

**NATIONAL ASSOCIATION OF OPIOID
TREATMENT PROVIDERS**

**NATIONAL
OPIOID SUBSTITUTION TREATMENT
PROVIDERS TRAINING PROGRAMME**

This workbook was written by a sub-group from the National Association of Opioid Treatment Providers led by Raine Berry and including Philip Townshend, Sheridan Pooley, Daryle Deering, Lee Nixon and Karen Vince.

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1. INTRODUCTION

This workbook is designed to be used in conjunction with training workshops provided by NAOTP. Its purpose is to provide a national standard for effective and responsive service delivery and to ensure that the skills and attitudes used by the workforce are enhanced to meet the specific needs of clients receiving OST.

The workbook provides an overview of the knowledge, attitudes and skills required to effectively provide OST in the specialist service, the prison setting, the primary health care/general practice setting and the community pharmacy. It explores the major concepts and issues involved in providing OST and describes the regulatory framework within which this treatment is provided and should be used in conjunction with the Practice Guidelines for Opioid Substitution Treatment in New Zealand (2008) and any regional or service protocols.

The objectives of the workbook are to:

- provide a comprehensive overview of OST, research and best practice required for effective treatment
- familiarise the reader with the Practice Guidelines for OST in New Zealand 2008 (MoH 2008)
- facilitate self-assessment/monitoring of the need for further knowledge and skill development.

A self-assessment questionnaire is contained at the end of each section of the workbook. Completed questionnaires should be sent to the programme co-ordinator to provide evidence of engagement in the programme and for allocation of a programme completion certification.

In designing this training programme the following frameworks have been considered:

Let's get real

Let's get real has a focus on the essential knowledge, skills and attitudes required of all people working in mental health and addiction services. The essential common values and attitudes that run throughout *Let's get real* are:

Values: respect; human rights; service; recovery; communities; and relationships.

Attitudes: people working in mental health and addiction treatment services are:

- compassionate and caring: sensitive and empathetic
- genuine: warm, friendly, fun, have aroha and a sense of humour
- honest: have integrity
- non-judgmental: non-discriminatory
- open-minded: culturally aware, self-aware, innovative, creative and positive risk takers
- optimistic: positive, encouraging and enthusiastic
- client: tolerant and flexible
- professional: accountable, reliable and responsible
- resilient
- supportive: validating, empowering and accepting
- understanding.

Te Tahuhu: Improving Mental Health 2005–2015: The Second New Zealand Mental Health and Addiction Plan (Ministry of Health 2005)

Te Tahuhu outlines 10 leading challenges including improving whanau ora, recovery and wellness for people, families, whanau and communities affected by mental health and addiction-related problems.

Major shifts in service in response to Te Tahuhu include:

- a more integrated and comprehensive system of care which provides early access to primary health care linked to an improved range of community-based specialist services built on collaborative relationships
- a culture of recovery and wellness that fosters leadership and participation by people affected by mental illness and addiction supported by a workforce effective in incorporating clinical and culturally responsive practice.

DAPAANZ Competencies

This workbook is aligned with the Drug and Alcohol Practitioners Association Aotearoa competencies Foundation, Generic and Vocational competencies currently in development and expected to be published 2011. When completed these will be available on the DAPAANZ website.

Development of the Training Programme

The training programme has been developed by the National Association of Opioid Treatment (OST) Providers (NAOTP) with support from the Ministry of Health and Matua Raki.

The workbook draws significantly on the Practice Guidelines for OST in New Zealand 2008, previous work conducted by the Goodfellow Unit, Department of General Practice and Primary Care, Auckland Medical School and from relevant Australian pharmacotherapy and opioid substitution guidelines and manuals.

NAOTP will offer companion workshops in partnership with other relevant organisations to address the clinical and practice skills required to provide an effective and high quality OST programme.

Training Credits

This OST training workbook and the companion workshops are not a substitute for tertiary education training however may be recognised as continuing education credits for professional bodies representing OST staff. The Ministry of Health and NAOTP both hold the position that all clinical staff working with clients on OST should at a minimum be working toward attaining a relevant postgraduate qualification.

Required Reading

Practice Guidelines for Opioid Substitution Treatment in New Zealand 2008

- * A separate book of key readings accompanies this workbook.

2. OVERVIEW OF OPIOID USE AND ADDICTION

This section provides an overview of opioids and opioid¹ dependence and its associated problems. The objectives are to:

- provide information about the epidemiology of opioid drug use and opioid drugs used by injecting drug users in New Zealand
- provide information about drug dependence and withdrawal
- identify the health, social and economic costs associated with illicit opioid use.

2.1 *Opioids and Opioid Dependence*

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, and methadone); homebake heroin, and opium poppies. Heroin, although the most common opioid used internationally, has not been widely available in New Zealand since the 1980s.

Morphine is a short acting drug with 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 most widely used illicit opioid used by New Zealand injecting drug users. These have variable but significant first-pass liver metabolism (the bioavailability of oral morphine is about 25% of injected doses).

Homebake is produced by ‘turning’ codeine so that it forms 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 a matter of preference or when their substance of choice is unavailable. These substances include over-the-counter products (e.g. Gees Linctus or products containing codeine), prescribed medications (pethidine, long-acting morphine and dextropropoxyphene, codeine or dihydrocodeine), and poppy seed tea (made from soaking or washing seeds in water and drinking the liquid).

Intravenous injection is the most common route used by opioid users for the administration of opioid drugs. Other ways of using opioids are smoking, snorting, inhaling from a heated sheet of foil, and oral consumption.

(See also Pharmacology and Pharmacokinetics of Opioids Section 3.)

¹ **Opioid**

The term opioid is used in this workbook to describe both opium-derived drugs such as morphine, codeine, opium, heroin, homebake and pharmaceutical drugs such as buprenorphine, and methadone.

2.2 *Epidemiology of Opioid Use and Dependence*

Opioid users constitute less than 1% of the world population of those aged 15 years and above (WHO 2004). National drug surveys on recreational drug use between 1996 and 2008 suggest that levels of opioid use, availability and price have remained constant, with approximately 1% reporting that they had ever tried opioids and less than 1% reporting current use (Field and Casswell 1999, Wilkins et al 2009).

Street morphine followed by street methadone were the most widely available and used opioids in 2008 (Wilkins et al 2009). Estimates of the prevalence of opioid dependence in New Zealand have varied in research reports. Sellman and colleagues (1996) estimated that there were between 13,500 and 26,600 people dependent on opioids. Surveys conducted in 1998 and 2004 of randomly-selected alcohol and other drug treatment workers found that 17% and 15% respectively of clients presenting to outpatient services did so mainly due to their opioid use (Adamson et al 2000; Adamson et al 2006). A study of clients presenting to two CADS outpatient treatment services supported these figures, finding that 15% of clients had a current diagnosis of opioid dependence and 24% had met criteria for opioid dependence in their lifetime (Adamson et al 2006).

Te Rau Hinengaro data (Oakley-Browne et al 2006) reported the 12-month prevalence of opioid dependence to be 2622 individuals (CI 983–5573); however this figure was lower than the number of people on OST programmes in New Zealand at the time. In 2008 the National Addiction Centre (Deering, Sellman et al 2008) conducted a two-arm survey (methadone treatment programmes and needle exchange programmes in Auckland, Tauranga and Christchurch) for the Ministry of Health of 97 regular (daily or almost daily) opioid users. Using a multiplier method they estimated the number of people with opioid dependence to be 9800 (CI 8802–10,798). A total of 4608 people were reported to be receiving methadone treatment, mostly in specialist OST services however this figure included 87 individuals in prison, 932 on GP authority (22%) and 208 individuals receiving methadone from approved/gazetted medical practitioners/services in Christchurch (123) and Tauranga (85). Overall, 1140 (25%) clients were receiving methadone within primary health care settings with the Christchurch specialist service having the highest proportion of clients receiving OST through GP authority (40%). Christchurch, Dunedin and Auckland reported the highest numbers prescribed for in prison, 20, 17 and 10 respectively. The numbers of individuals currently prescribed other opioid substitution medicines (primarily buprenorphine and dihydrocodeine) was not reported.²

2.3 *Opioid Dependence*

“Opioid dependence develops after a period of regular use of opioids, with the time required varying according to the quantity, frequency and route of administration, as well as factors of individual vulnerability and the context in which drug use occurs. Opioid dependence is not just a heavy use of opioids, but a complex health condition that has social, psychological and biological determinants and consequences, including changes in the brain. It is not a weakness of character or will” (WHO 2004).

² **GP Authority**

GP authority refers to a shared care arrangement where the client is seen in primary care and provided with a prescription for methadone or other opioid substitute medicine by the GP along with ongoing care for all other health concerns, but the control of the opioid substitute prescription remains with the specialist service, which authorises the prescription on a three-monthly basis or longer as arranged with Medicines Control.

The Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition Text Revision (DSM-IVTR) (APA 2000) defines the essential feature of drug or substance dependence as: “a cluster of cognitive, behavioural, and physiological symptoms indicating that use of the substance continues despite significant substance-related problems. There is a pattern of repeated self-administration that usually results in tolerance, withdrawal, and compulsive drug-taking behaviour”.

Most individuals with opioid dependence have significant levels of tolerance and will experience withdrawal on abrupt discontinuation of opioid substances. Opioid dependence includes signs and symptoms that reflect compulsive, prolonged self-administration of opioid substances that are used for no legitimate medical purpose or, if a general medical condition is present that requires opioid treatment, that are used in doses that are greatly in excess of the amount needed for pain relief. Persons with opioid dependence tend to develop such regular patterns of compulsive drug use that daily activities are typically planned around obtaining and administering opioids.

(Source: DSM-IVTR 2000.)

Criteria for Substance Dependence

A maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by three (or more) of the following occurring at any time in the same 12-month period:

- (1) tolerance, as defined by either of the following:
 - (a) a need for markedly increased amounts of the substance to achieve intoxication or desired effect
 - (b) markedly diminished effect with continued use of the same amount of the substance
- (2) withdrawal, as manifested by either of the following:
 - (a) the characteristic withdrawal syndrome for the substance
 - (b) the same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms
- (3) the substance is often taken in larger amounts or over a longer period than was intended
- (4) there is a persistent desire or unsuccessful efforts to cut down or control substance use
- (5) a great deal of time is spent in activities necessary to obtain the substance (e.g. visiting multiple doctors or driving long distances), use the substance (e.g. chain-smoking), or recover from its effects
- (6) important social, occupational, or recreational activities are given up or reduced because of substance use
- (7) the substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance (e.g. current cocaine use despite recognition of cocaine-induced depression, or continued drinking despite recognition that an ulcer was made worse by alcohol consumption)

Specify if:

With Physiological Dependence: evidence of tolerance or withdrawal (i.e. either Item 1 or 2 is present)

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

Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition Text Revision 2000

2.4 Tolerance and Neuroadaptation

(Source: *Pharmacotherapies, NSW 2001*).

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

Tolerance – repeated administration of the 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 which would be fatal in a non-tolerant individual.

Withdrawal – after a period of prolonged exposure to opioid drugs, stopping the administration of the drug leads to 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 inferred from observing tolerance and withdrawal. Neuroadaptation assumes adaptive changes occur in the CNS as a result of exposure to opioids.

Neuroadaptation begins immediately following the administration of an opioid agonist. Four hours after the administration of a single dose of morphine to a non-dependent subject, a mild withdrawal reaction can be precipitated by the administration of large doses of naloxone, indicating that a degree of neuroadaptation has already occurred.

With repeated administration of an opioid, where the interval between doses is sufficiently short to ensure that there is no time for neuroadaptation to completely reverse, neuroadaptation and tolerance quickly become established. It is possible to progressively raise the administered dose of an opioid until, within weeks, tolerance is such that the client can receive very large doses without evidence of toxicity.

However, tolerance to all opioid effects is partial. When a client has been stabilised on methadone at 80 mg/day (a dose which would be fatal in a non-tolerant person) for many months, blood levels fluctuate within a fairly narrow range and the client appears and functions normally. From about 30 minutes after the daily ingestion of the dose, blood levels are rising, and the client generally feels a sense of wellbeing, and increased energy. Although largely tolerant, some clients experience some euphoric effects as the blood level rises, and slight symptoms of withdrawal when the blood level falls.

The reversal of neuroadaptation begins rapidly when the level of opioid agonist drugs in the CNS begins to decline and is associated with an abstinence syndrome. After about three

weeks of regular opioid use, discontinuation is associated with the symptoms and signs of withdrawal.

The severity of opioid withdrawal is determined by two major factors:

- the greater the dose of opioid being administered regularly, the more severe the withdrawal syndrome on discontinuing
- the more rapid the rate at which the opioid is withdrawn, the more severe the withdrawal syndrome.

Since the more rapidly the drug is cleared from the body, the more pronounced the abstinence syndrome, withdrawal from short-acting drugs tends to be more severe than withdrawal from long-acting drugs. Morphine has a half-life of two to three hours, so blood levels decline fairly rapidly. Long-acting drugs such as methadone or buprenorphine have much more mild (but more prolonged) withdrawal syndromes on cessation. However even long-acting opioids will require slow discontinuation to avoid distressing reversal of neuroadaptation.

The most severe withdrawal reactions occur when an opioid antagonist is administered to a dependent client who at the time has a high level of circulating opioid agonist. By competitively inhibiting the agonist, the administration of naloxone or naltrexone abruptly blocks agonist effects; instead of declining over many hours, drug effects are reversed in minutes. The result is a very severe withdrawal reaction, with profound physiological and psychological effects.

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 CNS to the drug, and less time when there is no drug present. As a result pethidine, which has a very short half-life, seldom induces neuroadaptation even for an individual having two or three injections a day as for most of each 24-hour period there is almost no pethidine in the CNS. This avoids a physiological withdrawal syndrome on stopping pethidine, even after prolonged, daily exposure. In contrast, repeated exposure to a long-acting opioid such as methadone ensures a significant degree of neuroadaptation, because of constant exposure to the drug. After about three to four weeks of daily dosing with methadone, a withdrawal syndrome occurs on discontinuing the drug.

(Source: NSW Health 2001).

2.5 Withdrawal Symptoms

(Source: Practice Guidelines for OST in New Zealand, MoH 2008).

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

Symptoms of withdrawal from methadone usually begin 36 to 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 withdrawal is milder than withdrawal from methadone or morphine because of its slow dissociation from the *mu* receptor. Symptoms start within three to five days of the last dose and can last for several weeks.

Opioid withdrawal is rarely life threatening but can be extremely distressing. The severity of withdrawal is influenced by the duration of opioid use, general physical health and psychological factors such as the reasons for undertaking withdrawal and fear of withdrawal.

2.6 Problems Associated with Opioid Use and Dependence

“The cost of opioid use to individual users and to society as a whole is high. Studies indicate that opioid dependence results in significant costs to society through unemployment, homelessness, family disruption, loss of economic productivity, social instability and criminal activities. Major health consequences of opioid use include higher risk of premature death and, when opioids are injected, increased risk of blood-borne infections such as HIV and hepatitis B and C” (WHO 2004).

Opioid dependence is commonly a chronic and relapsing disorder with a high mortality rate, high rates of medical and mental health problems, criminal activity and significant social impairment (Deering et al 2008).

(a) Medical / Physical Problems

The majority of health risks associated with opioid addiction are related to the intravenous injection of foreign material and include:

- infection of injection sites which may cause problems such as scarring, thrombosis, thrombophlebitis, cellulitis
- systemic bacterial or fungal infections (usually as a result of non-sterile injecting practices) such as septicaemia, infective endocarditis, pneumonia, osteomyelitis, renal complications (glomerulonephritis)
- acute febrile reaction, often referred to as a ‘dirty hit’ (usually lasting 24 to 72 hours) sometimes associated with rigours and jaundice
- deposits of talc in the pulmonary microcirculation, with granuloma formation and fibrosis caused by injection of pharmaceutical tablets (many of which contain talc) (NSWH 2001)
- transmission of blood-borne viruses such as hepatitis C, hepatitis B, or HIV.

(b) Overdose and Toxicity

Opioid users who inject drugs of unknown potency are at high risk of overdose. Opioid toxicity is increased when used in conjunction with other drugs especially with other respiratory depressant drugs, such as alcohol and benzodiazepines. Post-mortem toxicological analysis indicates that in most opioid overdose deaths other drugs are present. Overdose can also produce pulmonary oedema, which is almost invariably present in fatal cases (NSWH 2001).

(c) Mental Health Problems

Dependent opioid users have been found to have greater incidence of depression, anxiety, suicidal ideation, antisocial personality disorder, alcohol abuse and dependence than the general population (NCETA 2004). A New Zealand outpatient study (Adamson et al 2006) which included clients presenting with opioid dependence, reported that overall 65% met current criteria for an anxiety disorder (PTSD 31%, social phobia 31%, specific phobia 22%, OCD 20%); 53% met criteria for a mood disorder (major depressive episode – single episode 10%, major depressive episode – recurrent 24%, bipolar 1 disorder 11%) and antisocial personality disorder 27%. These figures are likely to be reflective of, and may well be elevated in, the population of individuals presenting with opioid dependence.

(d) Quality of Life

Diminished quality of life as a result of: unemployment; impaired relationships with family and friends; financial and legal problems (including imprisonment) often as a result of the cost of funding their drug dependence and the effects of stigma of injecting drug use. This may affect the motivation and ability to seek help for drug addiction and/or its associated problems.

2.7 Dose Equivalence of Opioid Drugs

When pharmaceutical preparations are used, 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. Therefore, the risk of overdose in New Zealand is relatively low compared with the risk in countries where heroin is the dominant opioid used (MoH 2006).

It is important that practitioners working with individuals dependent on opioids be able to estimate the approximate equipotent doses of different drugs.

The following table shows single dose analgesic equivalence.

(Source: *Pharmacotherapies, NSW Health 2001*)

Single-dose Analgesic Equivalence		
	<i>Subcutaneous (mg)</i>	<i>Oral (mg)</i>
Morphine	10	60
Methadone	10	20
Buprenorphine	0.3	1 (sublingual tablet)
Codeine	120	200

The analgesic dose equivalence table reflects the peak activity of a single dose. However, in maintenance treatment, it's not the peak effect but the trough level achieved between doses that is important. Because the opioids listed have very different half-lives, the total daily dose equivalents required for maintenance treatment differ considerably from single-dose equivalents.

Maintenance Dose Equivalence (total daily dose)		
	<i>Subcutaneous (mg)</i>	<i>Oral (mg)</i>
Morphine	40	100
Methadone	10	20
Buprenorphine	1	2 (sublingual tablets)
Codeine	-	600

(Source: NSW Health 2001)

2.8 Self-assessment Questions

1. What are the most common opioid drugs used by people dependent of illicit opioids?
2. Describe tolerance and neuroadaptation.
3. What are the main features of opioid withdrawal and how long would withdrawal from methadone be expected to last?
4. What are the main medical problems associated with injecting drug use?

3. OPIOID SUBSTITUTION TREATMENT

The objectives of this section are:

- to introduce the historical context for the provision of OST
- to clarify the effectiveness of opioid pharmacotherapy in the treatment of opioid dependence
- to identify barriers to the effectiveness of OST.

“Substitution maintenance therapy is one of the most effective types of pharmacological therapy of opioid dependence. There is consistent evidence from numerous controlled trials, large longitudinal studies and programme evaluations, that substitution maintenance treatment for opioid dependence is associated with generally substantial reductions in illicit opioid use, criminal activity, deaths due to overdose, and behaviours with a high risk of HIV transmission” (WHO 2004).

3.1 ***Historical Context of Opioid Substitution Treatment***

Methadone substitution as a treatment for heroin dependence was first used in New York by Dole and Nyswander in 1964 after experience with inpatients established that regular oral methadone reduced drug craving and facilitated normal psychological and physical functioning. Methadone treatment was initially used for clients with a long history of severe problems associated with heroin dependence however the effectiveness of this treatment has resulted in methadone treatment being used more generally for treatment of opioid dependence.

(Source: University of Auckland, Goodfellow Unit 2000)

OST, primarily methadone treatment, can be provided by specialist addiction services, through services under the authority of the specialist services and by approved or gazetted primary health care teams. OST is provided in New Zealand in accordance with the Misuse of Drugs Act 1975. Unless approved or authorised under this Act it is an offence for a medical practitioner to prescribe controlled drugs for the treatment of opioid dependence (MoH 2008). Methadone is currently the only medication funded by PHARMAC for the treatment of opioid dependence in New Zealand though other medications such as Suboxone have advantages over methadone for some clients.

3.2 ***The Public Health Frame of Reference***

The HIV epidemic and the realisation that injecting drug use is the primary mode of transmission of HCV, have meant that OST treatment has become a crucial component of the public health response to the transmission of blood-borne viruses. OST also has other public health contributions to make. By reducing injecting drug use, and bringing opioid users into contact with health services, it allows for provision of a range of health care interventions that may not otherwise be accessed, such as management of mental health and medical problems and antenatal care for pregnant women.

3.3 ***Philosophical Approaches to Treatment***

Because of the very high rate of relapse to opioid use after abstinence-oriented treatment and as a consequence of the contribution of OST to public health goals regarding blood-borne viruses, OST programmes have moved from primary goals of stabilisation and withdrawal to the goal of reducing the harmful consequences of dependence on illicit opioids' use.

A harm reduction approach recognises treatment goals that are based on what a client is able and willing to achieve and to reduce negative health and other consequences associated with opioid drug use for the client, their whanau and the community. It is not regarded as essential to reduce drug use, although this may be a method of reducing harm. Thus abstinence is not the major goal of treatment as the chronic relapsing nature of opioid dependence means abstinence goals carry significant risk for clients (NSWH 2001).

Until recently the most widely used terminology for long-term OST in New Zealand has been ‘methadone maintenance treatment’. Consumer groups have argued for the re-conceptualisation of treatment away from ‘maintenance’ because of the perception that this often implies being ‘parked’ in maintenance once they have stabilised on methadone and has the connotation of OST being ‘lifelong’. The terms ‘methadone treatment’, ‘opioid substitution treatment’, and ‘opioid pharmacotherapy maintenance’ are also frequently used.

Alongside the shifting emphasis from ‘methadone maintenance’ treatment, there has been a re-emergence of a recovery focus which promotes the active supporting of clients to plan their own wellness. The methadone population is ageing, and some will choose to remain in treatment for very long periods of time (e.g. 20 years or more); however, consumers still want services to be working actively with clients to support their recovery from active addiction rather than simply being prescribers of a medication.

“Recovery in the context of OST is a process that may take time to achieve and effort to maintain. It is not simply about ceasing problem substance use but 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” (MoH 2008).

3.4 Objectives of Opioid Substitution Treatment

The objectives of opioid substitution treatment align with the National Drug Policy (2007–2012) to improve the health of New Zealanders by preventing and reducing the health, social and economic harms that are linked to the use of opioid drugs, and, in particular, to:

- contribute to improving the health, psychological and social functioning and wellbeing of clients, their families and their dependent children
- reduce the spread of infectious diseases associated with injecting drug use, especially hepatitis B and C and HIV/AIDS
- reduce the mortality and morbidity resulting from the misuse of opioid drugs
- assist individuals to achieve a successful withdrawal from non-prescribed opioids
- reduce episodes of other harmful drug use
- reduce crime associated with opioid use
- assist with recovery from opioid dependence and withdrawal from methadone, or other opioid substitute medicine, if appropriate and desired by the client.

(Source: Practice Guidelines for OST in New Zealand, MoH 2008)

Though not all these objectives will be achieved with each client, the aim is to reduce the risk of drug-related harm for each client and for the community by minimising withdrawal symptoms, reducing opioid drug craving and blocking the euphoric effects of other opioids. Treatment is essentially pragmatic in its approach, focusing on and giving priority to realisable goals. Improvement for clients is likely to be progressive and not all these objectives will be achieved by each client. Some clients will aim to cease all drug use; some will not.

“OST providers need to balance these objectives, within the resources available, with staff and client safety factors while maximising the client opportunities to pursue recovery from problem opioid use” (MoH 2008).

3.5 Other Treatment Options for Opioid Dependence

People dependent on opioids are not a homogeneous population and require a range of treatment options. They should be informed that methadone or other opioid substitution medicine will be the appropriate treatment for most people dependent on opioids however there is a range of other options available. These include detoxification, outpatient programmes, residential treatment programmes and therapeutic communities, and self-help groups. Any of these options can be utilised as standalone or concurrently with OST.

Managed Withdrawal

Managed withdrawal is the process of providing symptomatic relief to assist the individual to complete withdrawal and avoid adverse events associated with it. Fear of withdrawal can be a barrier to discontinuing drug use. However, contrary to the hopes of clients, families, and health professionals, assisting people to complete withdrawal is not usually followed by long-term abstinence from opioids. Most people who undergo managed withdrawal will return to opioid use within the following 12 months (usually, within the next month).

Managed withdrawal has established risks to opioid addicted patients as the loss of tolerance after withdrawal makes overdose more likely if opioid use is resumed and the chronic relapsing nature of opioid addiction make a return to use the most likely outcome of managed withdrawal. However those clients who, after an episode of detoxification, continue in some form of treatment, for example counselling, naltrexone,³ or maintenance with methadone appear to do better than those who do not (NSW Health 2001).

A treatment complication with managed withdrawal is that, paradoxically, clients seeking this can be overtly or covertly drug seeking for the medications used as symptomatic relief in withdrawals such as benzodiazepines. Managed withdrawal which has a drug-seeking component is unlikely to be effective long term.

Outpatient Programmes

Counselling interventions have been found to be useful for some clients receiving OST and has been shown to improve treatment outcomes in some studies (NSWH 2001). Psychosocial supports are offered to clients on OST by most specialist addiction services and primary health care teams in New Zealand. Psychosocial supports might include counselling, relapse prevention and other groups, and assistance with lifestyle issues such as parenting and advocacy with other services. Provision of peer support workers to work alongside clients on OST may also be a useful adjunct. Those services, including primary health care, not able to offer these services need to assertively assist their clients to access appropriate interventions when required.

³ Naltrexone is not registered in New Zealand for the treatment of opioid dependence.

See also Section 7 and 'Psychosocial Interventions', Practice Guidelines for OST in New Zealand (MoH 2008).

Therapeutic Communities

These are generally long-term highly structured residential programmes often based around principles of self-help and relapse prevention, motivational interviewing, dialectic-behavioural therapy and cognitive-behavioural approaches. Therapeutic communities attract and retain a relatively small proportion of opioid users. Those who remain longer in treatment have improved post-treatment outcomes compared with those not receiving treatment (NSW Health 2001).

Most therapeutic communities and some residential treatment programmes in New Zealand now accept clients on OST either on stable doses or as part of an assisted withdrawal, or reduction from methadone or another opioid substitute medicine.

For information on all New Zealand alcohol and drug and gambling treatment programmes and criteria for admission check www.addictionshelp.org.nz

Self-help Groups

Narcotics Anonymous (NA) is a self-help group for people addicted to drugs. It is based on the same principles, of recovery through the development of spiritual awareness, as Alcoholics Anonymous (AA) and has similar approach to meetings, and principles. Self-help groups are highly accessible, continuous over time and confidential (NSW Health 2001).

3.6 Cost Effectiveness of Opioid Substitution Treatment

“Opioid dependence treatment is effective in reducing illicit opioid use and its associated health and social costs. According to several conservative estimates, every dollar invested in opioid dependence treatment programmes yields a return of between \$4 and \$7 in reduced drug-related crime, criminal justice costs and theft alone. When savings related to health care are included, total savings can exceed costs by a ratio of 12:1” (WHO 2004).

A Christchurch study (Sheerin 2004) investigated the costs and benefits of methadone treatment amongst a Christchurch client sample and found treatment saved \$25,000 per life year. Sheerin calculated that by making OST more accessible and achieving stabilisation at an earlier age in combination with reducing the barriers to treatment for hepatitis C, the cost-effectiveness of methadone treatment as well as treatment for hepatitis C were enhanced.

3.7 Factors Influencing Treatment Effectiveness

“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” (WHO 2004).

Deering (2007) listed the components of effective methadone treatment as:

1. individualised therapeutic methadone doses
2. continuous OST and a goal of maintenance
3. individualised, comprehensive assessment and treatment planning

4. client and family education and orientation to OST
5. health promotion, harm reduction strategies and accessible physical health care
6. individualised psychosocial services targeted to meet client and family needs
7. skilled staff with positive attitudes towards OST and opioid dependent clients
8. client-centred treatment with an emphasis on engagement and therapeutic relationships
9. a system of care approach, with the scope of interagency linkages related to the needs of the local client group
10. clinical case management and monitoring of client outcomes.

OST is a longer-term intervention for opioid dependence; the research literature does not support time-limited treatment with the expectation of ‘cure’ (Goodfellow Unit 2000). The recent large multi-site outcome studies, for example, NTORS (Gossop et al 1998) and ATOS (Ross et al 2005) found that there is a linear relationship between retention in treatment and better outcomes such as improvements in physical and mental health and substantial reduction in opioid use, drug using behaviours and criminal activity.

See *The Practice Guidelines for OST in New Zealand* (MoH 2008) for an outline of the key principles of effective OST in New Zealand.

3.8 *Disadvantages of Opioid Substitution Treatment*

Clients identify the invasiveness of OST as a key disadvantage, in particular inflexibility of arrangements around takeaway doses, this has been referred to a “chemical handcuffing”. Restrictions of takeaways are required to prevent clients using multiple doses together to increase the euphoric effect and/or injecting or selling doses and thus increasing the availability of street opioids. However restrictions on takeaways are also a barrier in regard to entering OST (Deering et al 2008) as daily onsite dosing can interfere with the clients’ ability to obtain and retain paid employment, and to be able to be spontaneous in their movements and activities generally.

The most significant risk of methadone and other opioid substitute medicines is overdose, which can be fatal. The risk of overdose is greatest during commencement of OST followed by the period during and following withdrawal from the treatment. Once a stable dose is achieved (up to 12 weeks) the risk of overdose is then substantially reduced in comparison with the risk prior to or following treatment.

3.9 *Consumer Involvement in OST*

“Client involvement is supported at all levels and in all aspects of OST service design, delivery, planning and evaluation” (MoH 2008).

Meaningful consumer involvement in OST programmes in New Zealand includes the client’s involvement in treatment decisions and the input of consumers (including current and previously clients) into the development of the programme.

Client Involvement in Treatment Decisions

Clients have a right under the Health and Disability Code of Rights to be fully informed and give consent to treatment and to a clear complaints mechanism in the event of a dispute.

See also ‘Rights of the client’ Practice Guidelines for OST in New Zealand 2008 and the Health and Disability Commissioners’ Code of Patients’ Rights.

The consumer as part of the specialist service or primary health care team

Increased involvement of peers in the OST programme was identified by opioid users in a recent commissioned report for the Ministry of Health, as improving programmes (Deering et al 2008). OST consumer networks exist for all areas of New Zealand.

3.10 Whānau Ora, Family-Inclusive Practice, Working with the Client's Support People

The Practice Guidelines for OST in New Zealand (MoH 2008) promote a tripartite partnership approach between the client, the specialist service or primary health care team and the client's designated advocates (advisors, representatives, peer-support workers, family, whānau). This type of partnership approach can contribute to improved outcomes for clients and services.

3.11 Stigma

Discriminatory practices have been identified as primary barriers to accessing health care. Opioid users are often faced with negative attitudes based on stereotypes and fears which can result in discrimination, stigma and marginalisation.

Stigma can impact on treatment at every point, for example:

- many opioid users themselves share community-stigmatised attitudes to opioid use
- practitioners involved in delivering treatment can lack detailed information about addiction, have a history of being exploited by addicts or need support to maintain healthy boundaries with this complicated client group – this can be expressed through punitive and inflexible approaches to treatment
- political and community support for methadone treatment is inconsistent (from NSW 2001).

Deering et al (2008) propose that service providers strike a balance between public concerns about injecting drug use and the individual treatment needs, rights and aspirations of opioid dependent clients. However they acknowledge that “*given the continuing societal stigma associated with injecting drug use and injecting drug users, finding the appropriate balance is a major challenge, and is highly likely to be one of the drivers of variation in treatment approaches*”.

3.12 Attitudes and Values of the Workforce

The attitudes OST providers have towards the treatment are the best predictor of the programme's ability to retain clients, with higher punitive and abstinence orientation associated with lower retention of clients in programmes. For this reason specialist services value a team approach to treatment and primary care providers need the support of specialist services in dealing with conflicts with clients and treatment planning (Caplehorn et al 1996).

3.13 Self-assessment Questions

1. What are the main objectives of opioid substitution treatment in New Zealand?
2. How does a harm reduction approach to managing opioid dependence work in your practice?
3. What are some of the ways in which you have seen opioid users or people receiving OST discriminated against?
4. What are some strategies that you or your service could employ to reduce stigma?
5. Do you think drug users, given the self-inflicted nature of some of their medical complaints, deserve the same level of medical treatment as non-drug users?

4. PHARMACOLOGY AND PHARMACOKINETICS OF METHADONE AND BUPRENORPHINE

4.1 *Pharmacology*

(Source: Practice Guidelines for OST in New Zealand, MoH 2008)

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

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

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

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

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

Antagonists have no intrinsic pharmacological action but 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, precipitating withdrawal. They are often used therapeutically to reverse the effects of opioid overdose.

Methadone

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

Buprenorphine

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

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

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

4.2 Pharmacokinetics (what the body does to a drug)

Methadone

Methadone is fat soluble and binds to a range of body tissues, including the lungs, kidneys, liver and spleen. The concentration of methadone in these organs is much higher than in blood. There is then a fairly slow transfer of methadone between these stores and the blood which accounts for the relatively long acting nature of methadone. Methadone has high oral bioavailability (90%) 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% 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 dosing, 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 (30–40%) sublingual bioavailability, with the tablets taking between two and seven minutes to dissolve. The speed of dissolution may be enhanced by breaking the tablets into a few pieces (this may also help reduce diversion of the dose). Crushing the tablets into powder should be avoided as it tends to encourage swallowing.

Because buprenorphine is a partial agonist, its physiological and intoxicating effects usually plateau at a sublingual dose of 4–8 mg (some clients 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 has a higher affinity for opioid receptors than morphine or methadone potentially precipitating opioid withdrawal in a person who has recently used other opioids.

Buprenorphine is highly bound to plasma proteins. It is metabolised by the liver via the cytochrome P450 enzyme system into norbuprenorphine and other metabolites, which are excreted in the faeces (70%) and urine (30%). The half-life of buprenorphine is highly variable: 20–72 hours, with a mean of 36 hours. With stable dosing, steady state levels are achieved over seven days. Peak clinical effects occur one to four 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).

Buprenorphine with naloxone (Suboxone®) is available in New Zealand for the treatment of opioid dependence but is not publicly funded.

Naltrexone

Naltrexone is an opioid antagonist which binds to opioid receptors but produces no opioid effect. 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 relapse but not for opioid relapse.

4.3 Side-effects

Methadone

Side effects of methadone are shown in the table below. Many of these side effects may be confused with withdrawal symptoms and be experienced even when the dose is adequate hence the importance of noting times of day when these symptoms are experienced (e.g. mainly just prior to consuming, or, any time/throughout the day). It may be advisable to take serum level tests to determine adequacy of methadone dose.

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

(Source: Practice Guidelines for OST in New Zealand, MoH)

Buprenorphine

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

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

(Source: Practice Guidelines for OST in New Zealand, MoH)

4.4 Contraindications of Opioid Substitution Treatment

Relative contraindications

- Severe hepatic or respiratory insufficiency.

General contraindications

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

Precautions

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

Specific contraindications to buprenorphine

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

(Source: Practice Guidelines for OST in New Zealand, MoH 2008)

4.5 Overdose

The majority of deaths occurring during stabilisation on methadone involve the use of other drugs; in particular, other opioids. The overdose risk for methadone and illicit opioids relates to the build up of a reservoir of methadone caused by the drugs high level of tissue binding and as a result clients whose opioid tolerance does not exceed 50 mgs of methadone equivalent have a high risk of overdose during the stabilisation phase of OST despite the common perception that low tolerance clients have lower overdose risk in this period.

Any drug that has a synergistic or potentiating effect with opioids or which are potentially toxic to the liver (including alcohol, benzodiazepines and antidepressants) have the capacity to cause overdose when combined with methadone and the risk of overdose is more pronounced during the stabilisation phase of OST. As a result clients must be warned about the risks of using other drugs with methadone and closely monitored during this period.

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

Because of the long plasma half-life of methadone, naloxone (the opioid antagonist) should be given as a prolonged infusion when treating a methadone overdose. In this situation the client should be intubated to protect respiration and consideration may be given to giving less than a full dose of naloxone in the first instance as this is sufficient to raise consciousness without initiating a full scale (and distressing) withdrawal syndrome.

The 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, pulmonary oedema. The symptoms may last for 24 hours or more.

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

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

(Source: Practice Guidelines for OST in New Zealand, MoH 2008)

4.6 Drug Interactions

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

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

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

(Source: Practice Guidelines for OST in New Zealand, MoH 2008)

For information on specific drug reactions with methadone and buprenorphine see *Practice Guidelines for OST in New Zealand* (MoH 2008).

4.7 Self-assessment Questions

1. What is the expected elimination half-life of methadone when taken by a person on a stabilised dose?
2. How does buprenorphine work?
3. What are the most common side effects of methadone?
4. Describe the role of naloxone in an opioid overdose?
5. What is the meaning of ‘additive effects’ in regard to drug interactions?

5. ASSESSMENT

Section 5 covers the assessment required for clients presenting to services with substance use problems. The objective of this section is:

- to outline the information required to complete an appropriate comprehensive alcohol and drug assessment
- to highlight the importance of the therapeutic relationship in the treatment of clients on OST.

A comprehensive assessment covering the mental health, addiction, living situation, developmental, physical state history and a current risk assessment for the client will be carried out by the specialist OST service in order to decide the suitability of the client for this treatment. However assessment is an ongoing process rather than event and the assessment will be formally updated when:

- the client is being transferred to another specialist service or primary health care team, or from the primary health care team back to a specialist service
- if problems are appearing and
- after specific periods of time in treatment.

“The comprehensive assessment for a client’s suitability for OST should start within two weeks of the client presenting or being referred to the specialist service” (MoH 2008).

Assessment of risk is an important part of comprehensive assessment. Potential risks related to opioid dependence might include unsafe injecting practices, overdose, concurrent other drug or alcohol use, driving, and the broader risks related to self-harm, or harm to others, especially dependent children.

Documentation is also 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 people⁴ where appropriate) and the multidisciplinary team.

5.1 *The Comprehensive Assessment*

The goals of the initial comprehensive assessment are to:

- establish a diagnosis (**Note:** a client must meet the diagnostic criteria for opioid dependence, such as those outlined in the DSM IV and ICD-10, to be suitable for OST)
- facilitate client engagement in the treatment
- explore the treatment options and assist the client to make informed decisions about the treatment
- document an initial treatment plan that is agreed to by the client.

(Source: Practice Guidelines for OST in New Zealand 2008, MoH).

⁴ *The client’s support people can be anyone in the client’s network that they want to involve in the treatment process, e.g. a partner, whanau members, designated client advocate or support worker.*

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

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

(Source: Practice Guidelines for OST in New Zealand 2008, MoH 5)

The assessment should also include:

- details of any restriction notices that apply under section 25 of the Misuse of Drugs Act 1975 or section 49 of the Medicines Act 1981
- a record of any treatment options discussed with the client and assessed as being inappropriate or declined
- investigations, including a urine drug screen (to confirm level and nature of current use) and blood tests (for example, for liver function) and other relevant physical health checks.

(Source: Practice Guidelines for OST in New Zealand 2008, MoH)

Once opioid dependence and eligibility for OST is confirmed, a discussion around the programme rules and expectations and the side effects of methadone or other opioid substitute medicine would occur. Written information should also be provided for the client and their support people to read. Alternatives to OST would also be discussed.

“Once a client is assessed as being suitable for OST, treatment should begin as quickly as possible (that is, within two weeks)” (MoH 2008).

Admission to the OST programme will occur in the specialist OST service and would generally occur as soon as possible after assessment and after eligibility has been established. There will be national variations in regard to the time from presentation to admission due to the unique characteristics of individual services including prescriber availability and caseload allocation.

Historically assessment procedures have been largely deficit focused, designed to generate management plans arising out of problem lists. An assessment of the client's strengths and factors supporting recovery is important to record and to integrate into the management plan.

“The general assumption is that, the greater the problem severity and complexity, the greater the restrictiveness and potential duration of treatment. But comprehensive assessments of recovery capital can alter such decisions considerably” (White 2008).

Recovery capital in this context refers to factors that support the individual to maintain stability and a meaningful lifestyle and which draw on aspects of intrapersonal, interpersonal, and community resources.

The assessment session can also provide an excellent opportunity for the clinician to provide brief interventions to reduce immediate harm from injecting drug use. This should involve an examination of injecting practices and sites of injection⁵ and the provision of resource material and information on access to sterile injecting apparatus. In some situations it may also involve testing for hepatitis C and B and HIV, and immunisation against hepatitis B.

5.2 Enhancing a Client-centred Approach

The comprehensive assessment is an important process in the development of the therapeutic relationship with the client. The quality of the therapeutic relationship is a crucial component of positive treatment outcome especially given the relationship with the client receiving OST can sometimes span many years.

Factors contributing to the quality of health professional-client interaction include the skills and enthusiasm of health professionals and treatment philosophy and policies. Organisational issues, such as workload and communication between members of the multidisciplinary team, may also contribute to the effectiveness of treatment.

Key competencies relevant to ability to develop a good therapeutic relationship are cited as:

- the ability to engage a client appropriately while demonstrating satisfactory levels of warmth
- the ability to build rapport, and to be able to adopt a personal style that is consistent with, and meshes with, that of the client
- an ability to adjust the nature of the intervention according to the capacities of the client
- an ability to deal with difficult emotions, understand and work with a clients emotional context including client motivation (Roth and Piling 2007).

The following set of clinical strategies is recommended to facilitate a good therapeutic relationship with the client. These strategies have been empirically demonstrated to enhance the quality of support provided to drug users and to maximise the probability of behaviour change occurring.

⁵ * Note that track marks are not always in the obvious locations and some injecting drug users will go to considerable lengths to use sites that are less obvious and less easy to detect on examination.

* Excellent information on needle exchange programmes, ways of taking drugs, harm reduction and safe injecting practices can be obtained on the following website: www.needle.co.nz

<i>Regard the person's behaviour as their personal choice</i>	<ul style="list-style-type: none"> • Acknowledge that there are two sides to behaviour: benefits as well as costs. • Understanding and acknowledging the client's choices enhances their autonomy and responsibility.
<i>Let the person decide how much of a problem they have, i.e. how important it is for them to quit</i>	<ul style="list-style-type: none"> • Systematically explore benefits (likes) and costs (dislikes) as perceived by the client. • Use the examples and issues that the client raises. • Encourage the client to rate their motivation and confidence to change out of 10. If score is low, explore what would need to happen to increase this score. If the score is high, why?
<i>Avoid argumentation and confrontation</i>	<ul style="list-style-type: none"> • Confrontation within the client is the goal. • Separate information from the 'persuasive imperative'.
<i>Encourage discrepancy</i>	<ul style="list-style-type: none"> • Change is likely to occur when a person's behaviour is seen to be in conflict with their personal goals. • Use the decision balance to identify the areas of discrepancies.
<i>Help clients re-evaluate their substance use</i>	<p>Three ingredients are necessary for any behaviour change:</p> <ul style="list-style-type: none"> • concern with the current behaviour • belief that change will lead to improvement or things being better • belief that change is possible (self-efficacy).

(Source: NCETA, 2004, Alcohol and Other Drugs: A Handbook for Health Professionals (3rd edition). Commonwealth Department of Health and Ageing. Canberra. Chapter 13, Psychosocial Interventions).

5.3 Self-assessment Questions

1. What are the key components of the alcohol and drug section of the comprehensive assessment?
2. What signs might you expect to find of injecting drug use?
3. What information would you provide to a client about safe injecting practices? (See www.needle.co.nz.)
4. How confident are you with assessing for mental health problems?
5. If not entirely confident what will you do practically in order to address this?
6. How would you assess for strengths or 'recovery capital'?
7. Name three strategies you have used to strengthen the therapeutic relationship with a client on OST.

6. OPIOID SUBSTITUTION TREATMENT STAGES

Section 6 introduces the stages of opioid substitution treatment from induction through to ending treatment. The objective of this section is to provide information on the procedures required at each stage of the opioid substitution treatment process. This section does not include the special requirement of transferring the client to the primary health care service to have their wider health care needs met alongside OST. Section 8 addresses the specifics of OST in primary health care.

6.1 Induction

Induction into treatment, particularly where methadone is used as the substitute opioid requires balancing the needs of clients to have an adequate dose with the elevated risk of overdose as opioid levels accumulate. The risks of overdose need to be discussed with the client and their support people as the accumulating nature of methadone means prescribed doses will be conservative and clients may experience discomfort due to insufficient opioid effect until methadone reach therapeutic levels, this discomfort may motivate the client to other drug use.

“Most of the fatalities during induction into methadone treatment involve the use of alcohol and benzodiazepines in conjunction with methadone. Even in these cases, the level of methadone tolerance is an important factor in the risk of fatal overdose” (NSWH 2001).

For this reason the starting dose of methadone should be at a level considered safe in a non-tolerant person.

The Practice Guidelines for OST in New Zealand (MoH 2008) note that deaths in the first two weeks of methadone treatment have been associated with daily doses in the range of 25–100, with most deaths occurring in the 40–60 mg range. After the first two weeks, the risk of death due to opioid overdose during treatment falls to very low levels. Fatal overdose in the induction of clients onto buprenorphine are far less common.

The starting dose of methadone

Initial doses of methadone in OST should be based on the client’s treatment aims; history of quantity, frequency and route of administration of opioids; and use of other central nervous system depressants. Treatment should also take into account the client’s hepatic and renal functioning. In general, the initial daily dose will be in the range of 10–40 mg. The first dose of methadone should never be higher than 40 mg.

Following the first methadone dose, the key worker or doctor should observe the client’s response to the dose after 30 minutes and again three or four hours after the dose has been taken (at peak plasma level concentration) to assess for signs of toxicity or withdrawal.

It is recommended that the methadone dose not be increased for the first three to four days as methadone accumulation poses a considerable risk if doses are increased too rapidly. The client will need to be monitored for three to four hours after the third or fourth dose to exclude the risk of intoxication in relation to the peak plasma concentration. By the fourth day, the client should be close to achieving a steady state methadone level.

Where doses need to be increased in response to withdrawal reactions, the increment of increase should be 5–10 mg at a time and not more often than every three to four days.

(Source: Practice Guidelines for OST in New Zealand 2008)

The starting dose of buprenorphine

Buprenorphine is a partial agonist; this means that it can prevent a concurrently administered agonist drug from producing its full agonist effect. It can be provided in larger initial doses than the full agonists such as methadone and is both safe and effective when rapidly increased to higher dose levels in response to reactions (up to 16 mg by day three). It is also safer in overdose than methadone when combined with other CNS depressant drugs.

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

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

The first dose will usually be from 4–8 mg of buprenorphine. This may be repeated if assessment four hours later suggests that withdrawal is persisting. Splitting the first daily dose into twice-daily or three-times-daily doses reduces the chance of precipitated withdrawal.

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

(Source: Practice Guidelines for OST in New Zealand 2008)

6.2 Stabilisation

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

During the first two weeks of treatment, the aim is to avoid the client oscillating between intoxication and withdrawal. However, the client will not necessarily reach a stable dose during this period. Stabilisation would mean that the client is comfortable on a consistent regular dose without the need for constant dose changes and review and is able to work consistently towards agreed goals. For some clients, this will take a considerable time to achieve, and they may need significant input from the specialist service. Factors to consider when assessing stability include assessing the client's:

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

- reduction or cessation in involvement in drug-related criminal offending
- responsible management of dispensed medicine.

(Source: Practice Guidelines for OST in New Zealand 2008, MoH)

6.3 Ongoing Treatment

Once stabilisation has been achieved the focus of OST is on promoting the goals of OST as indicated in the client's treatment/management plan. The treatment plan will generally be regularly reviewed and will be in line with roles of specialist services as outlined in the Practice Guidelines for OST in New Zealand 2008. These roles include:

- transfer of stabilised clients to the care of GPs
- provision of specialist interventions to minimise the harms associated with opioid and other drug use and assist clients to make behavioural changes and lifestyle improvements
- treatment and management of people who are unsuitable for transfer to GP care
- provision of appropriate psychosocial support and liaison services
- screening, advice and treatment, or referral for co-existing medical disorders with particular reference to those related to intravenous drug use and protracted opioid use
- assessment and treatment (or referral for treatment) of co-existing mental health disorders
- consultation, liaison and referral to allied professionals in other health care and social service roles, including peer support and advocacy services.

6.4 Doses

Methadone doses

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

Any changes in dose should always be negotiated with the client.

(Source: Practice Guidelines for OST in New Zealand 2008, MoH)

Buprenorphine doses

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

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

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

(Source: Practice Guidelines for OST in New Zealand 2008, MoH)

Higher doses

Methadone doses of 80 mg/day and above and buprenorphine doses of between 12–24 mg have consistently been found to be associated with lower rates of illicit opioid use and longer retention in treatment than lower doses. The dose should be progressively raised to adequate levels in the first few months of treatment. It is important to address any concerns that a client might have about higher doses and to encourage clients to take an adequate dose.

(Source: Practice Guidelines for OST in New Zealand 2008, MoH)

“In all cases it is important that the dose selected is based on an assessment of the individual client” (WHO 2004).

Local service protocols may have more specific requirements in regard to dosing that should be followed. All local protocols however are expected to be consistent with the 2008 Practice Guidelines.

For information on maximum doses, transferring from methadone to buprenorphine or from buprenorphine to methadone see *Practice Guidelines for Opioid Substitution Treatment in New Zealand 2008*.

6.5 The Prescribing Process

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

- Methadone prescriptions are to be written on the approved H572M forms, unless the provider has the written authorisation of the Director-General of Health to use computer-generated forms, and are to be for no longer than 28 days' supply.
- The pharmacist must receive written prescriptions for methadone and other OST medicines (always with the amount prescribed written in words and figures) at least one day before the due date to supply (by law, the original must be received by the pharmacist within two working days) so that the pharmacist has time to prepare the documentation and dispensing plan. In some situations, it may be acceptable to fax through the prescription. As well, the client may be given the prescription to take to the pharmacy themselves.
- As per amendments to PHARMAC's close control rules, from June 2008, prescriptions should be endorsed as 'daily dispensing, close control', and the endorsement should be initialled in the prescriber's own handwriting. This allows the pharmacist to receive payment for each dose dispensed.
- Prescriptions should be started on a day of the week that the client is usually observed consuming their methadone, or other opioid substitute medicine, and not on a day that the client has a takeaway dose
- Prescriptions should not be started on a Saturday, a Sunday or a public holiday unless the prescriber is prepared to be contacted over those days should any questions arise and has an arrangement with the pharmacist beforehand for dispensing on those days.
- Specialist services and GP prescribers must always provide pharmacists with positive identification of clients ideally this will include a current named photograph of each client. Faxed photographs are often not legible and, if used, should be followed up with the posting out of an original.
- The prescriber, or the key worker, is responsible for notifying the pharmacist of any prescription changes (for example, cancelled doses, when the client attends another pharmacy temporarily and termination of treatment from that pharmacy).

- Only the prescribing doctor can make changes to scripts, that is, an altered dose, extra doses or changes to the pharmacy used for dispensing the prescription.
- Any changes to takeaway doses (usually a one-off) can be made according to the protocol and needs to be internally signed off as per local protocols. Such changes may be telephoned or faxed through to the pharmacy and must be noted in writing.
- Where possible, the pharmacist should be given at least one day's notice of changes to scripts.
- Where a prescription is cancelled, (other than for routine matters such as change of pharmacy), the client concerned will be informed directly. If direct contact is unable to be made with the client a fax message will be sent to the client, via the pharmacy informing them of the changes, and where appropriate, a letter will be sent to the client's home address, outlining the reasons for this intervention and giving notice wherever possible.
- Where a prescription is cancelled, (other than for routine matters such as change of pharmacy), the client concerned will be informed directly. If direct contact is unable to be made with the client a fax message will be sent to the client, via the pharmacy informing them of the changes, and where appropriate, a letter will be sent to the client's home address, outlining the reasons for this intervention and giving notice wherever possible.
- Where split doses are prescribed the controlled drug prescription must include clear instruction as to which part of the dose is administered and which, if any, is dispensed as a takeaway dose.

(Source: Practice Guidelines for OST in New Zealand 2008)

6.6 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. Prescriptions for other Schedule 2 controlled drugs, such as morphine, must be written on an H572 controlled drug prescription form and a copy kept for the file. N.B. At this time prescriptions for Suboxone can be written on a general prescription pad.

1. Actual date pharmacist is to begin dispensing.
2. Name and current residential address of client. It is **not** acceptable to use the pharmacy address as the client address.
3. NHI number.
4. Biodone Forte stamp is used. Stamp on all four copies unless using other formula, e.g. Biodone 2 mg/ml or Biodone Extra Forte 10 mg/ml. Note: Stamp should appear next to client address – **not** within the “Pharmacy Use” column.
5. Write current dose preferably in numeric and word form, e.g. 80 (eighty) mg. Note: if a client is undertaking any type of withdrawal from methadone, then the new prescription should state the current dose as the starting dose.
6. Write start date again (actual date pharmacist is to begin dispensing).
7. Total period of supply up to a maximum of **28** days. Write Close Control (or C.C.) beside dose and initial.
8. The maximum rate of any withdrawal regime must be specified.
9. Cross this sentence out. Errors have occurred here to the misunderstanding of this statement.
10. Write in days for which takeaways are authorised. For example: 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.
11. Name of pharmacy.
12. Sign prescription (and highlight any changes from the previous script)
13. Stamp or printed NZMC Reg. No., MO name and AMS address.
14. Top three copies to pharmacy by post. Bottom copy (blue) is kept on client file.

H572M	324071	Item count
MINISTRY OF HEALTH CONTROLLED DRUG PRESCRIPTION FORM		PHARMACY STAMP
Circle Y J A P 1 2 3 Z		
Prescription Date: / /	1	
Patient:		NHI No: 3
Address: 2		BIODONE FORTE 5 mg/ml 4 NO SUBSTITUTION Use safety Caps for Takeaways
R: METHADONE MIXTURE		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		14
Address:		PHARMACY COPY

6.7 Methadone Formulation

- All methadone dispensed to AMS clients must be the product prescribed. No substitution is permitted without authorisation.
- AMS preferred product is a 5 mg/ml solution, free of additives, in line with harm reduction philosophy.
- All requests for a change in formulation must be referred to the prescriber.

6.8 Decision not to Admit to the OST Programme

Where the client is not suitable for OST the medical officer will discuss with the assessing clinician and then inform the client of the reasons both in person and in writing where practicable. Appropriate alternative options and services will be offered to the client. The decision not to admit will be reviewed by the clinical team. The decision not to admit may also be presented for the information of the team.

6.9 Reviewing Treatment Progress

Clients will vary in their requirements for review, for example, clients in their first year of treatment and clients who are assessed to be unstable in relation to drug use, mental health or lifestyle issues will require more regular reviewing than stable clients who have been receiving OST for long periods of time. Some will require little more than regular prescriptions while others will require more time from prescribers, their key worker or other team members in regard to issues related to dose, intoxication, medical and mental health problems, lifestyle crises and other psychosocial issues.

The review allows the prescriber or the key worker to monitor progress and highlights to the client the progress that she/he is making. The review may also be an opportunity for providing harm- reduction information, for example, offering HCV and HIV tests to clients who have been engaged in at-risk behaviour, and reinforcing information on reducing risk of infection.

The Practice Guidelines for Opioid Substitution Treatment in New Zealand 2008 state “*Once dose stabilisation is achieved, the prescribing doctor can be expected to see the client at least every three to six months. Where possible, such reviews should also involve the key worker*”. The time frame has been deliberately left open to cater to the unique circumstances and operating systems of the different services. Specialist services and providers are expected however to review each client at least every six months, and more usually review the client three-monthly.

The key worker (sometimes known as the case manager) is expected to see the client at least once every three months and more often depending on the individual clients need. In some primary health care teams the key worker may be the GP prescriber.

A guide to what might be covered in a monitoring session is outlined in the *Practice Guidelines for Opioid Substitution Treatment in New Zealand 2008*. They include:

- a review of how the client is functioning in their social role and their employment/ education status and aspirations
- a discussion of links with other health and social service providers
- a discussion of ongoing substance use and misuse (including alcohol and tobacco)
- a discussion of the results of any urine drug screens

- consideration and review of dose adjustments and takeaway arrangements
- consideration of lifestyle and high-risk behaviour changes, including lapses and relapses
- a referral for the review of medical issues where needed
- a review of the client's mental state and management of co-existing mental health disorders
- a review of whanau ora – the client's relationship with their family/significant others
- information and/or referral to self-help groups and other support and ancillary services (e.g. peer support workers)
- a discussion of the client's adherence to service and treatment conditions
- an assessment of the client's suitability for transfer to primary health care (if this has not already occurred)
- consultation with other health care providers, for example, the community pharmacist, to gain corroborative information regarding the client's progress and any risk for that client.

A summary of the above should be available for the three-monthly (or longer as above) review. The treatment review should involve relevant members of the treatment team, particularly the prescriber, key worker, practice nurse or specialist counsellor as appropriate and ideally the community pharmacist.

As a result of the review and in collaboration with the client the treatment goals may need to be refined or revised.

For more information on reviews refer to *Practice Guidelines for OST in New Zealand 2008*.

6.10 Ending Opioid Substitution Treatment

Remaining in treatment for an adequate period of time is critical for treatment effectiveness. The appropriate duration of treatment for individuals depends on their problems and needs, but research indicates that for most people with drug dependence, the threshold of significant improvement is reached after about three months in treatment, with further gains as treatment is continued. Because people often leave treatment prematurely, and premature departure is associated with high rates of relapse to drug use, programmes should include strategies to engage and keep clients in treatment. Many clients need several years in treatment (WHO 2004).

6.10.1 Planned Withdrawal

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

Withdrawal should ideally occur only when the client has achieved a number of their treatment goals and has reached a stage of stability that gives them a reasonable chance of successfully achieving sustained abstinence from opioids.

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

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

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

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

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

(Source: Practice Guidelines for OST in New Zealand)

6.10.2 Involuntary Withdrawal

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

It is important to note that relapse is a feature of addiction and this should be taken into account.

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

Other situations where a client may be considered for involuntary withdrawal include the following:

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

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

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

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

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

Note: NAOTP is currently refining the second opinion requirement and its decision on this will override the guideline as presently written.

When subject to involuntary withdrawal, the client will be:

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

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

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

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

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

If a client has HIV/AIDS and may threaten to use unsafe behaviour if their treatment is terminated, the treatment provider should consult with the local Medical Officer of Health before treatment is terminated.

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

(Source: Practice Guidelines for OST in New Zealand)

For suggested reduction schedules for methadone and buprenorphine, information on last doses and transferring to naltrexone refer to *Practice Guidelines for Opioid Substitution Treatment in New Zealand 2008*.

6.11 Self-assessment Questions

1. What is the significance of examining the client three to four hours after the first dose of methadone?
2. Why is it recommended that buprenorphine not be administered while other opioids might still be in the individual's system?
3. What is the recommended starting dose of methadone and why is it set at this level?
4. How often is a review expected to occur?
5. In what circumstances would you consider terminating a client's OST against their will?
6. What would be a recommended reduction rate for a client voluntarily withdrawing from 80 mg of methadone and over what period of time?
7. What support services should be offered to a client withdrawing from OST?

7. PSYCHOSOCIAL INTERVENTIONS

Section 7 explores the importance of the provision of psychosocial interventions in the treatment of clients on opioid substitution treatment.

There is a strong evidence base showing improved outcomes when clients are voluntarily provided with both counselling and practical support during their OST. The Ministry of Health has indicated that it would like to see psychosocial interventions routinely offered to all clients receiving OST. It acknowledges that not all clients will need or want to be provided with interventions other than pharmacotherapy at any one time.

“No single treatment is effective for all individuals. Individuals seeking treatment for opioid dependence will have different patterns of risk and protective factors, and different psychological and social problems. Therefore services should be sufficiently varied and flexible to respond to the needs of clients, their severity of dependence, personal circumstances, motivation and response to interventions. The rational management of opioid dependence calls for the balanced combination of pharmacotherapy, psychotherapy, psychosocial rehabilitation and risk reduction interventions” (WHO 2004).

7.1 Defining Psychosocial Interventions

Psychosocial interventions include counselling (e.g. relapse prevention, cognitive-behavioural therapies, group psychotherapy, family/whanau therapy and education in life skills including parenting, budgeting and self care) and support (e.g. vocational counselling, employment, education/training, parenting, housing and financial assistance). Psychosocial interventions in the OST context should assume a family-inclusive and whanau ora approach.

“The provision of an opioid substitute medicine should never be considered an isolated intervention but always as part of a wider care programme. It is important that other problems, such as medical, social, employment/learning, mental health or legal problems are identified and addressed in order for the client to achieve stability and, in most cases, for recovery to be achieved” (MoH 2008).

The efficacy of counselling and psychosocial support for clients in OST has been identified as depending on the following factors:

- The client’s level of psychological wellbeing and need for counselling.
- The willingness of the client to engage in counselling, since motivation to engage in counselling appears to be a determinant of outcome.
- The service provider’s provision of counselling: whether onsite within a public clinic, or via referral from a GP – self-evidently access to counselling is a prerequisite of clients obtaining it.
- The degree of proactive case management – which will encourage and facilitate appropriate referral to counselling (Ritter and Chalmers 2008).

The range of support services that may be required in addition to the services provided by the specialist service or the primary health care team may include:

- dental services
- counselling services
- housing services
- financial advice
- parenting support
- education and training information
- children, young persons and whanau services
- psychological services
- mental health services
- infectious diseases services
- gastroenterology services.

The specialist service and primary health care are responsible for appropriate referral to these services.

7.2 Self-assessment Questions

1. What psychosocial interventions does your service/primary health care provide?
2. How accessible are these interventions?
3. If psychosocial interventions are not currently provided what would you suggest should be done to rectify this?
4. What does your local policy state about how frequently clients are offered psychosocial interventions?
5. Which clients should be prioritised to receive psychosocial interventions?

8. OPIOID SUBSTITUTION TREATMENT IN PRIMARY HEALTH CARE – A SHARED CARE ARRANGEMENT

Section 8 provides the rationale for transferring clients from the specialist service to the care of the primary health care team. It also outlines and clarifies the role and requirements of authorised GP or GP approved/gazetted working with OST clients.

The current service delivery model for OST services in New Zealand is through specialist services and primary health care teams. 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 logical primary environment for client management as *“The health care home for people receiving treatment and care for any long-term condition, including opioid dependency, is in primary health care”* (the general practice setting) (MoH 2009).

General practitioners (GPs) work under authority from a specialist service or a specified practitioner in accordance with the terms and conditions set out in Section 24 of the Misuse of Drugs Act (see Misuse of Drugs Act, Practice Guidelines for OST in New Zealand 2008). When a client moves to a shared care arrangement with their primary health care team, specialist services continue to provide support to clients (as assessed to be appropriate) and liaison with, and backup for authorised GP or GP approved/gazetted. Many OST specialist services in New Zealand have designated GP liaison positions to fulfil this role.

In New Zealand there are several gazetted/approved GPs who, although maintaining liaison with specialist services, manage clients on OST without the need for authorisation. These GPs may work for a PHO, which may be gazetted, or in their own supported practice. The Ministry of Health has indicated that it would prefer to gazette PHOs rather than individual GPs and expect some degree of involvement by the specialist services with these clients.

The route of entry to OST remains with the specialist services. Gazetted GPs or PHOs can not currently commence a client on OST who has not been transferred by a specialist service. Although the transfer of clients to a primary health care setting provides the potential for greater flexibility of service provision (Townshend et al 2001), many services have difficulties finding GPs to take over prescribing of methadone or other opioid substitution medicine. A 2008 report commissioned by the Ministry of Health (Deering et al 2008) identified the following barriers to the transfer of clients to primary health care settings as indicated by specialist service respondents.

- **GP-related barriers including:**

- lack of GP availability
- lack of training and confidence
- the reluctance of GPs to take on the administration burden
- lack of incentive funding.

A GP’s unwillingness to provide OST was considered by respondents to be influenced, in part by stigma.

- **The client-related barriers were:**

- cost
- perceived preference to remain with the specialist service, and
- perceived lack of readiness for transfer.

- **Staffing/service barriers included:**

- a perceived reluctance to transfer clients
- staff resource issues including resources to back up and support GPs.

Despite the barriers perceived by clients for transferring to the primary health care setting an Auckland study (Goodyear-Smith et al 2005) found that most surveyed clients receiving opioid substitution treatment in primary health care were “very satisfied with the standard of care”.

8.1 *Transfers from the Specialist Service to the Primary Health Care Sector*

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

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

As soon as possible after dose stability has been achieved, specialist services should proactively support the transfer of clients to a shared care arrangement with a GP for continued prescribing and care. In most cases, clients will stabilise within their first year of OST and become low risk in terms of their ongoing management. In such cases, it is considered best practice to have the client’s OST incorporated into a total health treatment plan that is administered by their primary health care team.

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

Before any transfer to shared care takes place, clients should participate in a comprehensive review with the specialist service’s case management team to determine their suitability for transfer to primary health care.

When involving the primary health care team in a shared care arrangement for OST clients the specialist service remains responsible for:

- managing the transitional arrangements with care and diligence
- maintaining a support and liaison role for the primary health caregiver
- accepting the return of any client who becomes ‘destabilised’ and can no longer be managed in a general practice (local protocols should be developed for the restabilisation of clients who are utilising specialist resources with or without actually returning to the specialist service)
- ensuring that GPs have a clear and immediate line of contact with relevant clinical staff if required
- conducting an annual (minimum) review with clients and organising contact with GPs at least twice a year

- notifying and updating pharmacies as to which GPs are authorised approved/gazetted to prescribe OST
- supporting the national primary health care training package for OST.

In many situations of transfer to the primary health care sector, the client will transfer to a GP working under the authority of the specialist service. In this case, the specialist service remains the responsible provider, while the authorised GP or GP approved/gazetted prescribes opioid substitution in accordance with written terms and conditions (protocols) laid down by the specialist service in relation to specified clients.

(Source: Practice Guidelines for Opioid Substitution Treatment in New Zealand 2008)

8.2 Requirements of GPs in Shared Care with a Specialist Service

GPs working with clients on OST should have attended relevant training in OST, specialist alcohol and other drug treatment, or have experience working with OST. The completion of this manual and the companion workshop (or equivalent) is considered to be an acceptable knowledge baseline for working with clients receiving OST. However further study at a tertiary level is still recommended.

The GP will ideally be working within a broader primary health care team that includes reception staff, a practice nurse and often other professionals. These other staff members are also likely to interact with the client and their family/whanau and significant others and provide support as appropriate. It is recommended that other staff, in particular practice nurses, attend any relevant training offered including the completion of this workbook. Specific training and information required to work effectively with OST clients would generally also be provided by the specialist service liaison person.

The GP, whether gazetted or authorised, should have a formal, agreed relationship with the specialist service and an established process and protocol for utilising the resources of the specialist services for advice and consultation; particularly if the client becomes destabilised (MoH 2008).

Clients must be informed of the conditions under which they can be returned to the specialist services. Additionally they should have access to the same level of psychosocial support available to clients who remain in specialist services and be informed of their ability to access psychosocial services provided by other alcohol and other drug treatment services. The GP and/or other primary health care team member should have an awareness of, be able to facilitate and/or in some cases be able to provide the support services needed by clients to maintain their stability. (See Section 7 Psychosocial Interventions.)

There are a number of restrictions related to the prescribing psychoactive drugs. For more information refer to the Practice Guideline for OST in New Zealand (MoH 2008).

8.3 Specific Requirements of Approved/Gazetted GPs

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

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

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

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

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

The Ministry of Health recommend that approved/gazetted GPs operating without formal support and oversight from specialist services should limit the number of opioid substitution clients in their care to five.

(Source: Practice Guidelines for Opioid Substitution Treatment in New Zealand 2008)

8.4 Self-assessment Questions

1. Why is primary health care considered to be the 'health home' for people receiving opioid substitution treatment?
2. What are the key requirements for GPs accepting the shared care of OST clients?
3. What are the responsibilities of the specialist service in regard to GPs prescribing on authority?
4. What are the benefits for clients in shared care with GPs and specialist services?
5. What is the difference between authority and gazetting?
6. What can primary health care offer the client that the specialist service cannot?

9. DISPENSING METHADONE AND BUPRENORPHINE

Section 9 provides an overview of issues and requirements facing the community pharmacist. The objectives of this section are to:

- clarify the roles and requirements of the community pharmacist
- look at strategies for managing difficult situations.

OST is most often dispensed by a community pharmacist although dispensing is also undertaken by prison nurses for prisoners on OST and at some specialist services. In rural areas where access to pharmacies can be restricted or non-existent innovative strategies for dispensing such as couriering methadone or other opioid substitution medicine to a responsible person or organisation (e.g. mental health service, community hospital, whānau member), might need to be explored.

The pharmacists are in a unique position in that they have the opportunity to engage with the client on a regular basis and to form a relationship that can be very important in the client's recovery process.

There are two ways in which a client can receive their OST medicine: as an administered dose consumed under observation or as a dispensed dose taken away to be consumed at a later time. For more information on takeaway doses refer to *Practice Guidelines for OST in New Zealand* (MoH 2008).

9.1 *Requirements of Pharmacists and Dispensers*

All pharmacists and dispensers need to comply with the legislation regarding controlled drugs, including the requirements for recording, storage and authorisations as detailed below. They must ensure that the correct medication is given to the right person at the right dose at the right time. This should include:

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

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

(Source: Practice Guidelines for OST in New Zealand)

Opioid substitution medicines, in particular methadone, can cause death from overdose if the incorrect dose is dispensed; for example a small discrepancy in volume of methadone can translate to a relatively large discrepancy in dose therefore cautious procedures need to be followed when measuring the dose. For more information on measuring refer to the *Practice Guidelines for OST in New Zealand*.

9.2 ***Administering Consumed Doses***

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

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

(Source: Practice Guidelines for OST in New Zealand)

9.2.1 **Administering Buprenorphine**

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

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

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

(Source: Practice Guidelines for OST in New Zealand)

9.3 ***Safety Requirements for Dispensing***

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

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

(Source: Practice Guidelines for OST in New Zealand)

Refer to *Practice Guidelines for Opioid Substitution Treatment in New Zealand 2008* for more information and guidelines on the special circumstances for granting additional takeaway doses.

9.4 Contact with the Prescriber

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

- does not collect their dose for 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 methadone or other opioid substitute medicine
- exhibits withdrawal symptoms
- deteriorates in their physical, emotional or mental state.

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

(Source: Practice Guidelines for OST in New Zealand, MoH 2008)

9.5 Managing Difficult Behaviour

The expectation of having to deal with difficult behaviour and difficult situations is a significant cause of concern among some pharmacists.

The Drug and Alcohol Services South Australia (DASSA) (2006) recommend that the following strategies may assist in avoiding potential problems from occurring:

- All infractions should be pointed out and the appropriate action taken.
- Don't turn a blind eye. This will weaken your position and will not help the client to understand the limits of acceptable behaviour.
- Provide reminders occasionally to reinforce the rules.
- Be even-handed or you might find yourself trying to explain your behaviour to another disgruntled client.

9.5.1 Intoxication

Opioid-related overdose deaths occurring in dose-stabilised clients are generally due to the combination of drugs, including alcohol, being taken. While a pharmacist cannot control what their clients do after being given their dose, they must ensure that they are in a fit state at the time of being dosed (DASSA 2006). Intoxication suggests that either the dose may be excessive or that the client has taken another drug. In either case it may be dangerous to dispense methadone or other opioid substitution medicine and a discussion may need to be had with the dispenser or the client's key worker to decide on what action to take.

Please refer to the section on managing intoxicated clients in the *Practice Guidelines for OST in New Zealand* (MoH 2008).

The most common symptoms of intoxication likely to be noticed by the pharmacist are contained in the following table.

<i>Symptoms</i>	<i>Drug</i>				
	<i>Alcohol</i>	<i>Benzodiazepines</i>	<i>Opioids</i>	<i>Cannabis</i>	<i>Amphetamine, Cocaine, Ecstasy</i>
Ataxia (unco-ordinated movements)	●	●		●	
Red eyes				●	
Dilated pupils			● (withdrawal)		●
Disinhibited	●	●		●	●
Drooling		●			
Hyperactive					●
Itching, scratching			● (especially heroin, morphine)		
Pinpoint pupils (1-2 mm in any light conditions)			●		
Sedation	●	●	●	●	
Slurred speech	●	●			
Smell of alcohol	●				
Tremor	● (withdrawal)				●
Slow breathing			●		
Paranoid thoughts				●	●
Slowed thought	●	●			

(Table sourced from: DASSA 2006)

9.5.2 Aggressive Behaviour

A client may become aggressive for a variety of reasons and it is important to deal with this effectively and defuse the situation to avoid losing control. Building a good relationship with the client may reduce the chances of such behaviour occurring. It is important that the pharmacist or dispenser remain client-oriented and try to address the problem.

(Source: DASSA 2006)

Try to separate aggression directed at a personal level from frustration. Many clients lack the skills to be able to adequately handle everyday pressures. If you don't feel your safety is at risk, escort the client to a quiet area away from other customers and staff to defuse the situation. Do not try to resolve major issues at times of stress as this may inflame the situation. Next time the client presents, try to address the issue of acceptable behaviour.

(Source: DASSA 2006)

Pharmacists should have standard procedures in place for managing inappropriate or unlawful behaviour or other disruptive incidents. The procedures should include how to access any support from the prescriber or specialist service and all incidents of difficult or unlawful behaviour should be reported to the prescriber or specialist service key worker (MoH 2008).

9.5.3 Suspected Diversion

There is a significant market for diverted methadone in New Zealand with prices generally around the \$1 per milligram being reported. There are a number of public health issues related to diversion such as overdose in non-tolerant individuals, accidental ingestion by children, and, not the least, the potential for creating opioid dependence. The injection of oral methadone may cause death from cardiac arrhythmia resulting from metabolic acidosis, hypophosphataemia, hypoglycaemia and hyperuricaemia (DASSA 2006). Although there is less evidence of the diversion of buprenorphine (buprenorphine prescribed in New Zealand currently contains naloxone (Suboxone) diversion does occur. All cases of suspected diversion should be reported to the prescriber or key worker.

9.6 Managing Other Issues

9.6.1 Dispensing Errors

It is essential that pharmacists have procedures in place to minimise the chances of error occurring. If a client is given a higher than normal dose the potential for complications, including death, is high depending on the percentage of the increase and the tolerance of the individual. All suspected errors should be immediately reported to the prescriber or in their absence the key worker.

As methadone and buprenorphine are long-acting opioids there are unlikely to be significant consequences to underdosing although if this persists withdrawal symptoms are likely to occur.

Readers should refer to the *Practice Guidelines for OST in New Zealand* (MoH 2008) for information on the requirements for managing both over- and under dosing.

DASSA (2006) has listed the following guide to avoiding dispensing errors:

- For methadone, one of the commonest, and potentially most dangerous, sources of error is the milligram–millilitre confusion. Most clients don't recognise the distinction and talk about 'mills' meaning milligrams. Doses on prescriptions and in records should be expressed in milligrams or in both milligrams and millilitres.
- Failure to notice dose changes on a prescription and simply continuing dosing at the same dose level. It is important to check the prescription each time a dose is supplied. A day book or diary can be used to record such changes and to pass on important information to other staff.
- Ensure that proper identification, including an authorised photograph, is included in each client's record card.
- If you have clients with similar names or a client is on a large or unusual dose, attach a warning note to their records.

9.6.2 Communication with Locum Pharmacists

A source of possible problems arises if locums employed in a pharmacy are not experienced in dosing clients on OST. It is the regular pharmacist's responsibility to ensure that:

- important issues relating to particular clients are clearly set out in a written form, preferably in the client's record folder or book
- relevant paperwork is up to date and unambiguous
- instructions for using measuring devices are accessible
- phone numbers of prescribers are accessible.

(Source: DASSA 2006)

9.6.3 Prescriptions for Other Drugs

Pharmacists have the right, and indeed a professional obligation, not to dispense a legal prescription if they think it may present a danger to the client.

(Source: DASSA 2006)

If a client is receiving a prescription for benzodiazepines or other opioids that has not originated from the OST prescriber, the pharmacist is obliged to share this information with the OST prescriber.

9.7 Self-assessment Questions

1. What are the requirements of pharmacists around ensuring that the correct person is receiving the dose?
2. What safety requirements should be considered when giving takeaway doses?
3. What are some of the circumstances under which you would make contact with the prescriber in relation to the client's wellbeing?
4. How would you manage intoxicated clients presenting for their methadone?
5. What is the procedure for dealing with a dispensing error when a client has received a higher than prescribed dose?

10. MANAGEMENT OF CLINICAL ISSUES

Section 10 covers a range of important clinical management issues and situations faced by the specialist service and primary health care team workforce. The objectives of this section are to:

- familiarise readers with the current New Zealand Practice Guidelines in relation to specific areas of opioid substitution treatment
- to highlight specific issues affecting the management of clients receiving opioid substitution treatment.

10.1 *Monitoring Drug Use*

“Monitoring drug use is often an uncomfortable process for both the prescriber and the client. Monitoring is however essential for safe prescribing and dosing although it may not work as well for this purpose if it is also used as a basis for punitive actions against clients who continue to use illicit drugs” (MoH 2008).

Although there are other less intrusive methods of drug testing such as hair analysis and oral fluid analysis, urinalysis remains the most widely used tool for identifying drug use.

The following four paragraphs are sourced from the Practice Guidelines for OST in New Zealand 2008.

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

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

Procedures should be in place to ensure the reliability of urine samples if voiding is not observed. The use of heat strips on collection bottles or alternatively the use of professional laboratory services to take samples is recommended. Even where the client is observed providing the urine sample the practical constraints on observation mean that samples will not always be an accurate indication of drug use as there is evidence that 10–15% of samples provided lack integrity (Townshend 2004).

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

DETECTION TIME FOR SELECTED DRUGS IN URINE	
<i>Drug</i>	<i>Time</i>
Alcohol (dose dependent)	24 hours
Amphetamines	2–3 days
Benzodiazepines (dose dependent)	
Prescription dose	3–5 days
High level misuse	6 weeks
Cannabis (tested to cut off level of 100 nanograms)	
One time use	2 days
Three times per week	2 weeks
Daily use	2–4 weeks
Very heavy use	4–6 weeks (may be up to 12 weeks)
Ecstasy (MDMA)	2–3 days
LSD	2–3 days
Heroin and Morphine	3 days
Hydromorphone	1–2 days
Methadone	3–4 days
Propoxyphene	2–3 days
Propoxyphene metabolites	3–6 days
Codeine	1–2 days
Barbiturates	2–3 weeks
Cocaine	1–5 hours
Cocaine metabolites	2–4 days
Phencyclidine	1-8 days

10.2 Takeaway Doses

A report commissioned by the Ministry of Health (Deering et al 2008) which included perspectives of service users and specialist service providers noted that inflexibility of takeaways (takeaway doses) to be a significant barrier to individuals seeking OST. The report noted that from a service users' perspective there is a need for greater flexibility in terms of takeaway arrangements.

Daily attendance at the pharmacy can be very time-consuming and interfere with other important aspects of the client's life such as employment, study, childcare, fulfilment of family responsibilities and travel, whereas allowing more flexibility in takeaways can contribute to improved quality of life and independence. The risks and benefits of granting, or not granting takeaways should be explored and individualised according to client stability and circumstances.

Takeaway doses are any doses of OST medicine that are not consumed under observation at the specialist service, primary health care practice setting or pharmacy premises or any other designated place where methadone or other opioid substitution medicine is dispensed.

The following four paragraphs have been sourced from Practice Guidelines for Opioid Substitution Treatment in New Zealand 2008.

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

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

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

Some or all of the following can be included in the specialist service's (or the primary health care team's) safety requirements:

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

10.3 Reintroducing Opioid Substitution Medicine after Missed Doses

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

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

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

(Source: The Practice Guidelines for OST in New Zealand 2008)

Reintroducing buprenorphine after one to three missed doses may not have the same potential for fatal overdose as methadone but clients should be assessed for signs of intoxication and withdrawal before dosing is recommenced. If more doses are missed the client may need to be re-inducted onto buprenorphine as if commencing treatment again.

Refer also to the pharmacist's responsibilities in regard to missed doses in the *Practice Guidelines for OST in New Zealand 2008*.

10.4 Managing Ongoing Drug Use

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

Multiple substance use is common among opioid users. A commissioned report for the Ministry of Health (Deering et al 2008) provided the following table of other drug use as estimated by services in clients with opioid dependence presenting in the previous 12 months.

	Mean %	Median %	Range %
Nicotine	82.5	90	4–96
Cannabis	74.8	85	6–94
Morphine	63.2	68	4–95
Methadone	55.3	60	4–96
Benzodiazepines	51.0	60	4–76
Alcohol	37.3	26	0–100
Methamphetamine	31.3	24	0.1–80

Deering et al (2008) raised safety concerns related to increasing rates of methamphetamine use amongst people with opioid dependence but noted that both users and staff ranked diazepam and alcohol as being more dangerous when combined with opiates.

“The hazardous use of other drugs, particularly sedatives (such as alcohol and/or benzodiazepines) in combination with opioids, significantly increases the risk of respiratory depression and death. However, the risks arising from other drug use (for example, overdose, serious illness, social deterioration) are usually less than the potential risk of increased hazardous drug use if OST is withdrawn” (MoH 2008).

The following five paragraphs are sourced directly from the *Practice Guidelines for OST in New Zealand 2008*.

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

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

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

Where clients are identified as using other opioids, benzodiazepines, amphetamines or alcohol in a manner or at levels that raise safety issues if combined with the prescribed substitution opioid they should not be given takeaway doses.

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

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

The Practice Guidelines for OST in New Zealand 2008 note that receiving third party information about a client's drug use can be a useful prompt for discussing drug use with the client but should never be used as a basis for changing the client's treatment.

The Ministry of Health is expected to publish a manual titled *Interventions and Treatment for Problematic Use of Methamphetamine and Amphetamine-type Substances* later in 2010. This will be available on their website and is expected to inform treatment of methamphetamine users.

10.4.1 Continued Opioid Use

When a client is not progressing well in treatment, clinicians should consider optimising treatment by increasing the intensity of the OST rather than reducing it. Optimising treatment may include: ensuring that OST is provided within evidence-based optimal levels, changing to another substitute medicine (if available), increasing case management or psychosocial interventions and increasing supervised consumption (MoH 2008).

Injecting methadone can be associated with significant harms, nevertheless it is not uncommon for clients to inject their prescribed medication. Where clients inject their methadone the procedure should be for takeaway doses to be restricted, they should be more closely monitored for other drug use or diversion and their treatment should be reviewed in a team case review in order to ensure that the best possible treatment is being provided, in the safest possible way.

10.4.2 Benzodiazepine Use

A significant number of opioid users presenting for OST may also be using benzodiazepines, often to relieve symptoms of withdrawal when the user is unable to access opioids. Studies

have shown that the proportion of those using benzodiazepines falls rapidly during methadone stabilisation, even in the absence of any direct intervention for benzodiazepine use (Gossop et al 2004).

Benzodiazepine users have been found to exhibit patterns of increased risk and poorer social functioning and mental health than other clients on OST (Deering 2007; Ross and Darke 2000).

The following five paragraphs are sourced directly from the *Practice Guidelines for OST in New Zealand 2008*.

OST service providers should advise clients about the interactions between benzodiazepines and methadone and buprenorphine.

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

It may be necessary in some instances to prescribe benzodiazepines to clients who are dependent on benzodiazepines as well as opioids, but such prescribing should be done with caution. The clinical rationale for prescribing of benzodiazepines and similar drugs should be clearly documented, and the client should be monitored closely and receive regular reviews. Any prescription in addition to methadone or another opioid substitution medicine must be at safe therapeutic levels.

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

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

Where benzodiazepines are prescribed, Medicines Control, Medsafe, should be informed to ensure that the client is using only one prescriber, and restriction notices may need to be issued.

10.4.3 Tobacco Use

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

Specialist services and GP prescribers should promote smoking cessation strategies and encourage and assist clients who want to stop smoking while on OST (MoH 2008).

10.4.4 Diversion

Diversion involves the selling or exchanging of methadone or other prescribed opioid substitution medicines. There are a number of risks associated with the diversion of opioids including overdose, harms related to injecting such as blood-borne viruses and not the least the potential for creating new opioid-dependent people. It is important that when assessing a

client for the suitability for takeaway doses that these potential harms are considered and balanced with the need for lifestyle flexibility.

10.5 Managing the More Difficult Client

Some clients on OST have significant personality problems. Realistic expectations, a non-judgmental attitude and patience are essential in the management of such clients. Assisting clients to identify and label emotions and reinforcing success in reducing the impulsiveness associated with personality disorders may improve the client's functioning and have a positive impact on the therapeutic outcome.

It is important not to exploit or punish those clients who are more difficult. Treatment should aim to break the familiar cycle of aberrant behaviour, punishment, and further difficulty.

Changing established patterns of behaviour does not happen in a short time and this is why longer durations of treatment are required to produce lasting change among dependent opioid users.

Treatment rules should be established upfront and agreed between the team and the client. Outbursts of rule breaking should be managed constructively, sometimes by soliciting the client's view as to how their rule breaking should be managed. This approach creates a very different experience for an illicit opioid user accustomed to being treated with punishment or rejection.

Sourced from: Goodfellow Unit Training Programme

10.5.1 The Power Imbalance

The imbalance of power between the client and professional must be acknowledged. It 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 this risk. However, the relationship must be handled sensitively, avoiding adversarial interactions with clients who resent their perceived powerlessness with respect to programme rules.

The professional is responsible for ensuring that power is not abused. Care must be taken to, for example, avoid emotional exploitation involving intrusive interest in the details of clients' lives and financial exploitation through excessive servicing or high charges.

Sourced from: Goodfellow Unit Training Programme

10.6 Driving and OST

The Practice Guidelines for OST in New Zealand 2008 state:

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

- *during the first seven to 10 days of OST*
- *for three to four days after any dose increases*
- *when undergoing a rapid reduction of opioid substitution medicine*
- *when the client uses alcohol or other drugs including some prescribed medications*
- *when the client has a medical or psychological condition that is likely to contribute to impairment.*

The implicit contract between OST services, their clients and their communities obliges the OST provider to ensure that prescribing opioid does not put the community at risk. This issue is particularly relevant with clients using high doses of powerful and controlled drugs. To ensure the safety of the community, client and service clients should be advised verbally and in writing not to drive (or operate heavy machinery) in any of these situations and where clients are known to disregard this advice the Land Transport Safety Authority should be notified.

Since the publication of the 2008 *Practice Guidelines* there have been a number of events that have activated the debate on driving and methadone. One significant event was the coroner's recommendations in relation to a case where a woman was killed in an accident caused by an individual on a methadone programme. This person was also positive for benzodiazepines at the time of the accident.

As a result of the coroner's recommendations a number of services have made alterations to their protocols around driving. In addition the Land Transport Amendment Act (2009) introducing new laws around drug-impaired driving may require alterations to the current guidelines and local protocols. The Act came into effect on 1 December 2009 and created a new offence of driving while impaired with evidence in the bloodstream of a controlled drug or prescription medicine.

See Appendix 1 for an example of a letter to clients regarding driving and drug use developed by Nelson AOD Service.

10.7 Transfers between Services

As with many other New Zealanders, there can be a range of legitimate reasons for clients on OST to move around the country. As much as possible, a client should not be disadvantaged in making such moves (MoH 2008).

Opioid substitution treatment is most safely delivered by specialist services within the locality where the client is living. *The Practice Guidelines for OST in New Zealand* (MoH 2008) state that “*transferring clients should be taken on by the specialist service in the area they have moved to within three months of relocation*”.

For information on expectations of both the transferring and receiving services refer to the *Practice Guidelines for OST in New Zealand 2008*.

The guidelines for OST in New Zealand 2008 also note that acceptance of transfer should not be conditional on withdrawal of any other substance use, (including use of illicit or prescribed benzodiazepines). They suggest that when the client is admitted to the OST programme in a new area a review of all substance use should occur and, if clinically appropriate, a benzodiazepine withdrawal should be negotiated.

In order to reduce problems for both clients and services in the transfer process the National Association of Opioid Treatment Providers (NAOTP) recommends that specialist services and primary health care team providers fully inform clients intending to transfer to another region about:

- the possible treatment differences (such as those related to prescribing, reviews, takeaways), wherever possible before a decision is made by the client to transfer
- any possible restrictions on dispensing in the area to which the client is intending to move
- the need to be reassessed at the new service

- the time limit of three months for prescribing out of region
- any requirements the client is required to meet when being prescribed out of region.

(Source: NAOTP minutes March 2009)

10.8 Withdrawal Management

The primary objective of withdrawal care is to achieve a client's goals in relation to their AOD misuse, with safety. This is supported by a thorough assessment of potential risks at presentation to AOD care (Kenny et al 2009).

Withdrawal management aims to reverse neuroadaptation by managing tolerance and withdrawal and promote the uptake of post-withdrawal options. In New Zealand withdrawal management may occur at home with specialist services and/or GP involvement, or in an inpatient treatment setting, e.g. medical detoxification unit. In some cases residential treatment facilities will offer withdrawal management as part of their programmes.

Withdrawal management involves a combination of pharmacological support and supportive care. Supportive care includes reassurance, attendance to hydration and nutrition. Pharmacological support includes complementary medications to reduce the severity of somatic symptoms include non-opioid analgesics, antiemetics, clonidine, benzodiazepines, and antispasmodics. Complementary medications have also been found to be effective to mediate withdrawal symptoms and massage and other physical/body therapies may be helpful.

While a range of health benefits often result from detoxification, there is no evidence that detoxification alone contributes to lasting abstinence from drugs in the longer term for more than a small minority (Goodfellow Unit 2000). Unfortunately relapse after detoxification is extremely common, therefore the preparation of a robust and detailed relapse prevention management plan is recommended. The plan should always include the role of the client's support people and may include a residential treatment option, is recommended.

The following four paragraphs are sourced from the Practice Guidelines for OST in New Zealand 2008.

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

The symptoms and signs of withdrawal from buprenorphine are generally milder than withdrawal from methadone or morphine because of its slow dissociation from the “mu” receptor. Symptoms start within three to five days of the last dose and can last for several weeks.

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

For a comprehensive guide to managing alcohol and drug withdrawal refer to *The Australian Alcohol and Other Drug Withdrawal: Practice Guidelines* 2009 which can be accessed on www.turningpoint.org.au, a New Zealand Managed Withdrawal Guideline will be available

from Matua Raki and Ministry of Health by mid-2010 and will be available on the MoH website.

10.9 Managing Co-existing Mental Health Problems

There is a high prevalence of co-existing mental health problem in clients with opioid dependence. These commonly include anxiety disorders, depression and personality disorders (Teesson et al 2005; Darke and Ross 1997; Ross et al 2005; Marsden et al 2000).

The Australian Treatment Outcome Study (ATOS) (Ross et al 2005) found that 49% of their total sample experienced severe psychological stress as indicated by the SF-12. Similarly the UK National Treatment Outcome Study (NTORS) found high rates of psychiatric symptoms in clients on OST (Marsden et al 2000).

A mental health assessment (see Section 5) should be undertaken on admission to OST and ongoing assessment and review should occur for clients with severe/persistent problems. Mental health problems are often reduced following stabilisation on methadone or another opioid substitute medicine. For example, many clients report that before they commenced on OST they experienced depressed moods and disturbed sleep and that these problems improved following stabilisation on methadone or buprenorphine. It is therefore not normally appropriate to initiate antidepressant treatment early in OST (MoH 2008).

If specialist services or primary health care teams are unable to provide mental health care or support they will need to actively facilitate referral and advocate for client access to other appropriate services (MoH 2008).

Methadone and buprenorphine may alter the pharmacokinetics of drugs prescribed for co-existing medical problems. Clients who are already on antidepressants, particularly tricyclic antidepressants and some selective serotonin re-uptake inhibitors (SSRIs), may need care during induction and withdrawal, as these drugs may interact with methadone (MoH 2008).

The workshop companion to this workbook will focus on responses to a variety of clinical and practical scenarios including mapping pathways and action plans in respect to managing clients with co-existing disorders.

For information on drug interactions associated with opioids refer to *The Practice Guidelines for OST in New Zealand*.

Clinical guidelines for the *Management of Co-existing Problem Disorders* manual (Todd 2010) can be accessed on the Matua Raki and Ministry of Health websites: www.matuaraki.org.nz and www.moh.govt.nz.

10.10 Medical Conditions

The physical health of people with opioid dependence has been found to be significantly poorer than for the general community (Ross et al 2005; Ryan and White 1996). Clients on OST commonly experience problems with the medical consequences of injecting drug use, may have medical issues as a result of involvement in the sex industry, have increased risks of transmitting blood-borne infections through unsafe sexual practices, and are more likely to have liver disease and respiratory problems (Deering 2007).

In clients with advanced liver disease, doses of both methadone and buprenorphine may need to be significantly reduced. Progressive liver disease, such as may be seen in hepatitis C, may

require gradual reduction of previously tolerated doses. In the case of kidney failure, dosage levels should also be monitored closely to ensure safety (MoH 2008).

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

10.11 Blood-borne Viruses

At least 90% of all new hepatitis C infections are the result of sharing or reusing drug injecting equipment that has been contaminated with blood containing the virus. The remaining 10% are the result of other risk behaviours which involve blood-to-blood contact such as non-sterile tattoo or piercing equipment, needlestick injuries in the healthcare setting, and vertical transmission from infected mother to their babies (Jang et al 2009).

There are six hepatitis viruses: hepatitis A, B, C, D, E and G. All affect the liver and cause damage to some extent. The long-term health consequences of infection from any of the six viruses include liver disease including inflammation, scarring, fibrosis, cirrhosis and, in some cases, liver cancer (Jang et al 2009).

HIV remains at low levels among New Zealand injecting drug users accounting for less than 3% of all new infections (Jang et al 2009). Hepatitis C however continues to spread due to it being already highly prevalent among injecting drug users before harm reduction measures, like needle exchanges were established. It is also more infectious than HIV (Jang et al 2009).

The following eight paragraphs sourced from the Practice Guidelines for OST in New Zealand.

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

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

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

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

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

Because of the risk of future hepatitis A and/or B infection, all clients who do not have protective levels of antibody should be advised to have a vaccination. Partners and relevant

family or whānau should also be advised to have immunisation if they have independent risk factors such as unsafe injecting practices.

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

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

Refer also to the *New Zealand Hepatitis C Handbook* (2009) which provides up-to-date information on the management of hepatitis C. The handbook can be accessed from the Ministry of Health, needle exchange programmes and the hepatitis C resource centres.

10.12 Dental Health

Dental health problems are common for people with opioid dependence and have many causes. Factors associated with poor dental health include: poor diet (e.g. irregular meal times, increased intake of sugar-based foods); poor attendance at the dentist and difficulty accessing dental care; and no regular toothbrushing, flossing or mouth rinsing.

Specialist services and primary health care teams should be active in supporting the prevention of serious dental problems by making opportunities to promote good dental care and supporting clients to access regular dental care.

10.13 Methadone and Risk of QTc Prolongation

Methadone may prolong the QT interval and/or induce torsade de pointes. The risk of QTc prolongation in clients who are using or being prescribed methadone is unpredictable and variable but may be potentially fatal. It is important, therefore, that clients are screened for this risk at entry to, and during OST, especially if other potential QTc prolonging medications are prescribed.

The Australasian Chapter of Addiction Medicine is currently developing a guideline for managing QTc prolongation.

10.14 Pregnancy and Breastfeeding

“Effective pharmacotherapy treatment of opioid dependence can substantially improve obstetric, perinatal and neonatal outcomes. Opioid substitution maintenance therapy also has an important role in attracting and retaining pregnant women in treatment and ensuring good contact with obstetric and community-based services including primary health care. Addressing childcare and family support issues for women continues to be a major gap in the delivery of services for women in most countries” (WHO 2004).

10.14.1 Methadone and Pregnancy

The following paragraphs dealing with pregnancy and breastfeeding are sourced directly from *The Practice Guidelines for OST in New Zealand 2008*.

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

Women entering OST who are of childbearing age should be advised about the effects of methadone, as well as other substance use (including alcohol and tobacco) should they become pregnant. Even when a female client's menstrual cycle is irregular/non-existent, pregnancy is still possible, and contraception should be discussed with the client.

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

If a pregnant woman on methadone is vomiting frequently, the treatment plan may need to be varied to allow for the use of anti-emetic drugs to stabilise serum opioid levels.

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

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

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

It is recommended that pregnant women who are receiving OST deliver their baby at a hospital where the newborn infant can be monitored under the supervision of an appropriately experienced paediatrician.

Methadone readily crosses the placenta, therefore, the neonate who has been exposed to methadone in utero should be monitored postnatally for withdrawal symptoms, using an accepted validated opioid withdrawal scale. Withdrawal symptoms in a newborn methadone infant may require treatment; potentially they can become life threatening if severe and untreated.

The neonate should be monitored for respiratory depression at delivery, as this may occur in some cases.

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

If a pregnant client is stable on methadone and is being managed by a GP, she does not need to be referred back to the specialist service. However, the GP should consult with a specialist service as required during the pregnancy and perinatal period.

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

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

10.14.2 Methadone and Breastfeeding

Methadone passes into breast milk only in small amounts, and clients should be encouraged to breastfeed where possible except in the rare case where it is contraindicated (for example, if the client is HIV positive). Advice should be given regarding the passage of other drugs, including prescribed and illicit drugs, into breast milk, particularly CNS depressants, which may dangerously sedate or cause respiratory depression in the neonate. Advice should be sought from specialist services or obstetric services that are experienced in the care of women dependent on opioids if required.

10.14.3 Buprenorphine in Pregnancy and Breastfeeding

The use of buprenorphine by pregnant and breastfeeding clients remains controversial, although evidence of its safety is increasing. However, there is concern about the presence of naloxone in the combination product, and if it is decided to use buprenorphine with pregnant or breastfeeding clients, buprenorphine without naloxone should be used. This combination is not currently registered for use in New Zealand.

10.15 Management of Acute and Chronic Pain

10.15.1 Acute and Surgical Pain

Addiction brings out neurophysiologic, behavioural, and social responses that increase people's experience of pain and complicate provision of adequate analgesia. These complexities are heightened for clients with opioid dependence receiving OST, for whom the neural responses of tolerance or hyperalgesia may increase the pain experience. As a consequence, opioid analgesics are less effective and higher doses administered at shortened intervals are required. Opioid agonist therapy provides little, if any, analgesia for acute pain. Fears that opioid analgesia will cause addiction relapse or respiratory and CNS depression are unfounded. Furthermore, clinicians should not allow concerns about being manipulated to cloud good clinical assessment or judgment about the client's need for pain medications. Reassurance regarding uninterrupted OST and aggressive pain management will mitigate anxiety and facilitate successful treatment of pain in clients receiving OST.

(Source: The Royal Australasian College of Physicians, Prescription Opioid Policy: Improving management of chronic non-malignant pain and prevention of problems associated with prescription opioid use, Sydney 2009)

The following paragraphs sourced directly from the Practice Guidelines for OST in New Zealand 2008.

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

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

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

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

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

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

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

Non-gazetted medical officers in institutions such as hospitals may need to be authorised by a specialist service doctor, or approved/gazetted GP, to prescribe for OST clients who are required to be in hospital for longer than three days.

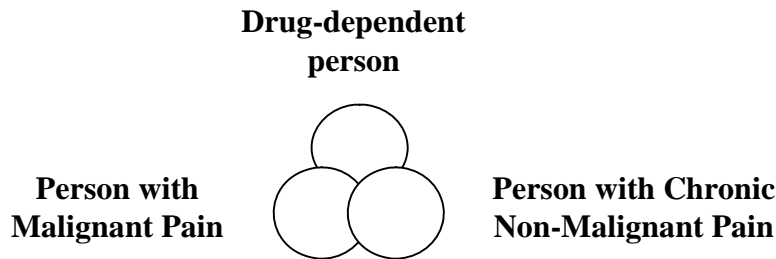
Note: Any medical practitioner can prescribe a controlled drug for a drug-dependent client who requires opioids for reasons other than treating substance dependence.

10.15.2 Chronic Non-malignant Pain

People who suffer chronic non-malignant pain (CNMP) and who are prescribed opioids are exposed to risks inherent in both under-prescribing and diversion of pain medications. There are some people with CNMP who are undertreated and poorly managed and others who are managed badly. There are also a number of people who experience CNMP and then become dependent on their medication, consequently posing a major public health problem with an impact on the health care system.

(Source: The Royal Australasian College of Physicians, Prescription Opioid Policy: Improving management of chronic non-malignant pain and prevention of problems associated with prescription opioid use, Sydney 2009)

There are three main groups of people who experience pain and require OST. The following paragraph, sourced from the manual above (RACP 2009) illustrates the cross-over that exists between the groups. The RACP notes that if one of these areas is being inadequately managed there will be flow-on effects to the other areas.



The other group of people who use opioids inappropriately are those people on OST who become frustrated with the logistics of acquiring OST, and subsequently purchase opioids on the black market or feign pain to receive prescription opioids fraudulently. A common method of obtaining prescription drugs for use, trade or sale involves the fraudulent presentation of disease to multiple doctors and pharmacies, a behaviour known as “doctor shopping” or drug-seeking behaviour (RACP 2009).

The following paragraphs are sourced from the Practice Guidelines for OST in New Zealand 2008.

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

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

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

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

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

Among other things, treatment should aim to:

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

The following paragraphs have been sourced from RACP Prescription Opioid Policy: Improving management of chronic non-malignant pain and prevention of problems associated with prescription opioid use (2009).

Opioid-induced hyperalgesia has been used to refer to:

- i. A decline in analgesic efficacy during opioid treatment for pain; and
- ii. An increased sensitivity to stimuli in individuals with opioid *addiction*.

It is very difficult to distinguish between ‘opioid-induced hyperalgesia’ and opioid *tolerance*. That the cellular mechanisms of opioid-induced hyperalgesia have much in common with those of opioid tolerance and of neuropathic pain (the latter traditionally considered to be relatively opioid-non-responsive) serves only to add to the confusion.

There may be two phenomena:

1. Clients on OST for addiction and who do not have pain may nonetheless develop increased sensitivity to noxious or potentially noxious stimuli. The clinical importance of this phenomenon is not clear.
2. It is not known whether clients with CNMP treated with long-term opioids develop such increased sensitivity. Such clients may develop a decline in analgesic efficacy that may be due to opioid tolerance or to other (usually psychosocial) factors but it is not appropriate to label that as opioid-induced hyperalgesia.

In the context of opioid treatment of CNMP, an undue emphasis on the idea of opioid-induced hyperalgesia can detract from considerations of tolerance or other stressors.

It is relevant to:

- i) the unresolved issue of ceiling effect of opioids in this situation
- ii) the practice of the dose of opioid

being increased in response to an apparent decline in analgesic efficacy when the opposite should be done because of opioid non-responsiveness or the development of dysphoric withdrawal phenomena.

To access the RACP’s Prescription Opioid Policy full document go to: www.racp.edu.au/page/health-policy-and-advocacy.

10.16 Issues Affecting Older Clients

As increasing numbers of OST clients are retained for long periods on methadone or other opioid substitute medicines a range of health issues related to past drug use and associated behaviours may emerge and complicate usual age-related health issues. Issues to look out for include:

- liver damage due to hepatitis B or C or excess alcohol use (or a combination)
- chronic airways disease and chronic lung damage from cigarette and/or cannabis smoking and previous injecting of tablet excipients, with the possible development of pulmonary hypertension
- chronic venous and/or arterial damage, making IV access difficult or impossible cardiac valve damage
- neurological damage, causing impaired memory and cognitive functioning

- the risk of drug interactions between methadone/buprenorphine and treatments used for other diseases, for example, antihypertensives, hypoglycaemics, antidepressants, antituberculin agents, anticonvulsants, antiretrovirals
- low mood
- fatigue
- overdosing as a result of reduced tolerance
- endocrine problems and an associated risk of osteoporosis
- cellulitis
- endocarditis (rare in the absence of IV use)
- osteomyelitis (rare in the absence of IV use) (MoH 2008).

Long-term use of methadone and other opioids can cause reduction in the sex hormones with altered sexual functioning and, in the long term, increased risk of osteoporosis, particularly in men and probably in post-menopausal women. These side-effects should be monitored, particularly in long-term and older clients, and appropriate health advice should be given and investigation, specialist assessment and treatment should be arranged as required (MoH 2008).

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

OST clients can also develop any of the diseases common in the elderly community, for example, hypertension, diabetes, chronic airways disease. Specialist services and primary health care teams should develop and co-ordinate plans to support the management of specific complications experienced by clients in the 40+ age group as well as those who have been on OST for longer than 10 years (MoH 2009).

10.17 Self-assessment Questions

1. What are the key benefits and risks of prescribing takeaway doses for clients on OST?
2. Why is it important to assess a client if they have missed three or more methadone doses?
3. What would be an effective strategy for addressing suspected ongoing drug use?
4. What strategies would you use to provide information on safe injecting practices?
5. What protocols does your service or practice setting have to handle issues around driving and drug use?
6. Why is detoxification alone not recommended for opioid dependent clients?
7. What common mental health problems should you look out for in clients on OST?
8. When would you consider prescribing antidepressant medication for a client on OST?
9. When would you consider sending a client for a polymerase chain reaction (PCR) test?
10. What is the significance of QTc prolongation in a client on methadone?
11. What are the benefits and risks of putting/keeping pregnant women who are opioid dependent on methadone?
12. What is the significance of hyperalgesia in the treatment of a client on OST who has chronic non-malignant pain?
13. Why is it problematic to provide additional relief for acute or surgical pain for a client on buprenorphine?

14. What health checks would you advise for a client in the 40-plus age group?

11. THE OST WORKFORCE

Section 11 outlines the needs and functions of key members of the OST team relevant to both specialist services and primary health care teams.

11.1 *The Roles of the OST Workforce*

11.1.1 Overview of functions

The OST team should, where possible, include a range of disciplines including the community pharmacist. In the specialist service these roles might include the programme manager or clinical director, medical officers, psychiatrists, nurses, social workers, addiction counsellors, support workers, psychologists, consumer advisors and peer support workers, administration staff and the pharmacist. In the primary health care or general practice setting the team generally comprises the GP, the practice nurse, other allied health professionals, administration staff and the pharmacist. Some PHOs and primary health care teams also employ addiction specialists. The specialist service key worker, or PHO/GP clinical co-ordinator/liaison person, should be seen as also being a part of this team along with other health professionals as appropriate.

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

11.1.2 The Key Worker/Case Manager

In OST key working (or case management) is more than a planned and co-ordinated 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.

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

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

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

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

In summary the role of the key worker is to:

- work with the client to develop a relevant network including family/whanau/service providers
- identify and record strategies to achieve goals and include these in a treatment plan
- co-ordinate and monitor treatment plan implementation and ongoing updates of treatment plan
- implement systems that ensure treatment progress using the various tools available for monitoring progress including formal treatment review, random urine drug testing, etc
- liaise closely with other members of treatment team, especially the prescriber
- provide psychosocial interventions and support or make arrangements for the provision of services as required by the client
- maintain current information about local services which OST clients are likely to need
- maintain comprehensive and confidential records which are stored securely.

Refer also to ‘Reviews by the key worker’ and ‘Reviews by a case-management team’ and ‘Clinical and administrative expectations of specialist OST treatment services in *The Practice Guidelines for OST in New Zealand 2008*.

11.2 *The Prescriber*

The prescriber at present is a general practitioner⁶ prescribing under authority of a specialist service, a gazetted general practitioner or a specialist service doctor. Nurse practitioners are expected to undertake OST prescribing roles within the next few years.

Overall, the prescriber is responsible for effective prescription of methadone or other opioid substitute medicine that minimises risks for clients, staff and the community. Within this broad goal, the prescriber will:

- prescribe and assess dose suitability as required (**note:** local protocols vary in regard to the ability of GP prescribers to alter doses)
- implement systems that minimise risks for clients, staff and community, for example the management of a takeaway regimen that minimises risks for the client, their family and the community
- liaise closely with other members of the specialist services or primary health care team, especially with the key worker (where the prescriber is not the key worker) and the pharmacist
- ensure pharmacists have a current named photograph of each client
- make arrangements for dispensing over public holidays and client holidays that account for relevant safety issues
- arrange for continued treatment for clients travelling abroad, considering relevant safety issues and any restrictions related to methadone, or other prescribed opioid substitution medicine, in the country(ies) of travel

⁶ *Medical practitioners working under authority are those practitioners who are working with particular clients in accordance with the terms and conditions set out in section 24 of the Misuse of Drugs Act (see Appendix 2: Misuse of Drugs Act 1975 s24).*

- maintain comprehensive and confidential records which are stored securely and in accordance with current legislation (Health (Retention of Health Information) Regulations 1996)
- where the primary health care team GP fills the role of prescriber, the GP will also attend to the other health needs of clients on OST including injection point infections, sexually transmitted disease, hepatitis C.

See also *Prescribing Process, Practice Guidelines for OST in New Zealand 2008*.

11.3 The Practice Nurse

The practice nurse, as part of the primary health care team, will interact with the client on a regular basis as the client collects prescriptions or attends GP appointments.

The practice nurse has a key role during these interactions in identifying and addressing life- and health-related issues and in supporting clients to address these issues.

In addition to providing 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 and/or other assessment tools.

Some general practices may assign a practice nurse as the key worker/case manager.

11.4 The Prison Nurse

The prison nurse, as part of health services provided in the prison setting, has a key role in monitoring the prisoner/client's progress and stability. In the prison context the nurse will also administer methadone, or other opioid substitution medicine, to the prisoner/client. In addition the prison nurse provides liaison with the provider service with regard to medication on arrival and pending release and any medical or mental health concerns.

11.5 The Community Pharmacist

Community pharmacists are a very important member of the OST team as they see the client regularly and frequently. Because of the relationship the pharmacist has with the client they 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 health care teams in particular when:

- they have concerns about the client's wellbeing, for example where the client presents intoxicated or exhibiting withdrawal symptoms or appears to have deteriorated in their physical, emotional or mental state
- doses are vomited – the pharmacist should supply as much information as possible to the specialist service or primary health care team such as time after dosing, condition of client prior to dosing, etc
- the client is not meeting the agreed requirements and conditions of their treatment, for example, does not present for their dose or is thought to be diverting their methadone or other opioid substitution medicine or exhibits abusive or threatening behaviour
- the client is withdrawing from OST.

In some areas pharmacists fulfil additional roles, e.g. passing on messages from the specialist service or primary health care team.

Note: This is a goodwill role and prescribers should be mindful that pharmacists are not treated as postal services.

The pharmacist may also be required to supply urinalysis and blood test forms to OST clients as requested by the prescriber. Pharmacists should understand the rationale for the tests in order to be an effective part of the process, for example understand the requirement for urinalysis samples to be taken randomly.

The pharmacist must dispense methadone and other opioid substitution medicines in accordance with the prescription and relevant legislation and, together with the pharmacy staff, maintain confidentiality of the client's personal information and treatment (MoH 2008).

In addition, the pharmacist should:

- provide a non-judgmental service that recognises the potential damage stigma may cause this group of health consumers, their families/whānau and significant others
- supervise consumption of methadone and other opioid substitution medicines on the pharmacy premises, preferably in a discrete venue
- liaise with the OST provider on a regular basis and maintain a communication network with the specialist service key workers or nurses, prescribing doctors or GPs and other pharmacists where appropriate
- listen to, and where appropriate respond to, any relevant health or other problems that the client may have and support them to raise any concerns with their key worker or the prescribing GP
- if requested and able to, facilitate the delivery of the first dose to the specialist service or prescribing GP, so that the client can be observed taking the opioid substitution medicine by the prescriber.

(Source: Practice Guidelines for OST in New Zealand 2008)

For more information on Pharmacist Dispensing refer to *The Practice Guidelines for OST in New Zealand*.

11.6 Workforce Training

The Practice Guidelines for OST in New Zealand (MoH 2008) state “all clinicians are expected to have some demonstrable commitment to ongoing alcohol and other drug treatment education”.

The guidelines outline the following educational and training requirements:

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

For information on specific OST training refer to the National Association of Opioid Treatment Providers (NAOTP) web page on the Matua Raki website: www.matuaraki.org.nz.

11.7 Self-assessment Questions

1. What do you consider are the most important roles of the key worker/case manager?
2. Describe the liaison/contact you have with the specialist service or primary health care team.
3. Why are pharmacists such an important part of the OST team?
4. What specific challenges do you think prison nurses face when dispensing methadone?

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GLOSSARY

Agonist	A substance which fully activates the neuronal receptor that it attaches to.
Antagonist	A substance which attaches to a receptor but does not activate it or if it displaces an agonist at that receptor it seemingly deactivates it thereby reversing the effect of the agonist.
Agonist – Antagonist	A drug (usually, if not exclusively, psychoactive) which exhibits some properties of an agonist and some properties of an antagonist.
Amphetamines	Are a psychostimulant drug that is known to produce increased wakefulness and focus in association with decreased fatigue and appetite.
Benzodiazepine	Benzodiazepines enhance 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 Bentley-derivative opioid of the phenanthrene class with extremely high binding affinity at the μ - and κ -opioid receptor.
Chemical handcuffing	A term used to describe the restrictive and invasive aspects of monitoring on an OST programme.
Depressants	Psychoactive drugs which temporarily diminish the function or activity of a specific part of the body or mind.
Dialectic behavioural therapy	A system of therapy originally developed to treat persons with borderline personality disorder (BPD) by Marsha M Linehan.
Diamorphine	Commonly known as heroin diamorphine hydrochloride belongs to a group of medicines called opioids.
Epidemiology	The study of factors affecting the health and illness of populations.
Homogeneous	Composed of parts or elements that are all of the same kind.
Hyperalgesia	An increased sensitivity to pain, which may be caused by damage to nociceptors or peripheral nerves.
Hyperuricaemia	An abnormally high level of uric acid in the blood.
Hypoglycaemia	A lower than normal level of blood glucose.
Hypophosphataemia	An electrolyte disturbance in which there is an abnormally low level of phosphate in the blood.
Maladaptive	Unsuitably adapted or adapting poorly.
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 psychoactive drug considered to be the prototypical opioid.
Naloxone	An opioid antagonist, used to counter the effects of opioid overdose.
Naltrexone	An opioid receptor antagonist used in the management of alcohol dependence and opioid dependence.
Neuroadaptation	Neuroadaptation is 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 chemical.

Opioid	A chemical that works by binding to opioid receptors, which are found principally in the central nervous system and the gastrointestinal tract.
Pharmacokinetics	A branch of pharmacology dedicated to the determination of the fate of substances administered externally to a living organism.
Pharmacology	The study of drug action.
Physiological	Consistent with the normal functioning of an organism.
Polymerase chain reaction	A technique in molecular biology to amplify a single or few copies of a piece of DNA across several orders of magnitude, generating thousands to millions of copies of a particular DNA sequence.
Psychosocial	The individuals psychological development in and interaction with a social environment.
Psychotropic medication	Any medication capable of affecting the mind, emotions, and behaviour.
Pulmonary oedema	Fluid accumulation in the lungs.
QTc prolongation – the QT interval	The QT interval is a measure of the time between the start of the Q wave and the end of the T wave in the heart's electrical cycle. A prolonged QT interval is a risk factor for ventricular tachyarrhythmias and sudden death.
Rhinorrhoea	Commonly referred to as runny nose, consists of a significant amount of nasal fluid.
Sleep apnoea	A sleep disorder characterised by having one or more pauses in breathing or shallow breaths during sleep.
Sublingual	Underneath the tongue.
Whanau Ora	A programme providing support for families.

READINGS

Defining Psychosocial Interventions in Opioid Substitution Treatment

Berry R 2009

Introduction

Opioid dependence can produce problems in multiple aspects of an individual's life including physical and mental health, family and parenting, accommodation, employment, financial and legal. Despite this little is known about the ways in which opioid substitution services (both specialist and in primary care) in New Zealand provide assistance, alongside pharmacotherapy, to their clients to address any of these issues if and when they should arise.

The title 'psychosocial interventions' is used in a number of the documents that inform opioid substitution treatment (OST) to describe a wide range of actions targeting mental health, family and individual issues. They may involve counselling* or psychological interventions, such as motivational interviewing, relapse prevention, cognitive behavioural or family therapy, and social support or practical assistance which may cover areas such as help with housing accommodation, training, employment, finances and parenting and providing linkage to self-help, recovery, spiritual, cultural and whanau groups.

* *The term 'counselling' is often used inappropriately to refer to contact with the case manager or key worker rather than to counselling approaches which is the meaning used in this report.*

Clients with opioid dependence are not a homogenous group therefore not all will require psychosocial interventions during their OST and a sizeable percentage of clients will do well with pharmacotherapy only. Psychosocial interventions are tailored to the needs of the individual client and would generally be targeted to clients with co-existing psychological and medical issues.

Literature Review

A review of the literature on the use of psychosocial interventions in OST indicates that until recently the OST field has relied on findings from the US studies of McLellan and colleagues (McLellan, Hagan, Levine et al 1998; Woody, McLellan, Luborsky et al 1995; McLellan, Arndt, Metzger et al 1993) to inform them that adding interventions including employment and legal advice, family therapy, and attention to medical and mental health problems substantially improve treatment outcomes for clients receiving OST.

Most studies have examined outcomes only in relation to continued opioid use and retention**. A Cochrane Review (Amato, Minozzi, Davoli et al 2004) found that structured psychosocial treatment gave added benefit to reducing the use of heroin during OST. However although there was a trend no clear benefit was found on either clients being retained in treatment or in relation to heroin use at follow-up.

** *It should be noted that in New Zealand retention is not an issue as it is in countries such as the United Kingdom, America and Australia as access to illicit opioids is more limited.*

Orford (2008), in his review of the research literature on addictive behaviour change, concluded that treatment research has been asking the wrong questions in the wrong way. He suggested that a broader, longer-term view of change and change-promoting systems is required involving the inclusion of self-help groups, faith communities, and social networks. Social networks included the networks of working relationships, or lack of them, that exist among the various services providing overlapping forms of help, and the networks of family members and friends who might be best placed to provide support for change.

When wider social issues are addressed during OST improvements in relation to reduced drug use have been found. For example, a Swedish randomised control study looking at retention and social functioning after combined buprenorphine intensive psychosocial treatment (Kakko, Svanborg, Kreek et al 2003) reported differences in the drug use of those receiving psychosocial treatment which included relapse prevention and assistance with addressing issues of housing and occupation. Similarly a UK survey of 107 former problematic heroin users who had achieved long-term abstinence (Best, Ghufraan, Day et al 2008) found that sustained abstinence was associated with social network factors (moving away from drug-using friends and support from non-using friends) and practical factors (accommodation and employment) as well as religious or spiritual factors.

Best, Day, McCarthy, et al (2008) in an article comparing Maslow's hierarchy of needs with the needs of a client presenting for addiction treatment, also noted that when services focus on reducing or ceasing substance use they may be not be picking up basic lower level needs such as housing, poverty, and poor health that may need to be solved before significant changes in substance use are seen.

Deering (2007), in her PhD study of methadone treatment in New Zealand highlighted the impact of opioid dependence and associated health-related risk factors such as unemployment, smoking, single parenting and relative poverty and chronic health issues such as hepatitis, respiratory and mental health problems. The importance of employment as an indicator of good treatment outcome was acknowledged in her research. She noted that rates of employment, in her cohort of clients receiving methadone treatment, were found to be very low (including casual work) in a time of high employment despite nearly 80% of clients indicating that they wanted to work in some capacity or receive some training. Deering recommended that following stabilisation on methadone an individualised continuing-care approach similar to other chronic health problems should be taken.

Although other studies have debated the extent of benefit gained from the provision of psychosocial interventions until recently little was written about the efficacy of specific interventions, the effective delivery of interventions, or about what clients report to be useful.

The UK National Institute for Health and Clinical Excellence (NICE 2007) reviewed a wide range of databases looking at the effectiveness of psychological interventions in combination with OST for their guidelines on psychosocial interventions for drug misuse. They concluded that:

- contingency management leads to clinically significant reductions in illicit drug use for people on methadone during treatment and at follow-up
- family and couples-based interventions can lead to a reduction in the use of illicit opioids
- short-term psychodynamic psychotherapy and standard and relapse-prevention cognitive behavioural therapy does not show benefit in reducing opioid use in clients in methadone treatment programmes.

*** *Contingency management is a system that operates by providing a variety of incentives in the form of vouchers, privileges, prizes or modest financial incentives to modify a client's drug misuse or to increase health-promoting behaviours. Contingency management is identified in the NICE guideline as having the strongest scientific evidence base for the most effective outcomes. It has also been found to be effective in reducing stimulant use (NICE 2007).*

Other approaches found to be useful were user support and advocacy, mutual aid (self-help) approaches, self-help manuals and websites, and techniques such as relaxation and guided imagery.

NICE (2007) noted that there are a number of gaps in ‘evidence-based therapy’ and state that the absence of empirical evidence for the effectiveness of a particular intervention is not the same as evidence for its ineffectiveness. These research gaps in the OST context may explain the NICE finding in regard to the efficacy of short-term therapy and relapse prevention. UK programmes generally have found it difficult to retain clients for longer than 12 months and these types of interventions may be better suited to clients who are in the process of reducing or who have ceased illicit drug use.

Following on from the NICE publication the Department of Health in England (2007), supported by the Welsh, Scottish and Northern Ireland governments, produced guidelines on the clinical management of drug misuse and dependence. These guidelines outline a number of key points in relation to the psychosocial components of treatment relevant to OST including that OST should always involve a psychosocial component and that psychosocial interventions should be targeted to addressing assessed need. In addition they highlight the role that case managers or key workers have in OST including the review of care or treatment plans and goals, provision of drug-related advice and information, harm reduction interventions, and interventions to increase motivation and prevent relapse as well as providing help to address social problems such as housing and employment. Further they suggest that a good therapeutic alliance is crucial to the delivery of any treatment intervention, especially a psychosocial one.

Findings from Deering’s 2007 study also reinforce the importance of the therapeutic relationship citing factors such as continuity of staff, staff attitudes and beliefs and having a psycho-therapeutic approach as significantly impacting on the quality of the therapeutic relationship.

A recent multisite debate in the UK (Roberts 2009) provided useful data gathered from a range of both professional and consumer perspectives. This distillation of opinions outlined six key messages including that choice in treatment should be promoted, i.e. OST services must also work with people to help them rebuild their lives and move on in their recovery. The findings from these debates suggest that people will struggle to address a drug problem successfully if they face stigma and marginalisation, homelessness and/or have no access to training, employment, or other meaningful activity. Furthermore they suggest that care pathways out of addiction involve a lot more than drug treatment per se and that a valid objection to a system that is over-reliant on “*parking people on methadone*” is that it has done too little to support clients to access social capital and move on with their lives.

The following comments from two London debate participants encapsulate the issue of the need for psychosocial components to be part of opioid substitution treatment.

“Drug treatment – whether it is focused on abstinence or maintenance – in and of itself is not going to solve the underlying problems that can make drug use problematic. Poverty is not soluble in methadone hydrochloride. Nor is a decrepit education system, or a lack of challenging and satisfying employment, or a shortage of decent housing.”

“The situation is very similar for ex-homeless clients: you can’t remove the substance use without all the other services being in place. Harm reduction or abstinence doesn’t matter, it comes down to the need to improve an individual’s quality of life over all else. This means recognising the complexity of people’s lives and support needs and that, for some people, success will not be measurable in a twelve-week period. It may take two to three years to see improvements and individual treatment successes.”

Finally, a quote from William White’s plenary speech at the American Association for the Treatment of Opioid Dependence Conference in New York, in April 2009:

“There is a growing consensus that recovery is far more than the removal of addictive substances from an otherwise unchanged life. The early cultural and professional misunderstandings and stigma attached to methadone led to justifications that focused on what methadone could subtract from an addicted individual’s life in terms of crime and broader threats to public safety and health. It is time we told the story of what the use of methadone and other medications combined with comprehensive and sustained clinical and recovery support services can add to the quality of life of individuals, families and communities. To achieve that, we will need to extend our vision beyond programmes of medication management toward the broader vision of sustained and person/family-centred recovery management.”

Summary of findings from literature review

The international literature indicates that ‘psychosocial interventions’ encompass:

- ‘psycho’ interventions, i.e. counselling, psychotherapy for issues such as reduction of drug use, maintenance of change, past trauma, and mental health problems
- ‘social interventions’, i.e. social support or practical help or assistance with gaining help for a range of issues, e.g. housing problems, unemployment, poverty, parenting issues, and the experience of discrimination and stigma.

The term ‘biopsychosocial’, not discussed in this document, includes ‘biological interventions’ which would cover the range of medical and physical problems that accompany opioid dependence.

There is significant evidence that psychosocial interventions, i.e. counselling and support services, improve outcomes in treatment clients receiving OST and that assessment of individual client need should form the basis of any interventions offered or provided.

Key findings from the literature review indicate that:

- clients on OST will struggle to address their drug problem if they face stigma and marginalisation, homelessness and/or have no access to training, employment, or other meaningful activity
- better outcomes in relation to reduction and cessation of illicit drug use are achieved when practical assistance is provided/facilitated, e.g. with housing and employment
- a planned approach to OST which provides psychosocial interventions in addition to pharmacotherapy achieves better client outcomes
- sustained abstinence is associated with factors such as moving away from drug-using friends and having supportive non-drug-using friends; having stable accommodation, being employed, and having cultural and spiritual support
- the amount and type of psychosocial input required depends on individual need with some clients requiring minimal or no input and others requiring significant input in addition to pharmacotherapy
- there is a strong evidence base for the effectiveness of contingency management i.e. positive reinforcement (not negative reinforcement) and family and couples therapy in combination with OST
- peer support and advocacy have been found by clients to be very useful
- the quality of the therapeutic alliance with the case manager or key worker is crucial to the delivery of effective psychosocial interventions.

Considerations for New Zealand Services

There are a number of issues arising out of this review that might be considered in the New Zealand context. Two key issues are firstly that psychosocial interventions, including counselling and practical and social support, do improve the treatment outcomes of clients on OST and secondly that opioid dependence should be viewed as a chronic health problem.

Most OST services in New Zealand (including primary health care teams) provide psychosocial interventions, although the extent of provision often varies. Whether services have the capacity to increase service provision would need to be addressed at a funder level. However, without significant financial input, specialist services (including primary health care teams) could easily be more responsive to the wider psychological and social needs of their clients by implement strategies such as:

- routinely providing information about self-help, whānau groups, cultural and peer support
- providing family and couples based interventions for clients who are in close contact with a partner or family member, especially if they continue to use drugs
- developing collaborative interfaces with housing, vocational/employment services and CYFS as well as with mental health services, client advocacy services and self-help/mutual help groups.

Additionally, many practical interventions such as assistance with accommodation and budgeting may be able to be addressed by employing more peer support workers to complement existing OST service provision.

As contingency management has been shown to have significant benefits in regard to reduction of drug use consideration of trailing it in New Zealand should be supported.

“Encouragement appears one of the most valued things staff can provide to clients; those who get it really appreciate it, those who don’t, want it. Having someone believe in you, in your ability to make positive change cannot be undervalued; this fits with the principles of a recovery and strengths-based approach which has proved to be effective in AOD and mental health service delivery” (Sheridan Pooley 2007).

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APPENDIX 1: EXAMPLE OF LETTER TO CLIENTS RE DRIVING MOTOR VEHICLES

Date: / /

RE: DRIVING MOTOR VEHICLES AND METHADONE

Both the New Zealand Land Transport Safety Authority book, *Medical Aspects of Fitness to Drive*, and the more recent and comprehensive Australian publication, *Assessing Fitness to Drive for Commercial and Private Drivers*, advise that drugs such as methadone, cannabis, benzodiazepines, alcohol and stimulants (such as methamphetamine) may impair the ability to drive to the extent that it may not be appropriate for people using them to hold a driver's licence.

We have reviewed the 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. The following are important points:

- Taking a stable dose of methadone on its own is unlikely to make a person unfit to drive. You should not drive while having adjustments to your dose.
- As everyone knows, excessive alcohol on its own is dangerous. However, the addition of *any* alcohol to methadone has an increased effect, making the user unfit to drive. If taking methadone, do not drink any alcohol if driving.
- People taking benzodiazepines on their own have five times the risk of accident. Those using cannabis double their risk of accident. The combination of either benzodiazepines or cannabis with methadone makes people unfit to drive. Those using either of these drugs regularly in combination with methadone must not drive and are not medically fit to hold a driver's licence.

This letter constitutes formal advice to you that if you are regularly using benzodiazepines or cannabis in addition to methadone you are advised not to drive a motor vehicle. Section 18 of the Land Transport Act requires any health professional to notify the Land Transport Safety Authority of any person who has been advised not to drive who they consider is not following that advice. The staff of this service have no option but to comply with this law.

Yours sincerely

Methadone Treatment Team
Nelson Alcohol & Other Drug Service

Received: Date:

Signed:.....