# 9 OST and the pharmacy

## 9.1 Responsibilities of the pharmacist

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

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

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

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

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

### 9.1.1 Providing a confidential service free from discrimination

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

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

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

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

### 9.1.2 Training

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

WHO 2009

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

### 9.1.3 Locums

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

### 9.1.4 Legislative requirements

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

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

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

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

## 9.2 The administration and dispensing process

A client can receive their medication either as an administered dose consumed under observation or as a dispensed dose taken away to be consumed at a later time. A ‘takeaway dose’ is any dose that is not consumed under observation (see Table 5 below for a stepwise description of the recommended dispensing and administration process).

### 9.2.1 Dispensing

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

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

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

### 9.2.2 Takeaway doses

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

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

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

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

### 9.2.3 Administering observed consumed doses

Clients receiving OST medication must consume the full prescribed dose under observation at the time of each administration. The procedure should involve the pharmacist:[[1]](#footnote-1)

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

### 9.2.4 Observing for intoxication

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

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

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

Table 5: Symptoms of intoxication with commonly used substances

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

Source: Hurley 2010

### 9.2.5 Minimising the risk of diversion

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

Methods for reducing the risk of diversion include:

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

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

Table 6: Dispensing and administration process for methadone and buprenorphine

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

## 9.3 Managing other aspects of OST provision

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

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

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

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

### 9.3.2 Managing challenging behaviour in the pharmacy

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

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

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

### 9.3.3 Missed doses

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

Pharmacists should adhere to the following guidelines for missed doses.

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

### 9.3.4 Changes to prescriptions

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

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

### 9.3.5 Cancelling or withholding doses

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

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

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

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

### 9.3.6 Dispensing errors

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

#### Underdosing

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

#### Overdosing

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

* The pharmacist must immediately advise the client of the error and the need for them to be medically assessed within 3–4 hours. The onus should not be solely on the client to seek medical assistance. The pharmacist, the prescriber or the specialist service key worker may need to facilitate a medical assessment.
* The pharmacist must warn the client of the risks associated with extra drug use, and against driving or operating machinery.
* The pharmacist should immediately contact the prescriber or specialist service, who may decide that the client requires hospitalisation. Following such a decision, the pharmacist should either telephone for an ambulance and keep the client at the pharmacy until it arrives, or accompany the client to the hospital to ensure that admitting staff receive clear information on the circumstances.
* If the client has left the pharmacy before the mistake is realised, the pharmacist must advise the prescriber or specialist service as soon as possible. The pharmacist must make a reasonable attempt to contact the client to request they seek a medical assessment as soon as possible. If the pharmacist is unable to contact the client, the responsibility to continue to attempt contact will sit with the prescriber (or delegated person). The pharmacist should also notify the prescriber in writing of the incident and any actions taken (refer also to section 4.1: Overdose).

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

Common sources of dispensing errors include:

* misidentification of clients (eg, confusing clients with similar names). Pharmacists should ensure appropriate identification (such as a photograph) is accessible to all staff working with OST clients, and place warnings in files and dispensing software where client names are similar
* failure to notice dose changes on prescriptions. Pharmacists can use a day book or diary to record such changes and pass on important information to other staff
* confusion of mg/ml doses for methadone. Where a dose appears unusual or large, pharmacists should double check the prescription, and note the correct dose in files and dispensing software.
1. A pharmacist or pharmacy technician may administer and observe the consumption of methadone or buprenorphine under the Health Practitioners Competence Assurance Act 2003, which included an amendment to section 8(2)(b) Misuse of Drugs Act 1975 allowing pharmacy technicians to handle controlled drugs. Pharmacists are responsible for ensuring clients are not intoxicated and that correct doses are dispensed prior to technicians administering them. [↑](#footnote-ref-1)