

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

2014

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MANATŪ HAUORA

Foreword

Tena koutou

In introducing the *New Zealand Practice Guidelines for Opioid Substitution Treatment* I would like to acknowledge the people whose lives are affected by opioid dependency in New Zealand. It is my hope that these guidelines will help ensure you have the best possible support in your recovery journey.

These revised guidelines contain practical and evidence-based advice for clinicians on best practice for the clinical assessment and treatment of clients with opioid dependence. They have been written in alignment with the forthcoming Australian guidelines on opioid substitution treatment (OST).

As previous guidelines have done, these guidelines strongly endorse a path that moves away from a maintenance-treatment model and towards client-led, recovery-focused treatment. They also outline a series of important developments in the provision of OST, including:

- development of clear advice for practitioners about ‘driving while impaired’, with reference to the Land Transport Amendment Act 2009. The guidelines provide a checklist for evaluating a person’s ability to drive safely
- funding of buprenorphine (with naloxone), which has given consumers a welcome choice in their treatment options, while also deterring substance misuse and diversion
- development of the Te Whare o Tiki framework, which guides the mental health and addiction workforce in effectively responding to the needs of people with complex and co-existing problems.

The guidelines highlight the importance of early transition planning, with an emphasis on transitioning stable clients to primary level care.

These guidelines support the direction set out in *Rising to the Challenge: The Mental Health and Addiction Service Development Plan 2012–2017* to enhance interventions for people with opioid dependence. *Rising to the Challenge* places emphasis on maximising access to OST services, extending the role of primary care in OST treatment and supporting people’s wider needs, including their physical, emotional and social wellbeing.

I would like to thank the skilled and dedicated people who work in the area of OST who are continually striving for the best outcomes for the people who seek their services.

I would also like to 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.

Noho ora mai

Dr John Crawshaw
Director of Mental Health
Chief Advisor, Mental Health

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Introduction

Opioid dependence is a complex, relapsing condition requiring a model of treatment and care much like any other chronic health problem. The Ministry of Health's investment in opioid substitution treatment (OST) has ensured that people with opioid dependence have access to a comprehensive treatment package that provides them with the opportunity to recover their health and wellbeing.

Specialist OST services are specified by the Minister of Health under section 24 Misuse of Drugs Act 1975 and notified in the *New Zealand Gazette*. Specialist services are the entry point for all people requiring OST unless there are exceptional circumstances and subject to the approval of the Director of Mental Health.

This document provides clinical and procedural guidance for specialist services and primary care providers who deliver OST. It updates and replaces *Practice Guidelines for Opioid Substitution Treatment in New Zealand* (Ministry of Health 2008b) and *New Zealand Clinical Guidelines for the Use of Buprenorphine (with or without Naloxone) in the Treatment of Opioid Dependence* (Ministry of Health 2010). In addition, it incorporates the documents *Prescribing Controlled Drugs in Addiction Treatment: section 24 Misuse of Drugs Act 1975* (Ministry of Health 2013b) and *National Guidelines: Interim methadone prescribing* (Ministry of Health 2007a).

In line with the Health and Disability Services (Core) Standards (NZS 8134.1:2008), the overriding principle of this document is that provision of OST is *person-centred* and *recovery-orientated*.

At the request of consumer groups, the 2008 *Practice Guidelines for Opioid Substitution Treatment in New Zealand* signalled a move away from the term 'methadone maintenance', due to its implication of a person being 'parked' in maintenance without ongoing psychosocial support. The term 'ongoing treatment' was instead used to describe the treatment process following the induction and stabilisation stages. This approach is continued in these guidelines.

The Ministry of Health advises that this document should be read alongside material provided by the National Opioid Substitution Treatment Providers Training Programme (NAOTP 2013 or any updated version).

Cultural context

To be effective and relevant to Māori, OST services need to recognise and be influenced by cultural and clinical factors and processes that support positive attitudes aimed at improving tangata whaiora health and wellbeing. *Te Puāwaiwhero: The Second Māori Mental Health and Addiction National Strategic Framework 2008–2015* (Ministry of Health 2008c) provides a clear direction for services, helping them to be more responsive to Māori across the mental health and addiction continuum.

The policies and procedures of all addiction treatment services need to reflect the requirements of the various relevant sector standards and satisfy the provisions of the Health and Disability Services (Safety) Act 2001 and the Code of Health and Disability Services Consumer's Rights 1996. They also need to be assessed in terms of the clinical and cultural safety of staff and clients and the effective delivery of services. 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 issues specific to Māori (including the Treaty) also be clearly addressed.

Variations to practice

All services providing OST in New Zealand are expected to provide a standardised approach underpinned by concepts of person-, family- and whānau-centred treatment, recovery, wellbeing and citizenship, in accord with these guidelines. Specialist services should not demonstrate any variation from the administrative and legislative requirements for service provision contained in these practice guidelines. However, in specific or unforeseen circumstances, they may need to vary their practice. In such instances the reasons for the variation must be discussed with the client¹ and their support person(s) and documented in the client's records or in the service delivery model documentation. Where significant variance is proposed, providers should seek collegial support from the National Association of Opioid Treatment Providers.

In addition, services need to communicate the rationale for the following to the Director of Mental Health at the Ministry of Health.

1. Inability to comply with timeframes for admission to OST or for transfers to other specialist services.
2. Inability to assist stabilised clients to transfer to their primary care provider.
3. Inability to provide psychosocial treatment.
4. All involuntary cessations of OST.
5. Prescribing above the maximum dose recommended in section 3 (ie, 120 mg methadone and 32 mg buprenorphine).

Services must report any instances of points 1–4 via their usual six-monthly reporting to the Ministry of Health. The Ministry of Health's Medicines Control team will monitor Point 5.

Specialist services must send a copy of all authorities to prescribe signed by the service's lead clinician (both specialist service medical practitioners under section 24(2)(b) Misuse of Drugs Act 1975 and shared care general practitioners under section 24(2)(d) (refer to Appendices 13 and 14)) via courier or standard post to:

Medicines Control
Provider Regulation
Clinical Leadership, Protection and Regulation
Ministry of Health
PO Box 5013
Lambton Quay
Wellington 6145

¹ 'Client' was chosen for this document as the preferred description for a tangata whaiora/person/consumer/service user receiving OST.

1 Opioid substitution treatment

There are two pharmacological approaches to treatment of opioid dependence – managed withdrawal and substitution treatment. As most people resume opioid use within six months of commencing opioid withdrawal a single detoxification episode should not be promoted as effective treatment.

WHO 2009

In New Zealand, OST attempts to promote a tripartite partnership approach between the client, the specialist service or primary care team, and the client's nominated support people (eg, advisors, representatives, peer-support workers, and family and whānau). This type of partnership approach can contribute to improved outcomes for clients and services.

1.1 Objectives of OST

The guiding principles of the Mental Health and Addiction Service Development Plan for 2012–2017, *Rising to the Challenge* (Ministry of Health 2012b), are to:

- actively challenge stigma and discrimination wherever they are encountered
- value communities as essential resources to support family and whānau wellbeing and the effective delivery of services
- expect recovery, and work in a way that will support it and that will build future resilience
- engender hope by demonstrating a belief in the talents and strengths of service users
- form authentic partnerships with service users at all levels and phases of service delivery
- promote the participation and leadership of service users at all levels of service delivery
- personalise services to the particular needs of the service user and their family and whānau
- strive to uphold the human rights of service users and their families and whānau
- respect diversity and demonstrate cultural competence
- encourage and support positive participation by families and whānau
- when working with Māori, take a whānau ora approach
- work collaboratively, transcending service boundaries between government sectors.

Alongside these overarching principles, the key objectives of OST in New Zealand are to improve the physical and psychological health and wellbeing of people who use opioids through:

- the reduction or cessation of illicit opioid use
- the reduction or cessation of injecting and the associated risk of blood-borne virus transmission
- the reduction of overdose risk
- the reduction of substance-related criminal activity
- support to initiate and promote client, family and whānau recovery journeys and access to recovery support systems and networks.

These objectives are achieved through strategies to reduce the risk of substance-related harm for each client and for the community by minimising withdrawal symptoms, reducing craving and blocking the euphoric effects of other opioids. Opioid Substitution Treatment is essentially pragmatic, focusing on and giving priority to realisable goals. Improvement for clients is likely to be progressive and individualised; for example, while some people will aim to cease all drug use, others will not.

1.2 Roles of specialist OST services

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

- comprehensive assessment for substance use and related issues
- individualised treatment planning within an integrated and recovery- and wellbeing-focused model
- stabilisation on an adequate individualised dose of opioid substitution medication
- provision of specialist interventions to minimise the harms associated with continued opioid and other substance use
- recovery planning and provision of appropriate psychosocial support to assist clients and their families and whānau to build and maintain recovery capital
- facilitating the transfer of stabilised clients to the care of their primary care provider
- screening, advice and treatment, or referral for treatment, for clients with co-existing medical problems
- assessment and treatment or referral for treatment of clients with co-existing mental health problems
- consultation with and referral to health care and social service providers, including peer support and advocacy services
- assisting clients to withdraw from OST medication as appropriate.

1.3 Recovery-orientated OST

Recovery orientated methadone maintenance is an approach to the treatment of opioid dependence that combines methadone pharmacotherapy and a sustained menu of professional and peer-based recovery support services to assist patients and families in initiating and maintaining long-term addiction recovery.

White and Mojer-Torres 2010

In a recovery-orientated system of care:

- a person-centred choice of treatment options is available
- treatment is strengths based
- service-user involvement in planning and delivery (and evaluation) of care is evident
- people with lived experience inform service delivery
- families are involved in the process
- there is a choice of OST medications
- there are strong relationships between prescribing and recovery-orientated services and the broader community (Scottish Government 2013).

Opioid substitution treatment services can practise in accordance with a recovery-oriented approach by:

- assisting people to stay well, building support structures, developing contingency plans and joint crisis plans, and negotiating safety plans and advance directives that respect clients' preferences
- developing partnerships with other agencies designed to meet the diverse range of clients' needs
- training people in self-management and in setting their own agendas when working with professionals
- helping people to define and achieve their goals in ways that are acceptable to them
- practising according to an individual's need rather than using standardised solutions defined by professionals
- promoting empowerment approaches such as the Wellness Recovery Action Plan or strengths-based approaches reviewing services, therapies and treatments using a recovery lens (Victorian Government Department of Health 2011).

Services should aim to provide recovery- and wellbeing-orientated practice, and use this as a measurable outcome in service evaluation.

Useful resources

Deering D, Sheridan J, Sellman JD, et al. 2011. Consumer and treatment provider perspectives on reducing barriers to opioid substitution treatment and improving treatment attractiveness. *Addictive Behaviors* 36: 636–42.

Ministry of Health. 2012. *Rising to the Challenge: The Mental Health and Addiction Service Development Plan 2012–2017*. Wellington: Ministry of Health.

White WL, Mojer-Torres L. 2010. *Recovery-Oriented Methadone Maintenance*. USA: Great Lakes Addiction Technology Transfer Centre, Philadelphia Department of Behavioural Health and Mental Retardation Services, and Northeast Addiction Technology Transfer Centre.

2 Entry into OST

2.1 Comprehensive assessment

There needs to be an initial, as well as an ongoing, process of comprehensive assessment for recovery that helps to underpin the core process of recovery care planning. Assessment for recovery aims to deliver an informed understanding of the person's wishes, substance use, and the severity and complexity of clinical and other problems; and it needs to identify their strengths and any key obstacles to their recovery. The assessment process needs to help individuals consider their current and potential future 'recovery capital'.²

National Treatment Agency for Substance Misuse 2012

A comprehensive assessment for suitability for opioid substitution treatment (OST) should start within two weeks of a person presenting to, or being referred to, an OST service or any part of an addiction service seeking assistance for an opioid problem. An appropriately trained and supervised clinician must carry out the assessment.

The goals of an initial comprehensive assessment are to:

- establish a diagnosis (note: to be suitable for OST a person must meet the diagnostic criteria for opioid dependence, such as those outlined in the *Diagnostic and Statistical Manual of Mental Disorders* (APA 2000, 2013) or the *International Statistical Classification of Diseases and Related Health Problems* (WHO 2010) diagnostic tools)
- establish the client's strengths, treatment-related issues and recovery capital
- facilitate engagement in treatment
- explore treatment options and assist the client to make informed decisions about treatment
- establish short-term goals and priorities
- document an initial individualised and holistic treatment plan that is negotiated or developed in collaboration with the client and their support people.

The initial comprehensive assessment should include details of the client's:

- reasons for and expectations of treatment
- historical and current substance use (including signs of intoxication or withdrawal, and physical evidence of past and current use, such as injection sites and associated bruising)
- past and present risk-taking behaviours (eg, sharing of injecting equipment, excessive and unsafe substance use, associated unsafe sexual practices)
- medical history (including blood-borne viruses, substance-related accidents, head injuries, overdoses, significant illnesses or hospital admissions, contraception, dental problems, cardiac risks and current prescribed, over-the-counter and complementary medicines)
- mental health and psychological history (including previous mental health substance use assessments and treatments and current psychological and mental health problems that may need consultation or referral for further assessment or intervention)

² 'Recovery capital' refers to the level of personal and other resources a person has at the start of a potential recovery process. Those with complex needs will require long-term support to help them to build up their recovery capital.

- risk of suicide or other acts of harm to themselves or others, or from others (including domestic violence and risk of harm to dependent children) (note: a risk management plan may need to be developed in this case)
- relevant legal history and current legal issues
- family and whānau history (including history of substance use, medical problems (including any cardiac problems or sudden deaths) and 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 (eg, employment, parenting or education))
- treatment goals and priorities.

Wherever possible the comprehensive assessment should, with consent, include input from the client's support people³ and from other services/personnel currently engaged in providing assistance to them.

Assessment of risk is an important part of the comprehensive assessment, and should inform the client's treatment plan. Potential risks related to opioid dependence include unsafe injecting practices, overdose, concurrent use of other substances (including alcohol and tobacco), impaired driving and broader risks related to self-harm, or harm to others: especially dependent children.

Nationally accepted comprehensive assessment templates can be found in *Screening, Assessment and Evaluation: Alcohol and Other Drug, Smoking and Gambling* (Matua Raki 2011a).

The assessment should also include:

- details of whether a restriction notice under section 25 Misuse of Drugs Act 1975 or section 49 Medicines Act 1981 applies
- a record of any treatment options discussed with the client and assessed as being inappropriate, or declined investigations, including a urine drug screen (to confirm current substance use) and blood tests (eg, for liver function and/or blood-borne virus) and other relevant physical health checks.

Documentation is a critical component of the comprehensive assessment. It provides a considered platform for discussing/negotiating the treatment plan and treatment goals with the client (and their support people as appropriate) and the multidisciplinary team (MDT).

2.2 The treatment plan

Assessments must be accompanied by an individualised treatment or management plan, to be reviewed and updated at regular intervals. Service providers develop treatment plans in collaboration with clients and, where possible, their significant others. A treatment plan must comply with Health and Disability Services (Core) Standard 3.5. It addresses the person's assessed problems as well as their strengths, treatment priorities, and recovery and wellbeing goals.

³ In this document 'support people' is used as a general descriptor for people who support a client, such as consumer advocates, other health professionals and significant others.

Service providers should explain expectations and processes for transfer to a primary care provider to clients and their significant others⁴ when they are considering OST. They should facilitate engagement with a primary care provider where a client is not already registered with such a provider, so that when the client is stabilised on OST seamless transfer is possible.

Once opioid dependence and eligibility for OST is confirmed, providers should initiate a discussion about alternative treatment options, pharmacological options (methadone or buprenorphine), OST service expectations, policies and procedures, and client rights and responsibilities relating to the initial phase of treatment. They should provide the client and their support people with written information to take away and read, and encourage them to note any areas requiring further clarification (refer to section 2.8: Informed consent and treatment information).

2.3 Other treatment options for opioid dependence

Opioid substitution treatment is the appropriate treatment for most people dependent on opioids; however, there are a range of other options available that service providers should outline to clients and their support people. These include managed withdrawal (refer to Appendix 8: Managed withdrawal), outpatient programmes, residential treatment programmes and therapeutic communities, and self-help groups. Discussion of alternative treatment options should include information on their effectiveness.

Naltrexone may be a useful relapse prevention tool for people who have ceased opioid use, as it blocks the effect of opioid drugs. It is approved for this use in New Zealand, but is currently only funded for the treatment of alcohol dependence.

2.4 Decisions not to admit to the OST programme

Services should be cautious when excluding clients seeking OST, because such clients often have poor clinical outcomes if they do not receive treatment.

(WHO 2009)

Where a service provider assesses a client as being unsuitable for OST, it must inform them of the reasons in person and in the presence of support people wherever possible. The provider must record the decision in writing, and offer appropriate alternative options. An MDT should review and document the decision not to admit a person to OST, in consultation with the referring agent and the client's primary care provider.

Use of other substances should not be the basis of a decision not to admit a client to OST if he or she meets criteria for opioid dependence.

⁴ In this document 'significant others' refers to people personally involved with a client, such as partners, family or whānau members and close friends.

2.5 Contraindications for OST

Methadone and buprenorphine may not be suitable for the following people:

- those with decompensated liver disease (such as with jaundice and ascites), as these drugs may precipitate hepatic encephalopathy and cause deterioration in the mental state
- those with acute asthma and other causes of respiratory insufficiency.

Precautions (although not contraindications) for both medications include high-risk multiple substance use, severe mental illness, low levels of neuroadaptation to opioids and significant co-existing medical problems (WHO 2009, page 27).

2.6 Priority admissions

When a service provider assesses a client as being suitable for OST, it should not delay entry. If delays are unavoidable, some clients may be eligible for priority access based on risk, but providers should consider each case on its own merit. Those who may be eligible for priority access include:

- pregnant women
- people with serious co-existing medical and mental health problems
- people arriving in New Zealand already established on OST programmes overseas.

2.7 OST for clients under 18

Service providers should not preclude OST on the grounds of age alone. Parental/guardian consent to treatment is not required if a young person is able to understand the reasons for OST and the associated process and risks, and agrees to that treatment. However, providers should seek parental/guardian support, where appropriate, for clients under 18 years of age. In all cases, they should carefully and fully document the consent process.

Clients under 18 years of age being considered for OST require their assessment for suitability to be supported by an opinion from an addiction medicine specialist and/or a child and youth psychiatrist.

Working with young people requires a positive youth development approach and sensitivity to issues pertinent to youth health in general. Ideally, young people receiving OST should be managed in specific youth addiction or mental health services, or in partnership with such services.

Young people 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.

2.8 Informed consent and treatment information

Prior to commencing OST, a client must have understood and signed consent for treatment. Service providers should give the client and relevant support people information (both written and oral) about treatment options and the side-effects of any proposed medication at the time of assessment. In addition, they must supply the client with written information on:

- their rights (including in terms of the Code of Health and Disability Services Consumers' Rights 1996) and their obligations/responsibilities to the service (refer to section 11.3: Rights of people receiving OST)
- the benefits, side-effects, and limitations of opioid substitution medicine – including the increased risk of overdose during induction (refer to section 4.1: Overdose)
- the potential effect of opioid substitution medication on activities such as driving and operating machinery (refer to section 4.2: Substance-impaired driving)
- the interactive effects of opioid substitution medication with alcohol and other substances (prescribed and illicit) (refer to Appendix 5: Drug interactions)
- the possible need for an electrocardiogram before commencing and during OST (with methadone) to establish QTc (refer to section 4.3: Methadone and cardiac safety)
- the process for making complaints (refer to section 11.4: The complaints procedure)
- the availability of consumer advocacy and peer support services.

Services need to provide a consent form that uses language that is understandable to clients. The person giving consent must be competent to do so, fully understand the process and voluntarily provide their consent before they sign the document.

Informed consent is an ongoing process. Throughout their OST, service providers need to fully inform clients of any changes in service delivery and any proposed changes to their treatment plan.

Consent forms should be documented, and accessible, in clients' medical records.

Service providers must confirm the identity of clients before commencing OST.

2.9 Choice of OST medication

Buprenorphine⁵ and methadone have both been found to be safe and effective for the treatment of opioid dependence (Gowing et al 2013). Both block opioid withdrawal, cravings and the reinforcing effects of opioids.

When choosing which medication to prescribe, the guiding factors should always be the preference and goals of the client. The choice could depend on a number of factors, such as personal characteristics, perceived effectiveness of the medication and experience of side-effects.

Key differences between buprenorphine and methadone that may influence the decision are outlined below.

⁵ In this document, 'buprenorphine' is used to indicate the combined product containing both buprenorphine and naloxone. Where the single product is referred to, this will be noted.

Buprenorphine	Methadone
Ceiling effect for respiratory depression	No ceiling effect
Caution should be taken if the client is using other central nervous system (CNS) depressants	Risk of overdose: <ul style="list-style-type: none"> • in induction stage • when used in combination with other CNS depressants (alcohol and benzodiazepines) • by opioid-naive people
Induction safer and easier, although there is a risk of precipitated withdrawal if it is commenced too soon after the last use of a full opioid agonist. If experienced, this can be a barrier for some clients (Gowing et al 2013)	Increases within the first four days risky due to methadone's accumulative effect
Stable doses reached more quickly	Can take longer to reach a stable dose
May be safer in situations where monitoring and supervision of consumption is lacking. Risk of diversion and misuse should, however, be considered	Higher risk of diversion and misuse
Can be taken alternate days	
The combined buprenorphine/naloxone formulation is not approved for use as a pain medication	Effective in pain control
Does not appear to induce significant QT prolongation; therefore maybe safer for people with cardiac problems	Appears to prolong the QT interval; cardiac arrhythmia adverse events have been reported
Common side-effects ⁶ include nausea, headache and anxiety (refer to Appendix 4: Side-effects)	Common side-effects include constipation, sleep apnoea and impact on sex hormones
Buprenorphine with naloxone is not currently recommended for use in pregnancy	Safe for use in pregnancy and breastfeeding
Greater clarity of thought and associated cognitive functioning (can be an advantage for people employed, studying or driving, and people taking other sedative medication)	Has sedating effects (can be an advantage for clients with anxiety)
Less severe withdrawal symptoms	Withdrawal symptoms generally more severe
Easier to transition in and out of treatment	Coming off methadone is generally a protracted process

Refer also to Appendix 3, Table 7: Methadone and buprenorphine pharmacology and pharmacokinetics comparison and Appendix 5: Drug interactions.

When selecting medication for women who are planning a pregnancy or are pregnant, service providers should undertake a maternal-foetal risk: benefit analysis (refer to section 6.7: Management of pregnant and breastfeeding women).

Useful resources

Matua Raki. 2011a. *Screening, Assessment and Evaluation: Alcohol and Other Drug, Smoking and Gambling*. Wellington: Matua Raki.

WHO. 2009. *Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence*. Geneva: World Health Organization.

⁶ There is considerable individual variation in the experience of side-effects with different opioids. If a client experiences side-effects with one medication, it is worth considering the other.

3 Stages of treatment

3.1 Induction

It is clear from research evidence that the effectiveness of opioid substitution maintenance therapy is dependent on timely entry into treatment, adequate medication dosage, duration and continuity of treatment, and accompanying medical and psychosocial services. Constructive (non-punitive) clinic responses to client problems improve retention and treatment outcomes.

World Health Organization, United Nations Office on Drugs and Crime,
Joint United Nations Programme on HIV/AIDS, 2004

Admission to an opioid substitution treatment (OST) service should occur as quickly as possible (ideally within two weeks) after eligibility has been established. In case of delay, a service may offer interim prescribing (refer to Appendix 18: Interim prescribing and 'Variations to Practice' on page 3 for reporting requirements).

Induction into OST, particularly using methadone, requires balancing adequate dosage with the elevated risk of overdose as opioid levels accumulate. Service providers must discuss the risk of overdose with clients and their support people, and inform them that the accumulating nature of methadone requires initial prescribed doses to be conservative. Clients may experience discomfort due to insufficient opioid effect until the dose reaches therapeutic levels. This may motivate them to use other drugs, which can have fatal consequences. Fatal overdoses in the induction of clients onto buprenorphine are less common (refer to section 4.1: Overdose).

Service providers should always administer a urine drug screen prior to initiating a client's first dose, and analyse this for the presence of opioids using confirmatory measures such as thin layer, gas or liquid chromatography.

3.1.1 The starting dose of methadone

Service providers should base initial doses of methadone on a client's treatment aims; their history of quantity, frequency and route of administration; the severity of their dependence; their tolerance to opioids; and their history of use of other central nervous system (CNS) depressants. The first dose should generally be in the range of 20–40 mg, and not higher than 40 mg. If a provider has doubt about a client's opioid tolerance, it should start that client on a low dose and closely observe the result.

Following a client's first dose, the prescriber or key worker should observe the client's response after 30 minutes, and again after 3–4 hours (ie, at peak plasma level concentration) to assess for toxicity or withdrawal. For this reason, providers should dispense the first dose in the morning.

Dose increases within the first three to four days pose considerable risk due to the effect of methadone accumulation. It takes an average of four days to achieve a steady state plasma level. The implications of this are that signs and symptoms of intoxication may appear on the third or fourth day of treatment. Prescribers or key workers should observe clients' response three to four hours after the dose on the fourth day to assess for toxicity.

Providers should start clients' treatment early in the week, so that they can monitor clients daily if necessary, and so that the maximum methadone serum level is reached when monitoring is available (if it is not available in the weekend).

Where a client's dose needs to be increased in response to continued withdrawal before day four, increments should be 5–10 mg at a time, and the provider should monitor effects daily. The provider should take the client's hepatic and renal functioning into account in decisions about dose increases.

Due to the risk of opioid overdose, particularly in people who have not previously been on methadone, prescribers or key workers should undertake frequent monitoring in the first two weeks (eg, at least daily for the first three days and then every two to four days until a stable dose is reached). After the first two weeks, the risk falls to very low levels. A standard written reminder of the risks should be provided to clients with their first increased dose; this could be provided by the pharmacist when they dispense the first dose increase.

Providers need to tailor dose increases to each individual. The expected therapeutic range is 60–120 mg; some clients will require doses in the upper end of this range to achieve stabilisation. The dose should be sufficient to ensure the client experiences the minimum of withdrawal symptoms, is retained in treatment, can function adequately in their social roles and is clinically stable.

Some clients do not cease all injecting within the titration period, even when a therapeutic dose has been achieved. Continued injecting alone at a reduced rate may not warrant further dose increase. For clients within the expected therapeutic range of 60–120 mg, a stabilisation period of some months may help determine whether the habitual injecting is related to dose insufficiency.

Many clients will experience variable levels of withdrawal symptoms during the induction phase, and will be tempted to 'top up' with illicit opioids, including diverted methadone. Providers should inform clients of the risks of overdose in this case, and advise them that if they do 'top up' they should wait until several hours after the peak effect of the prescribed methadone and use small doses. Continued use of illicit opioids to manage withdrawal symptoms may be an indication for dose increases.

3.1.2 The starting dose of buprenorphine

Buprenorphine is a partial agonist; that is, it can prevent a concurrent agonist drug from producing its full effect and has a ceiling effect, including on respiratory depression. Induction onto buprenorphine involves a very different philosophy to that of induction onto methadone. With methadone (a full agonist), induction aims to 'start low and go slow', whereas buprenorphine can be titrated quickly and is safe when rapidly increased to higher dose levels in response to withdrawal symptoms. It is also safer in overdose than methadone when combined with other CNS depressant drugs.

Buprenorphine (with naloxone) will displace other opioids from opioid receptors, but has less opioid effect. It can therefore precipitate withdrawal symptoms⁷ if given while other opioids are still active. Thus, providers should not give the first dose of buprenorphine until they observe objective signs of mild to moderate opioid withdrawal (such as anxiety, abdominal pain or joint pain, sweating). As a rough guide, this is likely to be:

- 8–12 hours after the last dose of intravenous morphine or home-bake heroin
- 12–14 hours after oral use of morphine or oxycodone
- 24 hours after a dose of less than 40 mg of oral or intravenous methadone, or oral use of sustained release morphine or oxycodone
- 24–48 hours after a dose of between 40 and 60 mg of oral or intravenous methadone.

The use of a validated rating scale such as the Clinical Opioid Withdrawal Scale (COWS) is recommended. A score of 8 or more indicates sufficient withdrawal symptoms to allow buprenorphine administration (refer to Appendix 9: The Clinical Opioid Withdrawal Scale).

It is important to prepare the client (and their support people) for the transition to buprenorphine prior to commencing induction. Providers should inform clients and support people of:

- the requirement for them to be in at least moderate opioid withdrawal beforehand (see timeframes above)
- the risk of precipitated withdrawal, and how it would be managed if it occurred
- the time the induction process will take, and the need for onsite monitoring on day one
- the possible need for an inpatient admission to conduct or complete the induction
- what will happen in the time it takes for a stable dose to be achieved, and the importance of not using other opioids to top up a perceived inadequate dose
- possible short- and long-term side-effects of buprenorphine.

Initiating buprenorphine for clients using short-acting opioids such as heroin, morphine (other than sustained-release preparation), codeine or oxycodone is usually not associated with severe precipitated withdrawal. Transfer from slow-release opioid preparations to shorter acting preparations for several days prior to transfer to buprenorphine is recommended. Transfer from longer acting opioids such as methadone can be more difficult, due to the risk of precipitated withdrawal (Gowing et al 2013). (Refer to section 3.4: Transferring from methadone to buprenorphine for recommendations on managing the transfer from methadone to buprenorphine.)

The recommended buprenorphine induction regime

Successful induction is dependent upon achieving adequate doses as quickly as possible, while concurrently minimising the risk of precipitated withdrawal (refer to section 3.4.1: Precipitated withdrawal). The recommended rate of induction to buprenorphine is 2–8 mg on day one, up to 16 mg on day two and 24 mg on day three, depending on the client's reported level of opioid use and observed response. In some cases a higher dose will be required by day three. Higher and more rapid dose increases should involve an addiction medical specialist or be undertaken in an inpatient setting where closer monitoring is available (Gowing et al 2013).

⁷ Precipitated withdrawal can occur if a person dependent on opioids receives a dose of a partial agonist too soon after their last dose of a full opioid agonist. Depending on the half-life of the antagonist or partial agonist used, precipitated withdrawal, when compared with a typical withdrawal syndrome, is often shorter lived but has a faster onset (eg, 60–90 minutes after the dose).

Table 1 provides a guide to buprenorphine induction over the first three days. Splitting the first day's dose in those with mild withdrawal signs reduces the risk of precipitated withdrawal (which will occur within the first 1–2 hours). For clients with significant medical problems or a high risk of concurrent use of other CNS depressants, a maximum dose of 4 mg on day one is recommended.

Table 1: Recommended doses of buprenorphine on days 1–3 of treatment induction

Day of induction	COWS <8 (mild withdrawal)	COWS >8 (moderate to severe withdrawal)
1	2–4 mg + 0–4 mg 1–2 hours later if necessary	8 mg
2	Increase by 2, 4 or 8 mg; maximum dose 16 mg	
3	Increase by 2, 4 or 8 mg; maximum dose 24 mg	

If a client experiences precipitated withdrawal, the general approach should be to continue buprenorphine dosing and provide symptomatic relief.

The prescribing doctor or another member of the specialist service team should monitor the client regularly every two to four days during the induction phase. After the first three days the dose can generally be increased, or decreased, by between 2 mg and 8 mg per day.

Typical optimal doses at the end of the first week are in the range of 12–24 mg per day. Dosage needs to be individualised according to the client's response (including subjective experience and degree of comfort, absorption, side-effects and continued use of other drugs).

Note: Swallowed buprenorphine will not be absorbed. Clients need to understand that absorption is sublingual.

3.2 Stabilisation

The term 'stabilisation' in this context is related to dose and to reduction or cessation of illicit opioid use, rather than general lifestyle and health stability, although it should be noted that changes in these areas may also occur quickly in OST. Criteria for assessing general stability is outlined in section 5.1: Takeaway doses.

The decision about appropriate dosage needs to be made jointly by the individual client, the prescriber and the key worker.

During the first two weeks of treatment, the aim is to avoid the client oscillating between intoxication and withdrawal. The client will not necessarily reach a stable dose during this period. A stable dose of methadone is usually reached within 1–3 months, but may take longer. A stable dose of buprenorphine can be established relatively quickly.

One indication of dose stabilisation is that the client is comfortable on a consistent regular dose without the need for dose review, and can work toward short-term agreed goals and treatment priorities. For some clients, this will take time to achieve; such clients may need significant input from the specialist service.

During the dose stabilisation process the prescribing doctor should be involved in the regular monitoring of clients – particularly those with unstable co-existing medical or mental health problems. This may take place through follow-up discussions with the key worker, or through discussions in routine multidisciplinary team (MDT) meetings that include input from the pharmacist, the client’s general practitioner (GP) and his or her support people.

A key worker, or another OST service clinical staff member, should see the client at least once a week until a stable dose is achieved. The key worker should then generally see the client fortnightly to monthly for the first six months. Service providers should review management of clients who are not progressing well medically or psychologically, or who are using other substances problematically (wherever possible with their significant others or support people), to identify issues related to lack of stabilisation or progress. Such clients may benefit from an amended approach and treatment plan, or more intensive intervention.

3.3 Ongoing OST

Once stabilisation has been achieved, the treatment plan should focus on the goals of OST. The treatment plan should be individualised, and will be regularly reviewed in line with the roles of specialist services outlined in section 1.2.

Once a client is on a stable dose and other identified problems are being adequately addressed and managed, the prescribing doctor, preferably with the key worker, should generally see them at least once every three to six months. A longer time period may be allowable in unusual circumstances (such as in the case of long-term stable clients unable to be placed with their primary care provider due to lack of availability). In these cases providers must document the rationale for the extended period in the client’s clinical notes.

Appointments with the key worker should be monthly or more frequently depending on the needs of the client, but should occur no less than three-monthly for the duration of treatment within the specialist service.

When a client has achieved a sustained period of stability, providers should facilitate transfer to a primary care provider. Management by a primary care provider provides the benefits of opportunistic care and treatment normalisation, and frees up the more intensive resources of the specialist service. A GP can prescribe OST medication on authority from a specialist service (refer to section 8: OST in primary care).

3.3.1 Ongoing methadone doses

Optimal methadone doses will generally be in the range of 60–120 mg daily. High-dose prescribing should not occur without prior discussion with the MDT and, potentially, liaison with an addiction medicine specialist. When doses over 120 mg or less commonly split doses (refer to section 5.6: Split methadone doses) are proposed, providers should also consider:

- review of diagnosis – with assessment and monitoring of co-existing mental health or other substance use problems
- a trial period to assess for sustained measurable change in function (ie, not just subjective change), with an agreement to return the dosage to 120 mg or below if there is no such change
- measurement of methadone serum levels over time – pre-dose trough and 4+ hour peak, with supervised dispensing in the four days prior to testing (refer to section 5.5: Measuring methadone serum levels)

- more frequent review (including through electrocardiograms)
- ensuring that dispensing arrangements are consistent with the risk of increased overdose and diversion potentially associated with higher methadone doses, the client's response to treatment and the client's commitments, such as employment
- avoidance of the use or prescription of other CNS depressants (especially benzodiazepines).

Providers should always consult with the client in relation to reviews of OST medication doses.

Note: The Ministry of Health's Medicines Control team will monitor prescribing above the maximum doses recommended in this section. Specialist services must send a copy of all authorities signed by the service's lead clinician (both specialist service medical practitioners under section 24(2)(b) Misuse of Drugs Act 1975 and shared care general practitioners under 24(2)(d) (refer to Appendix 15)) to Medicines Control (refer to 'Variations to practice' on page 3).

3.3.2 Ongoing buprenorphine doses

The effective daily dose range of buprenorphine for most clients is 12–24 mg per day. However, there is significant individual variation in sublingual absorption, and therefore in dose requirement. While it is uncommon for a client to be comfortable on a dose of less than 4 mg per day, many will be comfortably maintained on a dose of 8 mg per day.

Occasionally clients may benefit from a daily dose of buprenorphine above 32 mg, because of individual variability in pharmacokinetics and clinical responses. A prescribing doctor should only prescribe higher doses after careful deliberation in consultation with the MDT and an addiction medicine specialist, and with consideration to the points outlined in section 3.3.1: Ongoing methadone doses. The datasheet for buprenorphine (Suboxone®) published by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, specifies an upper daily limit of 32 mg; services should inform clients of this.

Due to buprenorphine's long action and ceiling effect on respiratory depression, service providers may consider less than daily dispensing for some clients, based on their progress in treatment and with careful monitoring of diversion and therapeutic risk. The main advantage of non-daily dispensing is that it allows less than daily attendance at the pharmacy, without the necessity for takeaway doses.

Services should not trial clients on a non-daily regimen until they are stabilised on an adequate daily dose. Service providers should trial initial non-daily doses as double the daily dose for alternate day schedules (eg, if a client is stabilised on 12 mg per day, then an alternate day dose would be 24 mg every two days), as long as single doses do not exceed 32 mg (Gowing et al 2013). It is recommended that, to reduce the risk of error and confusion in prescribing, clients on 'alternate day' regimens consume doses in the pharmacy on four consistent days per week (eg, a double dose on Monday, Wednesday and Friday and a single dose on Sunday).

When initiating a non-daily dosage regimen, service providers should review clients regularly – preferably at peak and trough dosing times – in order to observe intolerable side-effects or withdrawal effects at each end of the dosing interval, and adjust the dose accordingly.

Not all clients will find alternate day regimens acceptable; this may be particularly true for those on lower doses or reducing regimes. Conversely, increasing the dosing interval to three times weekly may be appropriate for some; if considering this approach, service providers should trial it after a successful switch to alternate day dosing. As a guide, if a 24-hour dose is less than 12 mg, the three-day dose should be three times the 24-hour dose, and if the 24-hour dose is 12 mg or greater, the three-day dose should be 32 mg (Gowing et al 2013).

3.4 Transferring from methadone to buprenorphine

Service providers should consider transferring clients from methadone to buprenorphine in the case of those who experience significant or dangerous side-effects from methadone, those whose cognitive functioning is sub-optimal on adequate methadone doses (for example, clients who are studying) and those wanting to come off OST who have found it difficult to reduce methadone doses. Buprenorphine is unlikely to offer a clinical advantage in clients who are stabilised on methadone and tolerating treatment well.

Before commencing a transfer from methadone to buprenorphine, it is important to assess the client for current or recent substance use, level of social support and co-existing medical and mental health problems. Although these factors do not preclude transfer, they may complicate it. Service providers should fully inform clients and their support people about aspects of the transfer process, including:

- the requirement to cease methadone and any other opioid use for at least 24 hours before buprenorphine can be commenced
- the time that the transfer will take
- the requirement for monitoring on day one for up to six hours
- the risk of precipitated withdrawal
- the possible need for an inpatient admission.

The following information is largely taken from *Clinical Guidelines for Transfer from Methadone to Buprenorphine* (Lintzeris 2013); it is reprinted with permission from Associate Professor Nicholas Lintzeris, Director of Drug and Alcohol Services, New South Wales Government.

Lintzeris' transfer guidelines differentiate low-risk from high-risk transfers. Clients considered at low risk for complications meet the following criteria:

- they routinely experience withdrawal features with their current methadone dose – this is more likely to occur with methadone doses below 60 mg
- they have no unsanctioned opioid or other substance use disorders
- they have no severe medical or mental health conditions that may be destabilised in transfer
- their social conditions are stable and supportive
- they have not undergone a previous complicated transfer
- they have a good understanding of the process.

All other clients are considered to be high risk for complications, and will require frequent monitoring, supportive care and symptomatic medication as required. The capacity to transfer clients to an inpatient unit in the event of severe complications should be available. Clients transferring from high doses (>100 mg methadone), those with unstable medical or mental health problems or those who lack social support may require a brief (1–3-day) inpatient admission.

Low-risk transfers can occur in an outpatient setting where there is capacity for frequent monitoring for 4–6 hours.

3.4.1 Day 1 of transfer

Service providers should administer the first dose of buprenorphine only when there is clear evidence that the client wishing to transfer is experiencing moderate opioid withdrawal symptoms, validated by the use of a scale such as COWS (see Appendix 9: The Clinical Opioid Withdrawal Scale). Usually this will occur at least 20–28 hours after the last methadone dose; however, clinical observation of withdrawal symptoms is more important than elapsed time or the size of the last dose. Providers should not attempt the transfer if the COWS score is less than 8.

Service providers should administer an initial dose of 2 mg buprenorphine when moderate withdrawal (a COWS score of >12) is apparent. It is important to start on a low dose, as precipitated withdrawal (PW) is likely to be evident within the first hour (or at least two) of the first dose being taken. A further dose of 6 mg can be administered one hour later if the initial dose does not precipitate withdrawal. Supplementary doses can be administered every 1–3 hours, according to withdrawal severity; for example, nothing if there is no or minimal withdrawal (a COWS score of <6); 4 mg if there is mild withdrawal (a COWS score of 6–11); or 8 mg if there is moderate to severe withdrawal (a COWS score of ≥12) (see Table 2 below).

Service providers should regularly monitor clients over a 4–6-hour period. Monitoring should include vital signs (blood pressure, pulse rate and temperature), mental state and severity of withdrawal. Providers should consider the client’s self-assessment of symptoms in the monitoring process. Monitoring and dose administration should continue until the client has had no withdrawal symptoms for at least one continuous hour.

Table 2: Monitoring and buprenorphine dosing guide on day of transfer

Time		Buprenorphine dose
0 hour	Monitor recent substance use, withdrawal, vital signs When client in moderate opioid withdrawal (COWS >12)	2 mg
1 hour	Monitor (withdrawal, vital signs)	6 mg
2 hour then every 1 hour	Monitor (withdrawal, vital signs) Moderate–severe withdrawal = COWS >12 Mild withdrawal = COWS 6–11 No or minimal withdrawal = COWS <6	Symptom triggered sliding scale 8 mg (to max 32 mg total) 4 mg (to max 32 mg total) 0 mg
Once client in minor withdrawal >1 hour	Outpatient: Discharge home. Provide take-away 4–8 mg buprenorphine dose to be used for moderate withdrawal discomfort. Symptomatic medication as required. Inpatient: Reduce monitoring + buprenorphine dosing as per sliding scale to six-hourly	

Table reprinted with permission of Associate Professor Nicholas Lintzeris.

Most clients transferring from methadone doses of over 20 mg will require buprenorphine doses of at least 8 mg on day one and often 16–32 mg on the first day: especially those transferring from higher methadone doses. Many clients will feel uncomfortable for the first two to five days on buprenorphine, and experience mild opioid withdrawal symptoms including headache, dysphoria, anxiety and sleep disturbances. Providing reassurance and symptomatic relief (typically for 1–3 days for clients not coping with persistent symptoms) and ensuring an adequate dose of buprenorphine are important.

It is not uncommon for clients to experience fluctuating withdrawal symptoms within the first 12–24 hours; however, symptoms will subside with time, and eventually respond to further doses of buprenorphine. Clients should remain hydrated; services should provide additional fluids for those experiencing severe sweating, vomiting and diarrhoea.

Service providers should check that support people are available when a client goes home on the first day of transfer, and that emergency contacts (including after-hours contact details) have been identified in advance.

Service providers should generally restrict symptomatic medication to alleviate the discomfort of moderate or severe PW.

3.4.2 Week 1 of transfer

After the first day it is recommend that service providers supervise clients as they administer buprenorphine doses as indicated in Table 3 below. Providers should review outpatients daily for the first three days, or until they are stabilised on buprenorphine (ie, there is resolution of any withdrawal symptoms or adverse events). Reviews should include an assessment of:

- withdrawal signs and symptoms (using COWS to document severity)
- any other substance use
- adverse reactions to buprenorphine (with particular attention to common side-effects during transfer; eg, sleep disturbances, anxiety or headaches)
- general health and wellbeing.

Providers may need to adjust doses according to a client’s use of other substances, side-effects or other medical conditions.

Table 3: Monitoring and buprenorphine dosing guide on days 2–5

Client in moderate–severe withdrawal	COWS >12	Total dose of previous day + 8 mg to maximum 32 mg
Client in mild withdrawal	COWS 6–11	Total dose of previous day + 4 mg to maximum 32 mg
Client in no or minimal withdrawal	COWS 0–5	Total dose of previous day + 4 mg to maximum 32 mg

Table reprinted with permission of Associate Professor Nicholas Lintzeris.

After the first week service providers should see clients at least weekly for the first month to monitor progress. If a client is experiencing persistent side-effects, a transfer back to methadone may be appropriate.

3.4.3 Precipitated withdrawal

Buprenorphine displaces methadone from the opioid receptors, causing a net reduction in opioid activity. There is potential for PW to occur within the first few hours and to peak at 2–4 hours after administration of the initial dose of buprenorphine.

A client may be experiencing PW if there is a sustained and marked increase in the severity of opioid withdrawal within the initial 3–6 hours after the first buprenorphine dose (eg, an increase in COWS score of >6 points). Onset of or marked increases in withdrawal more than six hours after buprenorphine dosing may reflect ‘underdosing’; in this case providers should give additional buprenorphine.

If PW occurs, providers should continue buprenorphine dosing and use symptomatic medication if necessary. Precipitated withdrawal symptoms are consistent with opioid withdrawal syndrome, and can vary in intensity.

Clients experiencing opioid effects at the time of the first buprenorphine dose are more likely to experience PW than clients who have experienced opioid withdrawal prior to their first buprenorphine dose. Factors impacting on the likelihood of experiencing PW include:

- the amount and time of last methadone dose. It must be emphasised that while, in general, higher doses of methadone produce greater opioid effects, there is considerable individual variation
- individual pharmacokinetic profile – in particular, whether the client is a ‘rapid’ or ‘slow’ methadone metaboliser. This is determined by a combination of genetic factors (CYP450 polymorphism), other medications and medical conditions (eg, liver disease or pregnancy) impacting upon methadone metabolism, elimination and distribution.

There is no absolute methadone dose at which PW can be predicted or excluded. It is less likely to occur in clients transferring from a dose of methadone that does not routinely ‘hold’ them for a 24-hour period. The dose at which this occurs varies between clients; for many, it is less than 40 mg and for others, it is experienced at higher methadone doses (between 60 and 100 mg).

Other factors that may impact on the onset and severity of PW include:

- buprenorphine dose – a high initial dose is often associated with more severe PW than lower doses. The day one dose is therefore usually administered in two or more divided doses, at least 1–2 hours apart
- use of other substances; for example, other opioids that will cause PW or a substance that impairs the client’s ability to adhere to the transfer procedure
- co-existing medical or mental health problems and psychosocial factors – clients with severe co-existing problems or unstable social circumstances may be less able to cope with the stress and potential complications of transfer
- client expectancy – if a client is poorly prepared for the possibility of PW, he or she is more likely to be distressed and confused by its onset, with potential negative consequences. Clients should be aware that it may take several days to stabilise on buprenorphine.

Table 4: Client risk factors for complicated methadone to buprenorphine transfer

Area of risk	Factors associated with high risk	Action
Methadone effects	Client not in significant opioid withdrawal at time of first intended buprenorphine dose. Clients on higher methadone doses (eg, >60 mg) and/or slow metabolisers (eg, able to miss a dose of methadone with minimal withdrawal) generally at greater risk, but must be individually assessed	Gradually reduce methadone dose (eg, 5 mg every 1–2 weeks) to a level at which client describes the dose no longer ‘holds’ adequately for 24-hour period. This involves frequent reviews and monitoring Aim to reach low doses if possible (eg, <40 mg), however transfer can occur from higher doses if client in significant withdrawal (eg, COWS>12) at ‘trough’ levels (prior to next dose)
Client information and expectancy	Client poorly informed of transfer procedures, potential complications or coping strategies	Inform clients (and support people) fully of potential complications and procedures. Provide written information, prepare supports and contingency plan for complications
Co-existing medical or mental health problems	Severe co-existing medical or mental health problems that may be destabilised during transfer, or impair client’s ability to cope with any transfer complications	Address any health concerns. Clients with complex problems that may become destabilised may require inpatient admission for transfer
Substance use	Client using other opioids that may contribute to PW and/or using other substances that complicate adherence to transfer procedures (eg, benzodiazepines, alcohol, stimulants)	Stabilise other substance use with appropriate interventions (counselling, withdrawal). Little point in continuing to reduce methadone dose if client using other opioids during dose reduction
Social conditions	Poor social conditions that impair client ability to adhere to transfer procedures or cope with any complications. This may include homelessness, transport difficulties or need to continue high level of function (eg, work commitments)	Stabilise social conditions. Clients without supports in the community (including housing, supportive friends, family) may require inpatient admission for transfer
Previous transfer attempt	Clients with difficult previous transfer from methadone to buprenorphine may be more likely to experience complications again	Examine how previous transfer occurred. Poor outcome may have been due to poor transfer process, and perhaps can be avoided

Table reprinted with permission of Associate Professor Nicholas Lintzeris.

3.5 Transferring from buprenorphine to methadone

Transferring from buprenorphine to methadone is usually less complex than transferring from methadone to buprenorphine. A provider might consider such a transfer if a client is unable to tolerate the side-effects of buprenorphine, or experiences an inadequate response to it. Methadone can be commenced 24 hours after the last dose of buprenorphine. Although the first dose of methadone should not exceed 40 mg, it may be appropriate to provide an initial dose of up to 60 mg if a client is transferring from buprenorphine doses above 12 mg per day (Gowing et al 2013).

As buprenorphine has a higher receptor affinity and a longer half-life than methadone, a client may experience a degree of opioid receptor blockade for several days after discontinuation. For this reason, providers should approach the first 1–2 weeks of methadone dose titration cautiously. Methadone’s agonist effect will increase as residual buprenorphine dissociates from the receptors.

Because buprenorphine is a partial agonist, the usual dose equivalency protocols may not be accurate for the purposes of estimating the equivalent dose of buprenorphine to that of a full agonist. Titration will require clinical observation and information. However, service providers should start a client currently on a low dose of buprenorphine on a comparatively low dose of methadone. (Refer to Appendix 7: Dose equivalence of opioid and benzodiazepine drugs.)

3.6 Reviewing progress

Many factors influence the frequency and format of client review in OST, including complexity of the individual client's case, the client's stability, duration of the client's treatment so far and availability of staff.

The review process allows clinical staff to monitor a client's progress. It presents an opportunity for reducing further potential harm (eg, it may involve hepatitis C (HCV) or HIV testing for clients at risk), reinforcing information on avoiding infection and addressing changes in the client's circumstances and needs over time.

Services may organise their own timeframes for formal client review. However, reviews should occur at least once every six months, and involve the client, the prescribing doctor and the key worker. Other members of the MDT and the client's support people should be involved as appropriate.

A review should include an overview of treatment progress, an updated assessment of risk and an update of the treatment plan with a recovery/wellbeing-orientated focus. It may also cover any of the following areas (and any other relevant areas):

- substance use (including alcohol and tobacco)
- checking of or for injection sites
- urine drug screens or blood tests
- adequacy of dose (taking account of withdrawal symptoms, side-effects and continued illicit opioid use)
- takeaway arrangements (including the safety of unsupervised doses)
- adherence to service and treatment conditions
- lifestyle and high-risk behaviour changes
- mental health and medical problems (including blood-borne virus risk/treatment)
- relationship with significant others
- education/employment and aspirations
- links with other health and social service providers
- suitability for transition to primary health care (if this has not already occurred)
- provision of information about and/or referral to self-help groups and other support and ancillary services (eg, peer support workers)
- the client's perception – and that of their significant others – of their quality of life.

Services should develop their own procedure to ensure all clients participate in regular reviews, and should record a summary of review procedures and outcomes on clients' clinical notes.

Following review, service providers should discuss clients' treatment plans, including the frequency of further treatment reviews, with the MDT.

3.6.1 Special reviews

More formal reviews may occur if a provider has concerns about a client's progress. These may benefit from input from others directly involved in the client's care.

Note: There may be exceptions to involving clients in special reviews; for example, when a client has threatened or committed violence. Engaging a consumer advocate in these circumstances may be helpful.

3.6.2 Reviews sought by a client

Services should have written procedures available for clients to follow should they independently seek a review of their treatment outside of the process described above.

3.7 Drug screening

Service providers should monitor clients' substance use, to support the validity of a client's self-report of substance use, to identify and discuss with the client substances shown in results but not reported to the service, and to inform decision-making in regard to a client's eligibility for takeaway doses. Drug screening should be used to inform client-orientated treatment alongside the input of the client, their significant others, pharmacists and support people. Treatment decisions should be based on clinical judgement and an understanding of the individual client's situation; not wholly on the results of drug screens.

The perceived need to observe urination should be balanced against the significant adverse effects of this process. Supervised urine drug screens are often an uncomfortable process for a client; they are not only embarrassing, but carry strong connotations of a surveillance agenda being valued over a therapeutic agenda. An appropriate environment and supervision by staff of appropriate gender are required. If a urine drug screen is not supervised, procedures to ensure authenticity, such as testing the temperature of the sample and observing whether it is diluted, should be in place. Providers should consider other less intrusive methods of screening.

Services are responsible for determining the frequency of the drug screening they undertake. Random testing may be more effective than a system of frequent screening.

Services should inform clients of the procedure and rationale for drug screening in writing, either as a specific handout or as part of a general information pack provided at admission.

3.8 Psychosocial interventions

Ensure interventions for opioid dependence promote harm reduction by maximising access to opioid substitution treatment and retention, supporting recovery and comprehensively addressing people's wider needs, including their physical, emotional and social needs. This will include extending the use of primary care that is well supported by specialist services to deliver interventions for opioid dependence (Ministry of Health 2012b).

Psychosocial support and engagement in ongoing OST provides clients with the time and opportunity to plan for their future. Opioid substitution treatment should be part of a wider care programme in which other issues, including those related to psychological functioning, medical problems, and social issues (employment, training, parenting, etc), are identified and addressed, in order for a client to achieve stability and for recovery capital to be built up and maintained. The role of specialist services and primary care providers in this context is to assist clients to work towards goals of sustained reduction or abstinence from illicit opioids and other problematic substance use; a healthy lifestyle; and improved interpersonal problem-solving skills, social networking and social functioning.

‘Psychosocial support’ refers to a broad range of social and psychological interventions. Social interventions might include support with practical issues, such as managing benefits, accommodation, education, training, parenting and legal problems. Psychological interventions might include ‘talking therapies’, such as motivational interviewing, cognitive behavioural therapy and contingency management to assist clients to clarify goals. Talking therapies can help to increase motivation to stop or reduce substance use, provide education and support in regard to increasing recovery capital and assist with wider community reintegration.

Interventions should be evidence-based and recovery-orientated. They should be tailored to individual needs, have defined goals, be well integrated into the overall service delivery system and be delivered by appropriately trained clinicians.

If specialist services or primary care providers do not provide psychosocial support, they need to have procedures and agreed plans in place for supporting clients to access appropriate services, and for liaison and cooperation with providers of those services.

Due to the nature of OST, including the inherent power issues involved in prescribing a controlled medication within a specialist OST service or primary care setting, it is not uncommon for issues to arise in regard to programme rules and restrictions. Specialist OST services should train their clinical staff to use a range of counselling and de-escalation skills so that they can resolve such problems as they arise. All interactions with clients, however short, provide an opportunity to provide some level of psychosocial support.

Services should provide clients with information about available psychosocial supports, self-help and family and whānau support groups, and cultural and spiritual guidance if appropriate.

3.9 Completing OST

The National Treatment Agency for Substance Misuse (2012) says of recovery after the OST process:

Entering and staying in treatment, coming off opioid substitution treatment and exiting structured treatment are all important indicators of an individual’s recovery progress, but they do not in themselves constitute recovery. Coming off OST or exiting treatment prematurely can harm individuals, especially if it leads to relapse, which is also harmful to society. Recovery is a broader and more complex journey that incorporates overcoming dependence, reducing risk-taking behaviour and offending, improving health, functioning as a productive member of society and becoming personally fulfilled. These recovery outcomes are often mutually reinforcing.

3.9.1 Planned withdrawal

Withdrawal from OST should ideally occur when a client has achieved their treatment goals and attained levels of stability and recovery capital that give them a reasonable chance of achieving abstinence from opioids, if that is their goal. The best outcomes are achieved when a client ceases OST voluntarily after a planned and gradual, stepped dose reduction (rather than a rapid dose reduction) and is able to control the frequency and amount by which their dose is reduced.

In all cases of withdrawal from OST, the prescribing doctor and key worker should work with the client to provide a suitable dose reduction programme that attempts to minimise withdrawal symptoms and cravings. In most cases gradual tapering is recommended, as it lessens the severity of withdrawal symptoms and helps clients adjust to coming off OST.

Service providers need to carefully monitor mental health problems (particularly mood and anxiety) and medical problems (including chronic pain issues) throughout the planned withdrawal process. Symptoms may be exacerbated, or become evident, as the dose decreases.

Service providers should offer relapse prevention and supportive counselling to all clients before, during and after OST withdrawal. Ongoing support is particularly important during the first 3–6 months after completing a planned withdrawal, as the risk of relapse is very high during this period. Providers should inform clients about resources available to help them maintain stability and reduce the risk of relapse, and ensure they have access to an ongoing support network, including peer support systems. Providers should also give clients' support people information about the withdrawal and after-care process, including information on how they can assist.

Services should offer clients who resume opioid use after a planned withdrawal of OST prompt readmission. The OST service or primary care prescriber and the client and their support people should negotiate this option and the timeframe for priority access before withdrawal is initiated.

Methadone reduction

Completion of methadone withdrawal is more likely to be successful if undertaken slowly over a long period of time, through a gradual stepped tapering regime involving dose reductions in only 25–50 percent of the weeks of the reduction process (Nosyk et al 2012). As a guide, the reduction rate might be between 5 and 10 percent of the current dose every 1–4 weeks depending on the individual characteristics of the client..

Buprenorphine reduction

As with methadone reduction, gradual reductions of buprenorphine doses are recommended. Clients who are able to maintain stability may be able to tolerate greater dose reductions; for example, up to 25 percent of the current dose every 1–4 weeks.

As the lowest available dose unit of buprenorphine is currently 2 mg, a service provider may consider alternate day dosing when a client has successfully reduced to this stage.

In general, clients should determine their own rate of OST medication withdrawal, including maintenance of a particular dose before further reduction.

3.9.2 Involuntary cessation of OST

Service providers should approach a decision to withdraw a client from OST medication against their wishes with caution. This course of action may increase the risk of fatal overdose, blood-borne virus infection, ill health, financial insecurity or debt, social instability or criminal offending. Involuntary withdrawal may have significant implications for others, including children, partners, families and whānau and the wider community.

Involuntary cessation of OST should be a last resort. Decisions relating to termination of treatment should be initiated only after input from a number of other sources (including the community pharmacist, the client's GP and the client's support people), and after all attempts have been made to resolve influencing issues.

Situations leading to a client being involuntarily withdrawn from OST should be outlined in discussions about consent to treatment, recorded in documents prior to commencement of treatment and reviewed as necessary throughout treatment. Examples of situations that may lead to consideration of involuntary withdrawal include the following:

- a client's pattern of frequent overdose or significant intoxication is so uncontrolled that opioid substitutes cannot be dispensed with sufficient safety (although it is important to note that lapses and relapses are features of addiction, and do not alone justify involuntary withdrawal)
- a client threatens violence, or is violent towards staff, other clients, a prescriber or a pharmacist (review of the circumstances associated with aggressive behaviour should always precede any decision to withdraw a client from OST)
- a client repeatedly displays an inability to keep to the safety requirements of the OST provider (eg, repeated diversion of medication or loss of doses, failure to keep doses secure or repeated lack of attendance at appointments).

Each situation requires exploration and consultation with the client, his or her support people and others involved in the client's care.

Injection of methadone or regular use of other drugs is not usually an indication for involuntary withdrawal from OST. Specialist services are expected to work with clients to reduce or cease illicit opioid use and other problematic substance use (refer to 6.1: Managing problematic substance use).

When considering the involuntary withdrawal of a client from treatment, the key worker, prescriber or other relevant clinical staff member must discuss the matter with the client, and provide them with written notifications before a decision is made.

The final decision to cease OST should be made by the prescribing doctor with the key worker and the MDT, including the service manager or the primary health care team (whichever applies), and preferably after a second opinion from an independent addiction medicine specialist (ie, one from a different service or DHB) or equivalent.

A second opinion can consider alternative strategies to avoid involuntary withdrawal. To make best use of this opinion, service providers should seek it before making a decision to cease treatment.

When a specialist service imposes involuntary cessation of OST, it needs to:

- give the client reasons for the withdrawal of OST in writing
- caution the client about risks of overdose (due to reduced tolerance) and driving and operating machinery during the withdrawal process
- offer the client support during the withdrawal process
- provide the client with a future-directed specific treatment plan
- inform the client of other treatment options available and assist with referral where appropriate.

Service providers should give clients the opportunity to appeal against the decision to cease OST against their wishes. Wherever possible, the service should retain the client in the programme pending resolution of the appeal. The service should provide the client with information about accessing a consumer advocate for the purposes of this process.

The rate of reduction in the case of involuntary withdrawal will depend on the circumstances, but rapid dose reduction is not recommended. A gradual reduction, as described in the case of a planned withdrawal, should be undertaken unless it is unavoidable (eg, in cases of violence on the part of the client).

In all cases of withdrawal from OST (planned or involuntary), service providers must document a discharge plan once it has made the decision to withdraw. In each case of involuntary cessation of OST, the service provider should initiate discussion about how the client might best re-engage in OST, and should document this discussion in the client's clinical notes.

Service providers must notify the Director of Mental Health of all cases of involuntary cessation of OST (refer to 'Variations to practice' on page 3).

3.9.3 Service provider responsibilities after the last dose

Prescribers must notify the pharmacy whenever a client's OST has been terminated.

Medical practitioners working under authority must notify their specified OST service when a client ceases OST.

If a client has been subject to a restriction notice, the prescriber or specialist service needs to notify the Ministry of Health's Medicines Control team that that client is no longer being prescribed opioid substitution medication.

Useful resources

Matua Raki. 2011b. *Substance Withdrawal Management: Guidelines for medical and nursing practitioners in primary health, specialist addiction, custodial and general hospital settings*. Wellington: Matua Raki.

4 Safety issues

4.1 Overdose

Methadone is associated with an increased risk of overdose, particularly in the first two weeks of treatment and when tolerance is reduced following withdrawal from opioid substitution treatment (OST). The majority of deaths that occur during the induction stage involve the use of other substances; particularly other opioids. Any substance that has a synergistic or potentiating effect alongside opioids (including alcohol, benzodiazepines and antidepressants) has the capacity to cause overdose when combined with methadone. Service providers must inform clients commencing or ceasing OST of the risks of using other drugs in combination with methadone, and closely monitor them during these periods. Although the risk of overdose involving the combination of buprenorphine with benzodiazepines and other sedatives is less, caution is still required.

Service providers should inform clients' significant others that deep snoring during methadone treatment can be a sign of dangerous respiratory depression, and that they need to report this to the service.

Signs and symptoms of a methadone overdose include: pinpoint pupils, nausea, dizziness, feeling intoxicated, sedation, 'nodding off', unsteady gait, slurred speech, snoring, hypotension, bradycardia (heart slowness), hypoventilation, itchiness, coma and pulmonary oedema. Symptoms may last for 24 hours or more.

Where a service provider suspects an overdose, it should refer clients to appropriate medical facilities (eg, accident and emergency services).

Because of the long plasma half-life of methadone, service providers should give naloxone (an opioid antagonist) as a prolonged infusion when treating a methadone overdose. In this situation the client may require intubation to protect respiration.

In overdose, partial agonists such as buprenorphine induce profound bradycardia, which may require intensive care treatment but is not usually fatal. Service providers should take the long duration of action of buprenorphine into consideration when determining the length of time needed to reverse the effects of an overdose. Due to buprenorphine's strong affinity to mu opioid receptors, the effects are not reversed by the usual doses of the opioid antagonist, naloxone. Doses of 10–35 mg per 70 kg may be required to reverse the effects of buprenorphine toxicity.

4.1.1 Consumption of takeaway doses by a child

Young children's inadvertent consumption of a client's takeaway dose of methadone or buprenorphine may be life-threatening. A fatal dose of methadone for children may be less than 10 mg.

Symptoms of opioid overdose in children are similar to those in adults; pinpoint pupils are most common. 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.

A service provider who becomes aware of or suspects opioid intoxication in a child should refer him or her to an accident and emergency department without delay, as respiratory depression may be observed for as long as 48 hours after ingestion. Providers should also consider naloxone administration. Treatment must include establishing an airway, maintaining adequate respiratory ventilation, maintaining fluid and electrolyte balance, emptying upper and lower gastrointestinal tracts and preventing aspiration of gastric contents.

4.2 Substance-impaired driving

Considerable risks arise if a client uses other substances, including alcohol, in combination with his or her OST medication and drives a motor vehicle. All services must have procedures in place to inform clients of the risks and to take action if they become aware of clients driving while impaired.

The Land Transport Amendment Act 2009 introduced new driving laws creating an offence of driving while impaired with evidence in the bloodstream of a controlled drug or prescription medicine (section 11A).

The New Zealand Transport Agency (NZTA) *Medical Aspects of Fitness to Drive: A guide for medical practitioners* (2009) advises that drugs such as sedatives, analgesics, anti-allergy drugs, antipsychotic drugs and antidepressants, anti-motion–sickness drugs, hypertensive medications, relaxants, ophthalmic agents and drugs of abuse – benzodiazepines, opioids, methadone, amphetamines, THC, hallucinogenic agents and cocaine – may impair a person’s ability to drive. The NZTA provides the following checklist when considering a person’s ability to drive safely:

- the impact of changing prescriptions and levels of medication
- the cumulative effects of medications
- the type of licence and type of driving undertaken
- the presence of multiple medical conditions
- other factors that exacerbate risk (eg, a history of illicit drug use and medication)
- the use of illicit or prescription drugs and medications that may cause sedation, euphoria, impaired motor coordination, blurred vision, hypotension or dizziness and exacerbation of other medical-related risks.

Current evidence concerning the effect of various drugs on driving – and in particular, the effect that drugs may have when used in combination with methadone or buprenorphine – highlights the following points:

- a. Methadone and buprenorphine may affect the capacity of clients to drive or operate machinery, particularly:
 - during the induction and stabilisation phases of treatment
 - following dose increases or during rapid reductions
 - when the client is taking other drugs (illicit or prescribed) or drinking alcohol
 - when the client has a medical or psychological condition that is likely to contribute to impairment
 - when doses of ≥ 120 mg of methadone or 32 mg buprenorphine are being administered.

- b. The addition of any psychoactive substance to methadone or buprenorphine may result in impaired driving. There is an increased risk of accidents with certain substances, especially CNS depressants including alcohol:

Medical practitioners should be aware of the effects of oral methadone and a combination of any illegal drugs on driving and where appropriate advise patients that they should not drive when taking oral methadone and illegal drugs.

NZTA 2009

- c. Many factors related to opioid use influence driver safety. As well as combined use of other substances, these include route of administration, dose, time of day, tolerance and individual reaction to the substance.
- d. Methadone should not cause significant psychomotor or cognitive impairment in people who abstain from other substance use:

An individual on an oral methadone treatment programme may continue to drive if the individual is stable on the programme and their methadone treatment is unlikely to affect their ability to drive safely.

NZTA 2009

- e. Buprenorphine has less effect on psychomotor performance than methadone; it may therefore be a preferable medication for people who need to drive or operate machinery regularly.

Opioid substitution treatment providers and practitioners must be knowledgeable about the risks associated with the use of opioid drugs, and in particular with the risks associated with methadone when used concurrently with other substances.

Specialist service clinicians and prescribing doctors have a responsibility to advise clients of possible effects and the degree of associated risk prior to admission, when their dose is increased and when they are known to be using, or have been prescribed, other medications that could contribute to impairment or alter the metabolism of the opioid medication. (Services could provide a standard written reminder of risk of overdose to clients at these times.) Service providers must record discussion and advice about driving on individual clients' clinical records.

If a client is considered medically unfit to drive, the prescribing doctor must advise him or her of this both verbally and in writing. If the risk is likely to be ongoing and the client's other substance use or psychological function indicates that they may not follow the advice, the prescribing doctor (ideally after consulting the multidisciplinary team (MDT)) must notify the NZTA. An example letter of notification under sections 18 and 19 of the Land Transport Act 1998 as well as an example letter advising an individual that they are unfit to drive can be found in the appendices of *Medical aspects of fitness to drive: A guide for medical practitioners* (NZTA 2009).

The letter advising the client that they have been declared medically unfit to drive should outline when and how they can expect their situation to be reviewed and the process for meeting requirements to resolve the situation. When it is resolved, the prescribing doctor needs to advise the NZTA.

4.2.1 Benzodiazepines and driving

There is substantial evidence that the use of benzodiazepines (prescribed or illicit) leads to increased risk of motor vehicle accidents. All use of benzodiazepines in combination with opioid substitution medication should be considered a safety risk.

The risk of driver impairment has been shown to increase significantly with increasing benzodiazepine blood-drug concentrations and with benzodiazepines with a long half-life (eg, diazepam, clonazepam and nitrazepam), particularly with doses greater than 20 mg diazepam equivalent (refer to Appendix 7: Dose equivalence of opioid and benzodiazepine drugs). Clients taking shorter acting benzodiazepines may also be unsafe to drive if the benzodiazepine is still exerting its effects.

As Zopiclone has been implicated in more fatal road accidents than would be expected from its half-life, it is not recommended as being safer than a benzodiazepine.

Alcohol and benzodiazepines have additive effects that significantly increase the risk of accident.

4.3 Methadone and cardiac safety

QT interval prolongation⁸ is evident in 10–15 percent of people on methadone. Methadone can prolong the QT interval and in rare cases induce torsade de pointes, which can be fatal. The risk of QTc prolongation in clients who are using, or being prescribed, methadone is unpredictable and does not appear to be dose dependent. Clients with a history of unexplained loss of consciousness or with family history of sudden cardiac death may be at higher risk for torsade de pointes. (Familial elongated QT affects approximately 1 in 2000 adults.) It is important therefore that service providers screen clients with this history for this risk at entry to and during OST, especially when the methadone dose is increased and when other potential QTc-prolonging medications are prescribed.

In the event of QTc prolongation greater than 500 milliseconds, service providers should seek advice from a cardiologist. Transfer to buprenorphine may be appropriate, as QTc interval prolongation is less likely with buprenorphine.

Risk factors for problematic QTc prolongation include:

- clinical or family history of QTc prolongation
- concurrent use of other QTc prolongation medications (eg, erythromycin or amitriptyline)
- female gender, especially after menopause
- older age
- hypokalaemia (low blood potassium).

Service providers might consider closer monitoring or consultation with specialists for clients with unexplained fainting or seizure episodes. Providers need to educate clients at risk of arrhythmia on symptoms to be aware of and cardiac referral arranged.

⁸ 'Long QT syndrome [is] a condition in which a specific type of ventricular tachycardia occurs that is associated with certain ECG abnormalities (a prolonged QT interval). Patients with long QT syndrome usually have no identifiable underlying cardiac disease, but appear to be born with the propensity to develop a particular variety of ventricular tachycardia under certain circumstances. (These circumstances can include exercise, or the administration of certain drugs.)' (http://heartdisease.about.com/cs/arrhythmias/a/cardarrhy_3.htm)

Providers should notify a client's GP and community pharmacist if that client has an increased risk of prolonged QTc so that concurrent prescribing of medications with the potential to prolong QTc may be avoided.

A Cochrane review (Pani et al 2013) evaluating the efficacy and acceptability of QTc screening for prevention of cardiac-related morbidity and mortality recently reported that evidence lacks for both the effectiveness and safety of QTc screening strategies in preventing long QTc-related cardiac morbidity and mortality in people receiving methadone treatment. The review recommends clinically relevant research to clarify this subject.

4.4 Drug interactions

Medication interactions and those caused by concurrent use of other substances including alcohol have the potential to impact on the safety and effectiveness of OST. Interactions that result in increased blood plasma levels of OST medication also carry a risk of sedation and overdose, while those that lead to reduced levels carry a risk of a reduction in treatment efficacy.

Of greatest concern is the combination of opioids with other prescribed or non-prescribed CNS depressants, which carries a risk of overdose. Service providers should note the following points.

- Although benzodiazepines have minimal effect on cardio-respiratory depression when used in isolation, mortality rates in cases of combined opioid and benzodiazepine use are markedly raised. Concurrent prescribing or use should be avoided wherever possible. If a client uses benzodiazepines at any level, or alcohol in excess, service providers may need to closely supervise OST, imposing greater dispensing restrictions, employing caution in dose determination and paying attention to treating the other substance use.
- Methadone and buprenorphine are both metabolised by the cytochrome P450 enzyme CYP3A4; methadone is also partially metabolised at CYP2D6. Because of buprenorphine's maximal opioid effect with increasing doses, interactions that cause the inhibition of metabolism at CYP3A4 are likely to be less clinically significant for buprenorphine than with methadone. When introducing a drug that inhibits or induces enzymatic metabolism, providers should monitor for signs of toxicity or methadone withdrawal, and adjust OST doses where necessary.
- Drugs that are known to cause QTc interval prolongation will increase the risk of torsade de pointes in combination with methadone.
- The significance of a drug interaction will vary between individuals, and is determined by factors such as dose and frequency, whether a medication is being initiated or stopped, co-existing medical problems and genetic expression of liver enzymes.

Refer to Appendix 5: Drug interactions for a list of medications that are associated with interactions when used in combination with methadone or buprenorphine. Where possible these medications should be avoided; consultation with an addiction medical specialist is recommended where there are safety concerns or concerns regarding treatment effectiveness.

Useful resources

Matua Raki. 2012. *Substance Impaired Driving: Treatment guidelines for addiction practitioners*. Wellington: Matua Raki.

NZTA. 2009. *Medical Aspects of Fitness to Drive: A guide for medical practitioners*. Wellington: New Zealand Transport Agency.

WHO. 2009. *Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence*. Geneva: World Health Organization.

5 Managing dose-related issues

5.1 Takeaway doses

Takeaway doses are any doses of opioid substitution treatment (OST) medication that are not consumed under observation at a pharmacy, specialist service, primary care practice or any designated place where OST medication can be safely dispensed.

Daily pharmacy attendance is time consuming, and can interfere with other aspects of a client's life. Flexibility in dispensing arrangements can improve quality of life and independence.

The multidisciplinary team (MDT) should clinically consider the risks and benefits of granting takeaway doses in consultation with the client and their chosen support people, and document the decision in the client's file. It is uncommon for a client to be prescribed takeaway doses early in their treatment. To be eligible for takeaway doses of either methadone or buprenorphine clients need to demonstrate stability, reliability and the ability to comply with the safety requirements of unsupervised consumption as specified by the individual specialist service.

Until a client is considered to be stable enough for their OST to be transferred to their primary care provider, consumption of OST medication should occur at a pharmacy or other dispensary, on at least three non-consecutive days per week. Less frequent and flexible dispensing can be considered for clients in GP care, clients with employment arrangements that require flexibility and stable clients living in rural areas where there are logistical difficulties in attending a dispensing service.

Prescribers must specify their safety requirements for takeaway doses in writing, and ensure copies of the requirements are provided to clients and pharmacists.

Prerequisites for granting takeaway doses might include the following stability measures.

- The client has been assessed as being able to take responsibility for their takeaway doses (such an assessment should include consultation with the pharmacist and significant others particularly when children are living in the household).
- Drug-seeking patterns are no longer evident in the client's behaviour.
- Drug screening shows a positive result for the opioid substitution medication prescribed.
- There is evidence of reduction or cessation of harmful or hazardous substance use (prescribed and non-prescribed), including alcohol.
- There is evidence of active participation in treatment (eg, the client has been attending doctor, key worker or primary care provider appointments) and progression towards meeting treatment and recovery goals.
- There is evidence of stability in social roles (eg, in housing, employment, parenting, education, sports, recreation, involvement in local community including voluntary work).
- There is evidence of stable relationships with others (eg, partners, children and other providers).

- Co-existing medical and mental health problems are well managed.
- There is no evidence of engagement in criminal activity.
- The client's home environment is conducive to wellbeing and recovery.

When considering providing takeaway doses, providers should take greater caution when higher doses of methadone (above 120 mg daily) or buprenorphine (above 32 mg daily) or concurrent prescribing of other opioids or benzodiazepines are involved. Restricted dispensing arrangements may be required in these cases.

5.1.1 Diversion

'Diversion' refers to the selling or exchanging of prescribed opioid substitution medication. The risks associated with the diversion of opioids include overdose, injecting related harms such as blood-borne viruses and the potential for new cases of opioid dependence. When assessing a client for suitability for takeaway doses, service providers should consider these risks.

5.1.2 Special circumstances for granting additional takeaway doses

Specialist services may provide takeaway doses for short periods in response to extraordinary circumstances, such as a family crisis, study away from home, planned holidays, unusual employment requirements (eg, working out of town or attending a conference) or an illness that prevents attendance at a pharmacy. In the latter instance it may be appropriate to arrange for a responsible person to act as agent for the client.

When a client requests additional takeaways, service providers should assess the client's stability and safety, the legitimacy of their circumstances and whether the positive effects of allowing short-term extra takeaway arrangements are likely to outweigh the destabilising effects of not allowing it. Providers should consider the needs of significant others in this assessment.

Wherever possible, service providers should encourage clients to nominate out-of-area pharmacies that are willing to dispense during any planned travel away from their regular pharmacy.

Usually clients should have no more than four takeaway doses in hand, although service providers can use their discretion in this regard.

5.2 Notice of prescription changes

Services should provide clients with information on how to request changes to prescriptions. Three days' notice by a client is usually sufficient to manage prescription changes; however, this may not always be appropriate. For example, if services have limited prescriber availability or if a client is travelling overseas (refer to section 5.7: Travelling overseas with opioid substitution medication), a longer period of notice may be required.

5.3 Replacement doses

5.3.1 Lost or stolen doses

Prescribers should not authorise replacement of lost or stolen takeaway doses except in circumstances that can be verified.

5.3.2 Vomited doses

If a client vomits within 30 minutes of consuming their methadone dose, a prescriber may replace the dose. As a general rule, 80 percent of a dose will be absorbed within 20 minutes of oral consumption. Whenever possible, prescribers should verify that a dose has been vomited before prescribing a replacement or part replacement dose. When a client makes repeated requests for replacement doses, the prescriber should review the client's takeaway arrangements.

Some vomiting of methadone doses can occur during pregnancy; this may warrant replacement because of the risk of withdrawal-induced miscarriage. In this case, rather than regularly replacing vomited doses, the prescriber should consider alternative solutions, such as splitting the dose (refer to section 5.6: Split methadone doses and section 6.7: Management of pregnant and breastfeeding women), changing the time of consumption, having the client sip the dose under observation or prescribing an antiemetic.

Due to the sublingual absorption of buprenorphine, vomiting should not affect its uptake.

5.4 Reintroducing opioid substitution medication after missed doses

Tolerance to opioids may be reduced if a client misses repeated doses of opioid substitution medication. This may increase the risk of overdose when the full dose is reintroduced. Service providers should use the following guide to be used.

Number of consecutive doses missed	Action recommended
One or two days	The usual dose can be dispensed, unless the person is intoxicated.
One dose (buprenorphine – alternate day dosing)	The pharmacist should administer the remainder of the dose for the dosing period if the client presents the following day and there is no evidence of intoxication, withdrawal or other clinical issues (eg, a client who usually consumes 24 mg on Monday, Wednesday and Friday but does not present on Wednesday may be given a 12 mg dose on Thursday, followed by the usual dose on Friday). If the client does not present until the next scheduled dosing interval, the normal dose should be dispensed.
Two or more doses (buprenorphine – alternate day dosing)	The prescriber or clinical staff member must assess the client before prescribing another dose as the equivalent of four days will have been missed. See 'Four to five days (buprenorphine)' below.
Three days	The prescriber or another clinical staff member must assess the client before prescribing another dose. Unless there is evidence of intoxication, the usual dose can be given. Alternatively, a half dose may be given that day if there has been no other drug use, and the usual dose resumed the next day.

Number of consecutive doses missed	Action recommended
Four to five days (methadone)	<p>The prescriber or another clinical staff member must assess the client before prescribing another dose.</p> <p>The first reintroduction dose should be 50 percent of the usual daily dose, with the aim of returning to the previous dose within seven days, increasing at a rate of between 10 and 20 mg per day until the previous dose is reached.</p> <p>The prescribing doctor or key worker should monitor the client for signs of sedation or over-medication during the reintroduction period.</p>
Four to five days (buprenorphine)	<p>The prescriber or another clinical staff member must assess the client before prescribing another dose.</p> <p>The first reintroduction dose should be 50 percent of the usual daily dose, with the aim of returning to the previous dose within three days, increasing by up to 8 mg per day (Gowing 2013).</p> <p>The prescribing doctor or key worker should monitor the client during these days.</p>
More than five days	<p>The prescriber or another clinical staff member must assess the client. If either buprenorphine or methadone is to be recommenced, standard induction should occur (refer to section 3.1.1: The starting dose of methadone and section 3.1.2: The starting dose of buprenorphine).</p>

Table adapted from Gowing et al 2013.

Missing doses is not a ground for withdrawing a client from OST unless there are associated significant breaches of the safety requirements of the programme, or evidence that treatment is not achieving a significant harm reduction.

The pharmacist or person administering OST must advise the prescriber or key worker if a client has missed more than one dose or is regularly missing a single dose (refer also to section 9.3.3: Missed doses concerning pharmacists' responsibilities in regard to missed doses).

5.5 Measuring methadone serum levels

Measuring methadone serum levels may be useful when:

- a client's responses to methadone OST does not align with the expected response
- the service provider is considering a change in the daily dose; particularly to a dose above 120 mg
- a client is suspected of poor compliance with the programme, or of diverting their dose (comparison of serum level measurements 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)
- there is doubt about the clinical indications for a dose increase, or the accuracy of reported methadone consumption information
- there is a suspected drug interaction
- the service provider is considering split doses (refer to section 5.6: Split methadone doses)
- a client is pregnant
- a client has serious liver or other physical disease and there may be methadone accumulation.

5.6 Split methadone doses

Split dosing is uncommon; it is mainly limited to cases of fast metabolism, either constitutionally or in pregnancy, or a need to achieve better pain management. Clients with constitutional fast metabolism (estimated at less than 10 percent of people) metabolise methadone rapidly. They may experience adequate peak methadone levels, but not maintain them for a sufficient duration. A peak:trough plasma concentration ratio of greater than or equal to 2:0 will confirm that this is the case.

Split doses frequently improve the treatment of confirmed fast metabolisers, pregnant women or clients requiring pain management, but providers should only consider split doses if a client has demonstrated that he or she is able to use the medication as prescribed and keep safe the unsupervised component of the dose. The client can consume the majority of the dose (at least 60 percent) under observation. Providers may periodically observe consumption of the whole daily dose, or both doses, to confirm continued tolerance (this may mitigate overdose risk in situations where there is poor compliance with unobserved doses and then a sudden resumption of whole-dose consumption; eg, after admission to hospital).

5.7 Travelling overseas with opioid substitution medication

Arrangements for OST during overseas travel may take six weeks to organise, and sometimes longer if the travel involves more than one country. Services should therefore advise clients that, unless their travel is urgent, they need to give adequate notice of their travel intentions. (Individual services may determine the length of notice they generally require of clients in this situation.)

If a client's overseas travel requires him or her 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 possession of opioid substitute medication. The prescription must comply with any special condition related to the entry of a person possessing methadone or buprenorphine to a foreign country. For customs purposes, the service should provide the client with a letter stating that he or she is in possession of OST medication for treatment of a medical condition, including details such as dose and the name and contact number of the prescriber. Service providers should advise clients that despite this precaution, their medication may be taken from them at any border. Clients also need to be aware prior to leaving that if they have a criminal record or any outstanding debts to New Zealand government agencies, they will be profiled and stopped at the border and are more likely to be searched for that reason.

Although New Zealand legislation allows for up to 30 days' supply of OST medication to be prescribed, safety should be a paramount concern when a service provider considers how many takeaway doses to allow a travelling client. If the client is likely to be out of the country for an extended period, providers could consider arranging an appointment with an overseas OST prescriber to ensure continuity of supply.

Prescribers should consider methadone tablets, rather than liquid, for at least a client's hand luggage, to fulfil Customs requirements and avoid leakage. All takeaway doses must remain in their original packaging with labelling.

Specialist services should be receptive to overseas visitors to New Zealand in receipt of OST. They can facilitate access to pharmacies for such visitors, and provide scripts if they have been negotiated with the service in the country of origin.

5.8 Withholding an OST medication dose

If a client's OST medication dose is withheld or cancelled and the OST service is unable to contact them directly, the service should send them a letter outlining the reasons for the cancellation via the community pharmacy (refer to section 9.3.5: Cancelling or withholding doses).

6 Management of clinical issues

6.1 Managing problematic substance use

Multiple substance use is common among people dependent on opioids, particularly at entry to treatment and during the stabilisation stage. Specialist services and general practitioner (GP) prescribers are expected to assist clients with reducing or ceasing use of other drugs (including alcohol) and minimising problems associated with it. However, opioid substitution treatment (OST) services should not focus on abstinence to the exclusion of substance using harm reduction.

Use of other substances, particularly sedatives (such as alcohol and benzodiazepines), in combination with opioids significantly increases the risk of death by respiratory depression, overdose, serious illness and social deterioration. However, this risk is usually less than the risk arising from increasing substance use if OST is withdrawn.

Opioid substitution treatment services must seek to therapeutically engage clients who continue problematic use of alcohol or other substances by monitoring for issues that may exacerbate problems (such as anxiety, depression, cognitive impairment, medical issues, or pain), and by:

- taking a non-confrontational approach
- setting clear expectations about behaviours, with clear rationales
- encouraging honest self-report within a therapeutic client-centred approach
- talking to clients about their own concerns regarding their substance use and associated behaviour
- acknowledging clients' experience and offering support to assist them to address and manage issues.

Due to high rates of co-existing mental health problems, specialist services should undertake routine screening for mental health problems that may influence or contribute to problematic substance use. When a service identifies a mental health problem, it should ensure the client has access to appropriate expertise and treatment. Integrated care is essential for the wellbeing of the client (refer to section 6.5: Managing co-existing medical and mental health problems).

Service providers should give clients and their support people appropriate advice and information about problematic substance use, its consequences and the range of effective interventions available, including information about safe injecting practice.

Clients who are using other substances unsafely should not receive takeaway doses, unless there are exceptional circumstances. In all cases service providers should closely observe such clients' consumption.

Services should provide clients with written summaries of any agreement regarding the consequences of continued problematic substance use (eg, loss of takeaway doses or changes in dispensing arrangements).

6.1.1 Continued opioid use

When a client is not achieving or maintaining stability, the aim should be to optimise treatment by increasing the intensity of the OST rather than reducing it. This approach may also involve ensuring the dose is provided within the therapeutic range 60–120 mg, changing opioid substitutes, increasing case management or psychosocial interventions and increasing supervised consumption.

It is not uncommon for some clients to inject their prescribed medication. This is potentially harmful, despite the fact that the levels of opioids being consumed are likely to be less. Where a service becomes aware of a client engaging in this practice, it should consider restriction of the client's takeaway doses and closer monitoring of his or her other substance use or diversion. In addition, the multidisciplinary team (MDT), including the pharmacist, should review the client's case, in consultation with the client and his or her support people.

6.1.2 Benzodiazepine use

Service providers should advise clients about interactions between benzodiazepines and opioid substitution medication (refer also to section 4.2.1: Benzodiazepines and driving).

Benzodiazepines are commonly used by people with opioid dependence for a variety of reasons, including the relief of withdrawal symptoms. In most cases, once a client achieves stabilisation on OST they reduce or cease regular benzodiazepine use.

Clients who continue to use benzodiazepines problematically require a treatment review, for the service to assess how they can safely continue with OST, including a review of dose and takeaway arrangements. Specialist services need to work with clients who are dependent on benzodiazepines (prescribed or illicit) to offer long-term reduction options, and relapse prevention, where it is clinically indicated. Where mental health problems (eg, an anxiety or mood disorder) are also a factor, services should provide appropriate pharmacological and psychological treatment.

The clinical indications for ongoing maintenance prescriptions for benzodiazepines are very limited, and not supported by the Royal Australian and New Zealand College of Psychiatrists for the treatment of mental health problems. It may be necessary in some instances to prescribe benzodiazepines to clients for reasons other than for dose reduction, but such prescribing should be done with caution. Any prescribing of benzodiazepines in addition to methadone or buprenorphine must be at safe therapeutic levels and supervised to the same high standard as prescription of OST (eg, service providers should supervise consumption of doses).

In order to minimise the risk of drug interactions, services should encourage clients to be honest with other prescribers about receiving OST, and to be honest 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 clients are known to be taking or prescribed. Specialist service providers need to inform clients of this obligation, and it should also be highlighted in service protocols. Specialist services and GPs should be in regular communication. While a client is on OST, medications with abuse potential (including benzodiazepines) should only be prescribed with agreement of the specialist service.

Service providers should inform the Ministry of Health's Medicines Control team if a client is found to be using more than one prescriber, and issue a restriction notice.

6.1.3 Tobacco use

Smoking tobacco is particularly common among people receiving OST. Specialist services and GP prescribers should regularly promote and provide smoking cessation strategies among their clients. Smoking cessation attempts have not been found to negatively affect OST outcomes, and may improve a client's chances of abstinence from illicit opioids in the long term.

6.2 Managing side-effects

The side-effects of methadone and buprenorphine are typical of opioid drugs. The most troublesome include excess sweating, reduced saliva leading to dental cavities (refer to section 6.5.4: Dental health), constipation, sleep apnoea, nausea, drowsiness, osteoporosis and reduced sexual function through loss of libido or impotence. Specialist services need to provide advice to clients on the side-effects of their prescribed medication and on treatments available, and help them to manage these effects (refer to Appendix 4: Side-effects).

6.3 Managing intoxicated presentations

Services should provide guidance to clients and pharmacists regarding clients presenting for doses when intoxicated. As a general rule, clients exhibiting signs of intoxication should not be given their dose, or any takeaway doses, until they are free of symptoms. A pharmacist may refer an intoxicated client to be seen at the specialist service, or ask them to come back later in the day. However, in most cases, it is appropriate to administer half the usual dose, with an instruction to the client to return later in the day, if he or she is no longer intoxicated, for the other half. Twice-daily administration of half doses (dependent on the client not being intoxicated when they present for the second dose) may be a useful time-limited intervention for those who repeatedly present intoxicated.

A partial dose may be appropriate where a pharmacist believes that to deny a dose would risk the safety of pharmacy staff. In such cases the pharmacist should liaise with the specialist service to discuss whether to change the dispensing arrangement and, if threats have been made, whether to involve the police.

Pharmacists should always notify the specialist service when a client presents in an intoxicated state for dispensing (refer to section 9: OST and the pharmacy).

6.4 Managing challenging behaviour

Some clients have significant behavioural and impulse control problems. Realistic expectations, a non-judgemental attitude and patience are essential in the management of such clients. Assisting clients to identify and label emotions and encouraging reductions in impulsiveness may improve clients' functioning and have a positive impact on their therapeutic outcomes.

Treatment should aim to break the familiar cycle of aberrant behaviour, punishment and further problems. Change in an established pattern of behaviour does not happen in a short time; longer durations of treatment are required to produce lasting change with some clients.

Key workers should discuss treatment policies and procedures ('the rules') with clients and their support people, and provide rationales for them upfront. Where a client does not follow a certain policy, the service should review his or her case as soon as possible; a support person should participate in this review wherever possible, to collaborate on minimising adverse consequences and avoiding recurrence. This approach is in keeping with the Code of Health and Disability Services Consumer's Rights 1996; it creates a very different experience for an opioid user accustomed to being treated with punishment or rejection.

Specialist services must acknowledge the imbalance of power between clients and professionals. This imbalance can cause problems, particularly with clients who are very vulnerable or who have difficulty with authority figures. Usually a negotiated consultation style will help minimise the risk. Service providers must endeavour to handle the relationship sensitively, avoiding adversarial interactions with clients who resent their perceived powerlessness.

Providers should record instances of challenging behaviour in clients' clinical notes.

6.5 Managing co-existing medical and mental health problems

A key objective of OST is to improve the health of people with opioid dependence. People with opioid dependence commonly present with a range of co-existing mental and physical health problems. This, combined with the emerging impact of an aging population of people receiving OST, has highlighted the need for primary and specialist services to implement a collaborative system of chronic care management.

Services should undertake a comprehensive assessment of clients' mental and physical health (refer to section 2.1: Comprehensive assessment) on admission to OST, and engage in structured ongoing review and monitoring of clients with persistent co-existing problems.

Specialist services should have frameworks in place for identifying and treating (or facilitating treatment for) co-existing mental health and medical problems. The service's protocols should clearly identify these frameworks, and the service should provide clients with information on the issues of co-existing problems.

If specialist services or primary health care teams are unable to provide pharmacological or psychosocial assistance for co-existing problems appropriate to clients' assessed needs, they need to actively facilitate referral, and advocate for clients to access other services.

The knowledge and skills required to respond effectively to the needs of clients with co-existing problems are outlined in *Te Whare o Tiki: Co-existing problems knowledge and skills framework* (Matua Raki 2013).

6.5.1 Mental health problems

Co-existing mental health problems that have been observed in people on OST include personality disorders, mood and anxiety disorders, and (rarely) psychotic disorders. In particular, post-traumatic stress disorder (PTSD) affects at least one-third of clients on OST; it is usually chronic and complex and compounded by multiple traumatic experiences.

Although mental health problems often improve once a client is stabilised on OST, underlying mental health problems frequently emerge as the chaotic effects and actions of active addiction gradually resolve.

Pharmacological self-management is common; services must explore the function other medications (such as illicitly obtained benzodiazepines) have in clients' self-management of otherwise untreated anxiety, depression and trauma-related issues.

Methadone and buprenorphine may alter the pharmacokinetics of drugs prescribed for co-existing medical and mental health problems. Tricyclic antidepressants have many side-effects in common with methadone, and should be avoided except in low doses for sleep or pain. The selective serotonin re-uptake inhibitors (SSRIs) have reported interactions with methadone, but these are rarely clinically relevant; the combination of methadone with SSRIs is very common, quite safe and often necessary. The most clinically relevant interactions between methadone and psychotropic medications involve the atypical antipsychotics; particularly quetiapine, which can increase QTc (refer to section 4.3: Methadone and cardiac safety). It is not necessary to avoid these medications altogether, but when they are prescribed, service providers should increase monitoring of the QTc interval (refer to Appendix 5: Drug interactions).

Specialist services and primary care providers need to have defined pathways in place for referral and ongoing co-management of clients on OST who require psychotropic medication and mental health care. These pathways should include addiction services, where they are located separately. Ideally specialist services should have the ability to treat people with mild to moderate co-existing mental health problems, as they may require concurrent or sequential interventions for treatment to be effective.

6.5.2 Medical problems

The majority of health risks associated with opioid dependence are related to the injection of foreign material. They include:

- infection of injection sites, which may cause problems such as scarring, thrombosis, thrombophlebitis and cellulitis
- systemic bacterial or fungal infections (usually as a result of non-sterile injecting practices) such as septicaemia, infective endocarditis, pneumonia, osteomyelitis and renal complications (glomerulonephritis)
- acute febrile reaction, often referred to as a 'dirty hit' (usually lasting 24–72 hours) and sometimes associated with rigors and jaundice
- deposits of talc and other extraneous matter in the pulmonary microcirculation, with granuloma formation and fibrosis caused by injection of pharmaceutical tablets
- transmission of blood-borne viruses such as hepatitis C and B, or HIV (refer to section 6.5.3: Blood-borne viruses).

Service providers may need to significantly reduce doses of both methadone and buprenorphine for clients with advanced liver disease. Progressive liver disease, such as that associated with hepatitis C, may require a gradual reduction of previously tolerated doses. Methadone and buprenorphine both undergo extensive hepatic metabolism; a minimal proportion of the dose is excreted unchanged via the kidneys. Service providers should still monitor serum methadone levels in renal failure, to ensure safety.

Service providers should monitor OST doses closely in clients with severe respiratory disease, to avoid respiratory depression or failure.

6.5.3 Blood-borne viruses

In New Zealand, hepatitis B and C are the most common of the blood-borne viruses seen in people with opioid dependence. Long-term health consequences of infection from any of the hepatitis viruses can include liver inflammation, scarring, fibrosis, cirrhosis and, in some cases, liver cancer.

All OST providers should be trained in HIV and hepatitis-related issues, and be able to provide information about blood-borne virus transmission, course and treatment to clients, their support people and other health and social service providers.

It is recommended specialist services offer tests for hepatitis B and C and HIV as part of a client's initial assessment. Services can only conduct testing with informed consent; ideally, they should provide pre-test and post-test counselling.

If a client undergoes these tests, OST providers have a duty of care to interpret the results correctly. Clients who are hepatitis C antibody-positive will likely test positive for life; they will not need to have a repeat antibody test, but will need initial assessment of their liver function and assessment of whether they are actively viraemic, using polymerase chain reaction (PCR) testing. Other useful tests services may consider are viral load and subtype of virus by genotyping. Service providers should monitor liver function tests as clinically indicated but at least annually, or as advised by a local infectious diseases specialist or a gastroenterologist.

Results of hepatitis and HIV testing must remain confidential to the client, the OST provider and the client's primary health care provider. In order to preserve privacy, services should enter a coded descriptor for the client on the blood test form.

Service providers should encourage clients to engage with a primary care provider, and to consent to health information sharing. This should be outlined in the consent for treatment documentation (refer to section 2.8: Informed consent and treatment information).

Service providers should advise clients with chronic hepatitis B or C, or who are suspected of having severe liver disease, of the antiviral treatments available, and should refer them a specialist (eg, a gastroenterologist or infectious diseases specialist) for treatment when appropriate.

Because of the risk of future hepatitis A or B infection, service providers should advise all clients who do not have protective levels of antibody to have a vaccination against these diseases. Providers should also advise clients' significant others to get immunised if they have independent risk factors, such as unsafe injecting practices.

6.5.4 Dental health

Dental health problems are common in people with opioid dependence, and have many causes. Factors associated with poor dental health include the reduced salivary flow associated with opioid use; poor diet (eg, irregular meal times or increased intake of sugar-based foods); poor attendance at the dentist or difficulty accessing dental care; and a lack of regular tooth brushing, flossing or mouth rinsing. In addition, the physiologic condition of opioid abstinence syndrome is a frequent and very common condition causing calcium depletion, contributing to dental problems and at the root of the common belief that methadone 'eats your bones and teeth'.

Specialist services and primary health care teams need to be active in supporting the prevention of serious dental problems by promoting and supporting clients' access regular dental care.

6.5.5 Health issues affecting older clients on OST

As increasing numbers of clients are retained for long periods in OST, a range of health issues related to past substance use and associated behaviours may emerge or become more problematic and complicate clients' usual age-related health issues. Specialist services and primary health care teams should develop and coordinate plans to support the management of specific complications experienced by clients in the 50+ age group, and those who have been on OST for a long period of time.

Issues to look out for include:

- progressive liver damage due to hepatitis B or C or excessive alcohol use (or a combination)
- progressive chronic obstructive pulmonary 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 intravenous access difficult for obtaining blood tests and in emergency situations
- a continued risk of infections such as cellulitis, endocarditis and osteomyelitis (rare in the absence of intravenous use) related to ongoing intravenous use and possibly also related to reduced immune function
- development of QTc interval prolongation as a result of age-related cardiac disease (refer to section 4.3: Methadone and cardiac safety)
- development of heart failure due to cardiac valve damage from past endocarditis
- development of chronic renal failure as a result of past kidney damage
- neurological damage, causing impaired memory and impaired sensory and cognitive functioning
- the risk of drug interactions between methadone/buprenorphine and treatments used for other problems; for example, antihypertensives, hypoglycaemics, antidepressants, antitubercular agents, anticonvulsants and antiretrovirals (refer to Appendix 5: Drug interactions)
- increased risk of low mood and depression and increased risk of suicide, especially in older men
- fatigue
- overdosing as a result of reduced tolerance
- increasing problems with the management of chronic pain related to past injuries and chronic illness
- endocrine problems and an associated risk of osteoporosis, and altered sexual function and lowered testosterone levels (see following paragraph).

Long-term use of methadone and other opioids can cause reduction in the sex hormones, altered sexual functioning and in the long term increased risk of osteoporosis, particularly in men and probably in post-menopausal women. Service providers should monitor these side-effects, particularly in clients who have been in treatment for a long period of time or have a history of fractures: especially those resulting from low trauma events. Providers should give appropriate health advice and arrange investigation, specialist assessment and treatment as required.

In the case of clients on OST who enter long-term residential care (eg, an aged care facility), service providers need to liaise with nursing and medical staff at the care facility to ensure ongoing OST is appropriate and safe (refer to Ministry of Health 2013a).

Note: Buprenorphine has less endocrine effects than methadone. Additionally it causes fewer adverse side-effects than methadone (and morphine) in older people. Service providers should consider transferring clients to buprenorphine as they age.

6.6 Management of acute and chronic pain

6.6.1 Management of acute and surgical pain and the peri-operative period

Addiction may precipitate neurophysiologic, behavioural and social responses that increase a person's experience of pain and complicate provision of adequate analgesia; for example, in the context of an operation. These responses are heightened for clients receiving OST, for whom the neural responses of tolerance or hyperalgesia⁹ may increase their experience of pain. As a consequence, opioid analgesics are often less effective for these clients, and they require higher doses administered at shortened intervals.

With good communication, frequent review and specialist consultation, most clients should be able to receive adequate analgesia. A wide range of non-opioid alternatives are available, including simple analgesics, local anaesthetic, nerve blocks, ketamine, tricyclics and gabapentin. In addition, education and alleviation of anxiety are proven to be beneficial in management of post-operative pain.

When a client on OST undergoes a surgical procedure, hospital staff can administer full OST doses throughout the hospital stay, and give additional opioids as appropriate for the procedure. If hospital staff withhold OST, they will need to meet the client's opioid requirement by adding it to the prescribed regime (eg, by converting the dose to morphine and administering it via patient-controlled analgesia (PCA)). Specialist service medical practitioners can authorise a hospital medical practitioner to continue to treat a client with controlled drugs in the interim if necessary, under section 24(2)(d) Misuse of Drugs Act 1975 (Ministry of Health 2013b, page 10).

Specialist services and primary care providers need to implement a clear policy or memoranda of understanding with hospitals in their region that outlines the protocols for planned and emergency admissions of clients on OST.

Clients should inform their OST provider if they are planning to undergo surgical, medical or dentistry treatment requiring pain medication. The OST provider can then liaise with the health professionals involved to advise them of the client's current OST and pain management. Service providers should ensure the client's medication, dose and dispensing details are correctly documented, in order to avoid dose error or double dosing. Providers should consider possible interactions with medications such as sedatives and anxiolytics (especially if the client has multiple physical problems) (refer to Appendix 5: Drug interactions).

In the case of an emergency admission where a client's OST provider is unavailable, hospital staff should contact the client's pharmacy when the client is next due to consume on the premises. Hospital staff should not dispense any doses of OST medication until they have confirmed both the current dose and the last dose dispensed with the pharmacy.

⁹ 'Opioid-induced hyperalgesia' refers to both a decline in analgesic efficacy during opioid treatment for pain and an increased sensitivity to stimuli in individuals with opioid addiction. It can be difficult to distinguish between opioid-induced hyperalgesia and opioid tolerance. Service providers should advise all clients on opioids for chronic non-malignant pain about hyperalgesia, tolerance and the risk of dependence.

If a client requires a prescription for opioid analgesia on discharge from hospital, hospital staff should liaise with the client's specialist service or primary care provider, and the medication should reduce in a timely manner. Discharge planning should ensure a smooth transition back to the previous OST regime.

Note: Any medical practitioner can prescribe a controlled drug for a person with a substance dependence who requires opioids for reasons other than treating opioid dependence. Such prescribing must take into account the risk of aberrant behaviour, so controlled dispensing (eg, dispensing daily or three times a week) should be considered the norm.

Analgesia for clients on methadone

Opioid substitution medications provide little, if any, analgesia for acute pain because of clients' increased opioid tolerance. Most clients receiving methadone treatment cannot achieve effective pain relief through conventional doses of opioids.

Analgesia for clients on buprenorphine

Additional pain relief from opioids is particularly challenging for clients on buprenorphine, due to the high affinity of buprenorphine for the opioid receptor: buprenorphine may partially block the effects of other opioids. Service providers should seek advice from a pain or addiction specialist.

Until further research is carried out into provision of analgesia to clients on buprenorphine (with naloxone), the best strategy for first-line management in elective and emergency situations may be continuation of buprenorphine throughout the peri-operative or trauma treatment period, with supplemental short-acting opioids. Other options include dividing the daily dose of buprenorphine into four administrations over a 24-hour period (with or without a dose increase), or switching to methadone and managing pain with additional opioids. The client may require careful monitoring in a high dependency unit. If a dose of buprenorphine is withheld for any reason and other opioids have been given in the interim, service providers should seek specialist consultation prior to re-introduction of buprenorphine, in order to avoid precipitated withdrawal (refer to section 3.1.2: The starting dose of buprenorphine).

6.6.2 Management of chronic non-malignant pain

People with chronic non-malignant pain (CNMP) often take prescribed or over-the-counter opioids such as codeine, slow-release morphine, oxycodone or injectable pethidine or morphine. Inappropriate use of these opioids (such as erratic dosing) may play a part in maintaining the degree of poor pain control, or dysfunction they experience.

Clients who have CNMP and use prescribed opioids in an uncontrolled manner may be usefully admitted to OST. Services can assist some such clients by facilitating appropriate dispensing regimes (eg, daily or three times a week dispensing on a 28-day prescription), close supervision and GP follow-up, with oversight from suitably qualified pain or addiction specialists. Opioid substitution treatment services and GP prescribers need to consult with specialist pain management services (preferably before the initiation of OST or any opioid pain relief) about the suitable management of these clients.

Managing people with CNMP who develop prescription opioid dependence

Some people with CNMP may have previously exhibited, or may develop, addictive behaviour for opioids. It is most important that clients with CNMP receive an individualised assessment prior to commencement of opioid treatment. This needs to include a careful and thorough drug and alcohol history, co-existing medical (including musculoskeletal examination) and mental health history, and psychosocial assessment, including a risk assessment for aberrance and self-harm. Treatment plans for such clients need to be comprehensive; opioid prescribing should be regarded as an aspect of treatment rather than the central component of the plan. Service providers should review treatment and examination frequently, and carefully supervise prescription and client progress.

When opioids are commenced for CNMP in a primary care or pain service setting, tool such as Gourlay's 'universal precautions', the DIRE screening tool (refer to Appendix 19) or an Opioid Treatment Agreement (Passik et al 2008) may be helpful in ensuring appropriate client selection. Such tools also make ongoing management of problematic substance use easier.

It can be difficult to distinguish between active addiction and pain-related behaviour, such as seeking additional opioids for the relief of undertreated pain. Service providers should entertain a suspicion of dependence when clients take escalating doses with diminishing relief from distress, claim to have lost prescriptions, request early prescriptions, obtain prescriptions from multiple prescribers or inject tablets designed for oral administration.

Among other things, treatment for CNMP should aim to:

- control and rationalise a client's use of opioids and other medications
- convert the client from parenteral to oral medication
- convert the client from short-acting to long-acting oral medication
- formalise clear lines of responsibility for treatment planning, prescription and monitoring, including through relapse and pain exacerbation plans
- take a multi-disciplinary approach to pain management focusing on non-pharmacological management such as physiotherapy, cognitive behavioural therapy, occupational therapy and sleep hygiene
- maximise benefit from non-opioid medications through regular review and weaning off of any medications or drugs for which the risk/benefit ratio has become unfavourable, or that is being abused. Where new medications are trialled, services should pay particular attention to their abuse potential, and aim to avoid a spiral of escalating pharmacotherapy.

Managing people with CNMP who are receiving OST

A significant number of people entering or already on OST also have chronic pain problems that, if inadequately treated, can impact on their stability in treatment. Genetic links between pain sensitivity and a predisposition to dependence and opioid-induced hyperalgesia are likely contributing factors. Treatment plans for these clients should adequately address the management of CNMP; services should arrange non-pharmacological treatment where possible. Comprehensive and assertive management, with input from both pain and addiction specialists, is recommended. Splitting the dose of methadone into twice daily, or the dose of buprenorphine into four times daily, may result in improved analgesia; however, opioids are not the mainstay of chronic pain management. If a service is providing opioids for the purpose of the treatment of dependence, then stability of opioid use should be the priority. Service providers should consider any request for split dosing in the light of the risks associated with liberal dispensing, and offer it as part of a broader pain management plan that maximises non-pharmacological management.

6.7 Management of pregnant and breastfeeding women

Service providers should give women entering OST who are of childbearing age information regarding the potential for pregnancy even in the absence of a regular menstrual cycle, and advise them about the effects of OST and other substance use (including alcohol and tobacco) on pregnancy. Providers should also inform such women of funding restrictions on the preferred buprenorphine preparation in pregnancy (refer to section 6.7.1: Choice of medication).

Illicit opioid use in pregnancy is associated with maternal and foetal acquisition of blood-borne viruses, preterm labour and delivery, intrauterine growth retardation, pre-eclampsia, placental abruption and intrauterine foetal death. Opioid substitution treatment in pregnancy has been found to reduce illicit drug use, improve maternal engagement in antenatal care and improve neonatal birth weight.

Pregnancies in untreated opioid-dependent women are considered to be high risk; they are associated with increased maternal and infant morbidity. Opioid substitution treatment services should take a collaborative approach to treatment of pregnant clients with obstetric and other services, with the primary goals of:

- engagement in OST and antenatal care
- addressing significant maternal health and social needs
- monitoring the neonate for adverse events at delivery and postnatal substance withdrawal.

Opioid substitution treatment services need to have pathways and established protocols in place for liaising with antenatal and postnatal care teams. Pregnant women who are opioid dependent face significant social stigma. Accordingly, OST staff should take on a consultation and liaison role, making information about the OST (including benefits and risks to the woman, foetus and neonate) available to other specialist addiction service staff, clients and their support people, GPs, nurses, obstetricians, paediatricians, midwives and pharmacists.

6.7.1 Choice of medication

Opioid agonist maintenance is thought to have minimal long-term developmental impacts on children when compared to the risk of maternal heroin use and resulting harms.

WHO 2009

Methadone and buprenorphine (without naloxone) (have been found to improve maternal and foetal outcomes with similar efficacy, although retention in buprenorphine treatment may be reliant on appropriate induction methods. Clinical experience and safety data in the use of buprenorphine in pregnancy have recently increased considerably. No significant concerns have been raised, and the use of buprenorphine is cautiously supported. However, few data remain available regarding the use of the combination buprenorphine/naloxone product.

Buprenorphine may be associated with lower severity of neonatal abstinence syndrome (NAS), indicated by lower levels of pharmacotherapy required for its treatment and shorter hospital stays in neonates; however, this has yet to be clearly established.

For pregnant women entering OST, methadone is currently the preferred treatment, as there is a greater body of data about long-term efficacy and safety with respect to its use in both pregnancy and breastfeeding. Additionally, induction onto buprenorphine necessitates mild withdrawal, which may place a foetus under unnecessary stress, and there is currently no mainstream funding in New Zealand for the buprenorphine mono-product (Subutex®). (See note below for information regarding applications for Subutex® funding.)

Service providers should give newly pregnant women already stabilised on either methadone or buprenorphine adequate information regarding the safety of buprenorphine and methadone in pregnancy, so that they can make an informed decision as to which product to continue with. Ideally, pregnant women should remain on that medication with those on buprenorphine transferring to the mono-product (Subutex®). However, for those women maintained on Suboxone® given the current lack of funding for Subutex®, the most appropriate option is to transfer to methadone. When service providers consider that such a transfer is likely to significantly increase the risk of relapse or other complications such as QTc interval prolongation, or in the case of clients who are adamant that they do not wish to take methadone and there is a risk of withdrawal from treatment, providers should conduct a risk:benefit analysis of the safety of continuing on the combination preparation in full consultation with the client. This should be clearly documented, and take into consideration the following:

- the growing body of evidence for the safety of the mono-product and the lack of published data regarding the combined preparation, compared with the body of data regarding methadone
- the poor bioavailability of naloxone via the sublingual route, and the removal of the contra-indication in pregnancy from the datasheet of the Suboxone® film product in other countries (eg, the United States)
- the comparative risk of illicit opioid use and injecting behaviour upon the pregnancy and foetus
- recommendations regarding breastfeeding (refer to 6.7.6: Breastfeeding).

Note: The prescription of buprenorphine alone (Subutex®) requires a controlled drug form. Services may apply for funding for Subutex® in pregnant and breastfeeding women via PHARMAC's named patient pharmaceutical assessment process; however, funding is not assured.

6.7.2 Dose changes during pregnancy

The dose of OST is not predictive of the incidence or severity of NAS; doses should not be reduced during pregnancy in an attempt to avoid its occurrence. Dose reductions are likely to increase risk of relapse to illicit opioid use, with corresponding greater maternal and foetal risk. The optimal OST dose in pregnancy is the lowest dose that maintains clinical stability.

Methadone metabolism and circulating blood volume may change significantly during pregnancy, leading to lower plasma methadone concentrations and symptoms of withdrawal. A client may require increased doses of methadone, usually in the late second or third trimester. Service providers should review doses in the days to weeks following delivery; reductions may be required to avoid sedation/toxicity. Providers may consider splitting the daily methadone dose into two 12-hour doses in addition to, or as an alternative to, a dose increase, in order to minimise the impact of pre-dose trough levels. Providers should review this decision after delivery, and aim to return the client their once-daily consumption.

6.7.3 Dose reductions and withdrawal

Pregnant women in OST should be encouraged not to cease it while they are pregnant. Although many women want to cease using opioids when they find out they are pregnant, opioid withdrawal is a high-risk option because a relapse to heroin use will affect the capacity to care for the child. In addition, severe opioid withdrawal symptoms may induce a spontaneous abortion in the first trimester of pregnancy, or premature labour in the third trimester. Relapse to heroin use during pregnancy can also result in poorer obstetric outcomes. OST is thought to have minimal long-term developmental impacts on children when compared to the risk of maternal heroin use and resulting harms.

WHO 2009

Women who withdraw from OST during pregnancy have similar relapse rates to those of non-pregnant opioid-dependent individuals who undergo detoxification (around 80 percent in the first six months). As well as increasing the risk of spontaneous abortion and premature delivery, maternal symptoms of opioid withdrawal may result in decreased foetal oxygen supply, passage of meconium and intra-uterine growth retardation. If dose reductions are proposed, they should only be undertaken in the second trimester of pregnancy, and only in small decrements. Dose reduction should not be undertaken if the pregnancy is in any way unstable. The size and rate of reductions should be flexible and responsive to symptoms experienced by the woman.

6.7.4 Management of nausea during pregnancy

Nausea and vomiting are very common in early pregnancy, and should be treated as a symptom of the pregnancy rather than as an opioid side-effect. Service providers should give pregnant clients diet and lifestyle advice as a first-line approach, and reserve medication for those women with more severe symptoms, or problematic vomiting related to consuming OST medications.

Service providers should consider giving the following dietary advice to pregnant clients suffering from nausea and vomiting in pregnancy (BPAC 2011).

- Drink small amounts often – dehydration can exacerbate nausea.
- Trial different kinds of fluids – sometimes fluids such as flat lemonade or diluted fruit juice are easier to manage than water.
- Avoid fatty or spicy food.
- Avoid having an empty stomach – eat a light snack every 1–2 hours between meals.
- Avoid very large meals.
- Early morning nausea may be helped by eating a dry biscuit or cracker before getting out of bed.
- Salty food such as potato chips or salted crackers may help, especially before meals.

A prescribing hierarchy of metoclopramide (first line)/prochlorperazine (second line)/cyclizine /promethazine/ondansetron is usually recommended in treating nausea and vomiting associated with pregnancy. However, OST service providers should note that metoclopramide efficacy may be reduced in those taking opioids, cyclizine is commonly misused and ondansetron is associated with QT interval prolongation.

Service providers should reassure clients that the majority of an oral methadone dose is absorbed within 20 minutes, and that sublingual absorption of buprenorphine is not affected by vomiting after the dose has been taken.

6.7.5 Neonatal abstinence syndrome and neonatal monitoring

Neonatal abstinence syndrome (NAS) is thought to occur in 60–90 percent of neonates exposed to methadone in utero. Similar incidence rates have been found with buprenorphine.

Since the occurrence and severity of NAS is difficult to predict, service providers should monitor all infants of opioid-dependent women for the development of withdrawal symptoms, which generally start within 48 hours of delivery, but may be delayed by up to 7–14 days. Experienced staff should administer a validated scale, such as the Modified Finnegan Scale (Finnegan 1986), to determine the presence and severity of withdrawal.

Where possible, infants of opioid-dependent women should receive follow-up care and monitoring for developmental abnormalities from paediatricians with experience in managing children with in-utero exposure to substances of abuse.

A number of factors have been found to affect NAS expression. Antenatal smoking and use of benzodiazepines are likely to increase incidence and severity. Conversely, breastfeeding and neonates rooming with their mothers rather than in a nursery may ameliorate symptoms.

6.7.6 Breastfeeding

Breastfeeding has many benefits, including mother-infant bonding, nutrition and prevention of childhood illness, and may reduce the severity of NAS. Service providers should encourage opioid-dependent mothers to breastfeed, with the possible exception of HIV-positive mothers, or those using alcohol or cocaine and amphetamine-type substances (WHO 2009).

Methadone is transferred into breast milk at very low levels. The American Academy of Paediatrics classifies methadone as compatible with breastfeeding (American Academy of Pediatrics Committee on Drugs 2001). Service providers should advise women who are breastfeeding while on high doses of methadone to wean slowly, to minimise any risk of withdrawal in the infant.

Buprenorphine is also transferred into breast milk at low levels. As infants swallow milk, absorption of buprenorphine from breast milk would be expected to be minimal, due to hepatic first-pass metabolism; however, the extent of oral bioavailability of buprenorphine in infants is unknown, due to immature hepatic function. The limited data regarding the effects of buprenorphine on the development of breastfed babies suggest it is safe to use; however, a cautious approach incorporating a risk:benefit analysis and fully informed maternal consent is recommended. Like pregnant clients, breastfeeding clients should use the buprenorphine mono-product (Subutex®), to avoid unnecessary exposure of the infant to naloxone.

Useful resources

BPAC. 2011. Nausea and vomiting in pregnancy. *Best Practice Journal* 40: 25–9.

Jones HE, Martin PR, Heil SH, et al. 2008. Treatment of opioid-dependent pregnant women: clinical and research issues. *Journal of Substance Abuse Treatment* 35(3): 245–59.

Ministry of Health. 2007. *New Zealand Smoking Cessation Guidelines*. Wellington: Ministry of Health.

Ministry of Health. 2012. *Communicable Disease Control Manual 2012*. Wellington: Ministry of Health.

Ministry of Health. 2013. *Medicines Management Guide for Community Residential and Facility-based Respite Services: Disability, mental health and addiction*. Wellington: Ministry of Health.

Ministry of Health. 2013. *Prescribing Controlled Drugs in Addiction Treatment: section 24 Misuse of Drugs Act 1975*. Wellington: Ministry of Health.

Ministry of Health. 2013. Residential care questions and answers. URL: www.health.govt.nz/our-work/life-stages/health-older-people/long-term-residential-care/residential-care-questions-and-answers (accessed 25 January 2014).

Passik SD, Kirsh KL, Casper D. 2008. Addiction-related assessment tools and pain management: instruments for screening, treatment planning, and monitoring compliance. *Pain Medicine* 9: S145–S166.

RACP. 2009. *Prescription Opioid Policy: Improving management of chronic non-malignant pain and prevention of problems associated with prescription opioid use*. Sydney: Royal Australasian College of Physicians.

Todd FC. 2010. *Te Ariari o te Oranga: The Assessment and Management of People with Co-existing Mental Health and Substance Use Problems*. Wellington: Ministry of Health.

7 Managing OST transfers

7.1 Transferring between specialist services

Clients on opioid substitution treatment (OST), like other New Zealanders, move around the country for a range of reasons. Unless there are exceptional circumstances, a client on OST should not be disadvantaged in making such a move.

Opioid substitution treatment is most safely delivered by specialist services within the locality where a client is living. In order to avoid the risks of 'out of region' prescribing, all clients transferring from one specialist service to another should be admitted to the service in their new location within three months of relocation. Instances where services are unable to comply with this timeframe will need to be reported to the Director of Mental Health (see 'Variations to practice' on page 3).

In order to reduce problems for both clients and services in the transfer process, specialist services and primary care providers should fully inform clients intending to transfer to another region about:

- possible treatment differences (such as those related to prescribing and takeaway doses)
- the need to be reassessed at the new service
- restrictions on dispensing in the new area
- the time limit of three months for prescribing out of region
- requirements they may have to meet when being prescribed in the new area (such as returning to the service to see a prescriber or key worker)
- the fact that if they are on GP authority with a primary care provider, they may need to be admitted to a specialist service in the new area for a period of time before they are eligible to be transitioned back to GP authority.

The referring service is expected to provide a comprehensive assessment, a current risk assessment, a summary of treatment and a current treatment plan to the new service as part of the transfer documentation. If a client is on GP authority in the originating area, the onus is on the specialist service in that area to provide the documentation, or to elicit the relevant information from the prescriber and client. Services should develop specific documentation for transfers (refer to Appendix 17: Inter-service transfer request for an example transfer document).

Admissions to a new service must not be conditional on discontinuation or withdrawal of any other substance use (including use of illicit or prescribed benzodiazepines). Following a client's admission to a new OST programme, the new service should undertake a routine review of all substance use, and clinically appropriate measures taken to assist the client to cut down or cease other substance use.

Communication between services is essential in the transferring process. While a client is awaiting acceptance into the new service, a clinical staff member from that service should see them at least monthly, or as advised by the originating service, and report back to the referring service.

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

Note: Authorising an 'out of area' GP to prescribe OST medication for a client while they are awaiting transfer acceptance is not recommended.

7.2 Transfers to a prison

When a client on OST is sentenced to prison (or likely to be on remand for longer than three months), specialist services should follow one of the following two pathways:

- a. If the person is in a local prison, the specialist service should either continue to prescribe opioid substitution medication for the person or authorise the prison medical officer to prescribe it (subject to the prison medical officer having undertaken appropriate training). Prescribers should review clients receiving OST in prison at least once every six months. The onus is on the service to organise such reviews, either by telemedicine (all prison services have these facilities) or face to face in the prison.
- b. If the person is in a prison out of area, the specialist service should authorise the prison medical officer to prescribe the opioid substitution medication. The service should then conduct six-monthly reviews by telemedicine. The service should provide the same level of support to the prison medical officer as it provides to GPs on authority (refer to section 8: OST in primary care).

If they are required to prescribe opioid substitution medication, prison medical officers must prescribe in accordance with guidelines in this document, and undertake appropriate training. A minimum requirement should be completion of the *Training Programme for Opioid Substitution Treatment Providers* workbook available from the National Association of Opioid Treatment Providers (2013), alongside training offered by a local specialist service or specifically arranged by the Department of Corrections.

All specialist services in areas where prisons are located should adopt the view that they are responsible for providing training to prison medical staff and medical officers, in the same way they provide training to GPs in the community.

It is recommended that each service allocate time to a designated clinician or clinicians to manage liaison with prisons in respect to clients on remand or sentenced to prison. Ideally those clinicians should also provide psychosocial support to all people receiving OST in prison, regardless of the location of their originating OST service.

Out-of-area clients being released into the local community need to be transferred to a local OST service. Originating services need to provide documentation for this procedure as indicated in section 7.1: Transferring between specialist services.

7.3 Transfers from overseas OST providers

Specialist services should admit clients who have been established on OST programmes overseas and have moved to New Zealand temporarily or permanently as quickly as possible, to avoid abrupt discontinuation of treatment.

Before prescribing commences for a client transferring from overseas, the service will need to have received verified confirmation of dose, copies of assessments and a summary of treatment progress (translated to English where relevant) from the originating country. Such clients must also provide proof of identity.

8 OST in primary care

Integration of opioid dependence treatment into primary care is one way to increase accessibility, although it may not be possible in all settings. Primary care practitioners will usually need support from the specialist system, through mentoring, training, consultation and referral. With such support, patients with quite complex comorbidity can be safely managed in primary care.

WHO 2009

The current service delivery model for opioid substitution treatment (OST) services in New Zealand is centred on specialist services and primary health care teams; entry into OST takes place through specialist services. Opioid substitution treatment aims to support clients to live as normal a lifestyle as possible within the constraints of treatment. For this reason, the primary health care setting is regarded as the logical environment for the long-term management of clients receiving OST.

General practitioners (GPs) work under authority from a specialist service lead clinician, or a specialist service medical practitioner approved by the lead clinician, in accordance with the terms and conditions set out in section 12: Prescribing controlled drugs in addiction treatment. When a client moves to a shared care arrangement with their primary care team, specialist services continue to provide support to clients and liaise with, and provide back-up to, the authorised GP.

A specialist service may transfer a client to an authorised GP to prescribe, administer and supply a controlled drug for the treatment of opioid dependence provided all legislative requirements are met.

8.1 Shared care with the primary care sector

Stabilisation and transfer of clients to shared care with a primary care provider is a key role of specialist OST services. Specialist services should begin planning to refer a client back to the care of their primary care provider at admission to OST, and facilitate this as soon as possible after dose stability has been achieved. If the client is unable to find a GP to offer OST services, the onus is on the specialist service to assist.

Transferring a client to shared care with the primary care sector offers the benefits of:

- allowing specialist services to focus on those with the most need for intensive specialist intervention
- improving social integration, by normalising clients' treatment
- instigating more comprehensive health care for clients.

Before any transfer takes place, clients should participate in a comprehensive review with the specialist service to determine their suitability for transfer.

In a shared care arrangement for an OST client, the specialist service remains responsible for:

- managing the transitional arrangements
- providing documentation to the GP, including an updated comprehensive assessment, a treatment summary and a current treatment and relapse prevention plan
- providing information to assist in any brief interventions the GP may need to implement if the client relapses
- ensuring the authorisation documentation for the arrangement is current and updated
- ensuring that GPs have a clear and immediate line of communication with relevant clinical staff
- conducting reviews (at least yearly) with the GP and the client
- liaising with GPs (at least twice a year) and providing them with ongoing support as required
- accepting the return of any client who becomes ‘destabilised’ and can no longer be managed in a primary care setting notifying and updating pharmacies as to which GPs are authorised to prescribe OST
- supporting the NAOTP training programme for OST providers, and ensuring local GPs and practice nurses have the opportunity to attend any education/training sessions provided by the specialist service.

A GP authorisation is limited to three months, although this period can be extended with the agreement of the Medical Officer of Health within the Ministry of Health’s Medicines Control team on request of a lead clinician (refer to section 12.7.2: Period of GP authority).

Note: Specialist services should not authorise out-of-area GPs (except for prison medical officers when a client is in prison) unless there are exceptional circumstances; for example, the client is in an out-of-area residential treatment programme.

8.2 Requirements of GPs in shared care with a specialist service

General practitioners who have accepted the transfer of an OST client in a shared care arrangement with a specialist service can continue the prescription of opioid substitution medication with the authority of the specialist service’s lead clinician or an approved medical practitioner working in the specialist service (Ministry of Health 2013b). The specialist service will remain the responsible provider; the authorised GP must prescribe the medication in accordance with written terms and conditions (protocols) defined by the specialist service in relation to the specified clients.

Ideally, GPs who are authorised to prescribe OST medication are working within a broader primary health care team. They are expected to undertake training relevant to managing clients receiving OST. At a minimum, this should involve attendance at training provided by the local specialist service and completion of the *Training Programme for Opioid Substitution Treatment Providers* workbook (National Association of Opioid Treatment Providers 2013). Other staff within the practice – in particular practice nurses – should undertake similar training.

There should be a formal, agreed relationship in place between authorised GPs and specialist services, and specialist services should establish protocols for providing advice and consultation to such GPs.

Specialist services must inform clients of the conditions under which responsibility for their care might return to the specialist service.

Clients in a shared care arrangement should have access to the same level of psychosocial support available to specialist service clients. Authorised GPs and other primary care team members should have an awareness of relevant support services, be able to facilitate access to them, and in some cases provide psychosocial interventions to maintain clients' stability (refer to section 3.8: Psychosocial interventions).

Useful resources

National Association of Opioid Treatment Providers. 2013. *Training Programme for Opioid Substitution Treatment Providers*. Wellington: Matua Raki.

9 OST and the pharmacy

9.1 Responsibilities of the pharmacist

Pharmacists fulfil an important function in supporting the community-based management of clients in opioid substitution treatment (OST), working alongside specialist services and general practitioners (GPs) to ensure best care. Community pharmacists are in a unique position in that they have the opportunity to engage with clients on a frequent basis and to form a relationship that can be very important in a client's recovery process.

The responsibilities of the pharmacist as a member of the OST multidisciplinary team are to:

- provide a confidential service that minimises the likelihood of a client experiencing stigma
- ensure all staff working with OST clients have received a minimum level of training in OST
- comply with legislative requirements for the dispensing, recording and storage of OST medications, and use auditable systems that minimise the risk of dispensing and administration errors
- ensure adequate supervision of the consumption of OST doses
- liaise with the OST provider on a regular basis and maintain a communication network with specialist service key workers or nurses, prescribing doctors or GPs and other pharmacists, where appropriate.

A pharmacist should notify the prescriber or specialist service by phone or in writing when a client:

- has missed collecting more than one dose
- presents as intoxicated at the point of dispensing
- exhibits abusive or threatening behaviour
- diverts or makes a serious attempt to divert their opioid substitute medication
- exhibits withdrawal symptoms
- deteriorates in their physical, emotional or mental state.

9.1.1 Providing a confidential service free from discrimination

Pharmacists should ensure that all pharmacy staff are aware of their obligations with respect to maintaining confidentiality and the protection of the health information of OST clients.

Most OST clients have experienced stigma to some extent. Such experiences can lead to feelings of anger, fear, distrust or helplessness, or a sense of being excluded from society. As clients attend pharmacies frequently, this setting has the potential to be a significant source of stigmatising experiences. Pharmacy staff can minimise the risk of such experiences by being aware of the potential for discrimination, taking a non-judgemental, empathic approach to clients and providing a sensitive service; for example, by making available a discreet area for supervised consumption.

Needle exchange is an important public health initiative to control the spread of blood-borne viruses, and its success is dependent on its confidentiality. It is not necessary for community pharmacists to inform OST services of the purchase or exchanging of needles and syringes by people known to be receiving OST.

Supplying injecting equipment provides an opportunity for pharmacists to offer brief interventions with respect to safe injecting behaviour, and the potentially destabilising pharmacokinetic and pharmacodynamic effects of the injection of takeaway doses or illicitly accessed substances. A decline in a client's physical, emotional or mental state is a reason for a pharmacist to contact the treatment team; this may occur in the context of increased injecting behaviour.

9.1.2 Training

Staff dispensing methadone and buprenorphine should have specific training in opioid-dependence treatment. This should include proper storage of controlled medicines, the nature of opioid dependence, the goals of treatment, therapeutic rapport, recognition of opioid withdrawal and intoxication, methods to minimize diversion of medication, and responses to difficult behaviours.

WHO 2009

All pharmacy staff regularly involved in the provision of OST must undergo training. At a minimum, this should involve completion of the *Training Programme for Opioid Substitution Treatment Providers* workbook (National Association of Opioid Treatment Providers 2013), training offered by the local specialist service and/or the online training available at www.blink.co.nz.

9.1.3 Locums

Locums require support to ensure the continuity and quality of service provision to OST clients. Pharmacists should ensure locums have undertaken training in OST, and that all important information regarding particular OST clients (including contact details of key workers and prescribers) and standard operating procedures for OST are readily accessible to locums.

9.1.4 Legislative requirements

As well as complying with the usual legislative requirements for controlled drugs, prescriptions for OST must be written by prescribers with the appropriate authority to prescribe controlled drugs for dependence.

Pharmacists should contact the specialist service upon receipt of OST prescriptions from prescribers not known to them.

Prescriptions for methadone must be written on an H572M form unless services have received notification from the Director General of Health of an exemption. In this case they may be printed and signed indelibly by the prescriber.

Prescriptions for the combination of buprenorphine/naloxone do not require a controlled drug prescription, but prescriptions for buprenorphine alone must be written on an H572 form (regulation 29 (1)(a) Misuse of Drugs Regulations 1977). All preparations of buprenorphine must be stored in a controlled drugs safe.

9.2 The administration and dispensing process

A client can receive their medication either 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 (see Table 5 below for a stepwise description of the recommended dispensing and administration process).

9.2.1 Dispensing

Safe dispensing of OST medication involves ensuring the legality of prescriptions; positively identifying clients (if necessary checking recent photographs provided by the specialist service or prescriber and/or checking photo identification provided by clients); and following correct labelling, record-keeping and filing procedures. Where administration or dispensing instructions are unclear on the prescription, pharmacists must contact prescribers or key workers for clarification.

Opioid substitution medication – in particular, methadone – can cause death from overdose if the incorrect dose is dispensed. Pharmacists must measure methadone preparations accurately, as a small discrepancy in volume can translate to a relatively large discrepancy in dose. For this reason, conical flasks or measuring cylinders should not be used. Acceptable methods for measuring methadone are:

- a self-zeroing dose-measuring pump/burette (eg, Dispensette®); this is especially useful when a pharmacy dispenses more than 10 doses per day. Pharmacists should take care to calibrate this apparatus regularly; errors and discrepancies in controlled drug balances have occurred due to their losing accuracy.
- a syringe (may be in conjunction with an adaptor cap, which fits directly onto the methadone stock bottle).

9.2.2 Takeaway doses

Pharmacists should emphasise to clients the importance of storing takeaway doses of methadone and buprenorphine in a cool place that is out of sight and reach of children (preferably in a locked container). Pharmacies should dispense takeaway doses as individual daily doses, with each day's dose packed in an appropriately labelled bottle with a child-resistant closure. Pharmacists should store takeaway doses in a sealable plastic bag in case of leakage.

Pharmacists should only dilute takeaway doses with water if the prescription specifically requires dilution and instructs the dilution volume or concentration. Labels must accurately reflect the contents of the bottle. Biomed, the manufacturer of Biodone®, makes the following statement regarding dilution: 'If pharmacists dilute with **distilled or purified water** and store in a single use glass or polypropylene bottle for 7 days (or less) at room temperature there should be no impact on product quality'. Note that regional and day-to-day variation in local water supplies means that use of potable water as a diluent is likely to impact unpredictably on product quality.

Pharmacists should note that collection of doses via an agent requires written approval from a prescriber or specialist service key worker. The pharmacist should check the agent's identification before providing the prescription. Where clients are in custody or hospital, pharmacists should direct enquiries about takeaway doses from police or hospital staff to the service or prescriber.

It is unsafe to reuse takeaway bottles, even after washing.

9.2.3 Administering observed consumed doses

Clients receiving OST medication must consume the full prescribed dose under observation at the time of each administration. The procedure should involve the pharmacist:¹⁰

- first checking the client for symptoms of intoxication or withdrawal from opioids or other illicit substances
- accurately measuring the prescribed dose
- giving the methadone dose to the client in a disposable cup (disposable cups must not be recycled, and must be disposed of safely) or giving the (crumbled) sublingual buprenorphine tablets to the client in a medication pottle
- observing the client taking the dose
- if diversion is strongly suspected or observed, notifying the prescriber or specialist service.

9.2.4 Observing for intoxication

Opioid-related overdose deaths in clients receiving OST are usually due to a combination of central nervous system (CNS) depressant drugs, including alcohol, being consumed. Pharmacists are responsible for assessing clients for intoxication prior to administration of the dose and should be able to recognise the signs of intoxication with common CNS depressants (see Table 5).

If a pharmacist observes signs of intoxication in a client, they should not dispense a dose, or any takeaway doses. In this case the pharmacist may either refer the client to be seen by the specialist service or GP, or ask them to come back later in the day when not intoxicated. Whenever a client presents in an intoxicated state, the pharmacist should notify the client's specialist service or GP. The pharmacist may consult with the prescriber as to what action to take.

In extreme circumstances, where a pharmacist feels that to deny a dose would risk the safety of pharmacy staff, an appropriate response may be to administer a partial dose.

¹⁰ A pharmacist or pharmacy technician may administer and observe the consumption of methadone or buprenorphine under the Health Practitioners Competence Assurance Act 2003, which included an amendment to section 8(2)(b) Misuse of Drugs Act 1975 allowing pharmacy technicians to handle controlled drugs. Pharmacists are responsible for ensuring clients are not intoxicated and that correct doses are dispensed prior to technicians administering them.

Table 5: Symptoms of intoxication with commonly used substances

Symptom	Drug				
	Alcohol	Benzodiazepines	Opioids	Cannabis	Amphetamine, cocaine, ecstasy
Ataxia (uncoordinated movements)	•	•		•	
Red eyes				•	
Dilated pupils			• (withdrawal)		•
Disinhibited behaviour	•	•		•	•
Drooling		•			
Hyperactive behaviour					•
Itching, scratching			• (especially heroin, morphine)		
Pinpoint pupils (1-2mm in any light conditions)			•		
Sedation	•	•	•	•	
Slurred speech	•	•			
Smell of alcohol	•				
Tremor	• (withdrawal)				•
Slow breathing			•		
Paranoid thoughts				•	•
Slowed thought	•	•			

Source: Hurley 2010

9.2.5 Minimising the risk of diversion

There is a significant market for diverted opioids in New Zealand; street prices around \$1 per milligram of methadone are reported. There are a number of public health issues related to diversion, including overdose in non-tolerant individuals, accidental ingestion by children and, not the least, potential for creating further opioid dependence. The injection of tablets that have been orally diverted holds particular risk (eg, systemic candida infections). Pharmacists should report all cases of suspected diversion to the prescriber or specialist service.

Methods for reducing the risk of diversion include:

- dispensing to one client at a time
- observing clients swallowing their methadone dose and confirming that the dose has been swallowed by having them speak or drink additional fluid afterwards
- crumbling buprenorphine tablets (this also decreases dissolution time) and observing the client for at least three minutes after sublingual administration
- checking that clients do not carry additional cups/drink bottles at the time of dispensing and do not hold anything in their mouth prior to receiving their dose.

Note: Crumbling tablets prior to administration has not been found to impact on the bioavailability of buprenorphine (Muhleisen 2003 and 2010; Simojoki et al 2010). Pharmacists may break up tablets with a tablet cutter, using a proprietary pill crusher or by applying light pressure with a spatula to the back of the foil strip prior to opening (ensuring tablets are not crushed into powder form, as this will lead to a proportion of the dose being swallowed in saliva). If a pharmacist gives tablets whole, he or she should tip them directly under the client's tongue from a clean medication pottle and observe the client until the tablets are dissolved (4–7 minutes), checking periodically to ensure the tablet remains in the client's mouth.

Table 6: Dispensing and administration process for methadone and buprenorphine

Step	Methadone	Buprenorphine
1	Ensure script is legal and starts on a consumption day; check for any communications regarding changes to dispensing. Correctly identify client, verifying identification if necessary. Assess for signs of intoxication (client should remove sunglasses). Ensure client does not have anything in their mouth (eg, chewing gum) and is not holding a drink bottle or other container.	
2	Measure dose using syringe, burette or Dispensette® into clear, disposable cup. Dispense takeaways as individual daily doses in appropriately labelled containers with child-resistant closures. Do not dilute takeaways unless specifically instructed by the prescriber. Give dose for observed consumption to client.	Break (crumble) tablets to reduce risk of diversion and reduce dissolution time. Place tablets into a clear medication pottle and instruct client to tip tablets under tongue. Advise client not to chew or suck tablets or swallow saliva. If tablets move away from position, instruct client to tip head forward to move them into place under the tongue.
3	Ensure whole dose is taken by having client drink and/or speak after dose. Ask client to place disposable cup into appropriate waste container before leaving, to reduce risk of diversion.	Observe client until satisfied tablets are not able to be diverted (three minutes). If whole tablets are given, supervise client until tablets have dissolved (4–7 minutes) and check his or her mouth periodically during dissolution)
4	Where applicable, hand takeaways to client, checking they are closed properly to avoid subsequent problems with claims of spillage. Ensure client is aware of safe storage requirements, especially if he or she lives with children.	Where applicable, give client dispensed takeaways. Ensure client is aware of safe storage requirements, especially if he or she lives with children.

9.3 Managing other aspects of OST provision

9.3.1 Concurrent non-OST prescriptions and over-the-counter medications

Pharmacists should be aware of the abuse potential of other medications, such as opioids or benzodiazepines, that may be prescribed to OST clients by prescribers other than their OST prescriber, and the risk of interactions between multiple CNS depressant drugs. Pharmacists should also carefully manage requests from clients for over-the-counter medications that may be misused, interact with OST medications or result in positive urinalysis (refer to Appendix 5: Drug interactions and Appendix 6: Approximate detection time for selected drugs in urine).

If a pharmacist has any concerns regarding medicines prescribed to a client on OST, they are entitled under the Health Information Privacy Code 1994 to inform both the OST prescriber and any other prescriber. Pharmacists are strongly encouraged to alert prescribers to clients presenting prescriptions from other prescribers.

Non-OST medications may be dispensed to clients at the same frequency as OST medications; dispensing is funded via registration of the client in the Co-Dispensing for Opioids Service.

9.3.2 Managing challenging behaviour in the pharmacy

Difficult behaviour and difficult situations involving OST clients are a significant cause of concern among some pharmacists. Pharmacists can reduce the likelihood of such situations arising by taking a consistent approach to OST dispensing that maintains firm, professional boundaries and a confidential and non-judgemental service.

When a pharmacist is confronted with challenging behaviour, de-escalation may be sufficient to manage the situation. Pharmacy staff should remain calm, listen to the individual's concerns in an empathic, non-confronting manner, emphasise a desire to help and try to make the individual more comfortable.

Pharmacists should not condone threatening and abusive behaviour by any client. In such a situation, pharmacy staff should follow the pharmacy's internal procedures, and contact police if necessary. Pharmacy staff should report all incidents of difficult or unlawful behaviour to the prescriber or specialist service (refer also to section 6.4: Managing challenging behaviour).

9.3.3 Missed doses

Pharmacies should not replace missed doses unless the prescriber agrees. Although a single missed dose of methadone or buprenorphine is unlikely to cause a client significant discomfort because of the drugs' long actions, some clients, especially those on lower doses, experience withdrawal sooner. In this case pharmacists should assist clients with advice about appropriate symptomatic relief.

Pharmacists should adhere to the following guidelines for missed doses.

- If more than one dose (methadone or buprenorphine) is missed: inform the prescriber or key worker.
- If three consecutive doses (methadone or buprenorphine) are missed: give no further doses until the prescriber or treatment team has assessed the client and authorised resumed dispensing.
- If a single dose of buprenorphine for clients on 'non-daily' consumption is missed: administer the remainder of the dose for the dosing period when the client presents (eg, a client who consumes 24 mg on Monday, Wednesday and Friday but does not present on Wednesday may be given a 12 mg dose on Thursday, followed by the usual dose on Friday) (refer also to section 5.4: Reintroducing opioid substitution medication after missed doses).

9.3.4 Changes to prescriptions

Only prescribers may make changes to prescriptions (eg, altering doses or approving extra/alternative dispensing at different pharmacies with an overlapping script). Key workers may request changes to takeaway doses (eg, frequency of takeaways (usually one-off)), but this needs to be internally signed off according to the individual service's protocols.

Pharmacists should confirm that any authorisation for prescription changes given over the telephone has actually originated from the prescriber by calling back immediately after the authorisation has been received. A written confirmation by fax should follow any telephoned request for changes; this may assist in the timely implementation of authorisation. The pharmacy must receive the original prescription that follows a verbal or faxed authorisation within two working days.

9.3.5 Cancellling or withholding doses

General practitioners, specialist service clinical staff or community pharmacists may cancel or withhold doses of OST medication or change/stop a client's takeaway arrangements in order to:

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

Any health professional who initiates a dose cancellation must notify the client directly. If this is not possible, they must send a letter, via the pharmacy, outlining the reasons for the intervention.

When a pharmacist cancels a dose, he or she 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 it within two business days. Wherever possible, pharmacists should consult with prescribers or key workers before withholding a dose.

9.3.6 Dispensing errors

Pharmacists must have procedures in place to minimise the chances of an error in dispensing. If a client receives a higher than normal dose of methadone, the potential for complications, including death, may be high. With buprenorphine the risk is much lower; however, on becoming aware of a dispensing error in this case, the pharmacist must still alert the client and prescriber, following the procedure outlined below so that appropriate monitoring and actions (such as reducing or stopping the following days dose) can occur.. Pharmacists should immediately report all suspected errors to the client and the prescriber or specialist service. They should inform the client of the need for urgent medical assessment, and call an ambulance if necessary.

Underdosing

Where a pharmacist has administered less than the prescribed dose, he or she must give the balance on the same day or not at all. The dispensing pharmacist must notify the client 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.

Overdosing

Where a pharmacist has administered more than the prescribed dose, he or she must follow this procedure.

- The pharmacist must immediately advise the client of the error and the need for them to be medically assessed within 3–4 hours. The onus should not be solely on the client to seek medical assistance. The pharmacist, the prescriber or the specialist service key worker may need to facilitate a medical assessment.
- The pharmacist must warn the client of the risks associated with extra drug use, and against driving or operating machinery.

- The pharmacist should immediately contact the prescriber or specialist service, who may decide that the client requires hospitalisation. Following such a decision, the pharmacist should either telephone for an ambulance and keep the client at the pharmacy until it arrives, or accompany the client to the hospital to ensure that admitting staff receive clear information on the circumstances.
- If the client has left the pharmacy 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 to request they seek a medical assessment as soon as possible. If the pharmacist is unable to contact the client, the responsibility to continue to attempt contact will sit with the prescriber (or delegated person). The pharmacist should also notify the prescriber in writing of the incident and any actions taken (refer also to section 4.1: Overdose).

Caution: Inducing vomiting may be dangerous, and is contraindicated if a 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 whether the entire dose has been eliminated.

Common sources of dispensing errors include:

- misidentification of clients (eg, confusing clients with similar names). Pharmacists should ensure appropriate identification (such as a photograph) is accessible to all staff working with OST clients, and place warnings in files and dispensing software where client names are similar
- failure to notice dose changes on prescriptions. Pharmacists can use a day book or diary to record such changes and pass on important information to other staff
- confusion of mg/ml doses for methadone. Where a dose appears unusual or large, pharmacists should double check the prescription, and note the correct dose in files and dispensing software.

10 The OST workforce and professional development requirements

10.1 The OST team

Opioid substitution treatment (OST) specialist service teams should ideally include a range of disciplines and roles, including a programme manager, a lead clinician, medical officers, psychiatrists, nurses, social workers, addiction counsellors, support workers, psychologists, consumer advisors, peer support workers, administration staff and an onsite or community pharmacist. In a primary care or general practice setting, the team usually consists of a general practitioner (GP), practice nurses, other allied health professionals, administration staff and a pharmacist. Some primary health organisations (PHOs) and primary care teams also employ addiction specialists. The specialist service key worker, or PHO/GP liaison person, should also be seen as part of the primary care team.

Services not able to employ peer support workers to work alongside clients need to assist their clients to access this type of support from outside the service.

The specific and complementary roles of key OST team members are detailed below.

10.1.1 The lead clinician

All specialist services are required to employ a lead clinician approved by the Director of Mental Health (see Ministry of Health 2013b). To be approved as a lead clinician under section 24(7)(a) Misuse of Drugs Act 1975 a person must be a senior specialist service medical practitioner involved in the treatment of addiction with controlled drugs, and at a minimum must demonstrate the qualities and skills outlined under section 10.2: Workforce training and professional development (refer also to section 12.5: Criteria for appointment of lead clinicians under section 24(7)(a) MODA).

10.1.2 The key worker/case manager

Opioid substitution treatment key working (or case management) is more than planning and coordinating delivery of service; it involves a therapeutic relationship with each individual client, frequently over a long period of time, within the context of their life situation. When a client is transferred to a GP working under authority from a specialist service, the GP or other member of the primary care team may become the lead key worker.

The primary tasks of the key worker are (but are not limited to):

- assisting clients to work towards negotiated goals of sustained reduction of, or abstinence from, opioids and other substances (including alcohol and nicotine)
- assisting clients to identify strategies to achieve their recovery goals
- supporting clients to develop a relevant supportive social network including linking with whānau and service providers that could help in their recovery
- providing psychosocial interventions or making arrangements for their provision
- coordinating and monitoring implementation and ongoing updates of clients' treatment plans
- implementing systems to ensure treatment progress using the various tools available for monitoring progress (eg, formal treatment review, random urine drug testing and outcome monitoring)
- liaising closely with other members of the OST team especially the prescriber and pharmacist
- maintaining comprehensive and confidential records and storing them securely
- facilitating involvement of peer support
- maintaining current information about local services and treatments clients may require (eg, managed withdrawal, hepatitis C treatments and support groups).

10.1.3 The prescriber

The prescriber is a specialist service lead clinician or medical officer, a GP prescribing under the authority of a specialist service or a gazetted GP. Nurse practitioners are expected to be able to prescribe OST medication in the near future.

Overall, the prescriber is responsible for effective and safe prescription of opioid substitution medication (refer also to Appendix 16: The prescribing process). He or she will:

- prescribe and assess dose suitability as required (note: local protocols vary in regard to the ability of GPs prescribing under authority to alter doses)
- implement systems (eg, takeaway regimens) that minimise risks for clients, the workforce and community
- liaise with other members of the specialist services or primary care team; especially the key worker
- refer clients for specialist treatment of problems not able to be treated within the OST service or primary care setting (eg, hepatitis C, pain or mental health issues) and liaise with relevant health professionals to ensure concurrent treatments occur within an integrated framework
- ensure arrangements are in place for dispensing over public holidays and other arranged holidays that take into account relevant safety issues
- arrange continued treatment for clients travelling overseas, considering safety issues and restrictions related to opioid substitution medication in the countries to which they will travel
- maintain comprehensive and confidential records and ensure they are stored securely and in accordance with current legislation (the Health (Retention of Health Information) Regulations 1996)
- if a GP, attend to the other health needs of clients, including injecting-related infections, sexually transmitted diseases and hepatitis C.

10.1.4 The practice nurse

The practice nurse, as part of the primary care team, will interact with clients on a regular basis as they collect prescriptions or attend GP appointments. The nurse has a key role during these interactions in identifying and addressing lifestyle and health-related issues and supporting clients to address them.

In addition to informal monitoring of the client on these occasions, the practice nurse may also assist with formal treatment review, completing or assisting the client to complete appropriate health surveys or other assessment tools.

10.1.5 The prison nurse

The prison nurse has a key role in monitoring prisoner/clients' progress and stability in terms of their OST. The nurse administers opioid substitution medication to prisoner/clients, and institutes procedures to minimise the risk of diversion. In addition, the prison nurse liaises with the provider service with regard to medication on a prisoner/client's arrival and pending release, and in regard to medical or mental health concerns.

10.1.6 The community pharmacist

Community pharmacists are important members of the OST team, as they see clients regularly and frequently (refer also to section 9: OST and the pharmacy). Because of the relationship the pharmacist has with the client, he or she can play a key role in clinical monitoring. Part of this role is to maintain close communication with other members of the specialist service and primary care teams, in particular when:

- the pharmacist has concerns about a client's wellbeing; for example, where the client presents with signs of intoxication or withdrawal or has deteriorated in their physical, emotional or mental state
- a client is not meeting the agreed requirements and conditions of their treatment; for example, misses doses, is thought to be diverting their opioid substitution medication or exhibits abusive or threatening behaviour
- a client is withdrawing from OST.

The pharmacist may also be required to supply urinalysis and blood test forms to clients if a prescriber requests them. Pharmacists should understand the rationale for such tests (eg, the requirement for urinalysis samples to be taken randomly).

In some areas, pharmacists fulfil additional roles, such as passing on messages from a prescriber to a client. This is a goodwill role; prescribers should be mindful not to treat pharmacists as postal services.

10.1.7 The consumer and peer workforce

Recovery orientated service provision relies on a greater emphasis on peer support for long-term recovery management.

White and Mojer-Torres 2010

The consumer and peer workforce involves a number of roles carried out by people with a lived experience of addiction. These roles can include peer support, advocacy and advice/consultancy.

Peer support workers work alongside clients in their recovery by providing relevant information and support and assisting them to connect with community supports and advocacy services. In addition, they consult and work with service providers, providing a service user perspective and promoting consumer rights and resources.

The consumer advocate role involves assisting clients to express their ideas and concerns, access information and services, defend and promote their rights and responsibilities, and explore choices and options. Consumer advisor/consultants operate at organisational and policy levels to promote service user perspectives and voices in service policies and practice (Matua Raki 2010) (refer to Appendix 10: Recovery-orientated treatment).

10.2 Workforce training and professional development

Clinical staff members in a specialist service must receive appropriate orientation, mentoring and supervision to enable them to develop experience and a high level of competence in the provision of OST. In some cases – especially that of smaller services – this may need to come from outside the service itself.

As a general guide, specialist service staff will have, or will be working to develop, the following qualities and skills:

- a knowledge of the principles of the Treaty of Waitangi, and its implications for clients
- an understanding of the inherent power imbalance in the relationship between a client and an OST provider
- a positive, recovery- and wellbeing-focused, client-centred and non-judgemental approaches and attitude
- a willingness to work with all clients, regardless of race, ethnicity, age, disability, sexual orientation, gender or health status, and experience or skills in working with diversity
- an inclusive attitude towards clients' support people
- flexibility in their approach to treatment, and a focus on treatment retention
- an awareness of key documents and publications relevant to OST and co-existing mental health and medical problems
- an understanding of and willingness to challenge stigma associated with addiction and OST
- a willingness to undertake further education in addiction, including study towards a relevant postgraduate qualification.

To ensure professionalism and consistency of service delivery, all OST clinicians are expected to demonstrate commitment to ongoing addiction treatment education, as follows.

- Senior clinicians (including doctors) and key workers in specialist services are expected to have, or be enrolled in study towards, relevant addiction qualifications (ideally postgraduate) or be experienced in the addiction treatment sector.
- Gazetted doctors are expected to have completed, or be enrolled in, relevant addiction postgraduate training.
- Authorised GPs (including prison medical officers), practice nurses and prison health nurses are expected to have received training in OST prescribing and client management. General practitioners are also expected to enrol in any local OST training and liaison events developed specifically for their sector.

- Pharmacists are expected to have completed training in dispensing OST medication.
- All clinical and medical staff working with clients on OST are expected to have completed the *Training Programme for Opioid Substitution Treatment Providers* workbook (National Association of Opioid Treatment Providers 2013).

Additionally, all specialist service clinical staff need to:

- receive regular clinical supervision
- have (or be supported to attain) a relevant tertiary qualification
- be a registered health practitioner with the Addiction Practitioners' Association of Aotearoa-New Zealand (dapaanz), or another relevant professional body, or be supported to work toward professional registration
- receive ongoing training in:
 - these guidelines and any local protocols pertaining to OST
 - the assessment and management of co-existing mental health problems
 - the management of co-existing physical health problems common in people with opioid dependence
 - the management of problematic substance use
 - the pharmacology and pharmacokinetics of opioids and drug interactions
 - recovery-orientated OST
 - Whānau Ora and family-inclusive practice.

Lead clinicians and medical practitioners must be members of appropriate professional organisations, such as the section of Addiction Psychiatry within the Royal Australian and New Zealand College of Psychiatrists or the Australasian Chapter of Addiction Medicine in the Royal Australasian College of Physicians, and be involved with the National Association of Opioid Treatment Providers (NAOTP).

In order to maintain proficiency in their field, services should support lead clinicians and senior staff members to attend specialist sector meetings and networking opportunities with other OST providers.

It is expected that services will support staff in leadership/management positions and medical officers working in OST to attend at least one NAOTP meeting each year, and senior medical staff who have influence in policy development in their services to attend the majority of NAOTP meetings.

Useful resources

Matua Raki. 2010. *Consumer and Peer Roles in the Addiction Sector*. Wellington: Matua Raki.

White WL, Mojer-Torres L. 2010. *Recovery-Orientated Methadone Maintenance*. USA: Great Lakes Addiction Technology Transfer Centre, the Philadelphia Department of Behavioural Health and Mental Retardation Services, and the Northeast Addiction Technology Transfer Centre.

11 Administrative expectations of specialist OST services

11.1 Record-keeping

Specialist opioid substitution treatment (OST) services must hold a record for each client that includes (but is not limited to):

- the client's National Health Index number, demographic information, current address and telephone number
- consent forms (for treatment and disclosure of personal information)
- a comprehensive assessment (including diagnoses) and treatment plan
- current treatment plans and progress notes
- a risk management plan (if appropriate)
- details of any contact with the client, including review summaries
- details of any variation to practice recommended in these guidelines
- laboratory test results
- the client's dose of OST medication, dispensing arrangements and pharmacy details
- the name of the client's current key worker and prescriber
- a complete and accurate medication record, including copies of controlled drug prescriptions (copies of non-controlled prescriptions should also be kept, where they are not held electronically)
- GP authorisation forms
- documentation of transfer between specialist services and primary care or prison
- restriction notices under section 25 Misuse of Drugs Act 1975 or section 49 Medicines Act 1981
- date of discharge, and factors involved in involuntary discharge, if relevant.

11.2 Reporting requirements

Specialist services must send complete, timely and accurate information on clients to the Programme for the Integration of Mental Health Data (PRIMHD). Additionally, every six months specialist services must provide the Director of Mental Health with statistical data related to a range of key areas. Templates are provided to all services by the Ministry of Health for this purpose.

11.3 Rights of people receiving OST

Consumers receive safe service of an appropriate standard, complying with consumer rights legislation; services respect consumer rights, facilitate informed choice, minimise harm and acknowledge people's cultural and individual values and beliefs.

Health and Disability Services (Core) Standards NZS 8134.1:2008

Services must supply all clients with information about:

- their rights under the Code of Health and Disability Services Consumers' Rights 1996
- peer support and consumer advocacy contacts
- limits of confidentiality under the Health Information Privacy Code 1994 (ie, situations under which the specialist service may need to break confidentiality)
- the range of treatment options and psychosocial interventions available
- OST medication pharmacology, side-effects and drug interactions
- the service's policies and procedures, including the complaints procedure.

11.4 The complaints procedure

Specialist services must implement a complaints management system that is easily accessible to clients and complies with legislation (including the Consumer Guarantees Act 1993 and the Human Rights Act 1993). The complaints management process should be linked to the service's quality and risk management system, to facilitate feedback and improvements in service delivery.

Services should inform all clients about the range of mechanisms available for making a complaint (including to the Health and Disability Commissioner) and their right to an independent advocate/support person. This information should be displayed prominently.

Due to the long-term nature of OST and the lack of options in regard to changing treatment providers, some clients may be concerned that making a complaint will affect their relationship with the specialist service and compromise their 'privileges'. The complaint process must therefore be sensitive to clients and respect their values and beliefs. Where client advocacy services are available, services should advise clients of the role of advocates in supporting the resolution of conflicts, and in the complaints procedure.

Services should not keep records of complaints in clients' clinical files.

11.5 Safety requirements of specialist services

The Health and Disability Services (Core) Standards (NZS 8134.1:2008) set out safety requirements for specialist services. (These standards amalgamate mental health and addiction service requirements.)

Each service should work to a set of safety requirements that addresses the personal safety of clients and staff, as well as safety in prescribing and dispensing doses, including takeaways. Services should discuss these safety requirements with clients and their support people where possible, as part of initial assessments and whenever relevant.

11.6 Local protocols in specialist services

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

Services' local protocols should outline the following aspects of their service delivery:

- clients' access to OST
- managing waiting lists
- managing pregnant and breastfeeding women
- managing clients requiring pain relief
- managing clients suspected of diverting opioid substitution medication
- transferring clients to the care of their primary care provider
- transferring clients between specialist services
- managing clients sentenced to prison
- reviewing progress on agreed goals
- pathways for clients seeking treatment reviews
- managing clients ending OST (both planned and involuntarily)
- accessing psychosocial treatment
- treatment of co-existing medical and mental health problems
- managing blood-borne viruses
- managing the needs of older clients
- advising clients on driving and OST
- reviewing safety and risk issues
- measuring treatment outcomes.

11.7 Civil defence emergencies

Specialist services should have a management plan in place in the case of civil defence emergencies, including a plan with local pharmacies for ensuring continuance of medication supply.

11.8 External review and service audits

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

The *Service Audit and Review Tool: Opioid Substitution Treatment in New Zealand* (Ministry of Health 2011 or any updated version) is available from the Ministry of Health's website: www.health.govt.nz. The Ministry of Health encourages services to undertake self-audits and peer review using this tool with the goal of improving the quality of OST provision.

Services may consider having a member of the National Association of Opioid Treatment Providers on their self-audit review team. The association works together with specialist services will coordinate and progress matters of mutual interest in the provision of OST, such as access, waiting lists, transfers between specialist services, involuntary withdrawal, variations to these practice guidelines and agreed clinical protocols.

Useful resources

Ministry of Health. 2011. *Service Audit and Review Tool: Opioid Substitution Treatment in New Zealand*. Wellington: Ministry of Health.

12 Prescribing controlled drugs in addiction treatment: section 24 Misuse of Drugs Act 1975

The document *Prescribing Controlled Drugs in Addiction Treatment: Section 24 Misuse of Drugs Act 1975* (Ministry of Health 2013b) has been integrated into these guidelines. The Ministry of Health advises that it should be read by opioid substitution treatment (OST) services alongside these guidelines and other relevant best-practice guidance.

12.1 Operation of section 24 Misuse of Drugs Act

Prescribing Controlled Drugs in Addiction Treatment provides guidance to help addiction treatment services comply with section 24 Misuse of Drugs Act 1975 (MODA). Section 24 applies when a medical practitioner prescribes a controlled drug as a treatment for a person's addiction to that or any other controlled drug.

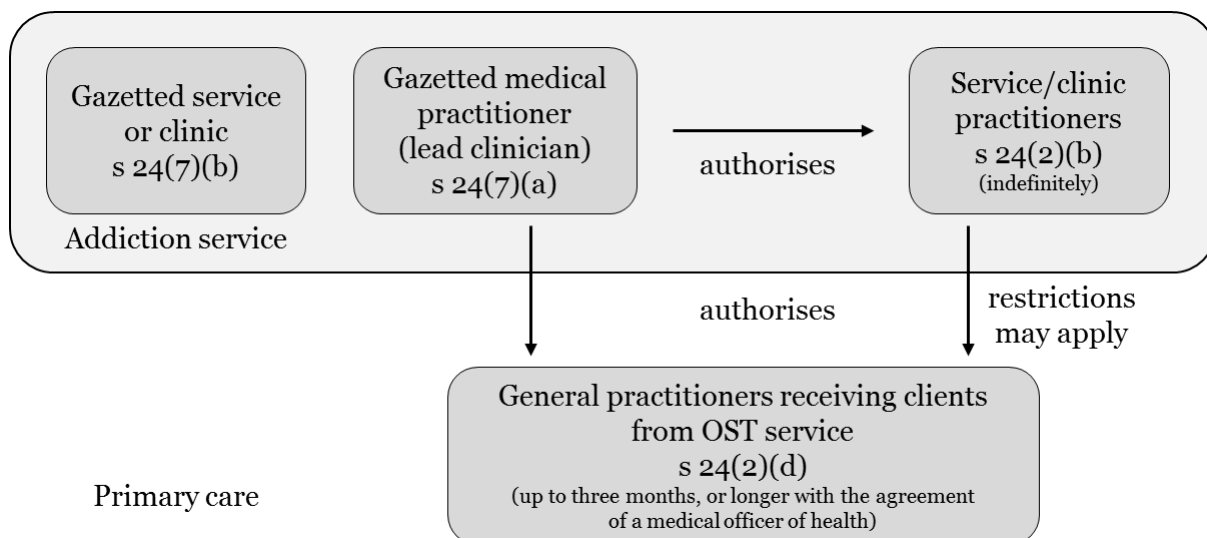
Section 24 MODA governs the prescription of controlled drugs for the treatment of addiction to a controlled drug or drugs. The Minister of Health has the power to specify which medical practitioners and services can prescribe controlled drugs for the treatment of addiction (section 24 is reproduced in these guidelines as Appendix 15).

The Minister can issue a *New Zealand Gazette* notice under section 24(7) specifying:

- a medical practitioner (s 24(7)(a))
- a service, by listing the clinics and other places constituting that service (s 24(7)(b)).

Within a typical specialist addiction service and the service's area of geographical responsibility (typically a district health board (DHB)), only the specialist service and its lead clinician should be specified in the *Gazette*, unless there is a good reason for approving another service and/or medical practitioner. Normally, specialist services are approved under section 24 to provide OST.

The following figure provides the model for service provision under section 24 MODA.



Section 24 envisages a suitable medical practitioner taking clinical leadership of addiction treatment with controlled drugs. This person is specified in a *Gazette* notice, and granted the power to approve other medical practitioners to prescribe controlled drugs for addiction treatment, either within a specified specialist service or in primary care. The clinical lead is responsible for ensuring that any medical practitioner he or she authorises has the knowledge and skills to undertake the tasks delegated to them.

Specialist services must send a copy of all authorities signed by the service's lead clinician (both specialist service medical practitioners under section 24(2)(b) MODA and shared care general practitioners (GPs) under section 24(2)(d) MODA) via courier or standard post to:

Medicines Control
 Provider Regulation
 Clinical Leadership, Protection and Regulation
 Ministry of Health
 PO Box 5013
 Lambton Quay
 Wellington 6145

The gazetted lead clinician can approve:

- medical practitioners working within the specialist service indefinitely section 24(2)(b) MODA
- medical practitioners working in primary care (eg, GPs) for up to three months, or longer with the agreement of a Medical Officer of Health section 24(2)(d) MODA.

Conditions may be attached to a *Gazette* notice specifying a medical practitioner. These conditions may include, but are not limited to:

- the nature of the addiction the medical practitioner can treat
- the particular controlled drugs the medical practitioner can prescribe
- a period of time for which the medical practitioner is approved
- the specified service or services in which the medical practitioner can operate
- limitations or conditions on the medical practitioner's ability to approve other medical practitioners as authorised prescribers.

12.1.1 Alternative forms of service provision under section 24 MODA

In some areas, someone other than a DHB addiction service organises section 24 prescribing. Appropriate collaborations between DHBs and primary care providers or non-governmental organisations can be beneficial for consumers of addiction services. They may enhance service provision by creating choice for consumers and improving integration between specialist services and primary care providers.

The Ministry of Health supports discussions among specialist services and primary care providers on innovative ways to improve prescribing for dependence under section 24 MODA. Emerging arrangements can be supported by *Gazette* notices under these guidelines where appropriate, to ensure that section 24 prescribing takes place under the clinical supervision of a suitably qualified person. Discussions should initially take place at the local level.

12.2 Protocol – designation of specialist services

The Director of Mental Health has the power to designate a specialist service under section 24(7)(b). The Director will designate a specialist service in accordance with the protocol set out below.

- a. An appropriate senior staff member within a specialist service, such as a clinical leader, service manager, chief executive or other senior manager, fills in an application form (refer to Appendix 12: Application to be specified as an addiction treatment service prescribing controlled drugs for dependence (section 24(7)(b) MODA) or Appendix 2 of *Prescribing Controlled Drugs in Addiction* Ministry of Health 2013b) and send it to the Director of Mental Health.
- b. The Director assesses the application and determines whether the service is able to give effect to relevant Ministry policies, including:
 - these guidelines
 - the *Let's get real* framework (Ministry of Health 2008a)
 - relevant service specifications, including the National Health Board's Alcohol and Other Drug Treatment Opioid Substitution Treatment Tier Three specifications.
- c. The Director approves or declines the application.
- d. If the application is approved, the Director issues a *Gazette* notice.

A designated specialist service has a continuing obligation to comply with relevant guidelines, standards and specifications. If a designated service feels that it may fail to meet the obligations above, a clinical leader or service manager should contact the Director of Mental Health to work through the issue. In some situations the Director may revoke the *Gazette* notice that approved the service.

12.3 Protocol – designation of lead clinicians

The Director of Mental Health has the power to designate a lead clinician under section 24(7)(a). The Director will designate a lead clinician in accordance with the protocol set out below.

- a. A senior clinical leader, chief executive or other senior manager nominates a lead clinician for a specialist service by writing a letter of recommendation to the Director of Mental Health.
- b. The nominee completes an application form (refer to Appendix 11: Application to be specified as a medical practitioner prescribing controlled drugs for dependence (section 24(7)(a) MODA) or Appendix 1 of *Prescribing Controlled Drugs in Addiction* Ministry of Health 2013b) and the nominee and nominator sign it. A curriculum vitae and appropriate references must be attached to the application form.
- c. The Director of Mental Health assesses the application and determines whether the person will be able to meet the lead clinician criteria (see below) and give effect to relevant practice guidelines. The Director consults the Ministry of Health’s Medicines Control team as part of this process.
- d. The Director approves or declines the application.
- e. If the application is approved, the Director issues a *Gazette* notice specifying the lead clinician and any conditions that attach to the approval.

As the Director can attach conditions to the designation of a lead clinician, a *Gazette* notice will normally expire after several years. During the term of the notice, the lead clinician has a continuing obligation to comply with the appointment criteria. If he or she is unable to comply, the Director may not renew the designation, or may revoke it.

12.4 Departure from appointment protocol

Some established services or medical practitioners may not fully meet the criteria for approval for a number of reasons, including geography, unique service structure and availability of resources. The Ministry of Health continues to support the emergence of novel service structures that can enhance an area’s provision of addiction treatment. The Director of Mental Health will therefore consider departures from the protocols described above on a case-by-case basis.

12.5 Criteria for appointment of lead clinicians under section 24(7)(a) MODA

The main criteria for medical practitioners to be specified as lead clinicians under section 24(7)(a) are derived from the following key values for addiction services:

- a recovery focus, which contributes to consumers living full and meaningful lives in the presence or absence of their addiction
- excellent services, focused on safety and the needs of consumers
- respect for consumers and their personal and cultural values
- giving effect to human rights, to protect or enhance a consumer’s dignity or mana
- reflecting the importance of relationships with consumers, to support and enhance relationships between consumers and the community.

The Director of Mental Health will consider other relevant criteria on a case-by-case basis.

To be considered for approval as a lead clinician under section 24(7) (a), a person must be a senior specialist service medical practitioner involved in the treatment of addiction with controlled drugs. At a minimum, they must meet the expectations of specialist service staff outlined in section 10: The OST workforce and professional development requirements and aim to give effect to all relevant aspects of these guidelines in their service.

12.5.1 Lead clinicians' responsibility for service quality

Lead clinicians should pursue service excellence by:

- promoting best clinical practice
- developing an organisational culture that is focused on a consumer-driven, evidence-informed, collaborative vision
- working with staff to promote a healthy, culturally safe workplace
- advocating for professional development for all staff
- creating and maintaining processes and activities that promote effective supervision, evaluation, coaching and support for all staff
- advocating for sufficient and appropriate resources.

12.5.2 Lead clinicians' responsibility for professional development

Lead clinicians should:

- hold appropriate qualifications and membership in specialist sector organisations
- maintain proficiency in their field by attending and contributing to specialist sector meetings and undertaking continuing education where appropriate.

12.5.3 Lead clinicians' responsibility for consumer focus

Lead clinicians should pursue a culturally appropriate, user-focused service by:

- creating and supporting organisational systems and a culture that is grounded in recovery, including peer support
- promoting and advocating for continuing cultural education, including Māori workforce development
- ensuring that all aspects of the service demonstrate unique Māori perspectives of health and health service delivery
- promoting non-discriminatory practice and implementing policies that examine and challenge stigma and discrimination
- ensuring effective communication with all consumers.

12.5.4 Lead clinicians' responsibility for managing relationships

Lead clinicians should demonstrate the importance of relationships for consumers by:

- creating and participating in community networks of relevant health and social service providers
- promoting and supporting integration between the specialist service and consumers' primary health care providers, including through a primary health care clinical coordination role
- leading and influencing others in developing positive relationships with whānau, hapū, iwi and communities
- creating and supporting participatory processes that reflect the importance of family, whānau and other social supports to consumers.

12.6 Operating a specialist service in compliance with section 24 MODA

Each specialist service prescribing controlled drugs for the purpose of addiction treatment must:

- be an approved service under section 24(7)(b) MODA
- employ a lead clinician approved under section 24(7)(a) MODA.

A medical practitioner does not become authorised to prescribe controlled drugs for addiction treatment by virtue of being employed by an approved service. Every medical practitioner prescribing controlled drugs for addiction treatment must be either:

- approved as a lead clinician under section 24(7)(a) MODA
- working in an approved service and authorised by the lead clinician under section 24(2)(b) MODA or
- working in primary care, in a relationship with the approved service, and authorised by the lead clinician or an authorised specialist service medical practitioner under section 24(2)(d) MODA.

12.6.1 Medical practitioners working within an approved service

A lead clinician can authorise any medical practitioner working within an approved service to prescribe controlled drugs for addiction treatment. This authorisation can last indefinitely, but in practice the lead clinician should review the authorisation regularly.

An authorised practitioner should as a minimum meet all of the criteria outlined in section 10.2: Workforce training and professional development. . Regular review of the practitioner's approval should involve an assessment of the practitioner's professional development, including continuing education and participation in appropriate clinical networks.

Specialist services must send a copy of all authorities signed by the service's lead clinician for any specialist service medical practitioners (s24(2)(b)) under section 24 MODA to the Medicines Control team.

12.6.2 Medical practitioners providing hospital care

A client can be treated with controlled drugs for addiction in hospital, for a maximum of three days, under section 24(9)(b) MODA. A hospital clinician treating a client for addiction with controlled drugs should notify the specialist service within three days of initiating treatment. The specialist service must then determine the most appropriate way to engage or re-engage with that client.

Gazetted or approved specialist service medical practitioners can authorise a hospital medical practitioner to continue to treat a client with controlled drugs in the interim if necessary, under section 24(2)(d) MODA. Appendix 14: Authority for a general practitioner to prescribe controlled drugs for the treatment of addiction contains a format for letters granting GP authorities that can also be used for hospital medical practitioner authorities.

12.7 Supporting consumers in primary care in compliance with section 24 MODA

12.7.1 Authorising medical practitioners working in primary care

General practitioners accepting transfer of a client from a specialist service to primary care can continue to prescribe controlled drugs to treat the client's addiction with the authority of the lead clinician or an approved medical practitioner working in the service.

A GP authority must be in writing in the format provided in Appendix 14: Authority for general practitioner to prescribe controlled drugs for the treatment of addiction (section 24(2)(d) MODA or Appendix 4 of Ministry of Health 2013b. This form must clearly state the scope of the authority: the client to whom the authority applies, the controlled drug to be prescribed and any dispensing or monitoring arrangements.

Services must send a copy of each GP authority to the dispensing pharmacy and to the Medicines Control team at the Ministry of Health. The information sent to each should be exactly the same, to ensure client safety and continuity of care in all events.

A GP authority may be granted where the GP:

- holds a current practising certificate that has never been revoked
- has not been the subject of a notice under section 23 MODA prohibiting him or her from prescribing controlled drugs
- has not been the subject of a notice under section 58 Medicines Act 1981
- has a suitable combination of experience, education and specialist service support in treating clients dependent on controlled drugs
- agrees to comply with relevant guidelines.

Specialist services have a responsibility to support GPs to whom they grant authority. They should regularly communicate with GPs about specific clients, and provide them with information about safety and best practice when prescribing controlled drugs to treat addiction. GPs must be able to:

- discuss management problems with specialist service clinicians
- request specialist reviews of clients when necessary
- transfer clients back to specialist services when necessary.

Normally, a lead clinician should grant a GP authority. However, if the lead clinician is not available or it is not practicable for him or her to grant approvals, any specialist service medical practitioner with appropriate approval from the lead clinician can issue a GP authority.

12.7.2 Period of GP authority

Subsections (3) and (5) of section 24 MODA limit the period of a GP authority to three months. This can only be extended with the agreement of the Medical Officer of Health within the Ministry of Health's Medicines Control team.

The policy of Medicines Control is to allow for six-month GP authorities where a service and lead practitioner can demonstrate safe and effective compliance with these guidelines and other relevant documents. To request consideration of a six-month GP authority, a lead practitioner should write a formal letter of request to the Medical Officer of Health in Medicines Control, explaining why a longer period is justified.

The Medical Officer of Health can be contacted by writing to:

Medical Officer of Health
Medicines Control
Provider Regulation
Clinical Leadership, Protection and Regulation
Ministry of Health
PO Box 5013
Lambton Quay
Wellington 6145

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Appendix 1: Glossary

Affinity	The strength with which a drug binds to its receptor
Agonist	A substance that fully activates the neuronal receptor it attaches to
Antagonist	A substance that attaches to a receptor but does not activate it
Amphetamine-type stimulant	A psychostimulant substance known to produce euphoria, increased wakefulness and focus in association with decreased fatigue and appetite
Authorised medical officer	A GP authorised by a specialist service to prescribe OST medication for the treatment of opioid dependence for a specified time and in specific places
Benzodiazepine	A drugs that enhances the effect of the neurotransmitter gamma-aminobutyric acid, which results in sedative, hypnotic (sleep-inducing), anxiolytic (anti-anxiety), anticonvulsant, muscle relaxant and amnesic action
Buprenorphine	A substance derived from the opioid alkaloid thebaine; a partial opioid agonist with high affinity for the mu opioid receptor
Combined preparation	A preparation for sublingual administration containing buprenorphine and naloxone (eg, Suboxone®)
Half-life	The time taken for the plasma concentration of a drug to reduce by 50 percent; can vary from person to person
Hyperalgesia	An increased sensitivity to pain, which may be caused by damage to nociceptors or peripheral nerves
Illicit substance	A substance of use that is either illegal or not prescribed to a particular person
Intrinsic activity	The degree to which a substance activates its receptors
Key worker (also known as case manager)	A clinician assigned responsibility for coordinating a client's care and treatment; may provide some or all planned psychosocial interventions
Lead clinician	A designated senior specialist service medical practitioner or psychiatrist responsible for approving medical practitioners to prescribe controlled drugs for addiction treatment within a specialist OST service or in primary care
Managed withdrawal	Management of the symptoms of withdrawal occurring upon cessation of a substance to which an individual is dependent; commonly called detoxification or detox
Metabolite	A product of the body's metabolism of a drug
Methadone	A synthetic opioid, used medically as an analgesic and a maintenance medication for the treatment of opioid addiction
Morphine	A potent opiate analgesic considered to be the prototypical opioid

Naloxone	An opioid antagonist with a short half-life used to counter the effects of opioid overdose; also used in combination with buprenorphine to deter misuse and diversion
Naltrexone	An opioid receptor antagonist with a long half-life used in the management of both alcohol dependence and opioid dependence
Neuroadaptation	The process by which the brain modifies its sensory input, in response to touch, heat, cold, pain, sight, sounds or smell or the presence of a substance
Opioid	A substance that works by binding to opioid receptors, which are found principally in the central nervous system and the gastrointestinal tract. The term includes all substances with morphine-like activity, including natural opiates and synthetic substances such as methadone
Opioid receptors	Proteins manufactured by nerve cells that mediate the effects of opioid drugs
Partial agonist	A substance that activates a receptor to a lesser degree than an agonist. When administered concurrently with an agonist, may appear to act as an antagonist, as it occupies receptors and prevents agonists from activating receptors fully
Peaks and troughs	'Peak' refers to the maximum concentration that methadone reaches in the blood (usually occurs approximately four hours after taking a dose). 'Trough' refers to the lowest concentration that methadone drops to in the blood over 24 hours (ie, prior to taking the next dose)
Pharmacokinetics	A term describing what the body does to and with substances administered to it
Pharmacology	The study of drug effects at their site of action
Physiological	Consistent with the normal function of an organism
Polymerase chain reaction	A technique in molecular biology to amplify a single or a few copies of a piece of DNA across several orders of magnitude, generating thousands to millions of copies of a particular DNA sequence
Pulmonary oedema	Fluid accumulation in the lungs
QT interval	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
QTc prolongation	A prolonged QT interval; a risk factor for ventricular tachyarrhythmias and sudden death
Recovery	A process, rather than a single event, which takes time to achieve and effort to maintain. Recovery involves accruing positive benefits as well as reducing harms, and moving away from uncontrolled substance use and its associated problems towards health, wellbeing and participation in society
Recovery capital	The personal, social and community resources developed by an individual in the process of recovery
Sleep apnoea	A sleep disorder characterised by one or more pauses in breathing or shallow breaths during sleep
Sublingual	Underneath the tongue

Appendix 2: Opioids and opioid dependence

Opioid dependence is a worldwide health problem that has enormous economic, personal and public health consequences. Problem opioid users constitute approximately 0.3 percent of the global population. As with other chronic conditions, opioid dependence tends mostly to follow a relapsing and remitting course (WHO 2009).

Opioids

In New Zealand, opioid dependence primarily involves the use of pharmaceutically sourced products (such as morphine, including morphine sulphate, LA-Morph® and m-Eslon®; codeine-based products; methadone; and oxycodone); home-bake heroin; and opium poppies.

Morphine and oxycodone are short-acting drugs with a rapid onset of effects when injected and significant lasting effects of up to three to six hours in regular users. Long-acting morphine tablets (ground tablets that are chemically treated or ‘turned’ with acetic anhydride into an injectable morphine/diamorphine mix) are the illicit opioid most widely used by New Zealand injecting drug users. These have variable but significant first-pass liver metabolism (the bioavailability of morphine taken orally is about 30–50 percent of an injected dose).

Home-bake is produced by converting codeine into a morphine/diamorphine mix.

Methadone is a long-acting opioid used in the treatment of opioid dependence, but also widely used illicitly either by injection or oral consumption.

People dependent on opioids often use other opioid-based products as well as their substance of choice, or when their substance of choice is unavailable. These substances include over-the-counter products (eg, products containing codeine) and prescribed medications (eg, pethidine, long-acting morphine, oxycodone, codeine and dihydrocodeine).

Intravenous injection is the most common method used for the administration of opioid drugs. Other methods include smoking, snorting, inhaling from a heated sheet of foil and consuming orally (refer to Appendix 3: Pharmacology and pharmacokinetics of methadone and buprenorphine).

The epidemiology of opioid use and dependence

New Zealand national drug surveys on recreational drug use between 1996 and 2010 suggest that levels of opioid use, availability and price have remained constant; over this timeframe, approximately 1 percent of New Zealanders reported that they had ever tried opioids, and less than 1 percent reported current use (Field and Casswell 1999; Wilkins et al 2012).

Street morphine, followed by street methadone, were the most widely available and used opioids in 2011 (Wilkins et al 2012). Recently there has been a sharp increase in the use of oxycodone, a full opioid agonist, by frequent injection (Wilkins et al 2012).

Estimates of the prevalence of opioid dependence in New Zealand have varied. A 2008 two-arm survey (involving methadone treatment programmes and needle exchange programmes in Auckland, Tauranga and Christchurch) of regular (daily or almost daily) opioid users estimated the number of people with opioid dependence in New Zealand to be 9142 (Deering et al 2008); half of these people were reported to be in treatment (Adamson et al 2012).

The nature of opioid dependence

Opioid dependence is a complex health condition that has social, psychological and biological determinants and consequences. Despite its low prevalence in New Zealand, it is associated with relatively high rates of mortality, medical and mental health problems, criminal activity and significant social impairment (Deering et al 2008).

Opioid dependence develops after a period of regular use of opioids. Factors affecting severity of dependence include quantity and frequency of use, route of administration, context in which use occurs and individual vulnerability.

The repeated administration of opioids can produce two important observable responses – tolerance and withdrawal – as follows.

- **Tolerance:** repeated administration of a drug produces a diminished effect as the body adapts to the presence of the drug. Tolerance to opioids can be dramatic. With repeated exposure to increasing doses of opioids, an individual can appear and function normally despite having taken doses that would be fatal in a non-tolerant individual.
- **Withdrawal:** after a period of prolonged exposure to opioid drugs, stopping the administration of the substance leads to certain physiological and psychological changes – an abstinence syndrome.

Tolerance and withdrawal are manifestations of adaptation to the presence of administered opioids. The term ‘neuroadaptation’ is used to describe the changes effected by tolerance and withdrawal. Neuroadaptation assumes adaptive changes occur in the central nervous system as a result of exposure to opioids.

In New Zealand, the *Diagnostic and Statistical Manual of Mental Disorders* (APA 2000 and 2013) and the *International Statistical Classification of Diseases and Related Health Problems* (ICD) (WHO 2010) are the diagnostic tools internationally used to classify mental health and substance-use disorders. Either tool can be used however the World Health Organization requires New Zealand’s Ministry of Health to report on opioid use disorders to international data collections under the ICD system.

Appendix 3: Pharmacology and pharmacokinetics of methadone and buprenorphine

Pharmacology

Opioid receptors are found throughout the brain, in the spinal cord, in the gastrointestinal system, in parts of the autonomic nervous system and on white cells. Opioids therefore 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, behaviour reinforcement, 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 – as follows.

- **Pure (or full) agonists** have affinity for, and bind to, receptors to induce changes in the cells that stimulate physiological activity. The potency of an agonist reflects the dose–response relationship, and is influenced by pharmacokinetic factors (how much of the substance gets into the systemic circulation and then reaches the receptors), by the affinity of the substance for the receptor and by the level of intrinsic activity of the substance 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 person who is receiving high doses of a pure agonist. There is an upper limit to the effect of partial agonists (a ‘ceiling’ effect), even with increasing doses. Buprenorphine is a partial agonist.
- **Antagonists** have no intrinsic pharmacological action, but occupy receptors and block the action of agonists. 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, thereby precipitating withdrawal. Naloxone is 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 and produces measurable concentrations in plasma within 30 minutes of oral administration. Peak plasma concentrations generally occur between two and four hours after an oral dose. Methadone is widely distributed throughout the body, with a volume of distribution of approximately 3–5L/kg. It has a highly variable elimination half-life. 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 (also known as an agonist-antagonist), exerting partial agonist effects at the mu opioid receptor and antagonist effects at the kappa receptor. It has low intrinsic activity but a high affinity for the mu opioid receptor, meaning it binds tightly but does not 'turn on' the receptor fully. It also has high affinity for the kappa opioid receptor but no intrinsic activity.

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

The high receptor affinity of buprenorphine also means 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.

Naloxone

Naloxone is an opioid antagonist that is combined with buprenorphine in the available funded product Suboxone®, to deter diversion and injecting. Naloxone has minimal bioavailability when administered sublingually in the recommended dose, but exerts an effect (withdrawal symptoms) if injected.

Naltrexone

Naltrexone is an opioid antagonist that binds to opioid receptors but produces no opioid effect (ie, no intrinsic activity). It blocks the effects of other opioids by preventing them from binding to receptors. It can be effective in preventing relapse to opioid use if taken daily, and can be stopped abruptly, as no withdrawal symptoms occur upon cessation of use. It is registered in New Zealand for the prevention of alcohol and opioid relapse, but not funded for opioid relapse.

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. The transfer of methadone between these stores and the blood occurs fairly slowly, which accounts for methadone's relatively long-acting nature. Methadone has high oral bioavailability (90 percent) as a result of low first-pass metabolism, and binds effectively to the opioid receptors, which means it provides an effective blockade from other opioid use and has a long elimination half-life. It is this combination of being orally active, providing an effective blockade and being long acting that makes methadone suitable for substitution treatment regimens.

Methadone is primarily broken down in the liver via the cytochrome P450 enzyme system. About 10 percent 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 two to four 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 consumption, methadone levels in the body reach a steady state (where drug elimination equals drug administration) after about five to 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 percent) sublingual bioavailability; tablets take between two and seven minutes to dissolve. The speed of dissolution may be enhanced by breaking the tablets into a few pieces or ‘crumbling’ them (this may also help prevent diversion of the dose). Providers should avoid crushing the tablets into powder, as this tends to encourage swallowing, which causes a subsequent loss of the bioavailable dose.

In some countries, such as Australia and the United States, a buccal film preparation (Suboxone Sublingual Film[®]) is available that is placed on the buccal mucosa inside the cheek and allows absorption of buprenorphine. This product is a combination product that includes naloxone to deter injection.

Because buprenorphine is a partial agonist, its physiological and intoxicating effects usually plateau at a sublingual dose of 4–8 mg (some clients 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, the maximal therapeutic effects of buprenorphine occur in the 12–24 mg dose range. 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 percent) and urine (30 percent). 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 seven 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).

Table 7: Methadone and buprenorphine pharmacology and pharmacokinetics comparison

	Methadone	Buprenorphine
Pharmacology	Full opioid agonist	Partial opioid agonist with high affinity for mu opioid receptor – will displace other full opioid agonists, precipitating a withdrawal syndrome
Onset of effects and time to peak effect	Onset: 30–60 minutes after dose (rapid gastric absorption; 85 percent of dose absorbed within 20 minutes) Peak effect: 2–4 hours after dose	Onset: 30–60 minutes after dose Peak effect: 1–4 hours after dose
Half-life	13–47 hours with regular dosing (mean 25 hours) Takes approximately four days to reach steady state after change in dose	20–72 hours (active metabolite norbuprenorphine accounts for long half life) Takes approximately seven days to reach steady state
Duration of clinical effect	16–30 hours (accumulates after repeated administration; doses should not be increased more often than every four days)	8–12 hours at low dose (eg, 2 mg) 24–72 hours at high dose (eg, 16 mg)
Method of administration	Oral	Sublingual (poor oral bioavailability) (dissolution time 2–10 minutes)
Precipitated withdrawal	Does not occur	Can occur – identified by time to onset (30–90 minutes post dose)
Metabolism	Primarily hepatic CYP 3A4 (major), CYP 2D6 (minor) +++ Affected by liver function	Hepatic CYP 3A4 Less clinical impact of liver function
Major drug interactions	Sedatives, opioid antagonists CYP 450 inducers/inhibitors Additive risk with other drugs that alter QT interval	Sedatives Opioid agonists and antagonists CYP 450 inducers/inhibitors
Overdose	Lethal dose in opioid naive adult 40–60 mg (in children 10 mg or less)	Ceiling effect on respiratory depression; safer than full agonist in overdose, although deaths have occurred when injected with benzodiazepines
Product funded for opioid substitution treatment	Biodone® 5 mg/ml (also 2 mg/ml and 10 mg/ml)	Suboxone® 2 mg and 8 mg sublingual tablets; contain naloxone (parenterally active opioid antagonist) to deter injection
Funding restrictions	None	PHARMAC special authority required

Appendix 4: Side-effects

Methadone

Table 8 shows common side-effects of methadone. Many of these may be confused with withdrawal symptoms, and can be experienced even when a dose is adequate. For this reason, it is important to note the times of day when symptoms are experienced (eg, whether they mainly occur just prior to consuming, or at other times). It can be helpful to administer serum level tests to determine adequacy of methadone dose.

Buprenorphine

The most common side-effects experienced with buprenorphine include cold or flu-like symptoms, headaches, sweating, sleeping difficulties, nausea and mood swings. Most adverse effects occur early in treatment; they are usually mild and subside with time. Side-effects 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 affect cognitive ability and attention. Symptoms including constipation, sexual dysfunction and (occasionally) increased sweating can persist for the duration of buprenorphine treatment.

Table 8: Common side-effects of opioid substitution medication, and management recommendations

Side-effects	Notes	Management recommendations
Constipation	A common side-effect	Give usual lifestyle advice to manage constipation. Use osmotic laxatives 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
Increased perspiration	Common, especially at peak effect	Symptoms may eventually reduce. Drink sufficient water. Reducing dose may help, if this can be achieved without compromising maintenance treatment
Sedation	Drowsiness may occur at peak effect whilst stabilising	Check peak serum levels of methadone Consider reducing dose if sedation continues to be a problem
Dry mouth	Opioids reduce the production of saliva which may accelerate tooth decay	Dental problems frequently pre-date OST treatment, but opioids do reduce salivary flow. Encourage chewing sugar-free gum to increase salivary flow and improved dental hygiene, and drinking water or other sugar-free fluid
Weight gain (methadone)	Occurs in a small number of people	Assistance with weight management strategies
Headache	Occurs during buprenorphine induction due to high uptake of buprenorphine onto opioid receptors	Usually transient; if becomes problematic a dose reduction may be appropriate
Lowered sex drive	Opioids may suppress gonadotrophin production (also increase long-term risk of osteoporosis)	Reduce dose, but needs to be weighed against compromising outcomes on OST
Menstrual irregularity	Common in women who take opioids	Provide education about the risk of pregnancy despite menstrual irregularity/amenorrhoea
Galactorrhoea	Due to mild/moderately increased prolactin levels	Check prolactin level and rule out pathology Consider specialist endocrinologist advice
Oedema	Particularly of feet and ankles, though uncommon	Usually resolves within a few weeks of starting treatment
Gastrointestinal effects	Eg, nausea/vomiting, reduced gastric emptying, elevated pyloric sphincter tone biliary tract outflow effects, loss/increase in appetite	To reduce nausea and vomiting, suggest that the person eat before consuming methadone dose and drink dose slowly Other symptoms may be reduced by reducing the dose if this can be achieved without compromising stability
Aching muscles and joints	Some individuals report rheumatic type pains and 'bone pain' – uncommon	Medical examination for any underlying pathology. May be symptomatic of withdrawal. Dose increase may be indicated
Shallow breathing		Reduce dose
Skin rash/itching		Appropriate skin lotion eg, BK lotion or similar emollient, oral anti-histamine Note: Itching may also be a sign of opioid intoxication

Table reprinted with permission of Auckland Opioid Treatment Service 2011.

Appendix 5: Drug interactions

The following table provides a summary of potentially significant interactions between methadone, buprenorphine and other substances. It is not exhaustive.

Table 9: Interactions between methadone, buprenorphine and other substances

Drug	Interacts with	Effect of interaction	Mechanism
Central nervous system (CNS) depressants including alcohol, benzodiazepines, other sedating drugs (eg, tricyclic antidepressants)	Methadone and buprenorphine	Major severity; risk greater with methadone	Additive CNS depression leads to increased sedation and increased respiratory depression. Consequent toxicity can lead to death
Drugs with known potential to prolong QTc interval (see full list, with associated levels of risk, at www.azcert.org/medical-pros/drug-lists/printable-drug-list.cfm)	Methadone	Major severity	Additive risk of torsades de pointes. Use combination with caution, and not in susceptible individuals (refer to section 4.3: Methadone and cardiac safety)
Significant inducers of cytochrome p450 3A4, 2D6 (eg, carbamazepine, phenobarbitone, omeprazole, rifampicin, phenytoin)	Methadone (3A4 and 2D6) and buprenorphine (3A4 only)	Clinically significant for methadone; potentially clinically significant for buprenorphine	Hepatic enzyme induction leading to increased metabolism and decreased plasma levels of OST. May require dose increase if withdrawal symptoms are present. Exercise caution when stopping, as plasma levels may rise rapidly (especially with methadone)
Significant inhibitors of cytochrome p450 3A4, 2D6 (eg, cimetidine, fluconazole*, isoniazid, ritonavir, idinavir, ketonazole*, erythromycin*, ciprofloxacin*, selective serotonin re-uptake inhibitors, grapefruit juice (* also increase risk of Q-T prolongation))	Methadone (3A4 and 2D6) and buprenorphine (3A4 only)	Potentially clinically significant, especially for methadone	Hepatic enzyme inhibition leading to decreased metabolism and increased plasma levels Monitor for symptoms of opioid toxicity/sedation
Other opioids	Methadone and buprenorphine	Major severity	Additive sedation and respiratory depression Also precipitation of opioid withdrawal when partial agonist (eg, buprenorphine) used in client already taking full agonist (eg, morphine, methadone) (refer to section 6.6: Management of acute and chronic pain)
Opioid antagonists (eg, naltrexone, naloxone)	Methadone and buprenorphine	Major severity	Blocks effects of opioid agonist, causing withdrawal
Antacids	Methadone	Unclear	Possible decreased gastric absorption of methadone may lead to decreased plasma levels
Urinary acidifiers and alkalinisers	Methadone	Potentially clinically significant, although methadone is around 85 percent hepatically cleared	Acidifiers (eg, vitamin C) may cause decreased plasma levels of methadone due to increased renal clearance. Alkalinisers (eg, Ural sachets) may increase plasma levels of methadone due to decreased renal clearance.(Note: One study found the half-life of methadone to be 19.5 hours with acidified urine and 42.1 hours with alkalinised urine)

Drug	Interacts with	Effect of interaction	Mechanism
Cyclizine, other sedating antihistamines	Methadone	Unclear	Anecdotal. Reports of potentiated effect when injected with opioids, possible additive psychoactive effects Avoid combination
Zidovudine (AZT)	Methadone	Potentially clinically significant	Increased plasma levels of Zidovudine due to decreased hepatic metabolism Use caution when increasing methadone dose, as this may result in AZT toxicity

For a full list of potential interactions between OST medications and other substances, including severity of interactions and evidence available, refer to individual OST drug monographs in the New Zealand Formulary: www.nzf.org.nz

Appendix 6: Approximate detection time for selected drugs in urine

Table 10: Approximate duration of detectability of commonly used substances and metabolites in urine

Substance	Duration of detectability
Stimulants	
Amphetamine	2–3 days
MDMA (ecstasy)	30–48 hours
Methamphetamine	48 hours
Cocaine	6–8 hours
Cocaine metabolite/benzoylecgonine	2–3 days
Benzodiazepines	
Short-acting (triazolam, temazepam)	24 hours
Intermediate-acting (flunitrazepam)	40–80 hours
Long-acting (diazepam, nitrazepam, clonazepam)	7 days or more
Opioids	
Methadone (maintenance dosing)	7–9 days
Codeine/morphine	24 hours
6-monoacetyl morphine	2–4 hours
Morphine glucuronides	48 hours
Codeine glucuronides	3 days
Propoxyphene/norpropoxyphene	6–48 hours
Dihydrocodeine	24 hours
Buprenorphine	48–56 hours
Buprenorphine conjugates	7 days
Oxycodone	2–4 days
Cannabinoids (delta-9-THC)	
Single use	3 days
Moderate use	4 days
Heavy use (daily)	10 days
Chronic heavy use	Up to 36 days
Other	
Phencyclidine (PCP)	8 days
LSD	24 hours
Nicotine	12 hours
Cotinine (nicotine metabolite)	2–3 days
Alcohol (dose-dependent)	24 hours
GHB	12 hours

Adapted from Wolff et al 1999, page 1282.

Appendix 7: Dose equivalence of opioid and benzodiazepine drugs

When a person uses pharmaceutical preparations of opioids illicitly (as is common in New Zealand), the amount taken illicitly is equal to or less than the pharmaceutical preparation, depending on the skill of the person 'turning' the tablets. As the user is often able to verify the dose being used the risk of overdose in New Zealand has been relatively low compared with the risk in countries where heroin is the dominant opioid used (Ministry of Health 2006).

Practitioners working with clients dependent on opioids should be able to estimate the approximate equipotent doses of different opioids. The doses indicated in Table 11 below are based on equivalence to the stated dose of morphine.

Table 11: Single-dose analgesic equivalence of opioids

	Parenteral injection (mg)	Oral (mg)
Morphine	10	30
Buprenorphine	0.3	0.4 (sublingual tablet)
Codeine	100	200
Fentanyl	0.1	NA*
Methadone	5	10
Oxycodone	10	20

* For transdermal fentanyl a 25 mcg/hour patch is equivalent to around 60–130 mg of oral morphine over 24 hours.

Practitioners should consider these dose equivalents as crude approximations only, as reports of opioid equianalgesic doses vary considerably, and many equianalgesic tables underestimate methadone potency. The accepted practice in converting from one opioid to another is to calculate the conversion to morphine equivalence first and then to the required substance (eg, methadone). This is because equivalence studies compare medications to morphine as a reference.

Methadone analgesic equivalence to morphine (and other opioids) varies significantly with chronic dosing and total daily morphine dose. The relationship between methadone dose and morphine dose is not linear, and is influenced by individual variables, such as incomplete cross-tolerance. An estimate of the oral methadone:oral morphine ratio in long-term dosing is 1:10; that is, in chronic dosing 10 mg oral methadone is approximately equivalent to 100 mg of oral morphine, or 30 mg of parenteral morphine.

Table 12: Benzodiazepine dose equivalence

Generic name	Commonly used trade name	Equivalent dose to 5 mg diazepam	Time to peak concentration	Elimination half-life	Duration of action
Diazepam	Valium	5 mg	30–90 minutes	20–48 hours	Long
Alprazolam	Xanax	0.5–1.0 mg	60 minutes	6–25 hours	Short
Clonazepam	Rivotril	0.5 mg	2–3 hours	22–54 hours	Long
Lorazepam	Ativan	1 mg	2 hours	12–16 hours	Short
Oxazepam	Serapax	15–30 mg	2–3 hours	4–15 hours	Short
Nitrazepam	Mogadon	2.5–5 mg	2 hours	16–48 hours	Long
Temazepam	Normison	10–20 mg	30–60 minutes:tablets 2 hours: capsules	5–15 hours	Short
Flunitrazepam	Rohypnol	1–2 mg	1–2 hours	20–30 hours	Intermediate
Triazolam	Halcion	0.25	1–3 hours	2–5 hours	Very short
Zopiclone	Imovane	7.5 mg		5 hours	Very short

Source: Matua Rakī 2011b

Appendix 8: Managed withdrawal

The primary aim of a managed opioid withdrawal is to reduce acute physical and psychological discomfort. This involves provision of both pharmacological support and supportive care. Opioid withdrawal may occur at a client's home with specialist services and/or GP involvement, or in an inpatient treatment setting (eg, a medical detoxification unit). In some cases residential treatment facilities offer withdrawal management as part of their programmes.

While a range of health benefits often result from managed withdrawal, there is no evidence detoxification alone contributes to lasting abstinence from opioids in the longer term. Relapse after opioid withdrawal is very common; service providers should therefore develop a negotiated and detailed relapse prevention plan with the individual client involved. The plan should always include the role of the client's support people, and may include a residential treatment option.

Supportive care includes reassurance, attendance to hydration and nutrition. Pharmacological support includes the prescription of medications for symptomatic relief, including non-opioid analgesics, antiemetics, clonidine, benzodiazepines and antispasmodics. Complementary medications, massage, acupuncture and other physical/body therapies may also be useful.

Although opioid withdrawal is rarely life threatening, completing withdrawal can be very difficult for some people. The severity of withdrawal is influenced by a number of factors, including the duration of a client's opioid use, the use of other substances (such as benzodiazepines), and general physical health and psychological factors, such as the client's reasons for undertaking withdrawal and their fear of withdrawal.

Severity of opioid withdrawal is determined by the dose (the greater the dose, the more severe the withdrawal symptoms), rate of reduction (the more rapid the rate of reduction, the more severe the withdrawal symptoms) and type of opioid used (withdrawal from short-acting opioids can be more severe than withdrawal from long-acting opioids).

Long-acting opioids, such as methadone or buprenorphine, may have less severe but more prolonged (10–20 days), withdrawal, due to their long half-lives. However, they require slow discontinuation, to avoid the distressing reversal of neuroadaptation.

The most severe withdrawal reactions occur when an opioid antagonist is administered to an opioid-dependent person with a high level of circulating opioid agonist. By competitively inhibiting the agonist, the administration of naloxone or naltrexone abruptly blocks agonist effects, and instead of declining over many hours, opioid effects are reversed very quickly. The result is a very severe withdrawal reaction with profound physiological and psychological effects (refer to section 3.4.3: Precipitated withdrawal).

Neuroadaptation is more likely to develop after regular exposure to long-acting opioids than short-acting ones, as long-acting opioids ensure more continuous exposure of the central nervous system to the drug, and less time when there is no drug present. After about three to four weeks of daily use of methadone or buprenorphine, a withdrawal syndrome occurs upon discontinuation.

If a client resumes opioid use after a period of withdrawal, there is a risk of overdose due to loss of tolerance. Service providers should advise clients of this regularly throughout the withdrawal process and at its completion.

Withdrawal symptoms

Common signs and symptoms of opioid withdrawal include disturbed sleep, yawning, muscle aches, abdominal and back pains, sweating, cramps, piloerection, fatigue, dilated pupils, diarrhoea, runny nose, sniffing, sneezing, drug craving, nausea, vomiting, restlessness, agitation and anxiety.

Less common symptoms include fear, irritability, weight loss, elevated blood pressure, headaches, urinary frequency, dysphoria, hot and cold flushes, lacrimation, twitching and light sensitivity.

Symptoms of withdrawal from methadone usually begin 36–48 hours after the last dose, and reach peak intensity within five to seven days. The 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 may be milder than withdrawal from methadone or morphine because of buprenorphine's slow dissociation from the mu opioid receptor. Symptoms start within three to five days of the last dose and can last for several weeks.

Appendix 9: The Clinical Opioid Withdrawal Scale

Name:				
Reason for this assessment:				
Date and time:				
Resting pulse rate: (record beats per minute) <i>Measured after person is sitting or lying for one minute</i> 0 pulse rate 80 or below 1 pulse rate 81–100 2 pulse rate 101–120 4 pulse rate greater than 120				
Sweating: <i>Over past half-hour not accounted for by room temperature or activity</i> 0 no report of chills or flushing 1 subjective report of chills or flushing 2 flushed or observable moistness on face 3 beads of sweat on brow or face 4 sweat streaming off face				
Restlessness: <i>Observation during assessment</i> 0 able to sit still 1 reports difficulty sitting still, but is able to do so 3 frequent shifting or extraneous movements of legs/arms 5 unable to sit still for more than a few seconds				
Pupil size: 0 pupils pinned or normal size for room light 1 pupils possibly larger than normal for room light 2 pupils moderately dilated 5 pupils so dilated that only the rim of the iris is visible				
Bone or joint aches: <i>If the person was having pain previously, only the additional component attributed to opiates withdrawal is scored</i> 0 not present 1 mild diffuse discomfort 2 person reports severe diffuse aching of joints/ muscles 4 person is rubbing joints or muscles and is unable to sit still because of discomfort				
Runny nose or tearing: <i>Not accounted for by cold symptoms or allergies</i> 0 not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks				

<p>GI upset: <i>Over last half-hour</i> 0 no GI symptoms 1 stomach cramps 2 nausea or loose stool 3 vomiting or diarrhea 5 Multiple episodes of diarrhea or vomiting</p>				
<p>Tremor: <i>Observation of outstretched hands</i> 0 No tremor 1 tremor can be felt, but not observed 2 slight tremor observable 4 gross tremor or muscle twitching</p>				
<p>Yawning: <i>Observation during assessment</i> 0 no yawning 1 yawning once or twice during assessment 2 yawning three or more times during assessment 4 yawning several times/minute</p>				
<p>Anxiety or irritability: 0 none 1 patient reports increasing irritability or anxiousness 2 patient obviously irritable or anxious 4 patient so irritable or anxious that participation in the assessment is difficult</p>				
<p>Gooseflesh skin: 0 skin is smooth 3 piloerection of skin can be felt or hairs standing up on arms 5 prominent piloerection</p>				
<p>Total scores The total score is the sum of all 11 items with observer's initials</p>				

Score: 5–12 = mild; 13–24 = moderate; 25–36 = moderately severe; more than 36 = severe withdrawal.

Source: Wesson and Ling 2003.

Appendix 10: Recovery-oriented treatment

Every clinical staff member should reflect recovery principles and promote recovery values in every interaction, acting to increase consumers' personal agency, acknowledge non-professional expertise, reduce power differentials, increase clients' opportunities, and validate hope.

Sainsbury Centre for Mental Health 2009

A focus on recovery has re-emerged in the addiction sector. This focus encourages services to develop recovery- and wellbeing-oriented systems of care to support and engage people with opioid dependence to consider their future (with or without opioid substitution treatment (OST)) and to plan their own recovery. The OST sector is also placing greater emphasis on the use of recovery and peer support systems and the integrated provision of health and social services to meet clients' identified needs.

Recovery is worked on and experienced by the client; it is not something services can do to a person. The contribution of specialist service staff is to support the person in their recovery journey.

Slade 2009

Recovery is an individual process or journey, rather than a predetermined destination. It is built on hope, in order to sustain a client's motivation and support his or her expectations of an individually fulfilled life. A recovery focus supports clients to gain a sense of control over their own problems, the services they receive and their lives, and to find opportunities to engage in wider society. It is culturally sensitive (National Treatment Agency for Substance Misuse 2012). It recognises that many people receiving OST have complex social and medical needs, which may require a long-term coordinated system of care management approach aimed at assisting the client to accrue and maintain their recovery capital.

Recovery-orientated treatment embraces a person-centred, wellbeing-focused and coordinated network of community-based services and supports that focus on building up and maintaining the strengths and capabilities of people with addiction problems.

The British expert group on recovery orientated treatment (National Treatment Agency for Substance Misuse 2012) has outlined the following steps (adapted) for improving recovery-orientated treatment.

- Treatment systems and services should have a clear and coherent vision and framework for recovery that are visible to people in treatment, owned by all staff and maintained by strong leadership.
- Services should provide purposeful treatment interventions that are properly assessed, planned, measured, reviewed and adapted.
- Services should provide 'phased and layered' interventions that reflect the different needs of people at different times.

- Services should provide treatment that creates the therapeutic conditions and optimism in which people – especially those with few internal and external resources (recovery capital) – can meet the challenge of initiating and maintaining change.
- Opioid substitution treatment programmes should optimise medication according to evidence and guidance.
- Services should measure clients' recovery by assessing and tracking improvements in severity, complexity and recovery capital, then using this information to tailor interventions and supports that boost individuals' chances of improving their progress.
- Services should develop integrated recovery-orientated systems of care that involve other services, such as those providing mutual aid, employment support and housing.
- Services should provide treatment that works alongside peers and families to give clients direct access to, or signposts and facilitated support to, opportunities to reduce and/or stop their substance use, improve their physical and mental health, engage with others in recovery, improve relationships (including with their children), find meaningful work, build key life skills and secure housing.

Staff of addiction services require a range of positive relationship skills and behaviours to practice congruent with a recovery paradigm. These include empathy and encouragement of responsible risk taking, a belief in people's strengths and resources (Sainsbury Centre for Mental Health 2009; Shepherd et al 2008) and expression of genuine curiosity in people as authorities on their own lives. Additionally, other attributes essential to recovery practice include resourcefulness in focusing on strengths and resources available, respecting people's wishes, using crises as opportunities for change and ultimately respecting people.

Appendix 11: Application to be specified as a medical practitioner prescribing controlled drugs for dependence (section 24(7)(a) MODA)

This form should be used by medical practitioners when applying to be able to prescribe controlled drugs for dependence under Section 24(7)(a) Misuse of Drugs Act 1975.

Name of addiction treatment service

Name of nominee

Position

Postal address

()

Telephone

()

Fax

Email address

Additional information

Please attach the following information to your application:

- A letter of nomination from a senior clinical leader or an executive officer
- A letter of application detailing your qualifications, work experience, clinical leadership experience and training in opioid substitution treatment
- A curriculum vitae and copy of current practising certificate
- At least two supporting references

- Evidence of continuing education and/or research in medication-assisted recovery and membership in appropriate professional organisation(s) such as:
- Section of Addiction Psychiatry within the Royal Australian and New Zealand College of Psychiatrists (RANZCP)
 - Australasian Chapter of Addiction Medicine (AChAM) in the Royal Australasian College of Physicians (RACP)
 - National Association of Opioid Treatment Providers (NAOTP).

Referees

Please give the names and contact details of at least two referees for the Director of Mental Health to contact.

Name:

Contact details:

Referee 1 details

Name:

Contact details:

Referee 2 details

Agreement

I (the nominee) agree:

1. to adhere to the *New Zealand Practice Guidelines for Opioid Substitution Treatment* (Ministry of Health 2014)
2. to a review of my status as an approved medical practitioner from time to time
3. that I have not been the subject of a Gazette notice under Section 23 Misuse of Drugs Act 1975
4. that I have not been the subject of a Gazette notice under Section 48 Medicines Act 1981
5. to advise the Ministry of Health of medical practitioners whom I authorise to prescribe controlled drugs for the treatment of dependence under Section 24(2)(b), (c) and/or (d) Misuse of Drugs Act 1975
6. that I 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.

Nominee signature

Print name

Date

Nominator signature

Print name

Date

Appendix 12: Application to be specified as an addiction treatment service prescribing controlled drugs for dependence (section 24(7)(b) MODA)

This form should be used by an addiction treatment service when applying to be able to prescribe controlled drugs for dependence under Section 24(7)(b) Misuse of Drugs Act 1975.

Name of addiction treatment service

Name of applicant

Position

Postal address of service

()

Telephone

()

Fax

Email address

Clinic and staffing information

Please provide the street address of each clinic in your service and information about the makeup of clinical staff in each clinic (this includes, but is not limited to, case workers, kaimirimi, nurses, psychiatrists and other medical practitioners, psychologists, pharmacists and social workers).

Clinic address	Clinician/qualification	FTE
Clinic 1		
Clinic 2		
Clinic 3		
Clinic 4		
Clinic 5		
Clinic 6		

Additional information

Please attach the following information to your application:

- a letter of application
- relevant protocols and procedures your service has in place to demonstrate compliance with the *New Zealand Practice Guidelines for Opioid Substitution Treatment* (Ministry of Health 2014) if applying to be an opioid substitution treatment service
- if necessary, application forms for the gazetting of medical practitioners under Section 24(7)(a) Misuse of Drugs Act 1975.

General agreement

I agree that:

1. our service will adhere to the *New Zealand Practice Guidelines for Opioid Substitution Treatment* (Ministry of Health 2014)
2. our service protocols and procedures are in keeping with the practice guidelines
3. our service complies with the Health and Disability Services (Core) Standards (NZS 8134:2008)

4. our service will collect and forward such statistical data as required by the Ministry of Health
5. our service will notify the Director of Mental Health of our staff composition (including prescribers responsible to this service) every six months.

Treatment programmes

I agree that:

1. each client will receive a written treatment plan that has been agreed between themselves and our service
2. each client 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 consumers
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 outlined 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 women using opioids.

Ministry of Health requirements

I agree that:

1. the Director of Mental Health will independently review our service as required
2. our service will provide the Director of Mental Health with any required information (eg, reports).
3. the Director of Mental Health will review this authority from time to time.

Applicant signature

Print name

Date

Appendix 13: Authority for service/clinic medical practitioner to prescribe controlled drugs for the treatment of addiction (section 24(2)(b) MODA)

This form should be used by medical practitioners when applying to be able to prescribe controlled drugs for dependence under Section 24(7)(a) Misuse of Drugs Act 1975.

I, [insert name of lead clinician], [insert name of specialist service], authorise:

[insert name of medical practitioner] _____ [insert name of specialist service] _____
Medical practitioner employed by the specialist service – specified under Subsection (7)(b)

to prescribe, administer or supply controlled drugs for the treatment of addiction to people who are or have been clients of [insert name of specialist service].

and

to authorise general practitioners receiving clients from [insert name of specialist service] as specified under Subsection (2)(d). [Delete this paragraph if inappropriate]

[Insert signature] _____ [Insert date] _____
Signature Date

[Insert name of lead clinician]
[Insert name of specialist service]

cc. [General practitioner]
[Dispensing pharmacy]
Service Register
Medicines Control, Ministry of Health, PO Box 5013, Wellington
(medicinescontrol@moh.govt.nz)

This authority expired because [insert reason] on [insert date].

[Insert signature] _____
Lead clinician

Appendix 14: Authority for a general practitioner to prescribe controlled drugs for the treatment of addiction (section 24(2)(d) MODA)

This form should be used by a lead clinician when authorising a general practitioner (GP) to prescribe controlled drugs for dependence under Section 24(2)(d) Misuse of Drugs Act 1975.

I, _____ [name of medical practitioner], _____ [specialist service], authorise:

GP name

GP practice

to prescribe controlled drugs for the treatment of addiction to:

Consumer name

NHI

Consumer address

The conditions of this authority are set out below.

<p>[Specify general or particular conditions of authority including, where relevant:</p> <ul style="list-style-type: none">• the particular controlled drug• monitoring requirements• dispensing arrangements.]	
---	--

This authority expires on _____ [date].

Signature

Date

[Medical practitioner]

[Specialist service]

cc. [GP]

[Dispensing pharmacy]

Consumer file

Medicines Control, Ministry of Health, PO Box 5013, Wellington
(medicinescontrol@moh.govt.nz)

Appendix 15: Section 24

Misuse of Drugs Act 1975

24 Treatment of people 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 the 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, the 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 that 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 the 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 three 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 three 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 purposes of this section:
 - (b) specify (by name or description) as a place at which controlled drugs may be prescribed, administered, or supplied for the purposes 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 that Act;
 - (b) the emergency treatment of a patient in a hospital care institution within the meaning of section 58(4) of the Health and Disability Services (Safety) Act 2001, for a period not exceeding three days;
 - (c) the treatment of any restricted person within the meaning of section 25.

Appendix 16: The prescribing process

The prescribing process for opioid substitution treatment (OST) described below applies to all prescribers, whether they are employed within a specialist service or 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.
- Buprenorphine does not require a controlled drug form when prescribed in combination with naloxone (Suboxone®). Prescriptions may therefore be written for up to three months' supply (84 days allows for consistency of dispensing days each week). Funding is provided via special authority from PHARMAC. It is recommended that prescribers endorse the prescription with an instruction to break or crumble tablets consumed under observation in order to reduce both supervision time and the risk of diversion.
- The pharmacist must receive written prescriptions for methadone and other OST medications (with the amount prescribed written in words and figures) at least one day before the due date to supply, so that he or she has time to prepare the documentation and dispensing plan. It may be acceptable to fax through the prescription; by law, the original must be received by the pharmacist within two working days. As well, the service may give the client the prescription to take to the pharmacy themselves. Note: there is a greater fraud risk with prescriptions not on controlled drug forms, such as those for buprenorphine/naloxone and benzodiazepines.
- The prescriber is responsible for determining the frequency of dispensing of OST medications; pharmacists will be reimbursed according to the maximum period of supply stipulated on the prescription. Pharmacists may dispense medications co-prescribed with OST medication with increased frequency if this is likely to improve adherence and minimise misuse.
- Prescriptions should be started on a day of the week that the client is usually observed consuming their OST medication, and not on a day that the client has a takeaway dose. In the case of prescriptions written on controlled drug forms, the Ministry of Health has agreed the prescription date may be written as the actual date the pharmacist is to begin dispensing, rather than the date of writing. This is to avoid the difficulties that arise due to controlled drug prescriptions being valid to be commenced for only seven days after writing in law.
- 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.
- Doses should be written in numeric and word form (eg, '80 (eighty) mg'). If a client is undertaking any type of withdrawal, the new prescription should state the current dose as the starting dose. The maximum rate of any induction or withdrawal regime must be specified.
- Prescriptions for all OST and co-prescribed medications should include the name of the pharmacy at which the medication is intended to be dispensed.

- Specialist services and GP prescribers must provide pharmacists with positive identification of clients; ideally, this will include a current named photograph of each client. Faxed photographs are often not legible; if used, they should be followed up with a better quality image via post. Prescribers may email an electronic image directly to the pharmacy.
- Prescribers or key workers are responsible for notifying pharmacists of any prescription changes (eg, cancelled doses, clients' temporarily attending another pharmacy or termination of treatment from a particular pharmacy).
- Only the prescriber can make changes to scripts (eg, altered doses, extra doses or changes to the pharmacy used for dispensing the prescription).
- Services may make changes to takeaway doses (usually a one-off) according to local protocols; these need to be internally signed off. Services may telephone or fax such changes through to the pharmacy; they must be noted in writing.
- Where possible, services must give pharmacists at least one day's notice of changes to scripts.
- Where a prescription is cancelled (other than for routine matters such as a change of pharmacy), services must inform the client concerned directly. If direct contact is not possible, the service will send the client a fax message via the pharmacy, informing them of the change. Where appropriate, the service will send a letter to the client's home address outlining the reasons for the intervention and giving notice.
- Where split doses are prescribed, the controlled drug prescription must include clear instruction as to which part of the dose is to be administered and which, if any, is to be dispensed as a takeaway dose.

Writing a prescription for opioids

The use of H572M controlled drug prescription forms is restricted to prescribing methadone for clients under the authority conferred by section 24(2) (d) Misuse of Drugs Act 1975. Prescribers must write prescriptions for other controlled drugs, such as morphine or buprenorphine (not in combination), on an H572 controlled drug prescription form and keep a copy for the file. Prescribers may write prescriptions for the combination of buprenorphine and naloxone (Suboxone®) on a general prescription pad.

The following figure reproduces the H572M controlled drug prescription form. Notes to assist prescribers in filling out this form follow.

- Write actual date pharmacist is to begin dispensing.
- Write name and current residential address of client. It is not acceptable to use the pharmacy address as the client address.
- Write client's NHI number.
- Specify strength (eg, 'Methadone liquid 5 mg/ml'); include brand if required
- Write current dose, preferably in numeric and word form (eg, '80 (eighty) mg'). Note: if a client is undertaking any type of withdrawal from methadone, the new prescription should state the current dose as the starting dose.
- Write start date again (actual date pharmacist is to begin dispensing).
- Write total period of supply, up to a maximum of 28 days.
- Specify maximum rate of any withdrawal regime.
- Cross this sentence out: errors have occurred due to misinterpretation.
- Write in days for which takeaways are authorised. For example, for a client on twice-weekly takeaways collecting and consuming dose on Mondays and Thursday write 'Tuesday, Wednesday, Friday, Saturday, Sunday', as these are the days for which takeaways are authorised.
- Write name of pharmacy.
- Sign prescription (and highlight any changes from the previous script).
- Stamp or print prescriber's, name, address and Medical Council of New Zealand registration number.
- Send the top three copies to the pharmacy, and keep the bottom copy (blue) on the client's file.

H572M	Item count
MINISTRY OF HEALTH 929661 CONTROLLED DRUG PRESCRIPTION FORM	PHARMACY STAMP
Circle Y J A P 1 2 3 4 Z	
Prescription Date: / / 1	
Patient: 2	NHI No: 3
Address:	
R : METHADONE MIXTURE 4	Pharmacy use
Daily dose of 5 milligrams per day	
Starting on / / 6	
Total period of supply 7 days.	
Daily dosage to be reduced by 8	
Daily doses of methadone are to be consumed on the pharmacy premises. 9	
Takeaway doses are only to be dispensed for days when the pharmacy is closed and when otherwise authorised.	
Takeaway doses are authorised for the following days:	
..... 10	
Prescription to be dispensed at: 11	
Practitioner's signature: 12	
NZMC Reg No: PIN No:	
Practitioner's Name: 13	
Address:	
	14
	PHARMACY COPY

Appendix 17: Inter-service transfer request

The following sample form is to be used by opioid substitution treatment (OST) services when transferring a client to another such service.

The referring service is also expected to provide a comprehensive assessment, a current risk assessment, a summary of treatment and a current treatment plan to the new service as part of the transfer documentation.

Date:	
New specialist service: Contact name: Phone no: Email:	
Referring specialist service: Contact name: Phone no: Email:	

Client's personal details

Name:			
Date of birth:		NHI:	
Current address:			
Phone:		Fax:	
Other:			
Requested destination:			
Intended address:			
Intended phone:			
Other relevant details:			

OST medication details

Current OST medication and dose:	
Takeaway arrangements:	

Monitoring/review information

Length of time with OST service:	
How often seen at the clinic (eg, monthly, every three months, every six months):	
Current scripting arrangement:	
Recent laboratory screen date and results:	
Last clinical review date:	
Risk features identified:	

Mental health and medical information

Current GP and contact details:	
Medical issues identified:	
Medical health issues identified:	
Diagnoses:	
Prescribed medications:	
Follow-up required:	
Other information:	

Reason for transfer

--

Other relevant details

--

For new service

Allocated key worker:	
Received:	<input type="checkbox"/> Comprehensive assessment <input type="checkbox"/> Risk assessment <input type="checkbox"/> Summary of treatment <input type="checkbox"/> Treatment plan

Adapted from Christchurch Methadone Programme documentation.

Appendix 18: Interim prescribing

Specialist opioid substitution treatment (OST) services should consider interim prescribing when they are unable to commence OST within the recommended timeframe of two weeks after assessment indicates suitability for OST.

The interim prescribing process is currently only applicable to the prescribing of methadone, with a maximum allowable dose of 60 mg.

The following is taken directly from the *National Guidelines: Interim methadone prescribing* (Ministry of Health 2007a), pages 10–12.

Eligibility

- Patients presenting for assistance at an opioid-treatment service will undergo a comprehensive assessment in line with usual procedure, including the development of an appropriate management plan.
- When a patient is found to have an established opioid dependence, opioid-substitution treatment is considered to be clinically indicated, and there is a longer than two-week waiting list, patients will be given the choice of undertaking an interim methadone-prescribing programme. Ideally, this programme should be delivered by the patient's general practitioner on the specialist service's authorisation or by an alternative prescriber (likewise authorised). This person is the 'authorised prescriber'. This is preferable to the patient not receiving opioid-substitution medication while on the waiting list.
- While on the interim methadone-prescribing programme, patients retain their place on the waiting list for the full treatment programme (ie, individualised dose and takeaway arrangements and the provision of a clinical case manager).

Consent to interim methadone-prescribing programme

- Patients sign a consent form before starting on an interim methadone-prescribing programme. The consent form includes an agreement that:
 - the patient will pay for all general practitioner or alternative prescriber consultations where appropriate
 - the patient will attend all review sessions as required on the programme
 - the maximum daily dose on the programme is 60 mg of methadone
 - split dosing is not possible
 - there are no takeaway doses on the programme.

Interim methadone prescribing

- The authorised prescriber starts each patient's daily dose at 20 mg of methadone. The first prescription is for 20 mg daily for one week.
- The authorised prescriber reviews the patient three hours after their morning dose on the first and the third day of treatment.
- The authorised prescriber then reviews the patient once a week until a dose of no more than 60 mg daily has been established. The authorised prescriber then reviews the patient once a month.
- The authorised prescriber may not increase the dose of methadone faster than 10 mg each week, up to a maximum daily dose of 60 mg each day. The typical pattern of prescribing on the programme is:
 - 20 mg daily for one week, then
 - 30 mg daily for one week, then
 - 40 mg daily for one week, then
 - 50 mg daily for one week, then
 - 60 mg daily thereafter.
- An authorised prescriber outside the specialist service cannot prescribe hypnotics to patients on the programme.

Monitoring of patients on interim methadone-prescribing programme

- The specialist service does not have to undertake urinary drug monitoring.
- The patient does not have to undertake counselling.
- The specialist service should provide the patient with advice, support and information about the specialist alcohol and other drug treatment services that may be able to offer psychosocial support while the patient is on the waiting list.

Missed doses

- The specialist service does not require the patient to take methadone every day. However, if the patient misses three consecutive doses, the subsequent dose must be half the usual dose before they can return to the full dose the following day.
- If the patient misses five consecutive doses, the authorised prescriber (who may consult the specialist service) must undertake a clinical review of the patient before the patient can resume the programme.

Appendix 19: DIRE score: patient selection for chronic opioid analgesia

For each factor, rate the client's score from 1-3 based on the explanations in the right hand column.

Score	Factor	Explanation
	Diagnosis	1 = Benign chronic condition with minimal objective findings or no definite medical diagnosis. Examples: fibromyalgia, migraine headaches, nonspecific back pain. 2 = Slowly progressive condition concordant with moderate pain, or fixed condition with moderate objective findings. Examples: failed back surgery syndrome, back pain with moderate degenerative changes, neuropathic pain. 3 = Advanced condition concordant with severe pain with objective findings. Examples: severe ischemic vascular disease, advanced neuropathy, severe spinal stenosis.
	Intractability	1 = Few therapies have been tried and the patient takes a passive role in his/her pain management process. 2 = Most customary treatments have been tried but the patient is not fully engaged in the pain management process, or barriers prevent (insurance, transportation, medical illness). 3 = Patient fully engaged in a spectrum of appropriate treatments but with inadequate response.
	Risk	(R = Total of P+C+R+S below)
	Psychological	1 = Serious personality dysfunction or mental illness interfering with care. 2 = Personality or mental health interferes moderately. Example: depression or anxiety disorder. 3 = Good communication with clinic. No significant personality dysfunction or mental illness.
	Chemical health	1 = Active or very recent use of illicit drugs, excessive alcohol, or prescription drug abuse. 2 = Chemical coper (uses medications to cope with stress) or history of chemical dependency in remission. 3 = No chemical dependency history. Not drug-focussed or chemically reliant.
	Reliability	1 = History of numerous problems: medication misuse, missed appointments, rarely follows through. 2 = Occasional difficulties with compliance, but generally reliable. 3 = Highly reliable patient with medications, appointments and treatment.
	Social support	1 = Life in chaos. Little family support and few close relationships. Loss of most normal life roles. 2 = Reduction in some relationships and life roles. 3 = Supportive family/close relationships. Involved in work or school and no social isolation.
	Efficacy score	1 = Poor function or minimal pain relief despite moderate to high doses. 2 = Moderate benefit with function improved in a number of ways (or insufficient information – hasn't tried opioid yet or very low doses or too short of a trial). 3 = Good improvement in pain and function and quality of life with stable doses over time.

Total score = D + I + R + E

Score 7–13: Not a suitable candidate for long-term opioid analgesia.

Score 14–21: May be a suitable candidate for long-term opioid analgesia.

Source: Miles Belgrade, Fairview Pain and Palliative Care Centre 2005.