence is to reduce the health, social and economic harms to individuals and the community arising from illicit opioid use. Pharmacotherapies for opioid dependence should be part of a comprehensive treatment program, with access to counselling and other ancillary services available to all individuals.

The objectives of pharmacotherapy treatment are to:

- bring to an end or significantly reduce an individual's illicit opioid use;
- reduce the risk of overdose;
- reduce the transmission of blood borne diseases; and
- improve general health and social functioning, including a reduction in crime.

These objectives are achieved by engaging and retaining people dependent on opioids in treatment.

1.2 Optimising the Benefits of Pharmacotherapy Treatment

Optimising the benefits of pharmacotherapy treatment for opioid dependence requires a balance between access and quality. Making a drug widely available improves access, but may compromise the quality and safety of treatment. Restricting a drug to use only in specialist settings limits its usefulness as an intervention. In general, the balance between accessibility and quality is best maintained when general practitioners are trained to prescribe pharmacotherapies, and are able to refer patients or to consult with specialist drug and alcohol services.

Jurisdictions vary in their requirements for treatment services. Access will be optimal where the model of service delivery involves general practitioners and other health service providers, supported by specialist drug and alcohol services, with jurisdictional monitoring and regulation.

Counselling services improve treatment outcomes over the provision of methadone alone

1.2.1 Quality of Care

Clinical care should be informed by and consistent with evidence based treatment guidelines. A quality of care approach should include:

- the provision of information to clients, including information about treatment options;
- the obtaining of informed consent;
- mechanisms for ensuring clients' confidentiality with formal written consent should information need to be shared or forwarded;

- grievance procedures;
- professional development for providers;
- regular monitoring and evaluation of clients' progress and of treatment services; and
- the opportunity for carers' participation.

1.3 Assessment for Treatment

The purpose of assessment is to identify clients' needs, determine their suitability for treatment and establish a treatment plan. A thorough assessment should precede all treatment and should involve comprehensive drug use, medical and psychosocial history, physical and mental state examination and, as clinically indicated, other appropriate investigations.

A medical practitioner with knowledge and skills in the treatment of opioid dependence should make the final decision about the suitability of a person for pharmacotherapy treatment.

Treatment with methadone or buprenorphine is only suitable for people who are clinically assessed as being opioid dependent. Where dependence does not exist other forms of treatment should be considered.

1.4 Informed Consent

Legally competent clients have a common law right to make their own decisions about medical treatment and a right to grant, withhold or withdraw consent, before or during treatment. The following principles should apply:

- The free and informed consent of each individual to undertake treatment should be obtained before treatment begins;
- Information should be given on all aspects of treatment, including the clients' obligations, prior to giving consent. Written information should cover:
 - an overview of policies and procedures of the treatment program (including expectations of individual behaviour and any costs involved);
 - the nature of the pharmacotherapy (how the drug works, addictive qualities, side effects and drug interactions);
 - hazards and problems associated with the use of the pharmacotherapy, including the risk of drug toxicity, particularly if there is also use of illicit or prescribed drugs, risk of overdose and accidental poisoning of someone for whom the pharmacotherapy was not prescribed; risks associated with ceasing treatment including, for example, the risk of overdose following naltrexone treatment and risks associated with injecting oral preparations.
 - information about other relevant health issues e.g. pregnancy and breast feeding;
 - information about safe procedures for storing pharmacotherapies, particularly out of reach of children;
 - alternative treatment options; and
 - confidentiality of treatment records.

5.5 Rights and Responsibilities

Written information should be provided to each individual outlining their rights and responsibilities in a form that the individual can take away. Clients who cannot read should be read their rights and obligations at the time they enter the program. A competent interpreter should be utilised for clients who are not fluent in English, and where possible, pamphlets in other languages should be available.

Written information provided to persons receiving pharmacotherapy should cover information about the legal obligations for clients receiving pharmacotherapy treatment, particularly as they apply to takeaway doses of these drugs, and the legal implications of using them other than prescribed and/or supplying them to others.

In accordance with applicable privacy law, there should be procedures in place for protecting clients' personal information and providing clients' access to their personal information in appropriate circumstances.

There should be a mechanism, established at the jurisdictional level, for resolving grievances between clients and those responsible for their treatment. Clients should have the right to access these procedures and be informed of them at the commencement of treatment and on request thereafter.

1.6 Monitoring Drug Use

Monitoring options commonly used in Australia include self-reporting, clinical observation and urine testing. The validity and reliability of these techniques can be improved when used in conjunction with one another.

Self-reporting, although a subjective measure can be a useful indicator of episodes of client drug use. Self-reporting may also help build an atmosphere of trust and goodwill between clinician and client.

Urine testing should only be undertaken with good reason, such as in the initial assessment of an individual, to confirm the clinical history or as part of program evaluation. Urine testing can also be useful when clients are unstable (such as in the early stages of pharmacotherapy treatment) and when there is some uncertainty about their drug use.

There is little evidence to support the use of urine drug monitoring as a deterrent against unsanctioned drug use. Test results should be used, in collaboration with the client, to review and improve the individual's progress in treatment.

For more detailed discussion of monitoring of drug use, refer to the clinical guidelines from the Royal Australasian College of Physicians Australasian Chapter of Addiction medicine for *Assessing suitability for unsupervised medication doses in the treatment of opioid dependency* (available from www.racp.edu.au/members/fyi/addictmed/clinical_guidelines06.pdf).

1.7 Maintenance of Client Records

Case records detailing clients' clinical history and progress in treatment should be established and adequately maintained.

Jurisdictions may set minimal standards for case records. These standards should cover content, quality, confidentiality, security and access.

1.8 Aftercare and Assertive Follow-up

At the end of pharmacotherapy treatment, continued follow up assistance should be offered. The individual should be encouraged to continue contact with a counsellor/case manager or medical practitioner.

1.9 Accreditation/Service Standards

Jurisdictions should have mechanisms in place to monitor and continually improve the quality of pharmacotherapy treatment. These mechanisms should ensure that specialist services are engaged in accreditation or formal quality improvement programs.

1.10 Safe Storage and Transport

Jurisdictions should have policies in place to ensure safe storage and transport of pharmacotherapies.

1.11 Management of Special Client Groups

Testing for blood borne viruses should be discussed with all patients and should be made available for all those who request it. Where possible, testing should be provided within drug and alcohol clinics to optimise the likelihood of linkage to post-test interventions.

1.11.1 HIV/AIDS

Clients who are HIV antibody positive should, where possible, be managed in collaboration with specialist services and community based support services.

Generally, clients who are HIV antibody positive are able to cope with the routine and conditions of pharmacotherapy treatment, and there is evidence¹⁵ that maintenance treatment improves compliance with and outcomes of treatment for HIV infection. However, the medical, psychological and social implications of HIV/AIDS may require some flexibility in the arrangements for ongoing treatment.

These clients may have a comorbid condition, and may be treated with pharmacological agents that may interact with their pharmacotherapy treatment (refer to Clinical Guidelines¹⁶).

Where partners or carers of clients with HIV/AIDS have also had a history of injecting drug use, additional support may be required.

15 Antela A, Casado JL, Gonzalez MJ, Perez P, Perez-Elias MJ, Montilla P et al. Influence of a methadone maintenance programme on the improved outcome of a cohort of injecting drug users with advanced HIV disease. *AIDS* 1997; 11(11):1405-1406.

16 *Clinical Guidelines and Procedures for the use of Methadone in the Maintenance Treatment of Heroin Dependence*, Commonwealth of Australia (2003)
National Clinical Guidelines and Procedures for the use of Buprenorphine in the Treatment of Opioid Dependence, Commonwealth of Australia (2006)
Clinical Guidelines and Procedures for the use of Naltrexone in the Management of Opioid Dependence, Commonwealth of Australia (2003)

1.11.2 Hepatitis A and B

Hepatitis A virus is primarily transmitted through the faecal-oral route. Outbreaks occur more easily in overcrowded areas where poor sanitary conditions exist. Outbreaks of hepatitis A have also been reported among injecting drug users.

High-risk sexual behaviours and injection drug use are the major risk factors for hepatitis B transmission.

All clients on methadone, buprenorphine or naltrexone who are found to have no immunity to the hepatitis A or B viruses should be encouraged to have, or be offered, hepatitis A and B vaccinations. Consideration should also be given to recommending or offering vaccination to the sero-negative partners and close family contacts of patients who are hepatitis B sero-positive and potentially infectious. There are currently four hepatitis A vaccines and two combined hepatitis A/hepatitis B vaccines registered for use in Australia. Clients who are chronically infected with hepatitis B should be referred to a gastroenterologist for specialist assessment and follow-up. While approximately 90% of those infected with Hepatitis B will clear the virus, 5-10% will become chronically infected and will require active management.

1.11.3 Hepatitis C

The spread of Hepatitis C virus (HCV) through injecting drug use is a major public health concern. In testing for HCV it is justifiable to determine not only HCV antibody status, but also the HCV genotype and viral load, as this information will assist in post-test discussions about treatment outcomes. The cost of this testing is covered by Medicare where the testing is being done in relation to the consideration of HCV treatment.

A high percentage of individuals entering pharmacotherapy programs will be hepatitis C positive. Patients should be made aware of the positive outcome of treatment (40-50% sustained viral suppression or clearance for those with genotype 1 or 4 infection and up to 85% sustained viral suppression or clearance for those with genotype 2 or 3 infections).

Strong links should be established between drug and alcohol clinical services and liver clinics where treatment can be offered. While treatment for HCV can be offered to individuals who are still using illicit drugs and to those on methadone or buprenorphine, many will want to stabilise their lifestyle and drug use before commencing treatment for HCV.

Where an individual has been infected with hepatitis C it is important to ascertain their hepatitis B status as co-infection with hepatitis B may cause the illness to be more aggressive and treatment involving interferon will require more detailed monitoring.

Education and counselling should be offered to explain the consequences of hepatitis C infection and to reduce high-risk behaviour and minimise the spread of the virus. Information should include advice on reduction in hazardous use of all drugs (including alcohol) and the management of ill health due to hepatitis C. Clients should be advised against sharing injecting equipment (including tourniquets, spoons and solvents), as well as razors, toothbrushes or other instruments which may be vehicles for the exchange of blood.

Further information on hepatitis C, including resources for consumers, is available from the Australian Hepatitis Council (www.hepatitisaustralia.com), the National Hepatitis C Resource Manual (www.health.gov.au/internet/wcms/publishing.nsf/Content/publicat-n.htm) and the Royal Australian College of General Practitioners (www.racgp.org.au/guidelines/hepatitisc).

1.11.4 Prisoners

This client group warrants special consideration, the aims being to increase well being and social functioning following release, as well as to reduce the risks to community safety and health.

Pharmacotherapy treatment with methadone or buprenorphine is appropriate for prisoners who:

- are receiving pharmacotherapy treatment at the time of imprisonment;
- are opioid dependent at the time of imprisonment and not receiving treatment; or
- continue unsanctioned use of opioids in prison in a manner which constitutes a significant risk of harm.

However, there could be a range of other constraints that may impact on the implementation of pharmacotherapy treatment for people in prison and in the criminal justice system.

Release from prison is a time of high overdose risk for opioid users due to their reduced tolerance to illicit opioids developed during imprisonment. The provision of treatment during imprisonment and pre-release, and, the provision of advice in relation to the higher risk of overdose, is important to reduce this risk.

Prisoners who have been through opioid detoxification should be considered for naltrexone treatment.

Criteria used to assess prisoners for pharmacotherapy treatment may differ from those used in the community. Specific written criteria should be developed regarding the use of pharmacotherapies in prisons.

Confidentiality of medical records of prisoners on pharmacotherapy treatment should receive special consideration so that these records are used for the clinical management of the individual while in custody, and not for custodial purposes. No prisoner should be forced to accept pharmacotherapy treatment or have treatment discontinued for disciplinary reasons.

Appropriate liaison between correctional centres and health services needs to be undertaken to ensure continuity of treatment for those released from prison.

1.11.5 Polydrug Use

Clients who are using alcohol or other non-opioid drugs in a potentially harmful way at the time of their entry to pharmacotherapy treatment should be counselled on the dangers of intoxication, the harms of polydrug use, including increased risk of overdose, and on ways to reduce or stop hazardous use of alcohol and other drugs.

Service providers also need to be aware that pharmacotherapy clients may develop significant new alcohol and other drug use problems. Some clients mistakenly believe that once on methadone, buprenorphine or naltrexone they will not develop other drug dependencies. This view should be addressed at induction and service providers should be alert to the possible development of new dependencies, and the need for appropriate interventions with such clients.

Clients who have multiple drug dependence should, where possible, be managed in specialist services that provide comprehensive, care. Options for these clients include selective detoxification.

1.11.6 Comorbidities

The occurrence of comorbid drug and alcohol and mental health problems is common and can result in significant disability. The risk of people with comorbid conditions “falling through the gap” between mental health and drug and alcohol services are an ongoing concern. The establishment and maintenance of collaborative networks and referral pathways are important to ensuring the provision of adequate and appropriate care for comorbidity.

Significant medical conditions may result in clients becoming unable to attend dispensing points daily for medication. In these situations, prescribers may need to work with care services both in the management of the client’s pharmacotherapy treatment and the comorbid medical condition.

1.11.7 Pregnancy

There is not yet adequate research to definitively establish the safety, efficacy (effect under ideal circumstances) and effectiveness (effect in practice) of buprenorphine during pregnancy. Methadone maintenance remains the first line treatment for opioid dependency in pregnancy. The risks of buprenorphine treatment during pregnancy, whilst not yet accurately quantified, are unlikely given the available evidence, to be greater than the risks associated with a return to opioid use. The key issue for women who want to remain on buprenorphine during pregnancy or breastfeeding is that they understand that the safety and effectiveness of buprenorphine has not yet been fully evaluated. Given the lack of knowledge of the effects on the foetus of chronic exposure to naloxone during pregnancy, use of the combination product (Suboxone®) in pregnancy is not recommended. For further information refer to the national clinical guidelines on methadone¹⁷ and buprenorphine¹⁸.

Antenatal care should be managed, where possible, in collaboration with obstetric services which specialise in the management of drug dependency. Some women may be initially reluctant to advise other health practitioners of the fact that they are on a pharmacotherapy program. Clients should be counselled about the benefits of a partnership approach between pharmacotherapy providers and obstetric services.

Patients who have children, or who live with children in their household should be assessed to ensure that adequate strategies are, or will be put in place, to appropriately store and handle pharmacotherapies, out of reach of children.

1.11.8 Driving

There is no evidence that methadone or buprenorphine, when administered in stable doses, impair driving ability¹⁹. Any effect on psychomotor performance is likely to be greatest during the induction and stabilisation stages of treatment or following dose increases. At such times patients should be advised to exercise caution in driving or operating machinery. Research evidence indicates that buprenorphine

17 *Clinical Guidelines and Procedures for the use of Methadone in the Maintenance Treatment of Heroin Dependence*, Commonwealth of Australia (2003)

18 *National Clinical Guidelines and Procedures for the use of Buprenorphine in the Treatment of Opioid Dependence*, Commonwealth of Australia (2006)

19 Lenne, M, Dietze, P, Rumbold, G, Redman, J. & Triggs, T. The effects of the opioid pharmacotherapy methadone, LAAM and buprenorphine, alone and in combination with alcohol, on simulated driving. *Journal of Drug and Alcohol Dependence* (72) 2003, 271-278.

has less effect on psychomotor performance than methadone and hence may be a preferable medication for people who need to drive or operate machinery regularly.

9.9.9 Aboriginal and Torres Strait Islander Peoples

In recognition of the challenges faced by Aboriginal and Torres Strait Islander peoples, this group warrants special consideration. The aim is to provide a diversity of treatment options to reflect the diversity of the Aboriginal and Torres Strait Islander peoples, maximise health, well being and social functioning, as well as to reduce the risks to community safety and health with a culturally sensitive approach. This is especially important given the substantially higher rates of mortality and morbidity experienced by this population group.

Section 2 Treatment with Schedule 8 Drugs – Methadone and Buprenorphine

2.1 Approval of Pharmacotherapy Prescribers

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

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

The number of clients 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 individual;
- whether the doctor is working full-time or part-time in the treatment of opioid dependence; and
- the type of clients and type of setting in which the doctor is providing treatment, including for example, the availability of other clinicians and ancillary services.

It is appropriate for limits on the number of clients to be varied according to the expertise of the prescriber and the available professional support. There will be some variability between jurisdictions in these limits, and also the processes of approval. Refer to the relevant jurisdictional authority for detailed information.

A doctor should see the patient on each occasion that they renew the prescription. However, the frequency and timing of that will be determined within jurisdictional regulations.

2.2 Other Service Providers

All service providers contributing to the treatment of opioid dependence should receive adequate orientation, training, support and supervision. This includes nurses, pharmacists and counsellors.

Limits may be placed on the number of clients able to receive methadone or buprenorphine at particular dispensing locations. Such limits are likely to vary according to the capacity of the dispensing point and the experience of staff, as well as circumstances in the particular locality. Refer to the relevant jurisdictional authority for detailed information.

2.3 Authorisation of Prescribing Methadone and Buprenorphine

Jurisdictions should have a formal mechanism to authorise the prescribing of methadone and buprenorphine to individual people dependent on opioids. Central jurisdictional records of these individual authorisations should be maintained.

2.4 Facilitated Entry

The assessment and admission into treatment of the following groups should be expedited in their interests and the interest of public health:

- opioid users who are HIV positive and their opioid using partner;
- opioid users who are chronic carriers of hepatitis B and their opioid using partner;
- pregnant opioid users and their opioid using partner; and
- individuals who are transferred from one setting to another (e.g. newly released prisoners who have been undergoing buprenorphine or methadone treatment while in custody or individuals recently released from a correction setting and not in treatment).

2.5 Methadone

Methadone can be dispensed in syrup or liquid form and should be taken orally under supervision. Physeptone® tablets instead of methadone syrup or liquid should only be dispensed in exceptional circumstances. Physeptone® tablets are registered in Australia for analgesia but not for the treatment of opioid dependency. It should also be noted that Physeptone® tablets are not funded under Section 100 of the Pharmaceutical Benefits Scheme (PBS), but are a restricted benefit. As such Physeptone® tablets should be authorised via a private prescription and not as a PBS item.

For further information regarding dosing, please refer to the Clinical Guidelines and Procedures for Methadone²⁰.

2.6 Buprenorphine

2.6.1 Buprenorphine Dosing

Two buprenorphine products are currently registered in Australia for the treatment of opioid dependence within a framework of medical, social and psychological treatment: the mono product (Subutex®) is a sublingual tablet containing buprenorphine hydrochloride in 0.4, 2 and 8mg strengths; the combination product (Suboxone®) is a sublingual tablet containing buprenorphine hydrochloride and naloxone hydrochloride in a ratio of 4:1. Suboxone® is available in two dosage strengths: 2mg buprenorphine and 0.5mg naloxone, and 8mg buprenorphine and 2mg naloxone. The properties of buprenorphine and naloxone are such that, when taken sublingually, Suboxone® will act as if it was buprenorphine alone. However if the combined preparation is injected, the naloxone will have a clinically significant effect such that it is likely to attenuate the effects of the buprenorphine in the short-term, and is also likely to precipitate withdrawal symptoms in opioid-dependent individuals using heroin or methadone. These properties of the combination product are intended to limit the abuse potential of buprenorphine. The effectiveness of this approach is under investigation.

20 *Clinical Guidelines and Procedures for the use of Methadone in the Maintenance Treatment of Heroin Dependence*, Commonwealth of Australia (2003)

Patients should not receive unnecessary medication, and since the naloxone in Suboxone® has no therapeutic benefit in itself, it is appropriate for supervised doses of medication to be in the form of the mono product (Subutex®), while takeaway doses should be the combination product. However, a patient receiving both supervised and takeaway doses would need multiple prescriptions, and there is potential for confusion. Hence, in situations where a patient might receive takeaway doses, it is appropriate for them to receive only one formulation (the combination product).

The combination product should not be used in pregnancy (see section 1.11.7) or for patients with a proven allergy to naloxone.

Under supervision, buprenorphine in either formulation, can be broken into coarse pieces (not a fine powder) to speed up dissolution and reduce the risk of diversion. Buprenorphine for takeaway doses should be left intact in the foil packaging to maintain quality.

2.6.2 Buprenorphine Withdrawal

Buprenorphine can be used in withdrawal from heroin, methadone and other opioids. Where possible, people using buprenorphine to withdraw from opioids should be linked with effective post-withdrawal treatments and aftercare.

The appropriate starting dose of buprenorphine and duration of withdrawal treatment will vary according to the clinical presentation of each individual. (For a more detailed discussion, refer to the National Clinical Guidelines and Procedures for Buprenorphine.) Takeaway doses of buprenorphine for people withdrawing from heroin should only be provided in exceptional circumstances and subject to jurisdictional guidelines.

2.6.3 Buprenorphine Maintenance

Buprenorphine has been shown to be an effective opioid substitution treatment and can be used as an alternative to methadone for long-term maintenance treatment. The choice between methadone and buprenorphine should take into account: patient preference; response to treatment; individual variation in absorption, metabolism and clearance rates; adverse effects; the logistics of participating in treatments; and general expectations of the treatment. Buprenorphine maintenance treatment may be more likely to support attempted withdrawal. At the same time it is relatively easy to transfer from buprenorphine to methadone if necessary, and the transition from buprenorphine to naltrexone may be easier than the transition from methadone to naltrexone.

However, **caution** should be exercised in the prescribing of buprenorphine to people under the age of 16 years, and buprenorphine should not be prescribed for anyone with known hypersensitivity or severe side effects from previous exposure to buprenorphine. Pregnancy and breast-feeding are listed as contraindications for the use of buprenorphine in Australia, principally due to the lack of robust data on the safety and effectiveness of buprenorphine in these circumstances (see also section 1.11.7).

On each occasion that a prescription for buprenorphine is provided or renewed, the prescriber should personally assess the individual's progress.

For further information regarding dosing refer to the National Clinical Guidelines and Procedures for Buprenorphine²¹.

²¹ *National Clinical Guidelines and Procedures for the use of Buprenorphine in the Treatment of Opioid Dependence*, Commonwealth of Australia (2006)

2.7 Acute Pain

Methadone or buprenorphine clients admitted to hospital should have their methadone/buprenorphine treatment continued. For more detailed information refer to the Clinical Guidelines and Procedures for Methadone²² or Buprenorphine²³.

Orally administered analgesia is the preferred option for clients receiving methadone or buprenorphine; however injectable analgesia should not be withheld where clinically indicated.

2.8 Chronic Pain

People with chronic pain conditions who experience dependence related problems may benefit from methadone or buprenorphine maintenance treatment. The patients with chronic pain for whom methadone or buprenorphine maintenance may be considered include those:

- using illicit drugs (heroin) in addition to prescribed analgesics;
- using large amounts of analgesics gained from multiple sources in an unsanctioned way; and
- unable to control their analgesic use (taking more and more) despite strategies such as having one nominated prescriber, dispensing small quantities of opioid each time, and dispensing frequently (e.g. daily or second daily).

A multi disciplinary approach is required for these people including representation from pain clinics and/or appropriate medical practitioners in drug and alcohol services.

2.9 Takeaway Doses

In general, methadone and buprenorphine should be consumed under direct supervision at a location approved by the responsible jurisdictional authority. While supervised dosing can be an important strategy to manage risks, it can also deter people from engaging with treatment services and can be a serious obstacle to both the ongoing participation in treatment and social reintegration. Hence, it is appropriate in certain circumstances, for a prescriber to authorise either regular or one-off takeaway doses for people receiving maintenance treatment. Takeaways generally should not be a consideration for people receiving withdrawal treatment as they require regular assessment throughout the withdrawal.

The authorisation of takeaway doses of methadone or buprenorphine should be subject to jurisdictional guidelines. In determining eligibility for takeaway doses consideration should be given to factors such as progress in treatment, lifestyle, distance, transport, home situation, and the presence of other drug users in the house, the presence of children in the house, employment and study commitments.

The Clinical Guidelines for *Assessing suitability for unsupervised medication doses in the treatment of opioid dependency*, developed by the Australasian Chapter of Addiction Medicine, Royal Australasian College of Physicians, is a useful resource for detailed guidance in this area (available from www.racp.edu.au/members/fyi/addictmed/clinical_guidelines06.pdf).

22 *Clinical Guidelines and Procedures for the use of Methadone in the Maintenance Treatment of Heroin Dependence*, Commonwealth of Australia (2003)

23 *National Clinical Guidelines and Procedures for the use of Buprenorphine in the Treatment of Opioid Dependence*, Commonwealth of Australia (2006)

There are a number of principles that should apply before takeaways are approved:

- the individual's treatment and circumstances should be stable;
- the prescribing of takeaway doses should be clinically appropriate and safe; and
- the prescriber should be satisfied that the takeaway doses will be properly cared for, administered as directed, and minimal risk of diversion.

Where there is concern about possible misuse of takeaway doses, they should not be provided, as there are significant risks associated with providing takeaway doses. These include:

- dose diversion and involvement in drug dealing;
- self administration by injection, with the risks of vascular damage and transmission of blood borne viruses; and
- overdose and death of the individual or of a third person, particularly children either through accidental ingestion or deliberate administration.

A structured approach to eligibility for takeaway doses is desirable. Such an approach should incorporate:

- a period of stable treatment with no takeaway doses (except in circumstances where access to 7-day supervised dosing is limited, for example where community pharmacies are not open on Sundays, and alternative dosing points are not available);
- a further period of stable treatment with limited access to takeaway doses; and
- eligibility for additional takeaway doses if stability is maintained.

Individual jurisdictions may vary in the limits applied to takeaway doses. For detailed information refer to the relevant jurisdictional authority.

2.9.1 Preparation and responsibility for takeaways

Jurisdictional authorities responsible for the control of methadone and buprenorphine should seek to minimise the injection or accidental consumption of takeaway doses as both these situations can be hazardous.

Takeaway doses should be supplied in a container with a child resistant closure and carrying the label "KEEP OUT OF REACH OF CHILDREN". There should be labelling warning of the possible associated hazards when driving or operating machinery. Other labelling and preparation requirements should be fulfilled in accordance with the regulations for the jurisdictional authority responsible for the control of methadone or buprenorphine.

Clients are responsible for the care and proper consumption of each takeaway dose once in their possession. Clients should be advised that, to avoid risk of consumption by children or other unauthorised people, takeaway doses should be stored in a place that is not easily accessible by people other than the client. Suitable storage includes a child-proof medicine cabinet or a locked cupboard in a high location. Unsuitable places include the fridge, the car glove box, under a bed, or in a handbag. Clients should be advised not to consume their methadone dose in front of children, and not to transfer methadone into other containers that could lead to it being mistaken for something else, and taken by accident.

In the event that an individual reports that takeaway doses have been lost, stolen or damaged, generally they should not be replaced.

2.9.2 Dilution of methadone takeaway doses

Diversion of methadone takeaway doses is illegal, and the intravenous administration of methadone takeaway doses places the patient at risk of illness, infection and overdose and is strictly against medical advice.

The addition of a diluting solution to increase the volume of takeaway doses may be undertaken in an attempt to reduce the likelihood of diversion and injection of methadone. Takeaway doses of methadone when diluted are most commonly increased in volume to a total of 100 or 200mls.

Jurisdictions should have in place policies that address the issue of dilution of takeaway doses. Jurisdictional policies should be mindful of the risks if a person administers the solution intravenously. Two preparations are available for methadone maintenance treatment in Australia. One preparation contains sorbitol that is potentially hazardous if injected.

2.9.3 Takeaway doses of buprenorphine

In general, the combination product (Suboxone®) should be prescribed for clients receiving takeaway doses of buprenorphine because this preparation is expected to have a lower risk of diversion.

Buprenorphine should be left in the foil packaging for dispensing of takeaway doses to ensure quality of the medication is maintained.

2.10 Transfers - Interstate

The transfer of people receiving methadone and buprenorphine treatment from one State/Territory to another should be arranged in accordance with the policies and procedures of each jurisdictional authority. Under usual circumstances transfer should not occur until arrangements have been finalised and this can take up to 4 weeks. A letter containing the following details should arrive at the new destination, prior to the arrival of the individual:

- identifying information (including photograph);
- methadone/buprenorphine dose;
- exact dates of transfer;
- details of any takeaway doses provided; and
- relevant clinical information as required by each jurisdiction.

2.11 Overseas Travel

Generally, takeaway doses should only be provided for the shortest period necessary for the individual to reach the destination.

Information on the availability of substitution treatment in different countries is available from www.indro-onlinde.de/nia.htm.

The following guidelines should apply to takeaway doses for overseas travel.

Where takeaway doses are required, the prescriber must contact the foreign consulate or embassy (for all countries to be visited) to clarify the country's position on foreigners entering the country in possession of prescribed methadone or buprenorphine.

The prescriber should ensure that the individual satisfies the foreign consulate's requirements in respect to process or documentation.

Provided there are no restrictions on entering the country of destination in possession of prescribed methadone or buprenorphine, authorisation for the provision of takeaway doses must be obtained from the state/territory authority responsible for the control of methadone or buprenorphine. The authority will consider the takeaway request in view of public and personal safety issues and in light of the justification provided by the prescriber.

It is strongly recommended where approval is given for takeaway doses that the embassy or consulate of **all** of the countries to be visited be contacted to confirm any special requirements for personal importation of methadone or buprenorphine (e.g. number of doses permitted). Usually a doctor's prescription or letter will be adequate to present to Customs to confirm that the drugs are required for the treatment of a medical condition and possession is in accordance with Australian laws. However, if the overseas authorities require a letter from the Australian Government, this must be obtained from the Treaties and Export Section of the Therapeutic Goods Administration (TGA).

The Treaties and Export Section of the TGA require at least ten (10) working days to process any requests, and are contactable on telephone (02) 6232 4321 or write to: The Manager, Therapeutic Goods Administration, MDP 88, PO Box 100, WODEN ACT 2606.

Instructions as to the purpose and use of the methadone or buprenorphine should be provided in both in English and the language of the country/countries to be visited.

2.12 Treatment Termination

The majority of terminations are initiated at the request of the client. Where clients are involuntarily withdrawn from treatment, the final decision to discontinue methadone treatment is the responsibility of the prescribing medical practitioner in consultation with the client. The jurisdictional authority responsible for controlling the supply of methadone and buprenorphine must be notified when the treatment of each client is terminated.

2.12.1 Voluntary termination

Dose reductions should be made in consultation with the client. In general, the slower the rate of reduction, the less severe are the effects of withdrawal. Continued reduction of dose producing or precipitating physical or psychological distress for the client is usually counter-productive. During

methadone withdrawal, therefore, dose reduction should occur at a rate that does not cause physical or psychological distress. It may be appropriate to maintain a client at a reduced dose for a period until the client feels comfortable recommencing the reduction regime. Clients usually benefit from psychosocial support, including counselling, at this time.

The Clinical Guidelines and Procedures for Methadone²⁴ or Buprenorphine²⁵ should be consulted for a flexible approach to dose reduction.

2.12.2 Involuntary termination

Rather than discharging a client from a methadone or buprenorphine program because of behavioural problems, the issue may in some instances, be resolved by referring the client to another program. Clients who are to be discharged from treatment must be advised of the risks of illegal drug use, and informed of other treatment options.

Where the client is to be involuntarily withdrawn from methadone or buprenorphine treatment, reduction in dosage should be gradual, and implemented where possible with counselling and support.

Rapid dose reduction or abrupt cessation of treatment may be warranted in cases of violence, assault, or threatened assault against staff or clients associated with the treatment program. In these circumstances the client should be offered referral to other treatment options.

2.13 Monitoring and Regulation

Each jurisdiction will be responsible for central monitoring and regulation of methadone and buprenorphine prescribing.

The Australian Government will be responsible for collating national treatment data with respect to methadone and buprenorphine, and this data will be collected and provided to the Australian Government by jurisdictions.

Jurisdictions should collect data on an annual basis on the number of clients registered in buprenorphine and methadone treatment, broken down by:

- treatment sector for prescribing (public prescriber, private prescriber and prison medical services);
- nature of medication prescribed; and
- nature of dosing points (public clinics, private clinics, community pharmacies and correctional facilities).

24 *Clinical Guidelines and Procedures for the use of Methadone in the Maintenance Treatment of Heroin Dependence*, Commonwealth of Australia (2003)

25 *National Clinical Guidelines and Procedures for the use of Buprenorphine in the Treatment of Opioid Dependence*, Commonwealth of Australia (2006)

Section 3 Naltrexone

3.1 Suitability of Naltrexone Treatment

Naltrexone is indicated as an adjunctive relapse prevention treatment in people who have withdrawn from opioids and who are seeking to remain abstinent.

3.2 Opioid Withdrawal Treatment

While naltrexone can be used to withdraw people from heroin, methadone and other opioids it is not registered in Australia with the Therapeutic Goods Administration for this purpose. Current research evidence²⁶ indicates that antagonist-induced withdrawal under anaesthesia has an increased risk of life-threatening adverse events, and no additional benefits relative to antagonist-induced withdrawal under minimal sedation and should not be pursued. Antagonist-induced withdrawal with minimal sedation is feasible,²⁷ and may be suitable for those with a clear commitment to abstinence and good support, who intend to enter antagonist-maintenance treatment.

The prescribing information for naltrexone lists opioid withdrawal as a contraindication.

Any use of naltrexone in opioid detoxification should be consistent with the recommendations in the national clinical guidelines for the use of naltrexone.²⁸ Antagonist-induced withdrawal should only be provided in facilities that have the capacity to retain people as inpatients in the event of severe withdrawal, and only following approval by that facility's drug review committee or other formal approval mechanism. Patients should be properly informed, and consent obtained, which includes information that the use of naltrexone in detoxification is off indication.

3.3 Naltrexone Relapse Prevention Treatment

If an individual is physiologically dependent on opioids they need to be detoxified before starting naltrexone. To avoid inadvertently precipitating a withdrawal reaction it is desirable to perform a naloxone challenge test prior to the first dose of naltrexone.

Patients should be provided with information regarding risks associated with cessation of naltrexone and return to opioid use, and in particular, the increased risk of overdose.

On each occasion that a prescription for naltrexone is provided or renewed the prescriber should personally assess the individual.

26 Gowing L, Ali R, White J. Opioid antagonists under heavy sedation or anaesthesia for opioid withdrawal. Cochrane Database of Systematic Reviews: Reviews 2006 Issue 2. Chichester, UK: John Wiley & Sons, Ltd. DOI: 10.1002/14651858.CD002022.pub2

27 Gowing L, Ali R, White J. Opioid antagonists with minimal sedation for opioid withdrawal. Cochrane Database of Systematic Reviews: Reviews 2006 Issue 1. Chichester, UK: John Wiley & Sons, Ltd. DOI: 10.1002/14651858.CD002021.pub2

28 *Clinical Guidelines and Procedures for the Use of Naltrexone in the Management of Opioid Dependence*. Commonwealth of Australia (2003).

Depot and implant preparations of naltrexone are under development, but such products are not currently registered in Australia. Use of these preparations is possible only under the Special Access Scheme under the Therapeutic Goods Act. People receiving such treatment should be informed that the products are experimental and unproven.

People receiving naltrexone maintenance treatment should have access to a comprehensive range of psychosocial treatments and supports.

3.4 Medication compliance

Naltrexone is reported to be most effective in clients who are highly motivated with good social support and who take the drug as part of a comprehensive occupational rehabilitation program, behavioural contract, or other compliance enhancing protocol.

Supervised dosing involving a supportive parent, partner or friend may, for some patients, improve compliance with naltrexone treatment.

3.5 Overseas Travel

As with other Schedule 4 drugs it is recommended that people using naltrexone obtain a letter from their doctor to present to Customs. The letter should state that the drug is required for the treatment of a medical condition. It is also recommended that the embassy or consulate of all the countries to be visited be contacted to confirm if the drug is permitted in their country.

3.6 Diverted Naltrexone

There are significant risks associated with diverted naltrexone. These include precipitation of acute opioid withdrawal in a third person.

The prescriber should be satisfied that the prescribed naltrexone will be properly cared for, administered as directed, and minimal risk of diversion.

Notes

Notes