

# Opioid Substitution Treatment

New Zealand Practice Guidelines

2003

# **Opioid Substitution Treatment New Zealand Practice Guidelines**

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MANATŪ HAUORA

## Foreword

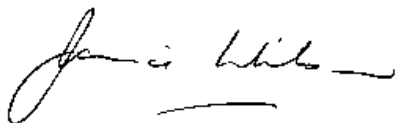
These *Opioid Substitution Treatment New Zealand Practice Guidelines* provide a framework for the effective, safe and responsive delivery of opioid substitution treatment and will supersede the *National Protocol for Methadone Treatment in New Zealand* (1996) from 1 February 2003.

Drug dependence is a condition characterised by a strong desire to repeatedly use a psychoactive substance that takes priority over other activities despite drug-related health, interpersonal and legal problems. Methadone maintenance treatment (MMT) is considered to be the effective opioid substitution treatment for most opioid-dependent people wanting to minimise harms associated with their illicit opioid use. MMT aims to minimise withdrawal symptoms, reduce opioid drug craving and reduce euphoric effects of injected opioids. For some people MMT provides an opportunity to reduce illicit drug use altogether.

There is an emphasis in these guidelines on the continuity of care that ranges from intensive intervention and active case management (stabilisation) to ongoing care in the primary health care system through appropriate general practitioners (GPs). A balance between accessibility to services and maintaining quality service delivery can be achieved when trained GPs who prescribe pharmacotherapies are able to refer clients to or consult with specialist alcohol and other drug services. No matter what setting, opioid substitution treatment will be more successful when services are accessible, entry is prompt, clinicians are non-judgmental and there is access when appropriate to allied medical, psychological, social and/or cultural services.

These Practice Guidelines acknowledge that some people may try other treatment options such as detoxification, outpatient and day programmes, attendance at therapeutic communities or other shorter-term residential services or attending self-help groups, before or during MMT. A few people may even want to use alternative pharmacotherapies.

The key principles of safety, stabilisation, assessment and review, treatment planning, clinical case management and integrated treatment are stressed in these guidelines. They also emphasise the particular skills (both professional and personal) and knowledge that reinforces the need for a trained, well-informed and accountable workforce.



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# Introduction

These Practice Guidelines have been revised to replace the *National Protocol for Methadone Treatment in New Zealand* (1996). They have been shaped in consultation with a reference group, perusal of similar guidelines and protocols and from the valuable feedback of those who made written and/or oral submissions. During the development of these Practice Guidelines, a number of issues were raised, which are set out below.

- Protocols vs Practice Guidelines – these guidelines address clinical practice as well as legislative requirements. Guidelines have a limited ‘shelf life’ thus emphasising the need for regular evaluation and review. They reinforce the importance of critical appraisal of practice, which in turn highlights ineffective and dangerous practices.<sup>1</sup> Statutory requirements are no less binding in guidelines as in written protocols.
- National vs regional inconsistencies of practice – these guidelines are expected to prevail over any local protocols made under it. Such local protocols may enhance the terms of these guidelines but shall not detract from them.
- The need to redevelop the audit tool and audit process to demonstrate service compliance with sector standards, service specifications and contracts but also to monitor best practice for all opioid substitution treatment providers.
- Alternative pharmacotherapies – a range of alternative pharmacotherapies is currently either not available in New Zealand/or still being tested for safety and efficacy. It is recognised that there is a small number for whom alternative pharmacotherapies such as dihydrocodeine and slow-release morphine preparations may well be appropriate. Many of the principles of best practice outlined in these guidelines will still apply.
- The need for guidelines to outline the minimum level of training considered appropriate for those working in this specialist area of work. There is now a number of courses (short courses and postgraduate) available at varying levels throughout the country that potentially offer a minimum set of knowledge and skills to base this work on. This has implications for auditing and workforce development, as well as for the process of giving authority to, and the gazetting of, medical practitioners.
- The Prison Opioid Substitution and Detoxification Protocol (agreed May 2000) is an agreement between the Department of Corrections, the Ministry of Health and the Health Funding Authority. Secure and humane containment is a feature of these protocols rather than the public health-focused harm minimisation approach taken in these guidelines. A number of submissions raised reservations about aspects of the Corrections protocol and its inclusion in these guidelines. Whilst they may not be endorsed by a number of practitioners in the alcohol and other drug treatment sector or by a number of service users, this protocol impacts on methadone maintenance treatment for a number of people and is therefore included in these guidelines.

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<sup>1</sup> *Toward Clinical Excellence* (2002) Ministry of Health, Wellington.

# Māori

## The Treaty

The Treaty of Waitangi establishes the unique and special relationship between Māori and the Crown. As an agent of the Crown the Ministry of Health considers the Treaty of Waitangi principles of partnership, participation, proactive protection of Māori health interests, co-operation and utmost good faith, to be implicit conditions of the nature in which our organisation responds to Māori health issues. The formal relationships between Māori and the Crown in the health and disability sector have formed around three key principles:

- **Partnership:** A relationship between Māori and the Crown of good faith, mutual understanding, and shared decision-making. Partnership is balanced by the principle of kawanatanga.
- **Participation:** The Crown and Māori will work together to ensure whānau, hapū, iwi, and Māori communities participate at all levels of the health and disability sector. This may include the development of Māori providers, including alcohol and other drug treatment services, but certainly means development of Māori responsiveness within existing services.
- **Protection:** The Crown actively contributes to improving the health status of Māori and ensures equal access to mental health services and alcohol and other drug services.

This commitment to the principles of the Treaty of Waitangi will be explicitly expressed in contracts between service providers and the Ministry of Health and/or its agent. Therefore all contracted providers shall demonstrate how the policies and practices of their provider organisation and service delivery will benefit Māori, their whānau and significant others.

## Sector standards

The policies and procedures of all alcohol and other drug treatment services need to reflect the requirements of the various relevant sector standards that will satisfy the provisions of the Health and Disability Services (Safety) Act 2001. They also need to be seen with a view to what they offer the service in terms of ensuring clinical and cultural safety for staff and clients as well as effectiveness of service delivery. It is noted that funding contracts and New Zealand health and service sector standards not only require the principles of the Treaty of Waitangi to be expressed in policy but that responsiveness to Māori issues (including the Treaty) are also to be demonstrated.

## Cultural diversity

Māori are a heterogeneous population and so the identification and understanding of the cultural and clinical factors and processes that predispose, precipitate and maintain particular attitudes and behaviour, as well those that may effect change, are important and central to developing effective and relevant management or treatment strategies. Those are all factors that may be ethnoculturally influenced and should be viewed in the context in which they occur if they are to assist a person to make changes.

# Objectives for Opioid Substitution Treatment in New Zealand

In New Zealand the objectives of opioid substitution treatment such as methadone maintenance treatment, in line with the National Drug Policy, are to improve the health of New Zealanders by minimising the harms associated with the use of opioid drugs, and, in particular, to:

- contribute to improving the health of service users as well as aspects of their personal and social functioning
- reduce the spread of infectious diseases associated with injecting drug use, especially hepatitis B and C and HIV/AIDS
- reduce the mortality and morbidity resulting from the misuse of opioid drugs
- assist individuals to achieve a successful withdrawal from opioids
- reduce episodes of illegal and other harmful drug use
- reduce crime associated with opioid use
- assist withdrawal from methadone maintenance treatment if appropriate and desired by the service user.

Not all these objectives will be achieved with each opioid-dependent person or to the same degree in each treatment setting. However, the aim is to reduce the risk of drug-related harm, as much as circumstances allow, for each person and for the community by minimising withdrawal symptoms, reducing opioid drug craving and blocking the euphoric effects of injected opioids. All MMT providers need to balance these objectives, within the resources available, with staff and service user safety factors.

In specific or unforeseen circumstances clinicians may need to vary their practice from that suggested in these guidelines. In such instances they should clearly document the reasons for such variations in the client records or in the service delivery model documentation. There should be no variation from the administrative and legislative requirements contained in these Practice Guidelines.

# 1 Specialist Opioid Substitution Treatment Services

- 1.0 Specialist opioid substitution treatment services (also known as the specialist service, methadone maintenance treatment programmes or methadone programmes) are specified by the Minister under section 24(5) of the Misuse of Drugs Act 1975 and notified in the *New Zealand Gazette*. They are, unless there are exceptional circumstances and subject to the approval of the Director of Mental Health, the entry point for all people requiring treatment of opioid dependence with a controlled drug.
- 1.1 Methadone maintenance treatment services provide for those who:
- need methadone dose stabilisation
  - are diagnosed as having severe opioid dependence *and* are the most unstable in terms of their opioid use
  - need high levels of specialist intervention to minimise the harms associated with opioid drug use and to make needed lifestyle and behavioural changes
  - need to manage relevant co-existing disorders.
- 1.2 Once a person on an MMT programme has reached an appropriate level of stabilisation, consideration will be given to transferring them to a primary health care setting where the prescribing of their medication can be managed within a community environment.
- 1.3 The roles of specialist opioid substitution services may include (but are not limited to):
- comprehensive alcohol and other drug assessment and treatment planning within a holistic model including biological (ie, alcohol and other drug, mental and physical health), social and cultural (eg, ethnic, age, gender, sexual orientation) factors
  - an assessment of risk to self, to others and from others (eg, relapse and wider safety issues such as sharing of injection equipment, high-risk sexual practices, suicidality, homicidality) as well as a risk management plan as appropriate
  - physical and psychological stabilisation on an adequate dose of methadone
  - transfer of people on a stabilised dose to the care of general practitioners (GPs)
  - provision of appropriate support and liaison services for people who receive MMT from specialist services and/or GPs
  - screening advice and referral for co-existing medical disorders (eg, chronic hepatitis)
  - treatment and management of people whose lifestyles or conditions make them unsuitable for transfer to GP care
  - consultation and liaison with allied professionals in other health care and social service roles.

Opioid substitution treatment provided by specialist providers should be underpinned by the principles of:

- safety
- stabilisation
- assessment and ongoing review
- treatment planning
- clinical case management
- integrated treatment.

## Entry into opioid substitution treatment services in New Zealand

### Eligibility requirements

- 1.4 The diagnostic criteria for opioid dependence, such as those outlined in the *DSM IV* and *ICD-10*, must be met.
- 1.5 The service user must consent to treatment and agree to comply with the conditions of treatment.

- Opioid substitution treatment should not be precluded on the grounds of age alone. There may be appropriate clinical considerations for its use. Parental/caregiver consent to treatment will almost always be required for those under the age of 18 years and careful documentation is required regarding the decision-making process.
- Those under of the age of 16 years being considered for opioid substitution treatment require supporting opinion from a specialist child or youth psychiatrist or paediatrician.

### Criteria for priority admission into specialist services

- 1.6 MMT should be readily available and entry into treatment be as prompt as possible.
- 1.7 Entry into an opioid substitution programme of a person who is assessed as suitable should not be delayed. If delays are unavoidable, people with certain conditions and/or in certain situations may have priority of access based on the risks of non-treatment but each case should be considered on its own merit. These people include:
  - those stabilised MMT service users transferring within New Zealand
  - New Zealanders who are stabilised MMT service users overseas returning home to New Zealand
  - pregnant opioid-dependent women and their opioid-dependent partners
  - people who have care of children, especially under the age of five years of age, or if they have sole responsibility for the children
  - those with serious medical conditions, such as HIV/AIDS, who can be stabilised and their opioid-dependent partners

- those who are hepatitis B carriers (HbsAg, HbeAg positive) and their opioid-dependent partners
- those with co-existing serious psychiatric disorders
- those partners of service users who are dependent on opioids.

### **Assessment and suitability**

1.8 The comprehensive assessment for suitability for an opioid substitution treatment such as MMT is to be started as soon as possible following acceptance of a referral to the specialist service. An approved assessor or assessors should carry it out. It is expected that an assessment will occur within three months of referral.

1.9 The goals of the initial comprehensive assessment are to:

- facilitate engagement in treatment
- determine suitability for opioid substitution treatment
- enable the service user to make informed decisions about treatment
- document an agreed initial treatment plan.

1.10 The comprehensive assessment should include:

- the client or service user expectations of treatment and perceived degree of motivation to change
- an alcohol and other drug-use history, (including tobacco, use of illegal and prescribed drugs, current medications and complementary therapies)
- current alcohol and other drug use (including signs of intoxication, withdrawal, physical evidence of past or current drug use such as needle marks and associated bruising)
- the person's medical history (including alcohol and other drug-related accidents, head injuries, overdoses, significant illnesses or hospital admissions), current GP and current medication
- investigations, including a urine drug screen (to confirm level and nature of current use) and blood tests (eg, for liver function, liver enzymes and other relevant physical health checks)
- assessment of past and present risk-taking behaviours (eg, sharing of injecting equipment, excessive and unsafe alcohol and other drug use, unsafe sexual practices)
- a mental health and psychological history (including previous mental health and/or alcohol and other drug assessment and treatment and current psychological and mental health/psychiatric problems/disorders that may need referral for further assessment, or intervention)
- an assessment of the risk of suicidality and other harm to self or others or from others
- relevant legal/forensic history (including current legal status)

- family/whānau history (including family history of alcohol and other drug use, mental health problems) and current relationships (indicate length of relationship, current status and stability)
- personal/developmental history, current social networks and social and role functioning (eg, employment/parenting) including identification of particular strengths and any educational or employment-related needs
- discovery of any restriction notices under section 25 of the Misuse of Drugs Act 1975 or section 49 of the Medicines Act 1981
- a record of various treatment options discussed, assessed to be inappropriate or declined
- diagnosis.

- Wherever possible, obtain corroborative evidence and include contact with family/whānau and significant others. Extra information will always be collected in ongoing assessments and reviews so that more comprehensive treatment plans can be developed.
- The initial assessment is an important opportunity to build a therapeutic relationship and clinicians need to take a non-judgemental and empathetic approach.
- The client or service user should be invited and encouraged to participate actively in treatment decisions from the start. Clients need to understand what is offered and the reasoning for all treatment options.

- 1.11 It is expected that a client transferring from another methadone clinic or programme should be newly assessed (updating current circumstances and status) as soon as possible before responsibility for methadone prescribing can be assumed.
- 1.12 The true identity of the person must be confirmed with, for example, their passport, driver's licence or birth certificate. Care should be taken to ensure that they are not receiving any other opioid treatment or drug treatment that could potentiate the dose of methadone prescribed.
- 1.13 Each person is informed of treatment options and the side effects of any proposed medication and considers them at the time of assessment. This is particularly necessary if there is a local waiting list for entry to MMT and the service user needs to consider other treatment options first.
- 1.14 The expectations and processes for transfer to an authorised<sup>2</sup> or approved<sup>3</sup> (also referred to as gazetted) medical practitioner are clearly explained for people choosing MMT as a treatment option.

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<sup>2</sup> A medical practitioner authorised under the Misuse of Drugs Act 1975 to prescribe, administer or supply any controlled drug for the treatment of dependency (see section 24 and the glossary).

<sup>3</sup> A medical practitioner approved or specified under the Misuse of Drugs Act 1975 and subject to conditions to prescribe, administer or supply any controlled drug for the treatment of dependency (see section 24 and the glossary).

- 1.15 Before consenting to the conditions of opioid substitution treatment and providing written consent to the immediate treatment plan the service user must first:
- be made aware of their rights as well as their obligations/responsibilities to the service (written consumer rights and service user information to be provided)
  - have information given to them about the effects (benefits, side effects, limitations) of methadone treatment (or any other opioid substitution treatment) and any other medication prescribed by the service
  - be informed about the potential effects of methadone and any other opioid use on a foetus if a service user becomes pregnant
  - be informed of the potential effect of methadone on activities such as driving and operating machinery
  - be informed of the interactive effects of methadone with alcohol and other drugs.

### **Eligibility restrictions and requirements**

- 1.16 Access to opioid substitution treatment may not be possible for those opioid-dependent people who cannot accept, and/or work within, the specialist service's safety requirements (see section 8).
- 1.17 A person is accepted for opioid substitution treatment based on a team decision that, at a minimum, consists of a medical officer and two clinical staff of a specified specialist opioid substitution service.

### **The treatment plan**

- 1.18 There will be a written treatment plan developed in collaboration with the service user. The plan will state the person's problems and their treatment goals and a suggested timeframe for achieving the goals. It will also need to give consideration to other programmes (both residential and non-residential) the service user may be involved in and the linkages that need to be made to facilitate co-ordination and continuity of care and to ensure treatment integration.
- 1.19 A copy of the treatment plan will be given to the client. On agreement by the service user the treatment plan may be shared with other parties (eg, probation officer, pharmacist). It will be regularly updated six-monthly, or as required, by the case worker<sup>4</sup> in collaboration with the client and, where possible, (with consent), the client's family/whānau or significant others and those involved with the client's treatment.

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<sup>4</sup> Likely to be the clinician assigned to have responsibility for the co-ordination of treatment of the service user. Their case management may include provision of all or some of the interventions planned and agreed to (see glossary).

- 1.20 There may be situations where the service user wishes to receive an opioid substitution treatment but does not want to participate in concurrent cognitive-behavioural or any other psychosocial therapeutic interventions offered (but not necessarily delivered) by the service. In such situations, once dose stability has been established, the case worker and service user must review the treatment plan to determine when the person will be medically safe enough to be transferred from the intensiveness of the specialist service to a primary health care setting.
- 1.21 The treatment plan will, when appropriate, state the agreed takeaway regime for the individual and the conditions under which this will be altered.

## Stabilisation and treatment

- 1.22 If there is to be a delay before a person can receive an opioid substitution treatment such as MMT, a specialist service may provide the person with advice, support and information on non-pharmacological alternatives to MMT or refer them back to, or on to, a specialist alcohol and other drug treatment service to undertake these roles.
- 1.23 Once the person is assessed as being suitable for the MMT programme, and there is a place on the MMT programme, they will be inducted into the programme and started on a stabilisation process.

- If suitable for the opioid substitution treatment, but there is a delay to the start of the programme, it is critical that the service user is told how long they may need to wait and how their situation will be monitored and reviewed. They also need to be aware of the expectations of the service of them while they are on the waiting list.
- If a specialist service operates a low dose methadone interim intervention option for those on a waiting list it is expected that wherever applicable the standards of safety and client/service user focus outlined in this document as well as clinical best practice be adhered to.
- Long waiting times are contrary to the intention and spirit of opioid substitution as a harm minimisation strategy.

## Stabilisation

- 1.24 When a person enters an opioid substitution programme such as MMT they should always:
- have a treatment plan, including short-term treatment goals, initially set in collaboration with their assessor and reviewed for relevance with their case worker
  - be expecting to be stabilised on an adequate<sup>5</sup> dose of methadone

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<sup>5</sup> Allowing for safety and effectiveness, this is a sufficient dose of methadone to provide for adequate personal comfort, retention on the programme and treatment.

- have their acute medical, psychological and social needs identified, including consideration of the needs of children in their care, and interventions provided or referrals made to the appropriate services

and should, wherever possible,

- have partners, family/whānau and any significant others (eg, probation officers, social workers) involved in aspects of their treatment where appropriate.

- Individual agencies may have their own local policy and procedures for many of the above treatment aspects, including management of any waiting list. Such policy and procedures will need to meet the requirements of the alcohol and other drug and mental health sector standards.
- Local protocols may enhance the terms of these Practice Guidelines but shall not detract from them.

1.25 When a person first enters an MMT programme at a specialist service, a case worker will be assigned to be responsible for co-ordinating their treatment and may provide some or all the interventions planned. When the person is transferred to a GP working under authority from the specialist service, the GP may become the lead case worker but the client may continue to work closely with specialist service staff and/or other allied health and social service professionals.

1.26 Stabilisation is a multi-faceted process that allows the person to make best use of an opioid substitution treatment such as MMT. The decision about what level of stabilisation is most appropriate for an individual needs to be made jointly by the prescriber, case worker (if different) and the service user. At a minimum, stabilisation on MMT would mean that the person can cope on a consistent regular dose of methadone without the need for constant dose changes and review and is able to work consistently towards agreed goals. For some people this will take a considerable time to achieve and they will need significant input from a variety of staff in the specialist service.

1.27 Other factors that could be considered when assessing stability include:

- harmful or hazardous use of other drugs (prescribed and non-prescribed), including alcohol
- attendance at clinic and/or other essential appointments, reliability concerning takeaways<sup>6</sup> and evidence of diversion<sup>7</sup>
- social and role stability (eg, housing, employment, parenting, education etc – predictors of ‘relapse’), ‘holding down’ a job and/or undertaking tertiary studies could be good evidence of stability

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<sup>6</sup> Doses of methadone consumed by a client without direct observation at the methadone clinic, pharmacy premises or by a medical provider.

<sup>7</sup> Diversion is defined as a failure to consume on site and selling, swapping or giving methadone to others.

- stability in relationships with others, partners, children, other providers
- status of co-existing mental or physical health problems
- involvement in drug-related criminal offending.

1.28 The case worker should see the service user at least once every week for the first three weeks, or more frequently if necessary, to continue the initial assessment, establish a therapeutic relationship and, importantly, to monitor safety.

### **First methadone dose**

1.29 Initial doses of methadone should be based on the individual's history of quantity, frequency and route of administration of opioids, use of other central nervous system depressants and should also take into account the person's hepatic and renal functioning. There may be some withdrawal symptoms that are not covered by the first dose. Steady state methadone blood levels are not generally achieved until after five days' dosing.

1.30 The commencement dose should aim to achieve an effective level of management of withdrawal symptoms, both physically and psychologically while minimising the likelihood of overdose. The first dose of methadone should never be higher than 40 mg.

1.31 Treatment should be started early in the week so that the maximum serum level is reached when there is monitoring available (such monitoring is generally not available in the weekend).

- Frequent clinical observation needs to occur to ensure service user safety during the induction process onto an adequate dose of methadone as this is the time when there is increased risk due to overdose.
- Education about overdose risk, particularly the risk of combining other drugs (including alcohol) with methadone, and strategies to manage overdose should be provided to each service user.

1.32 In general the initial daily dose will be in the range of 10–40 mg. Following the first methadone dose, the case worker or doctor should observe the person's response to methadone, both immediately and after three to four hours to exclude intoxication at the peak plasma level.

1.33 It is recommended that the methadone dose is not increased for the first 3–4 days of treatment as the client/service user will experience increasing effects from the methadone each day. Observe 3–4 hours after the third or fourth dose of methadone to exclude intoxication at the peak plasma level and by which time the person should be close to achieving a steady state.

- 1.34 Where doses need to be titrated against withdrawal symptoms the increment should be no more than 5–10 mg per day. A total weekly increase should not usually exceed 50 percent of the starting dose.

Any dose change in this or later phases of MMT should be organised whenever possible in face-to-face discussion with the service user in order to decrease distrust or misunderstanding.

- 1.35 Specialist services should advise people in writing not to drive or operate heavy machinery when having their dose of methadone increased. Once a stable level has been achieved methadone per se is unlikely to cause impairment unless combined with other drugs.

### **Subsequent methadone doses**

- 1.36 Maximum methadone doses will generally be in the range of 60–120 mg daily. Sometimes higher doses or, less commonly, split doses,<sup>8</sup> may be required to achieve stabilisation for individuals. Serum methadone level monitoring and specialist service consultation, in addition to consultation with the client and, if appropriate, their family/whānau or significant others (eg, pharmacist), should be considered in this instance. In some cases lower doses may be adequate.
- 1.37 Additional serum methadone levels (trough and, if required, a peak level) should be considered to avoid unnecessary dose increases and when:
- doses are approaching the higher rate of 120 mg daily
  - the person experiences withdrawal symptoms 15–24 hours after the last dose
  - splitting the daily dose is being considered
  - serious liver or other physical disease is present and there may be methadone accumulation.
- 1.38 The dose of methadone should be sufficient to provide for clinical stability, role functioning, minimisation of withdrawal symptoms and retention in treatment.
- 1.39 Methadone, ideally, should not be given to a person who is intoxicated. Specialist services and pharmacies involved in the dispensing of methadone should develop local protocols for dealing with people suspected of being intoxicated. All pharmacies would be expected to have a consistent protocol for notifying the appropriate service if the dose of methadone is administered or withheld.

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<sup>8</sup> Split dosing refers to the consumption of methadone more than once a day. This is to achieve a more stable serum level in the blood.

- 1.40 Methadone doses that are to be consumed on the premises must be swallowed in front of a specialist services staff member or pharmacist to minimise the risk of diversion. Care should be taken to minimise the possibility of takeaway<sup>9</sup> doses of methadone being sold, used against medical advice (eg, ‘doubling up’ or injecting) or used by others.
- 1.41 Concurrent sedative/hypnotic (eg, benzodiazepines) and harmful or hazardous alcohol use may be reasons to review admission to a programme, an increase in dose or to restrict takeaways. Any prescription in addition to methadone needs to be at safe therapeutic levels and for sound indications. The prescribing of benzodiazepines and similar drugs by specialist opioid substitution services will generally be an exception.
- 1.42 Restriction notices issued under section 25 of the Misuse of Drugs Act 1975 should also be considered.
- 1.43 There is a need to encourage clients/service users to be frank with other prescribers about their methadone dose, and with their methadone prescriber and case worker about other medications being taken in order to minimise risk of drug interactions. There is an obligation for health care providers to communicate in this regard in order to facilitate appropriate health care. Local protocols should highlight this obligation.
- 1.44 For drug interactions associated with methadone, see Appendix 2. For the role of the pharmacist in dispensing takeaway doses, see section 5.

## **Case management**

- 1.45 The prescription of an opioid substitute such as methadone should not be seen as an isolated intervention but as part of a wider care programme. It is often important to identify and address other problems, such as medical, social, employment/learning, mental health or legal problems, in order to achieve stability and retention in the programme. Thus, there will be degrees of involvement by the methadone programme case worker in active clinical case management<sup>10</sup> requiring linkages with other services and allied professionals, self-help groups, families/whānau and significant others.

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<sup>9</sup> Those doses of methadone consumed without direct observation at the methadone clinic, by a medical provider or by a pharmacist.

<sup>10</sup> Clinical case management is defined here as a set of functions that, once the service user is engaged in the treatment system, helps them access the health and social service resources they may need to address a substance dependence problem.

**Case management** in opioid substitution treatment is more than a planned and co-ordinated delivery of service; it involves a therapeutic relationship, frequently over a long period of time, with each individual client within the context of their life situation. It is expected that wherever possible the case manager has a significant intervention role to ensure that each client has their needs met in an integrated way and does not receive fragmented care from a range of disjointed services.

- 1.46 As part of an appropriate programme of care, clients are expected to:
- be fully informed about their service provider, treatment options for opioid dependence, including drug-free options
  - give informed consent in writing to their treatment
  - be involved in decision-making about treatment, case management and all other relevant aspects of service provision
  - once overall stability has been established, the case worker and service user need to agree on the conditions under which the person will be medically safe enough to be moved from the care of the specialist service to a primary health care setting to continue treatment.
- 1.47 Information on general health and welfare, employment, relationships and welfare and other relevant issues, including family/whānau and parenting skills, may be given as appropriate during reviews. People receiving MMT should be made aware of other health and social services available to them in the community.

### **Reviews by the prescribing specialist service doctor**

- 1.48 People receiving an opioid substitution treatment must be seen by the prescribing doctor or their locum prior to the initial dose and at least once during the first seven days of treatment.
- 1.49 During dose increases more frequent observation is advised. The prescribing doctor should see the service user regularly during the first three months of the stabilisation phase or until a stable and clinically effective dose is achieved.
- 1.50 The frequency of review will be determined by the stability of the service user. Once dose stabilisation is achieved, both the prescribing doctor and case worker in a combined treatment review meeting, would be expected to see clients/service users at least every 3–6 months.

### **Monitoring and review by the case worker**

- 1.51 People receiving methadone should be seen at least once a week for the first month or until a stable methadone dose and satisfactory life situation is achieved. However, clients/service users not progressing well (medically, psychologically or at risk of relapse) will benefit from more frequent and intensive intervention.
- 1.52 Once stabilisation has been achieved then people on opioid substitution could be seen at least once a month for the second and third months. More frequent

appointments can be made at the request of the individual, their family/whānau or significant other or the medical practitioner, or as their treatment plan suggests.

- 1.53 Once stabilisation is achieved, people on opioid substitution treatment should be seen at least once every three months. Depending on the needs of the service user the case worker may see people individually or in a group on a monthly basis or more often.
- 1.54 Regular monitoring sessions would be expected to include a review of progress in relation to the short-term and longer-term treatment plan and an updated ‘assessment’ of risk. The review may also include (but is not limited to):
- review of social and role functioning and employment/education status
  - review of physical and mental health, including co-existing disorders
  - discussion of linkages with other health and social service providers
  - discussion of poly-substance use and misuse
  - discussion of results of urine ‘drug’ screens
  - consideration of dose adjustment and takeaway arrangements
  - addressing lifestyle and high-risk behaviour changes, including lapses and relapses
  - referral for review of medical issues and for dose adjustment where needed
  - review of co-existing disorders
  - information and/or referral to self-help groups and other support and ancillary services
  - review of physical and psychological health
  - assessment of adherence to service and treatment conditions.

### **Reviews by a case management team**

- 1.55 A case management team should consist of the case worker and the prescribing doctor and at least one other member of the special service team. Consultation with the pharmacist may also be useful in some instances.
- 1.56 It is expected that the service user should be offered the choice to be involved in formal case reviews as it may result in a new treatment plan that will need to be mutually agreed. It may be useful if, with consent, family/whānau and significant others, including other relevant allied health or social service professionals, are also consulted.

The service user has a right to attend team meetings where their case is formally being reviewed and to have a support person present (eg, a consumer advocate, social worker etc).

1.57 Case reviews should normally include a summary of the areas covered in the case worker's monthly reviews and may include:

- treatment progress, measuring treatment outcomes against individual treatment goals
- an update of the treatment plan, which will need to be discussed with, and agreed to, by the service user
- a review of safety and level of physical stabilisation (at least twice a year minimum)
- strategies to enhance the capacity of the service user to transfer to either an authorised (if this is not already the case) or approved GP or to withdraw from methadone altogether
- consideration of alternatives or complementary interventions to MMT such as additional psychotherapeutic/social interventions, detoxification or residential treatment (which may or may not be drug free).

- Those clients on a three-monthly or longer appointment schedule may indicate a stability and readiness to be transferred to primary health care. This should be evaluated and arranged as soon as possible if appropriate.
- The case management team review should act as a quality assurance improvement mechanism for individual case workers.

1.58 A comprehensive medical review may be required where the person is seriously disabled (in terms of function physical or mental health).

## **Transfer between specialist services and regions**

- As with many other New Zealanders, there are legitimate reasons for service users or people on opioid substitution treatment to move around the country. As much as possible a service user on MMT should not be disadvantaged for needing to move.
- Prescribing to clients/service users once they have moved out of region may be successful for a limited period where there is obvious stability.

1.59 Where a service user is stable, out-of-region prescribing could occur for up to three months at which time a case management review should occur.

1.60 Before a service user transferring into a new service is prescribed methadone it is expected they will be reassessed by the new specialist service (utilising transfer documentation such as their transfer assessment and most recent case plan).

1.61 On acceptance and start of MMT in a new service, confirmation of the completed transfer is to be sent to the referring specialist service and cancellation of their previous prescription confirmed.

There is a need for clear documented agreement and protocols between the transferring service and the new service as to the transfer arrangements, including when the new service will take responsibility for prescribing.

## **Transfer to the primary health care sector**

- 1.62 The treatment of dependence by approved persons using controlled drugs is set out in the relevant Acts. There are five categories of prescriber, two with ministerial approval and three with (different) delegated authority:
- 1.63 MMT is appropriate in the primary health care/general practice setting, provided that certain conditions are met. The legislative requirements are outlined in Appendix 1. A specialist service may transfer a client/service user to an authorised GP or a GP approved to prescribe, administer and supply a controlled drug for the treatment of opioid dependence.
- 1.64 Before any transfer takes place, clients should participate in a comprehensive review with the case management team of the specialist service to determine their suitability to transfer to GP care.
- 1.65 The benefits of transferring the service user to the primary health care sector may include:
- allowing specialist services to focus on those service users with the most need for intensive specialist intervention
  - improving access to specialist services by more quickly moving on those most stable with a consequent reduction in waiting lists
  - improved social integration by normalisation of treatment for the service user (ie, not having to attend a ‘drug clinic’)
  - a more holistic management of a person and their whānau/family by a GP within a primary health care setting.
- 1.66 It is expected that responsibilities of a specialist service transferring clients/service users to primary health care include maintenance of a support and liaison role to the primary health caregiver and, as necessary, accepting back clients who become ‘destabilised’ and can no longer be managed in a general practice (for short or longer periods of time). Local protocols should be developed for the restabilisation of clients/service users utilising specialist resources with or without an actual return to the specialist service.

## **Requirements of GPs accepting a transfer from a specialist service**

- 1.67 The GP may be either approved or working under authority and should have attended relevant opioid substitution treatment or specialist alcohol and other drug treatment training or have experience working with opioid substitution treatment. In general, the GP will be working within a broader primary health care team that includes reception staff, practice nurse and often other professionals. In such situations, these other staff members are also likely to interact with the client/service user and his/her family/whānau and significant others and provide support as appropriate.
- 1.68 The general practitioner must confirm the person's true identity (see section 1.12).
- 1.69 The general practitioner should have a formal relationship with the local specialist opioid substitution service and an established process and protocol for utilising the resources of the specialist services should clients become destabilised.
- 1.70 The general practitioner should have an awareness of, be able to facilitate and/or, in some cases provide, the support services needed by clients/service users to maintain their stability.
- 1.71 Clients/service users must be informed of the conditions under which they can be returned to or utilise the resources of specialist services and must be informed of their ability to access psychosocial services provided by other alcohol and other drug treatment services.
- 1.72 People who are HIV/AIDS positive may be prescribed methadone by a GP. Furthermore, GPs should offer all their methadone clients/service users HIV and HCV testing as appropriate.
- 1.73 If the approved GP does not comply with the requirements of the relevant sections of these Practice Guidelines, the Director of Mental Health can and will revoke their approval.

## **Transfer to authorised GP**

- 1.74 In many cases, transfer to primary health care will be to a GP working under the authority of the specialist service. In this case, the specialist service remains the responsible provider, while the authorised general practitioner prescribes methadone in accordance with written terms and conditions (protocol) laid down by the service in relation to specified clients.
- 1.75 Normally it will be the responsibility of the specialist service to notify and update pharmacies as to which GPs are authorised to prescribe an opioid substitution.

- 1.76 Once a person is transferred to an authorised GP, it is expected that the GP will be responsible for implementing systems to ensure clinical safety and ongoing treatment. These systems may include random urine drug screens and management of a methadone takeaway regime that ensures the safety of the individual, their family/whānau and the community and ongoing contact for the service user with the specialist service for relevant programmes.
- 1.77 It is expected that GPs who provide services to people on MMT will have formal, agreed relationships with specified specialist services and approved GPs. These would include clear agreements (protocols) on the management of people who become destabilised or who need specialist support and on the responsibility for drug screens etc.
- 1.78 In general, authorised GPs will be working within a broader primary health care team that includes the practice nurse and often other professionals. In these cases non-medical staff members are likely to interact with the client/service user, his/her family/whānau and significant others and may also support the service user as appropriate.

## Transfer to approved GPs

To ensure consistent practice with regard to opioid substitution treatment, and to minimise the risk of isolation, it is recommended that approved GPs have ongoing contact and access to specialist service input.

- 1.79 Once a person is transferred to an approved GP, it is expected that the GP will be responsible for implementing systems to ensure clinical safety and ongoing treatment. These systems may include random urine drug screens and management of a methadone takeaway regime that ensures the safety of the individual, their family/whānau and the community, and ongoing contact for the service user with a specialist service for relevant programmes.
- 1.80 It is expected that GPs who provide services to people on MMT will have formal, agreed relationships with specified specialist services. These could include clear agreement (protocols) on the management of people who destabilise or who need specialist support, and on the responsibility for drug screens etc.
- 1.81 In general, approved GPs could be working within a broader primary health care team that includes the practice nurse and often other professionals. Non-medical staff in the primary health care team may support the service user as appropriate.

## **Transfer between GPs**

- 1.82 A general practitioner may from time to time be required to transfer one of their clients/service users on MMT to another GP who is either approved or working under authority.
- 1.83 The new prescriber must confirm the person's true identity (see section 1.12) before commencing any new prescription and clients/service users must be informed of the conditions under which they can return to or utilise the resources of a local specialist service. They should also inform new clients/service users of their ability to access psychosocial services provided by other alcohol and other drug treatment services.
- 1.84 It is expected that transferring and accepting GPs will be cognisant of their responsibilities to pharmacists (see 2.2).

## 2 Clinical and Administrative Expectations of Specialist Opioid Substitution Services

### Treatment outcomes by specialist services

- 2.0 Outcomes have been listed as objectives of opioid substitution treatment identified at the beginning of this document. It is expected that specialist services will annually review their performance against these outcomes through the use of the Ministry of Health's Audit Tool for Opioid Substitution Treatment Services or Ministry of Health approved treatment evaluation indices or measures.
- 2.1 A number of performance indicators for opioid substitution treatment are contained in the requirements of relevant sector standards.

### Staffing of specialist services

- 2.2 Specialist service staff should have:
- positive, client-centred and non-judgemental attitudes, including a high level of empathy with service users
  - a flexible approach to treatment focused on treatment retention
  - a desire to achieve harm minimisation and a realistic belief regarding service users' ability or desire to achieve abstinence
  - an understanding of the stigma associated with receiving MMT
  - ongoing specialist training and supervision relating to case management and the treatment of opioid dependence
  - awareness of key documents relevant to the treatment of people with severe mental health and alcohol and other drug problems
  - management skills that are specific to the opioid-using population
  - training and cultural support in working with diversity, including working with Māori, and Pacific peoples and other ethnocultures
  - training in the assessment and treatment of other addictions and of poly-drug abuse and drug interactions
  - training in the assessment and management of co-existing mental health problems and co-occurring problem gambling
  - ongoing clinical supervision and support.
- 2.3 Specialist services should employ staff who have been trained and supervised in working with substance dependence and opioid-dependent people in particular. In addition, small specialist services should have a formal relationship with other services to support the advancement of their work and the treatment of clients/service users.

2.4 Staff members in a specialist service must have appropriate orientation and supervision to enable them to develop experience and a high level of competence in the provision of opioid substitution treatment such as MMT. They should also be well informed about the available outreach services and information about safe practices for opioid users.

### **Level of training**

- By 2005 senior clinicians (including doctors) and case workers in specialist services would be expected to have, or be enrolled in, relevant alcohol and other drug postgraduate qualifications and/or be experienced working in the alcohol and other drug treatment sector.
- By 2005 an approved doctor would be expected to have completed, or be enrolled in, relevant alcohol and other drug postgraduate training equivalent to the currently available courses at the University of Otago and University of Auckland.
- By 2005 an authorised GP or practice nurse working in a primary health care setting, such as a general practice, should have completed, or be enrolled in, relevant postgraduate alcohol and other drug studies and, *at the very minimum* completed training equivalent to the current National Opioid Treatment Training programme.
- All workers should have some demonstrable commitment to ongoing alcohol and other drug treatment education.
- Pharmacists involved in dispensing methadone should aim to have completed training equivalent to the current National Opioid Treatment Training programme.

2.5 All staff should be willing to work with all service users, regardless of race, ethnicity, age, disability, sexual orientation, gender or health status, and be sensitive to these issues.

2.6 Where possible and appropriate, services should aim for a diverse workforce to maximise the ability to match staff to client demographics so that cultural/gender/sexuality characteristics can be more easily taken into account and so that the service user feels safe.

2.7 Tangata whai ora should be treated in accordance with the partnership principles of the Treaty of Waitangi.

2.8 Staff members should be supported to attend networking opportunities with other opioid treatment providers beyond their service. Staff should have ongoing training in issues related to opioid substitution treatment, case management and methadone maintenance treatment.

## **Administration**

2.9 Specialist services may develop their own local protocols and procedures provided they are consistent with, and not in conflict with, these Practice Guidelines or with relevant legislation, codes of practice and accountability requirements (see Appendix 6).

## Record keeping

2.10 Records must be held for all service users, and must include:

- National Health Index Number (NHI) and demographic information
- comprehensive alcohol and other drug assessment (including hepatitis serology, liver function and other laboratory tests) and initial treatment plan
- nominated GP
- the names of case worker and prescriber
- the date treatment commenced
- methadone dose and dispensing arrangements
- the name, address, telephone number and fax number of the pharmacy dispensing opioid prescriptions for that person
- the current treatment plan and progress (case) notes
- review summaries of treatment progress
- consent forms (for treatment, disclosure of personal information, etc)
- copies of GP authorisation forms for those in GP-managed treatment, and treatment review forms
- details of any transfers either between services or to an approved GP, or refusal of such a transfer and related factors
- any restriction notices under section 25 of the Misuse of Drugs Act 1975
- the discharge date and factors involved in discharge if this occurs.

## Reporting requirements

2.11 Specialist services must send complete, timely and accurate information to the Mental Health Information National Collection.

2.12 Services will also collect and forward, on a quarterly basis, statistical data related to waiting lists and the duration service users are on a specialist service programme or under authorised GP care to their District Health Boards and the Mental Health Directorate of the Ministry of Health.

## Service user rights

2.13 The service user should receive:

- information about their rights as service user, including their rights under the Code of Health and Disability Services Consumers' Rights and relevant patient and consumer advocacy contacts
- a copy of their treatment plan
- information about confidentiality and situations under which the service may need to break that confidentiality

- information about the range of treatment options available
- information about methadone as a substance and possible side effects of MMT
- information about the service's complaints procedure
- information about their obligations as service user.

2.14 Each person should receive a description of the treatment interventions the service offers.

2.15 All opioid substitution treatment services (including approved GPs) must comply with the relevant health sector standards that include sections on service user involvement in services.

2.16 Service users should be given clear verbal and written information about both voluntary and involuntary withdrawal processes and the conditions under which an involuntary withdrawal might be activated.

## **Complaints procedure**

2.17 Services will have clear written procedures that are available and accessible for individuals to seek a review of their service or their situation, particularly when a person is involuntarily discharged from, or refused access to, a local specialist service. Specialist services may limit the number of reviews available or make a time period before new reviews are accepted.

## **Case management**

2.18 Specialist services are contracted to provide case management for people who are opioid dependent and undergoing assessment, stabilisation of dose or who are receiving ongoing treatment. They may receive, or have access facilitated to, a range of services to help in their recovery in addition to their maintenance methadone or other pharmacotherapy.

2.19 Each person should have an allocated case worker who will take the responsibility for the development of a treatment plan with the person is matched to their needs and defines clear outcomes for treatment.

2.20 Each specialist service will have a clear local protocol for review of all service users, and which will include plans for movement of the person to authorised or approved medical practitioners as soon as possible.

2.21 To ensure appropriate treatment and care management, a multidisciplinary team should be involved in the overview of all cases. Services should have protocols to ensure that there are appropriate reviews of treatment progress, measurement of treatment outcomes against individual treatment goals and review of safety.

## Safety requirements of services

- 2.22 Safety requirements of services are set out in the Alcohol and Other Drug Treatment Service Standards and, similarly, in the National Mental Health Sector Standards.
- 2.23 Opioid Substitution Treatment Services prescribe potent opioids and often works with service users with complex circumstances. Services need to balance needs of the clients/service users with the safety requirements of their family/whānau, the service, the pharmacy and the general public.
- 2.24 Each service should develop a set of safety requirements that cover the areas of personal safety of clients/service users and staff as well as prescribing, dispensing, and takeaways. These safety requirements should be discussed with the service user as part of their initial assessment and as relevant during ongoing treatment.

## Local protocol requirements

- 2.25 Services should have local protocols that cover processes for:
- access to services
  - management of pregnant women receiving opioid substitution treatment or who are on any waiting list for such treatment.
  - management of people suspected of being intoxicated or of ‘diverting’ their methadone
  - management of aggression or violent behaviour
  - transfer of people to primary health care and processes for re-engaging them into to specialist services.
  - transfer of people between specialist services
  - review of progress of service users
  - measurement of treatment outcomes for clients/service users
  - review of safety issues.

Consistency of such protocols nationally will be assisted by the National Association of Opioid Treatment Providers and Specialist Services developing a position to co-ordinate and progress matters of mutual interest such as transfers between regions, agreed clinical protocols and guidelines (eg, on clients’ use of alcohol and other drugs).

## External review

- 2.26 The Ministry of Health or the District Health Board may at any time request an external audit based on the Audit Tool for Opioid Substitution Treatment Services. Copies of the Audit Tool are available from the Ministry of Health.
- 2.27 Service self-reviews and peer review processes using the Ministry of Health Audit Tool with the goal of improving the quality of opioid substitution treatments such as

MMT are encouraged, with consultation and support from the National Association of Opioid Treatment Providers.

## 3 Methadone Maintenance Treatment

### Prescribing process

The prescribing process described below applies to all prescribers, whether approved to prescribe or whether working under authority.

- 3.0 Methadone prescriptions are to be written on the approved H572M forms unless the provider has the written authorisation of the Director-General of Health to use computer-generated forms, and are to be for no longer than 28 days' supply.
- 3.1 Methadone prescriptions (amount prescribed written in words and figures) should generally be received by the pharmacist in writing either by letter that is posted or couriered before the due date to supply. In some areas this transmission may be possible by fax (the original is to be received by the pharmacist within two working days). As well, the service user may be given the prescription to take to the pharmacy.
- 3.2 The prescriber is responsible for notifying the pharmacist (with confirmation in writing) of:
  - any changes in methadone dose
  - cancelled doses of methadone when the service user attends another pharmacy temporarily
  - any changes in takeaway methadone dose approval or day(s) of takeaways
  - termination of treatment from that pharmacy at the end of the script.
- 3.3 Prescriptions should be started on a day of the week that the person is usually observed consuming their methadone and not on a day he or she has a takeaway dose and should be in weekly cycles rather than monthly.
- 3.4 Starting prescriptions on a Saturday, Sunday or public holiday should be avoided unless the prescriber is prepared to be contactable should any questions arise and has an arrangement with the pharmacist beforehand to dispense on these days.

### Takeaway methadone doses

- 3.5 Takeaway doses of methadone (takeaways) refer to any doses that are not consumed under observation at the specialist service, doctor's surgery or pharmacy premises.
- 3.6 It would be uncommon for a service user to have takeaway arrangements early in treatment. The provision of takeaways should be based on clinical decision-making by the case management team, including consultation with the service user and clearly documented in the case file. It is recommended that methadone should be observed to be consumed at the pharmacy or other dispensary on at least three non-consecutive days per week. Less frequent dispensing may be considered in the case of stable clients as a result of case management team review.

- 3.7 To be eligible for takeaways, individuals will at a minimum need to demonstrate stability and an ability to comply with the safety requirements of the service.
- 3.8 Prescribers will specify their safety requirements around takeaways in writing and ensure copies of the information are provided to the service user and the pharmacist. Prescriptions must clearly specify the days of the week that takeaway doses will be dispensed.
- 3.9 Some or all of the following can assess adherence to safety requirements of the prescriber:
- consulting with the person's case worker or members of the primary health care team as appropriate
  - assessment of the ability of the service user to take responsibility for their takeaways (may include consultation with family/whānau, significant others, particularly when children are living in the household)
  - an absence of drug-seeking behaviour patterns
  - urine drug screening showing a positive result for methadone and where other drugs of dependence are identified through the urine drug screen, conducting an assessment of harmful or hazardous use of other drugs, especially alcohol, benzodiazepines and amphetamines.
  - consulting with the dispensing pharmacist
  - evidence that the person actively participates in the management of their treatment (eg, through attendance at doctor, case worker and case management team appointments, progressing towards agreed treatment goals).

## **Safety requirements for dispensing**

- 3.10 The following requirements apply to all methadone dispensing but need to be particularly considered when giving a person takeaway doses.
- 3.11 Safety requirements must include assessment processes that ensure:
- potential to overdose is limited
  - the person is not unsafely intoxicated with other drugs
  - the person is advised on safe storage practices to enhance the safety of children and others in the household
  - potential for methadone diversion is limited.

## **Dispensing arrangements**

- 3.12 Takeaway methadone arrangements are to be reviewed regularly by the specialist service or by the authorised or approved GP as appropriate. Whenever the case worker and/or prescriber considers that the service user is not meeting the safety requirements as outlined in paragraph 2.9 of this protocol, these takeaway arrangements should be reviewed.

- 3.13 Planned holidays (or courses) require at least two weeks' notice. Service users are to be encouraged to nominate pharmacies to which prescriptions can be transferred on planned holidays. Generally, clients/service users should have no more than four doses in hand.
- 3.14 Takeaway doses can be provided for specific short periods in response to unforeseen circumstances or even on a regular basis. This may be useful in times of crises, courses of study away from home and when there is a legitimate illness that prevents presentation at a pharmacy or in other unforeseen circumstances. It is important to assess the stability and 'safety' of the service user, the legitimacy of their circumstances and whether the positive effects of short-term arrangements at an alternative clinic or pharmacy outweigh any likely destabilising effect of not allowing the variation.

### **Dose replacement policy**

- 3.15 Prescribers will not authorise replacement doses of methadone when doses are lost or stolen except in exceptional circumstances that can be verified. When requests are made for replacement doses, the prescriber needs to review the person's takeaway arrangements.
- 3.16 Should a person vomit within approximately 30 minutes of consuming their dose the decision to replace the dose may be only made by the prescriber or the specialist service medical officer.

- It is important for pregnant women to have their serum opioid levels as stable as possible to minimise risk to both the pregnancy and the foetus. Ideally, replacement doses would be authorised only after appropriate assessment of the woman's current medical need.
- Frequent vomiting by pregnant women on MMT might give rise to consideration of antiemetics to obtain stability in serum opioid levels.

### **Other drug prescribing**

- 3.17 GPs working under authority should not prescribe hypnotics, anxiolytics or strong analgesia without consulting the authorising medical practitioner or the relevant specialist service.

### **Last methadone dose**

- 3.18 Prescribers of methadone or the relevant specialist service must notify the pharmacy whenever treatment of a service user has been terminated.
- 3.19 Medical practitioners working under authority must notify their specified methadone treatment service when the service user ceases treatment and/or the GP withdraws methadone treatment.

## Ongoing support services

3.20 Ongoing support services should be available to clients/service users and either provided by the specialist opioid substitution service or by way of referral. In the case of GPs, they may be working within the context of a wider primary health care team that may have the resources to be able to provide directly some of the supports identified. These supports may include:

- information and education on health issues, especially on how to reduce the spread of infectious diseases such as HIV/AIDS, hepatitis B and C, and sexually transmitted diseases and living with HIV/AIDS, hepatitis B and C
- information on general health and welfare issues, including role and social functioning (eg, employment/education/training, parenting), should be available and accessible and may be given to the service user as appropriate. This should include issues around pro-social modelling, keeping children safe while parents are using drugs, or during relapse
- information and/or referral to other health and social services available to them in the community; for example, family planning agencies, budget services and childcare facilities, and support in the areas of child development and parenting
- concurrent cognitive-behavioural or other psychotherapeutic/social interventions (including ethnocultural programmes, self-help groups) offered, either by the specialist service or by another health or social service agency
- information on the after-hours emergency services available in the case of an overdose or other emergency. Specialist services and authorised GPs should have provision for crisis intervention, or access to such services, should the need arise.

## Relapse prevention

3.21 Clients/service users and (with consent and wherever possible) their families/whānau and significant others should be offered support and assistance to maintain the stability in their lifestyle gained from MMT. It is often forgotten that MMT itself is a relapse strategy.

3.22 The case worker or primary health care team and service user should work towards goals that relate to sustained reduction of intake of, or abstinence from, opioids and other psychoactive substances (including alcohol), support for healthy lifestyles and the development of new interpersonal problem-solving skills and development of role and social functioning.

3.23 Naltrexone is contraindicated while someone is taking methadone although it may be suitable after a person has safely withdrawn from methadone.

## Urine drug screens

- 3.24 Specialist services and other MMT providers may obtain urine samples for drug screening to test for the presence of psychoactive drugs, including methadone. Clients/service users need to be fully informed of this procedure and the rationale. Urine drug screening has some benefits in demonstrating recent drug use (but not the extent or the pattern of use) and is one way to obtain helpful information to assist in determining safety and progress in relation to treatment goals. It should be noted:
- urine samples may not be a reliable indication of drug use if voiding is not observed (there are other solutions such as the use of heat strips on collection bottles and use of professional laboratory services to take samples)
  - many clients/service users find supervised urine collection demeaning
  - false positive and false negative results do occur
  - urine drug screenings per se do not reliably reduce extraneous drug use.
- 3.25 When urine samples are taken (eg, at the initial assessment, prior to the first dose if admission to the programme is delayed and thereafter for monitoring purposes), procedures should be in place that ensure the integrity of the specimen, the service user and any staff member observing. If there is to be observation of the passage of urine there should be an appropriate environment for taking urine samples and staff of the appropriate gender should be involved.

## HIV and hepatitis testing and education

- 3.26 People commencing on methadone will tend to have high rates of blood-borne infections. Because of the risk of future hepatitis A and/or B infection, all those who do not have protective levels of antibody should be offered vaccination. The specialist service or GP needs to have adequate access to testing and treatment for Hepatitis A and/or B for people on opioid substitution treatment if and when appropriate.
- 3.27 All MMT providers (specialist services and GPs) should be trained in HIV and hepatitis-related issues and be able to provide education for clients/service users and other health and social service providers as part of their specialist consult and liaison role.
- 3.28 HIV and hepatitis B and C tests should be offered as part of the initial assessment by specialist services. Testing can be done only with informed consent. If the person chooses not to take the test, it should not influence their access to opioid substitution treatment. Follow-up HIV and hepatitis testing should also be offered at appropriate periods, especially where high-risk behaviours continue to occur. People who do not have protective levels of hepatitis B antibodies should be advised about immunisation.

- If tests are ordered then there is a duty of care to interpret the results correctly. Those who are hepatitis C antibody positive will not need to have a test repeated but will need initial assessment of their liver function and also assessment of whether or not they are viraemic by PCR testing for hepatitis CRNA.
- Any monitoring requirements for liver function and any other tests should be determined in consultation with local infectious diseases specialists or a gastroenterologist.

- 3.29 All people having an HIV test must consent to, and receive, pre- and post-HIV test counselling. Those having the test for hepatitis B and C should also receive pre- and post-HCV/HBV test counselling.
- 3.30 In order to preserve privacy the use of a code on a blood form should be offered.
- 3.31 All results of HIV and hepatitis testing should remain confidential to the individual and the MMT provider.
- 3.32 Hepatitis B vaccinations should be offered to all people who are not immune. Partners and families should also be offered immunisation if they have independent risk factors.
- 3.33 When a service user who is a hepatitis C and/or a hepatitis B carrier has achieved stability and ceased injecting drugs, referral for specialist assessment should be discussed. If they consent to this then a referral to an appropriate local specialist service (eg, a gastroenterologist or infectious diseases physician) can be made. Local protocols for referral should be developed.

## 4 Pharmacist Dispensing

Pharmacists provide an important function in supporting the community-based management of people on opioid substitution treatment such as MMT programmes. The community pharmacist works alongside the specialist services and general practitioner.

### Shared responsibilities of pharmacists and prescribers

4.0 Pharmacists and prescribers are part of the team of people working with clients/ service users in the process of delivering MMT.

4.1 Prescribers and their team should:

- acknowledge the pharmacist as an integral part of a multidisciplinary team caring for methadone service users
- adhere to the guidelines on prescribing set out in section 2 of this document
- acknowledge that pharmacists, in supplying methadone, are constrained by legislative requirements and prescribers must supply written prescriptions and authorisations within the required time
- provide support to community pharmacies dispensing methadone and communicate with them regularly.

4.2 The pharmacist must dispense methadone in accordance with the prescription and relevant legislation and maintain confidentiality of the personal information and treatment. If they are unclear, or have concerns about, any prescription they are expected to seek clarification from the prescriber.

4.3 In addition, the pharmacist should provide the following services:

- a non-judgemental service that recognises the potential damage stigma may cause this group of health consumers, their families/whānau and significant others
- supervise consumption of methadone on the pharmacy premises on the days the pharmacy is open for the supply of methadone
- liaise with the MMT provider on a regular basis and maintain a communication network with the dispensing nurse, specialist service case workers, other pharmacists and prescribing medical officers or GP and after-hours pharmacy where appropriate
- listen to, and be aware of, any relevant problems that the service user may be having and communicate these to the case worker or the prescribing GP
- liaise with the Medicines Control Advisor regarding the specialist service, GP MMT providers and any problems involved
- direct the service user back to the specialist service or prescribing GP if they have any problems (nausea, drowsiness) seemingly due to the methadone prescribed

- if requested and able to, facilitate the delivery of the first methadone dose to the specialist service or prescribing GP, so that the service user can be observed taking the methadone by the prescriber.

## **Methadone formulation**

- 4.4 Pharmacists will use an appropriate commercial methadone formulation. If a particular service user cannot tolerate the commercial formulations then the pharmacist will make contact with the prescriber to discuss an extemporaneous formulation that may be prepared.
- 4.5 When preparing an extemporaneous formulation, pharmacists must comply with the New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods, Part 3: Compounding and Dispensing, 1993.

## **Procedures for administration and dispensing**

- 4.6 Pharmacists will comply with all regulations regarding controlled drugs, including the requirements for recording, storage and telephoned prescriptions and authorisations as detailed below.
- 4.7 There are two ways in which a person can receive their medication: as an administered dose consumed under observation or as a dispensed dose taken away to be consumed. A takeaway dose of methadone is any dose that is not consumed under observation.
- 4.8 A pharmacist must ensure that the correct medication is given to the right person in the right dose at the right time. This should include:
- ensuring the legality of the prescription
  - sighting of photographic identification if the person is not known to the pharmacist. A detailed description by specialist service staff or the prescriber may suffice
  - following correct labelling, record keeping and filing procedures
  - observation of dose consumption when on the pharmacy premises.
- 4.9 Where pharmacists are dispensing to more than 10 people on a regular basis, an automatic self-zeroing, dose-measuring pump/burette (or an apparatus of a similar nature) should be used to facilitate measuring to minimise dose errors.
- 4.10 Unused methadone or the next day's doses must never be left on the dispensary bench overnight. It is recommended that, when filling the dose-measuring pump/burette (or an apparatus of a similar nature) for dispensing, the pharmacist uses sufficient for one day's supply only. Any unused methadone solution must be returned to the controlled drug safe when not required for immediate use. The dose-measuring pump/burette must be cleaned and stored appropriately for use the next day.

## Administration of consumed dose

- 4.11 The person receiving MMT must consume the full dose of methadone dispensed under observation at the time of each administration. The procedure should include:
- a measured dose
  - giving the disposable cup to the person
  - observing the service user swallowing the dose and confirm by having them speak and/or drink additional fluid
  - disposable cups must not be recycled and should, where possible, be disposed of in a biohazard container.

The preparation in advance of methadone doses for multiple clients may be a practical procedure but it is often associated with many of the reported dosing errors. An audit trail must be maintained up to and including the handing over of takeaway doses and the actual consumption of the dose by the service user.

## Takeaway doses of methadone

- 4.12 Takeaway methadone doses are to be dispensed as individual daily doses with each day's dose packed in appropriately labelled bottles with child resistant closures (CRCs). Pharmacists should ensure that those receiving methadone can open *and close CRCs correctly*, and are aware of the need for these CRCs. Pharmacists should emphasise the importance of storing takeaway doses in a cool place, out of sight from, and out of the reach of, children (preferably locked away).
- 4.13 In exceptional circumstances the prescriber may endorse the prescription not to be dispensed in a container with a safety cap, or the pharmacist may annotate the prescription to the effect that, because of infirmity the person cannot access the methadone so it has been supplied without a safety cap (see section G, Pharmaceutical Schedule).
- 4.14 Where a dose is being delivered via an agent, there should be written notification of the agent's approval to collect the dose(s) from the prescriber or specialist service case worker.

## Delivery of methadone

- 4.15 In some cases pharmacies may be requested to deliver methadone for consumption. This would apply most often in situations where the person is in police custody or in prison. Pharmacies should have a delivery plan that maximises the safety of the pharmacy staff, ensures that the correct person receives the prescribed dose of methadone and ensures that consumption is observed and confirmed.

## **Telephoned methadone prescriptions and authorisation of takeaway doses**

- 4.16 Pharmacists should confirm any authorisation given over the telephone has actually originated from the specialist service/ prescriber by calling back immediately. Use of written confirmation by fax may assist in the speedy actioning of any authorisation.
- 4.17 In accordance with regulation 34 of the Misuse of Drugs Regulations 1977, any changes in methadone dose given by telephone (the exception rather than the rule) must be confirmed in writing to the pharmacy together with confirmation of the cancellation of the amended prescription. The original of the new prescription must be sent to the pharmacy within two business days.
- 4.18 Sometimes a special request will be made to alter conditions related to takeaway doses of methadone. The specialist service or person's doctor must first approve these requests. If granted, the approval may be telephoned and then faxed through to the dispensing pharmacy who will verify the call or message as above. It is expected that the prescription will include the days takeaway doses are to be dispensed. All such variations should be documented in the specialist service or patient case notes.

## **Cancellation of administered or dispensed doses**

- 4.19 GPs, methadone service clinical staff (including case workers, pharmacists and clinical team leaders) or the dispensing pharmacist may cancel doses of methadone or cancel takeaway arrangements for people in order to:
- prevent a person from receiving a double dose of medication
  - prevent an intoxicated person from receiving additional medication
  - prevent situations that may endanger a person's health and life
  - ensure that an accurate medication serum level is obtained
  - re-establish contact with a client/service user where all other attempts have failed.

Decisions to cancel a methadone dose should not only consider the above but should also have regard to the safety of people who will next come in contact with the service user, whether at the pharmacy, clinic or at the GP practice. Pharmacists should, wherever possible, cancel a dose only after consultation with the prescriber or case worker.

- 4.20 Notification of all cancellations of methadone doses will be in writing.
- 4.21 Any of the above persons who initiate a methadone dose cancellation must notify the person directly of any cancellation. If direct contact is unable to be made with the person, a confidential letter will be sent to the person, via the pharmacy, outlining the reasons for this intervention.

- 4.22 When a pharmacist cancels a methadone dose, they must notify the appropriate prescriber or specialist service by phone on the day on which the dose was cancelled and follow up by providing written (email, letter or fax) verification of the intervention and the reason for that intervention within two business days.

## **Risk management**

- 4.23 The pharmacist should notify the prescriber by phone or in writing when the person:
- fails to present for their methadone dose
  - presents as intoxicated at the point of dispensing
  - exhibits abusive or threatening behaviour
  - diverts their methadone or makes a serious attempt to divert their methadone
  - is believed to have administered takeaway oral methadone intravenously
  - exhibits withdrawal symptoms
  - deteriorates in their physical, emotional or mental state.

The prescriber may be contacted when the client fails to present for one dose; however, it is strongly recommended they be contacted if two consecutive doses have been missed.

- 4.24 The pharmacist should not dispense to a service user who has not collected their medication for three consecutive days without authorisation of the specialist service or GP as the prescriber will need to:
- review the service user's situation before dispensing resumes
  - notify the pharmacist in writing if authorisation to resume dispensing is given.
- 4.25 The pharmacist should have current policy and procedures in place describing:
- procedures to minimise the risk of dispensing errors
  - specific actions to be taken in the event of a dispensing error
  - records that are made of action taken in the event of dispensing errors.
- 4.26 The pharmacist should contact the prescriber for clarification of any administration/dispensing instructions that are unclear on the prescription.
- 4.27 Where a pharmacist has administered less than the prescribed dose of methadone, the balance of the methadone dose must be given on the same day or not at all.
- 4.28 Where a pharmacist has administered a higher than prescribed or overdose dose of methadone to a service user, the pharmacist will:
- immediately advise the person of the medication error and the need for the person to be seen by the service or prescriber within three to four hours
  - as soon as possible advise the prescriber of the medication error if the person has already left the pharmacy. The prescriber (or person delegated) will make every effort to contact the person to advise and request the person to attend for a medical appointment

- notify the prescriber in writing of the incident and actions taken.

4.29 Pharmacists should have procedures in place for the management of abusive behaviour or other disruptive incidents. The procedures should include how to access any support from the prescriber service that might have been agreed upon.

## 5 Exit Procedures

- In all cases a discharge plan must be developed and documented once a decision to withdraw from treatment (voluntary or involuntary) has been made.
- Those persons who cease opioid substitution treatment voluntarily after a gradual withdrawal are less likely to relapse into illicit opioid use than those undergoing unplanned, involuntary withdrawal.
- Individuals vary greatly and it is best to allow clients/service users to control the frequency and amount by which their dose is reduced during voluntary reduction.

### Voluntary withdrawal

- 5.0 The best outcomes occur when the service user and the prescriber agree on the methadone withdrawal regime. Withdrawal should ideally occur only when a person has achieved a number of their treatment goals and has reached a stage of stability giving them reasonable chance of successfully achieving sustained abstinence from opioids.
- 5.1 Planned withdrawal from any opioid substitution treatment such as MMT should have a flexible end point and involve the offer of, or referral to, appropriate psychosocial and medical support (eg, in selected cases use of naltrexone may be beneficial). Other psychotropic medication (in particular hypnotics and sedatives) is not generally recommended during monitored withdrawal except when indicated for diagnosed psychiatric coexisting disorders and, even then, doses should be low for a specified short duration.
- 5.2 Monitoring and support during the period after treatment termination is particularly important if the person is to remain opioid drug free and the service user should be fully informed about the available resources to help maintain stability and reduce the risk of relapse.
- 5.3 A person who has completed withdrawal from methadone should have access back into methadone treatment if they are not able to maintain stability and without having to be placed on a waiting list. This option should be negotiated and agreed between the specialist service, prescriber and the service user before withdrawal is completed and should be for a realistic finite period following the last dose (eg, two months).

## Involuntary withdrawal

- Involuntary withdrawal has serious risks to the health of the service user and may well have implications for others, including the wider community.
- Flexibility and strategic thinking is encouraged rather than 'knee-jerk' treatment termination approaches. An important outcome measure of MMT is retention in treatment.
- Involuntary withdrawal should be a last resort and decisions relating to termination should be initiated only after careful consideration by the case management team and with input from a number of other sources.

5.4 Sometimes an involuntary reduction in methadone dose may occur, such as when the person has to serve a prison sentence longer than the period of withdrawal from methadone (see Prison Protocol in Appendix 8) or when the person is withdrawn from treatment for unacceptable behaviour. Services should have a management plan for these circumstances.

5.5 Methadone treatment providers may consider discharge of those people who do not adhere to the safety requirements or for whom methadone is not considered an effective treatment (ie, the benefits of opioid substitution treatment are outweighed by the negative outcomes and elements of risk). People may be considered for involuntary withdrawal in the following situations:

- regular overdose or intoxication from psychoactive substance use. It is important to note that relapse is a feature of addiction and this should be taken into account
- behaviour that is not acceptable to the specialist service, prescriber or pharmacist (violence or threat of violence to staff or other service users)
- inability to keep to the safety requirements of the MMT provider
- lack of engagement and co-operation such as repeated failure to keep appointments.

The injecting of methadone or use of other drugs (eg, cannabis), should not automatically be an indication for involuntary withdrawal of treatment.

5.6 Where possible, written or verbal warnings should be provided prior to withdrawing treatment.

5.7 Detoxification programmes, whether inpatient or outpatient, should be offered with an involuntary withdrawal of treatment. Rapid dose reduction should be avoided unless unavoidable; for instance, in cases of violence. The dose should be reduced gradually over at least 21 days and preferably over four to six weeks.

- 5.8 Before any decision to withdraw treatment involuntarily in a specialist service is made the case worker is expected to discuss the matter with the service user, and, where possible, (with consent) with the person's family/whānau and significant others, including GP. The final decision should be made by the prescribing doctor in consultation with the case worker and service manager or the primary health care team (whichever applies).
- 5.9 When involuntarily withdrawn, the service user will be:
- informed of other treatment options available
  - given the reasons for the discharge in writing
  - given a specified period of stand-down as agreed by the team
  - given an outline of the service's complaints procedure for review of the decision
  - offered service user support during the process.
- 5.10 The service user's GP and pharmacy is expected to be contacted and made aware that opioid substitution treatment has been withdrawn.
- 5.11 If a service user has HIV/AIDS and may be threatening unsafe behaviour if their treatment is terminated, the treatment provider should consult with the local Medical Officer of Health before treatment is terminated. Such consultations are privileged under the Health Act even though HIV is not officially a notifiable disease.
- 5.12 Each case of involuntary treatment withdrawal should be reviewed to determine how best the service user might re-engage in opioid substitution treatment.

## 6 Use of Methadone in Pregnancy

- 6.0 When women enter MMT, they should be informed about the effects of methadone, alcohol, nicotine and other drug use on a foetus if they become pregnant.
- 6.1 MMT during pregnancy can improve the health of the mother and the chances of a full-term healthy baby. The main risk to the health of the foetus is for the pregnant women to start and stop opioid use, particularly where this precipitates the opioid withdrawal syndrome. Pregnant women are a priority group for MMT.

- Methadone crosses the placenta and, in sufficient doses – usually a maternal dose of more than 30 mg daily – may cause respiratory depression in the newborn infant. Ventilation support, as required, is recommended in the management of respiratory depression of the newborn infant. The use of naloxone is contraindicated, as it may precipitate a severe abstinence syndrome.
- Withdrawal symptoms (neonatal abstinence syndrome) in the newborn methadone infant can be moderately severe if not appropriately treated and can be life threatening due to possible fluid and electrolyte imbalance and seizure. The newborn infant should therefore be under the care of an experienced paediatrician and preferably delivered in hospital.
- Methadone metabolism in the mother may be increased during pregnancy, leading to lower plasma methadone concentrations and, in some cases, symptoms of methadone withdrawal. In such cases, the methadone dose may need to be increased or given in divided doses. These arrangements should be reviewed postpartum when maternal physiology returns to the non-pregnant state. Monitoring of serum levels and dose effects need to continue postpartum to re-establish dose stability.

- 6.2 Pregnant women may be managed by a specialist service, an authorised GP or an approved GP. In each case, the responsible clinician will ensure each woman has information regarding the effect of MMT and illicit opioid use with nicotine, alcohol and other drug use on the foetus.
- 6.3 If a pregnant woman is stable on methadone and is being managed by a GP, she does not need to be referred back to the specialist service. However, the specialist service may provide support for the GP as part of the consultation/liaison role expected of all services.
- 6.4 Both GPs and specialist services will ensure that the pregnant woman has appropriate access to antenatal and postnatal care from practitioners aware of the antenatal and medical needs of women receiving MMT.
- 6.5 Each specialist service should have a local protocol for the management of pregnant opioid- and drug-using women. This local protocol should include liaison arrangements with the GP, obstetrician, paediatrician, midwife, postnatal nurses and pharmacists.

- 6.6 MMT service staff involved with mothers receiving methadone treatment have a consultation and liaison role to make education available to other specialist alcohol and drug service staff, opioid users, GPs, nurses, obstetricians, paediatricians, midwives and pharmacists about the benefits and risks to mother, foetus and baby of opioid substitution treatment.
- 6.7 Except where contraindicated for other medical reasons the benefits of breastfeeding outweigh the risks (except in the case of maternal HIV positive status) and therefore is to be encouraged. The amount of methadone present in breast milk is minute and unlikely to harm the infant in the first three to six months of life. Breastfeeding mothers should be advised to wean slowly off breastfeeding when they decide to stop to reduce the possibility of mild withdrawal symptoms being experienced by the baby.

## 7 Treatment of Pain

It should be noted that any medical practitioner can prescribe a controlled drug for someone who is drug dependent and who requires them for reasons other than treating substance dependence.

- 7.0 Methadone, when prescribed as an opioid substitution treatment, does not provide an analgesia for acute pain on its own.
- 7.1 For most people receiving methadone treatment, effective analgesia is achieved by conventional doses of opioids or other drugs additional to maintenance methadone. However, in some cases there may be cross-tolerance to pain relief. In such cases, expert advice should be sought from a pain professional.
- 7.2 For surgical procedures, full MMT doses can be administered throughout the hospital stay, and additional opioids given as appropriate for the procedure.
- 7.3 Cross-tolerance with opioid surgical premedications can occur in the methadone-maintained individual so that higher doses of these agents may be indicated; however, these should be instituted with caution, especially if the person has hepatitis C.
- 7.4 Note that mixed agonist-antagonist drugs, such as pentazocine (Fortral) and buprenorphine, can produce opioid withdrawal symptoms when used with MMT.
- 7.5 Clients/service users should inform their MMT provider if they are planning to undergo surgical or medical treatment. The treatment provider should then liaise with the medical or surgical service to confirm the timing and dose of methadone before and after the event and to ensure the methadone treatment is uninterrupted during hospital admission and convalescence.
- 7.6 There may be other instances where MMT providers, with the agreement of the service user, may need to advise hospital staff, dentists or other health professionals regarding MMT and pain management when the service user is undergoing treatment that may require pain medication.
- 7.7 People receiving methadone treatment may have hepatitis C and, consequently, their liver function may be impaired. This must be taken into account when prescribing. The dose of paracetamol, for example, needs to be well within the standard 4 g per day.
- 7.8 Where there is chronic, non-malignant pain syndrome in opioid-dependent people, there should be consultation and liaison between pain and MMT services and GPs. Ideally, this should have occurred before the initiation of opioid analgesia. Opioid medication for those with co-existing substance dependence will only rarely be appropriate and will require careful consideration and documentation.

## 8 Application for Approval to Offer Methadone Maintenance Treatment

- 8.0 It is an offence for a medical practitioner to prescribe controlled drugs for the treatment of dependence unless the practitioner is approved or authorised under the Misuse of Drugs Act 1975.
- 8.1 Approval to prescribe, administer or supply controlled drugs for the purposes of treating people dependent on controlled drugs will be given only to services or medical practitioners that fulfil the criteria set out by the Ministry of Health. In recommending services or medical practitioners for approval, the Ministry of Health will be guided by this protocol, other approved standards and processes and the following principles:
- (i) **A single authority in each area:** The central provider of alcohol and other drug services in the area will be the only services specified under section 24(5)(b) of the Act unless there is good reason to the contrary. These organisations will have accountability to the Ministry of Health for those services and medical practitioners working under their authority.
  - (ii) **Direct and ongoing relationship between the practitioner and support services:** When approving a medical practitioner under section 24(5)(a) of the Act that medical practitioner must have a direct and ongoing relationship with the central provider of alcohol and other drug treatment services for that area. This would involve a letter from the local specialist service stating their support for the approval of that medical practitioner and arrangements to ensure an ongoing relationship with that service.
  - (iii) **Teamwork:** The successful treatment of severe opioid dependence typically requires teamwork in a multidisciplinary environment. This principle is of particular importance when approving medical practitioners under section 24(5)(a) of the Act, in that it is a requirement that there be clearly documented intention that there will be an ongoing relationship with the local specialist treatment service provider.
  - (iv) **Efficiency/effectiveness:** There should be regional/subregional coherence in the provision of alcohol and other drug treatment services, including opioid substitution treatment, to ensure there is no ‘doubling up’ of services.

### Approval of methadone maintenance treatment services

- 8.2 The Minister of Health has delegated authority to the Director of Mental Health to specify places and medical practitioners so that they may provide services for those assessed as suitable for MMT.
- 8.3 The Director of Mental Health has adopted the criteria outlined below to decide whether to approve a service to be specified as a methadone treatment service or, when already approved, whether it can continue to remain as a specified place to deliver methadone treatment.

- 8.4 Each application must be made on the form contained in these guidelines and will be considered on its merits. In general, a service that does not meet the principles above, or the requirements of these guidelines, will not gain approval.
- 8.5 The Director of Mental Health will consider submissions from organisations, or persons wishing to run a specialist service, explaining why deviation from the specified criteria should be permitted.

### **The criteria**

- 8.6 To be approved as an MMT service the organisation must be a legal entity, be an established health service capable of offering continuity of service to the client group and have an approved or authorised medical practitioner working in the service.
- 8.7 The specialist service should be compliant with the relevant sections of the Alcohol and Other Drug Treatment Service Standard.
- 8.8 The specialist service should provide the Director of Mental Health with the names of all their clinical staff who work with opioid-dependent people. These staff members should include at least one registered medical practitioner specifically available at the service and at least one of the following who must be available during hours of service delivery:
- another health professional (eg, counsellor with relevant alcohol and other drug qualifications)
  - a clinical psychologist
  - a qualified social worker
  - a registered nurse.
- 8.9 All of the above should have training and/or experience in working with substance dependence, and with opioid-dependent persons in particular, to a level of competence acceptable to the Director of Mental Health.
- 8.10 The service will be responsible for informing the Director of Mental Health of any changes in the list of staff (including authorised GPs).
- 8.11 Services will comply with the provisions of the relevant Acts and adhere to these Practice Guidelines. From time to time, services may undergo an external audit process.

### **Existing services obligations**

- 8.12 If specialist services cannot fulfil any of the criteria set out above and in the Misuse of Drugs Act, 1975, the organisation or persons running the service should immediately inform the Director of Mental Health. A meeting will be arranged to resolve the situation to the satisfaction of the Director of Mental Health.
- 8.13 Where a service continues to be unable or unwilling to meet the criteria and, in the Director of Mental Health's opinion a satisfactory solution has not been found, the

Director of Mental Health may take action to revoke the notice given in the Gazette that specifies that place or prescriber as a provider of a methadone treatment service.

- 8.14 Before making a decision as to whether to revoke the status of a specialist service, the Director of Mental Health will accept and consider representations made by the organisation or persons running the service as to why the specified place should retain its status.

### **Medical practitioners working under authority**

- 8.15 Medical practitioners working under authority are those who are working with particular people in accordance with the terms and conditions set out in section 24 of the Misuse of Drugs Act (see Appendix 1).
- 8.16 This allows for MMT services to increase their medical capacity by using GPs working under authority to see more stable people.
- 8.17 GPs are suitable for managing methadone clients/service users when they have knowledge of these guidelines and agree to work within the requirements of the guidelines.
- 8.18 More specifically, the authorised GP prescriber needs to be familiar with:
- legal implications of the authorisation (ie, that authorisation is only for the named patients, for a set period, and in accordance with such terms and conditions as specified by the authorising medical practitioner)
  - treatment aims of the service
  - service policies, philosophy and procedures
  - appropriate record keeping
  - current methadone treatment issues
  - HIV/AIDS and hepatitis B and C treatment and prevention issues.
- 8.19 Conditions under which people can be transferred to the care of an authorised GP should be clearly set out in specialist service local protocols. These conditions should reflect best clinical practice and have consideration for the safety of the service user and the authorised medical practitioner.
- 8.20 The specified practitioner or service who authorises a medical practitioner to prescribe, administer or supply a controlled drug for the purposes of treatment of a controlled drug is responsible for ensuring those working under their authority comply with the sector standards and the requirements of these Practice Guidelines and have regular clinical supervision and access relevant training.

### **Application for approving medical practitioners**

- 8.21 Each application must be made on the form contained in these Guidelines and will be considered on its merits. In general, a medical practitioner that does not meet the

principles outlined at the start of this section or the requirements of these Guidelines will not gain approval.

8.22 Criteria used by the Ministry of Health in assessing applications for approving a medical practitioner include, but are not restricted to:

- the medical practitioner having a current annual practising certificate
- the medical practitioner having a practising certificate that has never been revoked
- the medical practitioner not having been the subject of a Gazette notice under section 23 of the Misuse of Drugs Act 1975 prohibiting him or her from prescribing controlled drugs
- the medical practitioner not having been the subject of a Gazette notice under section 48 of the Medicines Act 1981
- the extent of the medical practitioner's experience in providing treatment to people who are dependent on controlled drugs. In most cases this experience will be through working under the authority of a specialist service and a reference from that service is required
- the medical practitioner having the general support of the local specialist service
- the medical practitioner's agreement to comply with the requirements of these guidelines.

8.23 In addition, medical practitioners seeking to be specified by notice in the Gazette will be expected, as part of their continuing medical training, to keep up to date on opioid substitution treatment, MMT and related issues.

8.24 More specifically, the GP prescriber needs to be familiar with:

- legal implications of their role
- expectations of these Practice Guidelines
- appropriate record keeping
- current methadone treatment issues, HIV/AIDS and hepatitis B and C treatment and prevention issues.

### **Obligations of specialist services and approved medical practitioners to GPs working under authority**

8.25 There should be recognition of the varying levels of authorised GPs' expertise in prescribing methadone. In some situations, the specialist services or approved medical practitioner will specify the dose, dispensing frequency or takeaway regime in order to provide guidance and ensure that safety requirements are met. In other situations, only the written authority will be required from the specified service's authorising medical practitioner or chief executive officer. Consideration must be given to the overall responsibility that the approved medical practitioner has in supervising this situation.

- 8.26 The responsibilities of the approved medical practitioner or specialist service to the GP working under authority include ensuring that:
- proper authorisation is given to each GP for the named patient and that this is updated at three-monthly intervals
  - where authorisation is sought for longer than three months, approval is obtained through Medical Officers of Health
  - GPs have other information such as the safety aspects for methadone prescribing, suggested frequency of consultations, and methods of assessment and monitoring.
- 8.27 Because specialist services work with GPs under authority for a long period of time, the services also have a responsibility to:
- be available to discuss management problems with the GP
  - co-ordinate regular meetings with this group of GPs
  - review GP report forms
  - review patients at six-monthly intervals or at the request of the GP
  - take back into the service any patient whom the GP is no longer able to manage.

### **Revocation of authority**

- 8.28 Existing approved services or practitioners should ensure they comply with these Practice Guidelines to ensure continuation of approval.
- 8.29 If the GP working under authority does not comply with the requirements stated on the authorisation form, and specified in section 24(2)(d) of the Misuse of Drugs Act 1975, then the authority can and will be revoked, with the referring MMT service taking the person back under their direct care (see Appendix 1).

## Appendix 1: Glossary

Approved medical practitioner/service	Also known as ‘gazetted’. These medical practitioners or services have been approved by the Ministry of Health to prescribe, administer, or supply controlled drugs for the treatment of dependence subject to any general or specific conditions.
Authorised medical practitioner	An authorised medical practitioner, typically, is a general practitioner who is authorised by a specialist service to prescribe a controlled drug for the treatment of dependence to specified people for a specified time and in particular places.
Case worker	A case worker is usually the clinician assigned to be responsible for co-ordinating care and treatment and may provide some or all of the interventions planned. When the person is transferred to a GP working under authority from the specialist service, the GP may work closely with staff of the specialist service.
Diversion of methadone	Diversion is defined as a failure to consume on site and selling, swapping or giving methadone to others. Injecting the methadone or using the methadone against medical advice is more strictly ‘misuse’ not diversion.
Peak level	This is the maximum blood level that methadone reaches in the blood (approximately four hours after taking the dose).
Specialist service(s)	Specialist methadone programmes (specialist services) are those that have been specified by the Minister and notified in the New Zealand Gazette (published by the Department of Internal Affairs).
Stabilisation	Stabilisation is a multi-faceted condition and, at a minimum, would mean that a person can cope on a consistent regular dose of methadone without the need for constant dose changes and reviews and is able to work consistently towards agreed goals.
Takeaways	Takeaway doses of methadone refer to any individually packed, daily dose of methadone that is not consumed under observation at the specialist service, doctor’s surgery or pharmacy premises.
Trough level	The lowest level that methadone drops to in the blood over 24 hours (just prior to consuming the next dose).

## Appendix 2: Misuse of Drugs Act 1975 s24

### 24 Treatment of persons dependent on controlled drugs

- (1) Every medical practitioner commits an offence against this Act who, except as provided in subsection (2) of this section, prescribes, administers, or supplies any controlled drug for or to any person, whom the practitioner has reason to believe is dependent on that or any other controlled drug, in the course, or for the purpose, of treatment for dependence.
- (1A) Every registered midwife or designated prescriber commits an offence against this Act who prescribes, administers, or supplies any controlled drug for or to any person, whom the midwife or prescriber has reason to believe is dependent on that or any other controlled drug, in the course, or for the purpose, of treatment for dependence.
- (2) A medical practitioner may prescribe, administer, or supply any controlled drug for or to any such person if the medical practitioner –
  - (a) is for the time being a medical practitioner approved by the Minister under subsection (5)(a) and is acting in accordance with any general or specific directions imposed by the Minister under that approval; or
  - (b) is working in a place specified under subsection (5)(b) and is authorised, by a medical practitioner approved under subsection (5)(a) who is working in the same place, to prescribe controlled drugs; or
  - (c) is acting in the medical practitioner’s capacity as a medical officer employed in a place specified under subsection (5)(b), and is authorised in writing by the chief executive of the organisation that runs that place (acting under the general or specific direction of a Medical Officer of Health) to prescribe controlled drugs; or
  - (d) is acting in relation to a particular patient during the period prescribed in, and in accordance with the terms and conditions of, a permission in writing given by an approved medical practitioner (as described in paragraph (a)) or an authorised medical officer (as described in paragraph (c)).
- (3) Except with the concurrence of the Medical Officer of Health, no permission given under paragraph (d) of subsection (2) of this section shall be expressed to apply for any period longer than 3 months, but any such permission may from time to time be renewed by the approved medical practitioner or by the authorised medical officer, or any other medical officer similarly authorised and employed in the same hospital, for a period not exceeding, except as aforesaid, 3 months at any one time.
- (4) Any authority or permission given or renewed pursuant to subsection (2) or subsection (3) of this section may, by notice in writing to the person to whom the authority or permission was given, be withdrawn at any time by the person who gave or renewed the authority or permission, and shall be deemed to have been so withdrawn when the notice specifying the hospital, health centre, clinic, or place, in or from which the authority or permission was given or renewed, or specifying the medical practitioner by whom the authority or permission was given, as the case may

require, is revoked, or, in the case of an authority under paragraph (b) of the said subsection (2), such medical practitioner dies or ceases to work in the hospital, health centre, clinic, or place to which the authority relates.

- (5) The Minister may from time to time, by notice in the Gazette, do any 1 or more of the following:
- (a) approve any medical practitioner as a medical practitioner who may, subject to any general or specific conditions imposed by the Minister on the recommendation of the Director-General of Health, prescribe, administer, or supply controlled drugs for the purpose of this section:
  - (b) specify by name or description any licensed hospital (within the meaning of the Hospitals Act 1957), or any health centre, clinic, or similar place, as a place at which controlled drugs may be prescribed, administered, or supplied for the purpose of this section:
  - (c) revoke any approval or specification under this section.
- (6) Nothing in the preceding provisions of this section shall apply to –
- (a) The treatment of a patient, within the meaning of the Alcoholism and Drug Addiction Act 1966, while he is in an institution, within the meaning of that Act:
  - (b) The emergency treatment of a patient in any hospital within the meaning of the Hospitals Act 1957, for a period not exceeding 3 days:
  - (c) The treatment of any restricted person within the meaning of section 25 of this Act.

## Appendix 3: Pharmacokinetics

1. Methadone is plasma protein bound 85 percent, with a Vd of 5 l/kg. It is metabolised chiefly in the liver and excreted as glucuronides. Methadone is reabsorbed in the renal tubules, and this reabsorption decreases as the urinary pH decreases. Methadone metabolites are also excreted in the faeces via the bile.
2. Methadone and morphine differ chemically, but their actions and analgesic potency are similar. For intramuscular administration, 7.5–10 mg methadone is equivalent to 10 mg morphine. For oral administration, 60 mg morphine is approximately equi-analgesic to 20 mg of methadone.
3. Methadone accumulates in the body on repeated administration.
4. Signs of methadone intoxication in an adult:
  - pinpoint pupils
  - hypothermia
  - respiratory depression
  - bradycardia
  - pulmonary oedema (not always)
  - hypotension
  - coma
  - seizures.

Rhabdomyolysis, myoglobinuria, muscle necrosis, and renal failure may occur secondary to methadone intoxication and may result from muscle damage related to prolonged coma and immobilisation or from a direct toxic effect of methadone.

### Treatment

Ensure that the airway is clear and perform emergency cardiopulmonary resuscitation as necessary. Take the person to hospital as soon as possible where treatment with an infusion of naloxone can be commenced.

Overdose patients should remain in hospital for 24–72 hours due to methadone's long half-life.

### Toxic dose level of methadone

- For non-tolerant adults, doses of 50 mg of methadone or less have been known to be fatal, including doses taken orally. Potentially lethal overdoses of methadone can occur within 30 minutes to six hours after ingestion by non-tolerant or partially tolerant individuals.
- Parenteral administration of methadone has a similar onset to morphine with peak plasma levels within 15 minutes to two hours.
- Oral methadone has a much longer onset (single dose: measurable amounts in the plasma at 30 minutes, peak levels at four hours) and duration of action (single

dose: half-life 10–18 hours or longer). Multiple doses 24+ hours (15–60 hours have been reported).

#### 5. **Children who ingest methadone**

The fatal dose of methadone in children is 10–20 mg.

- Symptoms of opioid overdose in children are similar to those in adults, with pupillary miosis; however, the pupils may be normoreactive or, rarely, fixed and dilated. Infants may have drowsiness, coma and apnoea. Children are usually, but not always, symptomatic.
- Known or suspected methadone-intoxicated children should be hospitalised, since respiratory depression may be observed for as long as 48 hours after ingestion. Successful resuscitation with a narcotic antagonist may be followed by relapse. Treatment must include establishment of an airway, maintenance of adequate respiratory ventilation, precise supportive care to maintain fluid and electrolyte balance, naloxone, emptying of the upper and lower gastrointestinal tracts, and prevention of aspiration of gastric contents.

## Appendix 4: Drug Interactions Associated with Methadone

The drugs listed below are known to affect methadone metabolism and should therefore be used with caution by those being treated with methadone.

**Note:** Those with hepatitis C may have impaired liver function. This needs to be taken into account when the use of drugs metabolised in the liver is considered. The dose of paracetamol, for example, needs to be well within the standard 4 g per day. For more information on the management of people with HIV or hepatitis, see section 4 in this document.

Drug	Status of effect	Interaction	Mechanism
Alcohol	Clinically important	Increased sedation, increased respiratory depression; combination may also have increased hepatotoxic potential	Additive central nervous system depression
Benzodiazepines	Clinically important	Enhanced sedative effect	Additive CNS depression
Buprenorphine	Clinically important	Antagonist effect or enhanced sedative and respiratory depression	Partial agonist of opiate receptors
Carbamazepine	Clinically important	Reduced methadone levels	Stimulates hepatic enzymes involved in methadone metabolism
Chlormethiazole	Clinically important	Enhanced sedative effect	Additive CNS depression
Cimetidine	Two cases have been shown in patients taking methadone as analgesia	Possible increase in methadone plasma levels	Inhibits hepatic enzymes involved in methadone metabolism
Cisapride, domperidone, metoclopramide	Theoretical	Theoretically might increase the speed of onset of methadone absorption, but not the extent	Possibly by reversing the delayed gastric emptying associated with opioids
Cyclizine and other sedating antihistamines	Clinically important	Anecdotal reports of injection of cyclizine with opioids causing hallucinations	Additive psychoactive effects; anti-muscarinic effects at high doses
Desipramine	Clinically important	Raised desipramine levels by up to a factor of two	Unknown interaction not seen with other tricyclic antidepressants
Other tricyclic antidepressants	Theoretical	Enhanced sedative effect, which is dependent	Additive CNS dose depression
Erythromycin	In theory should interact but combination has not been studied	Increase in methadone levels	Decreased methadone metabolism
Fluconazole	In theory the same as ketoconazole		

<b>Drug</b>	<b>Status of effect</b>	<b>Interaction</b>	<b>Mechanism</b>
Fluoxetine	Clinically important	Raised methadone levels, but not as significant as for fluvoxamine	Decreased methadone metabolism
Fluvoxamine, other SSRI	Clinically important, theoretical	Raised plasma methadone levels	Decreased methadone metabolism
Grapefruit juice	Should interact in theory and there have been several anecdotal reports	Raised methadone levels	Decreased methadone metabolism
Indinavir	Clinically important	Raised methadone levels	Decreased methadone metabolism
Ketoconazole	Clinically important	Raised methadone levels	Decreased methadone metabolism
MAOI (including selegiline and moclobemide)	Severe with pethidine though unlikely with methadone and has never been described	CNS excitation delirium, hyperpyrexia, convulsions, hypotension or respiratory depression	Unclear; avoid the combination if possible
Naltrexone	Clinically important	Blocks effect of methadone (long acting)	Opioid antagonist – competes for opiate receptors
Naloxone	Clinically important	Blocks effect of methadone (short acting), but may be needed if overdose suspected	Opioid antagonist – competes for opiate receptors
Nevirapine	Clinically important	Decreased methadone levels	Increased methadone metabolism
Nifedipine	Has been demonstrated <i>in vitro</i> only	Increased nifedipine levels; no effect on methadone levels	Methadone decreases the metabolism of nifedipine
Omeprazole	To date, demonstrated only in animals	Increased methadone levels	Possibly affects methadone absorption from the gut
Phenobarbitone	Clinically important	Reduced methadone levels; increased sedation; additive CNS depression	Barbiturates stimulate hepatic enzymes involved in methadone metabolism
Phenytoin	Clinically important	Reduced methadone levels	Phenytoin stimulates hepatic enzymes involved in methadone metabolism
Rifampicin	Very important: most patients are likely to be affected	Reduced methadone levels	Rifampicin stimulates hepatic enzymes involved in methadone metabolism
Rifabutin	Occasionally clinically important	Decreased methadone levels	Increased methadone metabolism
Ritonavir	Clinically important	Ritonavir may increase plasma methadone levels	Inhibits methadone metabolism
Other protease inhibitors	Theoretical	May raise or lower methadone plasma levels	Inhibits methadone metabolism
Urine acidifiers (eg, ascorbic acid/vitamin C)	Clinically important	Reduced plasma methadone levels	Raised urinary excretion of methadone

<b>Drug</b>	<b>Status of effect</b>	<b>Interaction</b>	<b>Mechanism</b>
Urine alkalinisers (eg, sodium bicarbonate)	Clinically important	Increased plasma methadone levels	Reduced urinary excretion of methadone
Zidovudine	Clinically important	Raised plasma levels of zidovudine; no effects on methadone levels	Unknown
Zopiclone	Clinically important	Enhanced sedative effects	Additive CNS depression
Other opioids	Clinically important	Enhanced sedative effect	Additive CNS depression; enhanced respiratory depression
Other CNS depressant drugs (eg, neuroleptics, hyoscine)	Clinically important	Enhanced sedative effects, which are dose dependent	Additive CNS depression

Adapted from Drug Misuse and Dependence: Guidelines on clinical management, Department of Health, United Kingdom, 1999.

## Appendix 5: Selected Readings

- Adamson SJ, Sellman JD. 1999. The pattern of intravenous drug use and associated criminal activity in patients on a methadone treatment waiting list. *Drug and Alcohol Review* 17: 159–66.
- Amato L, Davoli M, Ferri M, et al. 2002. Methadone at tapered doses for the management of opioid withdrawal (Cochrane Review). *Cochrane Database Syst Rev* (1): CD003409.
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- Rounsaville BJ, Kosten TR. 2000. Treatment for Opioid Dependence: Quality and Access. *JAMA* 283: 1337–9.
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- Ward J, Mattick R, Hall W (eds). 1998. *Methadone Maintenance Treatment and Other Opioid Replacement Therapies*. Amsterdam: Harwood Academic Publishers.
- Weinrich M, Stuart M. 2000. Provision of methadone treatment in primary care medical practices: a review of the Scottish experience and implications for US Policy. *JAMA* 283(10): 1343–8.

## Appendix 6: Relevant Legislation and Codes of Practice

Services and medical practitioners approved under section 24 of the Misuse of Drugs Act 1975 are expected to comply with the legislation and guidelines outlined in the Nationwide Service Framework and Service Specifications, in particular:

### Legislation and codes

Alcoholism and Drug Addiction Act 1966  
Code of Health and Disability Service Consumers Rights Act 1994  
Health and Disability Services (Safety) Act 2001  
Health (Needles and Syringes) Regulations 1998  
Health and Disability Commissioner Act 1994  
Health Information Privacy Code 1994  
Human Rights Act 1993  
Medicines Act 1981  
Medicines Regulations 1984  
Misuse of Drugs Act 1975  
Misuse of Drugs Regulations 1984  
New Zealand Public Health and Disability Act 2000  
Official Information Act 1982  
Ombudsman Act 1975

### Ministry of Health and other relevant guidelines

- Guidelines for Effective Consumer Participation in Mental Health Services, 1995
- Guidelines for the Management of Suicidal Patients, 1993
- Guidelines for Referral to Obstetric and Related Medical Services, 1997
- Involving Families Guidance Notes: Guidance for involving families and whānau of mental health consumers in care, assessment and treatment processes, 2000
- Medical Aspects of Fitness to Drive: A guide for medical practitioners, 1999
- New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods, Part 3: Compounding and Dispensing, 1993
- Recovery Competencies for New Zealand Mental Health Workers, 2001
- Service Specifications
- Todd F, Sellman JD, Robertson PJ. 1999. *The Assessment and Management of People with Coexisting Substance Use and Mental Health Disorders*. Wellington: Alcohol Advisory Council, Ministry of Health and Mental Health Commission.

## **Professional codes of ethics and standards of practice**

Applicable to:

- medical practitioners, including psychiatrists
- registered psychologists
- pharmacists.
- nurses
- counsellors
- social workers
- occupational therapists.

## **Current sector standards and audits**

- SANZ. *Alcohol and Other Drug Treatment Service Standards*. Wellington: Standards New Zealand (to be published 2003).
- Audit Tool for Opioid Substitution Services (Ministry of Health, 2002).
- New Zealand Accreditation Board for Alcohol and Drug Services and SGS Healthmark, SGG International Certification Services (Pty) Ltd. 1996. *New Zealand Quality System Standards and Guidelines for Accreditation*. New Zealand.
- SANZ. 2001. *National Mental Health Standard: He whariki oranga hinengaro*. Wellington: Standards New Zealand.

# Appendix 7: Application Forms s24(5) Misuse of Drugs Act

## Front

<b>Applications as an approved practitioner (s24(5)(a) Misuse of Drugs Amendment Act 2000)</b>				
<p>This section applies to medical practitioners who wish to prescribe, administer or supply controlled drugs. They should have significant experience and training in alcohol and other drug-related treatment and opioid dependence in particular.</p> <p>Name of organisation:</p> <p>Address:</p> <p>Email:</p> <p>Telephone: <span style="margin-left: 200px;">Fax:</span></p>				
<b>Current employment situation</b>				
<p>1. Name of employer/practice:</p> <p>2. Number of years employed with that employer/ in this practice:</p> <p>3. Status of employment (eg, permanent, consultant):</p>				
<b>References</b>				
<p>4. Please attach a curriculum vitae with copy of current practising certificate.</p> <p>5. Please briefly describe the extent of your work experience and training in opioid substitution treatment.</p> <p>6. Please provide the names, addresses and telephone numbers of three referees for the Director of Mental Health to contact.</p> <p>7. Please provide a reference from the local specialist service supporting your application for approval to prescribe controlled drugs for opioid dependence. The reference should note protocols for regular consult and liaison, referral and service handover.</p>				
<b>Staff</b>				
Please fill in the following panel with information about all those who will be involved in opioid substitution treatment (this includes practice nurses, authorised prescribers, case workers or consumer advisors:				
Name	Position	Experience working in the AOD (years)	Alcohol and other drug qualifications	Prescribing methadone Yes/No
<p>Please provide position descriptions and/or CVs of doctors and senior staff of the service and indicate <b>whether any of the medical staff have been denied approval to prescribe controlled medicines in the past.</b></p> <p>* Is this staff member permanent, a visiting consultant or any other?</p>				

I agree:

1. To adhere to 'Opioid Substitution Treatment New Zealand Practice Guidelines' (Ministry of Health, 2002).
2. That my practice/service protocols and procedures are in keeping with the Practice Guidelines (please attach).
3. That my practice/service will comply with the Alcohol and other Drug Treatment Service Standard.
4. To a review of my status as an approved medical practitioner from time to time.
5. That I have not been the subject of a Gazette Notice under section 23 of the Misuse of Drugs Act 1975 prohibiting me from prescribing controlled drugs.
6. That I have not been the subject of a Gazette Notice under section 48 of the Medicines Act 1981.
7. That I will notify the Director of Mental Health of my/our staff composition (including prescribers responsible to this service) every six months from the date approval has been posted in the Gazette.
8. To advise the Director of Mental Health of medical practitioners whom I authorise to prescribe methadone under section 24(2)(b), (c) and/or (d) of the Misuse of Drugs Act 1975.
9. That I will prescribe only for people who have first been assessed as being suitable for opioid substitution treatment by a specialist treatment service specified to prescribe controlled drugs for the treatment of opioid dependence.
10. My/our practice/agency will ensure that that staff (including authorised prescribers) involved in opioid substitution treatment undertake relevant training and supervision to meet the minimum levels expected in the Practice Guidelines.
11. That my/our practice/agency will not establish a waiting list for methadone treatment or give any commitment of future treatment. All initial enquiries will be referred to the local specialist service.
12. That my/our practice/service will consult and liaise with the specialist methadone treatment service and relevant pharmacy on a regular basis.
13. That I will collect and forward such statistical data (eg, Annual National Methadone Census) and reports as required by the Ministry of Health.

*I agree that the information I have given is true and correct.*

*Signed:* .....

*Date:* .....

*Position:* .....

This authority, if granted, will be reviewed from time to time by the Director of Mental Health.

**Front**

<p><b>Application to be specified as a place of treatment for opioid dependence (s24(5)(b) of the Misuse of Drugs Amendment Act 2000)</b></p>				
<p>Name of organisation:</p> <p>Street address of service to be specified:</p> <p>Postal address:</p> <p>Email:</p> <p>Telephone: <span style="margin-left: 150px;">Fax:</span></p>				
<p>Name of person filing an application:</p> <p>Position:</p> <p>Legal status of organisation:</p>				
<p><b>Staff</b></p> <p>Please fill in the following panel with information about all those who will be clinically involved in opioid substitution treatment in your service (this includes, but is not limited to, case workers, social workers, nurses, psychologists and psychiatrists, pharmacists, kaimirimiri and doctors who may be authorised to prescribe methadone):</p>				
Name	Position	Experience working in the AOD (years)	Alcohol and other drug qualifications	Prescribing methadone Yes/No
<p>Please provide position descriptions and/or CVs of doctors and senior staff of the service and indicate <b>whether any of the medical staff have been denied approval to prescribe controlled medicines in the past.</b></p> <p>* Is this staff member permanent, a visiting consultant of any other?</p> <p><b>Note:</b> The Director of Mental Health requires updates of staff composition six-monthly from date of approval.</p>				

## Back

I agree that:

1. Our service will comply with the Opioid Substitution Treatment New Zealand Practice Guidelines.
2. Our service protocols and procedures are in keeping with the Practice Guidelines (please attach).
3. Our service will collect and forward such statistical data (eg, Annual National Methadone Census) as required by the Ministry of Health.
4. Our service will notify the Director of Mental Health of our staff composition (including prescribers responsible to this service) every six months from the date approval has been posted in the Gazette.
5. Our service complies with the Alcohol and other Drug Treatment Service Standard.

### Treatment programmes

6. Each service user will receive a written treatment plan that has been agreed between themselves and our service.
7. Each service user will have an assigned case worker.
8. Our staff will seek not only to minimise the harms of opioid use but also, within the resources available, to normalise the lives of service users.
9. Our staff will be trained in HIV and hepatitis issues.
10. Our organisation will have due regard for cultural and/or gender preference.
11. Our staff will undertake relevant training to meet the minimum training levels expected in the Practice Guidelines.
12. Our clinical staff (including doctors) will undertake clinical supervision on a regular basis from suitably experienced and qualified people.
13. Our service has a protocol for the management of pregnant opiate-using women.

### Ministry of Health requirements

14. We are willing to have our service independently reviewed, as required, by the Director of Mental Health.
15. We agree to provide the Director of Mental Health with any required information (eg, reports).

*I agree that the information I have given is true and correct.*

Signed: \_\_\_\_\_

Date: \_\_\_\_\_

Position: \_\_\_\_\_

This authority, if granted, will be reviewed from time to time by the Director of Mental Health.

# Appendix 8: Prison Opioid Substitution and Detoxification Protocol (Agreed May 2000)

## 1 Preamble

This protocol:

- supersedes the current Protocol for Methadone Treatment in Prisons
- forms an appendix to the National Protocol for Methadone Treatment in New Zealand
- constitutes an agreement between the Department of Corrections, the Ministry of Health and the Health Funding Authority.

## 2 Aims and objectives

Methadone treatment programmes have been extensively evaluated and show conclusively that clients maintained in treatment show a dramatic reduction in criminal activity over time.

In line with this information, treatment is being offered to clients on opioid substitution as outlined in the following document.

In doing this prisons will also endeavour to manage inmates who, when they arrive in prison, are on an opioid substitution programme according to their individual clinical and custodial management needs and in accordance with this protocol.

## 3 Eligibility

### 3.1 Methadone maintenance

Methadone maintenance will be provided only to those people on a bona fide methadone treatment programme prior to being committed to custody in accordance with the following conditions:

- a. *remand* inmates are maintained on methadone
- b. *sentenced* inmates are withdrawn from methadone, in accordance with the procedure in section 7, with the following exceptions:
  - maintain inmates who would be released before they are completely withdrawn from methadone
  - maintain inmates who are pregnant if that is recommended by their obstetrician in consultation with the prescriber and the prison medical officer
  - maintain HIV positive inmates if that it is recommended by a specialist medical practitioner in consultation with the prescriber and the prison medical officer
  - maintain inmates receiving interferon treatment for Hepatitis C if that is recommended by a specialist medical practitioner in consultation with the prescriber and the prison medical officer

- maintain inmates who have been granted leave by the Court to apply for release to home detention but whose application is yet to be determined by the District Prisons Board.

### **3.2 Methadone prescribed for pain relief**

Inmates who arrive at prison, and who are receiving methadone as a legitimate treatment for pain, shall continue to receive this.

Any continued prescription of methadone for this purpose is the clinical responsibility of the pain clinic/prescribing agency, in consultation with prison health staff.

Methadone for pain will be delivered in accordance with appropriate clinical guidelines.

### **3.3 Eligibility for other opioid substitution medications**

Inmates who arrive at prison, and who have been prescribed other opioid substitution medications whether through a clinic or an approved GP, shall continue to receive this medication subject to the provisions in section 6.3.

## **4 Funding**

The Health Funding Authority will continue to fund inmates who are maintained or withdrawn from opioid substitution in prisons.

Inmates retain their opioid substitution provider client place while they are being maintained or until they are withdrawn from opioid substitution drugs.

## **5 On reception**

When inmates receiving opioid substitution are received into prison, the prison medical officer or their representative will notify the community methadone clinic or other prescriber within four hours. After hours or at weekends or public holidays, the notification will be made as soon as possible.

## **6 Joint inmate management model**

### **6.1 General methadone treatment**

Methadone treatment will be managed by the inmate's methadone prescriber clinic of origin in conjunction with the prison medical officer.

Community methadone prescriber clinics of origin will have clinical responsibility for the methadone treatment of inmates. However, all decisions relating to dose adjustments will be in consultation with the prison medical officer.

Responsibility for writing prescriptions and medical supervision (including re-subscription) will be in accordance with Table 1 below.

## 6.2 Managing out-of-region methadone inmates

Methadone treatment for out-of-region inmates will be managed by the inmate's methadone prescriber clinic of origin in conjunction with the prison medical officer.

Community methadone prescriber clinics of origin will have clinical responsibility for the methadone treatment of out of region inmates. However, all decisions relating to dose adjustments will be in consultation with the prison medical officer.

If an inmate is out of region, the Medical Officer in the receiving prison will be temporarily authorised to prescribe for the treatment of drug dependence by the person's normal methadone prescriber clinic of origin in accordance with section 24 of the Misuse of Drugs Act 1975.

Responsibility for scripting and medical supervision (including re-subscription) for out-of-region inmates will be in accordance with Table 1 below.

**Table 1:** Responsibility for opioid substitution prescribing and medical supervision (including re-subscription)

Client category	Local clients	Out-of-region clients
Sentenced inmate being withdrawn from methadone	Clinic of origin/gazetted GP/ authorised GP (client place kept until withdrawal completed)	Clinic of origin/gazetted GP/ authorised GP (client place kept until withdrawal completed)
Methadone-maintained, short-sentence and remand inmate who is expected to be released before their next three-monthly check-up comes up	Clinic of origin/gazetted GP/ authorised GP (client place kept by clinic to ensure that inmate remains on the methadone programme following release from prison)	Clinic of origin/gazetted GP/ authorised GP (client place kept)
Methadone-maintained, short-sentence and remand inmate who is expected to be released after their next three-monthly check-up comes up	Prison doctor under authority from local prescriber (client place kept)	Prison doctor under authority from methadone prescriber clinic of origin (client place kept)
Other methadone-maintained, sentenced inmates (pregnancy, HIV+, interferon)	Prison doctor under authority from local prescriber (client place kept)	Prison doctor under authority from methadone prescriber clinic of origin (client place kept)
People on alternative medications prescribed for opioid dependence or withdrawal	On a case-by-case basis in consultation with prescriber in accordance with this protocol (client place kept if applicable)	On a case-by-case basis in consultation with prescriber in accordance with this protocol (client place kept if applicable)

## 6.3 Management of other opioid substitution medications

Other opioid substitution medications should be assessed and managed on a case-by-case basis by the inmate's prescriber in conjunction with the prison medical officer and in accordance with this protocol.

Community prescribers will have clinical responsibility for the opioid substitution treatment of inmates. However, all decisions relating to dose adjustments will be in consultation with the prison medical officer.

## **7 Procedures for managed withdrawal**

### **7.1 General methadone withdrawal**

Inmates will be withdrawn from methadone according to the following managed withdrawal guidelines:

- the methadone dose is reduced by 5 mg per day until the daily dose is reduced to 25 mg
- after reaching 25 mg, the methadone dose is reduced by 2.5 mg per day until complete withdrawal is achieved
- medication to address withdrawal symptoms is provided as necessary
- psychosocial support is provided as necessary.

Inmates may elect to withdraw from methadone without a managed withdrawal programme (that is, immediately) with assistance to minimise the side effects of the withdrawal.

Where there are exceptional clinical circumstances the General Manager, Public Prisons Service may approve an extended withdrawal programme. For inmates in the Auckland Contract Remand Prison, the General Manager of the Auckland Contract Remand Prison may approve an extended withdrawal programme.

Methadone clinics will take over the management of approved or authorised GP clients in situations where the approved or authorised GP has an objection to their client withdrawing from any opioid substitute.

### **7.2 Withdrawal from other opioid substitutes**

Withdrawal from other opioid substitution medications should be managed on a case-by-case basis by the inmate's prescriber in conjunction with the prison medical officer and in accordance with this protocol.

## **8 Opioid substitution administration**

### **8.1 Methadone administration**

Where possible, opioid substitution medications will be administered in the prison health clinic.

Prison health staff will administer the opioid substitution medications. Opioid substitution medications will be issued daily and in the morning where possible.

Opioid substitution medications will be administered in accordance with principles of safe practice.

## **8.2 Administration of other opioid substitutes**

The procedures for the administration of other opioid substitution medications should be determined on a case-by-case basis by the inmate's prescriber in conjunction with the prison medical officer and in accordance with this protocol.

## **9 Training for prison and community opioid substitution treatment staff**

The Prisons Service and opioid substitution providers will ensure that their health staff are appropriately trained to comply safely with the provisions of this protocol.

## **10 Confidentiality and records**

All communications concerning opioid substitution in prisons will comply with the Health Privacy Code.

