

Practice Guidelines for Opioid Substitution Treatment in New Zealand 2008

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Foreword

Practice Guidelines for Opioid Substitution Treatment in New Zealand 2008 contains practical and evidence-based advice for clinicians on best practice for clinically assessing, treating and also providing psychosocial support to clients with opioid dependence. They replace the guidelines that were published in 2003.

The new guidelines encompass a number of significant themes and important developments that have occurred over the last five years, including:

- the approval for the prescription of opioid substitution medication to clients/tangata whai ora entering prison who were already receiving opioid substitution treatment in the community
- the resolution to eliminate services' waiting lists, hence requiring the introduction of interim prescribing as one means of managing demand
- the strong emphasis on shifting practice from maintenance treatment to actively supporting clients/tangata whai ora to plan for their own wellness and recovery, free of opioid substitution medication
- the key focus on the timely transitioning of clients/tangata whai ora to primary health care services, recognising the new opportunities that now exist with Primary Health Organisations (PHOs) agreeing to provide services to people who have addictions.

These guidelines also take into consideration the prescription of alternative pharmacotherapies to methadone, some of which, while not subsidised, may be self-funded by clients.

I take this opportunity to acknowledge the role that the National Association of Opioid Treatment Providers (NAOTP) fulfils in providing leadership, advice and support to services and to express gratitude to that group and others who have contributed to these revised guidelines.

It is a very important step forward that clients/tangata whai ora and providers of opioid substitution treatment programmes are recognising and acting upon the need to move from maintenance-focused to recovery-focused treatment and that this is strongly endorsed in these revised guidelines.

Dr David Chaplow
Director of Mental Health

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Introduction

These practice guidelines have been revised to replace the *Opioid Substitution Treatment: New Zealand Practice Guidelines* from 2003. They have been shaped from consultation with the National Association of Opioid Treatment Providers (NAOTP), the work of a reference group, research into material from similar guidelines and regional protocols, and from the valuable feedback of those who either attended focus group meetings in Wellington, Christchurch and Auckland or participated in teleconference focus group discussions as well as others who made written and/or oral submissions. Focus meetings for clients/tangata whai ora were also held in both Christchurch and Auckland, and their feedback has contributed to the development of these guidelines as well.

In addition, in 2006, the Department of Corrections revised its methadone treatment policy to allow all prisoners who were on a specialist opioid substitution programme before entering prison to be maintained on opioid substitution while in prison. The policy, The Prison Opioid Substitution and Managed Withdrawal Programme was reviewed in 2007.

Māori

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 assessed with a view to what they offer the service in terms of ensuring clinical and cultural safety of staff and clients/tangata whai ora as well as delivering services effectively. It is noted that funding contracts and New Zealand health and service sector standards require not only that the principles of the Treaty of Waitangi be expressed in policy but that Māori issues (including the Treaty) also be clearly demonstrated.

Cultural diversity

Māori are a varied population. Effective and relevant clinical management or treatment strategies need to recognise and be influenced by cultural and clinical factors and processes that support positive attitudes and behaviour in the aim of improving client health and welfare. Te Puāwaiwhero: The Second Māori Mental Health and Addiction National Strategic Framework 2008–2015 provides a clear direction for services to support Māori.

1 Opioid Substitution Treatment in New Zealand

1.1 Key principles of effective opioid substitution treatment

- Opioid substitution treatment (OST) in New Zealand is underpinned by the principles of: engagement, cultural considerations, wellbeing, motivation, assessment, management and integrated care.
- Service provision will include a range of accessible, evidence-based interventions that address physical, psychological and social functioning.
- Specialist services work toward reducing the stigma of opioid dependence by encouraging social inclusion and providing culturally relevant, responsive and non-judgemental OST programmes.
- Clients/tangata whai ora on OST have the right to receive the same quality of care as other health care consumers.
- Clients/tangata whai ora aspire to lead healthy and fulfilling lives.
- The continuum of care in OST will range from harm reduction (the aim being to reduce harm associated with opioid and other drug use) to recovery (broadly, a process whereby clients/tangata whai ora are assisted to reach their full potential, with recovery not necessarily involving abstinence).
- Whānau ora and family inclusive practice is important in the delivery of OST.
- Client/tangata whai ora involvement is supported at all levels and in all aspects of OST service design, delivery, planning and evaluation.
- Specialist services support the movement of stabilised clients/tangata whai ora to the care of the primary health care sector and maintain functional links with GP prescribers and other relevant people involved in a client's/tangata whai ora's OST.

1.2 Objectives of opioid substitution treatment

In New Zealand, the objectives of OST, which line with the National Drug Policy (2007–2012), are to improve the health of New Zealanders by preventing and reducing the health, social and economic harms that are linked to the use of opioid drugs, and, in particular, to:

- contribute to improving the health, psychological and social functioning and wellbeing of clients/tangata whai ora and their families, including dependant children
- 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 other harmful drug use
- reduce crime associated with opioid use
- assist with recovery from opioid dependence and withdrawal from methadone, or other opioid substitute medicine, if appropriate and desired by the client/tangata whai ora.

Not all these objectives will be achieved with each person dependent on opioids 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 other opioids. All OST providers need to balance these objectives, within the resources available, with staff and client/tangata whai ora safety factors while maximising the client's/tangata whai ora's opportunities to recover from problem opioid use.

1.3 Specialist opioid substitution treatment services

Specialist opioid substitution treatment services are specified by the Minister of Health under section 24 of the Misuse of Drugs Act 1975 (see Appendix 2) 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 severe opioid dependence with a controlled drug.

The roles of specialist opioid substitution services include (but are not limited to):

- comprehensive alcohol and other drug assessment
- treatment planning within an integrated and holistic model and with a recovery focus
- stabilisation on an adequate dose of methadone or other opioid substitution medicine
- provision of specialist interventions to minimise the harms associated with opioid and other drug use and assist clients/tangata whai ora to make behavioural changes and lifestyle improvements
- transfer of stabilised clients/tangata whai ora to the care of GPs
- treatment and management of people who are unsuitable for transfer to GP care
- provision of appropriate psychosocial support and liaison services
- screening, advice and treatment, or referral for co-existing medical disorders with particular reference to those related to intravenous drug use and protracted opioid use
- assessment and treatment (or referral for treatment) of coexisting mental health disorders
- consultation, liaison and referral to allied professionals in other health care and social service roles, including peer support and advocacy services.

1.4 Framework of opioid substitution treatment services

Opioid substitution specialist services are currently provided through 17 District Health Boards (DHBs) and one non-government organisation. The specialist service is the entry point for clients/tangata whai ora requiring initial assessment and stabilisation.

Medical staff within specialist services and a number of GPs are authorised (by the specialist services) to prescribe opioid substitution. Some GPs are authorised independently and in some instances are authorised to supply specific services. In such cases, the Ministry of Health (the Ministry) specifies the services to be provided.

The Ministry supports the entry point to any authorised or gazetted opioid substitution treatment to be through the specialist service.

2 Entry into Opioid Substitution Treatment Services

2.1 Assessment and suitability

The comprehensive assessment for a client's/tangata whai ora's suitability for OST should start within two weeks of the client/tangata whai ora presenting or being referred to the specialist service. The assessment must be carried out by an appropriately trained and supervised clinician.

Once a client/tangata whai ora is assessed as being suitable for OST, treatment should begin as quickly as possible (that is, within two weeks).

The goals of the initial comprehensive assessment are to:

- facilitate client/tangata whai ora engagement in the treatment
- determine the client/tangata whai ora's suitability for OST (Note: A client's/tangata whai ora's use of other substances should not be a sole exclusion criteria)
- assist the client/tangata whai ora to make informed decisions about the treatment
- document an initial treatment plan that is agreed to by the client/tangata whai ora.

The initial comprehensive assessment should include details of the client's/tangata whai ora's:

- reasons for and expectations of treatment
- alcohol and other drug-use history (including tobacco, and prescribed drugs); current use (including signs of intoxication, withdrawal, and physical evidence of past or current drug use, such as needle marks and associated bruising)
- past and present risk-taking behaviours (for example, sharing of injecting equipment, excessive and unsafe alcohol and other drug use, unsafe sexual practices)
- medical history (including alcohol and other drug-related accidents, head injuries, overdoses, significant illnesses or hospital admissions, contraception, dental problems, cardiac risks, current GP and current medication)
- mental health and psychological history (including previous mental health and alcohol and drug assessments and treatments and current psychological and mental health/psychiatric problems/disorders that may need referral for further assessment or intervention)
- risk of suicidality or other possible acts of harm to themselves or others or from others (including domestic violence) (note: A risk management plan may need to be developed if any such events are revealed)
- relevant legal history
- family/whānau history (including family history of alcohol and other drug use, medical problems including any cardiac problems, sudden deaths or mental health problems) and current relationships (including length of relationship, current status and stability)
- personal developmental history (including any history of childhood abuse; current social networks, social and role functioning (for example, employment/parenting) and particular strengths; as well as any educational or employment-related requirements).

The assessment should also include:

- details of any restriction notices that apply under section 25 of the Misuse of Drugs Act 1975 or section 49 of the Medicines Act 1981
- a record of any treatment options discussed with the client/tangata whai ora and assessed as being inappropriate or declined
- a diagnosis (note: A client/tangata whai ora must meet the diagnostic criteria for opioid dependence, such as those outlined in the DSM IV and ICD-10, to be suitable for OST)
- investigations, including a urine drug screen (to confirm level and nature of current use) and blood tests (for example, for liver function) and other relevant physical health checks).

Wherever possible, (with consent from the client/tangata whai ora) corroborative evidence from support people (including family/whānau and significant others) should be obtained.

Extra information may 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 in all assessment situations.

The client/tangata whai ora and their support people should be invited and encouraged to participate actively in treatment decisions from the start. The client/tangata whai ora needs to understand what is offered in the OST and the reasoning for all treatment options.

The true identity of the client/tangata whai ora must be confirmed against, for example, their passport, driver's licence or birth certificate. Care should be taken to ensure that the client/tangata whai ora is not receiving any other opioid treatment or drug treatment that could potentiate increase the effect of the prescribed dose of methadone or other opioid substitute.

Information (both written and oral) about treatment options and the side effects of any proposed medication should be given to the client/tangata whai ora, and relevant support people, at the time of assessment.

The expectations and processes for transfer to an authorised or approved (also referred to as gazetted) medical practitioner should be clearly explained to the client/tangata whai ora when they are assessing OST as a treatment option.

Informed consent will need to be gained at every stage of the treatment process (see 2.4 Informed Consent and Treatment Information).

2.2 Delaying entry to opioid substitution treatment

If there is to be a delay in a client/tangata whai ora receiving OST, the specialist service will need to provide the client/tangata whai ora with advice, support and information on non-pharmacological alternatives to OST; refer them back to, or on to, a specialist alcohol and other drug treatment service who is able to undertake these roles; or facilitate the provision of an interim methadone prescribing programme. (See National Guidelines: Interim methadone prescribing at www.moh.govt.nz)

It is critical that the client/tangata whai ora be told how long they may need to wait for entry to OST and how their situation will be monitored and reviewed.

Specialist services must have strategies in place to keep waiting times to a minimum. Long waiting times are contrary to the intention and spirit of OST as a harm minimisation strategy.

2.3 Special client groups

2.3.1 Priority admissions

When a client/tangata whai ora is assessed as being suitable for OST, entry into a treatment programme should not be delayed. If delays are unavoidable, clients/tangata whai ora with certain conditions and/or in certain situations might be eligible for priority access based on the risks if they were not to receive treatment, but each case should be considered on its own merit. Such clients/tangata whai ora include:

- stabilised clients/tangata whai ora transferring within New Zealand
- those on OST programmes overseas who are returning home to New Zealand
- pregnant opioid-dependent women and their opioid-dependent partners
- those who have care of children, especially children under five years of age, or those who have sole responsibility for the children
- those with serious medical conditions, such as HIV/AIDS, and their opioid-dependent partners
- hepatitis B carriers (HbsAg, HbeAg positive, or HbeAg negative but HBV DNA positive) and their opioid-dependent partners
- those with co-existing serious psychiatric disorders
- those who are partners of clients/tangata whai ora who are also dependent on opioids
- those on interim methadone prescribing programmes who are likely to go to prison
- those who have relapsed after coming off OST
- those who have been released from prison and are seeking to re-engage and who are known to the specialist service.

2.3.2 Clients/tangata whai ora under 18 years of age

OST should not be precluded on the grounds of age alone. Parental/caregiver consent to treatment is not required if the client/tangata whai ora is able to understand the reasons for OST and the process and risks associated with the treatment and agrees to that treatment. However, parental/caregiver support should be sought, where appropriate, for those clients/tangata whai ora who are under 18 years of age, and in all cases, the consent process should be careful and fully documented.

Children under 16 years of age who are being considered for OST require their assessment to be supported by an opinion from an addiction medical specialist or child and youth psychiatrist. Such clients/tangata whai ora should be treated in a service where the clinicians are skilled in both the youth and addiction areas.

Clients/tangata whai ora under 18 years of age should receive the same level of treatment offered to adults (including dose and duration of treatment), and prescribers should follow the principles and requirements outlined in these guidelines.

Buprenorphine may be preferred over methadone for the treatment of clients/tangata whai ora under 18 years of age because it has a lower risk of harm in overdose and less severe withdrawal symptoms.

2.4 Informed consent and treatment information

Before consenting in writing to take part in a planned OST, and providing written consent to the immediate treatment plan the client/tangata whai ora must first be informed of and provided with written information on:

- their rights as well as their obligations/responsibilities to the service (see 9.5 Rights of the client/tangata whai ora)
- the effects (benefits, side effects, limitations) of methadone or any other opioid substitution medicine
- the potential effects of methadone, or another opioid substitute medicine, and the comparative risk of this compared with continuing injecting and illicit drug use in pregnancy
- the potential effect of methadone or other opioid substitution medicine on activities such as driving and operating machinery (see 2.5 Fitness to drive and operate machinery)
- the interactive effects of methadone, or another opioid substitution medicine, with alcohol and other drugs
- the possible need to have an ECG before commencing treatment, or while on OST, to establish the client's/tangata whai ora's QTc (see Appendix 1: Glossary) and risks of QTc prolongation.
- the process for making complaints (see 9.6 Complaints procedure)
- the availability of consumer and peer support services.

Informed consent should be viewed as an ongoing process. Clients/tangata whai ora need to be fully informed throughout the OST of any changes in service delivery and any proposed changes to their treatment plan.

2.5 Fitness to drive and operate machinery

Methadone and buprenorphine may affect the capacity of clients/tangata whai ora to drive or operate machinery particularly:

- during the first 7 to 10 days of OST
- for 3 to 4 days after any dose increases
- when undergoing a rapid reduction of opioid substitution medicine
- when the client/tangata whai ora uses alcohol or other drugs including some prescribed medications
- when the client/tangata whai ora has a medical or psychological condition that is likely to contribute to impairment.

Specialist service clinicians and prescribing doctors should advise a client/tangata whai ora of any possible effects and the degree of associated risk before the client/tangata whai ora enters OST, when their dose is increased and when they are known to be using or have been prescribed other drugs that could contribute to impairment or alter the metabolism of the opioid substitute medicine. Any advice given should be documented on the client's/tangata whai ora's records.

It is safer for a client/tangata whai ora to avoid driving a car or operating machinery until they are on a stable dose of methadone or buprenorphine. Once stabilised and with unchanging doses, it is unlikely that their driving skills will be impaired unless they have been consuming other substances.

If a client/tangata whai ora is considered medically unfit to drive, the prescribing doctor must advise them of this both verbally and in writing. If the risk is unlikely to be of short duration and the client's/tangata whai ora's other substance use or psychological function indicates that they may not follow the doctor's advice, the prescribing doctor (after consulting the multidisciplinary team) must notify New Zealand Transport Agency (formerly Land Transport NZ).

2.6 Contraindications to opioid substitution treatment

Relative contraindications

- Severe hepatic or respiratory insufficiency.

General contraindications

- Inability to give informed consent
- Lack of evidence of opioid dependence.

Precautions

- Medical conditions: caution should be taken when prescribing methadone and buprenorphine to clients/tangata whai ora with QTc prolongation, acute asthma, acute alcoholism, a head injury and raised intracranial pressure, ulcerative colitis, biliary and renal tract spasm; to clients/tangata whai ora who are prescribed monoamine oxidase inhibitors or within 14 days of stopping treatment.

Specific contraindications to buprenorphine

- Pregnancy and breastfeeding: currently there is increasing support for the use of buprenorphine (without naloxone) by clients/tangata whai ora who are pregnant or breastfeeding. The combination product is not recommended for use in pregnant or breastfeeding clients/tangata whai ora due to the lack of knowledge of the effect of naloxone (see 7.12.3 Buprenorphine in pregnancy and breastfeeding).

2.7 The treatment plan

Any assessment of a client/tangata whai ora must address the full gambit of that person's life. Treatment plans must therefore address a full range of social issues including housing, education and working aspirations, legal issues and health improvement.

The specialist service will develop a written treatment plan in collaboration with the client/tangata whai ora and where possible their support people (significant others, family/whānau). The plan should state the client's/tangata whai ora's problems as well as their strengths and treatment goals, including a suggested timeframe for achieving the goals. It should also give consideration to other appropriate programmes (both residential and non-residential) that the client/tangata whai ora may be involved in and links that could be made to facilitate co-ordination and continuity of care and ensure that the treatment integrates smoothly with these existing programmes.

The specialist service will need to record that the initial treatment plan and any subsequent treatment plans have been negotiated with, and agreed to by, the client/tangata whai ora (with

participation from their support people, if possible) and that the client/tangata whai ora has been offered a copy of the treatment plan, and all treatment plans need to be signed and dated by the client/tangata whai ora to acknowledge this understanding and acceptance of the plan.

The plan must be regularly updated (that is, six-monthly), or as required, by the key worker in collaboration with the client/tangata whai ora and, where possible, their support people and others involved with their treatment.

The treatment plan may be shared with other parties (for example, probation officer, pharmacist, GP, prison medical staff) with the client's/tangata whai ora's agreement, and written consent.

3 Commencing Treatment

3.1 Induction

The first dose in OST should aim to achieve an effective level of comfort, both physical and psychological, while minimising the likelihood of overdose.

Frequent clinical observation needs to occur to ensure the client's/tangata whai ora's safety during the induction process.

There is considerable research evidence that suggests that the first two weeks of methadone treatment is a time of increased risk of death due to methadone toxicity.

Deaths in the first two weeks of OST have been associated with treatment doses in the range of 25–100 mg of methadone per day, with most deaths occurring in the 40–60 mg range (see 7.7 Management of Overdose). After the first two weeks, the risk of death due to opioid overdose during treatment falls to very low levels.

As opioids induce respiratory depression and hypoventilation, clients/tangata whai ora should be cautioned against and provided with written information about using illicit/other opioids or sedative drugs such as benzodiazepines and alcohol concurrently while waiting to reach an adequate opioid substitution dose because such drugs can increase this effect.

3.2 The starting dose of methadone

Initial doses of methadone in OST should be based on the client's/tangata whai ora's treatment aims; history of quantity, frequency and route of administration of opioids; and use of other central nervous system depressants. Treatment should also take into account the client's/tangata whai ora's hepatic and renal functioning.

In general, the initial daily dose will be in the range of 10–40 mg. The first dose of methadone should never be higher than 40 mg.

Following the first methadone dose, the key worker or doctor should observe the client's/tangata whai ora's response to the dose after 30 minutes and again three or four hours after the dose has been taken (at peak plasma level concentration) to assess for signs of toxicity or withdrawal. For this reason, the first dose should be administered in the morning.

Treatment should be started early in the week so that the maximum serum level at day three or four is reached when monitoring is available (such monitoring is generally not available in the weekend).

It is recommended that the methadone dose not be increased for the first three to four days as methadone accumulation is significant and poses a considerable risk if doses are increased too rapidly.

The client/tangata whai ora will need to be monitored again three to four hours after the third or fourth dose to exclude the risk of intoxication in relation to the peak plasma concentration. By the fourth day, the client/tangata whai ora should be close to achieving a steady state methadone level. In rural areas, a pharmacist may be appropriate to conduct this monitoring.

Where doses need to be increased in response to withdrawal reactions, the increment of increase should be no more than 5–10 mg at a time and not more often than every three to four days.

Any dose change in this or later phases of OST should be organised whenever possible in face-to-face discussion with the client/tangata whai ora in order to mitigate the possibility of distrust or misunderstanding developing and to maintain an effective therapeutic relationship.

Maintaining a quality therapeutic relationship with clients/tangata whai ora has been shown to increase client/tangata whai ora retention on an OST programme and is associated with positive treatment outcomes (Deering 2007a; Ball and Ross 1991; Magura et al 1999).

3.3 The starting dose of buprenorphine

Buprenorphine is a partial agonist; this means that it can prevent a concurrently administered agonist drug from producing its full agonist effect (see Appendix 3: Pharmacology and Pharmacokinetics of Methadone and Buprenorphine). Buprenorphine has long-lasting action (Raisch et al 2002), resulting in minimal blood level fluctuations and prevents opioid withdrawal symptoms when taken regularly. It can be provided in larger initial doses than the full agonists such as methadone.

Moreover, buprenorphine is both safe and effective when rapidly increased to higher dose levels in response to reactions (up to 16 mg by day three) and is recommended for extending the therapeutic effect and encouraging a client's/tangata whai ora's retention on the treatment programme (see 10.2 Buprenorphine).

Since buprenorphine will displace other opioids from opioid receptors but has less intrinsic opioid activity, it can precipitate withdrawal symptoms if given while other opioids are active. Thus, the first dose of buprenorphine should not be given until objective signs of opioid withdrawal are clearly seen. This is likely to be:

- 8–12 hours after the client's/tangata whai ora's last dose of intravenous morphine or homebake
- 12–14 hours after oral use of morphine or poppy-seed tea
- 24 hours after a dose of less than 40 mg of oral or intravenous methadone
- between 36 and 48 hours after a dose of between 40 and 60 mg of oral or intravenous methadone.

The first dose will usually be from 4–8 mg of buprenorphine. This may be repeated if assessment four hours later suggests that withdrawal is persisting. It is recommended that the first dose be given early in the day so that any withdrawal symptoms that occur can be managed. Splitting the first daily dose into twice-daily or three-times-daily doses reduces the chance of precipitated withdrawal.

The prescribing doctor or another member of the specialist service team should monitor the client/tangata whai ora regularly; at least daily for the first three days, then every two to four days during the induction phase.

The dose should be titrated according to the client/tangata whai ora's:

- reported intoxication, withdrawal and cravings over the preceding 24 hours
- additional drug use, and reported reason for this use
- experience of side effects or other adverse effects
- adherence to the dosing regimen
- satisfaction with the dose.

3.4 Induction and blood-borne viruses

A significant number of injecting drug users are infected with hepatitis B or C, but this seldom poses problems during induction unless the client/tangata whai ora has advanced liver disease, detectable at clinical examination. Clients/tangata whai ora with end-stage liver disease should only be commenced on methadone or buprenorphine with extreme care and should be referred for a specialist opinion.

Many HIV medications interact with methadone and buprenorphine, and doses may need to be adjusted accordingly. Consultation with the HIV medication prescriber is recommended.

3.5 Stabilisation

Stabilisation is a multi-faceted process that allows the client/tangata whai ora to make the best use of OST. The decision about what level of stabilisation is most appropriate for an individual needs to be made jointly by the prescriber, key worker (if different) and the client/tangata whai ora.

During the first two weeks of treatment, the aim is to stabilise the client/tangata whai ora so that they do not oscillate between intoxication and withdrawal. However, the client/tangata whai ora will not necessarily reach a stable dose during this period. Further dose adjustments may be required after the client/tangata whai ora has been initially stabilised.

At a minimum, stabilisation would mean that the client/tangata whai ora is comfortable on a consistent regular dose without the need for constant dose changes and review and is able to work consistently towards agreed goals. For some clients/tangata whai ora, this will take a considerable time to achieve, and they may need significant input from the specialist service.

Other factors to consider when assessing stability include assessing the client's/tangata whai ora's:

- progress towards meeting treatment goals
- reduction or cessation of harmful or hazardous uses of other drugs (prescribed and non-prescribed), including alcohol
- attendance at the specialist service and/or other essential appointments
- stability within their social roles (that is, housing, employment, parenting, education)
- stability of their relationships with others, partners, children and other providers
- co-existing mental or physical health problems, if any, and whether these are well managed
- reduction or cessation in involvement in drug-related criminal offending
- responsible management of dispensed medicine.

Table 1: A comparison of induction with buprenorphine and induction with methadone

	Methadone	Buprenorphine
Pharmacology and Pharmacokinetics	<p>Long half-life, full agonist.</p> <p>Doses that exceed an individual's tolerance can result in respiratory depression and death.</p> <p>High bioavailability.</p>	<p>Long half-life, partial agonist.</p> <p>High affinity to, and slow dissociation from, receptors.</p> <p>Plateau on opioid effects (including respiratory depression) even with increasing doses.</p> <p>Poor oral availability necessitating a sublingual formulation.</p>
Induction	<p>Doses above 30 mg may be fatal in opioid-naïve clients/tangata whai ora.</p> <p>Should not start if the client/tangata whai ora appears intoxicated or sedated with opioids or other CNS-depressant drugs because of the risk of enhancing respiratory depression.</p> <p>Significant increases in plasma levels of methadone during the first days of treatment.</p> <p>Supervised dosing required at intervals during the first week to check for opioid toxicity.</p> <p>No risk of precipitated withdrawal.</p> <p>Methadone may be preferable to buprenorphine for clients/tangata whai ora who have severe pain.</p> <p>First doses in the range 10–40 mg.</p> <p>Dose at the end of the first week not usually > 50 mg.</p>	<p>Precipitated withdrawal risk: should only start once there is evidence of withdrawal (see 3.3 The starting dose of buprenorphine).</p> <p>High-dose rapid induction is safe and effective.</p> <p>Rapid induction produces side effects in some client/tangata whai ora: dizziness, nausea, sedation and headaches are common.</p> <p>Safer in overdose than methadone if combined with other CNS-depressant drugs, such as other opioids or benzodiazepines, but a fatal overdose in combination can still occur.</p> <p>Stabilisation can be achieved more rapidly than with methadone.</p> <p>Higher doses have a longer duration of action, permitting less-than-daily dosing once stabilised.</p>

Adapted from table 4.1.3 *Clinical Guidelines for Methadone and Buprenorphine Treatment of Opioid Dependence NSW Opioid Treatment Programmes* (NSWH 2007).

4 Ongoing Opioid Substitution Treatment

‘Once stabilisation on methadone is achieved, individualised goals focussed on promoting wellness, client self-management and community participation within a family and whānau context should assume a high priority’ (Deering 2007b).

4.1 Methadone doses

Optimal methadone doses will generally be in the range of 60–120 mg daily. Sometimes higher doses (or, less commonly, split doses – see 7.4 Split methadone dosing) may be required to achieve stabilisation. In such instances, serum methadone level monitoring (see 7.3 Measuring methadone serum levels) and specialist service consultation, in addition to consultation with the client/tangata whai ora and, as appropriate, their support people and pharmacist, should be considered. In some cases, lower doses may be adequate. Whatever the case, the dose should be sufficient to ensure that the client/tangata whai ora is clinically stable, can function adequately in their social roles, experiences the minimum of withdrawal symptoms and is retained in treatment.

Any changes in dose should always be negotiated with the client/tangata whai ora.

Doses that are to be consumed at a pharmacy must be swallowed in front of the pharmacist or pharmacy technician to minimise the risk of diversion. Care should be taken to minimise the possibility of takeaway doses of methadone (any dose that is not consumed under observation) being sold, used against medical advice (for example, ‘doubling up’ or injecting) or used by others.

4.2 Buprenorphine doses

The effective daily dose range of buprenorphine for most clients/tangata whai ora is 12–24 mg/day. However, there is significant individual variation in dose requirement. While a dose of 4 mg/day is rarely effective, some clients/tangata whai ora can be satisfactorily maintained on 8 mg/day.

Daily dosing is recommended for the initial period of stabilisation. Once stabilised, a significant proportion of clients/tangata whai ora can be adequately maintained by receiving a dose every alternative day and some every third day.

Before a trial of less-than-daily dosing is undertaken, the client/tangata whai ora would need to demonstrate stability on daily dosing of buprenorphine for at least two weeks.

4.3 Maximum doses

Because of individuals’ variability in pharmacokinetics and clinical responses, some clients/tangata may benefit from a daily dose of methadone above 150 mg or buprenorphine above 32 mg. A prescribing doctor should only prescribe higher doses after careful consideration and in consultation with the multidisciplinary team.

4.4 Transferring from methadone to buprenorphine

See also 10.2 Buprenorphine.

Transferring previously stable clients/tangata whai ora from methadone to buprenorphine carries a risk of destabilisation. Appropriate monitoring and support should be provided and transfers need to be well planned. If the client/tangata whai ora becomes destabilised, it may be best to return them to methadone treatment (Lintzeris et al 2006).

When methadone clients/tangata whai ora take a dose of buprenorphine, the buprenorphine displaces methadone from the opioid receptors causing a net reduction in opioid activity. To minimise the chance of precipitated withdrawal, clients/tangata whai ora should be on a methadone dose of less than 40 mg (ideally 30 mg or less) for at least one week before starting a buprenorphine treatment. Transition to buprenorphine from methadone doses greater than 60 mg are generally not recommended.

It is recommended that any client/tangata whai ora experiencing difficulty in the transition to buprenorphine be admitted as an inpatient with the prescription of symptomatic withdrawal medication, including clonidine.

The first dose of buprenorphine should be administered only when the client/tangata whai ora experiences mild to moderate observable opioid withdrawal signs. Usually this will occur at least 24 hours after the last methadone dose (see 3.3 The starting dose of buprenorphine).

On day two in the transition to buprenorphine, if the client/tangata whai ora has experienced no precipitated withdrawal, rapid titration of buprenorphine should commence.

Table 2: Conversion rates for low-dose methadone transfer

Last oral methadone dose	Initial buprenorphine dose
30 mg or greater	4 mg plus 0–4 mg plus 0–4 mg
Less than 30 mg	2 mg plus 0–4 mg plus 0–4 mg

Source: Lintzeris et al 2006

4.5 Transferring from buprenorphine to methadone

A transfer from buprenorphine to methadone may be appropriate when:

- the side effects of buprenorphine are intolerable for the client/tangata whai ora
- the client's/tangata whai ora's response to the buprenorphine treatment is inadequate.

Clients/tangata whai ora should be stabilised on daily doses of buprenorphine before transfer to methadone. If possible, the daily buprenorphine dose should be reduced to 16 mg or less for several days before transfer.

Methadone can be commenced 24 hours after the last dose of buprenorphine. The first dose of methadone should not exceed 40 mg. Clients/tangata whai ora who are transferring from lower doses of buprenorphine should receive lower doses of methadone (NSWH 2007).

4.6 Treatment reviews

4.6.1 Reviews by the prescribing specialist service doctor

Clients/tangata whai ora who are receiving OST must be seen by the prescribing doctor or their locum before receiving the initial dose and at least once during the first seven days of treatment.

During dose increases, more frequent observation is advisable.

The prescribing doctor or a specialist service nurse should see the client/tangata whai ora regularly during the first three months of the stabilisation phase or until a stable and clinically effective dose is achieved.

The frequency of review will be determined by the stability and other specific needs of the client/tangata whai ora. Once dose stabilisation is achieved, the prescribing doctor can be expected to see the client/tangata whai ora at least every three to six months. Where possible, such reviews should also involve the key worker.

4.6.2 Reviews by the key worker

Clients/tangata whai ora who are receiving OST should be seen by their key worker at least once a week for the first month or until a stable dose and satisfactory life situation is achieved. However, clients/tangata whai ora who are not progressing well (medically or psychologically or who are at risk of relapse) will benefit from more frequent and intensive intervention.

Once a stable dose has been achieved, the key worker should see the client/tangata whai ora at least once a month for the second and third months and at least once every three months thereafter. Depending on the individual's needs, the key worker may see clients/tangata whai ora individually or in groups on a monthly basis or more often as required.

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):

- a review of how the client/tangata whai ora is functioning in their social role and their employment/education status and aspirations
- a discussion of links with other health and social service providers
- a discussion of ongoing substance use and misuse (including alcohol and tobacco)
- a discussion of the results of any urine drug screens
- consideration and review of dose adjustments and takeaway arrangements
- consideration of lifestyle and high-risk behaviour changes, including lapses and relapses
- a referral for the review of medical issues where needed
- a review of the client's/tangata whai ora's mental state and management of co-existing mental health disorders
- a review of whānau ora – the client's/tangata whai ora's relationship with their family/significant others
- information and/or referral to self-help groups and other support and ancillary services (that is, peer support workers)

- a discussion of the client's adherence to service and treatment conditions
- an assessment of the client's/tangata whai ora's suitability for transfer to a primary health care setting
- consultation with other health care providers, for example, the community pharmacist, to gain corroborative information regarding the client's/tangata whai ora's progress and any risk for that client/tangata whai ora.

4.6.3 Reviews by a case management team

A case management team, at a minimum, should comprise the key worker and the prescribing doctor and at least one other member of the specialist service team. The community pharmacist should always be considered a member of the multidisciplinary care team and, in many instances, it can be useful to consult with them.

Client/tangata whai ora reviews should include a summary of the details covered in the key worker's monthly reviews and may also include:

- an assessment of the treatment's progress, measuring treatment outcomes against treatment goals
- an update of the treatment plan (including a relapse prevention plan) , which will need to be negotiated with, and agreed to, by the client/tangata whai ora and if possible their support people
- a review of safety (including the risk assessment) and stabilisation (at least twice a year)
- strategies to enhance the capacity of the client/tangata whai ora to transfer to either an authorised (if this is not already the case) or approved/gazetted GP or to withdraw from methadone or other opioid substitute medicine
- strategies to enhance recovery from opioid dependence
- consideration of alternatives or complementary interventions to OST such as additional psychotherapeutic/social interventions, detoxification or residential treatment.

Information on general health and welfare, employment, education, relationships and other relevant issues, including parenting skills, should be given as appropriate during case management team reviews.

Clients/tangata whai ora should be informed in writing about the scheduling of formal case reviews and their right to be involved and to have a support person attend. It is especially important to involve the client/tangata whai ora in any changes to the treatment plan. Also, it may be useful to consult, with the client's/tangata whai ora's consent, support people, as well as other relevant allied health or social service professionals.

Note: There may be exceptions to involving clients/tangata whai ora in their reviews, for example, when the client/tangata whai ora has threatened or committed violence.

Services will have clear written procedures available for clients/tangata whai ora to follow when seeking a review of their treatment, particularly when a client/tangata whai ora is involuntarily discharged from, or refused access to, a local specialist service.

4.7 Monitoring drug use

Monitoring a client's/tangata whai ora's drug use is:

- essential for safe prescribing and dosing
- a useful guide in assessing progress in treatment
- an aid to clinical decision-making.

Drug monitoring does not work as well for these purposes if it is also used as a basis for punitive actions against clients/tangata whai ora who continue to use illicit drugs. Moreover, monitoring improvements in the client's/tangata whai ora's health and social functioning during OST can indicate progress or change and a move away from illegal activities.

4.7.1 Urine screening

Clients/tangata whai ora need to be fully informed of the procedure and rationale for urine drug screening. Specialist services and GP prescribers may obtain urine samples for drug screening to test for the presence of psychoactive drugs, including methadone or other opioid substitution medicines. Urine drug screening has some benefits in demonstrating recent drug use (but not the extent or the pattern of use) and is one way of obtaining helpful information to assist in determining safety and progress in relation to treatment goals.

The following points should be noted.

- Many clients/tangata whai ora find supervised urine collection demeaning and culturally insensitive.
- False-positive and false-negative results do occur.
- Urine testing does not reduce drug use unless it is used in the context of contingency management (where individuals receive feedback, for example, vouchers for negative urine samples).
- There are significant financial and resource costs associated with urine drug screening.

The client/tangata whai ora should be able to pass a urine sample in an appropriate environment and staff of appropriate gender should be involved in supervising the collection of the sample.

Procedures should be in place to ensure the reliability of urine samples if voiding is not observed. The use of heat strips on collection bottles or alternatively the use of professional laboratory services to take samples is recommended.

4.7.2 Self-reporting

Self-reporting can be a reliable guide to drug use in settings where no negative consequences result from disclosure. However, there will always be clinical situations where clients/tangata whai ora are reluctant to make a full disclosure. The most reliable information is usually obtained from a combination of self-reporting, clinical observation and urine screening.

4.7.3 Screening for buprenorphine

Buprenorphine is difficult to detect from routine urine drug screening that relies on gas chromatography procedures, and such testing will not provide a consistent indication of whether buprenorphine is being consumed as prescribed. Serum and urine buprenorphine analysis may be reliably detectable by a liquid chromatography mass spectrometer. These are likely to be available in New Zealand sometime in 2009.

4.8 Prescribing process

The prescribing process described below applies to all prescribers, whether they be approved/gazetted to prescribe or are working under authority.

- 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.
- The pharmacist must receive written prescriptions for methadone and other OST medicines (always with the amount prescribed written in words and figures) at least one day before the due date to supply (by law, the original must be received by the pharmacist within two working days) so that the pharmacist has time to prepare the documentation and dispensing plan. In some situations, it may be acceptable to fax through the prescription. As well, the client/tangata whai ora may be given the prescription to take to the pharmacy themselves.
- As per amendments to PHARMAC's close control rules, from June 2008, prescriptions should be endorsed as 'daily dispensing, close control', and the endorsement should be initialled in the prescriber's own handwriting. This allows the pharmacist to receive payment for each dose dispensed.
- Prescriptions should be started on a day of the week that the client/tangata whai ora is usually observed consuming their methadone, or other opioid substitute medicine, and not on a day that the client/tangata whai ora has a takeaway dose. Prescriptions should be in weekly cycles rather than monthly.
- Prescriptions should not be started on a Saturday, a Sunday or a public holiday unless the prescriber is prepared to be contacted over those days should any questions arise and has an arrangement with the pharmacist beforehand for dispensing on those days.
- Specialist services and GP prescribers must always provide pharmacists with a current named photograph of each client/tangata whai ora. Faxed photographs are often not legible and, if used, should be followed up with the posting out of an original.
- The prescriber, or the key worker, is responsible for notifying the pharmacist of any prescription changes (for example, cancelled doses, when the client/tangata whai ora attends another pharmacy temporarily and termination of treatment from that pharmacy).
- Only the prescribing doctor can make changes to scripts, that is, an altered dose, extra doses or changes to the pharmacy used for dispensing the prescription.
- Any changes to takeaway doses (usually a one-off) can be made by the key worker but need to be internally signed off as per local protocols. Such changes may be telephoned or faxed through to the pharmacy and must be noted in writing.
- Where possible, the pharmacist should be given at least one day's notice of changes to scripts.

4.9 Takeaway doses

Takeaway doses can contribute greatly to clients/tangata whai ora:

- finding and retaining employment
- fulfilling family responsibilities
- being able to travel for work and leisure
- improving their sense of self-esteem and progress in treatment (Fraser et al 2007).

Takeaway doses (takeaways) are any doses of OST medicine that are not consumed under observation at the specialist service, doctor's surgery or pharmacy premises.

It is uncommon for a client/tangata whai ora to be prescribed takeaway doses early in their treatment. The provision of takeaways should be based on clinical decision-making by the case management team, in consultation with the client/tangata whai ora and their support people, and should be clearly documented in the client's/tangata whai ora's case file.

It is recommended that methadone, or other opioid substitute medicine, be observed to be consumed at the pharmacy or other dispensary on at least three non-consecutive days per week. Less frequent and flexible dispensing can be considered for stable clients/tangata whai ora to support community reintegration, employment, education/training aspirations and other worthwhile lifestyle activities.

To be eligible for takeaway doses, clients/tangata whai ora will need to demonstrate stability (see 3.5 Stabilisation), reliability and the ability to comply with the safety requirements as specified by the specialist service. Prescribers will specify their safety requirements around takeaway doses in writing and ensure that copies of the requirements are provided to the client/tangata whai ora and the pharmacist.

Some or all of the following can be included in the service's safety requirements.

- The client/tangata whai ora consults regularly with their key worker, members of the primary health care team and dispensing pharmacist as appropriate.
- The client/tangata whai ora has been assessed as being able to take responsibility for their takeaway doses. (Such an assessment should include consultation with family/whānau and significant others, particularly when children are living in the household.)
- Drug-seeking patterns are no longer present in the client's/tangata whai ora's behaviour.
- Urine drug screening shows a positive result for methadone, or other prescribed opioid substitute medicine, and where other drugs of dependence are identified through the urine drug screen, an assessment is conducted of the harmful or hazardous use of those other drugs, especially alcohol, benzodiazepines and amphetamines.
- There is evidence that the client/tangata whai ora actively participates in their treatment (for example, by attending doctor, key worker and case management team appointments) and is progressing towards agreed treatment goals.

Prescriptions must clearly specify the days of the week that takeaway doses will be dispensed.

Rural services may need to develop specific policies in regard to takeaway doses that acknowledge the impracticality of seven-day-a-week on-site dosing.

Takeaway arrangements are to be reviewed regularly by the specialist service or by the authorised or approved/gazetted GP as appropriate. A review of takeaway arrangements should also occur if the key worker and/or prescriber consider that the client/tangata whai ora is not meeting the safety requirements (outlined above). Any changes should be communicated to the client/tangata whai ora as soon as possible.

If a client/tangata whai ora is required to provide proof of employment to start or continue to receive takeaway doses, they could provide example payslips or bank account details that show the deposit of employment payments. Employers can only be contacted with the written consent of the client/tangata whai ora.

4.9.1 Safety requirements for dispensing

The following safety requirements apply to the dispensing of all methadone, or other opioid substitute medicines but need to be considered in particular for takeaway doses. Safety requirements must include assessment processes that ensure that:

- the potential for the client/tangata whai ora to overdose with the OST prescription is limited
- the client/tangata whai ora is not unsafely intoxicated with other drugs
- the client/tangata whai ora is able to provide safe storage for any OST prescription to ensure the safety of children and others in the household
- the potential for the OST drug to be diverted to an unspecified recipient is limited
- the client/tangata whai ora does not exhibit chaotic or unpredictable behaviour when presenting for their dose.

4.9.2 Special circumstances for granting additional takeaways

Takeaway doses can be provided for specific short periods in response to circumstances such as a family crisis, a course of study away from home, planned holidays, unusual employment requirements (such as working out of town or attending conferences or training courses) and when there is a legitimate illness that prevents a client/tangata whai ora presenting at a pharmacy.

At such times, it is important to assess the client's/tangata whai ora's stability and safety, the legitimacy of their circumstances, and whether the positive effects of short-term takeaway arrangements outweigh any likely destabilising effects of not allowing the variation. The needs of whānau and significant others should be considered.

Wherever possible, clients/tangata whai ora should be encouraged to nominate pharmacies that could take up the prescriptions during any planned departure from their regular dispensing pharmacy.

Generally, clients/tangata whai ora should have no more than four days' doses in hand, although flexibility should be considered for clients/tangata whai ora who demonstrate consistent stability.

5 Promoting Wellness and Recovery through Case Management and Psychosocial Interventions

The prescription of an opioid substitute medicine should never be considered an isolated intervention but always as part of a wider care programme. It is important that other problems, such as medical, social, employment/learning, mental health or legal problems are identified and addressed in order for the client/tangata whai ora to achieve stability and, in most cases, for recovery to be achieved.

Thus, the case worker will be involved to varying degrees in a client's/tangata whai ora's active clinical case management, with links to, for example, other services, allied professionals, self-help groups and families/whānau and significant others.

'While monitoring of substance use and individual and public health risk remain important, individual client goals focused on promoting wellness, client self-management and community participation within a family and whānau context should assume a high priority' (Deering 2007a).

5.1 Case management and co-ordination of care

OST case management is more than a planned and co-ordinated delivery of service; it involves a therapeutic relationship with each individual client/tangata whai ora, frequently over a long period of time, within the context of their life situation.

Specialist services are contracted to provide case management for all clients/tangata whai ora who are undergoing OST. When a client/tangata whai ora first enters an OST programme at a specialist service, a key worker will be assigned to be responsible for co-ordinating that client's/tangata whai ora's treatment and may provide some or all the interventions planned in the treatment of that client/tangata whai ora.

When the client/tangata whai ora is transferred to a GP working under authority from the specialist service, the GP may become the lead key worker, but the client/tangata whai ora may still continue to work closely with specialist service staff and/or other allied health and social service professionals.

It is expected that wherever possible the key worker will have a significant intervention role, ensuring that each client/tangata whai ora is supported in accessing a range of services that could help in their recovery and has their needs met in an integrated way so that they do not receive fragmented care from a range of disjointed services. Services should provide a framework for the enhanced care that they can provide to the client/tangata whai ora, and this framework should include counselling and co-ordination of other services as required.

The key worker or primary health care team should assist the client/tangata whai ora to work towards goals of sustained reduction of or abstinence from opioids and other psychoactive substances (including alcohol), a healthy lifestyle and improved interpersonal problem-solving skills, social networking and social functioning.

5.2 Psychosocial interventions

‘In respect to interventions provided, a wellness oriented system of care should incorporate a range of individual psychosocial interventions as well as family, cultural, gender-specific and peer-based interventions’ (Deering 2007a).

Clients/tangata whai ora and their families/whānau and significant others should be offered support and assistance to maintain the stability in their lifestyle gained from OST.

Clients/tangata whai ora should receive ongoing support services provided by the specialist opioid substitution service or by way of referral. Some GPs may be working within the context of a wider primary health care team that may have the resources to be able to directly provide some of the identified necessary supports.

Ongoing support may include, but is not limited to, providing:

- information and education on health issues, especially on living with, the treatments available for and minimising the spread of infectious diseases such as HIV/AIDS, hepatitis B and C, and sexually transmitted diseases
- information on general health and welfare issues, including social roles and social functioning (for example, employment, education/training, parenting, keeping children safe while the client/tangata whai ora is using drugs)
- information on and/or referral to other available community health and social services, such as family planning agencies, budget services and childcare facilities, and support in the areas of child development and parenting, accommodation and employment
- concurrent psychotherapeutic and social interventions (including ethno-cultural programmes and self-help groups) offered either by the specialist service or by other appropriate health or social service agencies
- information on the after-hours emergency services available in the case of an overdose or other emergency (Note: Specialist services and authorised GPs need to have services in place, or access to such services, that can provide crisis intervention should the need arise)
- the opportunity for involvement with consumer groups run by peers and supported by services.

The above information should be readily available and accessible and provided to clients/tangata whai ora and their support people as appropriate.

Psychosocial interventions encompass a wide range of actions from ‘talking therapies’, such as cognitive behavioural or family therapy, to supportive work on practical issues, such as help with benefits and accommodation. Interventions should be recovery focused, tailored to individual client/tangata whai ora needs, delivered by appropriately trained clinicians and well integrated into the overall service delivery system.

Structured psychological or social interventions should have clearly defined goals and be regularly reviewed and may be delivered alongside, or as part of, a client’s/tangata whai ora’s case management.

If specialist services or prescribing GPs are unable to provide psychosocial support or psychotherapeutic interventions, they need to refer the client/tangata whai ora to other appropriate services and have procedures and agreed plans in place for supporting the client/tangata whai ora to access these services.

Clients/tangata whai ora should be provided regularly with information about relevant self-help and whānau-support groups and about access to spiritual guidance.

5.2.1 Providing psychosocial interventions to clients/tangata whai ora in prisons

Specialist services are expected to provide psychosocial interventions to clients/tangata whai ora who are receiving OST while in prison. If the prisoner client/tangata whai ora comes from outside the prison's region, the service of that client's/tangata whai ora's origin should provide ongoing liaison with the client/tangata whai ora and should negotiate with the local specialist OST service to provide the client/tangata whai ora with a psychosocial intervention as required.

6 Transfers to other Specialist Services and to the Primary Health Care Sector

6.1 Transfers between specialist services

- Opioid substitution treatment is most safely delivered by specialist services within the locality where the client/tangata whai ora is living.
- As with many other New Zealanders, there can be a range of legitimate reasons for clients/tangata whai ora on OST to move around the country. As much as possible, a client/tangata whai ora should not be disadvantaged in making such moves.

Transferring clients/tangata whai ora should be engaged with the specialist service in their new domicile within three months of relocation.

Before a client/tangata whai ora transferring into a new service is prescribed methadone, or another opioid substitute medicine, the new specialist service should assess them, with reference to the client's/tangata whai ora's transfer documentation, such as their transfer assessment, including risk assessment and most recent treatment plan. (It is the responsibility of the transferring service or gazetted GP to provide the new service with these documents before the client/tangata whai ora presents to the new service). It is recommended that the client's/tangata whai ora's support people be involved in this process.

Once the client/tangata whai ora has been accepted and started OST in a new service, that service should send a confirmation of the completed transfer to the referring specialist service and confirm the cancellation of the client's/tangata whai ora's previous prescription.

Acceptance of transfer should not be conditional on withdrawal of any other substance use, (including use of illicit or prescribed benzodiazepines). When the client/tangata whai ora is accepted onto the OST programme in a new area, the specialist service of that area will review all substance use and negotiate a reduction in the use of benzodiazepine if it is clinically appropriate to do so.

6.2 Transfers from overseas

Specialist services must admit clients/tangata whai ora who have been stabilised on OST programmes overseas and have moved to New Zealand, either temporarily or permanently, as quickly as possible.

The new service should receive confirmation of dose, copies of assessments and a summary of treatment progress from the originating country before commencing prescribing.

6.3 Transfers from the specialist service to the primary health care sector

As soon as possible after dose stability has been achieved, specialist services should be proactively supporting the transfer of clients/tangata whai ora to their GP for continued prescribing and care.

In most cases, clients/tangata whai ora will stabilise within their first year of OST and become low risk in terms of their ongoing management. In such cases, it is considered best practice to have the client's/tangata whai ora's OST incorporated into a total health treatment plan that is administered by their GP.

A specialist service may transfer a client/tangata whai ora to an authorised GP or a GP approved/gazetted to prescribe, administer and supply a controlled drug for the treatment of opioid dependence provided all legislative requirements are met. (See Section 13 Application for approval to offer OST).

Before any transfer takes place, clients/tangata whai ora should participate in a comprehensive review with the specialist service's case management team to determine their suitability for transfer to the care of their GP.

Transferring a client/tangata whai ora to the primary health care sector offers the benefits of:

- allowing the specialist service to focus on those with the most need for intensive specialist intervention
- improving social integration by normalising the client's/tangata whai ora's treatment (that is, not having to attend a 'drug clinic')
- instigating a more holistic GP management of a client/tangata whai ora and their whānau/family within a primary health care setting.

In transferring a client/tangata whai ora to the primary health care sector, among other things, the specialist service is responsible for:

- managing the transitional arrangements with care and diligence
- maintaining a support and liaison role for the primary health caregiver
- accepting the return of any client/tangata whai ora who becomes 'destabilised' and can no longer be managed in a general practice (local protocols should be developed for the restabilisation of clients/tangata whai ora who are utilising specialist resources with or without actually returning to the specialist service)
- ensuring that GPs have a clear and immediate line of contact with relevant clinical staff if required
- conducting an annual (minimum) review with clients/tangata whai ora and organising contact with GPs at least twice a year
- notifying and updating pharmacies as to which GPs are authorised to prescribe OST
- supporting the national primary health training package for OST.

In many situations of transfer to the primary health care sector, the client/tangata whai ora will transfer to a GP working under the authority of the specialist service. In this case, the specialist

service remains the responsible provider, while the authorised GP prescribes opioid substitution in accordance with written terms and conditions (protocols) laid down by the specialist service in relation to specified clients/tangata whai ora.

6.4 Requirements of GPs who are accepting a transfer from a specialist service

The GP accepting a transfer of a client/tangata whai ora may be either approved/gazetted or working under authority and should have attended relevant training in OST, specialist alcohol and other drug treatment, or experience working with OST (see 9.2.1 Level of training).

The GP will be working within a broader primary health care team that includes reception staff, a practice nurse and often other professionals. These other staff members are also likely to interact with the client/tangata whai ora and their family/whānau and significant others and provide support as appropriate.

The GP, whether gazetted or authorised, should have a formal, agreed relationship with the specialist service and an established process and protocol for utilising the resources of the specialist services for advice and consultation; particularly if the client/tangata whai ora becomes destabilised.

The GP should have an awareness of, be able to facilitate and/or in some cases be able to provide the support services needed by clients/tangata whai ora to maintain their stability.

Clients/tangata whai ora must be informed of the conditions under which they can be returned to or utilise the resources of specialist services. Additionally they should have access to the same level of psychosocial support available to clients/tangata whai ora under the care of the specialist services and should be informed of their ability to access psychosocial services provided by other alcohol and other drug treatment services.

GPs should offer all their OST clients/tangata whai ora, and their significant others, HIV, HCV and HBV testing and referral for treatment as appropriate.

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

6.5 Specific requirements of approved/gazetted GPs

To ensure consistent practice with regard to OST, and to minimise the risk of a GP becoming isolated in their practice of prescribing OST, it is recommended that approved/gazetted GPs liaise regularly with specialist services and that the same standards and protocols be used by both services.

Once a client/tangata whai ora is transferred to an approved/gazetted GP, it is expected that that GP will be responsible for implementing systems to ensure clinical safety and ongoing treatment. These systems may include conducting random urine drug screens; managing a takeaway regime that ensures the safety of the individual, their children, their support people and the community; and providing contact with the specialist service and any relevant programmes provided by the specialist service or other appropriate services.

While approved/gazetted GPs are entitled to act independently, it is recommended that they be regularly reviewed and supported by other GPs involved in OST.

Approved/gazetted GPs are expected to provide the specialist service in their region with an annual summary of each client's/tangata whai ora's dose, takeaway arrangements, contact details, prescribed medication and treatment progress.

Approved/gazetted GPs will have received specialist opioid substitution training and have extensive knowledge and experience of working with people dependent on opioids. They will have previously been authorised to prescribe for at least one year.

It is recommended approved/gazetted GPs operating without formal support and oversight from specialist services should limit the number of opioid substitution clients/tangata whai ora in their care to five.

If the approved/gazetted 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.

6.6 Transfers between GPs

A GP may, from time to time, be required to transfer one of their OST clients/tangata whai ora to another GP who is either approved/gazetted or working under authority. The new GP prescriber must:

- confirm the client's/tangata whai ora's correct identity before commencing any new prescription
- check whether the client/tangata whai ora is on a restriction notice (see 7.8.4 Restriction notices) and update this information with Medicines Control, Medsafe
- be aware of their responsibilities to pharmacies (see 11.1 Shared responsibilities of pharmacists and prescribers).

7 Specific Clinical Situations

7.1 Replacement doses

Prescribers will not authorise replacement of lost or stolen doses except in exceptional circumstances that can be verified. When repeated requests are made for replacement doses, the prescriber may need to review the client's/tangata whai ora's takeaway arrangements.

Should a client/tangata whai ora vomit within approximately 30 minutes of consuming their methadone dose, the decision to replace the dose may be made only by the prescriber or a specialist service doctor. As a general rule, 80 percent of the dose will have been absorbed 20 minutes after oral consumption. Whenever possible, it should be verified that the dose has actually been vomited before a replacement dose is prescribed.

Pregnancy is commonly problematic with respect to vomited doses, and rather than regularly replacing vomited doses, the prescriber should consider alternative solutions, such as splitting the dose (and consuming the two parts at different times – see 7.4 Split methadone dosing), dosing at a different time of day, requesting that the client/tangata whai ora sip the dose slowly under observation and prescribing an effective antiemetic.

7.2 Reintroducing methadone after missed doses

Clients/tangata whai ora who miss three or more consecutive doses of methadone should be promptly reviewed by the specialist service or prescribing GP before dosing is recommenced.

In general, if one day is missed, there should be no change in dose. If two days are missed and there is no evidence of intoxication, the normal dose should also be administered. If repeated doses are missed, tolerance to opioids may be reduced, increasing the risk of overdose when treatment is reintroduced; therefore, if three or more doses are missed, the client/tangata whai ora must be assessed before a dose is prescribed again. Reintroduction doses are usually in the range of 50–70 percent of the full dose (see 11.11 Missed doses).

Missing doses should not be grounds for withdrawing the client/tangata whai ora from the OST programme unless there are associated significant breaches of the safety requirements of the programme or there is evidence that the treatment is not achieving harm reduction.

7.3 Measuring methadone serum levels

Measuring methadone serum levels may be indicated when a client's/tangata whai ora's clinical picture does not agree with the expected/typical responses to a given dose of methadone and when this additional clinical information would be of use in making decisions regarding changes in the methadone dose.

Clinical situations where measuring serum levels may be useful include:

- when a higher dose (that is, greater than 100 mg) is being considered
- where a client/tangata whai ora is suspected of poor compliance or of diverting their dose (Note: comparison of serum levels taken on the same individual within the last 6–12 months, with careful observation of dosing and retention of doses, may assist in determining compliance)
- when there is doubt about the clinical indications for a dose increase or accuracy of reported methadone consumption

- if there is a suspected drug interaction
- when determining the need for split dosing (see 7.4 Split methadone dosing)
- when a client/tangata whai ora is pregnant
- when a client/tangata whai ora has a serious liver or other physical disease and there may be methadone accumulation.

7.4 Split methadone dosing

Some clients/tangata whai ora metabolise methadone rapidly, that is, their peak methadone levels are adequate but are not maintained adequately. This is indicated by a peak:trough plasma concentration ratio of greater than or equal to 2:0. In such instances, clients/tangata whai ora may require split dosing.

Split dosing may also be useful:

- when clients/tangata whai ora exhibit a low tolerance to the nauseating side effects of methadone
- when the client/tangata whai ora is pregnant and experiences persistent nausea.

(In both these cases, split dosing may only be required for a short time.)

When split dosing is prescribed, the majority of the dose (at least 60 percent) should be the part that is consumed under observation. In addition, consumption of the whole daily dose should be observed on at least one day per week to ensure that the client's/tangata whai ora's tolerance to this dose is maintained. (This is to mitigate the chance of overdose in situations where the client/tangata whai ora has a poor compliance with unobserved split doses and then a whole-dose consumption is resumed suddenly on a more regular basis, for example, on admission to hospital.)

7.5 Notice of prescription changes

Specialist services' information packs to clients/tangata whai ora should include information on how to request changes to prescriptions. Clients/tangata whai ora should be asked to give at least three days notice for a requested change to their prescription. However flexibility is necessary in this area. If services have limited medical staff available or if the client/tangata whai ora is making an overseas trip (see 7.6 Travel arrangements), a longer period may be required.

7.6 Travel arrangements

Arrangements for treatment while a client/tangata whai ora travels overseas may take up to six weeks to organise. Therefore, unless the travel is urgent, the client/tangata whai ora should give adequate notice of their intention to travel (the exact amount of notice required should be determined by each service).

If overseas travel requires the client/tangata whai ora to carry takeaway doses, the prescriber must clarify with the consulate of the intended destination that country's position on a foreigner entering their country in the possession of methadone or other opioid substitute medicine. The prescribing doctor must comply with any special condition on the entry to a foreign country of a person possessing methadone or buprenorphine: providing a letter stating that the person is in possession of the drug to treat a medical condition.

To avoid breakages during the journey, tablets rather than liquid methadone should be considered. All takeaway doses should be in their original packaging, with labelling.

Specialist services must be receptive to helping people on OST who are visiting New Zealand from overseas to access pharmacies and scripting if required.

7.7 Managing overdoses

7.7.1 Methadone overdose

The majority of deaths occurring during stabilisation on methadone involve the use of other drugs, in particular, other opioids, alcohol, benzodiazepines and antidepressants, and clients/tangata whai ora must be warned about the risks of using other drugs with methadone.

Clients/tangata whai ora who are thought to have taken a methadone overdose require prolonged observation.

Significant others, family and whānau members should be warned that deep snoring during induction to methadone treatment could be a sign of dangerous respiratory depression and needs to be reported to the specialist service or GP prescriber. Heavy snoring during ongoing treatment may be associated with sleep apnoea and should also be reported.

Because of the long plasma half-life of methadone, naloxone should be given as a prolonged infusion when treating a methadone overdose.

Signs and symptoms of a methadone overdose include:

- pinpoint pupils
- nausea
- dizziness
- feeling intoxicated
- sedation/nodding off
- unsteady gait
- slurred speech
- snoring
- hypotension
- slow pulse (bradycardia)
- shallow breathing (hypoventilation)
- itchiness
- coma
- frothing at the mouth (pulmonary oedema).

Note: Symptoms may last for 24 hours or more.

7.7.2 Buprenorphine overdose

The risk of lethal overdose from buprenorphine in an opioid-tolerant individual is less than that associated with the use of other opioid medications, such as methadone. However, the effects of buprenorphine, due to its strong affinity to μ opioid receptors (see Appendix 3: Pharmacology and pharmacokinetics of methadone and buprenorphine), are not reversed by the usual doses of the opioid antagonist, naloxone. Doses of 10–35 mg/70 kg may be required to reverse the effects of buprenorphine toxicity.

The long duration of action of buprenorphine should be taken into consideration when determining the length of treatment needed to reverse the effects of an overdose (NSWH 2007).

7.7.3 Consumption of methadone or buprenorphine by a child and management of intoxication

Young children can inadvertently consume a client's/tangata whai ora's takeaway dose of methadone or buprenorphine. This is a potentially life-threatening situation. The fatal dose of methadone for children is 10–20 mg.

Symptoms of opioid overdose in children are similar to those in adults, with pinpoint pupils being most common. However, the pupils may also be normoreactive or, in rare cases, fixed and dilated. Infants may experience drowsiness, coma and apnoea. Children are usually, but not always, symptomatic.

Known or suspected opioid intoxicated children should be referred to a hospital emergency department without delay, since respiratory depression may be observed for as long as 48 hours after ingestion. Naloxone administration should be considered. Treatment must include establishing an airway, maintaining adequate respiratory ventilation, providing precise supportive care to maintain fluid and electrolyte balance, emptying the upper and lower gastrointestinal tracts, and prevention of aspiration of gastric contents.

7.8 Managing ongoing drug use

OST is not a treatment for other drug dependence, and although specialist services are expected to proactively work toward minimising harms associated with other drug use and to assist with reducing and stopping drug use, OST programmes are not expected to have an absolute abstinence focus.

Multiple substance use is common among opioid users. The hazardous use of other drugs, particularly sedatives (such as alcohol and/or benzodiazepines) in combination with opioids, significantly increases the risk of respiratory depression and death. However, the risks arising from other drug use (for example, overdose, serious illness, social deterioration) are usually less than the potential risk of increased hazardous drug use if OST is withdrawn.

Specialist services should make every effort to engage clients/tangata whai ora who continue to use other drugs (including alcohol and tobacco) therapeutically, by screening and assessing for issues that may exacerbate the client's/tangata whai ora's problems (for example, anxiety, depression, cognitive impairment, medical issues, pain) and by using motivational enhancement strategies such as:

- taking a non-confrontational approach
- setting clear boundaries about behaviour, expectations and dosing
- eliciting information about any concerns clients/tangata whai ora may have about their ongoing drug use and associated behaviour
- offering support to help a client/tangata whai ora deal with any issues.

The key worker or GP prescriber will provide the client/tangata whai ora, and their support people, with appropriate advice and information about the client's/tangata whai ora's drug use, its consequences and the range of effective interventions available.

Clients/tangata whai ora who are currently using other opioids, benzodiazepines, amphetamines or alcohol hazardously should not be given takeaway doses.

Information about safe injecting practices should be provided to clients/tangata whai ora who are using drugs intravenously.

Clients/tangata whai ora should be provided with written summaries of any agreement around changes to drug-using behaviour and the consequences to the treatment of the client/tangata whai ora who continue to use high-risk substances (for example, loss of takeaway doses and changes in dispensing arrangements).

Receiving third party information about a client's/tangata whai ora's drug use can be a useful prompt for discussing drug use with the client/tangata whai ora but should never be used as a basis for changing the client's/tangata whai ora's treatment.

'Notwithstanding that safety is a key underpinning principle for all interventions, of critical importance is a health focused and motivational approach with a treatment context that promotes honest self-reporting' (Deering 2007a).

7.8.1 Continued opioid use

When a client/tangata whai ora is not progressing well in treatment, clinicians should consider optimising treatment by increasing the intensity of the OST rather than reducing it. Optimising treatment may include: ensuring that OST is provided within evidence-based optimal levels, changing to another substitute medicine (if available), increasing case management or psychosocial interventions and increasing supervised consumption.

7.8.2 Benzodiazepine use

Benzodiazepine users exhibit patterns of increased risk and poorer social functioning and mental health than other clients/tangata whai ora on OST (Deering 2007; Ross and Darke 2000).

A significant proportion of illicit opioid users presenting for OST may also be using benzodiazepines, often to relieve symptoms of withdrawal when the user is unable to access opioids. Studies have shown that the proportion of those using benzodiazepines falls rapidly during methadone stabilisation, even in the absence of any direct intervention for benzodiazepine use (DeMaria et al 2000; Gossop et al 2004).

Clients/tangata whai ora who continue hazardous benzodiazepine use may require a treatment review to assess: the appropriateness of continuing with OST, the need for an increase in dose or the restriction of takeaway doses. However, specialist services should work with clients/tangata whai ora who are dependent on benzodiazepines (prescribed or illicit) and offer long-term withdrawal options where clinically indicated.

Specialist services need to advise clients/tangata whai ora about the interactions between benzodiazepines and methadone and buprenorphine.

It may be necessary in some instances to prescribe benzodiazepines to clients/tangata whai ora who are dependent on benzodiazepines as well as opioids, but such prescribing should be done with caution. The clinical rationale for prescribing of benzodiazepines and similar drugs should

be clearly documented, and the client/tangata whai ora should be monitored closely and receive regular reviews. Any prescription in addition to methadone or another opioid substitution medicine must be at safe therapeutic levels.

Supervision of clients/tangata whai ora who are receiving maintenance benzodiazepines must be of the same high standard as for OST.

In order to minimise the risk of drug interactions, clients/tangata whai ora should be encouraged to be honest with other prescribers about their methadone or other opioid substitution dose and with their OST prescriber and key worker about any other medication they are taking or have been prescribed. Health care providers, including pharmacists, are obliged to communicate with each other about all drugs known to be taken by clients/tangata whai ora in order to facilitate appropriate health care, and local protocols should highlight this obligation.

Where benzodiazepines are prescribed, Medicines Control, Medsafe, should be informed to ensure that the client/tangata whai ora is using only one prescriber, and restriction notices may need to be considered (see 7.8.4 Restriction notices).

7.8.3 Tobacco use

Nicotine is a highly addictive drug. New Zealand studies show a high prevalence of tobacco use in clients/tangata whai ora on OST programmes (Deering 2007; Dore et al 1999; Townshend 2003).

Specialist services and GP prescribers should promote smoking cessation strategies and encourage and assist clients/tangata whai ora who want to stop smoking while on OST.

7.8.4 Restriction notices

Clients/tangata whai ora on OST can be restricted to using certain classes of prescription medicines, for example, hypnotics, analgesics, antidepressants. Restriction notices for such uses can be issued under section 25 of the Misuse of Drugs Act 1975 and section 49(2) of the Medicines Act 1981.

Only the authorised prescriber(s) listed on the restriction notice can prescribe for the client/tangata whai ora named on the notice.

7.9 Managing side effects

7.9.1 Methadone

Table 3: Methadone

Side effect	Suggested intervention
Constipation	Encourage the client/tangata whai ora to consume plenty of fruits, vegetables and non-alcoholic fluids and to exercise regularly. If a laxative is required, prescribe osmotic laxatives to be taken regularly or stimulant laxatives in a short course. Bulking laxatives are contraindicated in people who take opioids due to less movement in the gut and the risks of further impaction.
Dental problems	Dental problems frequently predate methadone treatment, but methadone does reduce salivary flow. Encourage the client/tangata whai ora to chew sugar-free gum or use tooth mousse to increase salivary flow, to floss and brush regularly and to have regular dental check-ups.
Excessive sweating	Reducing the methadone dose may help, if this can be achieved without compromising the client's/tangata whai ora's stability. Loratadine or clonidine may be helpful in some situations.
Irregular menstrual cycle/amenorrhoea	Advise female clients/tangata whai ora about the risk of pregnancy even when their menstrual cycle is irregular/they are not menstruating (amenorrhoea).
Lethargy	Look for causes other than methadone. Reducing the methadone dose may help, if this can be achieved without compromising the client's/tangata whai ora's stability.
Nausea and vomiting	Encourage the client/tangata whai ora to eat before consuming their dose and to drink the dose slowly. Nausea is usually transient and will subside with time. It may be necessary to prescribe anti-nausea medication in some situations.
Oedema	Dose reduction may help but needs to be weighed against possible destabilisation.
Prolonged QT	Monitor, reduce or transfer the client/tangata whai ora from methadone treatment as necessary, depending on the severity, risk factors and other prescribed medicines being used concurrently. Consult a cardiologist where possible (see 7.18 Methadone and risk of QTc prolongation).
Reduced libido, sexual dysfunction, lowered testosterone levels	Reducing the methadone dose may help, if this can be achieved without compromising the client's/tangata whai ora's stability. Reduced libido may also be an indicator for hormonal assay.
Sleep disturbance	Give advice on sleep hygiene and simple relaxation techniques. Encourage the client/tangata whai ora to avoid using hypnotic drugs and alcohol as they may worsen sleep apnoea and have undesirable interactions with methadone.

(Adapted from table 2.2.1, NSW 2007)

7.9.2 Buprenorphine

The most common side effects experienced with the use of buprenorphine include cold or flu-like symptoms, headaches, sweating, sleeping difficulties, nausea and mood swings. Most adverse effects occur early in treatment, are mild and subside with time. They appear to be generally unrelated to the dose, however, nausea is more common with doses over 8 mg, and dizziness occurs more commonly at higher doses (Lintzeris et al 2006).

Buprenorphine, like other opioids, can effect cognitive ability and attention. Symptoms of constipation, sexual dysfunction and (occasionally) increased sweating can persist for the duration of buprenorphine treatment.

7.10 Clients/tangata whai ora who present intoxicated

Safety (of the client/tangata whai ora, clinical staff, pharmacy staff and others) is the key consideration in responding to those who present for their opioid substitution dose while intoxicated with opioids, alcohol or other drugs. As a general rule, clients/tangata whai ora exhibiting signs of intoxication should not be given their dose or any takeaway doses until they have been assessed as free of symptoms. This may involve the pharmacist either referring them to be seen at the specialist service or asking them to come back later in the day before giving the dose. In extreme circumstances where the pharmacist feels that to deny a dose would risk the safety of their pharmacy staff, it may be appropriate to administer a partial dose.

It may be appropriate to administer a half dose with an instruction to the client/tangata whai ora to return later in the day for the other half, which might then be given if the client/tangata whai ora is not intoxicated at that time. Twice-daily dispensing of half doses (dependent on the client/tangata whai ora not being intoxicated when they present for their doses) may be a useful intervention for those who repeatedly present intoxicated.

Clear guidance should be given to clients/tangata whai ora and pharmacists regarding the likely outcomes of a client/tangata whai ora presenting for doses in an intoxicated state.

The specialist service should be notified whenever a client/tangata whai ora presents in an intoxicated state at the pharmacy or dispensing point (see 11 Pharmacist dispensing).

7.11 Ageing clients/tangata whai ora

Older clients/tangata whai ora may have special health needs caused or exacerbated by either complications of lifelong drug and alcohol use or the problems associated with long-term OST. Complications may include:

- liver damage due to hepatitis B or C and excess alcohol use (or a combination)
- chronic airways disease and chronic lung damage from cigarette and/or cannabis smoking and previous injecting of tablet excipients, with the possible development of pulmonary hypertension
- chronic venous and/or arterial damage, making IV access difficult or impossible
- cardiac valve damage
- neurological damage, causing impaired memory and cognitive functioning
- the risk of drug interactions between methadone/buprenorphine and treatments used for other diseases, for example, antihypertensives, hypoglycaemics, antidepressants, antituberculin agents, anticonvulsants, antiretrovirals

- low mood
- fatigue
- overdosing as a result of reduced tolerance
- endocrine problems and an associated risk of osteoporosis
- cellulitis
- endocarditis (rare in the absence of IV use)
- osteomyelitis (rare in the absence of IV use).

Long-term use of methadone and other opioids can cause reduction in the sex hormones with altered sexual functioning and, in the long term, increased risk of osteoporosis, particularly in men and probably in post-menopausal women. These side effects should be monitored, particularly in long-term and older clients, and appropriate health advice should be given and investigation, specialist assessment and treatment should be arranged as required.

It is likely that buprenorphine has less endocrine effects than methadone.

OST clients/tangata whai ora can also develop any of the diseases common in the elderly community, for example, hypertension, diabetes, chronic airways disease. Specialist services and GP prescribers should develop and co-ordinate plans to support the management of specific complications experienced by clients/tangata whai ora in the 40+ age group as well as those who have been on OST for longer than 10 years.

7.12 Pregnancy, breastfeeding and opioid substitution treatment

7.12.1 Methadone and pregnancy

Pregnant women have priority access to methadone treatment.

OST has been shown to improve pregnancy outcomes for opioid-dependent women. This is likely to be the result of a combination of factors, including stabilisation of drug use (avoiding cycles of intoxication and withdrawal), facilitation of and support for the client/tangata whai ora accessing appropriate antenatal and postnatal care, and improvements in the client's/tangata whai ora's access to adequate nutrition and social services as required. There is no evidence that methadone treatment is teratogenic (that is, causes abnormalities in the foetus).

Women entering OST who are of childbearing age should be advised about the effects of methadone, as well as other substance use (including alcohol and tobacco) should they become pregnant (see above).

Even when a female client's/tangata whai ora's menstrual cycle is irregular the client/tangata whai ora is not menstruating during OST, pregnancy is still possible, and contraception should be discussed with the client/tangata whai ora.

It is important for pregnant women to have their serum opioid levels as stable as possible to minimise risks to both the client/tangata whai ora and their foetus. Methadone metabolism may change significantly during pregnancy, leading to lower plasma methadone concentrations and reports of symptoms of withdrawal. This is, however, highly variable. Increased doses of methadone may be required, usually in the late second or third trimester. Doses should be reviewed in the days to weeks following delivery as dose adjustments may be required.

If a pregnant client/tangata whai ora on methadone is vomiting frequently, the treatment plan may need to be varied to allow for the use of anti-emetic drugs to stabilise serum opioid levels (see 7.4 Split methadone dosing and 7.3 Measuring methadone serum levels).

If dose reductions are proposed, they should only be undertaken in the second trimester and in small increments. Dose reduction should not be undertaken if the pregnancy is in any way unstable. It is important to avoid withdrawal symptoms as this may induce potential distress in the foetus. The size and rate of reductions should be flexible and should respond to symptoms experienced by the pregnant client/tangata whai ora.

It is not uncommon for women on OST who find themselves pregnant to request to come off OST. In this event, the client/tangata whai ora should be fully informed of the risks to the foetus associated with staying on treatment compared with those relating to a relapse to illicit opioid use.

Any pregnant client/tangata whai ora who withdraws from OST in their first or third trimester of the pregnancy does so against all known medical advice due to the risk of spontaneous abortion or of precipitating delivery. It is recommended that OST services keep documentation detailing that this advice has been clearly communicated to any pregnant client/tangata whai ora. It is also recommended that any reductions in OST dosages are small.

- It is recommended that pregnant women who are receiving OST deliver their baby at a hospital where the newborn infant can be monitored under the supervision of an appropriately experienced paediatrician.
- Methadone readily crosses the placenta, therefore, the neonate who has been exposed to methadone in utero should be monitored postnatally for withdrawal symptoms, using an accepted validated opioid withdrawal scale. Withdrawal symptoms in a newborn methadone infant may require treatment; potentially they can become life threatening if severe and untreated.
- The neonate should be monitored for respiratory depression at delivery, as this may occur in some cases.

A pregnant OST client/tangata whai ora may be managed by a specialist service, an authorised GP or an approved/gazetted GP in combination with appropriately experienced obstetric services.

If a pregnant client/tangata whai ora 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 GP should consult with a specialist service as required during the pregnancy and perinatal period.

Every OST specialist service needs to have a clear protocol for managing pregnant clients/tangata whai ora. This local protocol should be flexible enough to address the range of different requirements that the client/tangata whai ora may have. Clear pathways for liaising with antenatal and postnatal care teams will also need to be in place.

Where possible, OST staff should take on a consultation and liaison role, making information about the benefits and risks of OST to mother, foetus and baby available to other specialist alcohol and drug service staff, opioid users and their support people, GPs, nurses, obstetricians, paediatricians, midwives and pharmacists.

7.12.2 Methadone and breastfeeding

Methadone passes into breast milk only in small amounts, and female clients/tangata whai ora should be encouraged to breastfeed where possible except in the rare case where it is

contraindicated (for example, if the client/tangata whai ora is HIV positive). Advice should be given regarding the passage of other drugs, including prescribed and illicit drugs, into breast milk, particularly CNS depressants, which may dangerously sedate or cause respiratory depression in the neonate. Advice should be sought from specialist services or obstetric services that are experienced in the care of women dependent on opioids if required.

7.12.3 Buprenorphine in pregnancy and breastfeeding

The use of buprenorphine by pregnant and breastfeeding clients/tangata whai ora remains controversial, although evidence of its safety is increasing. However, there is concern about the presence of naloxone in the combination product, and if it is decided to use buprenorphine with pregnant or breastfeeding clients/tangata whai ora, buprenorphine without naloxone should be used. This combination is not currently registered for use in New Zealand but can be obtained by any medical practitioner under section 29 of the Medicines Act 1981.

7.13 Needs of children of parents on OST

Drug misuse can place an enormous strain on the support people and families of drug users and may have serious negative effects on the long-term health and wellbeing of family members and whānau, and in particular dependent children.

Reducing harm to children from parental drug use should become a main objective of OST provision.

Effective OST of the parent can have major benefits for the development of the children in their care.

Consideration of the wellbeing of a client's/tangata whai ora's dependent children should occur at initial assessment and throughout treatment. The children's safety needs to be specifically considered when assessing the appropriateness of prescribing takeaway doses.

Where possible, OST staff should take on a consultation and liaison role, ensuring that information about the benefits and risks of OST to parents and children is available to all relevant family services.

Specialist services and GPs have a duty to notify Child, Youth and Family if they suspect that a child or young person may be at risk of harm through abuse, neglect or exposure to family violence.

7.14 Pain management

7.14.1 Acute and surgical pain

Methadone, when prescribed for OST, does not provide relief for acute pain on its own. For most clients/tangata whai ora receiving methadone treatment, effective pain relief is achieved by conventional doses of opioids or other drugs additional to methadone. However, in some cases, clients/tangata whai ora may be cross-tolerant to such pain relief treatment. In these cases, advice should be sought from a pain professional.

Where buprenorphine is the OST medicine being used, additional pain relief with opioids is problematic due to the high affinity of buprenorphine for the opioid receptor. Consultation with a pain professional should occur in these circumstances.

When an OST client/tangata whai ora is undergoing treatment that may require pain medication, OST providers should advise hospital staff, dentists or other health professionals of the client's/tangata whai ora's current OST and pain management.

For surgical procedures, full OST doses can be administered throughout the hospital stay, with additional opioids given as appropriate for the procedure.

Some clients/tangata whai ora can present a cross-tolerance for opioid surgical pre-medications, requiring higher doses of these medications; however, such dose increases should be instituted with caution, especially if the client/tangata whai ora has significant hepatic or renal impairment.

Mixed agonist-antagonist drugs, such as pentazocine (Fortral) and buprenorphine, can produce opioid withdrawal symptoms when used with OST.

Clients/tangata whai ora should inform their OST provider if they are planning to undergo surgical or medical treatment. The OST provider should then liaise with the other medical or surgical service to confirm the timing and dose of methadone suitable before and after the event and to ensure the methadone treatment is uninterrupted during the client's/tangata whai ora's hospital admission and convalescence.

Non-gazetted medical officers in institutions such as hospitals may need to be authorised by a specialist service doctor, or gazetted GP, to prescribe for OST clients/tangata whai ora who are required to be in hospital for longer than three days (see Appendix 2: Misuse of Drugs Act 1975 s24).

Note: Any medical practitioner can prescribe a controlled drug for a drug-dependent client/tangata whai ora who requires opioids for reasons other than treating substance dependence.

7.14.2 Chronic non-malignant pain

Studies have shown that a significant proportion of people entering OST have chronic pain problems and that lack of attention to this impacts on the client's/tangata whai ora's stability in treatment (Rosenblum et al 2003; Jamison et al 2000; Peles et al 2006). Genetic links between pain sensitivity and a predisposition to dependence and opioid-induced hyperalgesia are likely contributing factors. Chronic pain is associated with an increased incidence of depression and is an independent risk factor for both attempted and completed suicide (Tang and Crane 2006).

Opioid-dependent people with chronic pain are often taking prescribed or over-the-counter opioids such as codeine, slow-release morphine, oxycodone or injectable pethidine or morphine. It is reasonable to suspect that many people who are taking opioids for chronic pain have become dependent on opioids and that their dependency plays a part in maintaining the degree of pain and dysfunction that they experience. However, there are some circumstances in which the suspicion of dependence becomes more certain, for example, people who take escalating doses with diminishing relief from distress, claim to have lost prescriptions, obtain prescriptions from multiple prescribers or inject tablets that are designed for oral administration. Such people are demonstrably not in control of their drug use.

It can, however, be difficult to distinguish between active addiction and pain-related behaviour such as seeking additional opioids for the relief of undertreated pain.

Admitting these clients/tangata whai ora with chronic non-malignant pain whose use of prescribed opioids is assessed to be out of control may often be an appropriate way of supervising and stabilising their drug use.

Specialist services or GP prescribers must consult with pain management services (preferably before the initiation of OST or any opioid pain relief) about the suitable management of clients/tangata whai ora presenting with chronic non-malignant pain problems.

Among other things, treatment should aim to:

- control and rationalise a client's/tangata whai ora's use of opioids and other medications
- convert the client/tangata whai ora from parenteral to oral medication
- reduce the number of different drugs that a client/tangata whai ora uses
- improve the client's/tangata whai ora's psychosocial functioning.

For more information on chronic non-malignant pain management, refer to *Improving Management of People with Chronic Non-malignant Pain and Opioid Drug Dependence* (Royal Australasian College of Physicians 2008).

7.15 Coexisting mental health issues

There is a high prevalence of coexisting mental health disorders in opioid-dependent clients/tangata whai ora. These commonly include: depression, post-traumatic stress disorder, social phobia and antisocial personality disorder.

Research indicates that integrated treatment for both alcohol and drug and mental health problems is best practice (Mueser et al 2003; Todd et al 1999). Specialist services should routinely assess and provide treatment for clients/tangata whai ora who have coexisting mental health problems, since addressing symptoms may contribute to better outcomes, for example, improved occupational functioning and general health. If the specialist OST services are unable to provide mental health services or support themselves, they need to facilitate referral and advocate for client access to other services.

Many clients/tangata whai ora report that, before they commence on OST, they experience depressed moods and disturbed sleep. Mood usually improves after stabilisation on methadone or buprenorphine; therefore, it is not normally appropriate to initiate antidepressant treatment early in OST. Clients/tangata whai ora who are already on antidepressants, particularly tricyclic antidepressants and some selective serotonin re-uptake inhibitors (SSRIs), may need care during induction and withdrawal, as these drugs may interact with methadone (see Appendix 4: Drug interactions associated with opioids).

Antipsychotic drugs may potentiate the respiratory depressant effects of methadone.

7.16 Blood-borne viruses

Four viruses are currently of particular concern in the context of opioid use; hepatitis A, B and C and HIV. It is recommended that specialist services offer hepatitis B and C and HIV tests as part of a client's/tangata whai ora's initial assessment. Testing can be done only with informed consent. Clients/tangata whai ora being tested should also receive pre- and post-test counselling from a competent and knowledgeable practitioner. It is also recommended that follow-up testing be offered at appropriate periods, especially if the client/tangata whai ora continues to engage in high-risk behaviours.

All OST providers (specialist services and GPs) should be trained in HIV and hepatitis-related issues and be able to provide education about blood-borne virus issues for clients/tangata whai ora; their significant others, family and whānau; and other health and social service providers as part of their specialist consultation and liaison role.

If tests are ordered, the OST provider has a duty of care to interpret the results correctly. Clients/tangata whai ora who are hepatitis C antibody positive will not need to have a repeat test but will need initial assessment of their liver function and, as appropriate, assessment of whether or not they are viraemic, using polymerase chain reaction (PCR) testing for presence/absence and amount of virus and for hepatitis CRNA.

Liver function tests should be monitored as clinically indicated but at least annually, or as advised by local infectious diseases specialists or a gastroenterologist.

All results of HIV and hepatitis testing are to remain confidential to the client/tangata whai ora and the OST provider. In order to preserve privacy, testers should offer the use of a coded descriptor for the client/tangata whai ora on the blood-test form.

Because of the risk of future hepatitis A and/or B infection, all clients/tangata whai ora who do not have protective levels of antibody should be advised to have a vaccination. Partners and relevant family or whānau should also be advised to have immunisation if they have independent risk factors such as unsafe injecting practices.

Clients/tangata whai ora who decline to be tested for blood-borne viruses should be given advice on how to avoid transmitting viruses to or contracting viruses from others.

Clients/tangata whai ora with chronic hepatitis B and/or C or who are suspected of having severe liver disease should be advised of the antiviral treatments available and encouraged to have a specialist assessment (for example, from a gastroenterologist or infectious diseases physician), when appropriate, for treatment.

7.17 Dental problems

Dental problems can contribute to chronic ill health and wellbeing, but clients/tangata whai ora on OST cannot always afford to access appropriate dental care.

Specialist services and prescribers should encourage good dental hygiene and help clients/tangata whai ora to access appropriate treatment as needed.

7.18 Methadone and risk of QTc prolongation

Methadone may prolong the QT interval and/or induce torsade de pointes. The risk of QTc prolongation in clients/tangata whai ora who are using or being prescribed methadone is unpredictable and variable but may be potentially fatal. It is important, therefore, that clients/tangata whai ora are screened for this risk at entry to, and during OST, especially if other potential QTc prolonging medications are prescribed. (See Appendix 4: Drug interactions associated with opioids and <http://www.torsades.org/medical-pros/drug-lists/drug-lists.htm> for updated information).

8 Ending Opioid Substitution Treatment

8.1 Planned withdrawal

The best outcomes occur when the client/tangata whai ora ceases OST voluntarily after a planned and gradual withdrawal and when they are able to control the frequency and amount by which their dose is reduced.

Withdrawal should ideally only occur, but should not be limited to, when the client/tangata whai ora has achieved a number of their treatment goals and has reached a stage of stability that gives them a reasonable chance of successfully achieving sustained abstinence from opioids.

Planned withdrawal from any OST should be client/tangata whai ora directed, have a flexible end point and involve the offer of, or referral to, appropriate psychosocial and medical support.

Psychotropic medication (in particular hypnotics and sedatives) is not generally recommended during monitored withdrawal except when indicated for diagnosed coexisting mental health problems and, even then, doses should be low for a specified short duration. Complementary medicines and interventions should be considered.

Interventions such as relapse prevention should be offered to all clients/tangata whai ora undertaking withdrawal from OST. It is recommended that support people be given information about the withdrawal process and how they might assist the client/tangata whai ora.

Ongoing support after withdrawal is particularly important if the client/tangata whai ora is to remain opioid-free. Services need to ensure that clients/tangata whai ora are fully informed about the resources available to help them maintain stability and reduce the risk of relapse.

Clients/tangata whai ora who are unable to maintain stability after a planned withdrawal from OST should be readmitted to the specialist service promptly. This option and the timeframe for priority access should be negotiated and agreed between the specialist service, or GP prescriber, and the client/tangata whai ora before their withdrawal is completed.

8.2 Suggested methadone reduction schedule

Table 4: Suggested methadone reduction schedule

Dose	Reduction rate
Above 50 mg	5 mg per week or fortnight
30–50 mg	2.5 mg per week or fortnight
Below 30 mg	1–2 mg per week or fortnight

The above table should only be seen as a guide. Methadone reductions should have flexible end points, and rates of adjustment need to be flexible enough to support the individual needs of the client/tangata whai ora.

8.3 Suggested buprenorphine reduction schedule

Table 5: Suggested buprenorphine reduction schedule

Dose	Reduction rate
Above 16 mg/day	4 mg per week or fortnight
8–16 mg/day	2–4 mg per week or fortnight
Below 8 mg/day	2 mg per week or fortnight

Most clients/tangata whai ora will not be comfortable on alternate day doses of buprenorphine below 8 mg. For those on alternate day dosing, reductions may occur at a similar effective rate to those on daily dosing (for example, reductions of 2–4 mg every 1–2 weeks) until the client/tangata whai ora reaches a dose of 8 mg every other day. In order to have closer monitoring and support, at this point, clients/tangata whai ora should be transferred, where possible, onto a daily dosing equivalent and reduced as per daily dosing reductions.

There is no evidence to support dose reductions below 2 mg, using 0.4 mg tablets, since at lower doses, buprenorphine’s duration of action increasingly diminishes (NSWH 2007).

8.4 Involuntary withdrawal

A decision to exclude a client/tangata whai ora involuntarily from OST should not be taken lightly. This course of action may put the person at an increased risk of fatal overdose, contracting a blood-borne virus or criminal offending. Involuntary withdrawal may well also have significant implications for others, including children, partners, families, whānau and the wider community.

OST providers may consider discharging clients/tangata whai ora who do not adhere to the safety requirements of the OST programme or for whom OST is not considered an effective treatment (that is, the harm minimisation benefits of OST are outweighed by the negative outcomes and elements of risk).

Other situations where a client/tangata whai ora may be considered for involuntary withdrawal include the following.

- The client/tangata whai ora takes regular overdoses or is frequently significantly intoxicated from psychoactive substance use. (It is important to note that relapse is a feature of addiction, and this should be taken into account).
- The client/tangata whai ora threatens or is violent towards staff, other clients/tangata whai ora or the prescriber or pharmacist. (Review of the circumstances associated with aggressive behaviour should always precede any decision to withdraw a client/tangata whai ora from the OST programme).
- The client/tangata whai ora repeatedly displays the inability, despite warning, to keep to the safety requirements of the OST provider (for example, repeatedly diverts prescriptions, deals drugs or fails to keep appointments).

The injection of methadone or regular use of other drugs should not automatically be an indication for a client’s/tangata whai ora’s involuntary withdrawal from OST. Specialist services are expected to proactively work with clients/tangata whai ora to increase their motivation to reduce or stop injecting and other drug use.

Involuntary withdrawal should be a last resort, and decisions relating to termination of treatment should be initiated only after careful consideration and input from a number of other sources (including the community pharmacist, the client's/tangata whai ora's GP, and the client's/tangata whai ora's support people) and after all attempts have been made to solve any presenting issues, where appropriate.

Before any decision to withdraw OST is made, the key worker, prescriber or other relevant clinical staff member, must discuss the matter with the client/tangata whai ora and, wherever possible, written warnings should be provided before the decision is made to withdraw treatment.

The final decision should only be made by the prescribing doctor in consultation with the key worker and the case management team, including the service manager or the primary health care team (whichever applies), and after a second supporting opinion (by telephone) has been sought from an independent addiction medical specialist, or equivalent, selected from a list provided by the National Association of Opioid Treatment Providers (NAOTP).

When subject to involuntary withdrawal, the client/tangata whai ora will be:

- informed of other treatment options available
- given the reasons for the discharge in writing
- given an outline of the service's complaints procedure for review of the decision
- offered support, where appropriate, during the withdrawal process
- cautioned about risks of driving and operating machinery during the withdrawal process
- provided with a future directed specific treatment plan.

In all cases, a discharge plan must be developed and documented once a decision to withdraw from treatment (planned or involuntary) has been made.

All clients/tangata whai ora should be given a fair opportunity to present their case/appeal against a service's decision to involuntarily withdraw them from OST, and wherever possible they should be retained in the programme pending resolution of the appeal.

Detoxification programmes, whether inpatient or outpatient, and follow-up residential treatment (if available) should be offered with an involuntary withdrawal of treatment.

Rapid dose reduction is not recommended and should not be undertaken unless unavoidable (for example, in cases of violence). The dose should be reduced gradually over at least 21 days and preferably over four to six weeks.

If a client/tangata whai ora has HIV/AIDS and may threaten to use unsafe behaviour if their treatment is terminated, the treatment provider should consult with the local medical officer of health before treatment is terminated.

Each case of involuntary treatment withdrawal should be reviewed to determine how best the client/tangata whai ora might re-engage in OST.

8.5 Last dose

Prescribers of OST or the relevant specialist service must notify the pharmacy whenever a client's/tangata whai ora's treatment has been terminated.

Medical practitioners working under authority must notify their specified OST service when the client/tangata whai ora ceases treatment and/or the GP withdraws methadone or other opioid substitution medicine.

If the client/tangata whai ora has been subject to a restriction order, the prescriber or specialist service will also need to notify Medicines Control, Medsafe, that the client/tangata whai ora is no longer being prescribed methadone or other opioid substitution medicine.

8.6 Transferring to naltrexone

Naltrexone may help a client/tangata whai ora to abstain from opioid use following detoxification from methadone or buprenorphine. Naltrexone is an opioid antagonist that blocks the effects of opioids when taken regularly.

Administering naltrexone to a client/tangata whai ora who is physically dependent on opioids will lead to severe withdrawal.

Clients/tangata whai ora transferring from methadone to naltrexone should withdraw completely from methadone and allow a 14-day drug-free period for stored methadone to be eliminated from the body before commencing naltrexone treatment.

Those transferring from buprenorphine to naltrexone will require between 5 and 7 days between the last dose before commencing naltrexone (NSWH 2007).

Warning: There is an increased risk of overdose death on relapse following cessation of naltrexone.

9 Clinical and Administrative Expectations of Specialist Opioid Substitution Treatment Services

9.1 Treatment outcomes

Section 1.2 Objectives of Opioid Substitution Treatment lists the desired objectives of OST. It is expected that specialist services will periodically (at least every three years) review their performance against these objectives, using *Service Audit and Review Tool: Opioid Substitution Treatment in New Zealand* (Ministry of Health 2007b) or any updated version of this audit tool.

A number of performance indicators for OST are contained in the requirements of relevant sector standards.

9.2 Staffing

Specialist service staff should:

- be positive, client-centred and non-judgemental in their attitudes and have a high level of empathy for clients/tangata whai ora
- be flexible in their approach to treatment, focusing on treatment retention and being accessible to their clients/tangata whai ora
- believe in and work with clients/tangata whai ora towards minimising harm in regard to any ongoing drug use
- have an understanding of the inherent power imbalance in the client/tangata whai ora-specialist service staff relationship
- promote client/tangata whai ora autonomy and recovery through a range of proven strategies
- help clients/tangata whai ora develop skills to cope with relapse triggers or cues
- promote client/tangata whai ora participation in meaningful activities such as child rearing, homemaking, vocational training, education, full- or part-time employment, and volunteer work
- understand and challenge the stigma associated with receiving OST
- be aware of key documents relevant to the treatment of people with opioid dependence, other alcohol and other drug problems and coexisting mental health problems
- follow the principles of the Treaty of Waitangi and its implications for tangata whai ora in their practices
- be willing to work with all clients/tangata whai ora, regardless of race, ethnicity, age, disability, sexual orientation, gender or health status and be sensitive to these issues and where necessary receive training and cultural support in working with diversity
- be inclusive of the client's/tangata whai ora's support people (family/whānau or other significant people) in their practices
- receive ongoing clinical supervision and support
- have (or be supported to attain) a relevant tertiary qualification

- be a registered health practitioner with the Drug and Alcohol Practitioners' Association of Aotearoa-New Zealand (DAPAANZ) or another relevant professional body or be supported to work toward professional registration
- receive ongoing training in:
 - the Practice Guidelines for OST and local protocol requirements
 - the assessment and management of coexisting mental health and gambling problems
 - the management of co-existing health problems
 - blood-borne viruses and in particular HCV treatment
 - multiple substance abuse and drug interactions
 - the pharmacology and pharmacokinetics of opioids
 - the philosophy of recovery from drug dependence
 - smoking cessation interventions
 - client/tangata whai ora participation in OST treatment design and policy
 - whānau ora and family inclusive practices.

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/tangata whai ora.

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 OST. They should also be well informed about the available outreach services and information about safe practices for opioid users.

9.2.1 Level of training

- All OST clinicians are expected to have some demonstrable commitment to ongoing alcohol and other drug treatment education.
- Senior clinicians (including doctors) and key workers in specialist services are expected to have, or be enrolled in, relevant alcohol and other drug postgraduate qualifications and/or be experienced at working in the alcohol and other drug treatment sector.
- An approved/gazetted doctor would be expected to have completed, or be enrolled in, relevant alcohol and other drug postgraduate training. Authorised GPs or practice nurses working in primary health care settings, such as a general practice, at the minimum, should have received training in the expectations of OST prescribing and client/tangata whai ora care. GPs should also enrol in any future training developed specifically for their sector.
- Pharmacists involved in dispensing methadone should have completed training relevant to their role of dispensing OST.

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

Staff members should be supported to attend networking opportunities with other OST providers external to their service. It is recommended that clinical managers and/or specialist service clinical leaders attend NAOTP meetings.

Meetings of the New Zealand Chapter of Addiction Medicine of the Royal Australasian College of Physicians are held in conjunction with NAOTP meetings. Doctors who are not Fellows of the Chapter but who are involved in or have an interest in the medical treatment of addiction are encouraged to attend these meetings. It is expected that services will support medical officers working in OST to attend at least one of these meetings each year and that senior medical staff who have influence in policy development in their services will attend the majority of these meetings.

9.3 Record keeping

Records must be held for all clients/tangata whai ora, and must include details of:

- the client's/tangata whai ora's National Health Index (NHI) number and demographic information
- a comprehensive alcohol and other drug assessment (including hepatitis serology, liver function and other laboratory tests) and initial treatment plan
- the nominated GP
- the key worker and prescriber
- the date treatment commenced
- the dose and dispensing arrangements
- the name, address, telephone number and fax number of the pharmacy dispensing opioid prescriptions for that client/tangata whai ora
- the current treatment plan and progress notes
- perceived risk, including criminal behaviour and forensic history
- review summaries of treatment progress
- consent forms (for treatment, disclosure of personal information, etc)
- GP authorisation forms, for those in GP-managed treatment, and treatment review forms
- 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 or section 49 of the Medicines Act 1981
- the discharge date and factors involved in any involuntary discharge as appropriate.

9.4 Reporting requirements

Specialist services must send complete, timely and accurate information to The Programme for the Integration of Mental Health Data (PRIMHD). In addition, specialist services will provide the Director of Mental Health with:

- six-monthly statistical data (which contributes to the Director of Mental Health's annual report) related to waiting lists; GP care; buprenorphine prescriptions; transfers to correctional facilities and to and from other specialist OST services; interim prescribing; gender and ethnicity of all clients/tangata whai ora; psychosocial interventions provided or brokered out; withdrawals from the programme and deaths due to overdose.

9.5 Rights of the client/tangata whai ora

A client-centred approach must underpin all activities of the specialist service and GP prescriber.

The client/tangata whai ora must receive information about:

- their rights under The Code of Health and Disability Services Consumers' Rights
- relevant client/tangata whai ora and consumer advocacy contacts
- limits of confidentiality as per the Health Information Privacy Code 1994 (that is, situations under which the specialist service may need to break confidentiality)
- the range of treatment options available, the treatment interventions offered by the specialist service or GP prescriber service or access pathways to other services offering psychological or psychosocial interventions not provided by the service
- methadone or other opioid substitute medicine pharmacology, side effects and drug interactions
- the service's policies and procedures, including their complaints procedure.

Each client/tangata whai ora should receive, or be offered, a copy of their treatment plan and any updated, renegotiated treatment plans.

All OST services (including approved/gazetted GPs) must comply with the relevant health sector standards that include sections on client/tangata whai ora involvement in services.

Clients/tangata whai ora should be given clear verbal and written information about both planned and involuntary withdrawal processes and the conditions under which an involuntary withdrawal might be activated.

9.6 Complaints procedure

Specialist services will have a complaints management system that is accessible to clients/tangata whai ora and complies with legislation (including the Consumer Guarantees Act 1993 and the Human Rights Act 1993).

- Each service will follow a clearly documented complaints process that is implemented for the identification and management of client/tangata whai ora complaints and complies with legislative requirements. This process will be clearly communicated to clients/tangata whai ora in a form that is easily understood by the complainant and is appropriate to their communication needs and style.
- The complaint process will be sensitive to and respect the values and beliefs of clients/tangata whai ora.
- Any complainant will be informed of their right to have an independent advocate/support person.
- The complaint management process will be linked to the service's quality and risk management system to facilitate feedback and improvements in service delivery wherever practicable.

Complaints are not to be kept in the client's/tangata whai ora's clinical file.

9.7 Safety requirements of specialist services

Safety requirements of specialist services are set out in the Standards New Zealand NZS 8134:2008 Health and Disability Services Standards. These standards amalgamate mental health and alcohol and other drug service requirements.

OST services prescribe potent opioids and often work with clients/tangata whai ora who have complex circumstances. The services need to balance the client's/tangata whai ora's needs with the safety requirements of the client's/tangata whai ora's dependent children, family/whānau, the service, the pharmacy and the general public.

Each service should have a set of safety requirements that cover the areas of personal safety of clients/tangata whai ora and staff as well as safety in prescribing, dispensing and takeaways. These safety requirements need to be discussed with the clients/tangata whai ora, and their support people where possible, as part of the client's/tangata whai ora's initial assessment and wherever relevant during ongoing treatment.

9.8 Local protocol requirements

Specialist services may develop their own local protocols and procedures provided they are consistent and not in conflict with these practice guidelines or with relevant legislation, codes of practice and accountability requirements.

Services should have local protocols that cover processes for:

- clients/tangata whai ora accessing services
- managing any waiting list for admission to OST
- managing pregnant women who are receiving OST
- managing clients/tangata whai ora who are suspected of being intoxicated or of 'diverting' their methadone or other opioid substitute medicine
- transferring clients/tangata whai ora to primary health care services and re-engaging them into the specialist service for stabilisation or longer-term care
- transferring clients/tangata whai ora between specialist services
- reviewing a client's/tangata whai ora's progress
- managing clients/tangata whai ora who are in prisons
- managing clients/tangata whai ora who are coming off methadone
- providing psychosocial treatment
- providing information about driving and using dangerous machinery
- providing a pathway for clients/tangata whai ora who are seeking review of their treatment
- managing the specific medical issues of older clients/tangata whai ora
- managing treatment processes for blood-borne viruses, particularly HCV
- measuring treatment outcomes for clients/tangata whai ora
- reviewing safety and risk issues.

The NAOTP, together with specialist services, will continue to co-ordinate and progress matters of mutual interest in OST, such as access, waiting lists, transfers between regions, involuntary withdrawal and agreed clinical protocols and guidelines (for example, for the use of alcohol and other drugs), which aims to improve national consistency of such protocols.

In specific or unforeseen circumstances, clinicians may need to vary their practice from that suggested in these guidelines. In such instances they must clearly document the reasons for such variation in the client's/tangata whai ora's records or in the service delivery model documentation. There should be no variation from the administrative and legislative requirements contained in these practice guidelines.

Where local protocols vary from these guidelines, the specialist service will need to provide the Ministry with the justification for the variation.

9.9 External review

The Ministry or the appropriate District Health Board (DHB) will request external audits, based on the *Service Audit and Review Tool: Opioid Substitution Treatment in New Zealand* (Ministry of Health 2007b) or any updated version of this audit tool, of a Ministry determined set number of services per year. Copies of the Audit Tool are available from the Ministry of Health's website www.moh.govt.nz.

The Ministry encourages service self-audits and peer-review processes using the Ministry's Audit Tool with the goal of improving the quality of OST. Services may consider having a NAOTP member on their self-audit review team.

The Ministry, or local funder, may request an external audit of any service to determine the alignment of any local/regional protocols to these practice guidelines.

10 Other Opioid Substitution Medicines Used in New Zealand

10.1 Introduction

Although methadone is the only publically funded opioid substitute prescribed for the treatment of opioid dependence in New Zealand, a number of other opioids are also used for OST. Buprenorphine with or without naloxone is widely used in Australia and has a solid research base supporting its effective use in OST. Two other opioids with less research evidence of effectiveness in OST that are used by some specialist services are:

- Dihydrocodeine (DHC)
- slow release morphine.

Prescribers of other opioid substitute medicine for the purposes of OST should follow the methadone treatment options outlined in these practice guidelines.

10.2 Buprenorphine

Buprenorphine is available as two sublingual tablet preparations: without naloxone (Subutex®) and with naloxone (Suboxone®). Only Suboxone® is currently registered in New Zealand, but, under section 29 of the Medicines Act, Subutex® is available for named clients/tangata whai ora.

The addition of naloxone is designed to discourage the diversion of buprenorphine to unintended users. Naloxone is an opioid antagonist with low bioavailability by the sublingual route but high bioavailability by the parenteral route. When taken sublingually, Suboxone® is an effective opioid; when injected, the naloxone is predominantly effective, inducing withdrawal (see Appendix 3: Pharmacology and pharmacokinetics of methadone and buprenorphine).

Buprenorphine provides people who are dependent on opioids with:

- a wider selection of treatment options
- an alternative if they experience adverse side effects from methadone, including methadone-related torsade de pointes, sweating, constipation and sedation
- an alternative for detoxification from opioids
- a medication that is inducted more rapidly than methadone
- a medication with a good safety profile (that is, low risk of overdose) when not used in combination with other central nervous system depressants
- a less sedating medication.

Buprenorphine can be very useful for those requiring rapid induction into OST and for those who are undecided about seeking withdrawal from opioids or maintenance treatment.

10.2.1 Duration of action

Buprenorphine's duration of action varies depending on the dose prescribed. Clinical effects peak 1–4 hours after taking a sublingual dose. At low doses (for example, 2 mg), effects will usually continue to be experienced for up to 12 hours, whilst at higher doses (for example, 16–32 mg), effects may last as long as 48 to 72 hours. This allows for the potential to prescribe less than daily dosing.

10.2.2 Withdrawal syndrome

Buprenorphine differs from other opioids in that the onset of withdrawal after stopping is delayed and the withdrawal itself may be milder than that experienced with methadone, morphine or heroin.

Buprenorphine can be used at the end of a methadone-withdrawal programme and requires less adjunctive prescribing (Ministry of Health 2006).

10.2.3 Drug interactions

Other drugs with activity at opioid receptors (that is, opioid agonists and antagonists) interact with buprenorphine.

Drugs such as benzodiazepines that have the potential to cause CNS depression may cause additive sedative and respiratory depressant effects when taken with buprenorphine.

If buprenorphine is taken in conjunction with drugs that either induce (increase the activity of) or inhibit (decrease the activity of) cytochrome P4503A4 inhibitors, there is potential for plasma concentrations of buprenorphine to be decreased or increased accordingly.

See Appendix 4: Drug interactions associated with opioids for more information on drug interactions.

11 Pharmacist Dispensing

Pharmacists fulfil an important function in supporting the community-based management of clients/tangata whai ora on OST, with the community pharmacist working alongside the specialist services and GP to ensure the best care is given.

11.1 Shared responsibilities of pharmacists and prescribers

OST prescribers and their teams should:

- acknowledge the pharmacist as an integral part of a multidisciplinary team caring for OST clients/tangata whai ora
- consult the pharmacist, wherever possible, before making significant changes to a client's/tangata whai ora's treatment plan that affect dispensing.
- adhere to the guidelines on prescribing set out in Appendix 2: Misuse of Drugs Act 1975 s24 of these practice guidelines
- acknowledge that pharmacists are constrained by legislative requirements and prescribers must supply written prescriptions and authorisations within the required time (that is, pharmacists must receive all prescriptions at least one day before the starting date of the prescription and the originals of all telephoned or faxed prescription changes within two working days)
- provide training and support to community pharmacies who are dispensing opioid substitution medications and communicate with them regularly
- provide the pharmacist, including any pharmacies temporarily dispensing for the client/tangata whai ora, with a current named photograph of each client/tangata whai ora.
- notify the pharmacist if a client/tangata whai ora has transferred to a new pharmacy
- be accessible to the pharmacist (including providing an after-hours contact to attend to any issues arising, for example, scripting errors).

The pharmacist must dispense methadone and other opioid substitution medicines in accordance with the prescription and relevant legislation and, together with the pharmacy staff, maintain confidentiality of the client's/tangata whai ora's personal information and treatment.

In addition, the pharmacist should:

- provide 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 and other opioid substitution medicines on the pharmacy premises, preferably in a discrete venue
- liaise with the OST provider on a regular basis and maintain a communication network with the specialist service key workers or nurses, prescribing doctors or GPs and other pharmacists where appropriate
- listen to, and where appropriate respond to, any relevant health or other problems that the client/tangata whai ora may have and support them to raise any concerns with their key worker or the prescribing GP
- if requested and able to, facilitate the delivery of the first dose to the specialist service or prescribing GP, so that the client/tangata whai ora can be observed taking the opioid substitution medicine by the prescriber.

11.2 Methadone formulation

Pharmacists will use an appropriate commercial methadone formulation. If a particular client/tangata whai ora cannot tolerate the commercial formulations, the pharmacist will contact the prescriber to discuss preparing their own formulation for the client/tangata whai ora.

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).

It should not be necessary to dilute methadone taken at the pharmacy unless the client/tangata whai ora requests it or the prescriber requests it to prevent diversion. Dilution of takeaways with water may only occur if the methadone prescription specifically requires dilution and instructs the dilution volume or concentration.

If diluting, the pharmacist must ensure that the label accurately reflects the contents of the container and that the New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods; Part 3: Compounding and Dispensing (1993) has been adhered to.

The dilution of methadone takeaways to reduce the likelihood of diversion or misuse may affect the stability of the product.

11.3 Procedures for dispensing and administration

Pharmacists will comply with all legislation regarding controlled drugs, including the requirements for recording, storage and authorisations as detailed below.

There are two ways in which a client/tangata whai ora can receive their medicine: as an administered dose consumed under observation or as a dispensed dose taken away to be consumed at a later time. A takeaway dose is any dose that is not consumed under observation.

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
- positively identifying the client/tangata whai ora (checking a recent photograph provided by the specialist service or prescriber and/or checking photo identification provided by the client/tangata whai ora are alternatives if the pharmacist is uncertain about a client's/tangata whai ora's identity)
- following correct labelling, record keeping and filing procedures
- observing the consumption of doses onsite.

Where administration or dispensing instructions are unclear on the prescription, the pharmacist must contact the prescriber or key worker for clarification.

Methadone preparations must be measured accurately as a small discrepancy in volume can translate to a relatively large discrepancy in dose. For this reason, conical flasks and/or measuring cylinders should not be used. Acceptable methods for measuring methadone are:

- using a self-zeroing dose-measuring pump/burette (especially useful when there are more than 10 dispensings per day) (Note: If using a self-zeroing dose-measuring pump (for example, Dispensette®), care should be taken to calibrate the apparatus regularly as errors and discrepancies in controlled drug balances have occurred due to these devices losing accuracy)

- using a syringe (may be in conjunction with an adaptor cap, which fits directly onto the methadone stock bottle).

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 use 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. Pre-prepared takeaway doses must be stored in a controlled drug safe after hours.

11.4 Administering consumed doses

The client/tangata whai ora receiving OST must consume the full-prescribed dose dispensed under observation at the time of each administration. The procedure should include the pharmacist:

- checking the client/tangata whai ora for symptoms of intoxication or withdrawal from opioids or other illicit substances (see 7.10 Clients/tangata whai ora who present intoxicated) before providing the dose
- accurately measuring the prescribed dose
- giving the dose to the client/tangata whai ora in a disposable cup (disposable cups must not be recycled and must be disposed of safely)
- observing the client/tangata whai ora swallowing the dose and confirming this by having them speak and/or drink additional fluid
- if diversion is strongly suspected or observed to occur, notifying the prescriber and/or the specialist service.

11.5 Administering buprenorphine

Buprenorphine (with or without naloxone) is a sublingual tablet designed to be placed under the client's/tangata whai ora's tongue until the dose is absorbed. It has poor bioavailability if swallowed.

The sublingual absorption of buprenorphine is highly dependent on the length of time the drug is in contact with the oral mucosa, and it is important to ensure that the clients/tangata whai ora understand this. Giving clients/tangata whai ora whole tablets ensures the most gradual absorption, but whole tablets can be diverted more easily than tablets that have been broken into smaller pieces.

The tablet can take 2–7 minutes (depending on the size of the dose) to dissolve so requires a longer period of supervision of consumption than does methadone. The tablet will dissolve and be absorbed more quickly if the tablets are crumbled into smaller pieces (but not crushed into a powder as some of the dose may be lost in the client's/tangata whai ora's saliva). This process can be used if clients/tangata whai ora are suspected of not taking the full dose at the pharmacy but saving some or the entire dose for later misuse or diversion.

The manufacturer cannot guarantee the bioavailability of buprenorphine once crumbled, although this is common practice internationally. While the associated risks are generally outweighed by the benefits of reducing diversion, the Royal Pharmaceutical Society of Great Britain (RPSGB) has issued a statement that pharmacists in the United Kingdom should be aware of a possible compromise to bioavailability, and the decision to crumble the tablets should be made once all the risks and benefits have been considered. Crumbling the tablets is not a replacement for pharmacists being vigilant when administering buprenorphine.

The pharmacist should look inside the client's/tangata whai ora's mouth before the client/tangata whai ora leaves the pharmacy to ensure that the tablet has completely dissolved.

11.6 Takeaway doses

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 and reach of children (preferably locked away). It is recommended that takeaways be stored in a sealable plastic bag in case of leakage.

In exceptional circumstances, such as when the client/tangata whai ora is so infirm that they are incapable of accessing a dose that is protected in a CRC-proofed bottle, the prescriber may endorse the prescription or the pharmacist may annotate the prescription not to be dispensed in a container with a CRC.

Where a dose is being collected via an agent, there should be written notification, from the prescriber or specialist service key worker, of their approval for that agent to collect the dose(s). The pharmacist should check the agent's identification before providing the prescription.

It is unsafe to reuse takeaway bottles, even after washing, and this must not occur.

It may be practical to prepare in advance the methadone doses for multiple clients/tangata whai ora, but this practice has been associated with many of the reported dosing errors. An audit trail must be maintained up to and including the handing over of takeaway doses or the client's/tangata whai ora's consumption of the dose on the premises.

11.7 Delivery of methadone or other opioid substitute medicine

In some cases, pharmacies may be asked to deliver methadone or other opioid substitution medicine to the client/tangata whai ora for their consumption. This would apply most often in situations where the client/tangata whai ora is in police custody or in prison. Pharmacies should have a delivery plan that maximises the safety of the pharmacy staff and ensures that the correct person receives the prescribed dose and that consumption is observed if they are personally required to dispense to the client/tangata whai ora.

11.8 Telephoned methadone prescriptions and authorisation of takeaway doses

Pharmacists should confirm that any authorisation given over the telephone has actually originated from the prescriber by calling back immediately after the original authorisation has been received. A written confirmation by fax should follow any telephoned request for changes and may assist in the speedy actioning of any authorisation.

Changes to scripts, that is, altering doses or approving extra/alternative dispensing at different pharmacies with an overlapping script, must be made by the prescriber only. Changes to takeaway doses, that is, frequency of takeaways (usually one-off), can be requested by a key worker, but this request needs to be internally signed off as per local protocols.

The original of a new prescription must be received by the pharmacy within two business days. Any variation should be documented in the specialist service or client/tangata whai ora case notes.

11.9 Cancellation of administered or dispensed doses

GPs, specialist service clinical staff or the community pharmacist may cancel doses of methadone or other opioid substitute medicine or takeaway arrangements for clients/tangata whai ora in order to:

- prevent a client/tangata whai ora from receiving a double dose of medication
- prevent an intoxicated client/tangata whai ora from receiving additional medication
- prevent situations that may endanger a client's/tangata whai ora's health and life
- ensure that an accurate medication serum level is obtained
- re-establish contact with a client/tangata whai ora where all other attempts have failed.

Decisions to cancel a dose should also consider the safety of people who may next come in contact with the client/tangata whai ora, whether at the pharmacy, specialist service or GP practice.

Any of the people listed above who initiate a dose cancellation must notify the client/tangata whai ora directly of any cancellation. If it is not possible to make direct contact with the client/tangata whai ora, a letter must be sent to them, via the pharmacy, outlining the reasons for this intervention.

When a pharmacist cancels a dose, they must notify the appropriate prescriber or specialist service by phone on the day on which the dose was cancelled and follow this up by providing written (email, letter or fax) verification of the intervention and the reason for that intervention within two business days. Wherever possible pharmacists should consult with the prescriber or key worker before withholding a dose.

11.10 Risk management

The pharmacist should have current standard operating procedures in place describing:

- the procedures they take to minimise the risk of dispensing errors
- the specific actions to be taken in the event of a dispensing error
- the records that are made of action taken in the event of dispensing errors.

The pharmacist should notify the prescriber or specialist service by phone or in writing when the client/tangata whai ora:

- regularly misses their dose
- presents as intoxicated at the point of dispensing
- exhibits abusive or threatening behaviour
- diverts or makes a serious attempt to divert their methadone or other opioid substitute medicine
- exhibits withdrawal symptoms
- deteriorates in their physical, emotional or mental state.

Note: All reports to the prescriber or specialist service must be handled with sensitivity in order to preserve the safety of the pharmacist.

11.11 Missed doses

The pharmacist should contact the specialist service or GP prescriber if the client/tangata whai ora misses two or more consecutive doses (see 7.2 Reintroducing methadone after missed doses).

The pharmacist should not dispense to a client/tangata whai ora who has not collected their medication for three consecutive days without the authorisation of the specialist service or GP since the prescriber will need to:

- review the client's/tangata whai ora's situation before dispensing resumes
- notify the pharmacist in writing if authorisation to resume dispensing is given.

Missed doses of buprenorphine (with or without naloxone) should not be replaced. A single missed dose of buprenorphine is unlikely to cause adverse effects because of the drug's slow disassociation from and high affinity for the opioid receptor.

11.12 Incorrect dosing

11.12.1 Reduced doses

Where a pharmacist has administered less than the prescribed dose, the balance must be given on the same day or not at all. The dispensing pharmacist must notify the client/tangata whai ora immediately and ask them to return to the pharmacy that day for the remainder of the dose. They must also contact the key worker or prescriber as soon as possible and inform them of the error so that it can be recorded.

11.12.2 Increased doses

A client/tangata whai ora who receives a methadone or other opioid substitute dose in excess of that prescribed may be at risk of overdose. Where a pharmacist has administered a higher than prescribed dose, the following procedures should be followed.

- The pharmacist should immediately advise the client/tangata whai ora of the medication error and the need for them to be medically assessed within 3 to 4 hours. The onus should not be solely on the client/tangata whai ora to seek medical assistance. The pharmacist, the prescriber or the specialist service key worker may need to facilitate.
- The pharmacist must warn the client/tangata whai ora of the risks associated with extra drug use and against driving or operating machinery when a higher dose has been administered.
- The pharmacist should immediately contact the prescriber or specialist service who may decide that the client/tangata whai ora requires hospitalisation. In such cases, after consultation with the prescriber or specialist service, the pharmacist should either ring an ambulance and keep the client/tangata whai ora at the pharmacy until it arrives or accompany the client/tangata whai ora to the hospital to ensure that admitting staff receive clear information on the circumstances.
- If the client/tangata whai ora has left before the mistake is realised, the pharmacist must advise the prescriber or specialist service as soon as possible. The pharmacist must make a reasonable attempt to contact the client/tangata whai ora to request they attend for a medical appointment as soon as possible. If the pharmacist is unable to contact the client/tangata whai ora, the responsibility to continue to contact them will sit with the prescriber (or delegated person). The prescriber should also be notified in writing of the incident and of any actions taken.

Caution

Inducing vomiting may be dangerous and is contraindicated if the client has any signs of CNS depression. After the first 10 minutes, induced vomiting is an unsatisfactory means of dealing with methadone overdose as it becomes impossible after this length of time to determine if the entire dose has been eliminated.

11.12.3 Incorrect doses of buprenorphine

Although the risks associated with an incorrect dose of buprenorphine (with or without naloxone) are not as severe as those with other opioid medicines, the client/tangata whai ora will need to be monitored by an appropriately trained health professional or hospital emergency department staff for at least 6 hours after the dose if their usual daily dose of buprenorphine (with or without naloxone) is 4 mg or less and they were administered a dose of 16 mg or more or a dose of 64 mg or more (regardless of their routine daily dose).

The client/tangata whai ora should be reviewed by the specialist service or prescriber before their next dose of buprenorphine as the following day they may require a lower dose or no dose.

11.13 Managing difficult behaviour

Pharmacists should have standard procedures in place for managing inappropriate or unlawful behaviour or other disruptive incidents. The procedures should include how to access any support from the prescriber or specialist service.

All incidents of difficult or unlawful behaviour should be reported to the prescriber or specialist service key worker.

12 Application for Approval to Offer Opioid Substitution Treatment

12.1 Introduction

It is an offence for a medical practitioner to prescribe controlled drugs for the treatment of dependence unless the practitioner is authorised to do so under section 24(2) of the Misuse of Drugs Act 1975 (See Appendix 2: Misuse of Drugs Act 1975 s24).

Approval to prescribe, administer or supply controlled drugs for the purposes of treating people who are dependent on controlled drugs will be given only to services or medical practitioners that fulfil the criteria set out by the Ministry. In recommending services or medical practitioners for approval, the Ministry will be guided by the criteria listed in these guidelines (see 12.2.1 The criteria), other approved standards and processes and adherence to the following principles:

- **Each area must have a single authority:** The central provider of alcohol and other drug services in a single area will be the only service authorised to prescribe controlled drugs for the treatment of dependence under section 24(7) (b) of the Misuse of Drugs Act 1975 unless there is good reason to the contrary. This provider will be accountable to the Ministry for those services and for the medical practitioners working under their authority.
- **There must be a direct and ongoing relationship between the practitioner and support services:** In approving a medical practitioner under section 24(7) (a) of the Misuse of Drugs Act 1975, it must be demonstrated that the medical practitioner has a direct and ongoing relationship with the central provider of alcohol and other drug treatment services for that area. Evidence of such a relationship would take the form of a letter from the local specialist service stating their support for the approval of that medical practitioner and documented details of the arrangements that have been made between the practitioner and the specialist service to ensure an ongoing supportive relationship is maintained.
- **Services must demonstrate efficiency and effectiveness:** There should be regional/subregional coherence in the provision of alcohol and other drug treatment services, including OST, to ensure that there is no ‘doubling up’ of services.

12.2 Approval of opioid substitution treatment services

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 clients/tangata whai ora assessed as suitable for methadone or other opioid substitution medicine.

The Director of Mental Health has adopted the criteria outlined below (see 12.2.1) to decide whether to approve a service to be specified as an OST service or, when already approved, whether such a service can continue to remain as a specified place for delivering OST.

Each application must be made on the form accompanying these guidelines (see Appendix 6: Application forms for Misuse of Drugs Act 1975 s24) and will be considered on its merits. In general, a service that does not meet the principles listed above or the requirements of these guidelines will not gain approval.

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.

12.2.1 The criteria

To be approved as an OST service, a service must be a legal entity and be an established health service capable of offering continuity of service to the client/tangata whai ora group. There must also be an approved or authorised medical practitioner working in the service.

The service also needs to comply with the Alcohol and Other Drug Treatment Sector Standards.

As well as having at least one registered medical practitioner specifically available at the service, there must be at least one other health professional working for the service who is available during hours of service delivery. Such health professionals include: counsellors with relevant alcohol and other drug qualifications, clinical psychologists, qualified social workers or registered nurses.

All of the above health professionals need to 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.

OST services will be responsible for informing the Director of Mental Health annually of the numbers and designation of all staff (including authorised GPs).

Services will comply with the provisions of the Misuse of Drugs Act 1975 and adhere to these practice guidelines.

12.3 Existing services obligations

If a specialist service cannot fulfil any of the criteria set out above and in the Misuse of Drugs Act, the manager or clinical director of 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.

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 that service's authority to be a provider of an OST service.

Before making a decision about revoking the status of a specialist service, the Director of Mental Health will accept and consider representations made by the manager or clinical director of the service as to why the specified service should retain its status.

12.4 Medical practitioners working under authority

Medical practitioners working under authority are those practitioners who are working with particular clients/tangata whai ora in accordance with the terms and conditions set out in section 24 of the Misuse of Drugs Act (see Appendix 2: Misuse of Drugs Act 1975 s24).

GPs are suitable for managing OST clients/tangata whai ora when they agree to work within the requirements of these guidelines.

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

- the legal implications of the authorisation (that is, that authorisation is only for the named client/tangata whai ora, for a set period and in accordance with such terms and conditions as specified by the authorising medical practitioner)

- the treatment aims of the service
- the service's policies, philosophy and procedures
- appropriate record keeping processes
- current OST issues
- HIV/AIDS and hepatitis B and C treatment and prevention
- detoxification processes
- coexisting mental health disorders.

Conditions under which people can be transferred to the care of an authorised GP should be clearly set out in the specialist service's local protocols. These conditions should reflect best clinical practice and have consideration for the safety of the client/tangata whai ora and the authorised medical practitioner.

The specified practitioner or service that authorises a medical practitioner to prescribe, administer or supply a controlled drug for the purposes of treating opioid dependence is responsible for ensuring that those working under their authority comply with the sector standards and the requirements of these practice guidelines, have regular clinical supervision and access relevant training.

12.5 Application for approving/gazetting medical practitioners

Each application must be made on the form included in Appendix 6 with these guidelines and will be considered on its merits. In general, a medical practitioner who does not meet the criteria outlined above or the general requirements discussed in these guidelines will not gain approval.

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

- the medical practitioner having a current annual practising certificate that has never been revoked
- the medical practitioner not having been the subject of a *New Zealand Gazette* notice under section 23 of the Misuse of Drugs Act, prohibiting them from prescribing controlled drugs
- the medical practitioner not having been the subject of a *New Zealand Gazette* notice under section 48 of the Medicines Act
- the extent of the medical practitioner's experience in treating clients/tangata whai ora who are dependent on controlled drugs. In most cases, this experience will take the form of 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.

In addition, medical practitioners seeking to be specified by notice in the *New Zealand Gazette* will be expected, as part of their continuing medical training, to keep up to date on OST and related issues.

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

There should be recognition of the varying levels of authorised GPs' expertise in prescribing methadone or other opioid substitution medicines. In some situations, the specialist services or approved/gazetted medical practitioner will specify a client's/tangata whai ora's dose, the dispensing frequency or the takeaway regime in order to provide guidance and ensure that safety requirements are met. In other situations, only a written authority will be required from the specified service's authorising medical practitioner or chief executive officer.

The responsibilities of the approved/gazetted medical practitioner or specialist service to the GP working under their authority include ensuring that:

- proper authorisation is given to each GP for named clients/tangata whai ora and that this authority is updated at three-monthly intervals
- where authorisation is sought for longer than a three-month period, this approval is obtained through medical officers of health
- GPs receive other information such as the safety aspects for OST prescribing, suggested frequency of consultations and methods of assessment and monitoring.

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 GPs
- co-ordinate regular meetings with the GPs
- review GP report forms
- review clients/tangata whai ora at six-monthly intervals or at the request of the GPs
- take back into the service any client/tangata whai ora who a GP is no longer able to manage.

12.7 Revocation of authority

Existing approved services or practitioners should confirm that they comply with these practice guidelines to ensure continuation of approval.

If a GP working under authority does not comply with the requirements stated on the authorisation form (see Appendix 6: Application Forms for Misuse of Drugs Act 1975 s24) and specified in section 24 of the Misuse of Drugs Act, then the authority can and will be revoked, with the referring OST service taking the client/tangata whai ora back under their direct care (see Appendix 2: Misuse of Drugs Act 1975 s24).

Appendix 1:

Glossary

Approved medical practitioner/service	Also known as gazetted practitioners/services, these medical practitioners or services have been approved by the Ministry to prescribe, administer or supply controlled drugs for the treatment of a client's/tangata whai ora's dependence, subject to any general or specific conditions.
Authorised medical practitioner	An authorised medical practitioner, typically, is a GP 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.
Cytochrome P450 Enzyme System	The most important enzyme system of phase 1 metabolism. Drug interactions can occur when two drugs compete for the same enzyme at the same time or when one drug causes an enzyme to increase its activity (induction) or decrease its activity (inhibition), altering the blood plasma levels of other drugs that are metabolised by the same enzyme.
Diversion of methadone	Diversion is defined as a failure to consume on site and instead sell, swap or give methadone or another opioid substitute medicine to others. Injecting the methadone or using opioid substitutes against medical advice is more strictly defined as 'misuse' rather than diversion.
Family inclusive practice	Family inclusive practice takes a contextual view of addiction that ensures that significant members of the client's/tangata whai ora's social environment are included in the treatment process. The model supports the view that individuals influence other members in their environment, especially family and whānau, and that family and whānau in turn have an impact on these individuals.
Half-life	Distribution half-life is the time it takes for half of the amount of a particular drug to be distributed into the tissues. Elimination half-life is the time it takes for half the amount of the drug to be removed from the blood stream and occurs after distribution.
Key worker	A key worker is usually the clinician assigned to be responsible for co-ordinating a client's/tangata whai ora's care and treatment and who may provide some or all of the planned interventions.
Peak level	This is the maximum blood concentration that methadone reaches in the blood (approximately 4 hours after taking the dose).
Pharmacokinetics	Pharmacokinetics is the study of how drugs move in the body (for example, the time they take to be absorbed, how long they act, how they are distributed in the body and how they are eliminated from the body).

QT interval and QTc	<p>In cardiology, the QT interval is a measure of the time between the start of the Q wave and the end of the T wave in the heart's electrical cycle. The QT interval depends on the heart rate in that the faster the heart rate, the shorter the QT interval.</p> <p>QTc stands for corrected QT interval. The length of the QT interval varies inversely with heart rate and therefore shortens as heart rate increases. The QTc is an equation that results in a corrected QT interval or an interval adjusted for heart rate.</p>
Recovery	<p>Recovery is about building a satisfying and meaningful life, as defined by the client/tangata whai ora themselves, not simply about ceasing problem substance use. It involves accruing positive benefits as well as reducing harms, and moving away from uncontrolled substance use and the associated problems towards health, wellbeing and participation in society.</p> <p>Recovery is a process, not a single event, and may take time to achieve and effort to maintain. The process of recovery and the time required will vary between individuals. Aspirations and hope, both from the individual substance user, their families and those providing services and support, are vital to recovery. Recovery must be voluntarily sustained in order to be lasting.</p> <p>People do not recover in isolation. Recovery embraces inclusion or a re-entry into society, the improved self-identity that comes with taking on a productive and meaningful role and also the idea of 'giving back' to society and others, such as family members, who may have been adversely affected by an individual's substance use. Recovery-oriented services need to support the aspirations of each individual to help them to build recovery across all the above domains.</p>
Specialist service(s)	<p>Specialist opioid substitution programmes (specialist services) are those that have been specified by the Minister of Health and notified in the <i>New Zealand Gazette</i> (published by the Department of Internal Affairs).</p>
Stabilisation	<p>Stabilisation is a multifaceted condition and, at a minimum, means that a client/tangata whai ora can cope on a consistent regular dose of methadone or other opioid substitution medicine without the need for constant dose changes and reviews and is able to work consistently towards agreed goals.</p>
Takeaways	<p>Takeaway doses refer to any individually packed, daily dose of methadone or other opioid substitute medicine that is not consumed under observation.</p>
Trough level	<p>The trough level is the lowest concentration that methadone drops to in the blood over 24 hours (just prior to consuming the next dose).</p>

Appendix 2:

Misuse of Drugs Act 1975 s24

Treatment of persons dependent on controlled drugs

- (1) Every medical practitioner commits an offence who prescribes, administers, or supplies a controlled drug for or to a person who the practitioner has reason to believe is dependent on that or any other controlled drug,-
 - (a) in the course or for the purpose of treatment of the person for dependency; and
 - (b) otherwise than in accordance with subsection (2).
- (1A) Every midwife or designated prescriber commits an offence against this Act who prescribes, administers, or supplies a controlled drug for or to a person, who the midwife or prescriber has reason to believe is dependent on that or any other controlled drug, in the course of, or for the purpose of, of treatment of the person for dependency.
- (2) In the course or for the purpose of the treatment for dependency of a person who the practitioner has reason to believe is dependent on that or any other controlled drug, a medical practitioner may prescribe, administer, or provide a controlled drug for or to the person if the medical practitioner –
 - (a) is for the time being specified under subsection (7) (a); or
 - (b) is-
 - (i) working in an institution, clinic, or place for the time being specified under subsection (7)(b); and
 - (ii) for the time being authorised in writing to prescribe controlled drugs by a medical practitioner working in that institution, clinic, or place who is for the time being specified under subsection (7)(a); and
 - (c) is-
 - (i) acting in the medical practitioner’s capacity as a medical officer employed by a hospital care operator within the meaning of section 58 (4) of the Health and Disability Services (Safety) Act 2001 for the time being specified under subsection (7)(b); and
 - (ii) for the time being authorised in writing by the person in charge of the institution, acting under the general or specific directions of a Medical Officer of Health, to prescribe controlled drugs; or
 - (d) is acting-
 - (i) with the permission in writing, given in relation to that particular person, of a medical practitioner for the time being authorised by paragraph (a) or paragraph (b) or paragraph (c) to do so; and
 - (ii) during this period, and in accordance with the terms and conditions (if any), specified or imposed in the permission, or in any written modification of the permission, given by that medical practitioner.
- (3) Except with the concurrence of the Medical Officer of Health, no permission under subsection (2)(d) may specify a period longer than 3 months.

- (4) A permission under subsection (2)(d) may from time to time be renewed by the person who gave it, or any other medical practitioner authorised by that paragraph to give such a permission.
- (5) Except with the concurrence of the Medical Officer of Health, no renewal under subsection (4) of a permission under subsection (2)(d) may be for a period longer than 3 months.
- (6) An authority or permission given or renewed under subsection (2) or subsection (4)-
 - (a) may at any time be withdrawn by the person who gave or renewed it, by written notice to the person to whom it was given; and
 - (b) is deemed to have been withdrawn when, as the case may be,-
 - (i) the notice under subsection (7)(a) specifying the medical practitioner by whom the authority or permission was given is revoked; or
 - (ii) the notice under subsection (7)(b) specifying the institution, clinic, or place, in respect of which the authority or permission concerned was given or renewed is revoked; or
 - (iii) the medical practitioner by whom the authority or permission was given dies, or ceases to work in the premises, clinic, or place to which the authority relates.
- (7) The Minister may from time to time, by notice in the Gazette,-
 - (a) specify any medical practitioner (by name) 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) as a place at which controlled drugs may be prescribed, administered, or supplied for the purpose of this section-
 - (i) any hospital care institution within the meaning of section 58(4) of the Health and Disability Services (Safety) Act 2001; or
 - (ii) any clinic, or other place in which a medical practitioner for the time being specified under paragraph (a) works.
- (8) The Minister may from time to time, by notice in the Gazette, revoke or amend a notice under subsection (7).
- (9) This section does not apply to-
 - (a) the treatment of a patient, within the meaning of the Alcoholism and Drug Addiction Act 1966, while the patient is in an institution, within the meaning of the Act:
 - (b) the emergency treatment of a patient in a hospital care institution with the meaning of section 58(4) of the Health and Disability Services (Safety) Act 2001, for a period not exceeding 3 days:
 - (c) the treatment of any restricted person within the meaning of Section 25.
- (10) 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: Pharmacology and Pharmacokinetics of Methadone and Buprenorphine

Opioid pharmacology

Opioid receptors are found throughout the brain and spinal cord, in the gastrointestinal system, in parts of the autonomic nervous system and on white cells. Thus opioid drugs have diverse actions on many organ systems, but the most prominent effects are exerted on the central nervous system and the gastrointestinal tract.

Clinically the three most important subtypes of opioid receptor are: mu (μ), kappa (κ) and delta (δ). Mu and delta receptors are involved in systems that influence mood, reinforcing behaviours, respiration, pain, blood pressure and endocrine and gastrointestinal function. Kappa receptors, when activated, can produce endocrine changes and analgesia but appear to produce dysphoria rather than euphoria.

The principal effects of opioids are analgesia, sedation, respiratory depression and euphoria. Opioids have varying potency, bioavailability, speed of onset and duration of effect. They can be classified in three groups: pure agonists, partial agonists and antagonists.

Pure (or full) agonists have affinity for and bind to receptors to induce changes in the cells that stimulate physiological activity. Potency of an agonist reflects the dose-response relationship and is influenced by pharmacokinetic factors (that is, how much of the drug gets into the systemic circulation and then reaches the receptors) by the affinity of the drug for the receptor and by the level of intrinsic activity of the drug at the receptor level. Pure agonists include morphine, methadone, pethidine, heroin and oxycodone.

Partial agonists bind to a receptor but do not produce maximum stimulation. Because they occupy the receptor, they can prevent a concurrently administered agonist with weaker receptor affinity from producing its full agonist effect, resulting in withdrawal symptoms. This is most likely to occur when the partial agonist is administered to a client/tangata whai ora who is receiving high doses of a pure agonist. There is an upper limit to the effect of partial agonists (ceiling effect), even with increasing doses. Buprenorphine is a partial agonist.

Antagonists have no intrinsic pharmacological action but can block the action of an agonist. Naloxone and naltrexone are opioid receptor antagonists that can reverse the effects of agonists such as morphine and methadone. Opioid antagonists with a high affinity for opioid receptors can dislodge opioid agonists from the receptor, precipitating withdrawal. They are often used therapeutically to reverse the effects of opioid overdose.

Methadone

Methadone is a synthetic opioid agonist that is rapidly absorbed from the gastrointestinal tract with measurable concentrations in plasma within 30 minutes of oral administration. Peak plasma concentrations after an oral dose are generally between 2 and 4 hours. Methadone is widely distributed throughout the body, with a volume of distribution of approximately 3–5 L/kg. It has a highly variable elimination half-life (14–58 hours). The effects of methadone are qualitatively similar to morphine and other pure agonist opioids.

Buprenorphine

Buprenorphine is a semi-synthetic opioid derived from the morphine alkaloid, thebaine. It acts as a partial agonist (lesser known as an agonist-antagonist), exerting partial agonist effects at the mu receptor and antagonist effects at the kappa receptor (Reckitt Benckiser 2005).

Buprenorphine has low intrinsic activity but a high affinity for the mu opioid receptor, meaning that it binds tightly but does not ‘turn on’ the receptor fully. Buprenorphine also has high affinity for the kappa opioid receptor but no intrinsic activity.

The high receptor affinity of buprenorphine means that it dissociates slowly from the mu receptor. This results in a long duration of action (Raisch et al 2002), resulting in minimal blood level fluctuations, and prevents opioid withdrawal symptoms when taken regularly.

Opioid pharmacokinetics

Methadone

Methadone is fat soluble and binds to a range of body tissues, including the lungs, kidneys, liver and spleen. The concentration of methadone in these organs is much higher than in blood. There is then a fairly slow transfer of methadone between these stores and the blood. Because of its good oral bioavailability (90%) and long elimination half-life, methadone is taken in an oral daily dose.

Methadone is primarily broken down in the liver via the cytochrome P450 enzyme system. About 10% of methadone administered orally is eliminated unchanged. The rest is metabolised, and the (mainly inactive) metabolites are eliminated in the urine and faeces. Methadone is also secreted in sweat and saliva.

There is wide variability in the pharmacokinetics of methadone but, in general, blood levels rise for about 2–4 hours after an oral dose and then begin to fall. Onset of effects occurs about 30 minutes after ingestion. The apparent half-life of the first dose is 12–18 hours, with a mean of 15 hours. With ongoing dosing, the half-life of methadone is extended to 13–47 hours, with a mean of 24 hours. This prolonged half-life contributes to the fact that methadone blood levels continue to rise during the first week of daily dosing and fall relatively slowly between doses.

With daily dosing, methadone levels in the body reach a steady state (where drug elimination equals drug administration) after about 5–10 days. Thereafter, variations in blood concentration levels are relatively small, and good suppression of withdrawal is achieved. However, some people may experience withdrawal symptoms before their next dose is due.

Buprenorphine

Buprenorphine has poor oral bioavailability because it undergoes an extensive high first-pass metabolism in the small intestine and the liver. It has moderate (30–40%) sublingual bioavailability, with the tablets taking between 2 and 7 minutes to dissolve. The speed of dissolution may be enhanced by breaking the tablets into a few pieces (this may also help reduce diversion of the dose). Crushing the tablets into powder should be avoided as it tends to encourage swallowing.

Because buprenorphine is a partial agonist, its physiological and intoxicating effects usually plateau at a sublingual dose of 4–8 mg (some clients/tangata whai ora report greater intoxication with higher doses). For this reason, people who are used to high doses of street opioids or methadone may find buprenorphine an unsatisfactory alternative.

For most clients/tangata whai ora, the maximal therapeutic effects of buprenorphine occur in the 12–24 mg dose range.

Buprenorphine has a higher affinity for opioid receptors than morphine or methadone and can displace these drugs from the opioid receptor, potentially precipitating opioid withdrawal in a person who has recently used methadone or morphine.

Buprenorphine is highly bound to plasma proteins. It is metabolised by the liver via the cytochrome P450 enzyme system into norbuprenorphine and other metabolites, which are excreted in the faeces (70%) and urine (30%). The half-life of buprenorphine is highly variable: 20–72 hours, with a mean of 36 hours. With stable dosing, steady state levels are achieved over 7 days. Peak clinical effects occur 1–4 hours after sublingual administration, with continued effects for up to 12 hours at low doses (2 mg) but as long as 72 hours at higher doses (24–32 mg).

Methadone and buprenorphine and coexisting medical problems

Methadone and buprenorphine may alter the pharmacokinetics of drugs prescribed for coexisting medical problems. In those with advanced liver disease, doses of both methadone and buprenorphine may need to be significantly reduced. Progressive liver disease, such as may be seen in hepatitis C, may require gradual reduction of previously tolerated doses. In the case of renal failure, dosage levels should also be monitored closely to ensure safety.

Doses should also be monitored closely in clients/tangata whai ora who have severe respiratory disease to avoid respiratory depression or failure.

Opioid withdrawal

The signs and symptoms of opioid withdrawal include irritability, anxiety, restlessness, apprehension, muscular and abdominal pains, chills, nausea, diarrhoea, yawning, lacrimation, piloerection, sweating, sniffing, sneezing, rhinorrhoea, general weakness and insomnia.

Symptoms of withdrawal from methadone usually begin 36–48 hours after the last dose and reach peak intensity within 5–7 days. Most of the obvious physical signs of withdrawal cannot be observed after 21 days, but a general feeling of reduced wellbeing and periodic strong cravings for opioids may continue for weeks or even months.

The symptoms and signs of withdrawal from buprenorphine are similar to those found in withdrawal from other opioids, but withdrawal from buprenorphine is generally milder than withdrawal from methadone or morphine because of its slow dissociation from the mu receptor. Symptoms start within 3–5 days of the last dose and can last for several weeks.

Opioid withdrawal is rarely life threatening. However, completing withdrawal is difficult for most people. The severity of withdrawal is influenced by the duration of opioid use, general physical health and psychological factors such as the reasons for undertaking withdrawal and fear of withdrawal.

(This section has been adapted from the *Clinical Guidelines for Methadone and Buprenorphine Treatment of Opioid Dependence NSW Opioid Treatment Programmes*, NSW 2007).

Appendix 4: Drug Interactions Associated with Opioids

Medicinal interactions

Two or more drugs taken at the same time may exert their effects independently or may interact. The interaction may be potentiation or antagonism of one drug or another, or occasionally other effects. Nicotine and alcohol can also interact with other drugs.

Factors that may pre-dispose opioids to interact include the following.

- All opioids are central nervous system depressants and so will have at least additive effects with medicines (and other illicit drugs) that also have this property.
- Methadone and buprenorphine are both metabolised by the enzyme CYP3A4.
- The enzyme CYP2D6 is occasionally important in interactions. For example, it is responsible for the metabolism of oxycodone and for the transformation of codeine and tramadol into active metabolite. Methadone is a weak inhibitor of CYP2D6.

Some important drug interactions with methadone and buprenorphine

Interaction type	Drugs	Mechanism	Effect
CNS depressants and opioids (including buprenorphine)	Other opioids Benzodiazepines Many tricyclic antidepressants Many antipsychotics Older antihistamines Alcohol	Increased CNS depression	Additive effect – potentiation of respiratory depression
Drugs that increase methadone or buprenorphine levels	Cimetidine Ciprofloxacin Erythromycin Fluconazole Ketoconazole Nefazodone Fluvoxamine and possible other SSRIs	Increased blood levels of methadone or buprenorphine by inhibition of the enzyme CYP3A4	Dose of methadone or buprenorphine may need to be decreased to prevent toxicity or overdose and increased when the enzyme inhibitor is stopped to prevent withdrawal symptoms
Drugs that decrease methadone or buprenorphine levels	Anticonvulsants (eg, barbiturates, phenytoin, carbamazepine) HIV medicines (eg, efavirenz, nevirapine) Rifampicin (rapid and significant) Spironalactone St John’s Wort Urinary acidifiers (eg, high doses of Vitamin C)	Decreased blood levels of methadone or buprenorphine by induction of enzyme CYP3A4	Dose of methadone or buprenorphine may need to be increased to prevent withdrawal symptoms and decreased when the enzyme inducer is stopped to prevent overdose

Interaction type	Drugs	Mechanism	Effect
Buprenorphine and other opioid agonists	Methadone Morphine Other full agonists	Buprenorphine is a partial agonist and displaces other opioids from receptor sites	Can precipitate withdrawal symptoms – advise waiting until opioid is mostly eliminated (confirmed by presence of withdrawal symptoms) before taking buprenorphine
Opioid agonists or partial agonists with opioid antagonists	Naltrexone (active orally) Naloxone (active intranasally and parenterally)	Naltrexone and naloxone are full antagonists and displace other opioids (including buprenorphine) from receptor sites	Will precipitate withdrawal symptoms if taken when agonist or partial agonists have recently been taken
Methadone plus medicines known to have a risk of affecting QT intervals *	Amiodarone Chlorpromazine Clarithromycin Disopyramide Domperidone Droperidol Erythromycin Haloperidol Pentamidine Pimozide Quinidine Sotalol	Prolongation of QT interval	Generally accepted to have a risk of causing torsades de pointes. Should only be used very cautiously with methadone
Methadone plus medicines suspected of having a risk of affecting QT intervals *	Chloral hydrate Clozapine Lithium Moxifloxacin Ondansetron Quetiapine Risperidone Tamoxifen Venlafaxine	Prolongation of QT interval	Associated with torsades de pointes and/or QT interval prolongation. Use cautiously with methadone
Drugs affecting urine pH	Vitamin C Sodium bicarbonate (eg, urinary alkalinisers Ural™ and Citravescent™)	Affect excretion of methadone – increased excretion in acidic urine. Decreased excretion in alkaline urine.	Increased excretion may cause withdrawal; decreased excretion may cause toxicity.
Methadone and desipramine		Unknown – not seen with other tricyclic antidepressants	Desipramine levels raised by a factor of two with methadone. Potentially fatal due TCA toxicity.

Adapted from a table included in *Drug Misuse and Dependence: UK guidelines on clinical management*, Department of Health (England) and the devolved administrations 2007).

* For a more complete list and any updates on drugs affecting QT interval, see: www.torsades.org/medical-pros/drug-lists/drug-lists.htm

Appendix 5:

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 (under revision)

Code of Health and Disability Service Consumers Rights 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 1977

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 Referral to Obstetric and Related Medical Services, 1997

Family Inclusive Practice in the Addiction Field. A guide for practitioners working with couples, families and whānau

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

Relevant Service Specifications as listed in the Nationwide Services Framework, 2001

Te Kōkiri. The Mental Health and Addiction Action Plan 2006–2015

Te Puāwaiwhero: The Second Māori Mental Health and Addiction National Strategic Framework 2008–2015

Te Tāhuhu: Improving Mental Health 2005–2015: The second New Zealand Mental Health and Addiction Plan

Professional codes of ethics and standards of practice

Applicable to:

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

Current sector standards and audits

Ministry of Health. 2007. *Service Audit Tool and Review Tool: Opioid Substitution Treatment in New Zealand*. Wellington: Ministry of Health.

Standards New Zealand 2008. NZS 8134:2008 Health and Disability Services Standards. Wellington: Standards New Zealand.

Appendix 6: Application Forms for Misuse of Drugs Act 1975 s24

Front

Application as an approved practitioner (s24(7)(a) Misuse of Drugs Act 1975)

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.

Name of organisation:

Address:

Email:

Telephone:

Fax:

Current employment situation

1. Name of employer/practice:
2. Number of years employed with that employer/in this practice:
3. Status of employment (eg, permanent, consultant):

References

1. Please attach curriculum vitae with copy of current practising certificate.
2. Please briefly describe the extent of your work experience and training in opioid substitution treatment.
3. Please provide the names, addresses and telephone numbers of three referees for the Director of Mental Health to contact.
4. 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.

Staff

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

Please provide position descriptions and/or CVs of doctors and senior staff of the service and indicate **whether any of the medical staff have been denied approval to prescribe controlled medicines in the past.**

* Is this staff member permanent, a visiting consultant or any other?

I agree

1. to adhere to *Practice Guidelines for Opioid Substitution Treatment in New Zealand* (Ministry of Health, 2008)
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 Standards
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. that my/our practice/agency will ensure 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

Application to be specified as a place of treatment for opioid dependence (s24(7)(b) of the Misuse of Drugs Act 1975

Name of organisation:

Street address of service to be specified:

Postal address:

Email:

Telephone:

Fax:

Name of person filing an application:

Position:

Legal status of organisation:

Staff

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):

Name	Position	Experience working in the AOD (years)	Alcohol and other drug qualifications	Prescribing methadone Yes/No

Please provide position descriptions and/or CVs of doctors and senior staff of the service and indicate **whether any of the medical staff have been denied approval to prescribe controlled medicines in the past.**

* Is this staff member permanent, a visiting consultant or any other?

Note: The Director of Mental Health requires updates of staff composition six-monthly from date of approval.

Back

I agree that:

1. our service will comply with the Practice Guidelines for Opioid Substitution Treatment in New Zealand (MoH 2008)
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

1. Each service user will receive a written treatment plan that has been agreed between themselves and our service.
2. Each service user will have an assigned case worker.
3. 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.
4. Our staff will be trained in HIV and hepatitis issues.
5. Our organisation will have due regard for cultural and/or gender preference.
6. Our staff will undertake relevant training to meet the minimum training levels expected in the practice guidelines.
7. Our clinical staff (including doctors) will undertake clinical supervision on a regular basis from suitably experienced and qualified people.
8. Our service has a protocol for the management of pregnant opiate-using women.

Ministry of Health requirements

1. We are willing to have our service independently reviewed, as required, by the Director of Mental Health.
2. 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.

References and Bibliography

- 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, Perucci C, et al. 2005. An overview of systematic reviews of the effectiveness of opiate maintenance therapies: available evidence to inform clinical practice and research. *Journal of Substance Abuse Treatment*; 28: 321–9.
- Ball J, Ross A. 1991. *The Effectiveness of Methadone Maintenance Treatment*. New York: Springer.
- Bray K, Harwood T, Inder R, et al. 2007. Poppy seed tea and opiate abuse in New Zealand. *Drug and Alcohol Review* 26: 215–19.
- Cape G. 2001. Appropriateness versus practicality of MMT. *New Zealand Journal of Bioethics* 2: 23–5.
- Darke S, Ross J, Teesson M. 2007. The Australian Treatment Outcome Study (ATOS): what have we learnt about treatment for heroin dependence? *Drug and Alcohol Review* 26: 49–54.
- Dawe S, Harnett P. 2007. Reducing potential for child abuse among methadone-maintained parents: results from a randomized controlled trial. *Journal of Substance Abuse Treatment* 32: 381–90.
- Deering DE. 2007a. Methadone Maintenance Treatment in New Zealand. Unpublished Doctor of Philosophy Thesis, University of Otago, Christchurch School of Medicine and Health Sciences.
- Deering DE. 2007b. Health related findings from a follow-up study of clients receiving methadone maintenance treatment: treatment implications and areas for further research. *Addiction Treatment Research News*. 11 (3):9-10.
- Deering DE, Frampton CMA, Horn J, et al. 2004. Health status of clients receiving methadone maintenance treatment using the SF-36 health survey questionnaire. *Drug and Alcohol Review* 23 (3): 273–80.
- DeMaria PA, Sterling R, Weinstein SP. 2000. The effect of stimulant and sedative use on treatment outcome of patients admitted to methadone maintenance treatment. *American Journal of Addiction*, 9(2): 145–53.
- Department of Corrections. 2006. *Methadone Policy and Procedures*. Wellington: Department of Corrections.
- Department of Health. 1993. *New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods; Part 3: Compounding and Dispensing*. Department of Health, Wellington.
- Department of Health (England) and the devolved administrations. 2007. *Drug Misuse and Dependence: UK guidelines on clinical management*. London: Department of Health (England), the Scottish Government, Welsh Assembly Government and Northern Ireland Executive.
- Dore GM, Walker JD, Paice JR, Clarkson S. 1999. Methadone maintenance treatment: outcomes from the Otago Methadone Programme. *New Zealand Medical Journal* 112: 442–5.
- Drake RE, Mercer-McFadden C, Mueser KT, et al. 1998. Review of integrated mental health and substance abuse treatment for patients with dual disorders. *Schizophrenia Bulletin* 14(4): 589–608.
- Eap CB, Buclin T, Baumann P. 2002. Interindividual variability of the clinical pharmacokinetics of methadone. Implication for the treatment of opioid dependence. *Clinical Pharmacology* 41(14): 1153–93.

Fraser S, Valentine K, Treloar C, et al. 2007. *Methadone Maintenance Treatment in New South Wales and Victoria: Takeaways, diversion and other key issues*. National Centre in HIV Social Research University of NSW.

Giacomuzzi SM, Ertl M, Vigl A, et al. 2005. Driving capacity of patients treated with methadone and slow-release oral morphine. *Addiction* 100 (7): 1027.

Gossop M, Marsden J, Stewart D, et al. 2004. National Treatment Outcome Research Study (NTORS): 4–5 year follow-up results. *Addiction* 98: 291–303.

Gossop M, Stewart D, Marsden J. 2006. Effectiveness of drug and alcohol counselling during methadone treatment: content, frequency, and duration of counselling and association with substance use outcomes. *Addiction*, 101: 404–12.

Griffiths JD, Rowan-Szal GA, Roark RR, et al. 2000. *Contingency management in outpatient methadone treatment: a meta-analysis*. *Drug and Alcohol Dependence* 58: 55–66.

Humeniuk R, Ali R, White J, et al (Summarisers). 1999. *Proceedings of Expert Workshop on the Induction and Stabilisation of Patients onto Methadone. Findings of an expert workshop. 28 and 29 January 1999, Adelaide, South Australia*. Canberra: Publications Production Unit, Commonwealth Department of Health and Aged Care.

Jamison RN, Kauffman J, Katz ND. 2000. Characteristics of methadone maintenance patients with chronic pain. *Journal of Pain Symptom Management* 19: 53–62.

Justo D, Gal-Oz A, Paran Y, Goldin Y, Zeltser D. 2006. Methadone-associated torsades de pointes (polymorphic ventricular tachycardia) in opioid-dependent patients. *Addiction* 101: 1333–8.

Kakka J, Gronbladh L, Svanborg K, et al. 2007. A stepped care strategy using buprenorphine and methadone versus conventional methadone maintenance in heroin dependence: a randomized controlled trial. *American Journal of Psychiatry* 164: 5, 797–803.

Kina Families and Addictions Trust. 2006. *Family Inclusive Practice in the Addiction Field. A guide for practitioners working with couples, families and whānau*. Kina Families and Addictions Trust, Wellington, New Zealand.

Kranz MJ, Kutinsky IB, Robertson AD, Mehler PS. 2003. Dose-related effects of methadone on QT prolongation in a series of patients with torsade de pointes. *Pharmacotherapy*, 23(6): 802–5.

Land Transport Safety Authority (LTSA). 2002. *Medical Aspects of Fitness to Drive. A guide for medical practitioners*. Wellington: LTSA.

Lawrinson P, Roche A, Terao H, et al. 2008. Dispensing opioid substitution treatment: practices, attitudes and intentions of community-based pharmacists. *Drug and Alcohol Review* 27(1): 47–53.

Lenne M, Lintzeris N, Breen C, et al. 2001. Withdrawal from methadone maintenance treatment: prognosis and participant perspectives. *Australia New Zealand Journal of Public Health* 25(2): 121–5.

Lintzeris N, Clark N, Winstock A, et al. 2006. *National Clinical Guidelines and Procedures for the Use of Buprenorphine in the Treatment of Opioid Dependence*. Canberra: Commonwealth of Australia.

Lintzeris N, Mitchell TB, Bond A, et al. 2007. Pharmacodynamics of diazepam co-administered with methadone or buprenorphine under high dose conditions in opioid dependent patients. *Drug and Alcohol Dependence* 91(2–3): 187–94.

Lintzeris N, Pritchard E, Sciacchitano L. 2007. *Investigation of Methadone Dosing in Victoria: Factors influencing dosing levels*. Fitzroy, Victoria: Turning Point Alcohol and Drug Centre.

Magura s, Nwakeze PC, Kang SY et al. (1999). Programme quality effects on patient outcomes during methadone maintenance: a study of 17 clinics. *Substance Use and Misuse*, 93:1857–68.

- Magura S, Rosenblum A. 2001. Leaving methadone treatment: lessons learned, lessons forgotten, lessons ignored. *Mt Sinai Journal of Medicine* 68: 62–74.
- Mallick J, Johnston J, Goren N, et al. 2007. *Drugs and Driving in Australia: A survey of community attitudes, experience and understanding*. Melbourne: Australian Drug Foundation.
- McLellan A, Arnt D, Metzger D, et al. 1993. The effects of psychosocial services in substance abuse treatment. *Journal of the American Medical Association* 269: 1953–9.
- Ministry of Health. 2001. *Standards New Zealand: National Mental Health Sector Standard*. NZS8143. Wellington: Ministry of Health.
- Ministry of Health. 2002. *Family Violence Intervention Guidelines: Child and partner abuse*. Wellington: Ministry of Health.
- Ministry of Health. 2003. *Opioid Substitution Treatment: New Zealand Practice Guidelines*. Wellington: Ministry of Health.
- Ministry of Health. 2006. *New Zealand Clinical Guidelines for the Use of Buprenorphine (with or without Naloxone) in the Treatment of Opioid Dependence*. Wellington: Ministry of Health (unpublished).
- Ministry of Health. 2007a. *National Guidelines: Interim methadone prescribing*. Wellington: Ministry of Health.
- Ministry of Health. 2007b. *Service Audit and Review Tool: Opioid Substitution Treatment in New Zealand*. Wellington: Ministry of Health.
- Ministry of Health. 2008. *Te Puāwaiwhero: The Second Māori Mental Health and Addiction National Strategic Framework 2008–2015*. Wellington: Ministry of Health.
- Mueser KT, Noordsy DL, Drake RE, et al. 2003. *Integrated Treatment for Dual Disorders: Effective intervention for severe mental illness and substance abuse*. New York: Guilford Press.
- National Service Framework for Mental Health Services. 2004. *The Operational Policy Framework (2004)*. Available only to DHBs via email: webmanager@moh.govt.nz
- NSWH. 2007. *Clinical Guidelines for Methadone and Buprenorphine Treatment of Opioid Dependence NSW Opioid Treatment Programmes*. Sydney, Australia: New South Wales Health.
- 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*. Standards New Zealand: Wellington New Zealand.
- Neumann T, Spies C. 2003. Use of biomarkers for alcohol use disorders in clinical practice. *Addiction* 98(2): 81–91.
- NICE. 2007. *Naltrexone for the Management of Opioid Dependence: NICE technology appraisal guidance 115*. London: National Institute for Health and Clinical Excellence.
- Peles E, Bodner G, Kreek M, et al. 2006. *Corrected-QT intervals as related to methadone dose and serum level in methadone maintenance treatment (MMT) patients – a cross-sectional study*. *Addiction* 102: 289–300.
- Raisch DW, Fye C, Boardman KD, et al. 2002. Opioid dependence treatment, including buprenorphine/naloxone. *Annals of Pharmacotherapy* 36: 312–21.
- Reckitt Benckiser. 2005. *Suboxone® Data Sheet*. Reckitt Benckiser, Auckland, New Zealand.
- Reece AS. 2008. Experience of road and other trauma by the opiate dependent patient: a survey report. *Substance Abuse Treatment, Prevention, and Policy* 3: 10.

- Ritter A, Natale RD. 2005. The relationship between take-away methadone policies and methadone diversion. *Drug and Alcohol Review* 24: 347–52.
- Robertson JR, Raab GM, Bruce M, et al. 2006. Addressing the efficacy of dihydrocodeine versus methadone as an alternative maintenance treatment for opiate dependence: a randomised control trial. *Addiction* 101: 1752–9.
- Rosenblum A, Herman J, Fong C, et al. 2003. Prevalence and characteristics of chronic pain among chemically dependent patients in methadone maintenance and residential facilities. *JAMA*, 289(18): 2370–8.
- Ross, J, Darke, S. 2000. The nature of benzodiazepine dependence among heroin users in Sydney, Australia. *Addiction* 95, 1785–1793.
- Ross J, Teeson M, Darke S, et al. 2005. The characteristics of heroin users entering treatment: findings from the Australian outcome study (ATOS). *Drug and Alcohol Review* 24: 411–18.
- Rounsaville BJ, Kosten TR. 2000. Treatment for opioid dependence: quality and access. *JAMA* 283(10): 1337–9.
- Royal Australasian College of Physicians (the). 2008. *Improving Management of People with Chronic Non-malignant Pain and Opioid Drug Dependence*. Sydney: The Royal Australasian College of Physicians.
- Standards New Zealand. 2003. *Alcohol and Other Drug Treatment Service Standards*. Wellington: Standards New Zealand.
- Standards New Zealand. 2001. *National Mental Health Standard: He whāriki oranga hinengaro*. Wellington: Standards New Zealand.
- Scottish Advisory Committee on Drug Misuse Integrated Care Project Group. 2008. *Essential Care: A report on the approach required to maximize opportunity for recovery from problems substance use in Scotland*. Scottish Advisory Committee on Drug Misuse, Edinburgh.
- Sellman JD, Kendall NAS, Macleod AD. 1999. The use of opioid medications in patients with chronic non-malignant pain who have drug dependence. *Drug and Alcohol Review* 14: 109–13.
- Sellman JD, Harvey M, Deering DE. 2001. *South Island Methadone Project Report*. National Centre for Treatment Development (Alcohol, Drugs & Addiction).
- Sheridan J, Goodyear-Smith F, Butler R, et al. 2008. Barriers to, and incentives for, the transfer of opioid-dependent people on methadone maintenance treatment from secondary care to primary health care. *Drug and Alcohol Review* 27(2): 178–84.
- Sheridan J, Manning V, Ridge G, et al. 2007. Community pharmacies and the provision of opioid substitution services for drug misusers: changes in activity and attitudes of community pharmacists across England 1995–2005. *Addiction* 102: 1824–30.
- Sheridan J, Wheeler A, Walters C. 2005. Health problems and help-seeking activities of methadone maintenance clients at Auckland Methadone Service (AMS): potential for community pharmacy service expansion. *Harm Reduction Journal* 2: 25.
- Sievwright N. 2000. *Community Treatment of Drug Misuse: More than methadone*. United Kingdom: Cambridge University Press.
- Tang NKY, Crane C. 2006. Suicidality in chronic pain: a review of the prevalence, risk factors and psychological links. *Psychological Medicine* 36: 575–86.
- Teichtahl H, Wang D. 2007. Sleep-disordered breathing with chronic opioid use. *Expert Opinion on Drug Safety* 6(6): 641–9.

The Royal Australasian College of Physicians. 2008. *Improving Management of People with Chronic Non-malignant Pain and Opioid Drug Dependence*. Sydney, Australia: The Royal Australasian College of Physicians.

Todd F, Sellman JD, Robertson P. 1999. *The Assessment and Management of People with Co-existing Substance Use and Mental Health Disorders*. Wellington: Alcohol Advisory Council.

Townshend P. 2003. Conflict between Providers and Consumers in Opioid Substitution Therapy: A preventive ethics approach. Doctor of Philosophy thesis, University of Otago, Dunedin.

UK Drug Policy Commission: Recovery Consensus Group. 2008. *A Vision of Recovery*. United Kingdom Drug Policy Commission, London

Walker JM, Farney RJ, Rhondeau SM, et.al. 2007. Chronic opioid use is a risk factor for the development of central sleep apnoea and ataxic breathing. *Journal of Clinical Sleep Medicine* 3(5): 455–61.

Wang D, Teichtahl H, Drummer O, et al. 2005. Central sleep apnoea in stable methadone maintenance treatment patients. *Chest* 128: 1348–56.

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.

White WL. 2007. Addiction recovery: its definition and conceptual boundaries. *Journal of Substance Abuse Treatment* 33: 229–41.

Woody GE, McLellan AT, Luborsky L, et al. 1995. Psychotherapy in community methadone programs: a validation study. *The American Journal of Psychiatry* 152: 1302–8.

Yancovitz SR, Des Jarlais DC, Peyser NP, Drew E, Friedmann P, et al. 1991. A randomized trial of an interim methadone maintenance clinic. *American Journal of Public Health* 81: 1185–91.

